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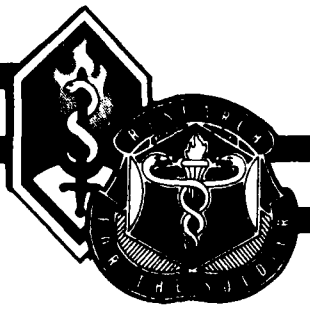

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Contact Lenses in the U.S. Army Attack Helicopter Environment: An Interim Report

By

Morris R. Lattimore

Sensory Research Division

December 1990

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

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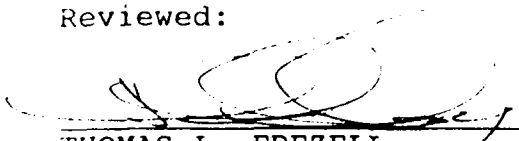

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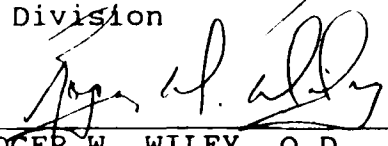

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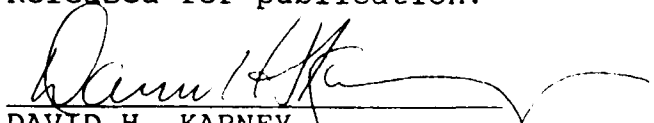

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Recent technological advances have had a major impact on military aviation. While modern methods of providing visual information via electro-optics/visionics systems have extended the aviator's operational envelope, these devices are becoming increasingly incompatible with spectacle wear. Since approximately 20 percent of Army aviators are ametropic (spectacle wearing), alternative means of providing a refractive error correction need to be investigated. One alternative being considered is the use of a contact lens correction.

For the past year, the U.S. Army Aeromedical Research Laboratory (USAARL) has been conducting a worldwide, AH-64 "Apache" contact lens research project in order to develop a comprehensive database on contact lens wear in a variety of environments. A three-tier contact lens fitting system is being used: two different types of soft lenses and one rigid gas permeable (RGP) lens type. The wearing schedule is set at a maximum of 7 days/6 nights

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of extended lens wear. Fundamental operational data is being chronicled by unit flight surgeons. Standard clinical data is being used in ongoing command deliberations on future medical policy decisions concerning contact lens wear by Army aviators. Basic research information is being gathered in an effort to determine the fundamental physiological response of the cornea to the presence of a contact lens.

The subjective assessment of contact lens applications within the aviation community is universal acceptance. While current clinical data indicate some ocular health risk, flight safety risks are minimal. Establishment of long-term contact lens efficacy likely will depend on the ensuing analysis of physiological data.

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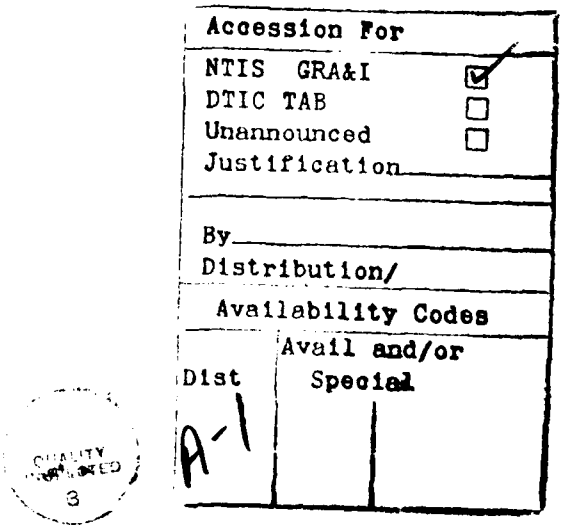

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Introduction[1]

Recent technological advances have had a major impact on Army aviation. While modern methods of providing visual information via electro-optics/visionics systems have extended the aviator's operational envelope, these devices are becoming increasingly incompatible with spectacle wear. Specifically, standard refractive error correction options for the M-43 protective mask have proven to be incompatible with the Helmet Display Unit (HDU) component of the AH-64 "Apache" Integrated Helmet and Display Sighting System (IHADSS). Glue-on and outsert packages push the HDU, a Maxwellian-view virtual imaging system, far enough from the ametropic aviator's eye to significantly reduce the available field-of-view; consequently, peripheral instrumentation and weapon system overlays cannot be visualized adequately. One alternative to spectacle wear being considered is the utilization of a contact lens correction.

