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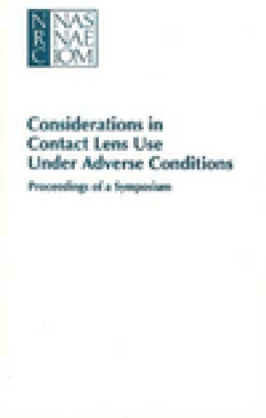

# Considerations in Contact Lens Use Under Adverse Conditions: Proceedings of a Symposium

Pamela Ebert Flattau, Editor; Working Group on Contact Lens Use Under Adverse Conditions, Committee on Vision, National Research Council

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# Considerations in Contact Lens Use under Adverse Conditions

## Proceedings of a Symposium

Pamela Ebert Flattau, Editor

Working Group on Contact Lens Use Under Adverse Conditions
Kenneth Poise, Chair

Committee on Vision
Commission on Behavioral and Social Sciences and Education
National Research Council

National Academy Press
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This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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# FOREWORD

The Committee on Vision is a standing committee of the National Research Council's Commission on Behavioral and Social Sciences and Education. The committee provides analysis and advice on scientific issues and applied problems involving vision. It also attempts to stimulate the further development of visual science and to provide a forum in which basic and applied scientists, engineers, and clinicians can interact. Working groups of the committee study questions that may involve engineering and equipment, physiological and physical optics, neurophysiology, psychophysics, perception, environmental effects on vision, and treatment of visual disorders.

In order for the committee to perform its role effectively, it draws on experts from a wide range of scientific, engineering, and clinical disciplines. The members of this working group were chosen for their expertise in research related to ocular response to contemporary contact lenses and for their familiarity with the application of those research findings to the use of contact lenses in extreme environments.

This report summarizes present understanding of the scientific, clinical, and technological issues surrounding the use of contact lenses. Symposium participants discussed the special occupational conditions experienced by military personnel in the aerospace environment that give rise to the question of whether contact lenses should or should not be used. The proceedings of the symposium will serve as the basis for further deliberations by the working group.

The results of this symposium will be of particular interest to those involved in the design of contact lenses and those responsible for occupational safety and health matters in the private sector.

SUZANNE MCKEE, CHAIR
COMMITTEE ON VISION

# PREFACE

In response to a request from the Triservice Aeromedical Research Panel (TARP), the Committee on Vision established the Working Group on Contact Lens Use Under Adverse Conditions. The working group was asked to: (1) summarize current scientific, clinical, and technological issues in the use of contact lenses, (2) review the operational requirements of military personnel relative to the use of contact lenses, and (3) identify the critical factors to be taken into account by TARP in adopting a formal position on the use of contact lenses by U.S. military personnel.

To accomplish these goals, the working group convened a symposium to review what is known about the design and use of contemporary contact lenses. Special emphasis was given to the use of lenses in extreme environmental conditions. Twenty-five specialists from the fields of optometry, ophthalmology, visual psychophysics, and engineering met for two days in November 1988 at Brooks Air Force Base, San Antonio, Texas, in conjunction with the fall meeting of the Triservice Aeromedical Research Panel. Participants essentially provided a tutorial on recent developments in the design and use of contact lenses.

The two-day symposium was organized around scientific and clinical considerations in the use of contact lenses. Following a series of briefings by military personnel, members of the first session were asked to address environmental effects on contact lens wear, including the effects of low oxygen and low humidity. The second panel considered environmental conditions and tear chemistry, corneal topography, and biochemical aspects of contact lens wear. The third panel explored preventive measures relative to lens design, including blink rate and mechanical aspects of contact lens performance. The fourth panel addressed issues related to ocular risks, such as infection, inflammation, and endothelial effects. The fifth panel reviewed limitations of contemporary materials with respect to selection criteria and task performance, including follow-up care. The program offered ample opportunity for formal and informal group discussion. The edited proceedings of the discussion together with the formal papers of the participants are the contents of this report.

In addition to the specialists who participated in the symposium, a number of people contributed in important ways to this project. Robert Miller of the Brooks Air Force Base staff facilitated arrangements for the symposium. Roger Wiley and his staff at the U.S. Army Aeromedical Research Laboratory assisted the working group in arranging for presentations by U.S. military personnel both at the symposium and at meetings of the working group. Pamela Ebert Flattau, the committee's study director, provided valuable assistance in organizing the symposium and preparing the proceedings report. As always, Carol Metcalf, the committee's administrative secretary, provided efficient and skillful support.

KENNETH POLSE, CHAIR
WORKING GROUP ON CONTACT LENS USE UNDER ADVERSE CONDITIONS

# CONTENTS

# CONTACT LENSES AND THE EYE: BASIC CONSIDERATIONS

# Environmental Gases and Contact Lens Wear

Gerald E. Lowther

## OXYGEN

Oxygen has been the most studied gas with respect to contact lens wear because the avascular cornea must obtain oxygen from the atmosphere. Without oxygen from the air, corneal swelling will occur, with resultant corneal clouding, decreased visual acuity, discomfort, and other long-term adverse effects. The cornea requires about 5 µl $O_2/mm^2$ cornea/hour (Hill and Fatt, 1963; Larke et al., 1981). This value varies with individuals from about 3 to 10 µl $O_2/mm^2$ cornea/hour (Larke et al., 1981).

Under open-eye conditions at sea level the anterior surface of the cornea has available about 20.9 percent oxygen ($O_2$ in air) or about 155 mmHg partial pressure. With the eye closed the oxygen level drops to about 7 percent. With contact lens wear the lens will impede oxygen from reaching the cornea. Therefore, considerable effort has gone into developing lenses that will supply oxygen to the cornea. Oxygen can be supplied under a lens by designing the lens such that tear exchange occurs with each blink, bringing in oxygen dissolved in the tears. This usually does not supply enough oxygen. An exchange of about 10–15 percent of the tear volume under a rigid lens can occur with each blink (Figure 1) (Fatt and Hill, 1970; Fatt, 1969; Cuklanz and Hill, 1969), but with a soft (hydrogel) lens less than 2 percent exchange occurs (Polse, 1979; Wagner et al., 1980). Therefore, to supply adequate oxygen to the cornea, lens materials must allow oxygen diffusion.

The oxygen supplied through a contact lens can be measured and specified in different ways. One method is a physical one in which the lens material is placed in a chamber with one side exposed to air and a sensor is placed on the opposite side to measure the oxygen flow. With this method the *Dk* value, termed *permeability*, is determined. The higher the *Dk* value the more oxygen will diffuse through a unit thickness of material. To determine the amount of oxygen that will diffuse through a given contact lens, the *Dk* value is divided by the lens thickness (*L*) to give a *Dk/L* value, which is called *transmissibility*. Clinically the transmissibility is the important value. The higher the value, the more oxygen will reach the cornea. Permeability is given as a number × $10^{-11}$ (cm$^{2}$2/sec)(ml $O_2$/ml mmHg). Transmissibility is given as a number × $10^{-9}$ (cm/sec)(ml $O_2$/ml mmHg). In both cases only the initial number is quoted with the units and power of 10 assumed.

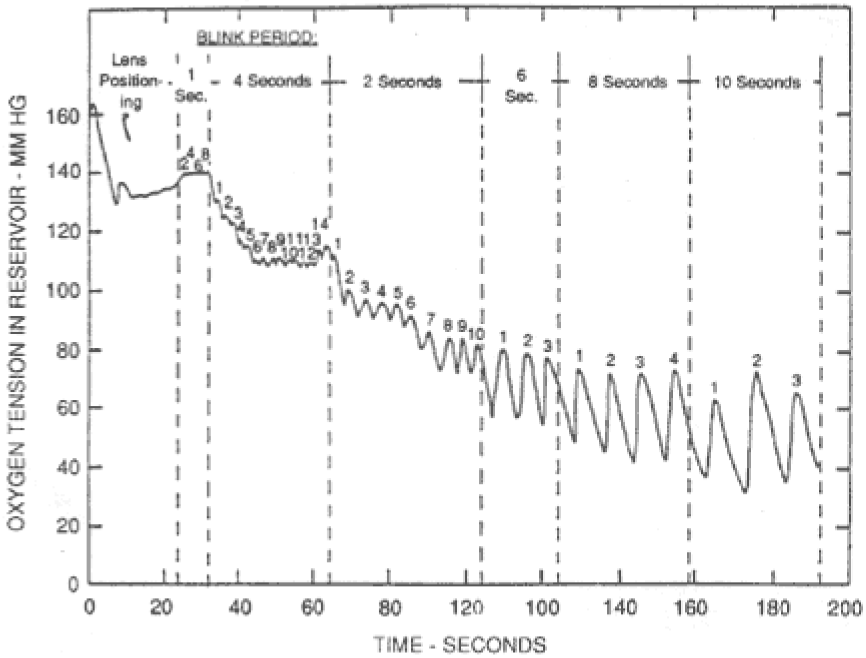

Figure 1
Oxygen tension under a rigid PMMA lens with different blink rates.
SOURCE: Fatt and Hill (1970). Reprinted by permission.

Another method of specifying the amount of oxygen going through a lens is by the equivalent oxygen percentage or equivalent oxygen performance (EOP). This is a biological test in which a sensor is placed against the corneal surface and the rate of oxygen utilized from a membrane over the sensor is determined. The rate can be determined with the eye under different oxygen atmospheres. A contact lens can be placed on the eye for a period of time and then removed, and the oxygen uptake rate can be measured again. Using this method one can say that the cornea had an oxygen thirst equivalent of a given percentage of oxygen. The EOP values will be between

0 percent and 20.9 percent. The higher the value the more oxygen transmitted through lens to the cornea. Plots are usually given as percent oxygen against lens thickness (Figure 2) (Hill and Mauger, 1980).

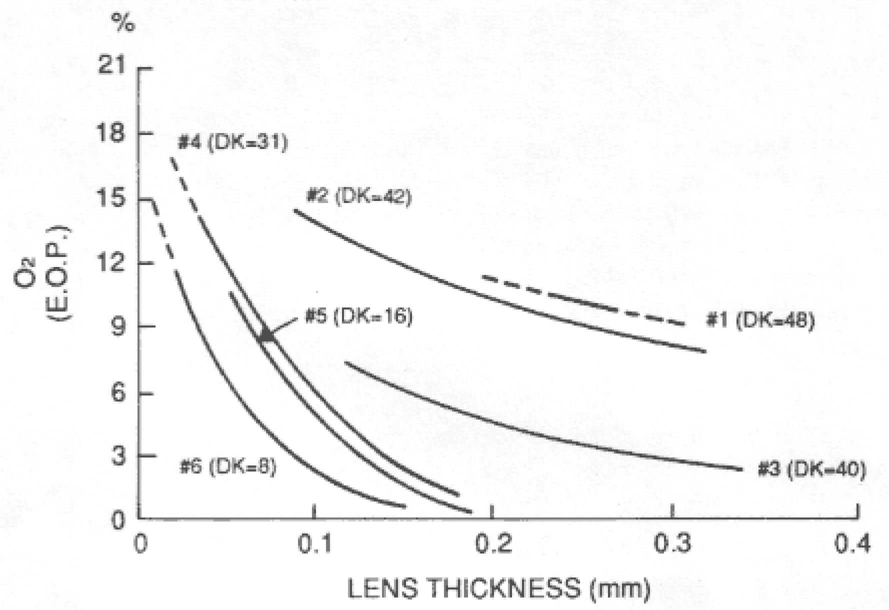

Figure 2
The relative equivalent oxygen percentage (EOP) of six hydrophilic contact lens materials over various ranges of lens thickness. A sample Dk value (see text) appears in parentheses for each in units multipled by $10^{-11}$ (cm$^2$/sec) ml $O_2$/ml × mmHg). SOURCE: Adapted from Hill and Mauger (1980).

An important question is the minimum oxygen that the cornea requires. Another important factor is how much of the required oxygen does the available contact lens materials provide. In terms of oxygen percentage to prevent corneal changes, values from 1.5 percent up to 18 percent have been quoted (see Table 1). Holden et al. (1984) found an average of 10.1 percent to prevent any edema (Figure 3). Holden and Mertz (1984) found that with daily wear 9.9 percent oxygen was required, whereas with extended wear, to limit the edema to no more than the physiological 4 percent swelling, an oxygen percentage of 17.1 was required. When extended-wear lenses are worn, with resultant overnight swelling, one would like the swelling to decrease during the day to baseline levels. To accomplish this Holden and Mertz (1984) found that an EOP of 12.1 percent was required. The transmissibility values required are as follows (values calculated based on water content and thickness:

EOP 9.9% Dk/L 24.1
EOP 12.1% Dk/L 34.3
EOP 17.1% Dk/L 87.0

With present hydrogel lenses the *Dk* value is related to the water content (Figure 4) (Sarver et al., 1981). The highest *Dk* value possible is about 50. Transmissibility is therefore related to only the water content and lens thickness. Thus, with the present hydrogel materials the amount of oxygen that can be supplied is limited. Table 2 gives the *Dk/L* values for different water contents and lens thicknesses.

TABLE 1 Estimates of the Critical Oxygen Requirements (COR) of the Cornea

| Author | Year | Criterion | COR (%) |
|---|---|---|---|
| Epithelium: Biochemical | | | |
| Uniack et al. | 1972 | Glycogen depletion | 5 |
| Uniack et al. | 1972 | LDH concentration | 5 |
| Hill et al. | 1974 | SDH reactivity | 5 |
| Hamano et al. | 1983 | Lactate | <13.2 |
| Epithelium: Structure/Function | | | |
| Fatt | 1968 | Oxygen consumption | 2.7 |
| Uniacke et al. | 1972 | Epithelial thickness | 5 |
| Millodot and O'Leary | 1980 | Sensitivity | >7.7 |
| Hamano et al. | 1983 | Mitosis | <13.2 |
| Masters | 1984 | Mitochondria | >10 |
| Benjamin and Hill | 1985 | Oxygen consumption | 15.6 |
| Stroma | | | |
| Polse and Mandell | 1970 | Corneal edema | 1.5–2.5 |
| Carney | 1974 | Corneal edema | 2 |
| Mandell and Farrell | 1980 | Corneal edema | 3.1 |
| Mizutani et al. | 1983 | Corneal edema | 15 |
| Holden et al. | 1984 | Corneal edema | 10.1 |
| Mandell | 1985 | Corneal edema | 7.4 |
| Brennan et al. | 1987 | Corneal edema (gas) | 10.9 |
| Brennan et al. | 1987 | Corneal edema (EOP) | 18.0 |
| Endothelium | | | |
| Williams | 1986 | Bleb response | 16.6 |

Source: Effron and Brennan (1987).

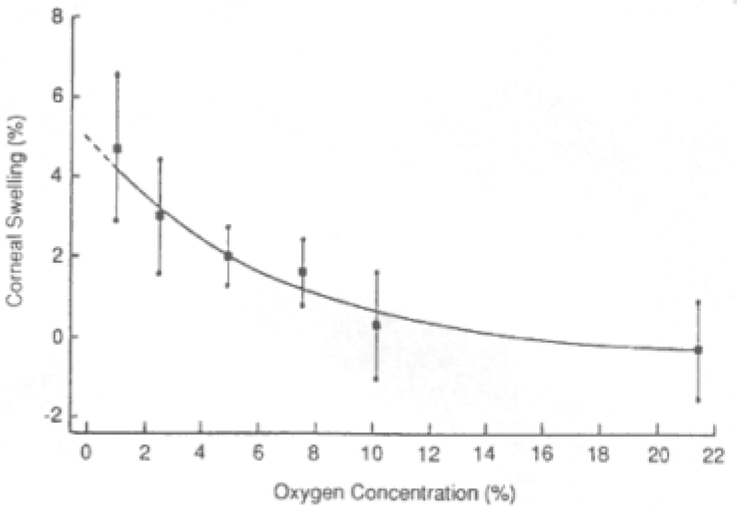

Figure 3
Mean corneal swelling for the group after 8 hr exposure to the various oxygen concentrations. The curve is an exponential fit. The error bars represent ±1 standard deviation. SOURCE: Holden et al. (1984). Reprinted by permission.

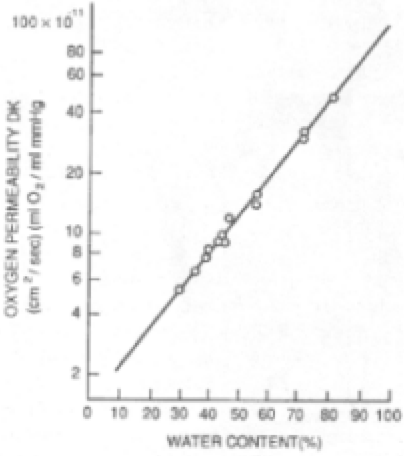

Figure 4
Oxygen permeability (Dk) of hydrogel lenses of various specific water contents (expressed in percentages). Dk is given in cm$^3$ × ml O$_2$/sec × ml × mmHg. Oxygen transmissibility was measured at a room temperature of 21°C. SOURCE: Sarver et al. (1981). Reprinted by permission.

TABLE 2 Dk/L Values for Different Water Contents and Lens Thicknesses

| Water content | Thickness (mm) | Dk/L |
|---|---|---|
| 38% | 0.035 | 21.1 |
| 38% | 0.06 | 12.3 |
| 38% | 0.12 | 6.2 |
| 55% | 0.035 | 44.7 |
| 55% | 0.06 | 26.1 |
| 55% | 0.12 | 13.0 |
| 75% | 0.06 | 63.1 |
| 75% | 0.12 | 31.5 |
| 75% | 0.20 | 18.9 |

If water is lost from the lens due to dehydration, the oxygen transmissibility will decrease accordingly.

