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**An Operational Evaluation
of Extended-wear Soft Contact Lenses
in an Armored Division**

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Introduction

Background

The increasing technological sophistication of military hardware has provided wider operational capability, has improved systems performance, and, in some cases, has enhanced personnel protection. Unfortunately, some of these advances also have created new problems for the soldier in the man-machine system. One of these problems involves the physical relationship between the operator and his military hardware. A very common incompatibility complaint is heard from the spectacle-wearing soldier required to view through various optical sighting and viewing systems.

Although no published estimates are available, a large proportion of military personnel wear corrective spectacles. However, the designs of many military systems are only minimally compatible, or are outright incompatible, with the soldier required to wear spectacles. A frequently used design approach to obviate this interface problem is to incorporate "user optics" into the instrument. This is done in almost all binoculars and military night vision goggles. The user simply dials in optics incorporated in the instrument to compensate for his/her refractive error. Unfortunately, there are several deficiencies associated with this straightforward approach. For example, if the system is monocular, the refractive error for only the viewing eye will be compensated while the other eye will remain uncorrected. A second shortcoming of this approach is that only spherical refractive errors can be corrected. For several reasons, cylindrical optics ordinarily used to correct astigmatic refractive errors cannot be incorporated into the design of viewing systems. This shortcoming presents a serious limitation since a high percentage of personnel requiring spectacles have varying amounts of astigmatism which cannot be corrected by user optics.

The sighting devices found in tanks and other fighting vehicles provide excellent examples of the interface problems confronting the spectacle-wearing soldier. The problems are compounded when the sights must be used in moving vehicles. Recognizing that this incompatibility might compromise soldier performance, personnel from the 2d Armored Division, Fort Hood, Texas, requested that the US Army Training and Doctrine Command Combined Arms Test Activity (TCATA) investigate the feasibility of using contact lenses in an armored environment. The US Army Aeromedical Research Laboratory (USAARL) was tasked to participate in the investigation as working proponent to provide technical and medical assistance in the design, conduct, and analysis of the study.

Objectives

The Fort Hood investigation entitled "Controlled Investigation of Contact Lenses and Operational Performance (CICLOPS)" was initiated to assess the safety and utility of soft contact lenses when worn by armored division personnel while performing their normal military duties. The specific study objectives were:

1. Estimate success rates in fitting and wearing selected extended-wear contact lenses.
2. Identify predictors of nonsuccess in wearing soft contact lenses.
3. Quantify the effects of the lenses on military job performance.
4. Identify medical logistical/personnel requirements to support soft contact lenses in the field.

This report supplements TCATA Test Report FT 484 which presents basic CICLOPS results, including limited clinical data, without interpretation or discussion. The present report provides additional clinical and physiological data, along with relevant data from the TCATA report. The emphasis is on medically-related issues and includes interpretive discussion, conclusions, and recommendations. A reading of both reports is necessary to obtain a complete picture of the results of CICLOPS.

Literature review

Corneal contact lenses have been used as alternatives to spectacle correction of refractive errors for over 50 years. Tremendous strides, especially in recent years, have been made in lens material/chemistry technology. While contact lens technologies continue to advance at a rapid pace, the basic physiological requirements of the human cornea remain unchanged. Some of the known cornea/lens interactions should be considered with respect to the present report and prior to any final decision concerning the acceptability of contact lenses by the military.

There are two general classes of contact lenses based upon the materials from which they are fabricated. "Hard" lenses retain their physical shape and dimensions when worn, while "soft" contact lenses assume the shape of the front surface of the cornea when placed upon the eye. The first material which received wide success in contact lens applications was polymethyl methacrylate (PMMA). PMMA lenses are "hard" and offer several advantages such as durability, ability to correct larger amounts

of astigmatism, relative ease in cleaning and maintenance, and relatively low cost. However, PMMA lenses have a serious (and for military use, critical) disadvantage. The PMMA material does not transmit oxygen. PMMA lenses cannot be comfortably or safely worn for more than 12 hours continuously.

The healthy cornea has no blood vessels to provide its nutrient requirements. Therefore, it receives these nutrients via passive diffusion and active transport from the inner part of the eye, from the tears, and, in limited amount, from the vascular beds located at the cornea periphery. The cornea requires oxygen to carry on metabolic activity, and most of this oxygen must come from the atmosphere. Since PMMA transmits virtually no oxygen, the corneal supply must be obtained from an alternate route when PMMA lenses are worn. This is accomplished by absorption of oxygen into the tears, which are then "pumped" underneath the contact lenses and across the cornea with each eyelid blink. However, this mechanism is inadequate and the cornea suffers an oxygen debt as long as the lenses are on the cornea. This results in corneal edema (tissue swelling caused by fluid retention) which can cause visual blurring when the PMMA lenses are removed--even when corrective spectacles are worn (Rengstorff, 1965). This visual blurring can last up to several days. The normal cornea is slightly edematous after sleep because of the reduced oxygen environment of the closed eye. PMMA lenses cannot be worn when the eyes are closed for extended periods of time (e.g., sleeping). The cornea of an open eye at sea level is exposed to an oxygen atmosphere of about 20 percent. Several recent studies (Holden and Mertz, 1984; White and Scott, 1984) have shown that an atmosphere of at least 10 percent is needed to deswell the cornea after sleeping, and about 13 percent is required to limit corneal swelling to an acceptable 4 percent thickness change. In addition to edema, continued corneal hypoxia will likely result in corneal neovascularization, striae, endothelial polymegathism, and possibly opacification (Mertz and Holden, 1981; Holden et al., 1983; O'Neal et al., 1984; Spoor et al., 1984).

In an effort to resolve the known shortcomings of PMMA lenses, new contact lens materials have been developed (Bailey, 1984). These include cellulose acetate butyrate (CAB), silicone, silicone methyl methacrylate (SMMA), hydroxyethyl methacrylate (HEMA), and glyceryl methacrylate (GMA). A variety of different contact lenses, both "soft" and "hard," have been made from these materials. All of these materials have different properties related to their capacity for fluid content, surface wettability, oxygen transmission, and dimensional stability. The major advantage of these new materials over PMMA is that they all have improved capacity for oxygen transmission through the lens which provides a more direct route for corneal oxygenation.

These new materials have allowed the development of many different types of lenses. Both the new "hard" and "soft" lenses have improved the ocular physiological response to the lenses and have enabled longer continuous wearing times with greater comfort. The extended wear versions of the new lenses are more fragile but are designed to allow continuous wear of the lenses for long periods of time (Masden and Everson, 1983; Janis and Hermann, 1983; Korb, 1984). There is much evidence which shows that many people can comfortably wear these new lenses for long periods, some more than a month. However, the literature also shows that some people cannot wear the lenses for these extended periods without developing ocular problems, some of a serious nature (Smolin et al., 1979; Wilson et al., 1981; Koetting, 1983; Stenson, 1983; Gordon and Kracher, 1985; Patrinely et al., 1985; Holden et al., 1985). The potential for certain ocular complications is greater for the individual wearing extended wear lenses than for the daily wear individual.

Corneal changes that have been reported with extended wear lenses include neovascularization and cellular morphological changes. The primary cause of neovascularization probably is prolonged corneal edema which initiates an inflammatory response (Stark and Martin, 1981). Other proposed causes are a reduction of gaseous interchange, an increase in toxic byproducts, trauma, and reaction to various disinfection solutions used with the lenses (Lowther, 1982). Corneal structural changes that have been associated with extended wear lenses are centered primarily in the posterior portions of the cornea (Schoessler, 1983; Holden et al., 1985). Blebs, spaces, and cellular polymegathism of the endothelial layer have been reported in association with the wear of both "hard" and "soft" lenses. Although the longterm effects of these changes are unknown, it is clear that individuals wearing such lenses will require much more intense and frequent clinical monitoring.

In addition to the corneal changes, another major adverse reaction with extended wear lenses is related to the eyelids. The development of large papillae has been demonstrated in the tarsal portion of the palpebral conjunctiva, usually of the upper lid (Korb et al., 1983). Termed giant papillary conjunctivitis (GPC), this condition may be the result of an allergic-like reaction to protein deposits on the contact lens and/or mechanical irritation from these deposits (White and Scott, 1984). Although the occurrence of GPC has been shown with both regular and extended wear "hard" and "soft" lenses (Allansmith et al., 1977), GPC seems to be more frequent with "soft" extended wear lens users. Proper lens cleaning, modifying the wearing schedule, or providing new lenses usually will remediate the GPC.

Because contact lenses have received wide acceptance in the civilian community, a frequently asked question has been, "Why aren't contact lenses approved for military issue and use?"

Perhaps this question is legitimate since literally millions of civilian patients successfully have worn various types of contact lenses. However, the occupation of soldiering is quite unlike most civilian occupations. The military operational environment is different as are the job performance requirements in that environment. Consequently, there is a need for specific data obtained in operational military environments.

At the time this study was initiated, "soft" contact lenses worn for extended periods of time offered the greatest potential to solve some of the interface problems now present with military systems. However, as frequently occurs, the solution also presents additional problems for consideration. Policy regarding the use of contact lenses in military environments ultimately will be established after a consideration of both the positive and negative aspects of extended wear lens use. This report provides data relevant to the eventual formulation of realistic military policy regarding contact lens use.

Materials and methods

Study design

The study was conducted with volunteer subjects on a minimal interference basis at Fort Hood, Texas, in three phases. Phase I, the fitting phase, started on 6 May 1985. During this period demographic and initial medical data were collected on all volunteers. Those selected to wear soft contact lenses (SCLs) were fitted and trained in the care, wear, and sanitation of the lenses. The volunteers selected to wear spectacles had their prescriptions validated and, if required, new spectacles were provided. The fitting of SCL participants continued beyond the beginning of phase II.

Phase II, the performance phase, started on 4 August 1985 and lasted at least 90 days for each subject. Participants followed their normal duty and training schedule in garrison and on training ranges. This phase provided a measurement period common across subjects and was primarily relevant to objective performance measures. The collection of medical data continued during this phase.

Phase III started on 19 November 1985, when the first successful SCL subject was released from the study. This phase was devoted to completing the collection of medical data and bringing each subject's participation to an orderly conclusion.

Subjects

A total of 311 subjects were used in this study; 215 wore extended-wear SCLs, while 96 subjects served as spectacle-wearing controls. All were male soldiers ranging in age from 18 to 43 years. All subjects were assigned to the 2d Armored Division located at Fort Hood. The job categories of most of the participants were related to armor, mechanized infantry, and air defense artillery duty assignments. Individuals in support categories were also included in the test to enlarge the medical database.

Selection of participants began with the screening of health records of troops in the participating battalions. Approximately 3,000 records were prescreened initially. Roughly one-quarter of these records contained a prescription for visual correction and received more detailed screening to eliminate conditions which would medically contraindicate their participation as a subject. These conditions included, but were not limited to, acute and/or subacute inflammations of the anterior segment of the eye; any disease that affected the cornea, conjunctiva or sclera; corneal hypoesthesia; low tear breakup time or insufficient lacrimation; a requirement to take certain medications, such as diuretics and decongestants, which might adversely affect tear production; a

history of moderate to severe allergy; refractive errors which could not be adequately compensated by available contact lens powers; and any systemic disease which might affect the eye or be aggravated by wearing contact lenses. The refractive error limits established for this study were -0.50 to -6.00 diopters of myopia, up to 1.25 diopters of astigmatism, and +1.00 to +4.00 diopters of hyperopia.

Eligible soldiers were briefed thoroughly on the proposed study. Potential risks and expected benefits were explained. It was stressed that the soft contact lenses would be turned in at the termination of the study. Emphasis was placed on the free contact lens fitting and evaluation provided, a benefit which is not ordinarily part of routine military eye care. At the end of the briefing, candidates were allowed time to ask questions and were given an opportunity to volunteer. Candidates for the Contact Lens Group were selected from the volunteers. Where possible, volunteers for the Spectacle Control Group were selected to approximate the visual parameters of the contact lens (CL) subjects. This attempt to form a matched control group was only partially successful. Each volunteer was required to sign a Volunteer Briefing Form, a Volunteer Agreement, and a Privacy Act Statement.

Contact lens materials

Three different types of extended-wear SCLs were used: (1) 71 percent water content (Perma-lens XL; CooperVision); (2) 55 percent water content (Hydrocurve II; Barnes-Hind); and (3) 38.5 percent water content (CSI T; Sola-Syntex). Appendix A contains a list of the respective lens manufacturers. This mix provided high, medium, and low water content lenses in a variety of base curves for reasonably broad fitting capabilities. All three lenses had been approved by the Food and Drug Administration (FDA) for continuous, extended-wear (up to 30 days) and are commonly marketed in the United States. The Permalens XL and CSI T lenses were available to correct myopia in 0.50 diopter steps from -0.50 to -6.00 diopters. The Hydrocurve II lens was available in the same negative parameters as well as in 0.50 diopter steps to correct hyperopia from +1.00 to +4.00 diopters. Lenses were available in sufficient quantities that they could be dispensed to the subjects directly from stock. Cleaning solutions, cases, storage materials, and fitting procedures recommended by the respective manufacturer were used. See Appendix B for a list of the solutions used. Manufacturer-furnished Patient Information Pamphlets and instructional videotapes were used to assist in training volunteers on proper handling, cleaning, and storage.

Clinical equipment

Table 1 lists the major items of medical equipment used in data collection and clinical monitoring during the study. Appendix C provides a list of equipment manufacturers.

Table 1
List of medical equipment

Item (quantity)	Purpose
Phoropter with stand, examination chair, and projector (4 each)	Ascertain visual acuity and subjective refraction
Objective automated refractor (1 each)	Determine objective refraction
Biomicroscope (4 each)	Global and tarsal examination
Manual keratometer (4 each)	Determine corneal curvature and uniformity
Automated keratometer (2 each)	Determine corneal curvature and uniformity
Noncontact tonometer (1 each)	Determine intraocular pressure

Clinical facilities

The Optometry Clinic of the 2d Armored Division Troop Medical Clinic (TMC) was the primary eye care facility used during the study. The building contained four examination rooms, a waiting area, and additional space for offices and storage of supplies. Darnall Army Community Hospital (DACH) was available to provide emergency medical services if required.

Medical personnel

Table 2 shows the number and specialties of medical personnel participating in the study.

Table 2

Medical support personnel

Job designation	SSI/MOS	Grade	Number
Optometrist	68K	O-5	1
Optometrist	68K	O-3	3
Logistics support NCO (clinic NCOIC)	91Y20	E-5	1
Eye specialist	91Y10	E-4	2
Medical specialist*	91A10	E-1 to E-4	5

*The five medical specialists departed at the conclusion of phase I, but two returned during phase III.

These staff members were provided by DACH, the 2d Armored Division, and the US Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland. The Health Services Command provided an additional optometrist during phase I to examine dependent personnel who would normally patronize the TMC. One of the eye specialists performed the functions of a logistics support noncommissioned officer (NCO). The optometrists and eye specialists participating in the test also performed their normal sick call duties during all phases and dependent care duties during phases II and III.

The only training required for the optometry staff and eye specialists was familiarization with the computerized instruments. All the optometrists and the eye specialists were experienced in fitting and handling of contact lenses. The medical specialists from USAMRIID were given training at the TMC and at the Academy of Health Sciences, Fort Sam Houston, Texas, prior to the start of the test. This training consisted of terminology, equipment familiarization and use, procedures for handling and cleaning lenses, and techniques for inserting and removing lenses. These medical specialists also received on-the-job training during the first week of the test.

Contact lens wearing and replacement schedule

Although manufacturers heavily advertise the use of extended-wear lenses for "up to 30 days continuous wear," most eye care practitioners recommend a shorter wear period. However, more frequent handling of the lenses increases the risk of bacteria being introduced into the eye, as well as the possibility of tearing or damaging the lens. Based upon these

considerations along with a general assessment of battlefield conditions, it was decided that the lenses in this study would be worn continuously for a period of 7 days plus or minus 1 day. This permitted some flexibility to accommodate requirements which would prevent lens removal at a specific time. It was recommended that normally on the 7th day of continuous wear, the lenses should be removed 2 hours prior to bedtime. They would then be cleaned and stored in the cases until the following morning. This same cycle was to be followed by all subjects unless contraindicated on an individual basis. This conservative approach to wearing time minimized physiological risks and interference with the individual's performance of duties.

The usable "life" of an extended wear lens is limited. In addition to physical deterioration of the lens material, there is frequently a buildup of deposits on the lens surface over a period of time. These deposits are comprised of cholesterol, protein, mineral salts (i.e., calcium phosphate), and mucin. They collect in microscopic imperfections of the lens surface and become difficult or impossible to remove. Deposits frequently contribute to physiological compromise to the eye. To minimize problems related to lens deposits, subjects in this study wore their lenses no longer than 4 months, at the end of which the old lenses were replaced with new ones.

Clinical procedures

The procedures for fitting, evaluating, and disinfecting the contact lenses were carefully developed to follow (or exceed) the research protocol required by the FDA of any practitioner evaluating a new lens.

Initial examination

At the first visit each subject was thoroughly evaluated for suitability for wearing extended-wear SCLs as outlined below:

- a. Complete medical history: Subjects filled out a Medical History Form (see Appendix D) and clinicians expanded the information during a subject interview.
- b. Keratometry: Measures of corneal curvature using standard procedures were required to be in the range from 39.00 diopters to 49.00 diopters.
- c. Biomicroscopy: This provided baseline data from microscopic evaluation of the following: lids, conjunctiva, limbus, cornea, anterior chamber, and tarsal plate.

Quantification of observations conformed to the classification codes in Appendix E.

- d. Visual acuity: A standard Snellen chart was used to measure visual acuity with and without correction.
- e. Horizontal visible iris diameter (HVID): This was measured with a millimeter ruler.
- f. Tonometry: Intraocular pressure was determined using a noncontact tonometer.
- g. Shirmer tear strip measurement: Moistening of 2-3 mm of the paper per minute is considered normal.
- h. Tear film breakup time (BUT): A tear breakup time (BUT) was considered unacceptable if less than 10 seconds.
- i. Refraction: Objectively and subjectively determined the spherical and/or cylindrical components to be corrected.

Fitting

If the subject met the selection criteria, he then was fitted with lenses to provide a comfortable, stable acuity of at least 20/25 binocularly. Any volunteer who could not achieve adequate comfort, acuity, and lens stability with any of the three available lenses was eliminated. Contact lens fitting was performed as outlined below:

- a. A trial lens was selected that had a diameter at least 1-2 mm larger than the HVID. The spherical power of the trial lens was selected to be as close as possible to the spectacle spherical equivalent.
- b. The lens was inserted and allowed to equilibrate to the pH, tonicity and temperature of the eye for approximately 15 minutes.
- c. The best corrected acuity was obtained by overrefraction and the quality of the retinoscopic reflex was evaluated. Vision had to be stable between blinks and the retinoscopic reflex had to be crisp. The lens had to center and move freely with each blink.
- d. The lens edge was observed for correct alignment and to make certain it did not impinge on the limbus.
- e. The examination was repeated after 1/2 hour of equilibration.
- f. The subject then was transferred to a technician for

training in insertion, removal, cleaning, disinfection, handling, storage, and proper wearing schedule. In addition, he was given a return visit appointment.

- g. Each volunteer also was carefully instructed on what symptoms might necessitate removal of the lenses and/or unscheduled professional care. A written summary of essential information, plus a Patient Information Pamphlet, were furnished. A name and telephone number also were provided as a point of contact should a problem arise during nonduty hours.

Followup examinations

Followup visits at 24 hours, 7 days, and every 30 days thereafter were scheduled routinely. The following procedures were performed at these visits:

1. Patient history: time lenses worn, comfort, quality of vision, ease of handling, ease of cleaning, and subject comments.
2. Acuity check with lenses in place.
3. Overrefraction to verify prescription.
4. Observation of the lenses on the cornea. The lenses were required to be centered and move on upward gaze and/or with a blink.
5. Removal of lenses and determination of corneal curvature.
6. Biomicroscopy with and without fluorescein evaluating the lids, conjunctiva, limbus, cornea, anterior chamber, and tarsal plate. Quantification of anomalies conformed to the classification format contained in Appendix E.
7. Cleaning of the contact lenses with a prophylactic surfactant cleaner and examination for deposits, foreign bodies, color changes or physical imperfections of the lens surface.
8. Reinsertion of the lenses after all residual fluorescein had dissipated from the eye.

Control subject examinations

Spectacle-wearing controls received an initial examination identical to the initial exam for CL participants, except for omission of the Shirmer tear test, iris diameter measurement, and tear breakup time. Each control's refractive prescription was verified and a new pair of standard-issue spectacles provided, if necessary. Two followup exams were scheduled - one 30 days after the first, and another at the end of the study. All eye care for controls during the study was provided at the supporting TMC. A record of all eye problems and eye-related clinic visits was maintained. Controls also were given the nonduty-hours point of contact for eye-related emergencies.

Emergency medical arrangements

In the event of adverse ocular symptoms or ocular injury, all participants (both CL wearers and controls) were instructed to contact the clinic or nonduty-hours point of contact immediately. Standing arrangements existed for prompt examination in suitable medical facilities, as required.

Data collection

Standardized data collection forms were used by all test personnel throughout the study. Complete data were recorded for both CL participants and controls during each exam (initial, followup, final). The following appendixes contain samples of these forms.

- Appendix F: Contact lens-wearer initial examination and fitting form
- Appendix G: Contact lens-wearer followup/final examination form
- Appendix H: Control group initial examination form
- Appendix I: Control group followup/final examination form

These forms were designed specifically for this study to facilitate ease of entry into a computerized database.

Self-administered paper-and-pencil questionnaires were used to obtain subjective information from CL participants at the end of the study. Issues addressed included user acceptability (including cosmesis), military job performance impact, problems encountered, problems in special environments, medical services, and training. Refer to the following Appendices for samples of these forms.

- Appendix J: Responses to the fitting and wear of contact lenses
- Appendix K: Contact lens-wearer responses to operational effectiveness
- Appendix L: Additional responses to comparison of contact lenses versus spectacles

A separate questionnaire was used to collect subjective information from control participants at the end of the study. Here the focus was on problems, disadvantages, and job/performance limitations encountered with spectacles. See Appendix M for a sample of this form.

The time required to conduct all medical examinations was recorded. The time started when the eye specialist began the examination and ended when the volunteer was considered to be comfortably wearing the CLs and visual acuity was acceptable or when a determination was made that the volunteer was disqualified or discontinued from this study. A separate time period was recorded for the training of the volunteers in wear and care of the lenses.

Medical personnel maintained records of quantities of lenses, cleaning solutions, cases, etc., used throughout the study. Information relative to medical resource and logistical requirements to support SCLs in garrison and in the field was obtained by a poststudy questionnaire completed by clinicians (Appendix N).

Results and discussion

General

At the end of the prescreening, recruiting, and fitting phase, 215 participants had been fit with extended-wear SCLs across a period of 14 weeks. Of these, 35 were wearing their own SCLs at the start of their participation or had worn contact lenses within the preceding 6 months. By arbitrary criterion, this group of 35 was considered to have current or recent experience with contact lens wear. The larger group of remaining subjects included 31 participants who had worn contact lenses at some point in the past, but not within 6 months preceding their enrollment in the study. For the purposes of data presentation, these two groups will be labelled "experienced" wearers and "inexperienced" wearers, respectively. Wherever appropriate, results for these two groups will be presented separately.