Current Army regulations prohibit the wearing of contact lenses by aviators while flying. Waivers to these regulations have been approved for volunteer subjects under the aegis of a controlled scientific investigation. Consequently, the U.S. Army Aeromedical Research Laboratory (USAARL) has initiated an Army-wide AH-64 contact lens research protocol in order to provide both an interim readiness fix and to develop a comprehensive database on contact lens wear in a variety of environments. Basically, the protocol has been organized from three different perspectives with concerns directed toward operational and flight safety issues, ocular health issues and their secondary effects on existing health-care delivery systems, and potential for long-term changes in corneal physiological integrity.

A standardized fitting and data collection protocol was established; specific baseline evaluations, in addition to standard clinical appraisals, included: endothelial morphological assessments, anterior lens surface pH recording, trans-lens oxygen uptake rate monitoring, and tear film osmolarity determinations. This basic research information is being gathered in an effort to determine the fundamental physiological response of the cornea to the presence of a contact lens. The clinical data will be of value as a reference for command deliberations on future medical policy decisions concerning contact lens wear by Army aviators. Fundamental operational data is being chronicled by specially trained unit flight surgeons in order to document the impact of routine

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[1] Presented at the AGARD Aerospace Medical Panel Symposium on Ocular Hazards in Flight and Remedial Measures, 22-26 October, 1990. London, UK.

contact lens wear on relevant aviation medicine issues. During that time, it is anticipated sufficient data will be obtained to provide the basis for an informed decision concerning overall Army policies regarding extended wear contact lenses.

Methods and materials

Two civilian contract optometrists and one technician are responsible for the provision of contact lens fitting and follow up examinations. Volunteer subjects from AH-64 units, and units fielded with the M-43 protective mask were provided with informed consent and an individual formal waiver to participate in the study. The 2-year study period will cover 200+ subjects at 9 different continental United States (CONUS) locations, plus 5 Federal Republic of Germany (FRG) locations.

The study is scheduled to conclude at the end of September 1991. A three-tier contact lens fitting system was utilized, with the initial lens of choice being a moderate to high water content disposable extended wear soft lens. Backup lenses consisted of a low water content standard extended wear soft lens utilized on a disposable basis, and a rigid gas permeable (RGP) lens used with a chemical disinfection system. All three types of lenses were approved by the United States Food and Drug Administration (USFDA) for routine use.

The wearing schedule was set at a maximum of 7 days/6 nights of extended lens wear, in accordance with USFDA recommendations. The subjects were instructed that the 7th night was to be passed without lens wear; worn soft lenses were to be discarded, and RGP lenses cleaned, disinfected, and stored overnight. After at least one full night of lens-free sleep, the subjects were instructed that they could apply a new soft lens, or resume wear of the cleaned and disinfected RGP lenses. This pattern of wear and rest was to be continued until the next scheduled quarterly follow-up evaluation.

Each quarterly follow-up examination adhered to the same testing protocol established for initial examinations. An additional component to each quarterly follow-up was the inclusion of a subjective questionnaire to query apparent effectiveness of contact lens wear in job performance. Generalized background information concerning flight hours and conditions is also being documented for future safety issue reference.

Results and discussion

To date, 223 volunteer subjects have been examined for possible contact lens wear: 31 subjects were not able to be fit with lenses, and 19 subjects had to be discontinued or withdrawn from the study after an initially successful contact lens fit. Therefore, although 86 percent of the volunteer subjects were successfully fitted with contact lenses, only 77 percent have been successful in wearing the lenses. Average length of time in the program is 10 months, with a range of 1 to 20 months.

The two areas of greatest difficulty involved those individuals dependent upon a near or reading correction (presbyopic) in the cockpit, and those exhibiting high amounts of ocular curvature distortion (astigmatism). Presbyopic subjects were not routinely fitted with lenses, since a reading overcorrection would defeat the purpose of contact lens wear in lieu of spectacles. Highly astigmatic subjects were not able to obtain adequate visual acuity with soft lenses; RGP lenses were demanding to fit and difficult to adapt to. As a result few subjects are successfully wearing RGP lenses.