If new hydrogel materials are developed that do not depend solely on water content for oxygen diffusion, the hydrogel lenses will allow for extended wear without the present physiological problems.

With rigid gas-permeable (RGP) lenses the oxygen permeability depends on the lens material chemistry. Usually silicone and/or fluorine is added to polymethylmethacrylate to obtain gas transmission. It is possible with these materials to obtain higher oxygen transmission than with hydrogels. Because of the difficulty of measuring the *Dk* values of rigid materials, different values have been reported for the same material. The original values were higher than the lenses performed clinically; thus, the new lower values are more nearly correct. Table 3 shows *Dk* values for some common rigid materials.

Soft silicone lenses have the highest oxygen permeabilities of all materials. They have been shown to actually cause less corneal swelling when worn during sleep than if no lens is on the eye (Sweeney and Holden, 1987). With new lens designs of this material, there is promise for extended wear and use under low oxygen levels.

An environmental factor that affects the amount of oxygen reaching the cornea is the amount of oxygen in the atmosphere. At altitudes higher than sea level the amount of oxygen obviously decreases. At 5,000 feet, instead of 21 percent oxygen, there is about 18 percent; at 11,000 feet there is 14 percent and at 29,000 feet there is 7 percent (Hill, 1976; Weissman, 1980). Since even at 29,000 feet the oxygen level is about equal to that with the closed eye, one would expect an extended-wear lens to not produce excessive edema problems over the short term. The edema levels with the open eye at the high altitudes would be about the same as during sleep with the extended-wear lenses. A study by Flynn et al. (1988) did not find any significant edema-related problems with simulated altitudes of 10,000 and 25,000 feet with hydrogel lens wear.

TABLE 3 Dk Values for Some Common Rigid Materials

| Material | Dk | Nominal Dk | Overnight edema (company rep.) |
|---|---|---|---|
| Boston IV | 17 | 26 | 12.9 |
| Paraperm 02+ | 18 | 39 | |
| Alberta N | 21 | 40 | 10.4 |
| Paraperm EW | 27 | 56 | 11.0 |
| Optacryl EXT | 28 | 59 | |
| Optacryl Z | 29 | 82 | 6.7 |
| Equalens | 36 | 72 | 10.2 |
| FlouroPerm | | 92 | 7.6 |
| Flouropolymer | 71 | 170 | 6.0 |
| Silsight | 85 | 400 | 2.0 |

Sources: Brennan et al. (1986) and LaHood et al. (1988)

## CARBON DIOXIDE

Carbon dioxide is a by-product of cornea metabolism and must be vented from under a contact lens. Only limited investigation of carbon dioxide has been carried out. It has been stated that $CO_2$ transmissibility is 5 to 22 times greater than that for oxygen (Fatt et al., 1969; Refojo, 1979). On this assumption it has been calculated that the $CO_2$ level under a hydrogel lens would be very low (about 3 mmHg) (Fatt, 1978). Recently, Holden et al. (1987) have shown that there is an increase in $CO_2$ with eye closure of less than 10 minutes (Figure 5) and with the wearing of hydrogel lenses (Figure 6). The partial pressure of $CO_2$ reaches approximately 50 mmHg.

## CORNEAL STROMAL PH

Bonanno and Polse (1987a, 1987b) found that the pH of the corneal stroma with the open eye was 7.54. With eye closure for 20 minutes, the pH dropped to 7.39 and returned to 7.54 within 10 to 15 minutes of eye opening. With a gas mixture in a goggle consisting of 6.7 percent $CO_2$, 7.1 percent $O_2$, and $N_2$, the pH dropped to 7.29. With a mixture of 5 percent $CO_2$ and air (same as $CO_2$ in the conjunctival vessels), the pH dropped to 7.38. This is the same as with the closed eye. With a thick hydrogel contact lens that provides very little $O_2$, the pH dropped to 7.15, whereas with pure $N_2$ in goggles, which also provides no $O_2$, the pH dropped to only 7.34. With a mixture of 95 percent $N_2$ and 5 percent $CO_2$, the pH dropped to 7.16. Therefore, anoxia caused only part of the drop in pH, and $CO_2$ buildup is required to decrease the pH, to that equivalent to wearing a tight lens.

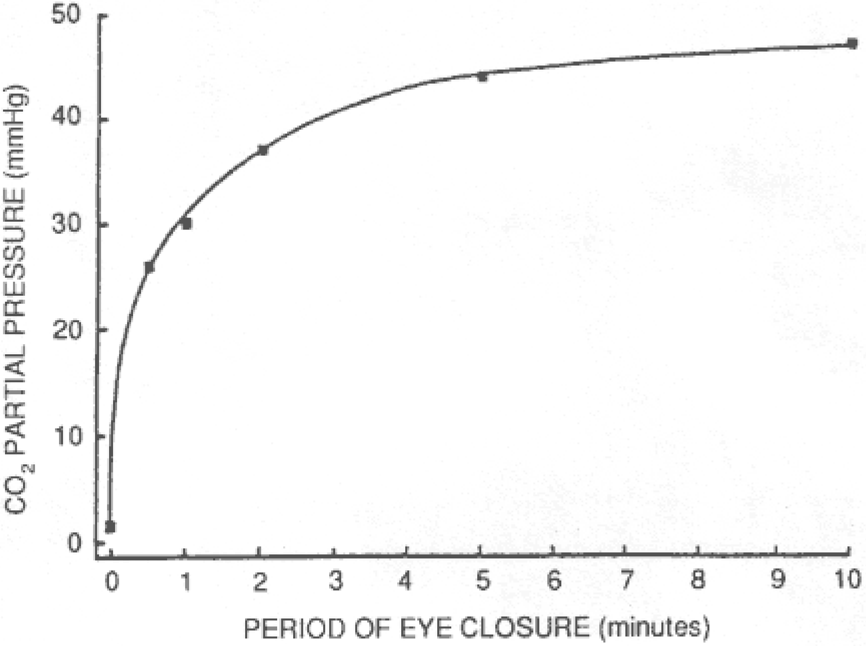

Figure 5
Carbon dioxide partial pressure at the anterior corneal surface immediately following short periods of eye closure.
SOURCE: Holden et al. (1987). Reprinted by permission.

## BUBBLE FORMATION UNDER LENSES WITH PRESSURE CHANGES

Simon and Bradley (1980) have reported that decompression divers developed bubbles of gas under rigid polymethylmethacrylate (PMMA) lenses. This occurred during decompression from 45.5 meters. The bubbles caused some corneal staining. The bubbles have high surface tension due to the short radius and will indent the cornea. Under hypobaric conditions, for example, at an altitude of 11,277 meters a few small bubbles developed but did not coalesce as with the hyperbaric (diving) conditions or cause corneal staining.

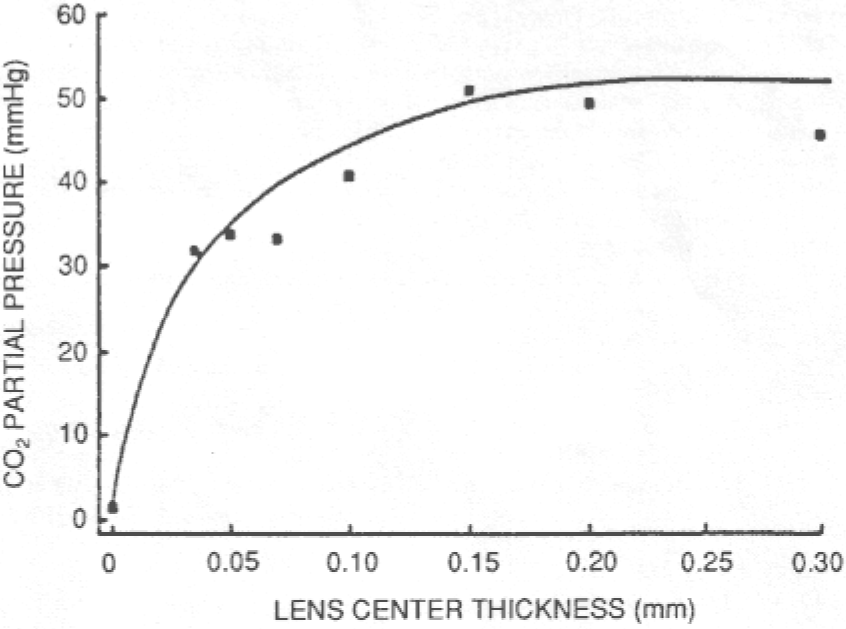

Figure 6
Carbon dioxide partial pressure at the anterior corneal surface immediately following 10 minutes wear of hydrogel lenses of various center thicknesses. SOURCE: Holden et al. (1987). Reprinted by permission.

## NOXIOUS GASES

Very little investigation has been done on the effect of absorption and concentration of other gases into contact lens materials. Nilsson and Andersson (1982) tested the concentration of trichlorethylene and xylene in low-water-content (38 percent) and high-water-content (75 percent) lenses exposed to fumes from the air. The lenses were not on eyes. They found a concentration of trichlorethylene (after a 10-minute exposure at 700 ppm) in the low-and high-water lenses of 88 times and 170 times that in air, respectively, after 10 minutes. Under the same conditions saline absorbed about 3 times the air concentration. With xylene and longer (90-minute) exposures, the concentrations were 93 and 224 times those in the air for the two lens materials. With a 60-minute soak in saline, only 10 percent was left in the lenses.

Despite the concern, there have been no reports of clinically significant problems with fumes and the wearing of contact lenses.

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# Hypoxia

George W. Mertz

## INTRODUCTION

*Hypoxia* means oxygen deficiency. Etymologically, the word is derived from *hypo,* which means "under" or "less than" in Greek, and the combining form *oxia,* which means "oxygen containing".

In the health care professions and related fields, hypoxia is a state of metabolic distress occurring in living tissue when its oxygen supply is reduced to such an extent that the normal aerobic respiration of its cells can no longer be sustained. If the tissue's oxygen supply is totally cut off, the condition is known as *anoxia*.

The amount of oxygen available for consumption by the cells of a given tissue is determined by the driving force or partial pressure of oxygen entering the tissue. The partial pressure of oxygen, known more commonly in biology as oxygen tension, is the proportion of the total pressure exerted by a gas mixture attributable to its oxygen component; it is a direct function of the number of oxygen molecules present. (Note: a similar definition applies to the oxygen portion of gas mixtures dissolved in liquids.) The oxygen tension of the atmosphere, for instance, is equal to the proportion of oxygen in the atmosphere (approximately 20.9 percent) multiplied by the total atmospheric pressure, which varies with altitude. At sea level, where the total atmospheric pressure is 760 mmHg, the atmospheric oxygen tension = 760 mmHg × 0.209 = 159 mmHg. A slight correction for the presence of a small amount of water vapor and carbon dioxide in the atmosphere reduces this to 155 mmHg, which is the value commonly encountered in the literature (Fatt, 1989). With increasing altitude, total atmospheric pressure drops (due to decreasing air density) and so, therefore, does atmospheric oxygen tension, but the proportion of oxygen in the atmosphere always remains constant (20.9 percent) regardless of altitude.

In order to supply enough oxygen for cells to carry out their intended biochemical functions, a tissue's ambient oxygen tension must exceed a certain critical threshold level. If the tissue oxygen tension falls below this critical level, a state of hypoxia is induced. At just what magnitude of oxygen tension the critical threshold of a tissue occurs depends on the tissue in question.

Regardless of etiology, any drop in a tissue's ambient oxygen tension below its critical threshold immediately initiates the shutting down of any oxygen dependent biochemical processes (aerobic metabolism) resident within its cells. The clinical ramifications of this depend on how crucial a role aerobic metabolism plays in the sustentation of the tissue's cellular vital functions, and on the degree to which the tissue has been deprived of oxygen, anoxia being the worst case.

In the human being, hypoxia can take various forms depending on the availability of oxygen both inside and outside the body. Table 1 lists some of the common forms of hypoxia. While most forms result from a reduction in the supply of oxygen of one manner or another, it is interesting to note that at least one form (histotoxic) occurs when oxygen is present in plentiful supply, yet cannot be properly utilized by the tissue's cells.

In the field of contact lenses, there has long been prodigious interest in the effects of hypoxia on human corneal tissue. Such interest is certainly reasonable, given: (a) the cornea's fundamental role in the visual process as the eye's entry window for light en route to the retina, for which the maintenance of corneal transparency is essential: (b) the cornea's critical dependence on aerobic metabolism for the energy required to (among other functions) maintain its transparency: (c) the cornea's dominant role in contact lens wear as the principal biological substratum on which a contact lens resides in situ: and (d) the barrier a contact lens forms between the cornea and its anterior oxygen supply, which restricts oxygen flow into the cornea, thus reducing tissue oxygen tension, often enough to levels below the critical hypoxia threshold to make hypoxia probably the most common adverse ocular response associated with contact lens wear.

## HYPOXIA AND CORNEAL PHYSIOLOGY

Transparency is the one feature that makes the cornea virtually unique among the other tissues of the body (the crystalline lens being the one notable exception). Although the physiological process responsible for this special property is still not fully understood, it has long been established, and demonstrated in various ways, that the transparency of the cornea is dependent upon its water content. The healthy cornea is about 78 percent

TABLE 1 Various Etiologies of Hypoxia/Anoxia in Human Body Tissue

| Condition | Cause/Description | Examples |
|---|---|---|
| Anemic | Insufficient tissue $O_2$ tension; | |
| anoxia[a] | Normal arterial $O_2$ tension; | |
| | EITHER reduced arterial hemoglobin with normal hemoglobin $O_2$ capacity | Anemia |
| | OR sufficient arterial hemoglobin with reduced hemoglobin $O_2$ capacity | Carbon monoxide poisoning |
| Anoxic anoxia[b] | Insufficient tissue $O_2$ tension;<br>Arterial anoxemia[b] ;<br>Sufficient arterial hemoglobin with normal hemoglobin $O_2$ capacity;<br>Incomplete hemoglobin oxidation due to anoxemia resulting in less $O_2$ being carried to tissues | High altitude living environments Asphyxiation/drowning<br>Pneumonia (reduces surface area for gas exchange from lungs to blood) |
| Diffusion hypoxia | Insufficient tissue $O_2$ tension;<br>Arterial hypoxemia due to nitrous oxide diffusion from plasma. reducing $O_2$ in lung alveoli | Recovery from surgery utilizing nitrous oxide anesthesia |

| Condition | Cause/Description | Examples |
|---|---|---|
| Histotoxic hypoxia/anoxia[c] | Sufficient tissue $O_2$ tension;<br>Cellular O2 utilization depressed by reduction of enzyme oxidase caused by poisoning of protoplasm | Cyanide poisoning |
| Stagnant (or hypokinetic) hypoxia/anoxia[c] | Insufficient tissue $O_2$ tension;<br>Normal arterial $O_2$ tension;<br>Tissue $O_2$ supply retarded by decreased circulation of blood flow through capillaries | Congestive heart failure Shock Cardiac thrombosis<br>Arterial spasm |

[a] In medicine, *anoxia*, meaning absence of tissue oxygen, is frequently used erroneously to indicate inadequate tissue oxygen content, which is the definition of *hypoxia*. Therefore, in the medical literature, one can expect the word *anoxia* used to mean either *anoxia* or *hypoxia.*

[b] Similarly to *anoxia*, *anoxemia*, meaning absence of oxygen in the blood, is also often misused in medicine to indicate insufficient blood oxygen content, which is more accurately defined by the word *hypoxemia*.

[c] Indicates that nearly identical definitions for the condition were found for both words.

SOURCES: Critchley (1978); Taber (1970).

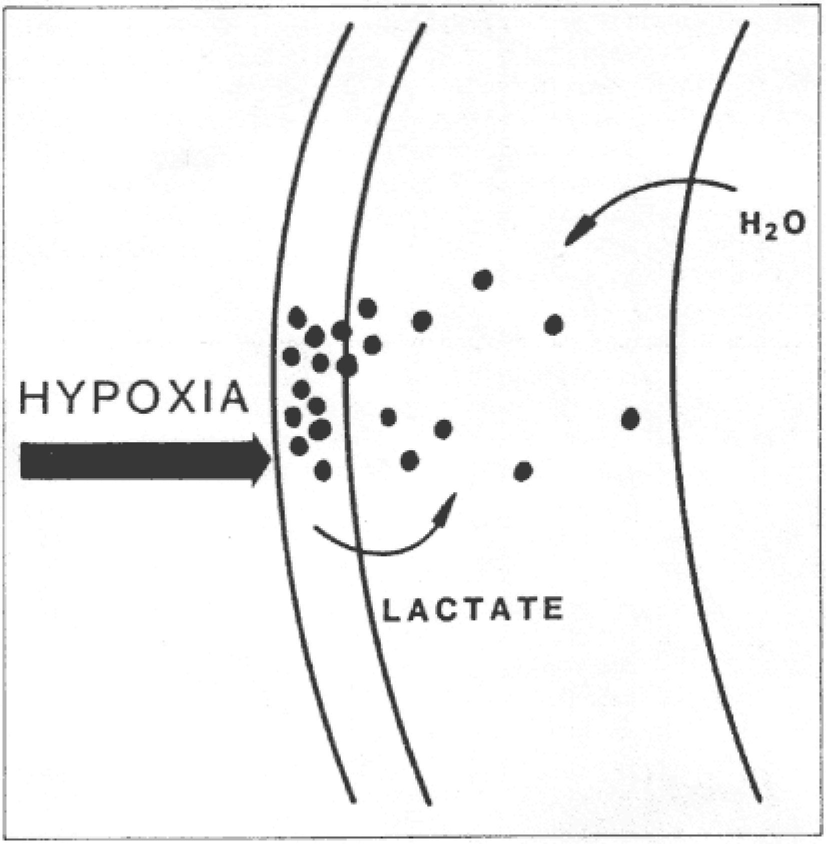

Figure 1
Lactate theory of how hypoxia induced build up of stromal lactate leads to corneal edema (Klyce, 1981). SOURCE: Efron and Holden (1986a). Reprinted by permission.

water by weight, which is substantially less than its surroundings. The tear film, which borders the anterior surface of the cornea, and the aqueous humor, which borders its posterior surface, both have a water content approaching 100 percent. This difference in water content between the cornea and its surroundings produces an Osmotic gradient resulting in a net influx of water flowing into the cornea. The cornea maintains its relatively dehydrated, or deturgescent, state primarily through an active pumping mechanism located in the endothelium, the single layer of cells that forms the cornea's posterior surface. Endothelial cells pump bicarbonate ions from the cornea into the aqueous, causing water to follow through passive diffusion, and thus leads to an equilibrium whereby the corneal stroma is maintained in its relative state of dehydration (Hodson and Miller, 1976). The endothelium is highly dependent on aerobic metabolism to satisfy the energy demands of its pumping mechanism. For this, it probably gets most of its oxygen supply from the aqueous (Kwan et al., 1972).