The spectacle wearers whose data are included in this report numbered 96, none of whom had worn contact lenses within the 6 months preceding the start of their participation. This number is different from the 111 spectacle wearers reported in the TCATA report. The reason for the difference lies in the fact that 15 of the 111 had begun their participation in the study as SCL wearers, then transferred to the spectacle group when SCL wear was terminated for some reason, usually after a few weeks. Because of the potential impact of this limited period of SCL wear on ocular physiology, it was deemed preferable to exclude them from this report.

The study spanned the months of May through December, though individual participants varied in their starting and ending dates. The last participant was fit on 12 August (only seven were fit after 15 July), and the first participant successfully completing his SCL wear period was released on 19 November. Consequently, each participant encountered a broad range of climatic conditions during his participation in the study. Temperatures ranged from 102 degrees F to 31 degrees F during the entire course of the study, with conditions generally dry and dusty. Rainfall during the first 5 months of the test period averaged 1.57 inches per month, while the average during October-December was 4.67 inches per month. Relative humidity generally ranged between 35 and 70 percent.

In spite of serious efforts, it was not possible to obtain complete data on every participant. Contact lens wearers occasionally missed scheduled examinations, usually for unavoidable reasons (e.g., field exercises, leave). Some attrition of participants occurred as the study progressed for medical, administrative, and personal reasons. Consequently, sample sizes vary for medically-related data obtained from the sequential examinations. Because the impact of attrition on data

interpretation especially is important for the CL group, monthly census figures for that group are presented in Table 3. While 6 months of SCL wear was targeted for every contact lens wearer, actual duration of wear ranged from 4 to 7 months at the time the study was concluded. The 30-day followup examinations for spectacle wearers were sufficiently sporadic and variable in timing that the associated data are excluded from this report.

Table 3

Contact lens group census by month

Day	Ending census	Average census	Attrition	
			Medical	Other
1	215	--	--	--
1- 30	201	208	10	4
31- 60	187	194	8	6
61- 90	174	180.5	4	9
91-120	151	162.5	6	17
121-150	132	141.5	3	16
151-180	119	125.5	6	7
>180	--	--	3	5

Grand average:	168.4			

Much of the information contained in the TCATA report, especially that related to performance, operational problems, and environmental conditions, is not repeated in the current report. The reader is encouraged to review carefully the findings in the TCATA report, along with those presented below, to obtain a comprehensive picture of the results of this study.

Demographic characteristics

The volunteers who participated as subjects in this test were assigned to eight different units of an armored division: two mechanized infantry battalions, four armored battalions, one cavalry squadron, and one air defense artillery (ADA) battalion.

Rank

Commissioned officers, noncommissioned officers, and enlisted personnel comprised the body of participants. The distribution of subjects across these three categories is shown

in Table 4. The proportion of commissioned officers was somewhat higher among the CL wearers than among the spectacle wearers, while the opposite relationship was true for noncommissioned officers. The proportion of enlisted personnel nearly was identical for the CL and spectacle wearing groups. The officers ranged in rank from 01 (second lieutenant) to 03 (captain), with the exception of one lieutenant colonel (05) in the CL group.

Table 4

Distribution of participants by rank

Rank category	CL wearers (N=215)	Spectacle wearers (N=96)
Commissioned officers	15%	5%
Noncommissioned officers (E5-E8)	36%	46%
Enlisted personnel (E1-E4)	48%	49%

Age

The distribution of subjects by age is presented in Figure 1. The CL and spectacle groups were quite comparable in terms of age distribution: In each group, 60 percent of the participants were age 25 and below. The median age of the spectacle wearers was 23.5 years (range, 18-41), while it was 24.0 years (range, 18-43) for the CL wearers.

Time in Army

The spectacle and CL groups were distributed fairly evenly in terms of participants' total time in the Army (Table 5). The median time in the Army was 2.8 years (range, 1 month to 22.4 years) for the CL wearers and 3.5 years (range, 6 months to 21.7 years) for the spectacle wearers.

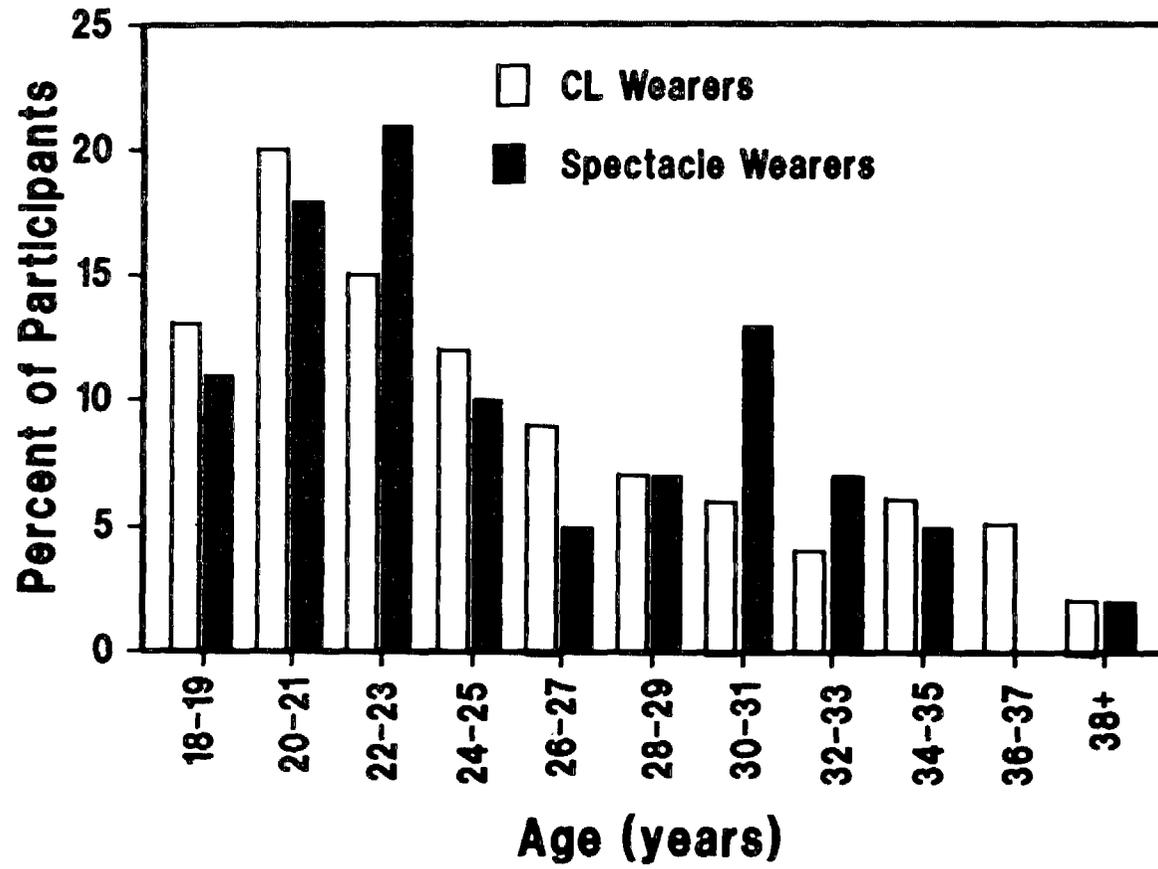


Figure 1. Distribution of contact lens wearers (N=215) and spectacle wearers (N=96) by age groups.

Table 5

Distribution of participants by total time in Army

Years	CL wearers (N=215)	Spectacle wearers (N=96)
0-2	32%	29%
3-4	31%	25%
5-6	11%	10%
7-8	7%	8%
9-10	5%	5%
11-12	3%	9%
13-14	4%	4%
15-16	4%	5%
> 16	3%	3%

Duty assignment

For the purposes of this report, duty assignments have been organized into three primary categories: M1 tank crewmembers, combat vehicle crewmembers (M2 and M3 fighting vehicles, improved TOW Vehicle, M106 mortar carrier), and ADA team members (Redeye, Vulcan, and Chaparral systems). All other duty assignments have been clustered in a "Miscellaneous" category, which includes a variety of combat, combat support, and combat service support specialties. Table 6 presents the distribution of participants across the categories of duty assignment. The groups are fairly well matched in their distribution patterns.

Table 6

Distribution of participants by duty assignment

Duty assignment	Inexperienced CL wearers (N=180)	Experienced CL wearers (N=35)	Spectacle control group (N=96)
M1 tank crewmember	30%	34%	26%
Combat vehicle crewmember (1)	42%	46%	47%
ADA team member (2)	7%	6%	5%
Miscellaneous (3)	21%	14%	22%

Notes:

1 - Includes crewmembers from M2 and M3 fighting vehicles, improved TOW Vehicle, and M106 mortar carrier.

2 - Includes Redeye, Vulcan, and Chaparral team members.

3 - Includes DRAGON gunners, mechanics, medical specialists, armorers, truck/jeep drivers, operations personnel, logistics personnel, and administrative personnel.

Spectacle wear time

In general, the CL group and spectacle group did not differ greatly in terms of total spectacle wear time. The median wear time was 10.1 years (range, 1 month to 35.7 years) for the spectacle group and 12.1 years (range, 4 months to 29.9 years) for the CL group. Among the spectacle group, 64 percent of the participants reported wearing spectacles fulltime. The corresponding figure for the inexperienced CL group and the experienced CL group was 76 percent (identical for both groups).

Contact lens wear history

Table 7 displays the number of participants who had worn contact lenses prior to the start of the study, broken out by category of CLs worn. All of the participants in the experienced CL group had worn SCLs prior to their enrollment in the study. In addition, four of the experienced CL subjects had worn hard CLs at some time in the past, but not less than 7 years prior to the start of the study. The median duration of hard CL wear had been 11 months. The majority (80 percent) of the experienced CL subjects were wearing SCLs at the start of their participation in

the study; none had a break in wear of more than 5 months. The median duration of prestudy SCL wear for the experienced CL participants was 26 months.

Table 7

Percentage of participants wearing contact lenses prior to the start of the study

Contact lenses worn	Inexperienced CL group (N=180)	Experienced CL group (N=35)	Spectacle group (N=96)
Soft CL only	11%	89%	3%
Hard CL only	4%	0	3%
Both soft and hard CL	2%	11%	1%

Among the inexperienced CL group, 17 percent of the subjects had worn CLs in the past: 20 had worn SCLs, 7 had worn hard CLs, and 4 had worn both. The minimum time between discontinuation of CL wear and the start of the study was 7 months for SCL wear and 13 months for hard CL wear. The median duration of CL wear time was 17.5 months for SCLs and 11 months for hard CLs.

Of the subjects in the spectacle control group, only 7 percent had worn CLs in the past: three had worn SCLs, three had worn hard CLs, and one had worn both. A minimum of 10 months had elapsed between discontinuation of CL wear and enrollment in the study.

Visual status

For the most part, only data from right eyes will be presented throughout this section because the differences between the two eyes within each group were negligible.

Uncorrected acuity

The uncorrected visual acuity was determined for both the control subjects and the CL subjects during their initial exam. Figure 2 presents the right eye uncorrected acuities for each group.

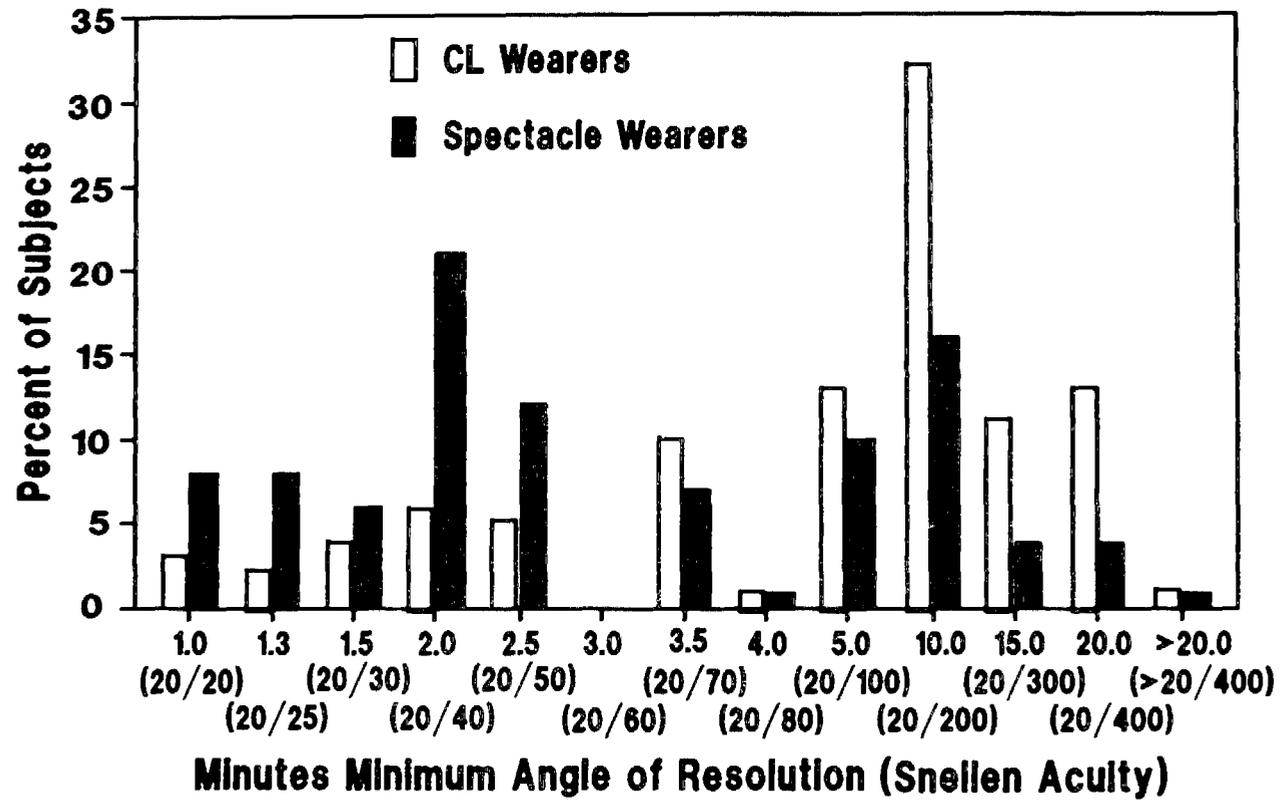


Figure 2. Uncorrected binocular visual acuities for contact lens wearers (N=215) and spectacle wearers (N=96). Both minutes of minimum angle of resolution (decimal values) and Snellen notations are indicated for the horizontal axis.

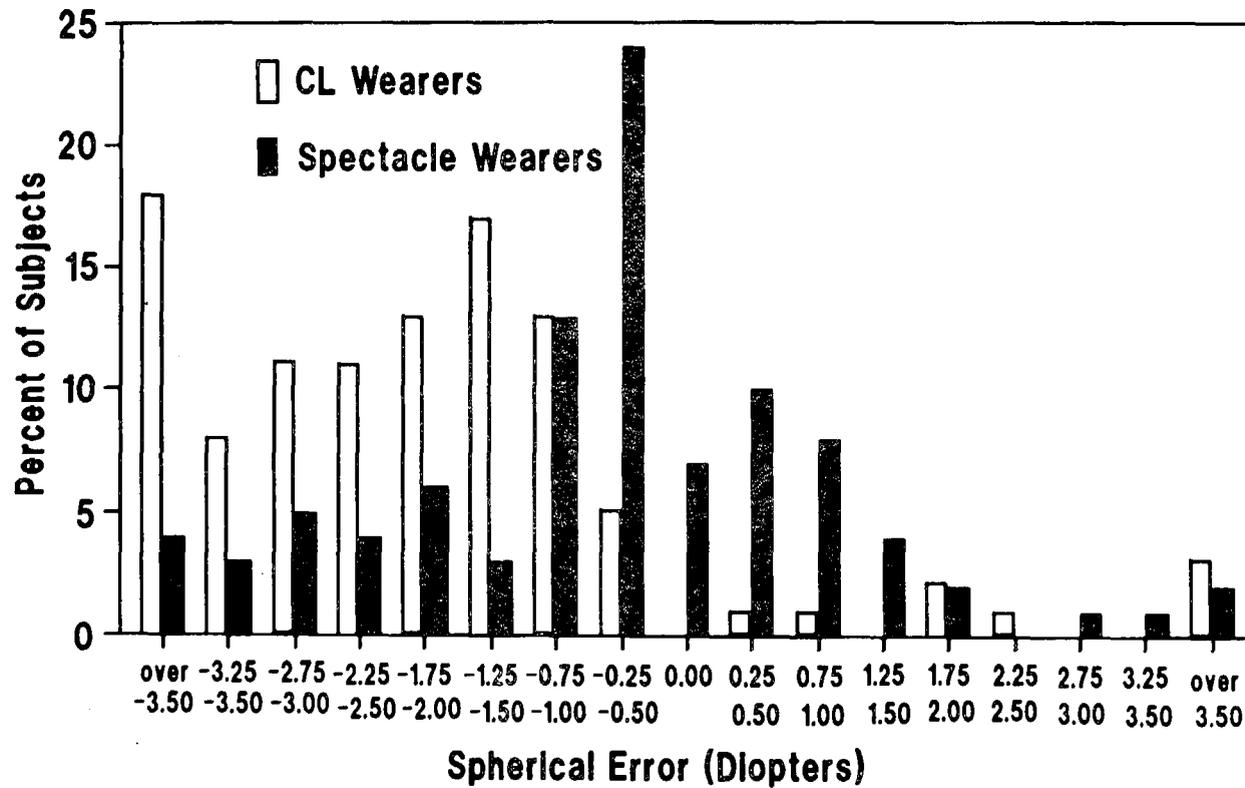


Figure 3. Distribution of spherical refractive errors (subjective refraction, right eye only) for contact lens wearers (N=215) and spectacle wearers (N=96).

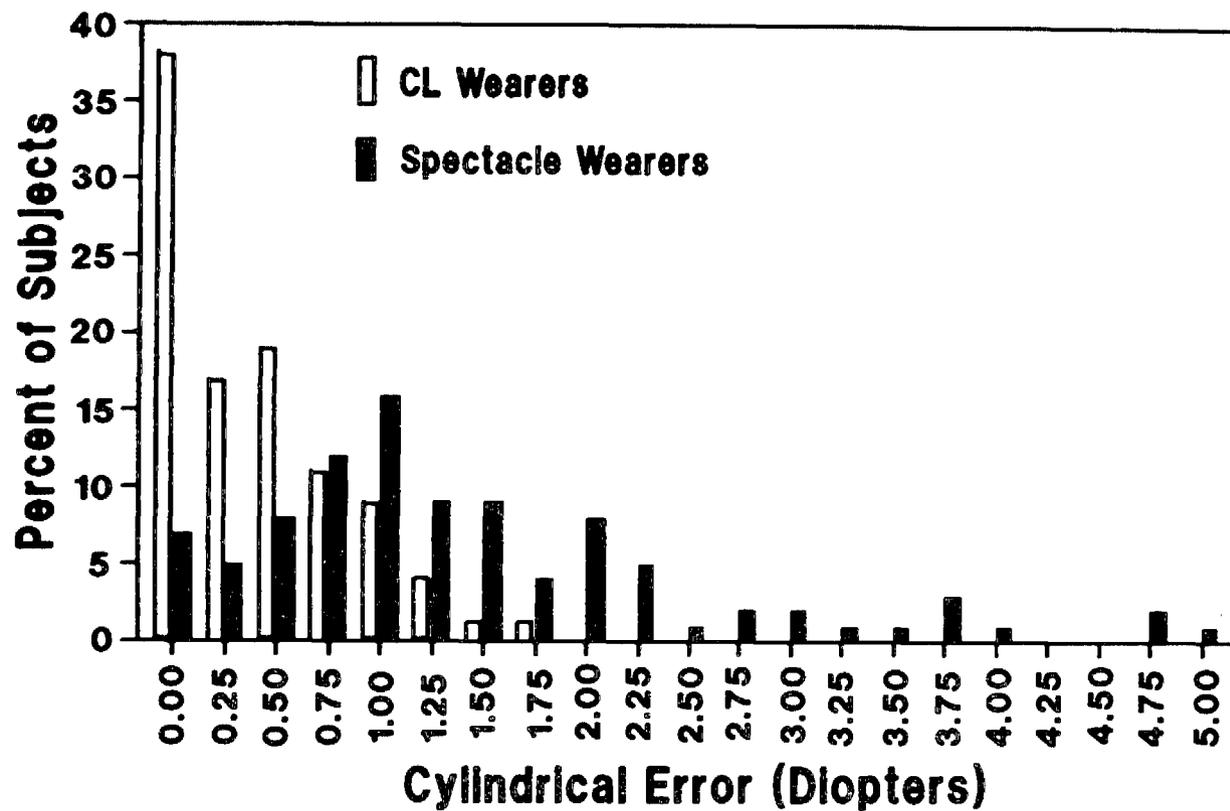


Figure 4. Distribution of cylindrical refractive errors (subjective refraction, right eye only) for contact lens wearers (N=215) and spectacle wearers (N=96).

Table 8

Corrected acuity (binocular)
at selected examinations

Visual acuity	CL wearers				Spectacle wearers		
	Initial (N=215)	7-day habitual (N=176)	90-day habitual (N=109)	180-day habitual (N=84)	Initial (N=96)	Final (N=70)	Final habitual (N=61)
20/20 or better	99%	90%	95%	95%	95%	97%	89%
20/25	1%	8%	5%	2%	4%	1%	8%
20/30	0	1%	0	2%	1%	1%	0
20/40 or poorer	0	1%	0	0	0	0	3%

The designation used to denote visual acuity is minutes (') minimum angle of resolution (MAR) followed by the equivalent Snellen notation in parentheses. While the range of uncorrected visual acuity of the two groups was the same, 1.0' MAR (20/20) to 22.5' MAR (20/450), the means were somewhat different. The mean for the CL group was 9.0' MAR (20/180) while that of the control group was 5.0' MAR (20/100). This difference is directly related to the higher mean spherical refractive error among the CL subjects (see below), which resulted largely from the criteria used in this study to select CL subjects.

Spherical refractive error

The spherical refractive error distribution (right eyes) of the two groups is shown in Figure 3. For the CL group, the errors ranged from plus 4.75 diopters to minus 7.50 diopters, with the mean being minus 2.18 diopters. For the control group, the range was from plus 7.75 diopters to minus 6.00 diopters and the mean was minus 0.51 diopter. This difference is also reflected in the unaided acuity difference discussed earlier.

Cylindrical refractive error

The cylindrical refractive error, or correction for astigmatism, manifested by the two groups of subjects is shown in Figure 4. The CL group data reflect the imposed limits in amount of cylindrical error allowed for subjects. The range is rather narrow, with the highest power being minus 1.75 diopters. The control group, on the other hand, shows a wide range extending to minus 5.00 diopters. For the CL wearers the mean was minus 0.39 diopters, while the mean for the spectacle wearers was minus 1.45 diopters.

