USAARL Report No. 90-1

Six-Month Evaluation of Extended Wear Soft Contact Lenses Among Armored Troops: Part I: Clinical Findings (Reprint)

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December 1989

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United States Army Aeromedical Research Laboratory
Fort Rucker, Alabama 36362-5292

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Unclassified
SECURITY CLASSIFICATION OF THIS PAGE

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1a REPORT SECURITY CLASSIFICATION	1b RESTRICTIVE MARKINGS
2a SECURITY CLASSIFICATION AUTHORITY	3 DISTRIBUTION / AVAILABILITY OF REPORT Approved for public relase; distribution unlimited
2b DECLASSIFICATION / DOWNGRADING SCHEDULE	
4 PERFORMING ORGANIZATION REPORT NUMBER(S) USAARL Report No. 90-1	5 MONITORING ORGANIZATION REPORT NUMBER(S)
6a NAME OF PERFORMING ORGANIZATION Sensory Research Division U.S. Army Aeromedical Rsch Lab	6b OFFICE SYMBOL (If applicable) SGRD-UAS-VS
6c ADDRESS (City, State, and ZIP Code) P.O. Box 577 Fort Rucker, AL 36362-5292	7a NAME OF MONITORING ORGANIZATION U.S. Army Medical Research and Development Command
	7b ADDRESS (City, State, and ZIP Code) Fort Detrick Frederick, MD 21701-5012
8a NAME OF FUNDING / SPONSORING ORGANIZATION	8b OFFICE SYMBOL (If applicable)
8c ADDRESS (City, State, and ZIP Code)	9 PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER
	10 SOURCE OF FUNDING NUMBERS

PROGRAM ELEMENT NO.	PROJECT NO.	TASK NO.	WORK UNIT ACCESSION NO.
62787A	3E162787 A879		168

11 TITLE (Include Security Classification)
Six-Month Evaluation of Extended-Wear Soft Contact Lenses Among Armor Troops: Part I, Clinical Findings (U) (Reprint)

12 PERSONAL AUTHOR(S) William G. Bachman, Bruce C. Leibrecht, John K. Crosley, Dudley R. Price, Patrick M. Leas, and Gerard A. Bentley

13a TYPE OF REPORT	13b TIME COVERED	14 DATE OF REPORT (Year, Month, Day)	15 PAGE COUNT
	FROM _____ TO _____	December 1989	13

16 SUPPLEMENTARY NOTATION
This report is a reprint of an article published in International Contact Lens Clinic, June 1989, 16(6):162-168

17 COSATI CODES		
FIELD	GROUP	SUB-GROUP
06	04	
20	06	

18 SUBJECT TERMS (Continue on reverse if necessary and identify by block number)
(U) Contact lenses, (U) Military environments, (U) Vision correction, (U) Ocular physiology

19 ABSTRACT (Continue on reverse if necessary and identify by block number)

This report addresses the clinical aspects of wearing contact lenses in an operational military environment. Male volunteers in an armored division wore extended-wear soft contact lenses (SCLs) or spectacles for up to 6 months, participating fully in their units' normal activities. Seventy-four percent of those successfully fitted with SCLs wore their lenses for the duration of the study, when administrative losses were factored out. More than one-third of the SCL wearers experienced one or more ocular conditions requiring at least a temporary suspension of lens wear. Corneal edema and corneal staining occurred rarely at clinically significant levels. Higher than expected rates of corneal vascularization were most likely influenced by measurement criteria. Relatively frequent conjuctival injection appeared to be largely due to local environmental factors.

20 DISTRIBUTION / AVAILABILITY OF ABSTRACT	21 ABSTRACT SECURITY CLASSIFICATION
☒ UNCLASSIFIED/UNLIMITED ☐ SAME AS RPT ☐ DTIC USERS	Unclassified

22a NAME OF RESPONSIBLE INDIVIDUAL	22b TELEPHONE (Include Area Code)	22c OFFICE SYMBOL
Chief, Scientific Information Center	(205) 255-6907	SGRD-UAX-SI

DD Form 1473, JUN 86 *Previous editions are obsolete*

SECURITY CLASSIFICATION OF THIS PAGE
Unclassified

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ABSTRACT

This report addresses the clinical aspects of wearing contact lenses in an operational military environment. Male volunteers in an armored division wore extended wear soft contact lenses (SCL) or spectacles for up to six months, participating fully in their units' normal activities. Seventy-four percent of those successfully fitted with SCL wore their lenses for the duration of the study when administrative losses were factored out. More than one-third of the SCL wearers experienced one or more ocular conditions requiring at least a temporary suspension of lens wear. Corneal edema and corneal staining occurred rarely at clinically significant levels. High rates of corneal vascularization were influenced by reporting criteria. Relatively frequent conjunctival injection appeared to be largely due to environmental factors.