The corneal epithelium, which is highly mitotic, is also very dependent on aerobic metabolism to meet its energy demands. Its primary supply of oxygen is from the atmosphere. If the cornea's atmospheric oxygen supply drops below approximately 74mmHg (Holden et al., 1984), as frequently occurs during contact lens wear, the cornea becomes hypoxic and its epithelial cells begin to respire anaerobically. When this occurs, the corneal stroma becomes edematous (swells). Corneal edema of a sufficient magnitude causes the cornea to become cloudy, and is ultimately, a threat to the tissue's transparency. It has been proposed (Klyce, 1981) that the edema associated with corneal hypoxia is caused by the excess amount of lactic acid produced by the epithelium under anaerobic conditions (see Figure 1). As lactate builds up in the stroma (along its pathway of elimination through the aqueous), an increase in osmotic pressure occurs causing more water to diffuse into the stroma than can be handled by the endotheliai pump.

## CORNEAL EDEMA

Corneal edema has received a great deal of attention in the literature because it is one of the few responses to the wearing of contact lenses that can actually be quantified. Hedbys and Mishima (1966) showed that the swelling of the cornea is linearly related to its thickness. Therefore, by measuring corneal thickness with a device known as a pachometer (or pachymeter) before and after the application of a potential stimulus to hypoxia (i.e, the wearing of a contact lens), the degree of corneal swelling (edema) can be established, usually expressed in terms of the percentage change in corneal thickness from a baseline value. Mandell and Polse (1969) were the first to apply electronics to the Haag-Streit pachometer to enable the instrument to measure corneal thickness with the necessary precision and accuracy for this purpose. For the last 20 years, a wide variety of pachometry studies have been conducted to characterize corneal swelling response to various stimuli under various conditions. For instance, it has been shown that the normal cornea swells approximately 4 percent during overnight sleep (Mandell and Fatt, 1965; Mertz, 1980). This is probably due, at least in part, to the reduced oxygen environment available to the cornea behind the closed lid (Table 2), where oxygen is supplied almost exclusively from the capillary plexus of the palpebral conjunctiva.

TABLE 2 Comparison of Ambient Conditions at the Anterior Surface of the Human Cornea: Opened Versus Closed Eye

| Condition | Units | Opened eye | Closed eye | Source |
|---|---|---|---|---|
| $O_2$ Tension | mmHg<br>(EOP) | 155<br>(20.9) | 55<br>(7.5)<br>61.4<br>(8.2) | Fatt et al. (1974)<br>Holden and Sweeney (1985) |
| $O_2$ Uptake | µl/cm$^2$/hr | 4.8 | 1.5 | Hill and Fatt (1963a<br>Hill and Fatt (1963b)) |
| pH | log [H$^+$]$^{-1}$ | 7.45 | 7.25 | Carney and Hill (1976) |
| Osmolality | mOsm/kg<br>(% NaCl) | 310<br>(0.97) | 285<br>(0.89) | Terry and Hill (1978) |
| Temperature | °C<br>(°F) | 31.4<br>(88.5) | 33.9<br>(93.0)<br>36.2<br>(97.2) | Hill and Leighton (1965)<br>Holden and Sweeney (1985) |
| $CO_2$ Tension | mmHg | 0 | 45 | Holden et al. (1987) |

## THE CLOSED EYE ENVIRONMENT

With the introduction of extended-wear contact lenses in the 1980s, there has been a great deal of interest in the closed eye environment. It is certainly appropriate to know what sort of environment the closed eye presents to contact lenses that are worn during sleep (Table 2).

Knowledge of the level of sleep-induced corneal edema (4 percent), which generally dissipates completely during the first few hours following awakening, has been a useful guide for contact lens designers in establishing the level of corneal edema that might be deemed tolerable during contact lens wear.

Studies of the corneal swelling response to the wearing of extended-wear lenses (Holden et al., 1983; Holden and Mertz, 1984) have shown that significant levels of corneal edema occur during the overnight wear of these lenses, but suggest that this might be a minimally tolerable situation so long as the lenses transmit enough oxygen during daytime open-eye wear to allow overnight swelling to subside to baseline levels.

## HYPOXIA AND ITS CLINICAL SEQUELAE

Figure 2 shows how corneal edema associated with contact lens wear can progress from relatively safe levels to levels that actually threaten the transparency of corneal tissue. The clinical observation (using a slit lamp biomicroscope)

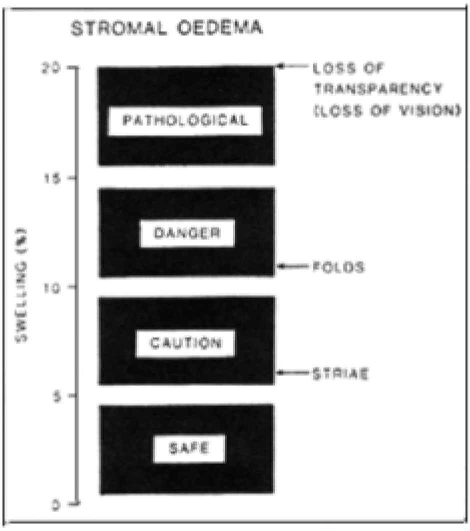

Figure 2
Stages of stromal edema of the cornea in terms of percentage increases in corneal thickness. SOURCE: Efron and Holden (1986a). Reprinted by permission.

of vertical striae in the posterior portion of the cornea is generally regarded as evidence of excessive corneal swelling associated with contact lens wear (Poise and Mandell, 1976).

Other adverse conditions can occur in the cornea associated with contact lens related hypoxia. These conditions, which include punctate keratitis, epithelial microcysts, stromal infiltrates, endothelial polymegethism, corneal vascularization, etc., are conveniently summarized in a pair of outstanding articles published by Efron and Holden (1986a, 1985b).

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# Contact Lenses and Corneal Energy Metabolites in the Rabbit

Morris R. Lattimore, Jr.

The U.S. Army's increased interest in contact lenses for aviators is driven primarily by the development of the AH-64 (Apache) attack helicopter. Integral to this flight platform are a sophisticated electrooptical display device and a specialized environmental protection system. These have combined to create a spectacle compatibility problem that can restrict operational efficiency. Fifteen to 18 percent of active Army aviators are ametropic; this situation exists as a result of some waivers to existing standards and the development of late-onset maturational myopia in some individuals. Without an alternative means of optical correction, these aviators, many with advanced skills and superior performance abilities, may face nonretention on flight duty.

The potential use of contact lenses by Army aviators has stimulated organizational interest in three areas: flight performance and safety, ocular health, and physiological/biochemical effects. A preliminary study at the U.S. Army Aeromedical Research Laboratory (USAARL) (Bachman, 1988) documented certain aspects of the first two issues. A new study will attempt to examine the third issue of physiological/biochemical effects of contact lens wear in an animal model. The remainder of this discussion will highlight four issues concerning contact lens wear, summarize the methodology being used by this investigator, and provide normative energy metabolite data for the corneal epithelium of the pigmented rabbit.

## PERTINENT ISSUES

The traditional concern pertaining to effects of contact lens wear has been the critical oxygen tension (COT) for supporting normal corneal function. The clinical measure for loss of normal corneal function is corneal edema or swelling. The avoidance of corneal edema has been shown to depend on sufficient amounts of oxygen reaching the tissue (Fatt and St. Helen, 1971; Fatt and Linn, 1976; Polse, 1979). However, there is some debate as to what constitutes a sufficient amount of oxygen available to avoid corneal insult.

Early estimates of tolerable hypoxia used gas-infused goggles to create an exposure to artificially low oxygen levels for 1.5 hours (Polse and Mandell, 1970); below a critical level of 2.5 percent oxygen (partial pressure of 19 mmHg) the corneas of experimental subjects reacted with increased hydration and edema. A similar goggle study (Mandell and Farrell, 1980) established the minimum oxygen requirement for the avoidance of corneal swelling to be at least 3.02 percent (equivalent to a partial pressure of 23 mmHg). A later study, using another hypoxia-inducing goggle system (Holden et al. 1984), implied that the above values were insufficient for normal corneal function. Holden et al. (1984) indicated that the minimum precorneal oxygen tension to avoid corneal edema was at least 10.1 percent (74 mmHg).

More recent work (Weissman et al., 1988), using hydrophilic contact lenses of varying oxygen transmissibility and monitoring central corneal thickness, has suggested the corneal COT could be in excess of 20 to 40 mmHg but not necessarily as high as 70 mmHg. However, the monitoring of corneal oxygen uptake rates (Benjamin, 1986) has provided evidence that 18 percent oxygen (137 mmHg) represents the minimum value for normal corneal respiration, although corneal swelling is not evident well below 18 percent oxygen. This could be interpreted as an indication that the clinical method of assessing loss of normal corneal function (i.e., corneal thickness) is inadequate. Lastly, other investigators (Efron and Brennan, 1987) have suggested the critical oxygen requirement of the cornea is that which is normally available from the natural environment, 20.9 percent (159 mmHg).

Contact lens wear has been shown to adversely affect the corneal epithelium in two animal models. Hamano and Hori (1983) documented the suppression of basal cell mitosis in rabbit corneal epithelium associated with contact lens wear. In addition, a loss of desmosomes and superficial epithelial sloughing has been documented within 8 hours after contact lens wear in the rabbit (Francois, 1983). A similar contact-lens-induced epithelial thinning has been demonstrated in the owl monkey (Bergmanson et al., 1985). It has been suggested that contact lenses may cause a delay in epithelial cell turnover characterized by the presence of abnormal, large, senescent surface cells (Lemp and Gold, 1986); other findings included trapped surface debris, intraepithelial pseudocysts, and increased uptake of water-soluble dyes, suggesting increased permeability of these surface cells.

An additional issue has surfaced in the past 2 years: carbon dioxide expiration. Previously, it had been calculated that hydrogel contact lenses may provide a barrier to carbon dioxide efflux from the cornea, although at the time it was considered to be an insignificant concern in terms of corneal physiology (Fatt et al., 1969). However, recent measurements of carbon dioxide calculation under hydrogel lenses (Holden et al., 1987), paired with the detection of a decrease in stromal pH following contact lens wear (Bonanno and Polse, 1986), indicate $CO_2$ to have the potential of being a significant factor in corneal physiology. While Holden et al. (1987) have tied the issues of carbon dioxide accumulation and tissue pH changes to the endothelial bleb response, it should be remembered that specific enzymatic activity (either by activation or inactivation) can be affected by pH changes. It is possible that an examination of corneal metabolic activity may answer pertinent questions regarding effects of contact lens wear.

Continuing along that line of thought, the typical corneal endothelial mosaic, consisting of cells of similar shape and size, may be altered by contact lens wear such that the normally uniform monolayer is transformed into a variety of cell shapes (pleomorphism) and a variety of cell sizes (polymegethism). Virtually every type of contact lens has been implicated in the induction of polymegethous changes (Snyder, 1982; Schoessler, 1983; Stocker and Schoessler, 1985; Holden et al., 1985). These polymegethous changes have been linked to the efficacy of the endothelial pump function, suggesting a cause and effect relationship (Rao et al., 1979, 1984; Holden et al., 1985; Sweeney et al., 1985; O'Neal and Polse, 1986). However, it may be possible that inhibition of the endothelial pump function is what alters cell shape and size, since some endothelial changes can be detected within minutes after placing contact lenses on the eyes of unadapted patients (Zantos and Holden, 1977; Barr and Schoessler, 1980; Kamiya, 1982). An immediate response could be indicative of a metabolic shift that occurs as a direct result of contact lens wear.

The application of a biochemical/metabolic approach is not a new one. Many studies have evaluated contact lens effects on corneal metabolism (Uniacke and Hill, 1972; Thoft and Friend, 1972, 1975). However, most of that work used techniques that involved traumatic separation of the corneal layers and/or bulk tissue extraction processes. As a result, multiple assays from the same cornea were not obtainable. In addition, results from such studies have yielded a variety of data with units based on wet weight, dry weight, or per milligrams of protein. Consequently, data comparison has been difficult, hampering the formation of a coordinated representation.

A microfluorometric energy metabolite assay technique (Lowry and Passonneau, 1972) has routinely been employed in the evaluation of regional brain metabolism (McCandless and Schwartzenburg, 1982; McCandless, 1985; McCandless and Abel, 1985). Moreover, this technique can readily be applied to the cornea (Lattimore, 1988). Advantages of this methodology include liquid nitrogen freezing of the entire globe in order to immediately suspend metabolic activity; cryosectioning and cross-sectioning with freeze drying of tissue samples to ensure stabilized metabolite levels; vacuum thawing to prevent condensation-stimulated enzyme activity; and microdissection of the sample, permitting a regional corneal metabolite analysis by dry weight. This method will permit a detailed investigation into the corneal metabolic response to induced stress. Data obtained for all metabolites will be in comparable units, establishing a standardized unit format for future reference. Thus far this technique has been applied to the corneal epithelium in the pigmented rabbit in order to provide initial normative data.

## METHODOLOGY

### Experimental Animals

Healthy, adult, Dutch-belted, pigmented rabbits were used as the experimental animals. The animals are housed in quarters approved by the National Institutes of Health under controlled artificial lighting conditions. The animals are maintained and the experiments conducted in accordance with procedures outlined in the *Guide for Laboratory Animals Facilities and Care* of the National Research Council (1965). Appropriately sized contact lenses are worn on one eye only for a predetermined period of time. Then, prior to sacrifice, the animals are anesthetized with intramuscular injections of Ketamine (30 milligrams/kilogram) and Rompun (7 milligrams/kilogram) and are sacrificed by cervical dislocation. The contact lens is removed, and the eye is excised immediately and immersed in liquid nitrogen to prevent significant change in metabolite levels. The contact lens is retained for protein analysis and histological sectioning.

### Processing Procedure

The rabbit eyes are transferred from the liquid nitrogen container into a -80°C freezer for storage until tissue processing can be accomplished. The cornea is removed from the globe by dissection under -80°C conditions in a Lehrer cryostat. The isolated cornea is cut into halves, which are mounted on a sectioning button by immersion in a dry ice-cooled hexane solution. The corneal button mount is then transferred to a cryostatic microsome where tissue sectioning is performed. The resulting central cornea cross sections are approximately 20 micrometers in thickness. The sectioned tissue samples are placed in a metal tissue holder, covered with glass slides, and inserted into a vacuum tube. The tube is placed in a -20°C freezer and attached to a vacuum pump. The tissue is then freeze dried for a 24-hour period. After the freeze-drying process is completed, the tissue can be kept at -20°C until it is assayed.

Samples needed for assay are thawed under vacuum for 1 hour to prevent condensation-stimulated enzyme action. The different layers of the cornea are clearly defined, which permits easy isolation of the corneal epithelium under a 3× binocular dissecting microscope. Tissue size is determined by dry weight, rather than by tissue section dimensions, which permits the analysis of very small and irregularly shaped specimens. The tissue samples are immediately weighed on a quartz fiber fishpole balance possessing μg sensitivity. After weighing and recovery, the samples are placed in an oil well rack for specific metabolite assay.

### Underlying Principles

The cycling system contains several enzymes that catalyze specific interrelated reactions yielding a "net reaction." A by-product of this multistep reaction is reduced nicotinamide adenine dinucleotide phosphate (NADPH), which fluoresces light of 460 nm wavelength when excited with ultraviolet radiation of 340 nm wavelength. By measuring the amount of this reduced pyridine nucleotide fluorescence, the original concentration of the assayed metabolite can be inferred by calculation (Lowry and Passonneau, 1972). Appropriate blanks and standards are employed to monitor the reliability of the assays. Individual enzymatic cycling and incubating techniques permit isolation of the specific metabolite being analyzed.

## RESULTS

Each assay result is based on 25 to 32 separate tissue samples from three eyes, one each from three different rabbits. Metabolite concentration units are nanomoles per microgram dry weight. For the specific assay values refer to Table 1.