Corrected acuity

A summary of the corrected binocular acuities of the two groups is contained in Table 8. Binocular acuities are presented here because they are more directly related to operational performance. For the CL group, data are presented for selected exams conducted throughout the study. Acuity recorded for the initial exam was obtained as part of the refraction performed by the optometrist. Those acuities for the remaining exams (7-day, 90-day, 180-day) were recorded through the habitually-worn contact lenses. Both the initial and the final exam acuities for the spectacle-wearers were obtained by the optometrist as part of a complete eye exam. The final habitual acuity was recorded during the final exam and was taken through the lenses worn by the subject throughout the study.

During their initial exam, 99 percent of the CL wearers achieved 1.0' MAR (20/20) or better. Among the spectacle wearers at the initial exam, 95 percent exhibited 1.0' MAR (20/20) or

better. At the 7-day exam, the acuities of the CL subjects were somewhat reduced. Although the procedural differences between the initial and 7-day exams likely account for much of this apparent reduction, other factors may have been involved, including:

- a. the inability of the soft lenses to fully compensate for allowable astigmatism (up to -1.25 diopters),
- b. initial adjustment to SCL wear,
- c. a possible need to change lens parameters.

The improvement in acuity noted at the 90-day visit could have been due partially to the attrition of subjects who were having problems with acuity. It was also likely related to progressive adaptation to SCL wear.

A comparison of the final acuities of the CL subjects and the spectacle wearers through their habitual lenses shows that the proportion achieving 20/25 or better was 97 percent for each group. Although the mean unaided acuity for the spectacle control group was somewhat better than the CL group, both groups were able to achieve comparable corrected acuities.

Ocular physiology

Tonometry

All CL subjects and spectacle controls received an intraocular pressure test during the initial exam and were within normal limits.

Keratometry

Corneal curvature was measured on all contact lens subjects and controls to decide on a suitable base curve of the contact lens to be fitted to each eye. There were no changes in mean keratometric measurements from the initial to the final exam for either the contact lens wearers or control subjects.

Table 9

Mean keratometric findings (diopters)

	CL wearers		Spectacle wearers	
	Initial	Final	Initial	Final
Flat meridian	43.46	43.40	43.45	43.54
Steep meridian	44.08	43.98	44.42	44.46

Shirmer tear test

All CL subjects received a Shirmer tear test. This is a commonly used clinical test to evaluate the rate of tear flow and determine whether a patient produces a sufficient amount of tears for comfortable wearing of contact lenses. Normal tear secretion moistens 15 mm of a filter paper strip in 5 minutes. The mean findings for contact lens subjects were 16.11 mm/5 min in the right eye and 16.18 mm/5 min in the left eye.

Tear breakup time (BUT)

The time the tear layer takes to form dry spots on the cornea when blinking is interrupted is called the tear breakup time. This time is a reflection of the stability of the tear film. Breakup time in normal subjects varies between 10 and 45 seconds. The CL subjects' mean breakup time was 20.69 seconds for the right eye and 20.64 seconds for the left eye.

Biomicroscopy

Biomicroscopy was performed on all CL subjects and controls. This procedure involves examining the eye using an instrument producing a slender beam of intense light to illuminate the transparent cornea or a wider beam for illuminating the sclera and adnexa. The illuminated ocular structures are viewed through a microscope. Biomicroscopy is a necessary objective procedure to determine (a) the suitability of a subject for contact lens wear, (b) the performance of both trial and fitted contact lenses on the eye and (c) the physiological response of the eye and adnexa to contact lens wear.

Although each subject received a biomicroscopic evaluation during each examination, only data from the initial and final examinations for controls and from the initial, 7-day, 90-day, and final examinations for CL subjects are presented in this report. The classification codes found in the biomicroscopy tables below are those recommended by the FDA for clinical investigations (Appendix E).

Edema

Corneal edema is a common complication of SCL extended wear, and is due primarily to oxygen deprivation. This increase in the amount of interstitial fluid in the cornea causes increased light scattering and a corresponding reduced transparency. The reduced transparency can be evaluated and graded by the clinician. When more severe edema is present, folds in the endothelial cell layer and Descemet's membrane occur, causing vertical white lines or striae to be seen. As can be seen from Table 10 the percentage of eyes exhibiting moderate degrees of micro-edema or gross edema was very small in CL participants; as expected, edema was nonexistent in the spectacle wearers. Slight micro-edema occurs commonly in extended-wear contact lens wearers, especially in the early part of the day when the cornea has not had time to deswell from overnight lid closure.

Vascularization

The cornea is normally avascular and derives its nutrients from the pericorneal vessels, from the tears, and from the aqueous humor. Corneal vascularization, or neovascularization, occurs with the appearance of new vessels filled with blood on the superficial epithelial surfaces in the limbal areas in contact lens wearers (Goldberg, 1970). This is thought to be an inflammatory process in response to edema, reduced oxygen and the retention of toxic byproducts in the tear layer. Sometimes these new vessels slowly extend two or more millimeters into the cornea. When contact lens wear is ceased blood disappears from the vessels. Six CL wearing subjects (three experienced and three inexperienced) were discontinued permanently during the study for vessel growth of greater than 2 mm. Table 11 shows the percentages of eyes exhibiting vascularization among the groups in this study. It is readily apparent that vessel ingrowth increased over the course of the study in all three groups. This would be expected in the contact lens participants, although not necessarily at the high rates reported. However, the spectacle wearing controls were free from contact lenses and/or ocular pathologies which would lead to an increased incidence of vascularization. Therefore, it appears that the clinicians involved in the study either (1) changed their reference criteria for the biomicroscope codes or (2) became more experienced observers after performing hundreds of biomicroscope examinations

Table 10

Percentage of eyes exhibiting edema

Classification	Code	Inexperienced CL wearers				Experienced CL wearers				Spectacle wearers	
		Initial (N=360)	7-day (N=292)	90-day (N=200)	Final (N=202)*	Initial (N=70)	7-day (N=64)	90-day (N=36)	Final (N=38)	Initial (N=192)	Final (N=140)
	0	98%	96%	93%	81%	97%	97%	100%	95%	100%	100%
Slight - localized	1	2%	3%	5%	14%	3%	3%	-	5%	-	-
Slight - generalized	2	-	1%	1%	2%	-	-	-	-	-	-
Moderate - localized	3	-	<1%	-	1%	-	-	-	-	-	-
Moderate - generalized	4	-	-	-	2%	-	-	-	-	-	-
Vertical striae	5	-	-	1%	-	-	-	-	-	-	-
Circumscribed gross	6	-	-	-	-	-	-	-	-	-	-
Generalized gross	7	-	-	-	-	-	-	-	-	-	-
Vertical striae/stromal	8	-	-	-	-	-	-	-	-	-	-
Folds in Descemets membrane	9	-	-	-	-	-	-	-	-	-	-
Circumscribed gross/stromal	10	-	-	-	-	-	-	-	-	-	-
Generalized gross/stromal	11	-	-	-	-	-	-	-	-	-	-

* Includes some cases of suspension which were deferred for disposition until the final exam.

Table 11

Percentage of eyes exhibiting vascularization

Classification	Code	Inexperienced CL wearers				Experienced CL wearers				Spectacle wearers	
		Initial (N=360)	7-day (N=292)	90-day (N=200)	Final (N=202)*	Initial (N=70)	7-day (N=64)	90-day (N=36)	Final (N=38)	Initial (N=192)	Final (N=140)
None	0	84%	78%	50%	40%	63%	53%	39%	37%	97%	70%
Vessel ingrowth, 1 quadrant	1	14%	20%	28%	25%	28%	28%	28%	21%	3%	27%
Vessel ingrowth >1 quadrant	2	3%	1%	19%	33%	9%	19%	28%	32%	-	1
Continuing growth <2 mm	3	-	-	2%	2%	-	-	5%	10%	-	1%
Continuing growth >2 mm	4	-	1%	<1%	-	-	-	-	-	-	-
Accelerating vascularization	5	-	-	1%	-	-	-	-	-	-	-

* Includes some cases of suspension which were deferred for disposition until the final exam.

over a 6-month period. If one ignores this apparent "learning curve," important differences still exist in the initial and final examinations of all three groups. First, experienced CL wearers exhibited a higher incidence of vessel ingrowth than did inexperienced wearers at the initial examination. By the final examination, both experienced and inexperienced SCL wearers had comparable percentages of vessel ingrowth that were higher than spectacle wearers.

The most likely reason for the high rates of vascularization found in contact lens wearers in this study is the manner of reporting. By using a very stringent criterion to report any amount of vascularization, incidence rates will be increased. Zucarro, Thayer, and Poland (1985) in a 5-year study of SCL wearers reported vascularization in only 3 percent of all followup examinations, but failed to report occurrences of less than 1.5 mm vessel extension inside the limbus. Nilsson and Persson (1986) reported no vascularization at all in a 2-year study of extended wear contact lens patients. They defined vascularization as growth greater than 1 1/4 mm. It appears then that extensions of 1 to 1 1/2 mm into the cornea are not considered significant.

Injection

Conjunctival injection is a dilation and engorgement of the conjunctival blood vessels. Contact lenses can be a factor in causing injection due to increased edema, mechanical irritation and sensitivity reactions to the solutions used in their storage and disinfection. However, transitory injection often is caused by local irritants such as dust, wind, smoke and exposure to bright light. Table 12 summarizes the percentages of eyes exhibiting injection over the course of this study. Spectacle wearers showed approximately the same total number of injected eyes at the final exam as at the initial with a shift from mild to severe. Inexperienced CL subjects began the study with the same percentages as the spectacle group, but progressed to higher percentages exhibiting codes 1 and 2 as well as individuals who presented hyperemia. Experienced CL subjects showed a much higher incidence of mild congestion initially. In this group the final exam indicated a relative increase in more severe congestion. The incidence of injection is much higher than found in the studies of Zucarro, Thayer, and Poland (1985) and Nilsson and Persson (1986). Conjunctival injection is a common finding, even in the absence of infection or insult, because it involves readily visible vascularized and transparent tissue backed by white sclera. The soldiers in this study, both spectacle wearers and CL wearers, seemed predisposed to injection. This may have been related to the environment in which they worked and their constant exposure to local irritants.

Table 12

Percentage of eyes exhibiting injection

Classification	Code	Inexperienced CL wearers				Experienced CL wearers				Spectacle wearers	
		Initial (N=360)	7-day (N=292)	90-day (N=200)	Final (N=202)*	Initial (N=70)	7-day (N=64)	90-day (N=36)	Final (N=38)	Initial (N=192)	Final (N=140)
None	0	70%	48%	33%	42%	49%	52%	44%	55%	69%	66%
Mild congestion and dilation of limbal vessels	1	25%	47%	53%	32%	45%	48%	39%	26%	28%	16%
Severe congestion and dilation of limbal vessels	2	6%	5%	11%	21%	6%	-	17%	18%	3%	18%
Conjunctival hyperemia	3	-	-	2%	5%	-	-	-	-	-	-

* Includes some cases of suspension which were deferred for disposition until the final exam.

Table 13

Percentage of eyes exhibiting staining

Classification	Code	Inexperienced CL wearers				Experienced CL wearers				Spectacle wearers	
		Initial (N=360)	7-day (N=292)	90-day (N=200)	Final (N=202)*	Initial (N=70)	7-day (N=64)	90-day (N=36)	Final (N=38)	Initial (N=192)	Final (N=140)
None	0	99%	97%	92%	97%	100%	98%	89%	94%	99%	100%
Minimal peripheral stippling	1	1%	2%	4%	3%	-	-	11%	3%	-	-
Superficial punctate	2	-	1%	3%	-	-	2%	-	3%	-	-
Epithelial dimpling	3	-	-	-	-	-	-	-	-	-	-
Abrasions of epithelium	4	-	<1%	<1%	-	-	-	-	-	1%	-
Deep abrasions, ulcerations	5	-	-	-	-	-	-	-	-	-	-
Foreign body staining	6	-	-	-	-	-	-	-	-	-	-

* Includes some cases of suspension which were deferred for disposition until the final exam.

Staining

Staining is a procedure whereby sodium fluorescein, a diagnostic agent, is introduced into the eye of a CL subject and viewed under magnification. This agent is used to tint the precorneal film layer and to expose changes in the corneal epithelium. The normal corneal epithelium does not stain, but epithelial changes may cause fluorescein staining when there is an interruption in the continuity of the corneal epithelium. The degree of staining is related to the severity of the damage. As can be seen in Table 13 the percentage of eyes exhibiting staining of any kind was very low. This not only documents the lack of corneal insult but indicates good contact lens removal technique on the part of the subjects, since improper removal of the lens can cause some epithelial cell loss.

Other complications

This classification includes complications which have not been discussed above. Table 14 shows that the only unusual occurrence was the high incidence of follicular hypertrophy observed for all groups. This is attributed to the endemic occurrence of mild vernal conjunctivitis at Fort Hood during the study period. Code 5, an "other" classification, includes such observations as papillae, pingueculae, blepharitis and coated lenses.

Suspension and attrition

In accordance with accepted clinical practice and the terms of the approved research protocol, CL wear was suspended temporarily when ocular complications developed. At least one period of suspended wear occurred for 72 CL wearers during the course of the study. This number includes three cases where suitable replacement lenses were not available. The remaining cases were all related to ocular physiology, with 56 inexperienced CL subjects and 13 experienced CL subjects developing suspension-related ocular complications over the course of the study.

Causes of suspension

The various ocular complications resulting in suspended CL wear are presented in Table 15. Some individuals were suspended from CL wear more than once (none more than three times), resulting in 87 cases of suspension for medically related reasons. The most common cause of suspension was inflammation of some segment of the anterior portion of the eye, the conjunctiva, or the eyelids, accounting collectively for 41 percent of the total number of suspensions. Abrasions, staining, and epithelial defects of the cornea collectively accounted for 29 percent of

Table 14

Percentage of eyes exhibiting other complications

Classification	Code	Inexperienced CL wearers				Experienced CL wearers				Spectacle wearers	
		Initial (N=360)	7-day (N=292)	90-day (N=200)	Final (N=202)*	Initial (N=70)	7-day (N=64)	90-day (N=36)	Final (N=38)	Initial (N=192)	Final (N=140)
None	0	76%	90%	94%	84%	80%	90%	94%	84%	86%	82%
Increase in sebaceous secretion	1	4%	1%	-	<1%	1%	5%	-	-	-	-
Follicular hypertrophy	2	11%	4%	5%	10%	6%	-	6%	11%	10%	14%
Traumatic iritis	3	-	-	-	-	-	-	-	-	-	-
Opacity or scarring of cornea	4	<1%	-	-	-	-	-	-	-	-	-
Other (see text)	5	8%	5%	1%	5%	13%	5%	-	5%	4%	4%

* Includes some cases of suspension which were deferred for disposition until the final exam.

the total number of suspensions. These two categories -- inflammations and physical corneal changes -- encompassed 94 percent of the total suspensions among experienced CL wearers. The sample sizes in this study do not support serious estimates of incidence rates.

Table 15

Number and causes of medically-related contact lens wear suspensions

Cause	Number of occurrences	
	Inexperienced CL wearers	Experienced CL wearers
Conjunctivitis	13	8
Corneal abrasion	13	3
Corneal staining	7	0
Overwear syndrome	6	0
Giant papillary conjunctivitis	5	1
Corneal edema	4	0
Use of medication	3	0
Foreign body involvement	2	0
Iritis	2	1
Neovascularization	2	1
Keratoconjunctivitis	2	0
Keratitis	2	1
Phlyctenule	2	0
Corneal ulcer	1	0
Epithelial defects	0	2
Dermatitis (eyelids)	1	0
Sensitivity to solutions	1	0
Ocular hypertension	1	0
Eye trauma	1	0
Decreased visual acuity	2	0

Cross-study suspension trend

The rate of occurrence of ocular complications resulting in suspension of CL wear declined as the study progressed. This trend can be seen in Table 16, which combines data for the inexperienced and experienced CL groups since the two showed similar trends. The rates in Table 16 are based on average monthly census figures, which rules out dwindling sample size as a direct factor in the relative frequency of suspended CL wear. This declining trend has been noted elsewhere in the literature (Koetting, 1983) and may be related to progressive attrition of

complication-prone subjects as cumulative CL wearing time increases. It is possible that the trend would have reversed at some point if this study had lasted longer. It should be noted that the cross-study trends for specific ocular conditions varied somewhat. For example, corneal abrasion and corneal staining tended to occur early (between 1 and 60 days of wear), giant papillary conjunctivitis occurred fairly evenly throughout the course of the study, and overwear syndrome tended to occur in the last half of the study.

Table 16

Incidence of medically-related contact lens wear suspensions by month

Day	Average census	Number of suspensions	Rate of suspensions
1- 30	208	27	13.0%
31- 60	194	15	7.7%
61- 90	180.5	17	9.4%
91-120	162.5	11	6.8%
121-150	141.5	8	5.7%
151-180	125.5	7	5.6%
>180	---	2	---

Suspension duration

The length of medically-related CL wear suspensions varied considerably. Two cases recorded as exceeding 100 days in duration were the result of the subjects failing to return to the clinic for reevaluation prior to being administratively removed from the study. When these two cases were disregarded, the duration of suspension ranged from 1 day to 59 days, with a median duration of 6 days. The distribution of actual durations is presented in Figure 5.

No cases of ocular complications were observed in the spectacle control group, aside from the findings from the biomicroscopy examinations presented elsewhere in this report. Of course, the control subjects were not examined as often as the CL wearers, and suspension of CL wear was not a prospect for the spectacle controls.

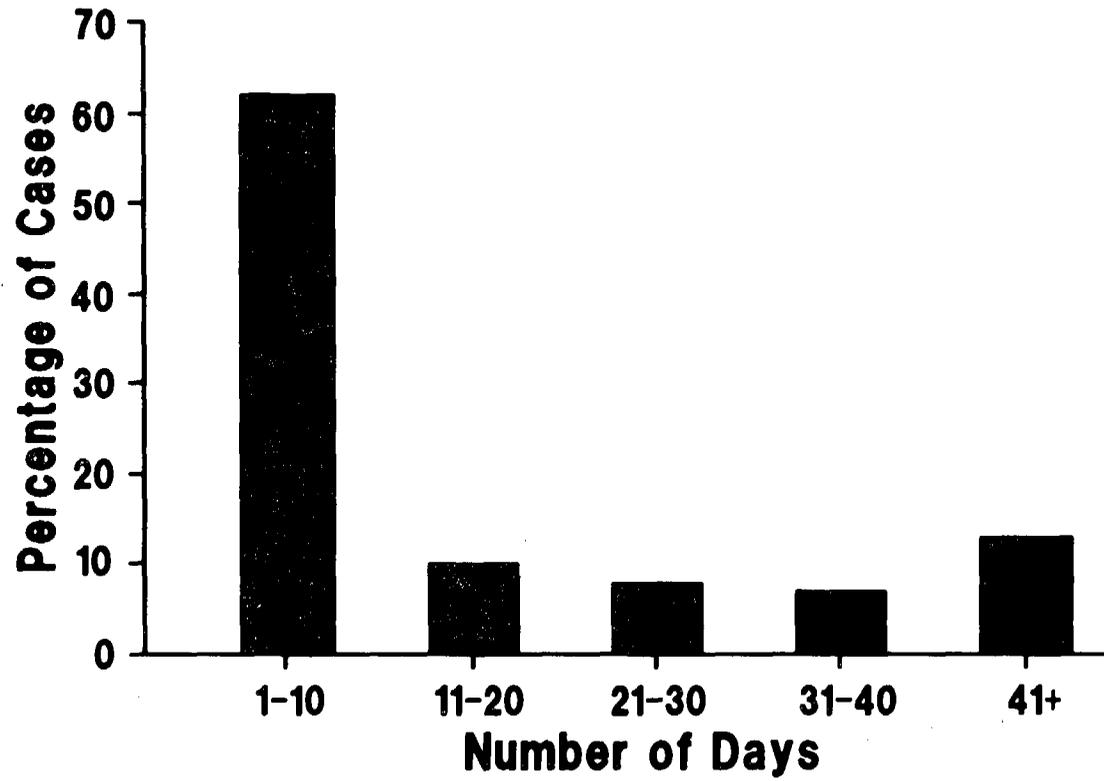


Figure 5. Distribution of durations of contact lens wear suspensions related to ocular physiology (number of cases = 85).

Incidence and causes of attrition

Ocular conditions which posed unacceptable jeopardy to the CL wearers, as specified in the approved research protocol or identified by the optometrist's clinical judgment, occurred occasionally, necessitating removal of subjects from the study. In addition, a number of subjects were discontinued before the end of the study due to administrative circumstances or self-withdrawal. The attrition resulting from these combined causes was labelled "permanent discontinuation" in the TCATA report. The cases of attrition are listed in Table 17 according to the nature of the cause. A total of 64 CL subjects failed to complete the study for administrative or personal reasons. The distribution of nonmedical attrition across the course of the study can be seen in Table 3.

The number of CL participants failing to complete the study for medically related reasons was 40 with 34 inexperienced wearers and 6 experienced wearers as shown in Table 17. These figures were compared to the respective census at the start of the study, excluding those subjects who eventually withdrew for nonmedical reasons. The results (Table 18) reveal that 27 percent of the inexperienced CL wearers and 24 percent of the experienced wearers developed attrition-precipitating complications within 6 months of CL wear. The most frequent causes of early withdrawal were discomfort, dissatisfaction with acuity, and giant papillary conjunctivitis. These three conditions together accounted for 68 percent of the cases of medically related attrition. The numbers for the various causes in Table 17 are too small to permit individual comparisons between groups.

Table 17

Number and causes of cases of attrition
among contact lens participants

Cause	Number of cases	
	Inexperienced CL wearers (N=180)	Experienced CL wearers (N=35)

A. Nonmedical		
Missed appointments	17	1
Discharge or ETS	16	5
Reassignment	10	3
Lack of interest	6	0
Lenses not available	3	0
Lost or damaged lenses	1	1
Extended TDY	1	0
	54	10
B. Medically related		
Discomfort	12	2
Dissatisfaction with acuity	5	0
Discomfort and dissatisfaction with acuity	2	0
Giant papillary conjunctivitis	6	0
Neovascularization (>2mm)	3	3
Decreased visual acuity (>7 days duration)	2	0
Blepharitis	1	0
Corneal staining	1	0
Corneal stromal infiltrates	0	1
Tight lens syndrome	1	0
Insertion problems	1	0
	34	6

Table 18

Incidence of medically-related attrition among contact lens participants across entire study

	Adjusted census*	Number of occurrences	Rate of occurrence
Inexperienced CL wearers	126	34	27%
Experienced CL wearers	25	6	24%

*Determined by subtracting the total number of nonmedical attritions from the starting census.

Cross-study attrition trend

As the study progressed, the rate of occurrence of attrition-precipitating ocular complications generally declined (Table 19). Forty-five percent of the total cases of attrition occurred within the first 60 days of the study. This trend is similar to the progressive decline described above for suspension-precipitating complications, though not as pronounced. This similarity is probably due to commonality among the factors leading to CL wear-related ocular complications in general. Since the rates in Table 19 are based on average monthly census figures, the declining trend is not an artifact of decreasing sample size. It has been noted previously in the literature (Koetting, 1983) and is understandable if it is assumed that individuals who are more susceptible to CL-induced complications tend to experience attrition earlier. The rate of attrition during the sixth month of the study was relatively high due to the fact that several cases of suspension were deferred for final disposition until the end of the study. It should be noted that the trend of declining medical attrition across time did not hold for the experienced CL group, whose six cases of medically related attrition were spread evenly between the first and second halves of the study.