INTRODUCTION

A large proportion of U.S. Army personnel wear spectacles to correct for ametropia. Reinke[1] estimates the proportion of spectacle wearers to be greater than 48%. Unfortunately, spectacle wearing soldiers frequently face problems when interfacing with military hardware, since spectacles are minimally compatible or outright incompatible with many military systems. Examples of such systems include protective masks, binoculars, weapons sights, night vision goggles, and helmet mounted displays. To make matters worse, rain, dust, sweat, and condensation clinging to spectacle lenses can compound operational problems for ametropic troops.

Contact lenses, especially extended wear lenses, offer an appealing alternative for solving the compatibility and environmental problems faced by spectacle wearing soldiers. A number of investigators have studied contact lens wear among military personnel. As early as 1952, McG[illegible]y and Enoch[2] evaluated clinical, environmental, and performance aspects among 10 enlisted soldiers te[illegible] several types of contact lenses available at the time. In the years since, military aviators have received the most frequent attention; several researchers[3-9] used mainly clinical measures with sample sizes ranging from 1 to 55, while one investigator[10] used a retrospective questionnaire among 7 British Army pilots. Some studies have focused on ground troops,[11-16] and reports addressing contact lens wear among

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civilians in extreme environments[17-20] offer information relevant to military applications. However, the literature furnishes little data from large sample studies combining clinical and survey methodologies with military personnel.

This study was initiated to assess the safety and utility of soft contact lenses (SCL) when worn by troops in an armored division while performing their normal military duties. In the armor environment, 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. The specific study objectives were: (1) estimate success rates in wearing selected extended wear contact lenses; (2) determine the impact of extended wear on ocular physiology; (3 evaluate the acceptability of wear and care aspects; and (4) assess the impact on military job performance. This report addresses findings relevant to the first two objectives; a follow-on article (to appear in the July 1989 issue) will present subjective patient responses pertaining to the latter two objectives. Bachman et al.[21] have provided a full account of the study's methods and results.

MATERIALS AND METHODS

Subjects A total of 311 volunteers participated in this study; 215 were fitted with extended wear SCL, while 96 served as spectacle-wearing controls. Ranging in age from 18–43, all were male soldiers stationed at Ford Hood, Texas. Most of the subjects were crew members of tanks, combat vehicles (tracked personnel and weapons carriers), or air defense artillery weapons (antiaircraft missiles or guns).

The 311 subjects resulted from prescreening a large number of health records of ametropic troops. Prescreening was followed by thorough clinical evaluation to identify conditions that would medically contraindicate 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; any systemic disease that might affect the eye or be aggravated by wearing contact lenses; and refractive errors that could not be compensated adequately by available contact lens powers.

Contact Lens Materials At the time this study was initiated, soft contact lenses worn for extended periods of time offered the greatest potential to solve soldier-system interface problems. Three different types of extended wear SCL were used: (1) 71% water content (Permalens XL; CooperVision); (2) 55% water content (Hydrocurve II; Barnes-Hind); and (3) 38.5% water content (CSI T; Sola-Syntex). This mix provided reasonably broad fitting capabilities. The Permalens XL and CSI T lenses were available to correct myopia in 0.50 diopter steps from −0.50 to −8.00 diopters. The Hydrocurve II lens was available in the same myopic corrections, as well as in 0.50 diopter steps to correct hyperopia from +1.00 to +5.00 diopters. Lenses were available in sufficient quantities so 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.

The SCL subjects were instructed to wear their lenses continuously for a period of 7 days plus or minus 1 day. On the 7th day of continuous wear, the lenses were to be removed 2 hours prior to bedtime, cleaned, and stored in the cases until the following morning. This conservative approach to wearing time minimized physiological risks and interference with the individual's performance of duties. Six months of wearing time were targeted for each subject. To minimize problems related to lens deposits, subjects wore the same lenses no longer than four months, at the end of which the old lenses were replaced with new ones.