TABLE 1 Normative Corneal Epithelial Energy Metabolite Concentrations (nanomoles per microgram dry weight)

| | Glucose | Glycogen | ATP | PCr |
|---|---|---|---|---|
| Mean concentration | 5.45 | 38.23 | 12.09 | 8.06 |
| Standard deviation | 1.22 | 10.30 | 2.24 | 2.13 |

SOURCE: Data were obtained from three eyes, one each from three different rabbits.

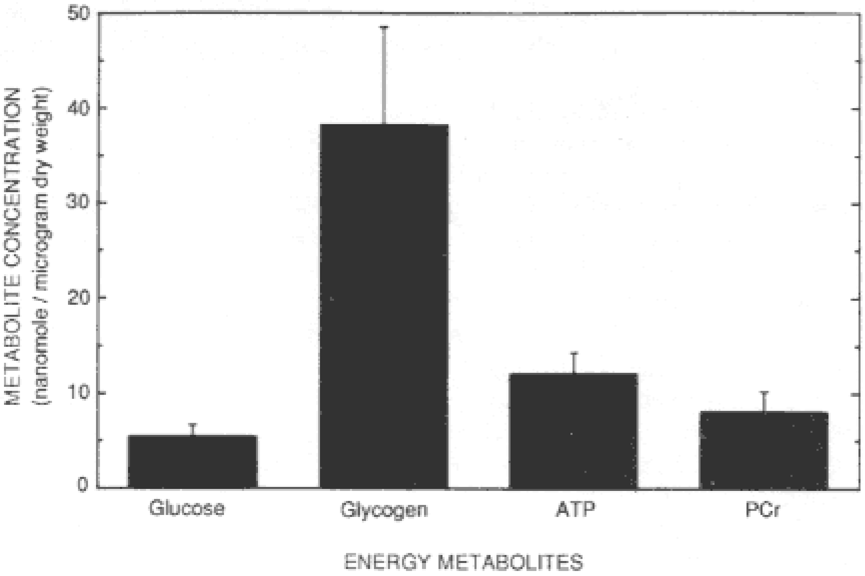

Figure 1
The normal rabbit corneal epithelium possesses a large amount of glycogen, a small amount of free glucose, and moderate amounts of ATP and PCr. The error bars represent one standard deviation, highlighting the relative precision of each assay.

## DISCUSSION

Earlier research efforts have not been able to document a coordinated picture of the corneal energy metabolite distribution pattern because of a limitation of bulk extraction methods: essentially only one assay can be performed per cornea. The microfluorometric technique permits numerous assay repetitions per cornea. Regional assays can be performed as well, allowing separate determinations of epithelial, stromal, and endothelial metabolite levels. Epithelial data are presented in bar-chart format in Figure 1 to illustrate the interrelationship between metabolites in the normal rabbit cornea.

The corneal epithelium in the rabbit possesses a large amount of storage glucose or glycogen. Although free glucose is suggested to be present in adequate amounts to sustain purely anaerobic activity (Riley, 1969), studies have shown glycogen mobilization to be quite responsive in times of stress (Uniacke and Hill, 1972; Thoft and Friend, 1975). With the microfluorometric technique it will be possible to document the relationship between free glucose and glycogen throughout the cornea as contact-lens-wearing time is varied.

Prior researchers have inferred, because of a decreased oxygen availability during contact lens wear, that glycogen depletion represents an increase in epithelial glucose consumption as a result of glycolytic compensation. However, if stromal pH changes reflect actual epithelial intracellular conditions, then the glycogen depletion may represent merely decreased activity in the enzyme system responsible for glycogen synthesis or, on the other hand, increased activity in the enzyme system responsible for glycogen degradation. Such a condition could field increased levels of glucose within the involved tissue, perhaps beneficial for ready availability to fuel an elevated rate of glycolysis or perhaps detrimental as a source of increased hydrostatic pressure.

Note that PCr, a high-energy phosphate bond reservoir, is found at approximately two-thirds the levels of ATP. The relatively high energy reserve has been used to explain the ATP sparing, at the expense of PCr, that occurs following corneal exposure to ultraviolet radiation (Lattimore, 1988). A similar relationship between ATP and PCr likely exists in association with contact lens wear; it then will be possible to depict the interaction between energy stores and fuel stores, thereby allowing a more complete determination of the influence that contact lens wear exerts on corneal function.

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# Environmental Conditions and Tear Chemistry

Leo G. Carney

The tear film is of crucial importance in maintaining the integrity of the underlying ocular tissues. It is also directly exposed to an environment that is constantly varying. The ability of the tear fluid to contain the resultant changes in its characteristics within narrow confines contributes importantly to the health and function of those anterior ocular tissues.

One way in which the ocular environment is varied is by the application of a contact lens—tear chemistry can then certainly be affected. A second viewpoint within the present context is, however, that tear chemistry changes may produce contact lens changes. Both of these aspects will be briefly considered.

At the outset it should be said that tear changes from environmental effects are a multifaceted topic, and I will select just a few of the possible features, namely tear pH, buffering, proteins in general, and enzymes. Crucial topics such as sampling influences will be ignored.

## TEAR PH

Perhaps the most distinctive feature of the literature on human tear pH is the broad spectrum of values it has come to contain. Even with the exclusions of extreme disease conditions, a span of about pH 5.2 to 8.6 remains. To account for this range, several fundamental questions might be explored: How different are individuals from one another? What variations might a given individual show? What is the effect of environmental challenges, including contact lens wear?

From many of our studies a population average of about pH 7.45 emerges. Tear pH is nevertheless a highly individualized function, both among subjects and even more particularly for a given subject at different times of the day.

Tear pH tends to shift, on the average, in the alkaline direction as the day progresses. The slope is small, about 0.013 pH units/hour, but statistically significant. Although not perfectly reproducible from day to day, the majority do exhibit recurrent patterns of tear pH change. Such patterns differ considerably from patient to patient in their cycloid characteristics.

A relevant feature here is the proneness for patients to have a more acid tear pH following prolonged eye closure, in this case at the end of a night's sleep. Since this more acid state is rarely sustained for more than an hour under normal open-eye conditions, it would appear to be related to a possible increase in acid by-products associated with the relatively anaerobic conditions during sleep.

A continually shifting tear pH is thus a natural characteristic of the unfitted eye. How then does the wearing of contact lenses affect this property of tears? The possibility that contact lens might induce an acid shift in tears, say through acting as a reservoir for acid by-products of corneal metabolism, has been confirmed in some cases. However, there remains individuality in responses, and opposite pH shifts can be found.

The differential long-term effects of routine hygiene and cleaning regimens are possible additional components to be considered.

Lastly, does the added presence of a contact lens under prolonged eye-closure conditions (i.e., extended-wear situations) influence tear pH? Restricted periods of eye closure do have acid shifts associated with them, ultimately becoming similar in magnitude to those found during normal sleep.

## TEAR BUFFERING

Fluctuations in normal tear pH do exist, therefore, but in a confined range. Tear fluid buffering is therefore important; this buffering is most often attributed to the bicarbonate system, but other mechanisms also likely contribute.

Tear pH responses to incremental titrations with acid and base can be compared with pH responses of an unbuffered reference solution. The enhanced resistance of the nonaqueous tear components to the pH change is a measure of the magnitude of tear buffering.

The buffering is more substantial in response to acid challenge than it is to challenge with base. The substantial buffering capacity indicated by the plateau in the responses in the tear pH range of 7.0 to 7.7 may be a reflection principally of the bicarbonate system. However, other buffering systems would be expected to contribute in tears just as in other biological fluids. The major nonbicarbonate buffer components would likely be the various protein fractions present in tears. These protein contributions may explain the subtle but measurable discontinuities in pH response. The pres ence of a unique pattern of protein constituents, and one that is subject to environmental influence, may be of significance in ultimately interpreting its overall pattern of pH response.

Contact lens wearing can and does induce changes in this characteristic, but the considerable intersubject variations in both the form of the response curves and in the overall buffering capacity may, at this stage, be the more relevant and overriding influence.

Details of the bicarbonate buffering system in tears are usually based on calculations and assumed constants. We have recently investigated this and have been able to establish the pH/p$CO_2$ relationships for tears. This was done by equilibrating tears with gases of p$CO_2$ tensions of 34.5, 69.0, and 82.8 mmHg and also later allowing exposure to room air. The results show that for a closed-eye tear pH value of 7.25 the p$CO_2$ would be approximately 55 mmHg, much as would be expected. On the other hand, for an open-eye value of 7.45 the p$CO_2$ would be approximately 25 mmHg, that is, tears in situ are not air equilibrated. This feature becomes even more relevant given the recent information on carbon dioxide accumulation beneath hydrogel contact lenses.

## ACID-BASE INFLUENCES ON CONTACT LENSES

The role of tear fluid buffering in damping tear pH changes may also influence the success of contact lens wear. Tear fluid pH has been demonstrated to be important in protein adsorption onto hydrogel lenses. Additionally, it influences the water content and, hence, the oxygen permeability, dimensions, and fitting characteristics of some current hydrogel contact lenses.

For example, the dehydration characteristics of hydrogel lenses under open- and closed-eye conditions can be used to demonstrate the effect. Medium-water-content lenses can display greater absolute decreases in water content than higher-water-content lenses, depending on the ionic nature of the polymer. This is at least in part a consequence of the pH of the environment. Diminishing the magnitude of tear pH shifts, particularly during the closed-eyelid phase of extended wear, protects the integrity of the contact lens and hence ultimately the cornea itself.

## TEAR ENZYMES

Finally, I would like to look at quite a different aspect of tear chemistry: glycolytic enzymes and enzymes of the tricarboxylic acid cycle. These are known to be present in tear fluid. The source of these enzymes is not the lacrimal gland but rather the underlying ocular tissues. Thus, tear chemistry can reflect corneal and conjunctival biochemical responses to environmental stresses, including hypoxia and contact lens wear.

An appropriate system to indicate the activity of the parent metabolic pathways is the determination of the ratio of two enzymes, lactate dehydrogenase (LDH) and malate dehydrogenase (MDH), in the tears. The principal reason for monitoring the relative activities of two enzymes is to surmount the considerable variability in absolute enzyme levels resulting from the nonuniform dilution effect of reflex tears.

It should in fact be possible to quantify the severity of metabolic stress by determining the magnitude of elevation in the tear LDH/MDH ratio.

In the normal open-eye situation the tear LDH/MDH ratio is relatively constant. Overnight lid closure raises the ratio in an almost twofold increase. Shorter periods of lid closure (of 2, 4, and 6 hours' duration) cause an increase in the ratio that is a function of the period of stress.

When various hypoxic environments are used, a significant correlation is found between the magnitude of elevation of the ratio and the severity of the hypoxia. However, environments with oxygen concentrations of 1 percent or less do cause disproportionately greater effects.

Following wear of contact lenses, tear LDH and MDH activities are again altered, so the LDH/MDH ratio is elevated. The magnitude and time course of this elevation is influenced by contact lens type, fit, and duration of wear. The ratio changes in a way that would be predicted from the expected severity of hypoxic challenge.

## CONCLUSION

In summary, the tear fluid is unique among body fluids because of its exposed situation. The subsequent environmental challenges do bring about changes in its characteristics, the tear chemistry role being to ensure that the health of the underlying tissues is sustained throughout.

## ACKNOWLEDGEMENT

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# Tear Evaporation Considerations and Contact Lens Wear

Miguel F. Refojo

The tear film is essentially composed of three layers: (1) the outermost is the oily layer, which retards water evaporation; (2) the middle, thickest layer, consisting of an aqueous solution of salts, proteins, enzymes, and mucins; and (3) a mucoid layer, consisting of a mixture of glyoproteins, which forms the interface between the hydrophobic corneal epithelium and the aqueous layer of the tear film. A good tear film is essential for the tolerance of contact lenses.

Normally, a substantial amount of the water in the tear film is lost by evaporation. The evaporation rate of normal tears depends on temperature, relative humidity, and air flow over the eye as well as on the palpebral aperture and rate of blinking (Rolando and Refojo, 1983). The rate of complete to incomplete blinks is also a factor in tear evaporation. When a contact lens is placed on the eye, the tear film structure is altered on the surface of the lens and on the ocular surface near the lens. The lens disrupts the three-layer structure of the tear film, and as the lipid layer becomes discontinuous, the rate of tear evaporation increases (Cedarstaff and Tomlinson, 1983).

Contact lenses can be classified as rigid lenses, elastomeric lenses, and hydrogel lenses. All contact lenses alter the tear film, because they interact with the tear components and because they interfere with the lid-cornea congruity. Because of the physicochemical properties and design characteristics that determine the way each kind of lens is fitted on the eye, each type of lens interacts differently with the tear film.

If there is tear film over a contact lens, water from the film evaporates between blinks. When the tear film dries over a contact lens, solid residues from the tear coat the lens surface. Lipid and protein deposits on lenses transform an originally wettable surface into a surface that the tear film does not wet uniformly. A nonwetting lens lacks the lubricating effect that the tear film provides for lid movement over the lens and will result in an irritated eye and lens intolerance.

Most contact lenses are not covered between blinks with a stable tear film (Doane, 1988, 1989). If the lens is a hydrogel lens, water evaporates from the lens itself. Also, water from the tear film that separates the lens from the corneal epithelium can pervaporate (permeate and evaporate) through high-water thin hydrogel lenses and from silicone elastomeric contact lenses (Refojo and Leong, 1981). The tear film that spreads over rigid contact lenses by the blink retracts immediately upon opening the eyelids. Tear film retraction is caused by the suction force of the tear meniscus at the lids' margins (Doane, 1988).

## WATER EVAPORATION FROM HYDROGEL LENSES

A large proportion of the water in a hydrogel is not bound in the polymer network and therefore can be lost by evaporation (Refojo, 1976).

### Effects of Lens Hydration

When two hydrogel lenses of low and high water content but of equal thickness are placed on a subject's eye, the lenses dehydrate. The dehydration is slower in low-water lens than in high-water lens. Thus, a high-water-content lens reaches a steady state of hydration on the eye more rapidly than does a lower-water-content lens. Furthermore, more water evaporates in equal time from the lens of higher hydration than from the lens of lower hydration (Andrasko, 1983).

Water evaporates, of course, from the lens surface, but as a hydrogel lens surface dries, more water diffuses from the bulk of the lens to its surface where evaporation continues. Water may also permeate from the tear film that separates the lens from the epithelium. Thus, given two hydrogel lenses of equal thickness but different hydration, water diffusion from the bulk of the lens to its surface will be easier in the high-hydration lens because the polymer network is looser and easier for the water to diffuse than in a tighter network lens. As a lens dehydrates, its base curve becomes steeper. High-water-content lenses dehydrate more than similar lenses of lower hydration under the same conditions, and therefore high-water-content lenses have a greater tendency to tighten on the eye than do lower-hydration lenses.

### Effect of Lens Thickness

When lenses of equal hydration but different thickness are used under the same conditions of wear, more water, in absolute terms, evaporates from the thicker lenses in equal time than from the thinner lenses. However, the thinner lenses become proportionately more dehydrated than the thicker lenses and reach a steady state of dehydration on the eye more quickly than the thicker lenses (Andrasko, 1983).

### Effect of Abnormally Fast Lens Drying

When the surface of a hydrogel lens dehydrates faster than the bulk moisture of the lens can diffuse to the surface, the polymer at the surface contracts and the lens roll up due to the stresses created in the lens network by the nonuniform swollen state of the lens. These dried, distorted lenses can be easily expelled from the eye by lid motion.

When a hydrogel lens is placed on the eye, it dehydrates to some extent, decreasing the oxygen transmissibility of the lens, increasing the contact lens refractive index, and decreasing the lens thickness and radii of curvature so that the lens becomes steeper. The power of the lens increases with dehydration in plus lenses and decreases in minus lenses.

### Pervaporation of Tear Water Through Silicone Elastomeric Lenses

There are two mechanisms of permeation of fluids through membranes: bulk flow, in which the driving force is the difference in hydrostatic pressure of the permeant across the membranes; and activated diffusion, in which the driving force is the difference in concentration (or partial pressure in gases or vapors) of the permeant across the lens. The transmission of gases and vapors through contact lenses is by activated diffusion.

Pervaporation is a type of vapor permeation by activated diffusion in which the membrane separates a liquid from its vapor phase. Water pervaporation through a contact lens occurs when water from the tear film that separated the lens and the corneal epithelium penetrates the lens and evaporates from its surface. This is particularly relevant with silicone rubber lenses due to their extremely high water vapor permeability. When the surface of a silicone rubber lens is not covered by a tear film, moisture that separated the lens from the cornea epithelium pervaporates through the lens, and the lens will adhere to the epithelium (Refojo and Leong, 1981).

## EFFECT OF TEAR WATER EVAPORATION ON EYES WITH RIGID CONTACT LENSES

The tear film on rigid contact lenses is very unstable due to their unusual hydrophobic surfaces. In addition, the tear film, which the blink may spread on the lens, is rapidly retracted by the suction force in the tear meniscus, which forms at the lid's edge. Depending on the fitting technique, a rigid lens will, upon opening the eyelids, be in contact with the upper or the lower tear meniscus. Tear evaporation is also a factor in tear drying on rigid lenses (Doane, 1988).

Because a rigid contact lens disrupts the lid-ocular surface congruity, the lids cannot spread the tear film on the ocular surface. The 3 o'clock and 9 o'clock positions are the sections of the cornea under the palpebral aperture that are more exposed to water evaporation and desiccation of the tissue. The result is a localized epithelial damage at the 3 and 9 o'clock positions of the cornea next to the lens.

## HYDROGEL CONTACT LENS WEAR IN AIRCRAFTS

Due to comfort and stability of the lens in the eye, it seems at this time that the best choice of contact lenses for aircraft pilots would be hydrogel contact lenses.