Table 19

Occurrence of medically-related attrition among
contact lens participants by month

Day	Average census	Number of occurrences	Rate of occurrence
1- 30	208	10	4.8%
31- 60	194	8	4.1%
61- 90	180.5	4	2.2%
91-120	162.5	6	3.7%
121-150	141.5	3	2.1%
151-180	125.5	6*	4.8%*
>180	--	3	--

* Includes several cases of suspension which were deferred for final disposition until the end of the study.

Relationship between suspension and attrition

Among the 69 CL subjects experiencing at least 1 case of medically-related suspension of CL wear, 3 eventually withdrew from the study because of discomfort and/or visual acuity problems and 13 were dropped for other medical reasons. Thus of the 40 medical attritions, 40 percent had presented at least 1 ocular complication previously. The rate of medical attrition among subjects experiencing suspension (32 percent, computed after factoring out nonmedical attritions) was modestly higher than the comparable rate (24 percent) for those who had not developed a previous ocular complication. This latter finding might suggest that some individuals are more susceptible to adverse physiological effects of SCL wear.

Combined ocular complications

Both suspension and attrition of CL wearers reflect the occurrence of ocular complications. Accordingly, a comprehensive picture of ocular complications can be obtained by combining the data for suspension and attrition. A total of 79 CL subjects developed at least 1 ocular complication. This translates into a proportion of CL subjects equal to 47 percent when the average census across the entire study is used for computation. In other words, on a 6-month equivalent basis 47 percent of those wearing CLs developed one or more ocular condition(s) requiring at least a short suspension of CL wear. Table 20 presents the monthly rates of occurrence for combined ocular complications. The trend

of declining rates across time, discussed above, is evident in this table.

Table 20

Monthly incidence of ocular complications associated with contact lens wear suspension and/or attrition

Day	Average census	Number of occurrences	Rate of occurrence
1- 30	208	37	17.8%
31- 60	194	23	11.9%
61- 90	180.5	21	11.6%
91-120	162.5	17	10.5%
121-150	141.5	11	7.8%
151-180	125.5	13	10.4%
>180	--	5	--

The complication rates observed in this study do not necessarily reflect those which might be experienced in garrison, field, or combat environments. The extensive control measures and precautions built into this study would not be feasible in those environments.

Contact lens wear success rates

Those CL participants at the end of the study who had not been terminated for medical reasons are defined as medically successful CL wearers. However, those CL participants who were terminated for administrative or personal reasons can be labelled neither medically unsuccessful nor successful. Consequently, nonmedical attritions should be factored out when computing success rates for this study. Of the 215 CL subjects who started the study, a total of 151 (126 inexperienced wearers, 25 experienced wearers) remained in the study to a definitive disposition. Among the inexperienced wearers, 92 of 126 (73 percent) were medically successful after 4-7 months of CL wear. The success rate for experienced wearers (19 of 25, or 76 percent) was comparable. In other words, when nonmedical attritions are factored out, three out of every four CL wearers reached the end of the study without being discontinued for medically related reasons, regardless of whether they were experienced in CL wear at the start. Table 21 presents a breakdown of success rates computed at the end of succeeding

months of CL wear. The analysis factors out nonmedical attritions. It can be seen, for example, that the success rate after 3 months of CL wear was 89 percent. It is not reasonable to project the trend line beyond the end of the study, though presumably the progressive success rates would continue to decline. It is safe to assume that medical attrition would not reach zero within 12 months of continuous CL wear (Koetting, 1983).

Table 21

Success rates across increasing periods
of contact lens wear

Day	Adjusted census, day 1*	Ending census	Success rate
1- 30	211	201	95%
1- 60	205	187	91%
1- 90	196	174	89%
1-120	179	151	84%
1-150	163	132	81%
1-180	156	119	76%
1-181+	151	111	74%

* Determined by subtracting the cumulative number of non-medical attritions from the starting census.

From the success rates observed in this study, it is difficult to estimate a realistic success rate for a typical Army unit. The extensive precautions and intensive medical attention incorporated into this study would not be expected in a normal garrison setting, let alone field and combat environments. On the other hand, the limited contact lens types and parameters available in this study may have resulted in some preventable attritions. On balance, the 75 percent 6-month success rate may be the best available for estimation purposes at the moment.

Contact lens wear success rates were computed for different age groups, and the results are seen in Table 22. While success rate generally declined as age increased, the highest success rate was experienced by the oldest group (36 and over). A comparison of success rates among different job clusters (Table 23) revealed the highest rate occurred among ADA team members. This was also the smallest job cluster represented in the study.

and any conclusion about the influence of job related factors on CL wear would be circumspect.

Table 22

Contact lens wear success rates by age

Age	Adjusted starting census*	Ending census	Success rate
<21	25	19	76%
21-25	58	44	76%
26-30	36	26	72%
31-35	19	12	63%
>35	13	10	77%

*Determined by subtracting the number of nonmedical attritions from the starting census.

Table 23

Contact lens wear success rates by duty assignment

Duty assignment	Adjusted starting census*	Ending census	Success rate
M1 tank crewmember	49	35	71%
Combat vehicle crewmember	61	47	77%
ADA team member	10	9	90%
Miscellaneous	31	20	65%

*Determined by subtracting the number of nonmedical attritions from the starting census.

Among the spectacle control group, 16 subjects were discontinued for administrative and personal reasons. No cases

of attrition for medical reasons occurred among the control subjects.

Questionnaire data - lens wear and care

Questionnaires were administered to 135 of the 180 inexperienced CL wearers, 25 of the 35 experienced CL wearers, and 84 of the 96 spectacle wearers at the conclusion of their participation in the study. This was done to obtain information concerning difficulties or problems encountered while they wore corrective lenses during the study. Not every individual answered every question.

In reviewing and interpreting the results presented in this section, the reader should bear in mind two tempering considerations. First, the corrective lens frame of reference for CL subjects was different than for spectacle wearers, since most of the latter had no experience with CLs. This may have differentially influenced questionnaire responses involving direct or indirect comparison between the two types of corrective lenses. Second, the CL wearers generally may have been motivated to present a favorable picture of the contact lenses. This could have influenced them to underestimate the frequency or severity of lens-related problems. These kinds of considerations are encountered frequently in using questionnaires.

Use and care problems

Table 24 shows the responses from participants on how often they experienced problems during the handling and care of corrective lenses. Inserting contact lenses was the only activity that proved to be a periodic problem for more than 12 percent of both inexperienced and experienced CL wearers. In contrast, both handling and cleaning were reported to be at least a periodic problem for 44 percent or more of the spectacle wearers.

Table 24

Percentage of participants reporting problems related to use and care of corrective lenses

Activity	Never	Seldom	Sometimes	Often	Always

Inexperienced CL wearers (N=135)					
Inserting	11%	44%	36%	4%	5%
Removing	70%	23%	4%	1%	2%
Handling	55%	34%	7%	4%	0
Cleaning	67%	21%	9%	3%	0
Disinfecting	80%	14%	4%	1%	1%

Experienced CL wearers (N=25)					
Inserting	32%	40%	20%	4%	4%
Removing	76%	20%	4%	0	0
Handling	64%	28%	4%	4%	0
Cleaning	68%	28%	4%	0	0
Disinfecting	80%	16%	0	4%	0

Spectacle wearers (N=84)					
Handling	27%	28%	28%	12%	4%
Cleaning	26%	24%	24%	20%	6%

Table 25 indicates the degree of severity reported for the lens use and care problems experienced by participants. The great majority (more than 70 percent) of CL wearers found any problems they encountered to be minor. Approximately 50 percent of the spectacle wearers reported their problems with handling and cleaning to be moderate or severe.

Table 25

Questionnaire responses on extent to which lens use and care problems were bothersome

Activity	Number responding	Minor	Moderate	Severe
=====				

Inexperienced CL wearers				
Inserting	120	78%	20%	3%
Removing	38	89%	11%	0
Handling	59	81%	14%	5%
Cleaning	44	73%	27%	0
Disinfecting	24	71%	29%	0
Experienced CL wearers				
Inserting	17	71%	24%	6%
Removing	6	100%	0	0
Handling	9	89%	11%	0
Cleaning	8	75%	25%	0
Disinfecting	5	80%	20%	0

Spectacle wearers				
Handling	60	45%	43%	12%
Cleaning	62	52%	39%	10%

Table 26 displays the acceptability of problems experienced by the participants when handling and caring for their prescriptive devices. The majority of all participants reported handling and care problems to be moderately or highly acceptable.

Table 26

Questionnaire responses on acceptability of lens use and care problems experienced

Activity	Number responding	Highly accept	Mod accept	Neither accept nor unaccept	Mod unaccept	Totally unaccept
=====						

Inexperienced CL wearers						
Inserting	120	46%	36%	11%	3%	3%
Removing	41	44%	34%	22%	0	0
Handling	61	48%	25%	21%	5%	2%
Cleaning	43	47%	35%	16%	2%	0
Disinfecting	27	33%	44%	15%	7%	0
Experienced CL wearers						
Inserting	17	47%	29%	0	18%	6%
Removing	6	67%	33%	0	0	0
Handling	9	33%	56%	0	11%	0
Cleaning	8	38%	25%	13%	0	25%
Disinfecting	5	20%	40%	20%	20%	0

Spectacle wearers						
Handling	61	8%	56%	18%	10%	8%
Cleaning	62	8%	52%	23%	11%	6%

Table 27 shows responses from spectacle wearers on how often they experienced problems peculiar to their spectacles and how bothersome the problems were. Lost or broken spectacles were not considered a major problem. However, dirty, smeared or poorly adjusted spectacles did frequently plague the spectacle wearing group in this study.

Table 27

Problems reported by spectacle wearers

Problem	#	Frequency			#	How bothersome		
		Often	Some- times	Never		Severe	Moder- ate	Minor
Glasses slipping down nose	84	52%	39%	8%	77	19%	49%	31%
Glasses falling off or dis- lodging	84	20%	44%	36%	54	22%	41%	37%
Loss of glasses	82	7%	30%	62%	31	13%	32%	55%
Lenses covered with dust or dirt film	84	57%	38%	5%	80	28%	44%	29%
Lenses covered with dust or dirt spots	83	52%	40%	8%	76	28%	45%	28%
Smearing of lenses	84	51%	41%	8%	75	24%	45%	31%
Sweat streaks on lenses	84	43%	42%	15%	70	21%	47%	31%
Raindrops on lenses	84	36%	56%	8%	77	23%	47%	30%
Fogging of lenses	84	29%	63%	8%	77	29%	39%	32%
Scratching or chipping of lenses	84	19%	46%	35%	55	15%	44%	42%
Broken lenses	84	5%	26%	69%	26	15%	31%	54%
Bent frames	84	18%	39%	43%	48	21%	38%	42%
Broken frames	84	7%	38%	55%	38	18%	39%	42%
Discolored frames	83	5%	27%	69%	26	8%	50%	42%
Lenses falling out of frames	84	6%	42%	52%	40	18%	38%	45%
Loose earpieces	84	10%	32%	58%	35	23%	40%	37%
Loss of screws	84	21%	40%	38%	52	33%	33%	35%
Discomfort from frame	84	30%	44%	26%	62	29%	44%	27%

Comfort

Table 28 displays the responses of all three groups on the comfort of CLs and spectacles. Almost 90 percent of both groups of CL wearers reported their lenses were comfortable or very comfortable to wear. Only 50 percent of spectacle wearers gave this same response.

Table 28

Questionnaire responses on comfort of lenses

Response	Inexperienced CL wearers (N=135)	Experienced CL wearers (N=25)	Spectacle wearers (N=83)
Very uncomfortable	0%	0%	8%
Uncomfortable	4%	4%	16%
Neither comfortable nor uncomfortable	7%	8%	27%
Comfortable	34%	16%	46%
Very comfortable	55%	72%	4%

Table 29 presents the frequency of problems reported with discomfort from SCLs by both CL wearing groups. Eye irritation, blurred vision and light sensitivity were the complaints that more frequently caused problems for both groups.

Table 29

Questionnaire responses regarding
discomfort-related complaints (CL wearers)

Complaint	Always	Often	Some- times	Seldom	Never
Inexperienced CL wearers (N=131-135)					
Eyelid irritation	1%	1%	15%	29%	54%
Eye irritation	1%	6%	28%	40%	25%
Eye pain	0	2%	10%	28%	60%
Blurred vision	2%	9%	34%	35%	21%
Reduced tear flow	1%	5%	16%	23%	55%
Light sensitivity	4%	8%	15%	23%	50%
Experienced CL wearers (N=25)					
Eyelid irritation	0	4%	4%	28%	64%
Eye irritation	0	8%	20%	48%	24%
Eye pain	0	0	8%	24%	68%
Blurred vision	0	4%	28%	52%	16%
Reduced tear flow	0	0	12%	32%	56%
Light sensitivity	8%	8%	8%	28%	48%

Table 30 shows the severity of problems experienced with the discomfort associated with SCL wear. As can be seen, a substantial majority of CL wearers found problems they encountered to be minor.

Table 30

Severity of discomfort-related complaints (CL wearers)

Complaint	Number responding	Minor	Moderate	Severe
Inexperienced CL wearers				
Eyelid irritation	61	80%	16%	3%
Eye irritation	100	71%	24%	5%
Eye pain	54	74%	19%	7%
Blurred vision	105	66%	30%	5%
Reduced tear flow	60	73%	25%	2%
Light sensitivity	64	66%	28%	6%
Experienced CL wearers				
Eyelid irritation	9	89%	0	11%
Eye irritation	19	63%	32%	5%
Eye pain	8	75%	13%	13%
Blurred vision	21	81%	19%	0
Reduced tear flow	11	82%	18%	0
Light sensitivity	13	62%	31%	8%

Wear schedule adherence

Table 31 documents the adherence of the two CL groups to the recommended wearing schedule; 8 percent of both groups never or only once in a while adhered to the wearing schedule. As previously stated the subjects were instructed to wear their lenses for 6 to 8 days and then remove them for 1 night, cleaning and disinfecting the lenses at that time. About one in four CL wearers wore their lenses more than 10 days between cleanings on at least one occasion. A small percentage of both groups exceeded even this time frame. The maximum time between consecutive cleanings was 3 to 4 weeks for a few subjects. This indicates that there will be noncompliant individuals when contact lenses are worn.

Table 31

Adherence to recommended wearing schedule

Response	Inexperienced CL wearers (N=135)	Experienced CL wearers (N=25)
Always	38%	28%
Most of the time	45%	48%
About 1/2 the time	9%	16%
Once in a while	5%	0
Never	3%	8%

Personal motivation

Motivation plays a significant part in the success of any program. In contact lens fitting, desire and motivation are the first considerations in accepting a patient. Table 32 displays the attitudes of all three groups in this study towards their corrective lenses. More than 90 percent of both CL groups liked their contact lenses moderately or very much. This contrasts with 18 percent of spectacle wearers who liked their spectacles moderately or very much. The reasons reported most often for their dislike were that spectacles got in the way, were uncomfortable, and that Army spectacles were ugly.

Table 32

Attitude toward wearing corrective lenses

Response	Inexperienced CL wearers (N=135)	Experienced CL wearers (N=25)	Spectacle wearers (N=82)
Like very much	80%	92%	7%
Like moderately	13%	4%	11%
Neither like nor dislike	4%	0	28%
Dislike moderately	2%	4%	22%
Dislike very much	0	0	32%

Both experienced and inexperienced CL participants were queried as to their desire to continue wearing CLs (Table 33). All subjects were aware that they would have to relinquish their CLs at the end of the study. Ninety-four percent of inexperienced wearers and 96 percent of experienced wearers indicated that they would want to continue to wear contact lenses.

Table 33

Desire to continue wearing CLs

Response	Inexperienced CL wearers (N=134)	Experienced CL wearers (N=25)
Definitely want to wear	87%	88%
Somewhat want to wear	7%	8%
Do not care one way or other	4%	0
Somewhat do not want to wear	1%	4%
Definitely do not want to wear	1%	0

Questionnaire data - operational aspects

The questionnaires completed at the end of the study included items addressing operational issues related to the wear of corrective lenses. Generally, these items pertained to visual ability, job or task performance, environmental problems, and operational settings. In completing the questionnaires, subjects were asked to respond on the basis of their experience in the study. However, where CL wearers were asked to compare CLs with spectacles they presumably relied in large measure on their previous experience with spectacles. As pointed out in the preceding section, CL wearers may have been motivated to underestimate difficulties associated with their contact lenses. Some of the items were not applicable to all subjects, usually because a given subject may not have experienced all tasks or settings. Occasionally a subject failed to respond to one or more specific items, presumably because of oversight.

Visual confidence

Both CL wearing and spectacle wearing participants were almost unanimously confident in their ability to see adequately (Table 34). However, more than three-fourths of the CL wearers were "highly confident," compared to just half of the spectacle wearers. A large majority of the CL participants (77 percent of the inexperienced wearers, 92 percent of the experienced wearers) felt they could see better with SCLs than with spectacles (Table 35). The larger proportion of the experienced CL group in this category is consistent with their greater cumulative CL wearing experience, but may also reflect some self-selection. Fewer than 8 percent of the CL wearers felt they could see better with spectacles than with contact lenses.

Table 34

Questionnaire responses regarding confidence
in ability to see adequately

Response	Inexperienced CL wearers (N=135)	Experienced CL wearers (N=25)	Spectacle wearers (N=83)
Highly confident	77%	80%	50%
Moderately confident	22%	20%	46%
Hardly confident	0	0	*
Not at all confident	<1%	0	4%

* Spectacle wearers were not given this response choice.

Table 35

Questionnaire responses comparing ability to see
with contact lenses vs. spectacles

Response	Inexperienced CL wearers (N=135)	Experienced CL wearers (N=25)
See better with SCLs	77%	92%
No difference	16%	4%
See better with spectacles	7%	4%

Overall job performance

The majority of CL participants (83 percent of the inexperienced wearers, 96 percent of the experienced wearers) judged that wearing SCLs had improved their overall job performance (Table 36), while less than 5 percent felt it had not. Interestingly, after 4 to 7 months of CL wear, 14 percent of the inexperienced CL subjects did not feel they could say whether job performance had improved or not. When subjects were asked to compare SCLs with spectacles in terms of how much they helped in performance of duties, the response patterns seen in Table 37 emerged. For garrison duties, 82 percent of the inexperienced wearers and 96 percent of the experienced wearers felt that SCLs were at least somewhat better than spectacles. The overall figures are similar for field duties, although the relative proportion in the "much better" category declines, especially for experienced subjects. Fewer than 3 percent of the CL participants felt that spectacles were better than SCLs in garrison; however, the proportion climbed to 13 percent when field duties were considered.

Table 36

Questionnaire responses regarding job performance
impact of wearing contact lenses

Response	Inexperienced CL wearers (N=135)	Experienced CL wearers (N=25)
SCLs improved job performance	83%	96%
SCLs did not improve job performance	3%	4%
No opinion	14%	0

Table 37

Questionnaire responses comparing role of contact
lenses vs. spectacles in performing duties

Response	Garrison		Field	
	Inexperienced CL wearers (N=135)	Experienced CL wearers (N=25)	Inexperienced CL wearers (N=134)	Experienced CL wearers (N=25)
CL much better	67%	92%	58%	68%
CL somewhat better	15%	4%	20%	28%
No difference	16%	0	8%	0
Spectacles somewhat better	<1%	4%	7%	0
Spectacles much better	<1%	0	7%	4%

Task related factors

The CL participants were asked to compare SCLs with spectacles in terms of visual ability afforded while performing various tasks. These tasks included sighting, aiming, and surveillance under different conditions. As can be seen in Table 38, the proportions of subjects judging they could see better with SCLs exceeded 75 percent for most of the tasks. The smallest proportions favoring SCLs (62 percent of the inexperienced wearers, 68 percent of the experienced wearers) occurred for reading and writing. The reason for this most likely lies in the inability to remove contact lenses when it might be appropriate for close-up work. Not surprisingly, nearly all of the CL subjects favored SCLs when wearing protective masks. The proportion of respondents favoring spectacles for the various tasks did not exceed 11 percent for either group.

Table 38

Questionnaire responses comparing task related visual
ability for contact lenses vs. spectacles

Task	Inexperienced CL wearers				Experienced CL wearers			
	Percent reporting				Percent reporting			
	# perf'g task	Better w/SCL	Better w/spec- tacles	No diff	# perf'g task	Better w/SCL	Better w/spec- tacles	No diff
Sight/aim rifle	120	85%	3%	12%	22	82%	5%	13%
Sight/aim thru opt devices	117	91%	3%	6%	22	95%	0	5%
Surveil, <1000m, naked eye	124	75%	9%	16%	25	88%	4%	8%
Surveil, <1000m, thru opt devices	121	85%	3%	12%	24	92%	0	8%
Surveil, >1000m, naked eye	121	69%	11%	20%	25	80%	4%	16%
Surveil, >1000m, thru opt devices	120	82%	5%	13%	24	88%	0	12%
Reading and writing	133	62%	8%	29%	25	68%	8%	24%
Wearing prot mask	128	95%	2%	2%	25	96%	0	4%

Table 39 presents the proportions of participants encountering difficulties when performing different job-related tasks (e.g., map reading, physical fitness exercises). Also included are figures for those reporting removal of spectacles or CLs to perform the tasks. The proportion of CL wearers reporting difficulties did not exceed 8 percent except for swimming, where 53 percent of the inexperienced CL group and 48 percent of the experienced CL group reported difficulties. Similarly, 49 percent of the inexperienced CL wearers and 38 percent of the experienced CL wearers indicated they removed their CLs when swimming. For other tasks, the rate of CL removal was consistently small (generally, 2 percent or less). Spectacle wearing subjects reported substantial incidence of difficulties for several tasks, especially those involving physical activity or hardware requiring ocular compatibility (e.g., optical sights, night vision goggles). A substantial proportion of the spectacle wearers reported difficulty sighting/aiming a rifle (40 percent) and sighting/aiming with optical devices (43 percent). In parallel fashion, frequent removal of spectacles occurred for several tasks.