Clinical Procedures Following the initial examination, each SCL wearer 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. All subjects began immediately with extended lens wear. Followup visits at 24 hours, 7 days, and every 30 days thereafter were scheduled routinely.

Spectacle-wearing subjects received an initial examination similar to the initial exam for SCL participants. Each participant'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.

RESULTS AND DISCUSSION

The SCL wearers were fit across a period of 14 weeks. The study spanned the months of May through December, with individual participants varying in their starting and ending dates. Consequently, each participant encountered a broad range of climatic conditions. Temperatures ranged from 102°F to 31°F, with conditions generally dry and dusty. Rainfall during the first five months of the test period averaged 1.57 inches per month, while the average during October through December was 4.67 inches per month. Relative humidity generally ranged between 35% and 70%.

The SCL and spectacle groups were quite comparable in terms of age distribution: in each group, 60% 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 SCL wearers.

Visual Status The range of uncorrected visual acuity of the two groups was the same, 20/20 to 20/450. However, the mean for the SCL wearers was 20/180, while that of the spectacle wearers was 20/100. This

difference is related directly to spherical refractive errors, which for the SCL wearers ranged from +4.75 diopters to −7.50 diopters, with the mean being −2.18 diopters. For the spectacle wearers, the range was from +7.75 diopters to −6.00 diopters and the mean was −0.51 diopter.

The cylindrical refractive error data for the SCL wearers reflected the imposed limits on correctable cylindrical error allowed for this group. The range was rather narrow, from plano to a high of −1.75 diopters. The spectacle wearers, on the other hand, exhibited a wide range extending to −5.00 diopters. For the SCL wearers the mean cylinder was −0.39 diopters, while the mean for the spectacle wearers was −1.45 diopters.

A summary of the corrected binocular acuities for selected exams is contained in Table 1. Acuities recorded for the SCL wearers' initial exam were obtained as part of the refraction; the acuities for the remaining exams were recorded through the habitually worn contact lenses. Both the initial and the final exam acuities for the spectacle wearers were obtained as part of a complete eye exam.

During their initial exam, 99% of the SCL wearers were correctable to 20/20 or better. Among the spectacle wearers at the initial exam, 95% were corrected to 20/20 or better. At the 7-day exam, the acuities of the SCL subjects were somewhat reduced. This reduction may have been related to the inability of the soft lenses to fully compensate for allowable astigmatism, initial adjustment to SCL wear, and/or a possible need to change lens parameters.

The improvement in SCL wearers' 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 corrected acuities of both groups shows the proportion achieving 20/20 or better was 95% for SCL subjects and 97% for spectacle wearers.

Ocular Physiology Summary data from selected biomicroscopy examinations (initial, 90-day, and final) appear in Table 2. The classification codes are those recommended by the Food and Drug Administration for clinical investigations.

Vascularization. Table 2 shows the percentages of eyes exhibiting vascularization. It is readily apparent that vessel ingrowth increased over the course of the study. The reason for the high rates of vascularization found is the stringent criterion to report any measurable amount of vascularization. Zucarro, Thayer, and Poland[22] in a 5-year study of SCL wearers reported vascularization in only 3% of all followup examinations, but recorded only occurrences of at least 1.5 mm vessel extension inside the limbus. Nilsson and Persson[23] reported no vascularization at all in a 2-year study of extended wear contact lens patients. They defined vascularization as growth greater than 1.25 mm. It appears then that extensions of 1–1.5 mm into the cornea have not been considered significant.

Injection. Table 2 summarizes the percentages of eyes exhibiting injection over the course of the study. The incidence of injection is much higher than found in the studies of Zucarro, Thayer, and Poland,[22] Nilsson and Persson,[23] and Rengstorff et al.[24] The SCL wearing soldiers in this study seemed predisposed to injection, as did their spectacle wearing counterparts. This may have been related to the environment in which they worked and their constant exposure to local irritants, such as dust, wind, smoke and fumes.

Staining. As can be seen in Table 2, the percentage of eyes exhibiting staining of any kind was very low.

Edema. As Table 2 shows, the percentage of eyes exhibiting moderate degrees of microedema or gross edema was very small.

Other Complications. This classification includes observations not discussed above. Table 2 shows the only unusual occurrence was the high incidence of follicular hypertrophy. This is attributed to the endemic occurrence of mild vernal conjunctivitis at the test installation during the study period. The "other" classification in this category includes such observations as papillae, pingueculae, blepharitis, and coated lenses.