It is well known that hydrogel contact lenses dehydrate in the eye and that the degree of dehydration of the lens on the eye depends on the type of contact lens (i.e., high or low water of hydration) and on the thickness of the lenses used. Other important factors on lens dehydration in the eye are the ambient relative humidity, air movement over the lens, palpebral aperture, and rate of blink.

Under normal conditions of wear at 18 percent relative humidity, Andrasko and Schoessler (1980) found that hydrogel contact lenses dehydrate in the eye to about 20 percent below normal hydration of the lens "in the bottle." When a lens dehydrates, the lens develops a water imbibition pressure, which increases exponentially with the degree of dehydration. The water imbibition pressure for hydrogels, particularly of low hydration is very high, on the order of 4,000–5,000 mmHg for a hydrogel of equilibrium swelling 40 percent $H_2O$, which has dehydrated only to about 5 percent below its normal hydration (Refojo, 1976). A steady state of hydration is obtained when the amount of water that evaporates from the lens equals the amount of water imbibed by the lens from the tears.

Even in the low-humidity conditions of aircrafts, hydrogel contact lenses have been well tolerated, without irritation or dislodgement (Nilsson and Rengstorff, 1979). Therefore, with no air drafts over the face of the pilot (i.e., air from the air conditioner blowing on the pilot's face), in a normal-blinking individual with normal tears, a hydrogel lens will not continue to dry until it becomes "bone dry," but rather the lens will acquire a steady state of hydration that is probably not too different from the steady-state hydration of lenses used under normally higher humidity conditions. Although research is lacking on the quantitative dehydration of hydrogel lenses in the eye under the low-humidity conditions of high-altitude aircraft, pilots using hydrogel lenses under these conditions do not seem to have major problems, such as intolerance, loss of lenses, or poor vision. Changes in lens fitting in subjects flying in a commercial aircraft cabin were most noticeable, as the relative humidity was sharply reduced at the beginning of the flight from the normal 47 percent to 11 percent relative humidity (Eng et al., 1982). It is important to recall here that parameter changes on dehydration of hydrogel contact lenses in the eye might be minimal with low-water lenses, but substantial parameter changes will take place in lenses of high hydration (Gundel and Cohen, 1986).

The critical variable in the dehydration of hydrogel lenses in all conditions of wear is blinking, and this is particularly true for lens wearers flying in an aircraft (Corboy and Tannehill, 1973). Patients with hydrogel contact lenses have been found to blink more frequently than patients without lenses (Carney and Hill, 1984). However, after the patients have adapted to the lenses, their blink pattern seems to depend on the visual task being performed (Pointer, 1988). Therefore, a pilot using hydrogel lenses must conscientiously blink (i.e., complete blinks) and frequently blink. Good blinking in subjects with hydrogel lenses is important not only to maintain lens hydration but also to maintain good visual acuity. A pilot needs good visual acuity at all times; therefore he or she must blink to maintain good visual acuity and at the same time will rehydrate the lenses.

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# Mechanical Aspects of Soft Contact Lenses

James T. Jenkins

My colleagues and I at Cornell University are interested in the physical principles that govern how a soft lens stays positioned on the eye, how it is moved from this centered position by the action of the blink, and how it returns to a centered position following a blink (e.g., Jenkins and Shimbo, 1984; Knoll and Conway, 1987). We are also concerned with the orientational positioning of the lens; this involves the match between the back surface of the lens and the corneal topography.

One of the things we are interested in predicting is the thickness of the tear film behind the contact lens. This tear film is important both to the mechanical behavior of the lens and to the health of the eye.

## ELASTOHYDRODYNAMICS

The lid provides the overwhelming force in the problem of lens positioning (Miller, 1967). Roughly every 5 seconds it comes crashing down on this delicate structure. Surprisingly, it does not have too great an influence on it, largely because the tear film behind a soft contact lens is so thin.

In any case, following a blink the lens is deformed and displaced slightly; it then recovers its original position in the period between blinks. The way it recovers this centered position is essentially by balancing the forces associated with the elastic deformation against the viscous resistance of the fluid in the tear film behind it. It is this process that we would like to understand better.

The parameters that characterize the mechanics of the lens include the profile of the lens thickness. So we suppose that we know how the thickness varies from the center to the edge, and, when we are dealing with a toric lens, we suppose that we know how the thickness varies as we move around any circle at a fixed radius. The mechanical property of the lens material that we employ is its resistance to stretching. In engineering terminology this is Young's modulus of the material.

The name of the interaction is *elastohydrodynamics*. This is a term that indicates there is a deformable body (the lens) that is interacting with a viscous fluid (the tear film beneath it).

It must be pointed out that there is a difference between the mechanical behavior of a soft lens and that of a hard lens. The hard lens is essentially rigid. The forces that maintain its adherence and drive its centering are associated with the curvature of the tear film at its edge. These forces, in conjunction with the action of the lid, permit a tear film of greater thickness behind the lens; consequently, there is much more movement of the hard lens on the eye.

In modeling the soft lens, the central portion is taken to be an elastic sheet that resists stretching, and the region near the edge is considered to be an elastic shell that resists bending. Usually there is no need to worry about the bending resistance unless we are trying to change the curvature of the lens rather dramatically, but that is exactly what is happening at the edge of the lens.

## AN ILLUSTRATION

Now I would like to illustrate the way these mechanical principles are used in an effort to solve perhaps the simplest problem that could be formulated for this lens-cornea system—that is, simply to predict the shape of the lens centered on an axisymmetric cornea with a given negative pressure behind it.

We start out with a standard lens and a standard cornea (Figure 1). I do not think anyone would argue with this picture of the cornea and a spherical lens sitting with its edge on the sclera.

Imagine that this lens is gradually drawn down on the eye with a negative pressure applied to its back. What we would like to do is to predict the evolution of the shape of the lens with the change in the negative pressure behind it.

What happens as the pressure is gradually decreased? First, the lens begins to translate toward the cornea. The edge of the lens begins to move away from the center, and, near the edge, the lens rotates about the line of contact. Eventually, the slope of the lens at the edge becomes equal to that of the sclera. Then, with further decrease in pressure, the point at which edge contact begins moves toward the center. Throughout, the central portion of the lens has been approaching the cornea. At some value of the pressure the center of the lens touches the center of the cornea, and, with further decreases, the point at which central contact is made moves toward the edge.

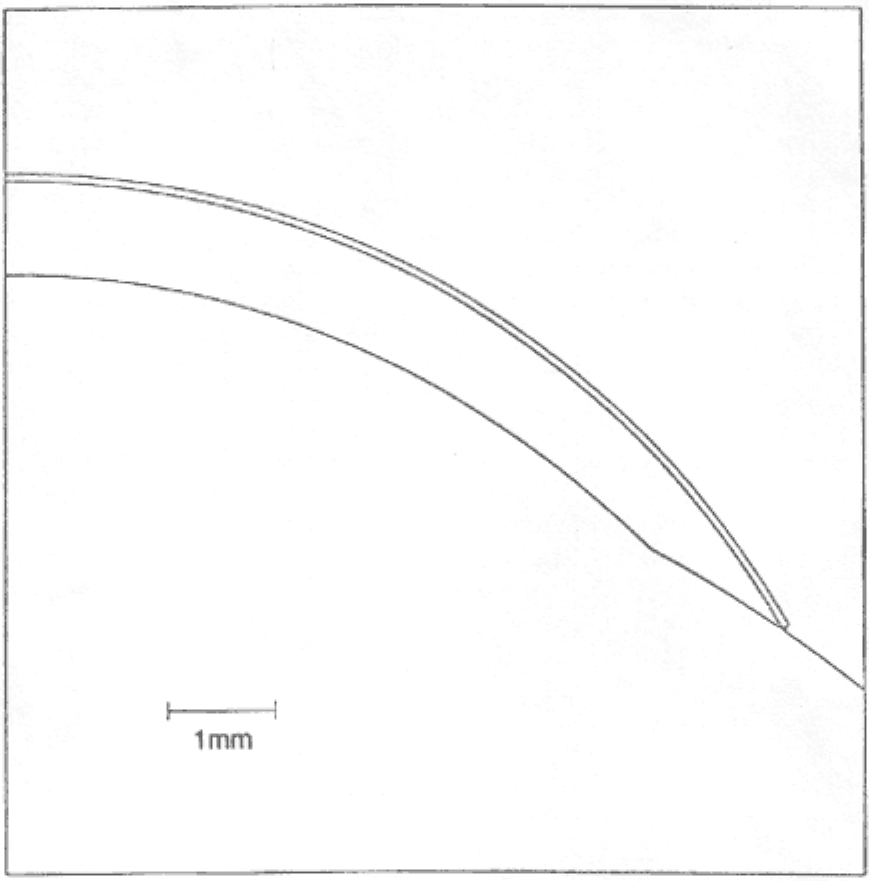

Figure 1
Soft lens on the eye. The central radius of curvature of the cornea is 0.78 cm, its diameter is 1.20 cm, and its shape factor is 0.6. The sclera is a sphere of radius 1.30 cm. The lens is spherical with a back radius of 0.84 cm, a diameter of 1.45 cm, and a uniform thickness of 0.07 cm; its Young' modulus *E* is equal to $4 \times 10^6$ dynes/cm$^2$.

I should say that this is not just a story I have made up. This is the scenario that evolves as we determine solutions to the differential equations that describe the balance of forces within the lens (Askari and Jenkins, 1989). So this is a solution to a mathematical problem resulting from our model for the mechanical behavior of the lens.

Figure 2 shows the evolution of shape as the pressure decreases. This is a prediction based typical lens material and a realistic thickness. Figure 3 shows the corresponding evolution of the pressure on the back of the lens as the regions of contact develop.

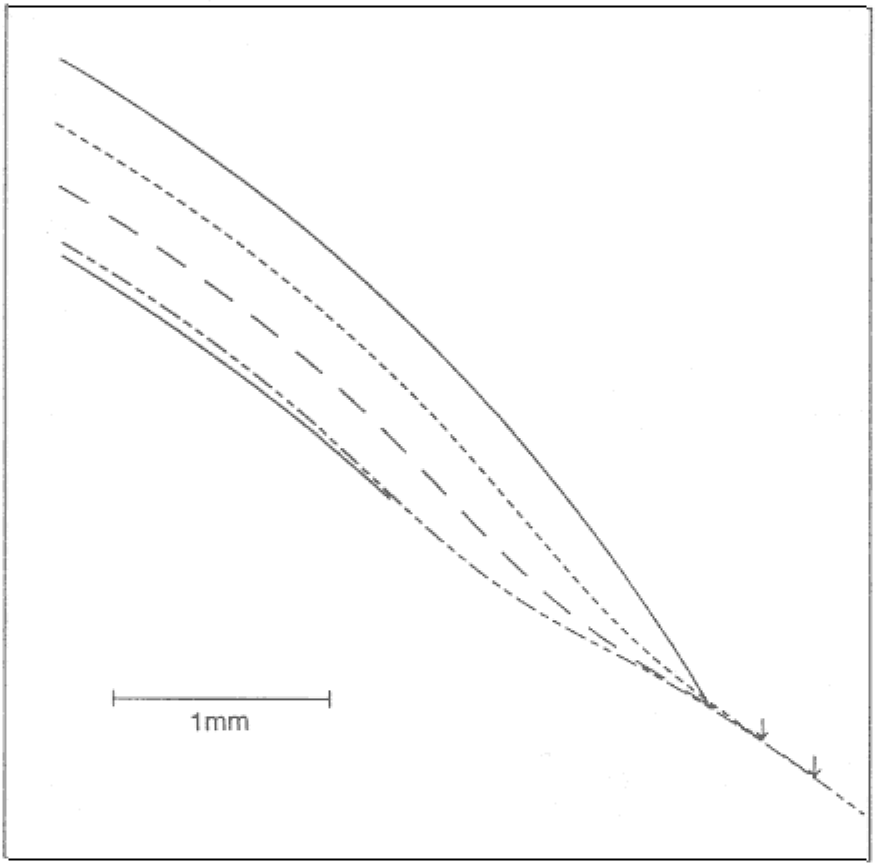

Figure 2
Deformed configurations of the soft lens of Figure 1. Shown with the undeformed shape are successively more deformed configurations corresponding to decreasing tear film pressure $P$ Values of $(P/E) \times 10^4$ are equal to 0 (undeformed), -0.12 (edge tangent to sclera), -0.40 (edge rolling in), and -0.77 (lens touches center of cornea).

We have predicted the deformed configuration of the soft lens, the pressure distribution applied to its back, and the tear film thickness beneath it. In addition, the levels of pressure agree with those observed in experiments (Martin and Holden, 1986). However, there is an embarrassment of riches, because for every value of the negative pressure there is a distorted configuration. The lens is like a suction cup. When we push down on a suction cup and ask what the equilibrium configuration is, there are any number of them, depending on how hard we push down.

The question is: Does the system seek a solution that is in one sense or another more natural? The way this question is phrased in a mechanical context is in terms of the total energy of the system—that is, the energy stored in the lens as a result of its being stretched and bent and the energy that we have invested in drawing the lens toward the cornea. Plot that as a function of pressure, and, if that shows a minimum, we will say that the configuration at that value is the one the lens seeks on the eye. The results are plotted in Figure 4.

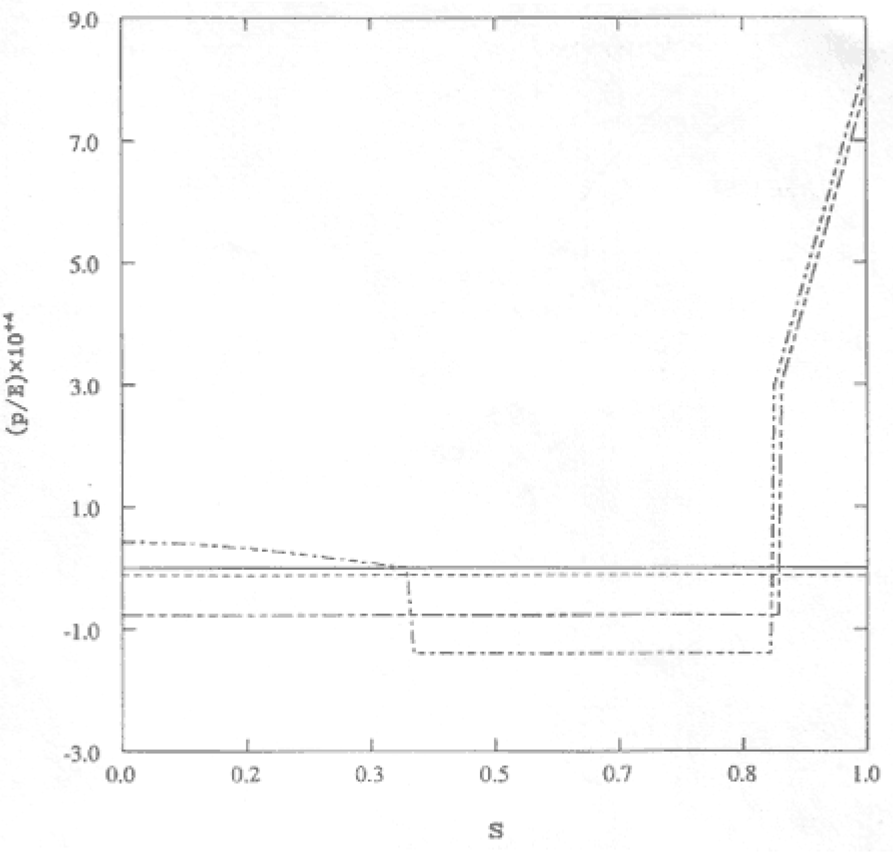

Figure 3
Distribution of pressure *p* on the back of the soft lens for several values of the tear film pressure *P*. Graphed is $(p/E) \times 10^4$ versus the fraction s of arc length along the lens for $(P/E) \times 10^4$ equal to 0, -0.12, -0.77, and -1.40.

My hope had been that, once the lens was in contact with the cornea, this curve would start to go up. This would be the case if there were a minimum of energy. Unfortunately, as the lens contacts the cornea on the center line and this central contact begins to spread, the energy decreases further. The purely mechanical analysis predicts that the configuration with the least energy is that with the lens in complete conformity with the eye. This is unrealistic; it indicates that the model is too simple.

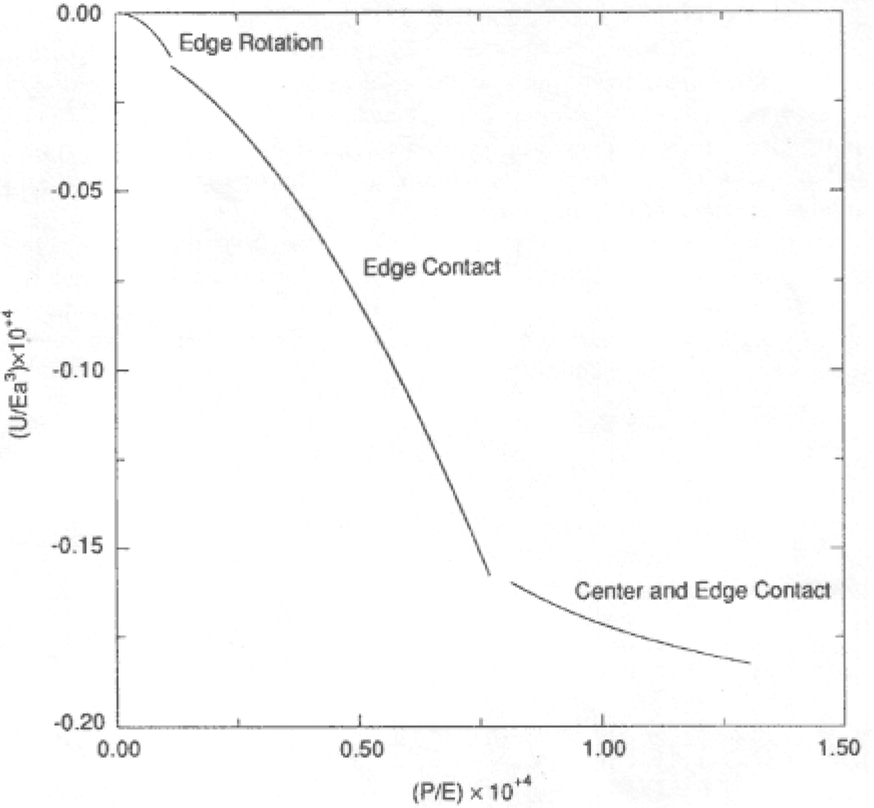

Figure 4
Total energy *U*, normalized by the cube of the central radius *a* of the lens and Young's modulus versus the normalized tear film pressure.