Table 39

Proportion of participants reporting task difficulties
and removal of corrective lenses

Task	Inexperienced CL wearers			Experienced CL wearers			Spectacle wearers		
	# perf'g task	Percent reporting Diffi- culty	Lens Removal	# perf'g task	Percent reporting Diffi- culty	Lens removal	# perf'g task	Percent reporting Diffi- culty	Lens Removal
Read map	132	4%	<1%	25	0	0	80	6%	5%
Shoot compass azimuth	121	2%	0	25	0	0	76	5%	3%
Assemble/ disassemble indiv wpn	131	2%	0	25	0	0	77	4%	3%
Perform PT	134	5%	2%	25	0	0	74	39%	35%
Fuel vehicle	121	3%	0	23	0	0	77	6%	5%
Perform vehicle maint	129	5%	2%	25	8%	8%	79	16%	15%
Perform routine duties	135	4%	1%	25	4%	0	80	6%	6%

(Continued)

Table 39 (Continued)

Task	Inexperienced CL wearers			Experienced CL wearers			Spectacle wearers		
	# perf'g task	Percent reporting Diffi- culty	Lens removal	# perf'g task	Percent reporting Diffi- culty	Lens removal	# perf'g task	Percent reporting Diffi- culty	Lens removal
Perform manual labor	130	4%	2%	25	0	0	79	27%	23%
Read	134	7%	1%	25	8%	0	83	5%	4%
Write	134	4%	<1%	25	0	0	83	4%	4%
Drive vehicle	132	6%	3%	25	4%	0	80	11%	6%
Sports activi- ties	133	8%	4%	25	4%	0	73	53%	41%
Wear NVG	134	2%	<1%	24	0	0	52	75%	69%
Use night vision sights	134	<1%	0	24	0	0	57	53%	51%
Swim	77	53%	49%	21	48%	38%	--	--	--
Don prot mask	128	2%	0	23	0	0	72	67%	64%
Perform tasks w/ prot mask	126	4%	<1%	22	0	0	72*	39%	--

* Protective mask worn with optical inserts.

When CL participants were asked to indicate their preferences (SCLs or spectacles) for selected tasks, the results summarized in Table 40 emerged. The proportions of inexperienced and experienced CL wearers preferring SCLs were never appreciably below 90 percent, except for a simulated combat exercise with minimum sleep, where the proportion fell to 83 percent for both groups. The reason for the latter may be related to the occurrence of problems associated with wear and care of contact lenses (see earlier section entitled "Questionnaire data - lens wear and care").

Table 40

Questionnaire responses regarding corrective lens preference for performing various activities

Activity	Preferred by inexperienced CL wearers (N=74-97)			Preferred by experienced CL wearers (N=17-18)		
	SCLs	Spec-tacles	No pref	SCLs	Spec-tacles	No pref
Physical exercise	93%	2%	5%	100%	0	0
Sports	92%	2%	6%	100%	0	0
Routine duties	92%	1%	7%	100%	0	0
Manual labor	93%	1%	6%	100%	0	0
Vehicle fueling	89%	2%	9%	100%	0	0
Vehicle maintenance	92%	3%	5%	100%	0	0
Truck/veh ops, day	92%	3%	4%	100%	0	0
Truck/veh ops, night	92%	3%	4%	100%	0	0

(Continued)

Table 40 (Continued)

Activity	Preferred by inexperienced CL wearers (N=74-97)			Preferred by experienced CL wearers (N=17-18)		
	SCLs	Spec- tacles	No pref	SCLs	Spec- tacles	No pref
Guard duty or pa- trol on foot, day	92%	4%	3%	100%	0	0
Guard duty or pa- trol on foot, night	92%	5%	3%	100%	0	0
Night gun exercise	95%	3%	3%	94%	0	6%
Simulated combat exercise w/minimum sleep	83%	11%	6%	83%	11%	6%

Note: Not all CL participants were given the opportunity to respond to the questionnaire from which these data were obtained.

Environmental factors

The reported occurrence of difficulties associated with different environmental conditions is displayed in Figure 6. Among CL wearers the relative occurrence of environmentally linked difficulties was only slight to modest (less than 25 percent) in all but three conditions - dust, wind, and smoke. Dry air and tear gas were also somewhat problematic. In contrast, among spectacle wearers the occurrence of environmental difficulties was substantial (greater than 30 percent) in 7 of 12 conditions queried. Rain and dust were especially problematic (81 percent and 68 percent, respectively). The spectacle-related difficulties are understandable in terms of physical problems characteristic of spectacle lenses (rain or sweat streaking, fogging, dust coating, glare, etc.). The CL-related difficulties can be related to ocular physiology (e.g., sensitivity to drying and airborne substances). The occurrence of difficulties during exposure to tear gas used in chemical defense training was substantially lower among CL wearers than spectacle wearers.

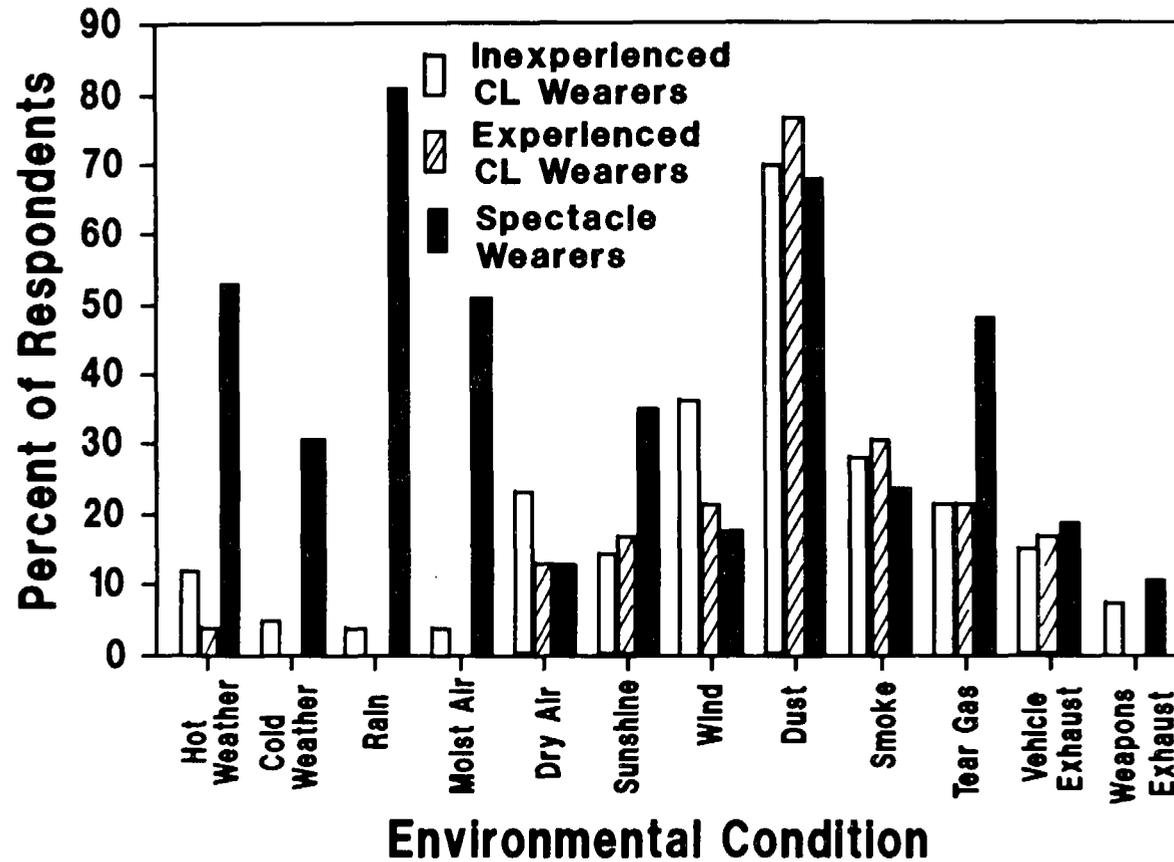


Figure 6. Percent of respondents reporting corrective lens-related difficulties associated with various environmental conditions. Inexperienced CL wearers, N=135; experienced CL wearers, N=25; and spectacle wearers, N=84.

A similar finding has been reported before (Kok-van-Aalphen et al., 1985).

In response to environmental difficulties, CL wearers occasionally reported substituting their spectacles in lieu of contact lenses. Such was the case for dusty environments (32 percent), windy weather (12 percent), smoke (9 percent), dry air (8 percent), exposure to vehicle exhaust (8 percent), and exposure to tear gas (6 percent). CL subjects frequently reported that they avoided wearing their contact lenses when in the field.

CL participants' preferences for SCLs or spectacles in the different environmental conditions appear in Table 41. The proportion of subjects preferring SCLs was 70 percent or greater for every condition except dusty environments. In the latter

Table 41

Questionnaire responses regarding corrective lens preference in various environmental conditions

Environmental condition	Inexperienced CL wearers				Experienced CL wearers			
	Number exper'g cond	Preferred SCLs	Spec- tacles	No pref	Number exper'g cond	Preferred SCLs	Spec- tacles	No pref
Hot weather	96	89%	3%	7%	18	100%	0	0
Cold weather	88	89%	3%	8%	18	100%	0	0
Rain	94	88%	1%	11%	18	100%	0	0
Moist air	94	87%	2%	11%	18	100%	0	0
Dry air	90	84%	9%	8%	17	94%	6%	0
Sunshine	95	88%	4%	7%	18	100%	0	0
Wind	94	70%	19%	11%	18	100%	0	0
Dust	95	42%	43%	15%	18	50%	50%	0
Smoke	88	72%	19%	9%	18	94%	0	6%
Tear gas	61	74%	21%	5%	12	75%	17%	8%
Vehicle exhaust	87	75%	7%	18%	17	89%	6%	6%
Weapons exhaust	84	79%	6%	15%	17	94%	0	6%

case, 42 percent preferred SCLs and 43 percent preferred spectacles, with 15 percent having no preference. With the exception of dust, smoke, wind, and tear gas, the proportion of participants preferring spectacles was less than 10 percent for both groups.

Situational factors

Participants were asked to indicate if they had encountered difficulties related to CL or spectacle wear in a variety of military situations (e.g., field training, airborne operations), provided they had participated in the respective operations. The number of subjects with experience in the selected situations ranged from a low of 14 CL wearers and 20 spectacle wearers for airborne operations to 156 CL wearers and 82 spectacle wearers for field training. The response patterns are presented in Table 42, which includes data for off duty and garrison settings as baseline situations. Among the CL subjects, the relative occurrence of lens-related difficulties was only slight to moderate (25 percent or less) for all settings except field training. The number of experienced CL wearers participating in airborne and air assault operations (n=2) was too small to produce a reliable estimate of the frequency of difficulties for these operations. The higher incidence of difficulties during field training (34 percent for inexperienced CL wearers, 36 percent for experienced CL wearers) may well have been related to problems encountered in cleaning the CLs during the longer periods spent in the field (see the earlier section entitled "Questionnaire data - lens wear and care"). In contrast, spectacle wearers reported substantial (30 percent or greater) occurrence of difficulties for four of the seven operational settings about which they were queried. CL wearers occasionally reported substituting their spectacles in place of SCLs during specific military operations (27 percent during field training, 14 percent during air assault operations, 8 percent during a deployment exercise).

Table 42

Number of participants reporting situational difficulties related to corrective lens wear

Situation	Inexperienced CL wearers		Experienced CL wearers		Spectacle wearers	
	# re- spond- ing	% re- port- ing	# re- spond- ing	% re- port- ing	# re- spond- ing	% re- port- ing
Offduty	135	7%	25	0	*	*
Garrison	135	5%	25	0	81	15%
Field training	131	34%	25	36%	80	44%
Deployment exercise	80	11%	18	6%	67	31%
Airborne ops	12	0	2	0	16	19%
Air assault ops	19	11%	2	50%	19	32%
Special ops	28	4%	6	0	22	23%
Combat ops	15	13%	4	25%	10	30%

* Spectacle controls were not queried about offduty difficulties.

For the various military situations listed in Table 42, the CL participants were asked to express their preferences for SCLs or spectacles regardless of whether or not they had participated in the respective operations during the study. The resulting preference patterns appear in Table 43. For half the situations, 70 percent or more of the subjects preferred SCLs. In the remaining cases, a substantial proportion of the respondents checked "don't know." If these subjects are removed from the analysis, the proportion of participants preferring SCLs was less than 70 percent in only two cases -- airborne operations and air assault operations among inexperienced CL wearers. With "don't know" respondents excluded, 15 percent or less of the subjects

preferred spectacles in every case except field training among the inexperienced CL wearers (19 percent) and air assault operations among experienced CL wearers (21 percent).

Table 43

Questionnaire responses regarding corrective lens preference in various situations

Situation	Preferred by inexperienced CL wearers (N=132-135)				Preferred by experienced CL wearers (N=25)			
	SCL	Spect	No pref	Don't know	SCL	Spect	No pref	Don't know
Off duty	96%	2%	2%	0	96%	0	4%	0
Garrison	91%	3%	6%	0	96%	0	4%	0
Field training	76%	19%	4%	0	92%	4%	4%	0
Deployment exer	72%	9%	4%	15%	84%	4%	4%	8%
Airborne ops	30%	5%	10%	55%	40%	8%	4%	48%
Air assault ops	34%	5%	10%	51%	40%	12%	4%	44%
Special ops	42%	5%	7%	46%	48%	4%	4%	44%
Combat ops	48%	9%	7%	35%	56%	4%	8%	32%

Logistical and personnel support

The resource and logistics oriented questionnaires completed by each optometrist following the end of the study recorded opinions regarding the adequacy of the lens materials, facilities, personnel, and related resources used in the study. In addition, inventory records of the lens related materials issued were maintained throughout the study.

Clinical facilities

The primary clinical facility (TMC) used for this study was judged to be adequate in some respects and deficient in others. The examination rooms were adequate in number (one per optometrist) and size. However, the clinic personnel were all in agreement that the waiting area and screening area were too small for patient flow. Contact lens fitting and dispensing requires prolonged technician/patient interface; associated training should be conducted in a quiet setting, as it is often stressful to the patient. A dedicated area in division optometry facilities would be recommended if contact lens issue were to be authorized.

Personnel

All optometrists disagreed or strongly disagreed that the normal complement of professional personnel assigned to a division would be adequate to support contact lens issue and care. Questions concerning numbers of eye technicians mirrored these responses. The present staffing (TO&E) of a division calls for two optometrists and three technicians except for light divisions, which call for one optometrist and two technicians. While this study was not designed to determine exact manpower requirements, it is apparent that enhanced manpower would be required to adequately support contact lens use in a division.

Equipment

The TO&E equipment normally found in a division eye clinic was augmented extensively to support this test. Of the equipment listed in Table 1, only the first group of items (phoropter with stand, examination chair and projector) are found in the division TO&E. The clinicians participating in this study all agreed that the equipment supplied was adequate to support the study and that the same equipment would be adequate to support a division if that division was authorized Army-provided contact lenses. They all disagreed or strongly disagreed that the TO&E equipment now found in a division clinic would be adequate. Some of the medical equipment used in this study was for research purposes only and would not be required for routine clinical eyecare. However, a keratometer, whether it be manual or automated, and a biomicroscope are absolutely essential for the fitting and care of a contact lens patient. The work cannot be accomplished without these two instruments. Other small items unique to contact lens care are required in this type of program. Examples are wet inspection cells, plastic tweezers and dispensing mirrors. Therefore, both major and minor equipment essential to contact lens fitting and care would have to be incorporated into the TO&E of a division eye clinic.

Contact lenses

No attempt was made in this study to compare the performance/suitability of the three types of extended wear SCLs against each other. The different lens materials were used to optimize fitting capabilities. However, only one of the four participating optometrists felt that the lenses provided for this study were sufficient in parameters and types. One difficulty was that the low water content lens was not available for use until late in the fitting phase. Two of the clinicians expressed the opinion that even with the three types of lenses available, some of the subjects were not optimally fit, which may have contributed to increased ocular complications. All optometrists agreed or strongly agreed that a higher percentage of soldiers in a division could successfully wear contact lenses if there were no restrictions on lenses available to them.

Two specific groups of spectacle wearing soldiers were prohibited from wearing contact lenses in this study. First were those who required bifocal correction. No attempt was made to provide bifocal contact lenses or reading glasses to wear over the contact lenses, which are two of the ways to deal with presbyopia. The second group would include those individuals who have 1.25 diopter or more of astigmatism. While the first group may comprise a small percentage of older soldiers, the second group would include a significant number of spectacle wearing soldiers. Astigmatism is generally caused by a toroidal anterior surface of the cornea, leading to unequal refraction of incident light in different meridians. Since spherical soft contact lenses mold or drape to the shape of the individual's cornea, they do not provide correction for astigmatism. A much more sophisticated soft contact lens termed a "toric" lens would be required to correct for this vision problem. The lens of choice to correct for astigmatism is not a soft lens at all, but a "hard" lens which is rigid in configuration.

The contact lenses provided for this study were procured in a bulk order and dispensed to the subjects at the end of the training session. It must be understood that this is a unique way to provide contact lenses. Usually contact lenses are fitted from a trial or fitting set, and ordered from a laboratory specifically for a patient. This method was considered too time consuming for this research study. Only one of the clinicians involved in this study agreed that the bulk order method of procuring contact lenses was adequate to support the study. The major difficulty with a bulk order is that it requires an "educated guess" concerning the distribution of refractive errors which will be present in the clinic. Soft contact lenses come in glass vials immersed in isotonic saline, and as such have a "shelf life" or expiration date. This shelf life is usually 4-5 years and means that lenses cannot be stored indefinitely for dispensing. Other parameters can affect the way a soft contact

lens will fit on the eye, including base curve, diameter and water content. It becomes obvious that many variables must be considered when attempting to stock contact lenses for dispensing "on the spot."

A total of 1106 lenses were expended in the study. This included some lenses that were defective or rendered unusable by handling, etc. The average census (number of eyes) was 337 across the 6 months of the study, yielding 3.3 lenses expended per eye. To meet the terms of the research protocol, lenses were required to be replaced after 4 months of wear at the most. Therefore, the minimum number of SCLs used for a successful 6-month subject would have been two per eye if none were lost, torn, etc.

Table 44 displays the number of lenses replaced during the study and the reasons for replacement.

Table 44
 Number of contact lenses replaced
 over the study

Reason	Number
Planned replacement	195
Lost	93
Parameter change	193
Deposits	38
Torn	44
Discolored	2
Other*	38

*Includes such things as foreign bodies imbedded in the lenses, lenses coated with mucoid substance, lenses with irregular edges, etc.

Table 45 displays the number of spectacle lenses replaced during the study for the spectacle control group. In addition to the lenses replaced, seven spectacle frames required replacement or repair.

Table 45

Number of spectacle lenses replaced
over the study

Reason	Number
Lost or misplaced	8
Broken	6
Scratched	3
Parameter change	30
Other	2

The SCLs used in this study were selected by a medical panel of vision experts. All four study optometrists agreed or strongly agreed that the selection of lenses to be used in a division should be the prerogative of the eye care professionals in the division. In the same vein all clinicians agreed that the actual ordering and procurement of the contact lenses should be handled by the staff of the optometry clinic rather than a pharmacy or supply facility.

Solutions and cases

The solutions used in this study were those recommended by the contact lens manufacturers as compatible with their lenses. Table 46 presents the total volume of each solution issued and the average volume per subject (computed against the study's average census.)

A total of 389 contact lens cases were issued during the study, resulting in 2.3 cases being used per subject.

Table 46

Volume of solutions issued during the study

Solution	Total volume issued (oz)	Average volume per subject (oz)
Disinfection solution	2920	17.3
Weekly cleaning solution	584	3.5
Saline	3337	19.8
Rewetting drops	258	1.5

Contact lenses cannot be worn or maintained without the proper solutions and cases. Unfortunately every solution will not work with every contact lens, and solutions have to be tailored to specific lenses. As with contact lenses, solutions have a shelf life, usually 2 years. This precludes their being stored for indefinite periods of time. The amount of the various solutions used is directly proportional to the frequency of cleaning. That is, a daily-wear patient will use more solution than an extended-wear patient, etc. Constant resupply must be considered in supporting the contact lens wearing soldier.

Clinic hours expended for SCL wearers

Each examination form captured the amount of time required for the specific examination. The following are average times required to perform each type of examination.

- a. Initial examination: 56.4 minutes
- b. Fitting session: 39.6 minutes
- c. Training in handling and care of lenses: 21.0 minutes
- d. Followup examinations: 42.0 minutes
- e. Final examination: 54.0 minutes

Initial examination, fitting and training of a subject were accomplished on the same day, if possible. These three procedures required a total of 117 minutes, or about 2 hours. Four to six spectacle-wearing soldiers would normally be examined in an eye care facility in this same time period. Followup examinations required 42 minutes or about the time required to examine two spectacle-wearing soldiers. Followup examinations were scheduled every 30 days for this study. This would be unnecessary and too intensive for nonresearch settings. A more realistic approach for clinical care would be a followup examination every 4 to 6 months for contact lens wearing soldiers. It becomes readily apparent that 1 new contact lens wearing soldier will consume the same amount of clinic time required for 8 to 12 spectacle-wearing soldiers during a 12-month period. Additionally, in this study there were 131 nonroutine examinations, requested by either the patient or the optometrist. This means that an additional scheduling burden is generated by the contact lens patient. These patient or optometrist requests are likely to be of a more immediate nature than the usual request for an eye examination for spectacles.

Conclusions

As the first major field evaluation of contact lenses conducted by the US Army, this study provides substantive findings relevant to Army policy regarding contact lens use. The results of this study represent part of a larger database that is intended to address a variety of operational settings, environmental factors, and job demands. Additional research will be required before substantive policy issues can be addressed systematically. Based on the major findings obtained in the armor environment of this study, the following conclusions are presented:

1. There were few substantial differences between experienced and inexperienced CL wearers for any of the clinical and questionnaire measures recorded. When differences did occur, they are noted below.

2. When CL wearers discontinued for administrative reasons were factored out, 74 percent of those fitted successfully completed the study. This 6-month rate was somewhat artificially constrained by the limited types and parameters of SCLs used. On the other hand, the rate may have been elevated by the conservative medical practices followed and by the well-motivated participants.

3. Nearly all of the participants, both CL and spectacle wearers, were moderately or highly confident in their ability to see adequately. Most of the CL wearers felt they could see better with their SCLs than with spectacles.

4. The great majority of CL wearers indicated that SCLs had improved their overall job performance and provided better ability to see in performing specific job-related tasks. A comparable proportion preferred SCLs for performing a variety of military activities. In general, the experienced wearers were slightly, but consistently more likely to judge their SCLs favorably than the inexperienced wearers.

5. Ninety-four percent of the CL participants expressed a desire to continue wearing SCLs.

6. More than one-third of the CL wearers experienced one or more ocular conditions requiring at least a temporary suspension of SCL wear.

7. It is difficult to use the results of this study to estimate realistic success rates or ocular complication rates for typical Army units. The extensive precautions and intensive medical attention incorporated in this study would not be available. Further, typical CL wear would not cease at the end of 6 months.

8. Both corneal edema and corneal staining occurred rarely at clinically significant levels. Slight to moderate edema increased across the course of the study for inexperienced wearers, but not for experienced wearers.

9. Corneal vascularization occurred more frequently than expected among the participants. This was most likely influenced by measurement peculiarities (e.g., stringent classification criteria).

10. Conjunctival injection was common among both CL-wearing and spectacle-wearing participants. This appeared to be largely related to factors in the local environment (e.g., dust, wind) and, for the CL wearers, reaction to SCLs and/or solutions.

11. CL wearers, especially inexperienced wearers, frequently reported problems with inserting their SCLs. However, reported problems with handling and cleaning corrective lenses were substantially more common among spectacle wearers than CL wearers. Frequent problems unique to spectacles included dirty or smeared lenses and downward slippage.