Suspension of Lens Wear In accordance with accepted clinical practice and the terms of the approved research protocol, SCL wear was suspended tempo-

TABLE 1
Corrected Acuity (Binocular) at Selected Examinations

	SCL Wearers				Spectacle Wearers	
Visual Acuity	Initial (n = 215)	7-day (n = 176)	90-day (n = 109)	Final (n = 84)	Initial (n = 96)	Final (n = 70)
20/20 or better	99%	90%	95%	95%	95%	97%
20/25	1%	8%	5%	3%	4%	2%
20/30	0	1%	0	2%	1%	1%
20/40 or poorer	0	1%	0	0	0	0

TABLE 2
Percentage of Eyes Exhibiting Biomicroscopy Classifications (SCL Wearers)

Classification	Initial (n = 430)	90-day (n = 236)	Final (n = 240)*
	VASCULARIZATION		
Ingrowth, 1 quadrant	16%	28%	24%
Ingrowth, >1 quadrant	4%	20%	33%
Continuing growth, <2 mm	—	3%	3%
Continuing growth, >2 mm	—	<1%	—
	INJECTION		
Mild congestion	28%	51%	31%
Severe congestion	6%	12%	20%
Hyperemia	—	2%	4%
	STAINING		
Minimal stippling	1%	5%	3%
Superficial punctate	—	3%	<1%
Epithelial abrasions	—	<1%	—
	EDEMA		
Slight, localized	2%	4%	13%
Slight, generalized	—	<1%	2%
Moderate, localized	—	—	1%
Moderate, generalized	—	—	2%
Vertical striae	—	<1%	—
	OTHER COMPLICATIONS		
Increased sebaceous secretion	3%	—	<1%
Follicular hypertrophy	10%	5%	10%
Other (see text)	9%	<1%	5%

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

rarily when ocular complications developed. At least one period of suspended wear occurred for 69 SCL wearers (42% of the average census) during the course of the study. The various conditions resulting in suspended SCL wear are presented in Table 3. Some individuals were suspended more than once (none more than three times), resulting in 87 cases. The most common cause of suspension was inflammation of some segment of the anterior portion of the eye or ocular adnexa, accounting for 41 percent of the total number of suspensions. Abrasions, staining, and epithelial defects of the cornea collectively accounted for 29% of the total number of suspensions.

Attrition Ocular conditions that posed unacceptable jeopardy to the SCL wearers occurred occasionally, necessitating removal of subjects from the study. In addition, a number of SCL wearers were discontinued before the end of the study due to administrative circumstances or self-withdrawal. The cases of attrition are listed in Table 4 according to the nature of the cause. A total of 64 SCL subjects failed to complete the study for administrative or personal reasons.

TABLE 3
Medically-Related SCL Wear Suspensions

Cause	Number of Suspensions
Conjunctivitis	23
Corneal abrasion	18
Corneal staining	9
Overwear syndrome	6
Giant papillary conjunctivitis	6
Corneal edema	4
Iritis	3
Neovascularization	3
Keratitis	3
Corneal ulcer	1
Other*	11

*Includes dermatitis (eyelids), phlyctenule, ocular hypertension, eye trauma, use of medication, sensitivity to solutions, and decreased visual acuity

TABLE 4
Attrition among SCL Wearers

	Cause	Number of Attritions
A	Nonmedical	
	Missed appointments	18
	Discharge from service	21
	Reassignment	13
	Lack of interest	6
	Lenses not available	3
	Lost or damaged lenses	2
	Extended travel	1
		64
B.	Medically related	
	Discomfort	14
	Dissatisfaction with acuity	5
	Discomfort and dissatisfaction with acuity	2
	Giant papillary conjunctivitis	6
	Neovascularization (>2 mm)	6
	Decreased visual acuity (>7 days duration)	2
	Blepharitis	1
	Corneal staining	1
	Corneal stromal infiltrates	1
	Tight lens syndrome	1
	Insertion problems	1
		40

The number of SCL participants failing to complete the study for medically-related reasons was 40. This figure was compared to the census at the start of the study, excluding those subjects who eventually withdrew for nonmedical reasons, to yield a six-month attrition rate of 26%. Three conditions—discomfort, dissatisfaction with acuity, and giant papillary conjunctivitis—accounted for 68% of the cases of medically-related attrition.