What must be taken into account, and this is crucial, is that other aspects of the system are involved in determining the tear film thickness behind the lens. For example, when this lens is on the eye, there is a constant exchange of water between the lens, the atmosphere, the tear film, and the cornea. This probably determines the volume of tear film available.

These aspects of the system aren't mechanical but chemical. The water moves through the system in response not only to changes in water but also to changes in oxygen, lactic acid, salt, or other chemical constituents.

This chemical component must be included in order to place the me chanical system in its proper context. So, at the moment, we are using a simple model for transport of water and salt across the cornea (Klyce and Russell, 1979), the tear film, and the contact lens (Yasuda et al., 1971), with evaporation into the atmosphere (Hamano et al., 1980), in order to understand how the interaction between the mechanical part of the system and the chemical and evaporative parts of the system serve to determine the volume of tear film behind the lens.

In terms of the importance for the task at hand, I think this indicates that extremes of humidity can have a profound influence on the mechanical behavior of this system. Next we hope to be able to quantify this and to be able to predict the natural configuration of a soft lens on an eye over a range of atmospheric humidities.

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# CONTACT LENSES AND THE EYE: COMPLICATIONS

# Medical Problems Associated with Contact Lens Use

Robert P. Green, Jr.

Military medicine supports commanders by providing for the individual warrior's medical needs. As part of that support, it provides commanders with the medical knowledge and data to make managerial decisions. It is in that context that we must assess the risks versus the benefits of contact lenses. Ultimately, a military commander will decide whether to commit money and people to provide soft contact lenses to aviators.

Military medicine must help commanders define the benefits and risks of soft contact lenses. Some of the visual benefits are obvious and have been covered by previous speakers (e.g., increased visual field, elimination of lens fogging). Medical personnel will find it hard to easily define other benefits. Aircrew members may simply report that they are "better." Before we let what may be vague benefits override known possible risks, we should ask commanders to ensure that reported benefits and risks be as clearly defined as possible. This is important so that commanders can clearly understand what they are choosing in the form of visual benefits and accepting in the form of ocular risks. Commanders must support and encourage medical personnel to gather as objective data as possible. We must know whether contact lenses improve bomb and range scores, as well as whether test subjects (aviators) develop complications over the long term.

## RATES OF COMPLICATIONS

At the present time over 23 million people wear contact lenses in the United States (Kirn, 1987). Only 28 percent of them are males (Stehr-Green et al., 1987). Yet in terms of complications men are more represented than females (Stehr-Green et al., 1987). Therefore, in the military, where there are more males than females, a higher complication rate might occur than in the civilian community.

It is unclear what the incidence is of ocular complications from contact lenses. In one large study from Japan (Hamano et al., 1985), the investigators looked at 124,821 eyes of 66,218 patients and asked, "How many people had eye problems, defined by pain, that precipitated a visit to a medical institution?" The rate for polymethylmethacrylate (PMMA) hard contact lens wearers was 1.6 percent; for soft contact lens wearers, it was 1.2 percent; and for rigid gas-permeable lenses (RGP), it was 0.6 percent. The results of that study yielded rather low numbers. In fact, only 14 eyes developed corneal ulcers—a rate of 0.011 percent.

In another study, 70 aphakic patients wore soft contact lenses for 3 to 7 years (Salz and Schlanger, 1983). Eleven percent developed corneal vascularization, 17 percent developed bacterial conjunctivitis, and 7 percent developed corneal ulcers. These are rather alarming percentages.

The Food and Drug Administration estimates that the risk ratio for extended-wear versus daily-wear soft lenses is about 10 to 1 (Kirn, 1987). Good prospective studies of soft contact lenses to define risk factors and complication rates have not been done and are needed.

## CONTRAINDICATIONS

Most of the medical contraindications are relative. They include chronic hyperemia, chronic conjunctivitis, vernal conjunctivitis, chronic allergic conjunctivitis, symblepharon of the conjunctiva, pterygium, chronic staphylococcal blepharitis, stye, chalazion, trichiasis, entropion, ectropion, corneal degenerations, corneal dystrophies, corneal vascularization, recurrent keratitis, corneal ulcers, and dry eyes.

## NONMEDICAL CONSIDERATIONS

The nonmedical problems associated with contact lenses have for the most part been discussed—edge glare, fluctuating vision with blinking and dehydration, bubbles beneath lenses, and displacement under positive G's. The aircraft environment is not totally hospitable. Humidity ranges from 5 to 10 percent. Current fighter aircraft have been "set" so that they cannot be stressed above 9 G's. Studies at the U.S. Air Force School of Aerospace Medicine have observed subjects wearing contact lenses up to 8 G's. In November 1988 the USAF/SAM Human Use Committee approved the testing of humans to 12 G's in light of the development of new aircraft and tactics.

## MEDICAL COMPLICATIONS

Medical complications from soft contact lenses can range from temporary and relatively insignificant ones that can ground an aviator for hours to days to more serious corneal problems that may affect an aviator's entire flying career. Examples of less worrisome problems include thimerosol toxicity, corneal edema, giant papillary conjunctivitis, corneal deposits, pseudodendritic keratitis, and corneal abrasions. Examples of the more serious corneal complications include vascularization, molding, and infections.

The issue of corneal infections in association with contact lenses is evolving into a major problem. There has been an alarming increase in the number of reports of serious contact-lens-related infectious ulcerative keratitis (Stevson, 1986). From 20 percent (Alfonso et al., 1986) to 70 percent (Ormerod and Smith, 1986) of corneal infections occur in contact lens wearers. In addition, individuals who get corneal infections in association with contact lens wear have worse bacteria cultured from their corneas. Aviators who suffer a corneal infection may be grounded for a long time or even permanently.

In one study involving 573 eyes with corneal infections (Alfonso et al., 1986), those persons who had been wearing contact lenses had gram-negative bacteria cultured in 78 percent of culture positive cases versus only 45 percent for those not wearing contact lenses. Most of these gram-negative organisms, 75 percent in one study (Cohen et al., 1987), are pseudomonas, a particularly destructive organism in the cornea. Furthermore, a new and more difficult to treat organism is making its appearance on the scene—acanthamoeba. It is not killed by hydrogen peroxide sterilization, but only by heat. Of corneas infected with this new organism, 83 percent wore contact lenses (Stehr-Green et al., 1987).

The effectiveness of soft contact lens sterilization is even in question. In one study by Mondino et al. (1986), 9 of 11 people (82%) using daily-wear soft contact lenses who developed an ulcer were not caring for their lenses properly. This is reassuring because it suggests that education might help. On the other hand, among individuals using extended-wear soft contact lenses in the same study, 12 out of 29 (41%) who developed corneal ulcers were caring for their lenses religiously. That is frightening.

Further, in at least one large study, 82 percent of 210 randomly selected contact lens patients were not using the directed procedures for sterilization and cleaning (Roth, 1978). In another study up to 52 percent of patients wearing contact lenses had contaminated contact lens care systems, with 13 percent of commercial contact lens solutions being contaminated (Donzis et al., 1987).

While heat sterilization may kill bacteria and acanthamoeba, it markedly shortens the life of daily-wear lenses and cannot be used with the higher-water-content extended-wear lenses. Hydrogen peroxide sterilization is effective against bacteria, but it does not easily kill acanthamoeba. Further, it is not known what concentration of residual $H_2O$ is safe for the eye. Although most companies aim for a residual hydrogen peroxide level of no more than 50–60 ppm after neutralization, in actuality the residual concentration varies from 1 to 300 ppm. Rabbit studies have shown that a hydrogen peroxide concentration of $<3$ ppm caused a significant increase in corneal hydration and alteration in corneal metabolism (Hartstein, 1985, 1988). The long-term effect on the human cornea of chronic exposure to higher levels of hydrogen peroxide is unknown.

It is known that soft contact lenses cause polymegethism and pleomorphism, although less than the older PMMA hard contact lenses. At least with hard contact lenses, this has not been shown to be totally reversible (Mac Rae et al., 1986).

## CONCLUSION

There are other significant issues that must be addressed also. How much is soft contact lens use by military aviators going to cost? How many eye care professionals will be needed to care for these patients? How many aircraft sorties and how much space in aircraft going to the front will be used for contact lens support instead of for the transportation of guns, ammunition, and troops? Will the use of contact lenses help a military organization to achieve its goals?

Operational commanders need to talk with the medical people. The operational commander will, ultimately, make the decision to implement a soft contact lens program for aviators. However, the commander must judge whether a clear operational advantage exists to justify military sponsorship of what some might consider the excessive expenditure of money, men, and equipment for a program that will not be suitable for everyone and will cause harm to some.

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# Adverse Reactions Associated with Contact Lens Use

Oliver Schein

Adverse reactions from contact lens wear range from minor epithelial trauma to visual loss from ulceration. There are two complications of contact lens wear that may result in permanent compromise to visual acuity.

The first is corneal neovascularization. Normally, the cornea is avascular, except for the limbal region. When vascularization extends more than 2 millimeters inside the clear cornea, we consider it pathologic. It is thought to be secondary to chronic hypoxia and inflammation. Typically this is seen with soft lenses and in particular with extended-wear soft lenses.

Early neovascularization is of no long-term visual consequence once recognized, but it does provide a clue to corneal health. It will respond favorably to cessation of the lens. Figure 1 shows an example of advanced neovascularization in the setting of aphakic extended wear. This degree of vascularization clearly leads to a decrease in visual acuity.

The most important potential consequence of contact lens wear is corneal ulceration. This usually takes the form of microbial keratitis (Figure 2). Although extended-wear contact lenses are singled out in Figure 2, the rationale shown here applies equally to daily-wear lenses. Figure 2 illustrates that the development of microbial keratitis presumably requires only two factors. The first is some compromise of the corneal surface in the form of an insult to the epithelium whether through cumulative anoxia or mechanical abrasion. The second is the inoculation of a sufficient quantity of pathogenic organisms to allow infiltration of the anterior stroma.

It is clear that contact lens use has the ability to compromise the epithelium. More controversial is the origin of the bacterial inoculum. Whether this develops in the eye with attachment of bacteria to the soft lens or whether the inoculum derives from contaminated lens care products is unclear. However, in general terms it is certainly true that microabrasions of the cornea and the bacterial ecology of contact lens wear in general work in concert to produce infection. It is evident that bacterial contamination appears at least at present to be an inevitable consequence of soft contact lens wear.

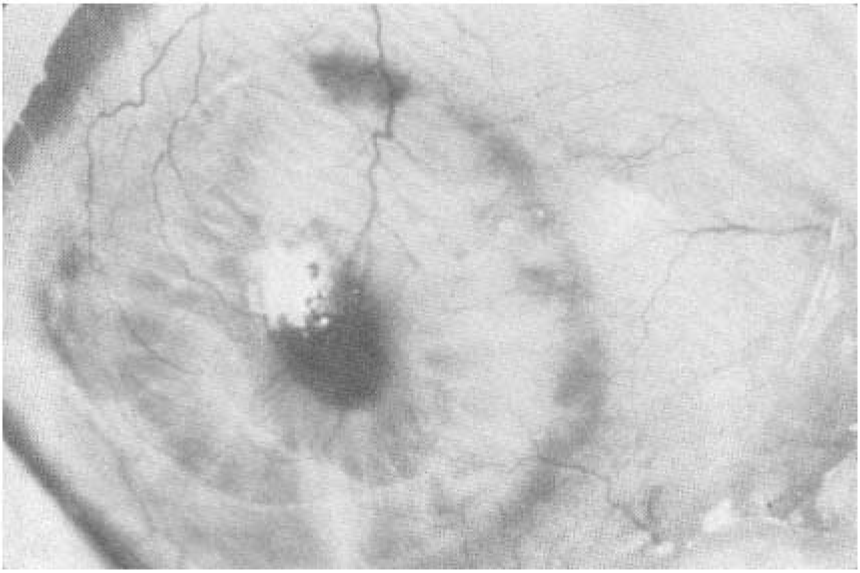

Figure 1
Advanced neovascularization of the cornea.

Figure 3 shows dramatically the adherence of gram-negative bacteria to the soft contact lens of an asymptomatic patient.

Duran et al. (1987) placed new soft contact lenses of both high and low water content, incubated in vitro with pseudomonas, and showed rapid and irreversible bacterial adhesion and proliferation on the contact lens surface in conjunction with the elaboration of a bacterial biofilm. This begins within minutes of exposure and underscores the potential danger of contaminated solutions, which theoretically can then infect soft lenses in the absence of lens deposits, breaks, or abnormalities in the lens itself.

This has its reflection in a clinical correlate. Donzis et al. (1987) cultured contact lens paraphernalia of asymptomatic contact lens users presenting for routine follow-up and found that about half of the lens cases tested were contaminated. About 13 percent of the commercial lens care products were also contaminated, and 12 out of 12 homemade saline solutions were culture positive, including 2 with acanthamoeba. This contamination was seen with all lens types, with all wearing patterns, and in patients who followed recommended procedures.

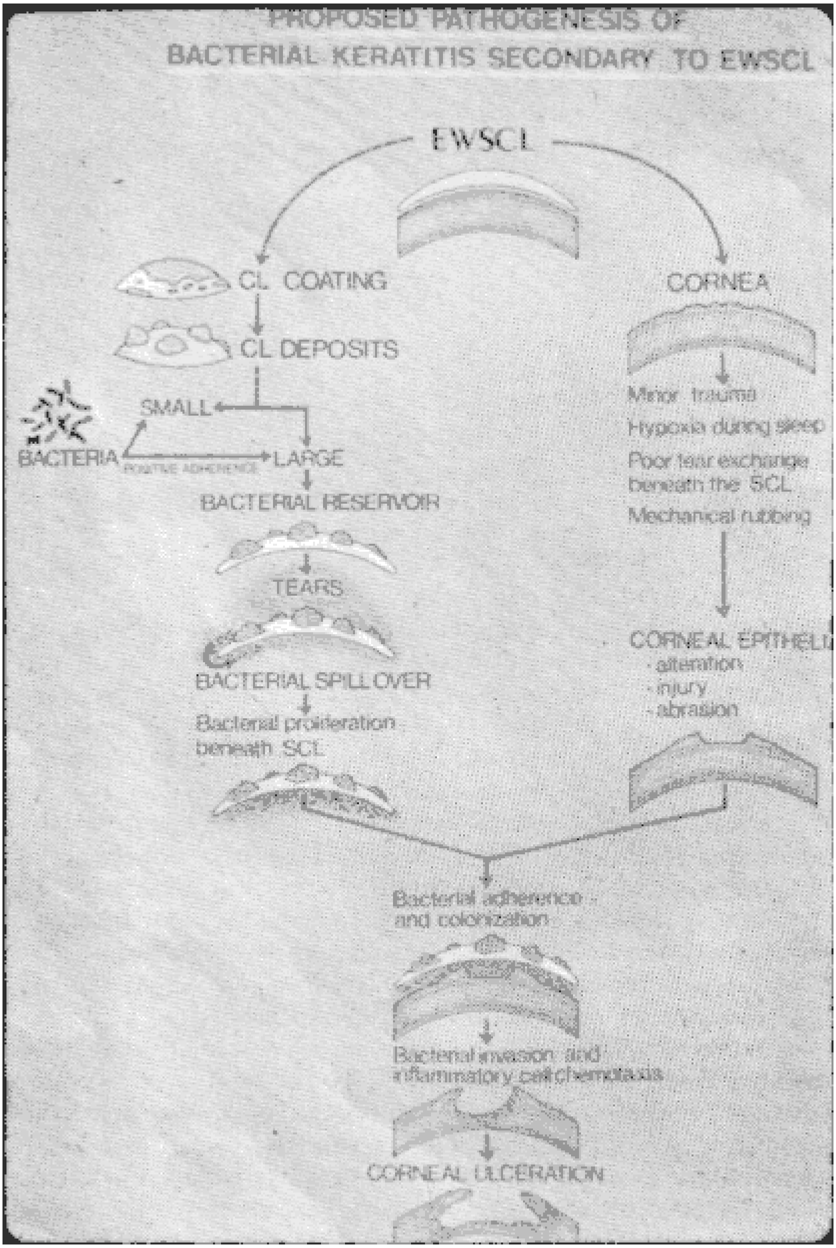

Figure 2
Proposed pathogenesis of microbial keratitis associated with contact lense use (courtesy of Dr. Thomas John).