12. Eighty-nine percent of the CL wearers reported their lenses to be comfortable or very comfortable.

13. Noncompliance with the recommended CL wearing/cleaning schedule was substantial.

14. Among CL participants, environmental difficulties were infrequent except for conditions involving dust, wind, and smoke. A large majority of CL wearers preferred SCLs over spectacles for a wide variety of environmental conditions, except those involving dust.

15. Environmental difficulties were commonly reported by spectacle wearers, especially for rain, dust, hot weather, and high humidity.

16. Spectacle wearers frequently reported spectacle-related difficulties when performing tasks requiring strenuous physical activity or equipment compatibility (e.g., aiming a rifle or sighting through optical devices). In contrast, CL wearers reported frequent task-related difficulties only for swimming.

17. Spectacle wearers frequently reported situational difficulties during field training, deployment exercises, and air assault operations. At the same time, CL wearers reported frequent situational difficulties only for field training.

18. While this study was not designed to determine exact resource requirements, it is clear that additional manpower and

equipment would be required to adequately support routine CL use in a division.

19. Availability of the broadest possible range of CL types and parameters would be essential to comprehensive CL usage in a division. Unique procurement procedures might well be required to insure timely availability of contact lenses as well as associated supplies.

Recommendations

1. Because of the limitations of this study, the findings should be generalized to operational units with caution.

2. In order to support establishment of Army policy, further research should be conducted to address the following:

a. Selected operational settings (e.g., aviation, special operations, airborne, NBC operations, field training).

b. New types of contact lenses (e.g., rigid gas permeable lenses, disposable lenses).

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Appendix A

List of contact lens manufacturers

Barnes-Hind, Incorporated
8006 Engineer Road
San Diego, CA 92111

CooperVision, Incorporated
3000 Winton Road, South
Rochester, NY 14623

Sola-Syntex
P.O. Box 39600
Phoenix, AZ 85069

Appendix B

Contact lens solutions used

CooperVision, Incorporated
3000 Winton Road, South
Rochester, NY 14623

1. Pliagel Cleaner
2. Unisol Preservative-free Saline Solution
3. Clerz 2 Lubricant
4. Permalens Care Kit II

Allergan Pharmaceuticals
2525 Dupont Drive
Irvine, CA 92713

1. Extenzyme (enzymatic cleaner for extended-wear soft contact lenses)
2. Hydrocare Cleaning and Disinfecting Solution

Barnes-Hind, Incorporated
8006 Engineer Road
San Diego, CA 92111

1. Soft Mate Weekly Cleaning System
2. Soft Mate Disinfection Solution
3. Soft Mate ps Saline Solution
4. Soft Mate ps Comfort Drops
5. Soft Mate Deluxe Chemical Disinfection Kit

Appendix C

List of equipment manufacturers

Humphrey Instruments, Incorporated
3081 Teagarden Street
San Leandro, CA 94577

Marco Equipment, Incorporated
P.O. Box 10187
Jacksonville, FL 32247

Reichert Scientific Instruments
Eggert and Sugas Roads
Buffalo, NY 14215

Haag-Streit AG
3097 Liebefeld
Berne, Switzerland

Nikon Instruments
623 Stewart Avenue
Garden City, NY 11530

Appendix D

Medical history

CICLOPS DATA COLLECTION FORM 2

MEDICAL HISTORY

1. Name _____ 2. Date

3. SSAN _____ - _____ - _____

4. Statement of examinee's present health and medications currently used (follow by description of past history, if complaint exists).

5. Have you ever worn contact lenses? 1. ___ YES 2. ___ NO

6. Do you wear glasses? 1. ___ YES 2. ___ NO

7. Do you wear contact lenses? 1. ___ YES 2. ___ NO

8. Do you have vision in both eyes? 1. ___ YES 2. ___ NO

9. Have you ever had or have you now:

	1. YES	2. NO	3. DON'T KNOW
a. eye trouble?	_____	_____	_____
b. ear, nose or throat trouble?	_____	_____	_____
c. chronic or frequent colds?	_____	_____	_____
d. sinusitis?	_____	_____	_____
e. hay fever?	_____	_____	_____
f. thyroid trouble?	_____	_____	_____
g. adverse reaction to serum, drug, or medicine?	_____	_____	_____
h. dry eyes?	_____	_____	_____
i. allergies?	_____	_____	_____
j. sensitivity to light?	_____	_____	_____

SSAN _____ - _____ - _____

k. watery eyes?

l. eye injury?

m. eye surgery?

n. eye disease?

10. Have you been refused employment or been unable to hold a job or stay in school because of sensitivity to chemicals, dust, sunlight, etc? (if yes, explain fully in item 11). 1. ___ YES 2. ___ NO

11. Explanation:

12. Physician's summary and elaboration of all pertinent data:

13. Investigator's ID _____

Appendix E

Quantification of slit-lamp observations

QUANTIFICATION OF SLIT-LAMP OBSERVATIONS

The following classifications are to be used in reporting slit-lamp examination results:

	Classification Number
I. EDEMA	
A. None	0
B. Micro-edema: Intercellular accumulation of fluid which is limited to the epithelium and is seen only by the use of the slit-lamp.	
1. Slight amounts in the epithelium, seen only by retro-illumination:	
a. Localized--over less than 50% of the cornea	1
b. Generalized--over more than 50% of the cornea	2
2. Moderate amounts in the epithelium, seen by direct illumination:	
a. Localized--over less than 50% of the cornea	3
b. Generalized--over more than 50% of the cornea	4
C. Gross Edema: Intracellular cystic accumulation of fluid viewed by the naked eye using oblique flashlight illumination.	
1. Early case, without any stromal involvement:	
a. Vertical striae	5
b. Circumscribed--over less than 50% of the cornea	6
c. Generalized--over more than 50% of the cornea	7
2. Clinical case, with stromal involvement:	
a. Vertical striae	3
b. Folds in Descemet's membrane	9
c. Circumscribed--over less than 50% of the cornea	10
d. Generalized--over more than 50% of the cornea	11
II. VASCULARIZATION (See procedure which follows)	
A. None at initial or follow-up examination	0
B. Vascularization, when first observed:	
1. Obvious vessel ingrowth limited to 1 quadrant	1
2. Obvious vessel ingrowth involving more than one quadrant	2
C. Vascularization, subsequent examinations:	
1. Vascularization stable with no further ingrowth	3
2. Continuing growth of less than 2 mm	4
3. Continuing growth greater than 2 mm	5
4. Other (explain)	6
III. INJECTION	
A. None	0
B. Mild congestion and dilation of the limbal vessels which was not characteristic of the pre-fitting condition (within 1.0 mm of limbus)	1
C. Severe congestion and dilation of the normal limbal vessels	2
D. Conjunctival hyperemia due to excess lacrimation and epiphora	3
IV. STAINING	
A. None	0
B. Minimal, variable, peripheral stippling	1
C. Superficial punctate staining	2
D. Epithelial dimpling associated with gas bubbles under the contact lenses	3
E. Abrasions of the epithelium. Note if appears caused by placement or removal	4
F. Deep corneal abrasions, ulcerations, permanent scars or other severe complications (explain)	5
G. Foreign body track staining	6
V. OTHER COMPLICATIONS	
A. None	0
B. Adnexal changes or changes in the lacrimal or appendages of the eye:	
1. Increase in sebaceous secretion in the tear fluid	1
2. Follicular hypertrophy of the lymphoid follicles of the tarsal conjunctiva	2
3. Traumatic iritis	3
4. Permanent damage caused by opacity or scarring of the cornea (may or may not impair vision)	4
C. Other (explain)	5

Appendix F

Contact lens clinical evaluation
initial examination and fitting

SSAN _____ - _____ - _____

OBJECTIVE REFRACTION

17. a _____ . _____ b _____ . _____ c _____
SPHERE CYLINDER AXIS

18. a _____ . _____ b _____ . _____ c _____
SPHERE CYLINDER AXIS

SUBJECTIVE REFRACTION

19. a _____ . _____ b _____ . _____ c _____
SPHERE CYLINDER AXIS

20. a _____ . _____ b _____ . _____ c _____
SPHERE CYLINDER AXIS

CORRECTED ACUITY

21. 20/____

22. 20/____

23. OU 20/____

KERATOMETRY

24. a _____ . _____ b _____ . _____ c _____
HORIZONTAL VERTICAL AXIS

25. a _____ . _____ b _____ . _____ c _____
HORIZONTAL VERTICAL AXIS

26. _____ AESTHESIOOMETRY 27. _____

28. _____ MM/MIN. SHIRMER 29. _____

30. _____ MM HVID 31. _____

32. _____ SEC. BUT 33. _____

34. 0. _____ MM PACHOMETRY 35. 0. _____

36. _____ MHG TONOMETRY 37. _____

QUANTIFY BIOMICROSCOPE EXAMINATION

38. _____ EDEMA 39. _____

40. _____ VASCULARIZATION 41. _____

42. _____ INJECTION 43. _____

44. _____ STAINING 45. _____

46. _____ OTHER (EXPLAIN IN 63) 47. _____

48. 1.YES _____ 2.NO _____ ARE LID TARSAL PLATES NORMAL? 49. 1.YES _____ 2.NO _____

SSAN _____

63. COMMENTS:

SIGNATURE

Appendix G

Contact lens clinical evaluation
followup/final examination

SSAN _____

RIGHT EYE

LEFT EYE

CONTACT LENS RX

21. a. _____ b. _____ c. _____
B.C. SPHERE DIAM.

22. a. _____ b. _____ c. _____
B.C. SPHERE DIAM.

23. _____ LENS ID

24. _____

25. 20/____ ACUITY WITH LENSES

26. 20/____

27. OU 20/____

28. a. _____ b. _____ c. _____ REFRACTION
SPHERE CYLINDER AXIS OVER LENS

29. a. _____ b. _____ c. _____
SPHERE CYLINDER AXIS

30. 20/____ ACUITY WITH OVERREFRACTION

31. 20/____

32. OU 20/____

33. a. _____ b. _____ c. _____ KERATOMETRY
HORIZONTAL VERTICAL AXIS

34. a. _____ b. _____ c. _____
HORIZONTAL VERTICAL AXIS

35. 0. _____ MM PACHOMETRY

36. 0. _____

37. _____ MHG TONOMETRY

38. _____

QUANTIFY BIOMICROSCOPE EXAMINATION

39. _____ EDEMA

40. _____

41. _____ VASCULARIZATION

42. _____

43. _____ INJECTION

44. _____

45. _____ STAINING

46. _____

47. _____ OTHER (EXPLAIN IN 73)

48. _____

49. IS THE PATIENT MEDICALLY QUALIFIED TO CONTINUE WEARING CONTACT LENSES?

1. _____ YES 2. _____ NO

50. 1. YES _____ 2. NO _____

IS THE CONTACT LENS PRESCRIPTION ACCURATE?

51. 1. YES _____ 2. NO _____

52. 1. YES _____ 2. NO _____

IS A NEW CONTACT LENS REQUIRED?

53. 1. YES _____ 2. NO _____

Appendix H

Control group clinical evaluation initial examination

CICLOPS DATA COLLECTION FORM 3
CONTROL GROUP
CLINICAL EVALUATION INITIAL EXAMINATION

1. INVESTIGATOR _____ 2. _____
Name ID
3. PATIENT _____ 4. _____
Name SSAN
5. AGE _____
6. SEX: 1. __MALE 2. __FEMALE
7. UNIT ADDRESS _____

OCULAR EXAMINATION

8. START OF EXAMINATION D D M M M Y Y : H H : M M
9. END OF EXAMINATION D D M M M Y Y : H H : M M
- RIGHT EYE UNCORRECTED ACUITY LEFT EYE

10. 20/____ 11. 20/____

HABITUAL SPECTACLE PRESCRIPTION

12. a _____ b _____ c _____ 13. a _____ b _____ c _____
SPHERE CYLINDER AXIS SPHERE CYLINDER AXIS

ACUITY WITH HABITUAL PRESCRIPTION

14. 20/____ 15. 20/____
16. OU 20/____

RIGHT EYE

SSAN _____ - _____ - _____

LEFT EYE

OBJECTIVE REFRACTION

17. a SPHERE b CYLINDER c AXIS

18. a SPHERE b CYLINDER c AXIS

SUBJECTIVE REFRACTION

19. a SPHERE b CYLINDER c AXIS

20. a SPHERE b CYLINDER c AXIS

ACUITY WITH REFRACTION

21. 20/

22. 20/

23. OU 20/

KERATOMETRY

24. a HORIZONTAL b VERTICAL c AXIS

25. a HORIZONTAL b VERTICAL c AXIS

26. 0.

MM PACHOMETRY

27. 0.

28.

mHg TONOMETRY

29.

QUANTIFY BIOMICROSCOPE EXAMINATION

30.

EDEMA

31.

32.

VASCULARIZATION

33.

34.

INJECTION

35.

36.

STAINING

37.

38.

OTHER (EXPLAIN IN 49)

39.

40. 1.YES 2.NO

ARE LID TARSAL PLATES NORMAL?

41. 1.YES 2.NO

42. 1.YES 2.NO IS THE PRESENT SPECTACLE PRESCRIPTION ACCURATE?

43. 1.YES 2.NO

44. 1.YES 2.NO IS A NEW SPECTACLE PRESCRIPTION REQUIRED?

45. 1.YES 2.NO

46. IS THE SUBJECT MEDICALLY QUALIFIED TO WEAR CONTACT LENSES? 1.YES 2.NO

SPECTACLE PRESCRIPTION

47. a SPHERE b CYLINDER c AXIS

48. a SPHERE b CYLINDER c AXIS

SSAN _____

49. COMMENTS:

SIGNATURE

Appendix I

Control group clinical evaluation followup/final examination

SSAN _____ - _____ - _____

RIGHT EYE

KERATOMETRY

LEFT EYE

18. a. _____ b. _____ c. _____ 19. a. _____ b. _____ c. _____
HORIZONTAL VERTICAL AXIS HORIZONTAL VERTICAL AXIS

MM PACHOMETRY

20. 0. _____ 21. 0. _____

mHg TONOMETRY

22. _____ 23. _____

QUANTIFY BIOMICROSCOPE EXAMINATION

24. _____ EDEMA 25. _____

26. _____ VASCULARIZATION 27. _____

28. _____ INJECTION 29. _____

30. _____ STAINING 31. _____

32. _____ OTHER (EXPLAIN IN 52) 33. _____

34. 1. YES__ 2. NO__ IS THE HABITUAL SPECTACLE PRESCRIPTION ACCURATE? 35. 1. YES__ 2. NO__

36. 1. YES__ 2. NO__ IS A NEW SPECTACLE PRESCRIPTION REQUIRED? 37. 1. YES__ 2. NO__

NEW SPECTACLE PRESCRIPTION

38. a. _____ b. _____ c. _____ 39. a. _____ b. _____ c. _____
SPHERE CYLINDER AXIS SPHERE CYLINDER AXIS

REASONS SPECTACLE LENSES REPLACED

40. _____ *LOST OR MISPLACED 41. _____

42. _____ BROKEN 43. _____

44. _____ SCRATCHED 45. _____

46. _____ *PARAMETER CHANGE 47. _____

48. _____ *OTHER 49. _____

SSAN _____ - _____ - _____

50. *EXPLAIN IN DETAIL

51. DID THE SPECTACLE FRAME REQUIRE REPLACEMENT OR REPAIR? 1. YES ___ 2. NO ___

52. COMMENTS

SIGNATURE

Appendix J

Responses to the fitting and wear of contact lenses

CICLOPS DATA COLLECTION FORM 25
(QUESTIONNAIRE)

RESPONSES TO THE FITTING AND WEAR OF CONTACT LENSES

Data Collector _____
Name Grade Unit

1. Name _____ 2. Grade _____
3. SSAN _____ - _____ - _____ 4. Date _____
M M D D Y Y
5. Unit _____
6. Duty assignment _____

INSERTING CONTACT LENSES

7. How often did you have problems inserting your contact lenses?
1. _____ ALWAYS 2. _____ OFTEN 3. _____ SOMETIMES 4. _____ SELDOM 5. _____ NEVER
8. If you had problems, how bothersome were they?
1. _____ MINOR 2. _____ MODERATE 3. _____ SEVERE
9. Briefly describe the nature of the problems:

10. How acceptable to you were the problems you experienced?
1. _____ HIGHLY ACCEPTABLE 2. _____ MODERATELY ACCEPTABLE 3. _____ NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. _____ MODERATELY UNACCEPTABLE 5. _____ TOTALLY UNACCEPTABLE
11. How acceptable to you was the amount of time required for inserting your contact lenses?
1. _____ HIGHLY ACCEPTABLE 2. _____ MODERATELY ACCEPTABLE 3. _____ NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. _____ MODERATELY UNACCEPTABLE 5. _____ TOTALLY UNACCEPTABLE

REMOVING CONTACT LENSES

12. How often did you have problems removing your contact lenses?

1. ___ ALWAYS 2. ___ OFTEN 3. ___ SOMETIMES 4. ___ SELDOM 5. ___ NEVER

13. If you had problems, how bothersome were they?

1. ___ MINOR 2. ___ MODERATE 3. ___ SEVERE

14. Briefly describe the nature of the problems:

15. How acceptable to you were the problems you experienced?

1. ___ HIGHLY ACCEPTABLE 2. ___ MODERATELY ACCEPTABLE 3. ___ NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. ___ MODERATELY UNACCEPTABLE 5. ___ TOTALLY UNACCEPTABLE

16. How acceptable to you was the amount of time required for removing your contact lenses?

1. ___ HIGHLY ACCEPTABLE 2. ___ MODERATELY ACCEPTABLE 3. ___ NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. ___ MODERATELY UNACCEPTABLE 5. ___ TOTALLY UNACCEPTABLE

HANDLING CONTACT LENSES

17. How often did you have problems handling your contact lenses?

1. ___ ALWAYS 2. ___ OFTEN 3. ___ SOMETIMES 4. ___ SELDOM 5. ___ NEVER

18. If you had problems, how bothersome were they?

1. ___ MINOR 2. ___ MODERATE 3. ___ SEVERE

19. Briefly describe the nature of the problems.

20. How acceptable to you were the problems you experienced?

1. ___ HIGHLY ACCEPTABLE 2. ___ MODERATELY ACCEPTABLE 3. ___ NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. ___ MODERATELY UNACCEPTABLE 5. ___ TOTALLY UNACCEPTABLE

21. How acceptable to you was the amount of time required for handling your contact lenses?

1. _____ HIGHLY ACCEPTABLE 2. _____ MODERATELY ACCEPTABLE 3. _____ NEITHER ACCEPTABLE
 NOR UNACCEPTABLE 4. _____ MODERATELY UNACCEPTABLE 5. _____ TOTALLY UNACCEPTABLE

COMFORT OF CONTACT LENSES

22. Generally, how comfortable were your contact lenses?

1. _____ VERY COMFORTABLE 2. _____ COMFORTABLE 3. _____ NEITHER COMFORTABLE NOR
 UNCOMFORTABLE 4. _____ UNCOMFORTABLE 5. _____ VERY UNCOMFORTABLE

23. If uncomfortable, briefly describe the nature of the discomfort:

24. How acceptable to you is this degree of comfort or discomfort?

1. _____ HIGHLY ACCEPTABLE 2. _____ MODERATELY ACCEPTABLE 3. _____ NEITHER ACCEPTABLE
 NOR UNACCEPTABLE 4. _____ MODERATELY UNACCEPTABLE 5. _____ TOTALLY UNACCEPTABLE

25. How often did you experience the following problems?

	1.ALWAYS	2.OFTEN	3.SOMETIMES	4.SELDOM	5.NEVER
a. EYELID IRRITATION	_____	_____	_____	_____	_____
b. EYE IRRITATION	_____	_____	_____	_____	_____
c. EYE PAIN	_____	_____	_____	_____	_____
d. BLURRED VISION	_____	_____	_____	_____	_____
e. REDUCED TEAR FLOW	_____	_____	_____	_____	_____
f. LIGHT SENSITIVITY	_____	_____	_____	_____	_____
g. OTHER (SPECIFY)	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
h. OTHER (SPECIFY)	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

26. How bothersome were the problems you experienced in question 25?

	1.MINOR	2.MODERATE	3.SEVERE
a. EYELID IRRITATION	_____	_____	_____
b. EYE IRRITATION	_____	_____	_____
c. EYE PAIN	_____	_____	_____
d. BLURRED VISION	_____	_____	_____
e. REDUCED TEAR FLOW	_____	_____	_____
f. LIGHT SENSITIVITY	_____	_____	_____
g. OTHER (SPECIFY) _____	_____	_____	_____
h. OTHER (SPECIFY) _____	_____	_____	_____

CLEANING CONTACT LENSES

27. How often did you have problems cleaning your contact lenses?

1. _____ ALWAYS 2. _____ OFTEN 3. _____ SOMETIMES 4. _____ SELDOM 5. _____ NEVER

28. If you had problems, how bothersome were they?

1. _____ MINOR 2. _____ MODERATE 3. _____ SEVERE

29. Briefly describe the nature of the problems:

30. How acceptable to you were the problems you experienced?

1. _____ HIGHLY ACCEPTABLE 2. _____ MODERATELY ACCEPTABLE 3. _____ NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. _____ MODERATELY UNACCEPTABLE 5. _____ TOTALLY UNACCEPTABLE

31. How acceptable to you was the amount of time required for cleaning your contact lenses?

1. _____ HIGHLY ACCEPTABLE 2. _____ MODERATELY ACCEPTABLE 3. _____ NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. _____ MODERATELY UNACCEPTABLE 5. _____ TOTALLY UNACCEPTABLE

32. How often have you been able to stay on the 7 day wearing/cleaning schedule?

1. ___ ALWAYS 2. ___ MOST OF THE TIME 3. ___ ABOUT HALF OF THE TIME
4. ___ ONCE IN A WHILE 5. ___ NEVER

33. What was the longest time between one lens cleaning and the next?

1. ___ LESS THAN 7 DAYS (SPECIFY) _____
2. ___ 7 DAYS 3. ___ 8 DAYS 4. ___ 9 DAYS 5. ___ 10 DAYS
6. ___ MORE THAN 10 DAYS (SPECIFY) _____

DISINFECTING CONTACT LENSES

34. How often did you have problems disinfecting your contact lenses?

1. ___ ALWAYS 2. ___ OFTEN 3. ___ SOMETIMES 4. ___ SELDOM 5. ___ NEVER

35. If you had problems, how bothersome were they?

1. ___ MINOR 2. ___ MODERATE 3. ___ SEVERE

36. Briefly describe the nature of the problems:

37. How acceptable to you were the problems you experienced?

1. ___ HIGHLY ACCEPTABLE 2. ___ MODERATELY ACCEPTABLE 3. ___ NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. ___ MODERATELY UNACCEPTABLE 5. ___ TOTALLY UNACCEPTABLE

38. How acceptable to you was the amount of time required for disinfecting your contact lenses?

1. ___ HIGHLY ACCEPTABLE 2. ___ MODERATELY ACCEPTABLE 3. ___ NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. ___ MODERATELY UNACCEPTABLE 5. ___ TOTALLY UNACCEPTABLE

SSAN _____

39. How available were cleaning solutions and supplies to clean and care for your contact lenses?

1. ___ ALWAYS 2. ___ OFTEN 3. ___ SOMETIMES 4. ___ SELDOM 5. ___ NEVER

MEDICAL SUPPORT FOR CONTACT LENSES

40. How satisfied or dissatisfied were you with the support provided by medical personnel in examining and helping you care for your contact lenses?