Average wearing time was 4.4 days by follow up examination. Subjective questionnaire response had a mean wearing time of between 6 and 7 days. The refractive error distribution peaked at -0.75 diopters with a skewed distribution toward higher amounts of myopia. The military rank distribution of participants approximately split between commissioned and warrant officers; the enlisted ranks included a few crew chiefs and aerial observers. Lens type distributions matched the refractive error distribution, except for RGP lenses, which were equally distributed across refractive error. The distribution of subjects by age was bimodal, with peaks near ages 27 and 37. Because of the bimodal age pattern, there was some concern that our sample was not representative of Army aviation in general, so the Aviation Epidemiology Data Register was queried regarding the entire aviation population. All of the 1989 flight physical data were reviewed (as was 6 months worth of 1990 data); a similar bimodal distribution was obtained, thereby reassuring the investigators that the sample was not biased in some fashion.

Thus far, safety issues have not arisen, although two contact lens wearers happened to be involved a midair mishap. Both occupied the front seat of involved AH-64s, neither individual was at the controls at the time of the mishap, and U.S. Army Safety Center assessments did not include contact lens wear as a factor in the mishap. Additional areas of interest included clinical and basic physiological data: anterior contact lens surface pH, lens hydration, tear film stability, corneal thickness, objective biomicroscopic examination, and endothelial

morphology. These subjects will be addressed both individually and in a correlated format through the open literature prior to final government technical report.

Subjective questionnaire data were highly supportive of contact lens wear while performing flight duties. Approximately 90 percent of subjects felt their flight performance with contact lenses was equal to or better than with spectacles after 1 month of contact lens wear; after 3 months, all subjects felt their flight performance with contact lenses was equal to or better than with spectacles. Confidence in flight abilities with contact lenses paralleled the above findings, as did combat effectiveness estimates and endorsement of a routine program. Of some concern is the fact that 35 percent of the subjects admit on anonymous questionnaire to wearing their lenses longer than the 7 day maximum; 10 percent admit to going longer than 10 days continuous wear. This information could be valuable to attempts at modeling risk of adverse effects.

The true disposable contact lenses and wetting solutions have cost an average of $415/aviator/year; the annual cost of RGP lenses was essentially identical. However, the annual cost of the standard soft lens that was used as a disposable was $835/aviator. These costs are minimal compared to the expenses incurred via normal high performance aircraft training and operational activities. However, there are hidden costs to a proposed routine contact lens program that must be further documented: Optometric manpower requirements for required fittings and follow-up exams are still being evaluated, establishment of a logistical train for resupply is still under consideration, and finally the potential for adverse medical effects that are linked to routine contact lens wear can cost units in terms of operational availability of some aviators.

Ocular health incidents or adverse effects have been varied. Of the six medical events recorded, three cases are thought to be contact lens-related and three independent of contact lens wear. All cases involved subjects wearing soft lenses. One case of acute, localized ulcerative keratitis has been confirmed. The ulcer (and its secondary scar) was located superiorly off the visual axis, so visual acuity was unaffected. The individual was on Duty Not to Include Flight (DNIF) status for 10 days. Once the acute infection resolved, normal full flight duties (FFD) were resumed. The subject resumed contact lens wear 6 weeks after resuming flight duties. Two cases of generalized keratoconjunctivitis have been observed. Both were linked to a superficial corneal abrasion judged to be associated with improper soft lens removal techniques. Neither involved DNIF; recovery occurred within 3 days for both. The last three cases

were thought to be unrelated to contact lens wear and included: one case of viral keratoconjunctivitis (FFD), one case of anterior uveitis (DNIF 6 days), and one acute allergic response (DNIF 2 days).

Summary

Subjective approval of routine contact lens wear has been high, as have subjective performance assessments. Ocular risk for severe infection is difficult to establish from current data. However, cost in terms of lost flight duty time is being monitored. Medical costs, in terms of logistic and professional personnel requirements still have to be established. If current trends continue, it is possible a decision on the routine wear of contact lenses could be positive. However, because of unique difficulties encountered by presbyopes and high astigmats a significant portion of spectacle-wearing aviators will not be able to wear contact lenses. Consequently, routine contact lens wear represents only a partial solution to spectacle incompatibility problems. Therefore, developmental hardware alternatives must be included in future system programming or a large number of aviators will be prevented from performing certain flight duties.

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