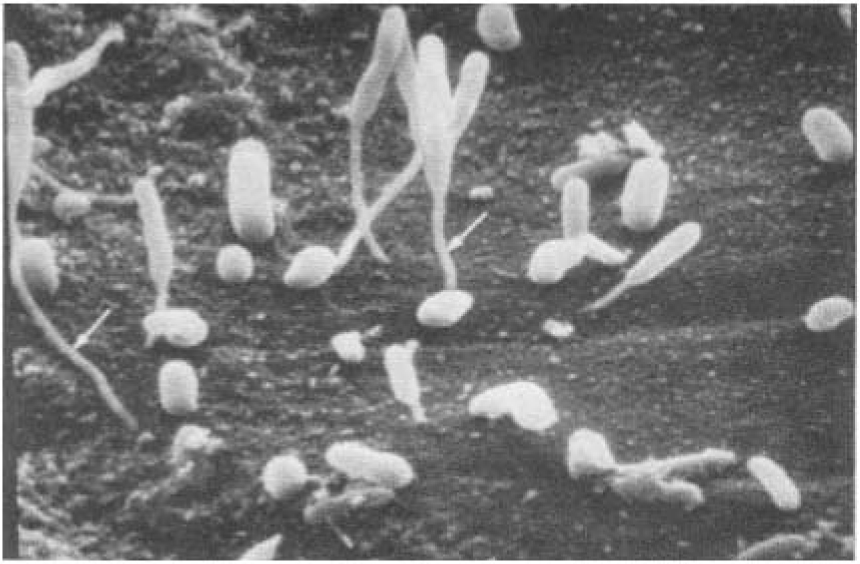

Figure 3
Pseudomonas aeruginosa to soft contact lens of asymptomatic patient (courtesy of Dr. Mathea Allansmith).

## MICROBIAL KERATITIS

Microbial keratitis associated with contact lens use can take many forms and presents with the full spectrum. Figures 4 through 6 are taken from three patients who were all cosmetic contact lens wearers between the ages of 20 and 30. Figure 4 is that of a 20-year-old undergraduate student who presented on the same day as her initial complaints with three small infiltrates, the largest of which had an epithelial defect surrounding it, on top of it. This was cultured and grew staphylococcus. She was treated promptly and aggressively and healed within a number of days. No visual sequelae resulted from the infection; however, it did cause significant pain and concern over the short term.

The man in Figure 5 was not quite so lucky. He presented about 24 to 48 hours after initial symptoms. Figure 5 was taken 6 months after treatment. His (visual) acuity is 20/20. However, the scar in his corneal stroma extends into the visual access, and he is miserable under brightly lit conditions.

Unfortunately, despite widespread publicity concerning contact lens infections, there are still severe cases. Figure 6 is shows a 25-year-old woman who had worn extended-wear contact lenses on a weekly basis—she removed them every 7 days—for 4 years. Three days after her last standard

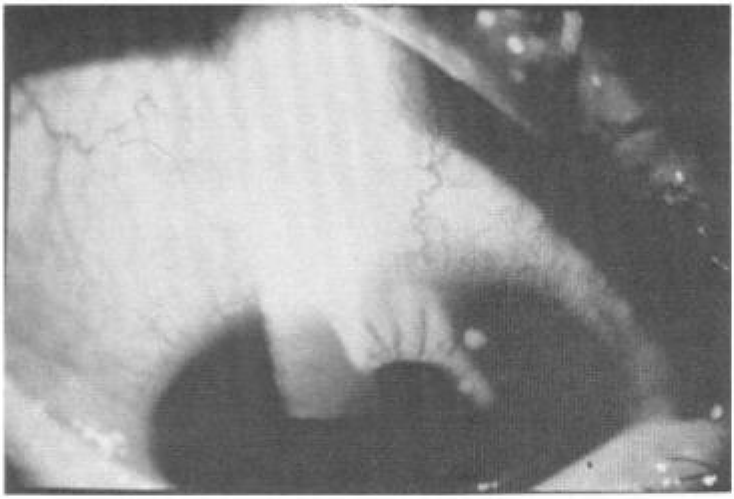

Figure 4
Peripheral staphylococcal corneal ulcer associated with cosmetic soft contact lens wear.

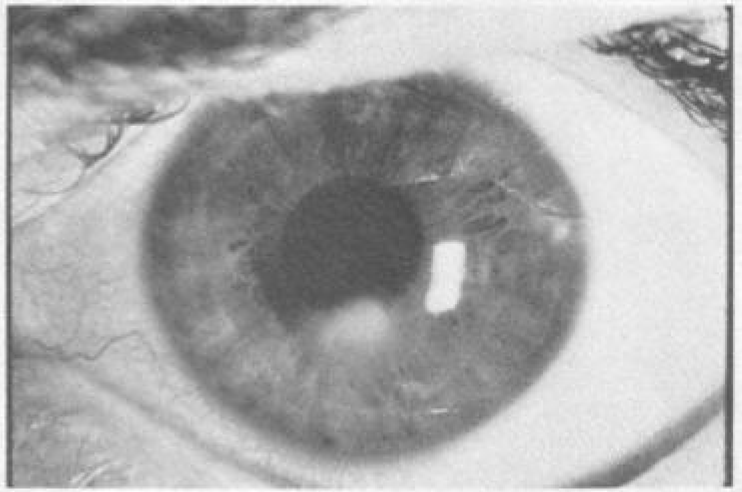

Figure 5
Six months after treatment for contact-lens-associated infection with paracentral scar.

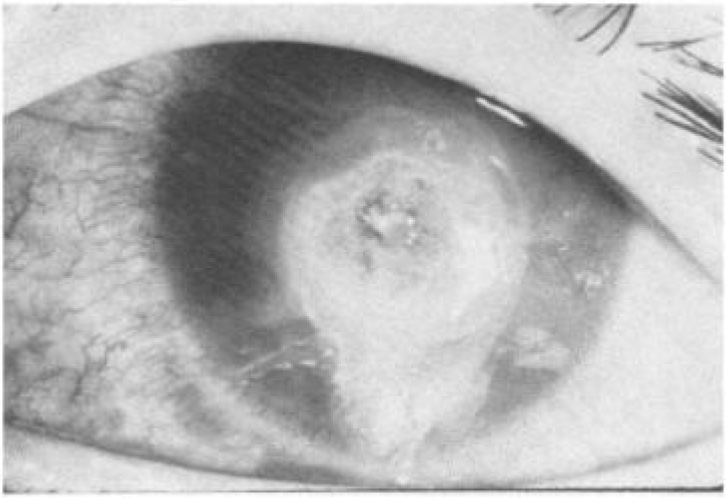

Figure 6
Corneal perforation from pseudomonas aeruginosa contact-lens-associated infection.

cleaning, she developed a foreign body sensation and immediately removed the lens. The next morning she was seen by general practitioner, who treated her with sulfa drops. The following day her vision decreased. She then saw a local ophthalmologist, who referred her to me the same afternoon. The photograph in Figure 6 was taken within an hour of presentation. Her cornea was already perforated and what is shown in Figure 6 is some tissue adhesive that was used to stabilize her anterior chamber. I cultured pseudomonas both from the cornea and from one solution and her contact lens case. She has required penetrating keratoplasty for restoration of her globe.

Finally, it is important to mention acanthamoeba acanthamoeba keratitis. Figure 7 is a photograph of the cornea of a medical student who wore extended-wear lenses only at night when on call. He developed acanthamoeba keratitis, which is still under treatment. It is a very difficult infection to treat, and our present armamentarium is quite inadequate. Epidemiologically, this infection is linked to the use of homemade saline and to swimming with contact lenses in place. The best thing about this devastating infection is that it is rare.

Chart 1 presents the microbiology of cases of lens-associated microbial keratitis that we reviewed over a 4-year period at the Massachusetts Eye and Ear Infirmary. During this time contact-lens-related ulcers accounted for about 30 to 40 percent of all cases of corneal ulceration. As shown in the table the gram-positive and gram-negative organisms are about evenly divided, but there are certain patterns. Staphylococci and the streptococci account for about 90 percent of the gram-positives, and there is a disproportionate contribution of pseudomonas in the gram-negatives.

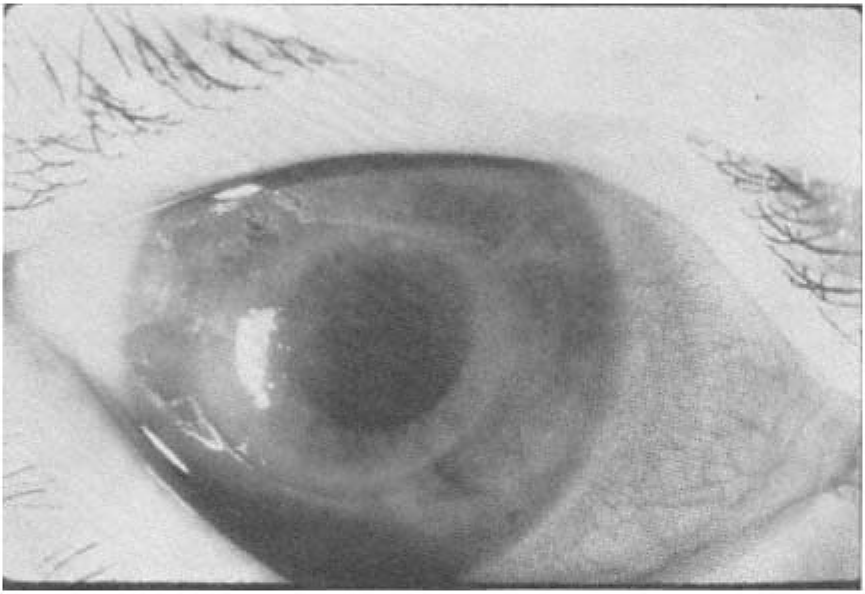

Figure 7
Acanthamoeba keratitis.

These cases also include the aphakic and some therapeutic lenses. Considering only the lenses used for cosmetic purposes, they are mostly gram-negative, and almost all of them are pseudomonal.

## DIAGNOSIS AND THERAPY

Diagnosis is based on clinical presentation wherein all infiltrates underlying an epithelial ulceration are presumed microbial. We take cultures by scraping the cornea and then start "shotgun" antibiotic therapy based on the microbiology shown above, typically with fortified aminogylcoside and cephalosporin antibiotics. In the setting of cosmetic use, we add either ticarcillin or piperacillin since these medications are synergistic with aminoglycosides against pseudomonas. Antibiotic choice and regimen are then suited to culture results and clinical course.

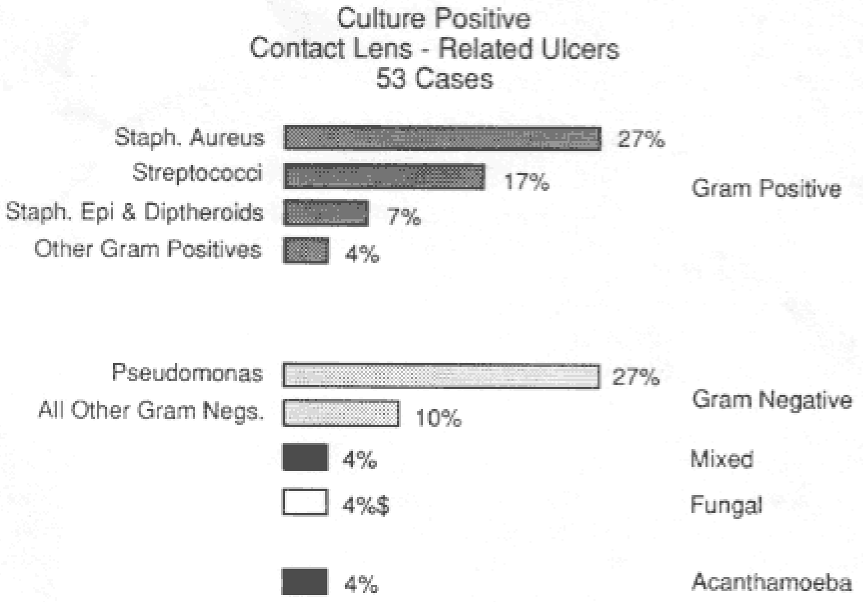

Chart 1
Microbiology of Contact-Lens-Associated Keratitis

## MILITARY APPLICATIONS

The preceding comments illustrate some of the medical background concerning contact-lens-related infections. I sense, however, that what is really important not just from the military perspective but from the civilian perspective as well is some concept of the rate at which such infections occur, the relative risk by various lens types, and the hygiene strategies that may impinge on the infection rates. This information, unfortunately, is very difficult to come by. Most studies to date involving large numbers of patients are from the contact lens industry. These are frequently premarket-approval trials in which both patients and eye care professionals are chosen on a selected basis, and the situation clearly does not resemble a real-life context.

With respect to the minor epithelial consequences of contact lens wear that result in pain, irritation, and discontinuation of lens wear on a temporary basis, the military has found that more than a third of soft contact lens wearers experience one or more ocular conditions requiring at least a temporary suspension of lens wear (Bachman et al., 1987).

What about the more important complications? What about microbial keratitis?

Two major studies have recently addressed this issue (Schein et al., 1989, and Poggie et al., 1989). The first, a case-control study of ulcerative keratitis among soft contact lens wearers, found that the relative risk of ulcerative keratitis was 10 to 15 times greater among users of extended-wear lenses. Additionally, this risk increased along with extent of time since removal of the lens for cleaning. Risk for this condition was only marginally affected by lens hygiene habits. Of lens-care-related issues, failure to clean the contact lens case (potentially a difficulty in military settings) was the most important.

The second study estimated the incidence of ulcerative keratitis among soft contact lens wearers. Thus study, using the entire population of Maine, New Hampshire, Vermont, Rhode Island, and Massachusetts as its base, found a rate of approximately one case of ulcerative keratitis per 500 wearers of extended-wear lenses per year, and one per 2,500 per year for wearers of daily-wear soft lenses.

One may extrapolate from these studies to estimate 12,000 cases of soft-contact-lens-associated ulcerative keratitis per year in the United States. These studies have led to a reduction in suggested wearing time for extended wear lenses by the Food and Drug Administration from 30 to 7 days. Whether this is sufficient remains to be seen. From a military perspective, if one assumes a population of 15,000 aviators wearing soft contact lenses on various schedules, one may estimate perhpas 15 cases of ulcerative keratitis per year in this population. Is this acceptable from a military standpoint? This is the kind of analysis the military must undertake before making a commitment.

Finally, given the rates estimated for ulcerative keratitis, it is clear that the internal military studies performed to date cannot address this question. These military trials may provide interesting information on costs and minor irritation that impede successful lens use in the field. However, the statistical power of these military studies in insufficient to estimate the risk of infection in military settings and such extrapolations are unwarranted.

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# Corneal Topography and Contact Lenses

Stephen D. Klyce

The cornea is a unique part of the ocular tunic, serving both as a tough coat to resist trauma and as a highly refractive, transparent optical element in the visual pathway. It is in essence an armored window, the port of entry for light to the eye and the visual system. But while the individual collagen fibers that give strength to the cornea are stronger than steel—collectively enmeshed as they are in a viscous extracellular matrix of sugar-protein macromolecules—they can be rearranged by abnormal forces such that the shape of the cornea can be altered.

Since the corneal surface is the major refracting element in the eye, even small changes in its shape can alter visual acuity. Visual acuity of 20/20 or better is required for air-to-air combat as well as for any other mission relying on direct visual sighting such as marksmanship. A major consideration is the fact that, while people can be fit with contact lenses to provide this acuity in the refracting lane of the clinic, contact lenses can and do produce both acute and chronic changes in visual acuity. With every blink of the eye (and the blink rate is increased with contact lens wear), the lenses are compressed and decentered to varying degrees. This causes a postblink defocusing that can last a second or more. When the lenses dry, lose their mobility, or center improperly, a series of blinks is required before proper acuity is achieved.

## CHRONIC EFFECTS

The chronic effects of contact lens wear on acuity are well known. Contact lenses can alter the shape of the cornea, and this fact was exploited vigorously for a time when practitioners sought to predictably change the shape of the cornea with contact lenses. However, this effort, called orthokeratology, was largely abandoned following negative results of a carefully controlled clinical trial by Polse et al. (1983). Unintentional or spontaneous changes in corneal shape are also a fairly common problem—changes that cause a loss of a line or more of visual acuity on the Snellen Chart—and these changes are not often reported because they occur so slowly that patients are unaware of the change until some loss of function is detected, such as having trouble reading highway signs. This problem is exacerbated by emotional ties to the contact lens modality to achieve adequate visual acuity.

At Louisiana State University (LSU) Eye Center in New Orleans, we have been interested in the problem of contact-lens-induced corneal warpage for several years now, since we were not able to address this problem adequately with the routine clinical tools available in the past such as the keratometer and the photokeratoscope. However, we have developed methods over this period that finally allow accurate assessment of the corneal topographic alterations that can be produced by contact lenses, and I will briefly review this technology and present a few case reports.

Clinical keratometers measure the power of the corneal surface from four points about 3 millimeters apart and it is assumed that the cornea is purely spherical or ellipsoidal, despite the fact that Mandell (1970) clearly showed over 30 years ago that corneas, even for a normal population, clearly deviated from spherical or ellipsoidal models. Many subsequent research papers attempted to reconstruct true corneal shape by computer analysis of photokeratoscopic images.