1. ___ VERY SATISFIED 2. ___ SATISFIED 3. ___ NEITHER SATISFIED NOR DISSATISFIED

4. ___ DISSATISFIED 5. ___ VERY DISSATISFIED

41. Briefly explain any dissatisfaction:

42. How satisfied or dissatisfied were you with the care/services provided by medical personnel in examining and helping you care for your contact lenses during non-duty hours?

1. ___ VERY SATISFIED 2. ___ SATISFIED 3. ___ NEITHER SATISFIED NOR DISSATISFIED

4. ___ DISSATISFIED 5. ___ VERY DISSATISFIED

43. Briefly explain any dissatisfaction:

CONTACT LENSES TRAINING

44. Indicate with a check mark how adequate or inadequate the training program was in teaching you the following tasks with contact lenses:

	Very 1.Adequate	2.Adequate	Neither Adequate nor 3.Inadequate	4.Inadequate	Very 5.Inadequate
a. Insertion	_____	_____	_____	_____	_____
b. Removal	_____	_____	_____	_____	_____
c. Cleaning	_____	_____	_____	_____	_____
d. Disinfection	_____	_____	_____	_____	_____
e. Handling	_____	_____	_____	_____	_____
f. Storage	_____	_____	_____	_____	_____
g. Proper Wearing Schedule	_____	_____	_____	_____	_____
h. Medical Warning Symptoms	_____	_____	_____	_____	_____
i. Other (Specify) _____	_____	_____	_____	_____	_____

45. Briefly explain inadequate ratings:

ENVIRONMENTAL

46/47. Indicate with a check mark whether or not the following environmental conditions made wearing contact lenses difficult. If yes, did you substitute your spectacles for your contact lenses?

<u>ENVIRONMENTAL CONDITION</u>	<u>46.DIFFICULTY</u>			<u>47.SUBSTITUTED SPECTACLES</u>	
	1.YES	2.NO	NOT AP- 3.PLICABLE	1.YES	2.NO
a. Hot weather	_____	_____	_____	_____	_____
b. Cold weather	_____	_____	_____	_____	_____
c. Rain	_____	_____	_____	_____	_____
d. Moist Air (High Humidity)	_____	_____	_____	_____	_____
e. Dry Air (Low Humidity)	_____	_____	_____	_____	_____
f. Sunny weather	_____	_____	_____	_____	_____
g. Windy weather	_____	_____	_____	_____	_____
h. Dust	_____	_____	_____	_____	_____
i. Smoke	_____	_____	_____	_____	_____
j. Exposure to chemical agents	_____	_____	_____	_____	_____
k. Exposure to vehicle exhaust	_____	_____	_____	_____	_____
l. Exposure to weapons exhaust	_____	_____	_____	_____	_____
m. Other (specify)	_____	_____	_____	_____	_____

48. Briefly explain the problems caused by environmental conditions:

LIGHT CONDITIONS

49. Did you experience difficulty seeing in bright light while wearing contact lenses?

1. ___ YES 2. ___ NO

50. How frequently do you wear sunglasses to reduce glare when wearing contact lenses on sunny days?

1. ___ ALWAYS 2. ___ MOST OF THE TIME 3. ___ ABOUT HALF OF THE TIME
4. ___ ONCE IN A WHILE 5. ___ NEVER

51. How necessary is it for you to wear sunglasses to reduce glare while wearing contact lenses?

1. ___ ABSOLUTELY NECESSARY 2. ___ NECESSARY 3. ___ HELPFUL, BUT NOT NECESSARY
4. ___ NOT NECESSARY AT ALL

52. Did you experience difficulty seeing after dark while wearing contact lenses?

1. ___ YES 2. ___ NO

GENERAL ATTITUDE TOWARD WEARING CONTACT LENSES

53. Do you see better with contact lenses or spectacles?

1. ___ MUCH BETTER WITH CONTACT LENSES 2. ___ MODERATELY BETTER WITH CONTACT LENSES
3. ___ NEITHER IS BETTER THAN THE OTHER 4. ___ MODERATELY BETTER WITH SPECTACLES
5. ___ MUCH BETTER WITH SPECTACLES

54. How confident are you in your ability to see adequately when you are wearing contact lenses as compared to spectacles?

1. ___ HIGHLY CONFIDENT 2. ___ MODERATELY CONFIDENT 3. ___ NO DIFFERENCE 4. ___ HARDLY
CONFIDENT 5. ___ NOT CONFIDENT AT ALL

55. Do you like or dislike wearing contact lenses?

1. ___ LIKE VERY MUCH 2. ___ LIKE MODERATELY 3. ___ NEITHER LIKE NOR DISLIKE
4. ___ DISLIKE MODERATELY 5. ___ DISLIKE VERY MUCH

56. Briefly explain why you like or dislike wearing contact lenses:

57. Do you feel that wearing contact lenses improved your personal appearance?

1. ___ YES 2. ___ NO

58. Do you think that others with whom you have a close relationship (mother, father, wife, girlfriend, friends, etc.) like or dislike your wearing contact lenses?

1. ___ LIKE VERY MUCH 2. ___ LIKE MODERATELY 3. ___ NEITHER LIKE NOR DISLIKE
4. ___ DISLIKE MODERATELY 5. ___ DISLIKE VERY MUCH

59. Are you interested in continuing to wear contact lenses?

1. ___ DEFINITELY WANT TO WEAR 2. ___ SOMEWHAT WANT TO WEAR
3. ___ DO NOT CARE ONE WAY OR THE OTHER
4. ___ SOMEWHAT DO NOT WANT TO WEAR 5. ___ DEFINITELY DO NOT WANT TO WEAR

60. If you are not interested in continuing to wear contact lenses, briefly explain why:

61. Are you worried or concerned that wearing contact lenses might cause eye problems requiring medical treatment?

1. ___ HIGHLY CONCERNED 2. ___ MODERATELY CONCERNED 3. ___ NEITHER CONCERNED OR UNCONCERNED
4. ___ HARDLY CONCERNED 5. ___ NOT AT ALL CONCERNED

62. What was your immediate supervisor's attitude toward your wearing contact lenses?

1. ___ DEFINITELY WANTS ME TO WEAR THEM 2. ___ SOMEWHAT WANTS ME TO WEAR THEM
3. ___ DOES NOT CARE ONE WAY OR THE OTHER
4. ___ SOMEWHAT DOES NOT WANT ME TO WEAR THEM
5. ___ DEFINITELY DOES NOT WANT ME TO WEAR THEM 6. ___ DO NOT KNOW

63. Were you given a different job in your unit because you wore contact lenses?

1. ___ YES 2. ___ NO

64. If you were give a different job because you wore contact lenses, please explain:

65. Did you have problems making scheduled appointments?

1. YES 2. NO

66. Reasons you had problems making scheduled appointments (forgot, couldn't get off work, leave, etc.):

67. Were there any circumstances where you avoided wearing your contact lenses?

1. YES 2. NO

68. What were the circumstances where you avoided wearing your contact lenses (reasons, numbers of times, and how long each time)?

69. Did you have any problems adhering to the prescribed wearing schedule?

1. YES 2. NO

70. Reasons you had problems adhering to the prescribed wearing schedule:

71. General Comments:

Appendix K

Contact lens wearer responses to operational effectiveness

ANNEX 26 TO APPENDIX G
DATA COLLECTION PLAN

CICLOPS DATA COLLECTION FORM 26
(QUESTIONNAIRE)

CONTACT LENS WEARER RESPONSES TO OPERATIONAL EFFECTIVENESS

Data Collector _____
Name Grade Unit

1. Name _____ 2. Grade _____

3. SSAN _____ - _____ - _____ 4. Date _____
M M D D Y Y

5. Unit _____

6. Duty assignment _____

GENERAL TASK PERFORMANCE

7. Compared to spectacles, are contact lenses better or worse in helping you to perform duties in garrison?

1. ___ CONTACT LENSES MUCH BETTER 2. ___ CONTACT LENSES SOMEWHAT BETTER
3. ___ NO DIFFERENCE BETWEEN THE TWO
4. ___ SPECTACLES SOMEWHAT BETTER 5. ___ SPECTACLES MUCH BETTER

8. Compared to spectacles, are contact lenses better or worse in helping you to perform duties in the field?

1. ___ CONTACT LENSES MUCH BETTER 2. ___ CONTACT LENSES SOMEWHAT BETTER
3. ___ NO DIFFERENCE BETWEEN THE TWO
4. ___ SPECTACLES SOMEWHAT BETTER 5. ___ SPECTACLES MUCH BETTER

9. Did you wear contact lenses in the following situations?

<u>SITUATION</u>	1.YES	2.NO	3.NOT APPLICABLE
a. Off duty	_____	_____	_____
b. Garrison	_____	_____	_____
c. Field training	_____	_____	_____
d. Deployment exercises	_____	_____	_____
e. Airborne operations	_____	_____	_____
f. Air assault operations	_____	_____	_____
g. Special operations	_____	_____	_____
h. Combat operations	_____	_____	_____
i. Other operations (Specify) _____	_____	_____	_____

10. Which type of correction would you prefer to wear in the following situations?
Mark only one response per situation.

<u>SITUATION</u>	Prefer 1.Contact Lenses	Prefer 2.Spectacles	No 3.Preference	4.Don't Know
a. Off duty	_____	_____	_____	_____
b. Garrison	_____	_____	_____	_____
c. Field training	_____	_____	_____	_____
d. Deployment exercises	_____	_____	_____	_____
e. Airborne operations	_____	_____	_____	_____
f. Air assault operations	_____	_____	_____	_____
g. Special operations	_____	_____	_____	_____
h. Combat operations	_____	_____	_____	_____
i. Other operations (Specify) _____	_____	_____	_____	_____

SSAN _____

11. Briefly explain your preferences in the preceding question:

12/13. Did you experience difficulties while wearing contact lenses in the following situations? Did you substitute your spectacles for your contact lenses?

SITUATION	12. DIFFICULTY			13. SUBSTITUTED SPECTACLES	
	1. YES	2. NO	NOT AP- 3. PLICABLE	1. YES	2. NO
a. Off Duty	_____	_____	_____	_____	_____
b. Garrison	_____	_____	_____	_____	_____
c. Field training	_____	_____	_____	_____	_____
d. Deployment exercises	_____	_____	_____	_____	_____
e. Airborne operations	_____	_____	_____	_____	_____
f. Air assault operations	_____	_____	_____	_____	_____
g. Special operations	_____	_____	_____	_____	_____
h. Combat operations	_____	_____	_____	_____	_____
i. Other operations (Specify) _____	_____	_____	_____	_____	_____

14. Briefly explain any difficulties experienced in question 12 above.

SPECIFIC TASKS PERFORMANCE

15. Indicate whether you can see better while wearing contact lenses or spectacles for each of the following tasks:

	Better With 1.Contacts	Better With 2.Spectacles	No 3.Difference	Did not Perform 4.this task
a. Sighting/aiming rifle	_____	_____	_____	_____
b. Sighting/aiming through optical devices (e.g. tank sights)	_____	_____	_____	_____
c. Surveillance within 1000 meters with the naked eye	_____	_____	_____	_____
d. Surveillance within 1000 meters through optical devices	_____	_____	_____	_____
e. Surveillance beyond 1000 meters with the naked eye	_____	_____	_____	_____
f. Surveillance beyond 1000 meters through optical devices	_____	_____	_____	_____
g. Reading/writing	_____	_____	_____	_____
h. Wearing protective mask	_____	_____	_____	_____
i. Other tasks (Specify) _____	_____	_____	_____	_____

16. Did you have difficulty performing the following tasks while wearing contact lenses?

	1.YES	2.NO	DID NOT PERFORM THIS 3.TASK
a. Donning protective mask	_____	_____	_____
b. Performing tasks with protective mask on	_____	_____	_____
c. Reading a map	_____	_____	_____
d. Shooting azimuth with magnetic compass	_____	_____	_____
e. Disassembling/assembling individual weapon	_____	_____	_____
f. Physical training	_____	_____	_____
g. Fueling vehicles	_____	_____	_____
h. Vehicle maintenance	_____	_____	_____
i. Routine duties	_____	_____	_____
j. Manual labor type work	_____	_____	_____
k. Reading	_____	_____	_____
l. Writing	_____	_____	_____
m. Driving	_____	_____	_____
n. Wearing night vision goggles	_____	_____	_____
o. Using night vision sights	_____	_____	_____
p. Swimming	_____	_____	_____
r. Sports	_____	_____	_____

17. Briefly explain any difficulties noted in question 16 above.

SSAN _____ - _____ - _____

18. If you answered yes to any task in question 16, did you remove your contact lenses to complete the task?

	1. YES	2. NO
a. Donning protective mask	_____	_____
b. Performing tasks with protective mask on	_____	_____
c. Reading a map	_____	_____
D. Shooting azimuth with magnetic compass	_____	_____
e. Disassembling/assembling individual weapon	_____	_____
f. Physical training	_____	_____
g. Fueling vehicles	_____	_____
h. Vehicle maintenance	_____	_____
i. Routine duties	_____	_____
j. Manual labor type work	_____	_____
k. Reading	_____	_____
l. Writing	_____	_____
m. Driving	_____	_____
n. Wearing night vision goggles	_____	_____
o. Using night vision sights	_____	_____
p. Swimming	_____	_____
q. Sports	_____	_____

19. Did you experience any vision problems caused by perspiration?

1. _____ Yes 2. _____ No

Appendix L

Additional responses to comparison
of contact lenses versus spectacles

ADDITIONAL RESPONSES TO COMPARISON OF CONTACT LENSES VERSUS SPECTACLES

SECTION 1

Data collector _____
Name Grade Unit

1. Name _____ 2. Grade _____
 3. SSAN _____ - _____ - _____ 4. Date _____
M M D D Y Y
 5. Unit _____
 6. Duty assignment _____

SECTION 2

WHICH OF THE FOLLOWING ENVIRONMENTS DID YOU EXPERIENCE DURING THE TEST?
FOR THOSE YOU MARK YES, WHICH TYPE OF CORRECTION DEVICE DID YOU PREFER TO WEAR?

	DID YOU EXPERIENCE THIS ENVIRONMENT?		WHICH DID YOU PREFER?		
	No	Yes	Contact Lenses	Spectacles	No preference
7. Hot weather	a. 2. _____	1. _____ →	b. 1. _____	2. _____	3. _____
8. Cold weather	a. 2. _____	1. _____ →	b. 1. _____	2. _____	3. _____
9. Rain	a. 2. _____	1. _____ →	b. 1. _____	2. _____	3. _____
10. Moist air (high humidity)	a. 2. _____	1. _____ →	b. 1. _____	2. _____	3. _____
11. Dry air (low humidity)	a. 2. _____	1. _____ →	b. 1. _____	2. _____	3. _____
12. Sunny weather	a. 2. _____	1. _____ →	b. 1. _____	2. _____	3. _____
13. Windy weather	a. 2. _____	1. _____ →	b. 1. _____	2. _____	3. _____
14. Dust	a. 2. _____	1. _____ →	b. 1. _____	2. _____	3. _____
15. Smoke	a. 2. _____	1. _____ →	b. 1. _____	2. _____	3. _____
16. Exposure to chemical agents (CS gas, etc.)	a. 2. _____	1. _____ →	b. 1. _____	2. _____	3. _____
17. Exposure to vehicle exhaust	a. 2. _____	1. _____ →	b. 1. _____	2. _____	3. _____
18. Exposure to weapons exhaust	a. 2. _____	1. _____ →	b. 1. _____	2. _____	3. _____

SECTION 3

WHICH OF THE FOLLOWING TASKS DID YOU PERFORM DURING THE TEST? FOR THOSE YOU MARK YES, WHICH TYPE OF CORRECTION DEVICE DID YOU PREFER TO WEAR?

	DID YOU PERFORM THIS TASK?		WHICH DID YOU PREFER?		
	No	Yes	Contact Lenses	Spectacles	No preference
19. Physical training	a. 2.	1. →	b. 1.	2.	3.
20. Sports	a. 2.	1. →	b. 1.	2.	3.
21. Routine duties	a. 2.	1. →	b. 1.	2.	3.
22. Manual labor type work	a. 2.	1. →	b. 1.	2.	3.
23. Vehicle maintenance	a. 2.	1. →	b. 1.	2.	3.
24. Fueling vehicle	a. 2.	1. →	b. 1.	2.	3.
25. Operating in truck/ vehicle at night	a. 2.	1. →	b. 1.	2.	3.
26. Operating in truck/ vehicle during day	a. 2.	1. →	b. 1.	2.	3.
27. Night gunnery exercises	a. 2.	1. →	b. 1.	2.	3.
28. Guard duty/or patrolling on foot during the day	a. 2.	1. →	b. 1.	2.	3.
29. Guard duty/or patrolling on foot during the night	a. 2.	1. →	b. 1.	2.	3.
30. Simulated combat exercises with minimal sleep	a. 2.	1. →	b. 1.	2.	3.

SECTION 4

31. ARE YOU AUTHORIZED TO BE ISSUED ARMY ISSUE SUN, WIND, DUST GOGGLES? 1. Yes 2. No 3. Don't know

32. DO YOU HAVE THE ARMY ISSUE SUN, WIND, DUST GOGGLES? 1. Yes 2. No

33a. IF YES TO QUESTION 32, WHEN DO YOU WEAR THEM?

.....

33b. (leave blank) 33c. (leave blank) 33d. (leave blank)

Appendix M

Spectacle wearer responses to operational effectiveness

SSAN _____ - _____ - _____

8. Did you experience difficulties while wearing spectacles in the following situations?

	1.YES	2.NO	3.NOT APPLICABLE
a. Garrison	_____	_____	_____
b. Field training	_____	_____	_____
c. Deployment exercises	_____	_____	_____
d. Airborne operations	_____	_____	_____
e. Air assault operations	_____	_____	_____
f. Special operations	_____	_____	_____
g. Combat operations	_____	_____	_____
h. Other operations (Specify) _____	_____	_____	_____

9. Briefly explain any difficulties experienced in question 8 above.

SSAN _____

SPECIFIC TASKS PERFORMANCE

10. Did you have difficulty performing the following tasks while wearing spectacles?	1.YES	2.NO	3.DID NOT PERFORM TASK
a. Donning protective mask	_____	_____	_____
b. Reading a map	_____	_____	_____
c. Shooting azimuth with magnetic compass	_____	_____	_____
d. Disassembling/assembling individual weapon	_____	_____	_____
e. Physical training	_____	_____	_____
f. Fueling vehicles	_____	_____	_____
g. Vehicle maintenance	_____	_____	_____
h. Routine duties	_____	_____	_____
i. Manual labor type work	_____	_____	_____
j. Reading	_____	_____	_____
k. Writing	_____	_____	_____
l. Driving	_____	_____	_____
m. Wearing night vision goggles	_____	_____	_____
n. Using night vision sights	_____	_____	_____
o. Sports	_____	_____	_____

11. Briefly explain any difficulties experienced in question 10 above.

SSAN _____

12. If you answered yes to any task in question 10, did you remove your spectacles to complete the task?

	1.YES	2.NO
a. Donning protective mask	_____	_____
b. Reading a map	_____	_____
c. Shooting azimuth with magnetic compass	_____	_____
d. Disassembling/assembling individual weapon	_____	_____
e. Physical training	_____	_____
f. Fueling vehicles	_____	_____
g. Vehicle maintenance	_____	_____
h. Routine duties	_____	_____
i. Manual labor type work	_____	_____
j. Reading	_____	_____
k. Writing	_____	_____
l. Driving	_____	_____
m. Wearing night vision goggles	_____	_____
n. Using night vision sights	_____	_____
o. Sports	_____	_____

13. Did you experience any vision problems caused by perspiration? 1.YES _____
2.NO _____

SSAN _____

14. Describe any vision problems caused by perspiration:

15. Did you experience any problems seeing after dark while wearing spectacles?

1. YES _____ 2. NO _____

16. Describe any problems experienced seeing after dark with spectacles:

17. Did you have problems with the protective mask optical inserts falling out of the mask? 1. YES _____ 2. NO _____

18. Did you have difficulty performing tasks with the protective mask on while wearing optical inserts? 1. YES _____ 2. NO _____

19. How often did you experience the following problems?

	1.NEVER	2.SOMETIMES	3.OFTEN
a. Glasses slip down nose	_____	_____	_____
b. Glasses fall off/dislodge	_____	_____	_____
c. Loss of glasses	_____	_____	_____
d. Lenses covered with dust/dirt film	_____	_____	_____
e. Lenses covered with dust/dirt spots	_____	_____	_____
f. Smearing of lenses	_____	_____	_____
g. Sweat streaks on lenses	_____	_____	_____
h. Raindrops on lenses	_____	_____	_____
i. Fogging of lenses	_____	_____	_____
j. Scratching or chipping of lenses	_____	_____	_____
k. Broken lenses	_____	_____	_____
l. Bent frames	_____	_____	_____
m. Broken frames	_____	_____	_____
n. Discolored frames	_____	_____	_____
o. Lenses falling out of frames	_____	_____	_____
p. Loose earpieces	_____	_____	_____
q. Loss of screws	_____	_____	_____
r. Discomfort from frame	_____	_____	_____
s. Other (Describe) _____	_____	_____	_____

20. How bothersome were the problems you experienced in question 17?

	1.MINOR	2.MODERATE	3.SEVERE
a. Glasses slip down nose	_____	_____	_____
b. Glasses fall off/dislodge	_____	_____	_____
c. Loss of glasses	_____	_____	_____
d. Lenses covered with dust/dirt film	_____	_____	_____
e. Lenses covered with dust/dirt spots	_____	_____	_____
f. Smearing of lenses	_____	_____	_____
g. Sweat streaks on lenses	_____	_____	_____
h. Raindrops on lenses	_____	_____	_____
i. Fogging of lenses	_____	_____	_____
j. Scratching or chipping of lenses	_____	_____	_____
k. Broken lenses	_____	_____	_____
l. Bent frames	_____	_____	_____
m. Broken frames	_____	_____	_____
n. Discolored frames	_____	_____	_____
o. Lenses falling out of frames	_____	_____	_____
p. Loose earpieces	_____	_____	_____
q. Loss of screws	_____	_____	_____
r. Discomfort from frame	_____	_____	_____
s. Other	_____	_____	_____

SSAN _____ - _____ - _____

21. Did you have difficulty with sun glare while wearing spectacles? 1.YES ___ 2.NO ___
22. Did you have difficulty sighting/aiming a rifle while wearing spectacles?
1.YES ___ 2.NO ___ 3.NOT APPLICABLE ___
23. Did you have difficulty sighting/aiming through optical devices while wearing spectacles? 1.YES ___ 2.NO ___ 3.NOT APPLICABLE ___
24. Did you have difficulty performing surveillance within 1000 meters without optical devices while wearing spectacles? 1.YES ___ 2.NO ___ 3.NOT APPLICABLE ___
25. Did you have difficulty performing surveillance within 1000 meters through optical devices while wearing spectacles? 1.YES ___ 2.NO ___ 3.NOT APPLICABLE ___
26. Did you have difficulty performing surveillance beyond 1000 meters without optical devices while wearing spectacles? 1.YES ___ 2.NO ___ 3.NOT APPLICABLE ___
27. Did you have difficulty performing surveillance beyond 1000 meters through optical devices while wearing spectacles? 1.YES ___ 2.NO ___ 3.NOT APPLICABLE ___

HANDLING SPECTACLES

28. How often did you have problems handling your spectacles?
1. ___ ALWAYS 2. ___ OFTEN 3. ___ SOMETIMES 4. ___ SELDOM 5. ___ NEVER
29. If you had problems, how bothersome were they?
1. ___ MINOR 2. ___ MODERATE 3. ___ SEVERE
30. Briefly describe the nature of the problems:

31. How acceptable to you were the problems you experienced?
1. ___ HIGHLY ACCEPTABLE 2. ___ MODERATELY ACCEPTABLE 3. ___ NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. ___ MODERATELY UNACCEPTABLE 5. ___ TOTALLY UNACCEPTABLE
32. How acceptable to you was the amount of time required for handling your spectacles?
1. ___ HIGHLY ACCEPTABLE 2. ___ MODERATELY ACCEPTABLE 3. ___ NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. ___ MODERATELY UNACCEPTABLE 5. ___ TOTALLY UNACCEPTABLE

SSAN _____ - _____ - _____

COMFORT OF SPECTACLES

33. Generally, how comfortable were your spectacles?

1. VERY COMFORTABLE 2. COMFORTABLE 3. NEITHER COMFORTABLE
NOR UNCOMFORTABLE 4. UNCOMFORTABLE 5. VERY UNCOMFORTABLE

34. If uncomfortable, briefly describe the nature of the discomfort:

35. How acceptable to you is this degree of comfort or discomfort?

1. HIGHLY ACCEPTABLE 2. MODERATELY ACCEPTABLE 3. NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. MODERATELY UNACCEPTABLE 5. TOTALLY UNACCEPTABLE

36/37. How often did you experience the following medical problems? How bothersome were they?