Suspension and attrition both 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 SCL subjects developed at least one ocular complication. This translates into a proportion equal to 47% when the average census across the entire study is used for computation. In other words, on a six-month equivalent basis, 47% of those wearing SCL developed one or more ocular condition(s) requiring at least a short suspension of SCL wear.

The rate of occurrence of ocular complications declined as the study progressed. The trend for both suspension-precipitating complications and total complications can be seen in Table 5, where rates are based on average monthly census figures. A similar declining trend has been noted elsewhere in the literature[25] and may be related to progressive attrition of complication-prone subjects as cumulative SCL wearing time increases.

Among the spectacle wearers, 16 subjects were discontinued for administrative and personal reasons. No ocular complications or cases of medically-related attrition occurred among the spectacle wearers. It should be noted the spectacle wearing participants were not examined as often as the SCL wearers.

SCL Wear Success Rates Those SCL participants at the end of the study who had not been removed for medical reasons were defined as medically successful SCL wearers. However, those SCL participants, who were discontinued 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 SCL subjects who started the study, a total of 151 remained in the study to a definitive disposition. Of these, 111 (74%) successfully completed the study. In other words, when nonmedical attritions were factored out, three out of every four SCL wearers reached the end of the study without being discontinued for medically-related reasons. This six-month rate was somewhat artificially constrained by the limited types and parameters of SCL used. On the other hand, the rate may have been elevated by the well-motivated participants.

TABLE 5
Monthly Rates of Ocular Complications among SCL Wearers

Day	Average Census	SCL Wear Suspensions		Total Ocular Complications	
		Number	Rate	Number	Rate
1–30	208	27	13.0%	37	17.8%
31–60	194	15	7.7%	23	11.9%
61–90	180.5	17	9.4%	21	11.6%
91–120	162.5	11	6.8%	17	10.5%
121–150	141.5	8	5.7%	11	7.8%
151–180	125.5	7	5.6%	13*	10.4%*
>180	—	2	—	5	—

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

CONCLUSIONS

Because of methodological limitations, the results of this study should be generalized with caution. The major findings obtained in the armor environment support the following conclusions.

1. When SCL wearers discontinued for administrative reasons were factored out, 74% of those fitted successfully completed the study.
2. More than one-third of the SCL wearers experienced one or more ocular conditions requiring at least a temporary suspension of SCL wear.
3. Both corneal edema and corneal staining occurred rarely at clinically significant levels.
4. Corneal vascularization occurred frequently. This was influenced by stringent classification criteria.
5. Conjunctival injection was common, apparently due largely to environmental factors.

Acknowledgments

Special thanks go to the 2d Armored Division, Fort Hood, Texas for providing volunteer participants and administrative support. The U.S. Army Training and Doctrine Command's Combined Arms Test Activity, Fort Hood, Texas, provided extensive support in planning and conducting the entire study, with Mr. Terry Glover serving as project officer. Dr. Stephen Bisik and Dr. Theodore Felton provided invaluable clinical optometric support. We thank Ms. Carolyn Johnson and Ms. Jimmie Henderson for report typing, and Staff Sergeant Nonikon Fallana and Sergeant Rosalinda Ibanez for technical support.

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Clinical Implications

This observational study focused on the success rate and ocular physiological response associated with the extended wearing of soft contact lenses (SCL) by armor troops over the course of six months. Reported results indicate that a significant number of people (74%) completing the study were able to tolerate the extended wear of the study's SCL and that a substantial number of SCL wearers (better than 40%) did develop periodic problems that required at least temporary suspension of SCL wear.

The medically related reasons for suspension of SCL wear were generally of a serious nature, reminding us that the application of the extended wearing of the SCL does offer significant ocular risks along with potential benefits. The impact of lens care system and patient compliance on the study results were not reported. Care system and compliance issues prompt the thought that disposable SCL for extended wear (a modality not available at the time that this study was conducted) may improve the success rate for a patient population such as those in armor troops.

I must agree with the authors that the results of the study should be generalized with caution due to limitations in various areas of the study methodology.

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Bruce C. Leibrecht holds a PhD in Experimental Psychology from Michigan State University. He has served as a Research Psychologist with the U.S. Army Medical Research and Development Command since 1969. He is currently Director of the Sensory Research Division of the U.S. Army Aeromedical Research Laboratory, a position he has held since 1981. Having been active in several areas of biomedical research, he is the author of a number of published scientific articles.

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