<u>PROBLEM</u>	<u>36.HOW OFTEN</u>			<u>37.HOW BOTHERSOME</u>		
	1.NEVER	2.SOMETIMES	3.OFTEN	1.MINOR	2.MODERATE	3.SEVERE
a. Eye irritation	_____	_____	_____	_____	_____	_____
b. Light sensitivity	_____	_____	_____	_____	_____	_____
c. Other (specify)	_____	_____	_____	_____	_____	_____
d. Other (specify)	_____	_____	_____	_____	_____	_____

CLEANING SPECTACLES

38. How often did you have problems cleaning your spectacles?

1. ___ ALWAYS 2. ___ OFTEN 3. ___ SOMETIMES 4. ___ SELDOM 5. ___ NEVER

39. If you had problems, how bothersome were they?

1. ___ MINOR 2. ___ MODERATE 3. ___ SEVERE

40. Briefly describe the nature of the problems:

41. How acceptable to you were the problems you experienced?

1. ___ HIGHLY ACCEPTABLE 2. ___ MODERATELY ACCEPTABLE 3. ___ NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. ___ MODERATELY UNACCEPTABLE 5. ___ TOTALLY UNACCEPTABLE

42. How acceptable to you was the amount of time required for cleaning your spectacles?

1. ___ HIGHLY ACCEPTABLE 2. ___ MODERATELY ACCEPTABLE 3. ___ NEITHER ACCEPTABLE
NOR UNACCEPTABLE 4. ___ MODERATELY UNACCEPTABLE 5. ___ TOTALLY UNACCEPTABLE

MEDICAL SUPPORT

43. How satisfied or dissatisfied were you with the support provided by medical personnel in examining and helping you care for your spectacles?

1. ___ VERY SATISFIED 2. ___ SATISFIED 3. ___ NEITHER SATISFIED NOR DISSATISFIED
4. ___ DISSATISFIED 5. ___ VERY DISSATISFIED

44. Briefly explain any dissatisfaction:

SSAN _____

ENVIRONMENTAL

45. Indicate with a check mark whether or not the following environmental conditions made wearing spectacles difficult:

<u>ENVIRONMENTAL CONDITION</u>	1. YES	2. NO
a. Hot weather	_____	_____
b. Cold weather	_____	_____
c. Rain	_____	_____
d. Moist Air (High Humidity)	_____	_____
e. Dry Air (Low Humidity)	_____	_____
f. Sunshine	_____	_____
g. Wind	_____	_____
h. Dust	_____	_____
i. Smoke	_____	_____
j. Exposure to chemical agents	_____	_____
k. Exposure to vehicle exhaust	_____	_____
l. Exposure to weapons exhaust	_____	_____
m. Other (specify) _____	_____	_____

46. Briefly explain the problems caused by environmental conditions:

47. Do you usually have one or more spare pair(s) of spectacles? 1. ___ YES 2. ___ NO

48. If you answered YES to question 47, how often do you carry a spare pair of spectacles on your person?

1. ___ ALWAYS 2. ___ MOST OF THE TIME 3. ___ ABOUT HALF OF THE TIME

4. ___ ONCE IN A WHILE 5. ___ NEVER

49. If you answered YES to question 47, and if you do not carry spare spectacles on your person, can you reach a spare pair of spectacles within 30 minutes? 1. YES
2. NO

50. How frequently do you wear sunglasses to reduce glare when wearing spectacles on sunny days?

1. ALWAYS 2. MOST OF THE TIME 3. ABOUT HALF OF THE TIME

4. ONCE IN A WHILE 5. NEVER

51. How necessary is it for you to wear sunglasses to reduce glare while wearing spectacles on sunny days?

1. ABSOLUTELY NECESSARY 2. NECESSARY 3. HELPFUL, BUT NOT NECESSARY

4. NOT NECESSARY AT ALL

GENERAL ATTITUDE TOWARD WEARING SPECTACLES

52. Are you confident in your ability to see adequately when you are wearing spectacles?

1. HIGHLY CONFIDENT 2. MODERATELY CONFIDENT

3. NOT AT ALL CONFIDENT

53. Do you like or dislike wearing spectacles?

1. LIKE VERY MUCH 2. LIKE MODERATELY 3. NEITHER LIKE NOR DISLIKE

4. DISLIKE MODERATELY 5. DISLIKE VERY MUCH

54. Briefly explain why you like or dislike wearing spectacles:

55. Were you ever given a different job in a unit because you wore spectacles?

1. YES 2. NO

56. If you were given a different job because you wore spectacles, please explain:

57. Were there any situations or conditions in which you deliberately avoided wearing your spectacles?

1. YES 2. NO

Appendix N

Professionals/clinicians questionnaire

PROFESSIONALS/CLINICIANS QUESTIONNAIRE (CICLOPS)

INSTRUCTIONS

1. Please answer all questions based on your experiences in the Contact Lens Armor Study.
2. Select only 1 answer per question.
3. Space for written comments is provided at the end of the questionnaire.
4. Please return completed questionnaire in self-addressed envelope provided.

NAME _____

QUESTIONNAIRE

1. The optometrists available were adequate in number to support the Armor Contact Lens Study.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

2. This same number of optometrists would be adequate to support the 2AD if that division were authorized Army-provided contact lenses.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

3. The technicians available were adequate in number to support the Armor Study.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

4. This same number of technicians would be adequate to support the 2AD if that division were authorized Army-provided contact lenses.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

5. The normal complement of professional personnel assigned to the 2AD would be adequate to support that division if it were authorized Army-provided contact lenses.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

6. The ophthalmic equipment available in the TMC was adequate in quantity to support the Armor Study.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

7. The same equipment would be adequate in quantity to support the 2AD if that division were authorized Army-provided contact lenses.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

8. The types of TO&E ophthalmic equipment standard to the 2AD would be adequate to support that division if it were authorized Army-provided contact lenses.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

9. The contact lenses provided for the Armor Study were sufficient in parameters and types.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

10. The method of procuring the lenses, i.e., a one time bulk order of lenses to be dispensed, was adequate to support the study.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

11. The contact lens supporting materials and solutions provided were adequate in quantity to support the Armor Study.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

12. The method of procuring the materials and solutions, i.e., a one-time bulk order, was adequate to support the study.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

13. The Troop Medical Clinic Optometry Facility was adequate in size to support the Armor Study.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

14. This same facility would be adequate in size to support the 2AD if that division were authorized Army-provided contact lenses.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

15. The 6-8 day schedule of extended contact lens wear was adequate for troops in the Armor Study.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

16. The administrative methods for insuring compliance with follow-up examinations were adequate for the study.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

17. Based on your experience with this study, authorized contact lens wearing soldiers should be issued a spare pair of contact lenses:

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

18. Authorized contact lens wearing soldiers should be issued plano sunglasses.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

19. Contact lens wearing soldiers must have back up spectacles and gas mask inserts.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

20. A much higher percentage of 2AD soldiers under the age of 40 could successfully wear contact lenses if all types of lenses were available to the practitioner.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

21. Troops of an armored division can be expected to wear contact lenses as successfully in the field as in garrison.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

22. The majority of optometrists and ophthalmologists in the Army today are sufficiently proficient in contact lens care to have supported this study without additional training.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

23. If an optometrist or ophthalmologist, who is not proficient in contact lens care, were assigned to an armored division in which contact lenses were authorized, he or she should be required to become proficient.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

24. Procurement of contact lenses and supplies for soldiers of an armored division should be handled by the Pharmacy of the medical treatment facility.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

25. Procurement of contact lenses and supplies for soldiers of an armored division should be handled by the Eye Clinic of the medical treatment facility.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
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26. Most of the contact lens related eye problems seen in the Armor Study were probably due to poor hygiene.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
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27. Subjects who exhibited contact lens related eye problems in the Armor Study generally followed the proper procedures in seeking medical help.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
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28. Bifocal contact lens services are not warranted for soldiers in an armored division.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
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29. The selection of the types of contact lenses and supplies to be used in an armored division should be the prerogative of the eye care professionals in the division.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
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30. The selection of the types of contact lenses and supplies to be used in an armored division should be determined by an AMEDD medical panel of vision experts.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
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31. Most contact lens wearing soldiers could successfully wear their lenses with the gas mask for up to 72 hours.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

32. Contact lens wearing soldiers should be identified as such by their dog tags.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

33. Contact lenses provide a viable solution to soldier system interface problems.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

34. Overall, the advantages outweigh the disadvantages for contact lens wear in an armored division.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

35. Based on what we know now, contact lenses should be authorized for use in an armored division.

Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
-----	-----	-----	-----	-----

36. Considering the average number of clinic hours for each exam (initial, follow-ups, final), what proportion of the clinic time was handled by technicians?

- | | | |
|------------------|---------------|---------------|
| a. Less than 10% | b. 10% to 20% | c. 20% to 30% |
| d. 30% to 40% | e. 40% to 50% | f. Don't know |

37. If the 2AD were to use Army-provided extended-wear contact lenses routinely, what rate of ocular complications would you expect, in comparison with the rate found in the Armor Contact Lens Study?

- a. Much lower
- b. Somewhat lower
- c. About the same
- d. Somewhat higher
- e. Much higher
- f. Don't know

38. If the 2AD were to deploy with extended-wear contact lens wearers and fight for 3 weeks on an integrated battlefield (excluding NBC warfare), what proportion of the contact lens wearers would you expect to become casualties due to lens-related complications?

- a. Less than 5%
- b. 5% to 10%
- c. 10% to 15%
- d. 15% to 20%
- e. 20% to 25%
- f. More than 25%
- g. Don't know

39. If troops of an armored division were authorized to wear extended contact lenses during peacetime, the wearing schedule should be _____ days.

40. If troops of an armored division were authorized to wear extended contact lenses in combat, the wearing schedule should be _____ days.

41. Follow-up examinations for contact lens wearing soldiers in an armored division should be scheduled every _____ months.

42. Contact lens wearing soldiers in an armored division should be given a supply of solutions sufficient to last _____ months.

43. For each of the listed contact lens related complications, please estimate the most likely impact on the typical 2AD soldier's capability to fight in combat.

	No Perf Degrad	Mod Perf Degrad	Casualty Less than 24 hours	Casualty More than 24 hours
Conjunctivitis	-----	-----	-----	-----
Corneal Abrasion	-----	-----	-----	-----
Giant papill conj	-----	-----	-----	-----
Neovascularization	-----	-----	-----	-----
Corneal staining	-----	-----	-----	-----
Corneal edema	-----	-----	-----	-----
Keratitis	-----	-----	-----	-----
Iritis	-----	-----	-----	-----
Keratoconjunctivitis	-----	-----	-----	-----
Foreign body	-----	-----	-----	-----
Epithel defects	-----	-----	-----	-----
Phlyctenule	-----	-----	-----	-----
Corneal stromal infilt	-----	-----	-----	-----
Blepharitis	-----	-----	-----	-----
Corneal ulcer	-----	-----	-----	-----

Glossary

acuity - clearness; sharpness of vision.

- unacceptable acuity with soft contact lenses while fitting -- acuity worse than 20/25 while using both eyes.
- dissatisfaction with acuity -- patient was dissatisfied with acuity regardless of what was measured.
- reduction in acuity lasting more than 7 days -- a reduction lasting 7 days or more regardless of measurement of one line of letters on the acuity chart.
- 20/25 -- A person with 20/25 vision must stand at a point 20 feet away to see the same line of letters that a person with 20/20 vision could see at 25 feet.

adnexa or adnexa oculi - the appendages of the eye, as the lacrimal apparatus, the eyelids, and the extraocular muscles.

aesthesiometry - procedure to test corneal sensitivity.

anterior chamber - the space in the eye filled with fluid (aqueous humor) generally bounded anteriorly by the cornea and posteriorly by the crystalline lens.

antigen - any substance which is capable, under appropriate conditions, of inducing the formation of antibodies. Antigens may be soluble substances such as toxins and foreign protein or particulates such as bacteria and tissue cells.

aqueous humor - the clear, watery fluid which fills the anterior and the posterior chambers of the eye.

astigmatic/cylindrical errors - a reduction in acuity resulting from an unequal curvature of the refractive surfaces of the eye. The toroidal shape causes unequal refraction of the incident light in different meridians resulting in a nonuniformly-blurred image.

automated keratometer - instrument that measures the curvature of the cornea.

automated objective refractor - instrument that measures the refractive state of the eye objectively. It gives the objective prescription.

binocular - the use of both eyes simultaneously in such a manner that each retinal image contributes to the perceived object of regard.

biomicroscope (slit lamp) - instrument used to magnify the external portion of the eye and eyelids for stereoscopic viewing and examination.

bleb (ocular) - a small pocket of transparent fluid located in the cornea.

blepharitis - inflammation of the eyelids.

conjunctiva - a mucous membrane extending from the eyelid margin to the corneal limbus, forming the posterior (inside) layer of the eyelids and the anterior layer of the eyeball.

conjunctivitis - inflammation of inner lid surfaces or transparent external covering of the eye globe.

contact lens - an optical device worn on the anterior surface of the eye, used primarily to correct refractive error. There are basically two classifications of contact lenses, rigid and soft.

- rigid (hard) - these lenses are hydrophobic. They do not bind to or absorb water.
- soft - these lenses are hydrophilic. They absorb and bind water to their structures.
- high water content soft contact lenses (SCL) - 70 percent water or greater (when in the hydrated state (in saline solution), 70 percent of the lens is fluid and 30 percent is the plastic which holds the shape).
- medium water content SCL - 45-70 percent water.
- low water content SCL - less than 45 percent water.
- extended wear SCL -- contact lenses that are not removed for sleeping and have been approved by the Food and Drug Administration for up to 30 days of wear without removing for cleaning and disinfecting.

contrast sensitivity - ability to distinguish or perceive subtle brightness differences in a spatial pattern.

contrast sensitivity chart - chart used to measure contrast sensitivity.

cornea -- the transparent structure forming the anterior part of the eye.

corneal abrasion - an abrasion, usually mechanical, which disrupts the normal physiological state of one or more layers of the cornea.

corneal edema - swelling of the corneal tissue due to retention of excess fluid.

corneal staining - dye showing corneal epithelium disruption on the front surface. Fluorescent dye under a blue light temporarily will stain and make visible areas of the cornea that have been disrupted by contact lenses.

corneal stromal edema - swelling of the middle layer of the cornea.

corneal ulcer - infection, which usually follows epithelial damage, resulting in continual erosion of the cornea; potentially sight-threatening if not treated quickly and correctly.

cylindrical errors - see: astigmatic/cylindrical errors.

deposits - protein, lipids, and minerals normally found in tears which can adhere to contact lens surfaces. Foreign debris may be included in this group.

dermatitis - inflammation of the skin.

Descemet's membrane - the noncellular fourth layer of the cornea, located between the endothelium and the stroma.

diopter - a unit of measurement to designate the refractive power of a lens or optical system, the number of diopters being equal to the reciprocal of the focal length in meters.

dioptric adjustment - mechanism to change the power of a lens.

edema - see: corneal edema.

endothelium (ocular) - the single-cell innermost layer of the cornea.

endothelial photography - microphotography of the deepest single-cell layer of the cornea.

epithelial defects - a disruption in the integrity of the epithelium or epithelial cells, due to trauma, disease, or hypoxia.

epithelium - as relates to the eye, the outermost layer of the globe.

fitting (contact lens) - process by which a contact lens is selected that results in proper lens alignment, adequate movement in relation to the front surface of the eye, and optimum visual acuity.

fluorescein - a fluorescent dye used externally in the eye to identify any irregularity in the conjunctival layer.

follicular hypertrophy - an increase in size, not number, of cells forming certain glands found in the eyelids, causing changes in physiological function and physical appearance.

giant papillary conjunctivitis - conjunctival inflammatory reaction to soft contact lens wear; it is a response of an individual's immune system to denatured protein adherent to the anterior surface of the contact lens.

global examination - examination of the eye, both internally and externally, for any abnormalities.

habitual visual acuity - visual acuity normally manifested by an individual either with or without optical correction.

hyperemia (retinal) - congestion of the retinal blood vessels.

hyperopia - farsightedness; a refractive error which occurs because the eyeball is short or the refractive power of the lens is weak. The point of focus for rays of light from distant objects falls behind the retina.

hyposesthesia - partial loss of sensation.

hypoxia - deficiency of oxygen.

infiltrates - the diffusion or accumulation in a tissue or cells of substances not normal to it or in concentrations in excess of the normal.

injection - congestion of conjunctival blood vessels; redness of the eye.

intraocular pressure - fluidic pressure inside the eye which maintains its globular shape.

iris - portion of the eye which determines the size of the pupil and is responsible for eye color.

iritis - inflammation of the iris.

keratitis - inflammation of the cornea.

keratoconjunctivitis - inflammation of the conjunctiva and cornea.

keratometer - instrument used to measure the anterior curvatures of the cornea.

lacrimation - the secretion of tears.

lens stability - satisfactory movement and centering of a contact lens on the eye.

lensometer - an instrument that measures power of an optical device, usually spectacle lenses.

limbus (corneal) - an annular transitional zone, approximately 1 mm wide, between the cornea and the bulbar conjunctiva and sclera.

minimum angle of resolution - the minimum separable angle as determined by the identification of form targets and represented by the reciprocal of the Snellen fraction, e.g., $20/40 = 2$ minutes of arc.

myopia - nearsightedness; a refractive error which occurs because the eyeball is long or the refractive power of the lens is strong. The point of focus for rays of light from distant objects falls in front of the retina.

neovascularization - see: vascularization.

noncontact tonometry - procedure used to measure the internal pressure of the eye without mechanically touching the eye; employs a puff of air.

ocular hypertension - pressure inside the eye which is above that normally found in the general population.

O.D. (oculus dexter) - referring to the right eye.

O.S. (oculus sinister) - referring to the left eye.

O.U. (oculi uniter) - using both eyes together as a unit.

opacification - the loss of light transparency by tissues or structures of the eye which are normally transparent.

ophthalmoscope - a hand-held instrument used to view the inside of the eye.

overrefraction - determination of any remaining refractive error by examining the eye with a given optical correction in place.

overwear syndrome - a term applied to the wear of contact lens in excess of that recommended, the syndrome includes abnormal eye responses such as redness, itching, burning, and pain.

palpebral tarsi - conjunctiva overlying the tarsal plates which consist of dense fibrous and some elastic tissue in the upper and lower lids.

papillae - small nipple-shaped projections or elevations containing a tuft of blood vessels, found on the portion of the eyelid in contact with the eye. They result from a nonspecific conjunctival reaction.

phlyctenule - a small vesicle, blister, or ulcerated nodule of the cornea or conjunctiva.

phoropter - instrument used to determine the prescription for corrective lenses. Contains banks of lenses used to measure refractive error.

pingueculae - a small, slightly raised, yellowish, nonfatty thickening of the conjunctiva.

polymegathism - abnormal changes in size and shape of corneal endothelial cells.

presbyopia - a reduction in accommodative or focusing ability associated with age necessitating the use of special lenses to permit normal vision at near.

refraction - procedure used to determine refractive error.

refractive error - a defect in the eye that prevents light rays from being brought to a clear focus on the retina.

retina - innermost coat of the eye; formed of light sensitive nerve elements.

retinoscope - an instrument used to objectively determine refractive error.

retinoscopic reflex - the reflected image observed during the act of shining a light into the eye and performing an objective examination of refractive error.

sclera - the white, fibrous outer layer covering all of the eye except for the cornea.

sensitivity reaction - inflammation of the conjunctiva and/or cornea, often secondary to the use of contact lenses and/or their solutions.

Shirmer tear test - procedure used to assess the quantity of tear production.

slit lamp - see: biomicroscope.

Snellen chart - a visual acuity test chart made up of Snellen test type.

spherical error - refractive error of farsightedness or nearsightedness which does not include astigmatism.

spherical equivalent - a single lens whose effective power is equal to the total effective power of a combination of lenses. Determined by combining the spherical error with one-half the cylindrical error.

staining - see: corneal staining.

stippling - pinpoint areas of discontinuous or devitalized corneal epithelium which can be stained and seen with biomicroscopy.

striae (ocular) - a minute line, band, groove, or channel found most frequently in the cornea.

stroma - the lamellated connective tissue constituting the thick middle layer of the cornea.

subjective refraction - process by which a subject's prescription is determined by incorporating their response to various lens combinations.

tarsal plate - a thin plate of dense fibrous and some elastic tissue in the upper and lower eyelids, giving them their shape and firmness.

tarsal exam - examination of the conjunctiva overlying the tarsal plates of the eyelids.

tear breakup time - procedure used to assess the quality of tears and their ability to wet the cornea.

tight lens syndrome - adverse ocular response due to an immobile contact lens.

tonometry - a procedure to determine the intraocular pressure of the eye, usually by measuring the impressibility of the globe or cornea.

toric lens - contact lens designed to correct for astigmatism.

vascularization - new blood vessel growth into the normally vessel-free cornea.

vision correction - the improvement in visual acuity resulting from the application of a corrective lens.