## LSU STUDIES

At LSU we were first concerned with accurate corneal surface reconstruction from photokeratoscopic images for which there is, unfortunately, no exact solution (Klyce, 1984). However, better approximations of true shape are nearly complete at LSU (cf. Wang et al., 1989). The more difficult task was to design graphical presentation schemes that could portray corneal distortions in a fashion permitting rapid interpretation by the clinician. Stereo-pair wire models of corneal surface distortion failed for the majority of the clinical audience. However, when color-coded contour maps of corneal surface powers were presented, clinicians could easily interpret their meaning and use them for diagnosis, for evaluation of refractive surgery, and for guidance in the correction of astigmatism following corneal transplantation and cataract procedures (Maguire et al., 1987). We have transferred these concepts to the corneal modeling system (CMS), a state-of-the-art automatic corneal topography analyzer manufactured by Computed Anatomy, Inc. in New York (Gormley et al., 1988). With this device it is now possible to evaluate in detail the effects of contact lens wear on corneal shape. The standard CMS graphic display is a color-coded contour map of corneal surface powers. For this report a gray scale version of the display was used. In each of the cases of contact-lens-induced corneal warpage presented below, only one eye is shown, but both eyes were similarly affected. Details of this study can be found in Wilson et al. (1990a, 1990b).

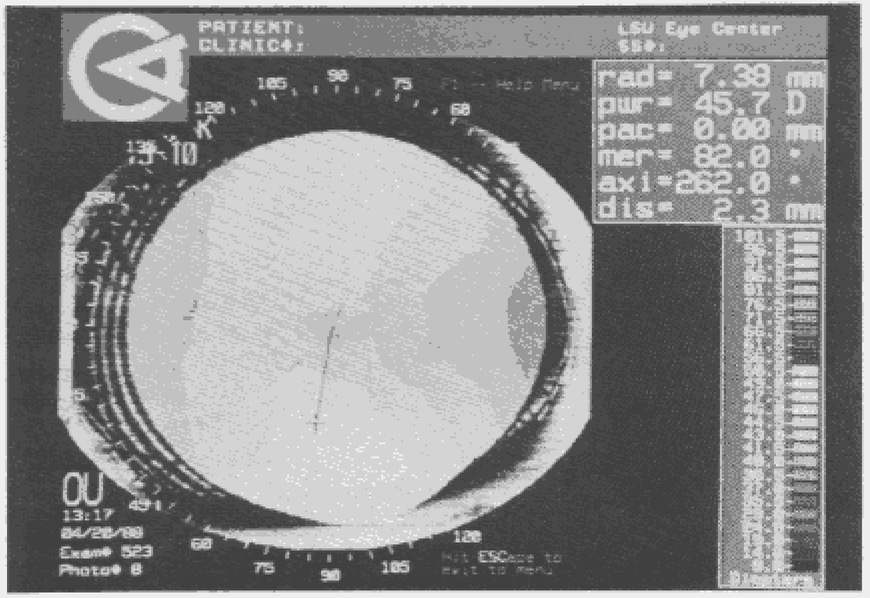

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Figure 1
Gray scale contour map of suspected keratoconus in a right eye, typically an inferior region of the cornea with higher than normal power. The cross-hair lies at the apex of the putative cone, and the score box in the upper right-hand corner reads 45.7D at this point. The key in the lower right indicates that over the near-normal range of corneal powers (1.5D intervals) lower powers are represented by dark shades, higher powers by lighter shades. If there were powers below 34D, they would be represented by an intensity-graded series of cross-hatching at SD intervals; if there were powers above 51.5D, they would be represented by an intensity-graded series of meshing. SOURCE: S.E. Wilson, and S.D. Klyce, LSU Eye Center, unpublished data.

## CASE REPORTS

### Case 1

Figure 1 presents data for a patient who complained of red and irritated eyes. With contact lenses she was seeing only 20/50. Her best corrected refraction was 20/25 in each eye. Both lenses were mobile, but both were riding low. With the CMS her power distribution was suggestive of early keratoconus in both eyes. To test the possibility of contact-lens-induced warpage, she was instructed to leave her lenses out for 1 month. On her return, corneal topography analysis was repeated, and her corneas now (Figure 2) exhibited regular corneal cylinder. Evidently the lenses had sphericized the superior corneal cylinder, leaving the lower cylinder intact. She was refitted with rigid gas-permeable lenses, achieving 20/20 acuity in each eye.

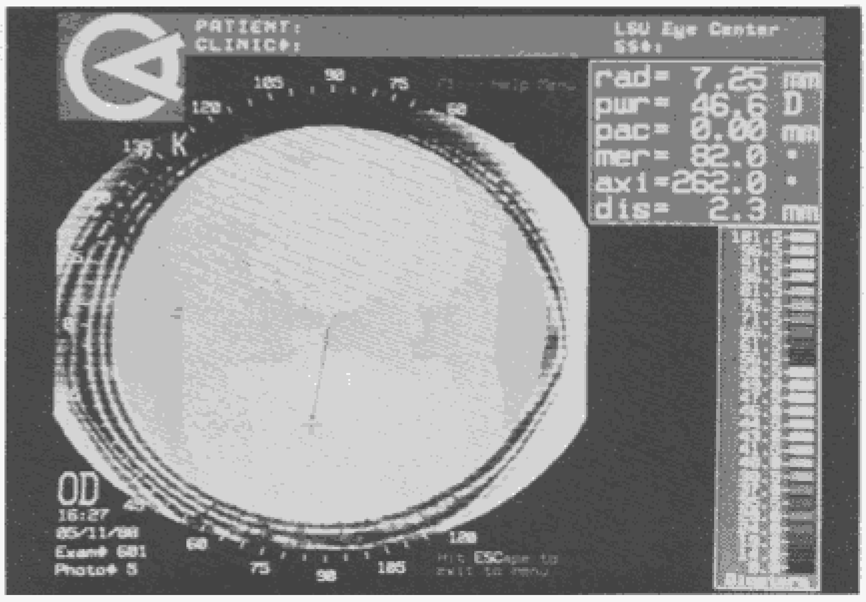
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Figure 2
Same cornea as in Figure 1, 1 month after discontinuance of contact lens wear. The corneal power distribution now shows a regular corneal cylinder. Apparently the lenses in both eyes were riding low, flattening the cornea superiorly, which led to the keratoconic pattern seen at the patient's first visit. SOURCE: S.E. Wilson and S.D. Klyce, LSU Eye Center, unpublished data.

## Case 2

Another patient presented with pain and glare sensitivity in both eyes. She was wearing Hydrocurve soft contact lenses with a base curve of 9.5 millimeters. The lenses were mobile, but keratometry and keratoscopy showed irregular mires and central distortion (Figure 3). She was instructed to discontinue contact lens wear for 3 weeks. On her return, she was asymptomatic and the corneal distortion seen on her first visit was absent (Figure 4). She was fitted with SoftMate contact lenses with a steeper base of 9.0 millimeters and is doing well with them.

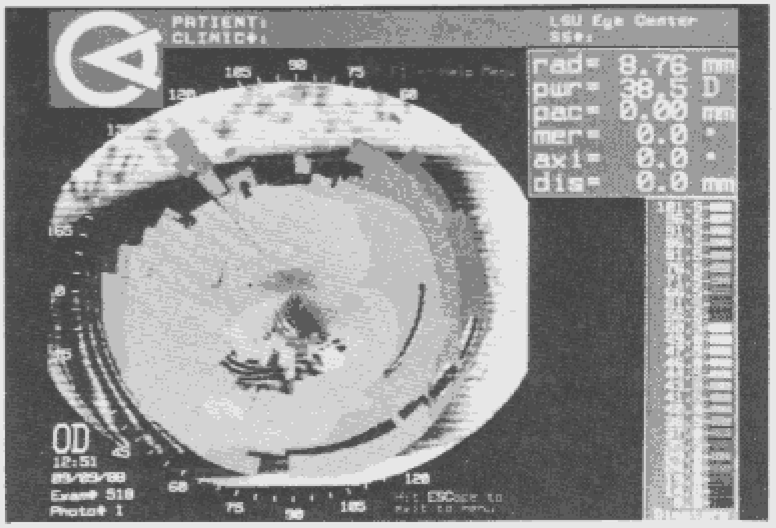

Figure 3
Central corneal distortion with irregular keratoscope mires in the right eye of a patient fitted contact lenses with perhaps too flat a base curve. SOURCE: S.E. Wilson and S.D. Klyce, LSU Eye Center, unpublished data.

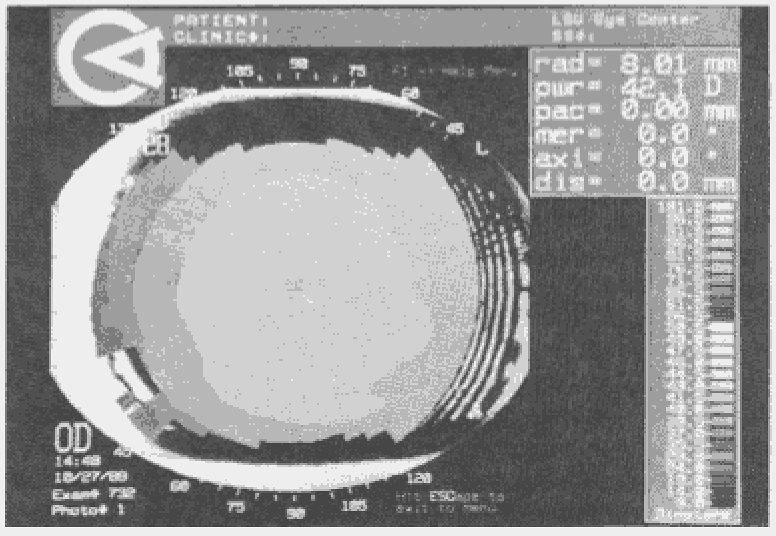

Figure 4
The cornea of Figure 3 was completely normal 3 weeks after discontinuing contact lens wear. The concentric rings of power shown here are typical for a cornea deemed "spherical" with keratometry. The lower power in the corneal periphery is normal and can partly correct for spherical aberration in the eye. SOURCE: S.E. Wilson and S.D. Klyce, LSU Eye Center, unpublished data.

## SUMMARY

In summary, I have presented several concerns regarding the use of contact lenses for military personnel. Acute or chronic fluctuations in visual acuity can degrade performance, leading to loss of functionality, but the impact of this in terms of overall military performance is unknown. Advances in technology have made it possible to evaluate contact lens effects on corneal shape. This technology should be used in prospective studies to determine the risk factors associated with contact lens wear in adverse conditions.

## ACKNOWLEDGMENT

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# Treatment of Giant Papillary Conjunctivitis

Mathea R. Allansmith

Contact lenses have become so familiar that both patients and physicians are likely to think of them as innocuous objects. They are widely prescribed for cosmetic reasons as well as to correct a variety of conditions that impair sight. But even the best tolerated contact lens is a prosthetic device on the surface of the eye and, like all prostheses, is foreign to the body. The tissues of the eye and its adnexa therefore mobilize normal responses to foreign bodies. For many contact lens wearers, the result may be minor inconvenience and relatively inconsequential problems with lens tolerance. For others, however, erythema, itching, increased mucus production, and formation of giant papillae on the upper tarsal conjunctiva may make prolonged wearing of contact lenses impossible. This disease related to wearing contact lenses and other ocular prostheses is now recognized as giant papillary conjunctivitis (GPC).

It is estimated that GPC affects 1 to 5 percent of the 12 million wearers of soft contact lenses in the United States and perhaps 1 percent of the 8 million wearers of rigid contact lenses. The prevalence of GPC among wearers of hard [polymethylmethacrylate (PMMA)] contact lenses in one large contact lens practice was carefully studied. Of the 200 subjects wearing PMMA contact lenses, 21 (10.5%) had elevated papillae larger than 0.3 millimeters in diameter. Of the control group of 500 non-lens-wearing subjects, only 3 (0.6%) showed elevated papillae larger than 0.3 millimeters in diameter (and two of these were later found to have the early stages of vernal conjunctivitis).

The age distribution of GPC patients is difficult to determine because it is a function of (1) who wears contact lenses, (2) how long they wear them, and (3) what type they wear. Contact lens wearers are usually in their second or third decade. The average length of time patients have worn contact lenses before developing GPC is 8 months for soft contact lenses and 8 years for hard contact lenses.

Patients who develop GPC secondary to their wearing contact lenses for purely cosmetic reasons could, albeit reluctantly, change from contact lenses to wearing eyeglasses. But the proper care of patients who *must* wear contact lenses (e.g., in the event of keratoconus of high myopia) requires a range of hygienic and medical interventions to manage the possible adverse reactions to wearing contact lenses and to prevent the onset of GPC.

As early as 1950 allergic reactions to wearing plastic contact lenses were reported (MacIvor, 1950). Spring (1974) noted the similarity of a contact-lens-associated disease to vernal conjunctivitis. Complications have been associated with the introduction of hydrogel lenses (Binder, 1980). Lens deposits have been identified as a major complication of extended-wear soft contact lenses (Binder, 1979) and a possible contributing factor to GPC (Allansmith and Ross, 1987). The relationship between lens deposits and GPC, however, is not clear.

There is no completely successful treatment of contact-lens-associated GPC (Donshik et al., 1984). Removal of the lenses and application of topical corticosteroids and cromolyn sodium have been recommended. We are beginning to understand enough about the pathophysiology of GPC to propose a program for the total management of the disease.

## DESCRIPTION OF GPC

The most salient feature of GPC is the presence of giant papillae on the upper tarsal conjunctiva. Giant papillae are arbitrarily defined as papillae with a diameter greater than 1.0 millimeters (Korb et al., 1980). Macropapillae (papillae with a diameter of 0.3 to 1.0 millimeters) are also abnormal.

GPC shows features of being an immediate type 1, IgE-mediated hypersensitivity and a type IV delayed reaction. The immediate hypersensitivity is mediated by specific IgE bound to mast cells in the conjunctival, but the nature of the specific antigen or antigens has not been discovered. The delayed inflammatory reaction is mediated by sensitized lymphocytes, reacting with antigen to release lymphokines, with resultant tissue inflammation and tissue damage.

Cellular infiltration of the conjunctival epithelium with mast cells, eosinophils, basophils, and polmorphonuclear leukocytes, as well as an occasional lymphocyte, is regularly observed in GPC. Eosinophils are present in conjunctival scrapings in somewhat less than one-fourth of individuals with GPC. The involvement of mast cells, basophils, or eosinophils in abnormal positions in the conjunctival tissue reflects the disturbed nature of the immune apparatus in GPC. All GPC patients examined had one of the following abnormalities: mast cells in the epithelium, eosinophils in the epithelium or substantia propria, or basophils in the epithelium or substantia propria (Allansmith et al., 1978).

Meisler and colleagues (1981) found a high percentage of IgE-containing plasma cells (27%) in patients with GPC associated with wearing an ocular prosthesis. Tear IgE levels have been found to be significantly elevated in patients with GPC, and tear IgE and IgG levels were higher in the more symptomatic eye of the patient (Donshik and Ballow, 1983). In 8 of the 18 symptomatic patients studied, tear IgM levels were measurable. In asymptomatic contact lens wearers and control subjects, no IgM could be measured.

Immediate hypersensitivity of IgE-dependent anaphylactic mechanisms alone cannot account for the histologic picture in GPC. The degree of mast cell degranulation and tissue edema and the increase in eosinophils seen in IgE anaphylactic reactions (Allansmith et al., 1981) do not include such features of GPC as increased tissue mass, presence of many inflammatory cells, extensive infiltration with eosinophils, increased number of mast cells in the substantia propria and epithelium, and the presence of basophils.

The cellular infiltrate of giant papillary conjunctivitis and vernal conjunctivitis suggests a common immunologic basis for the two diseases (Allansmith et al., 1979). The mechanism of GPC is probably a basophil-rich delayed hypersensitivity (similar to cutaneous basophilic hypersensitivity) with a possible IgE humoral component. In (genetically) predisposed individuals, irritation caused by the foreign body combined with grinding the antigen repeatedly against the conjunctiva is thought to trigger a hypersensitivity response.

Mechanical trauma is important in the pathogenesis of GPC. The condition is nearly universally present in patients with ocular prosthesis in whom excess mucous production can be observed. Abrasion of the upper palpebral conjunctiva by exposed suture ends (suture barb giant papillary conjunctivitis) has been reported and resolves with removal or trimming of the offending sutures (Jolson and Jolson, 1984; Nirankari et al., 1983).

Studies of the ultrastructure of tissues from GPC patients and vernal conjunctivitis patients (Henriquez et al., 1981) disclosed that patients with vernal conjunctivitis have more mast cells in the epithelium and substantia propria of the conjunctiva than do patients with GPC and that the mast cells are more completely degranulated. The greater number of mast cells in vernal conjunctivitis can explain the further findings of greater mediator-associated changes: higher tear histamine levels, more eosinophils, greater itching and inflammation, and more corneal pathology.

Buckley (1985), however, has suggested on the basis of histologic evidence that there might be two types of GPC. One type closely resembles vernal keratoconjunctivitis and is found among atopic patients. A second form of GPC, unlike the first, is characterized by epithelial hyperplasia, nonspecific cellular infiltrates, and the absence of eosinophils. Although two forms of the disease may exist, the fact that mast cells within the conjunctival epithelium play a major role in the pathophysiology gives an important clue to effective treatment.

## DIAGNOSIS OF GPC

Early diagnosis is an essential component of the treatment of GPC. But, unfortunately, the earliest clues to the development of GPC in soft lens wearers are minor and are usually dismissed by patients as inconsequential: increased mucus in the nasal corner of the eye on arising and itching immediately after removing the lens. Patients, thinking that these minor signs and symptoms are "normal," may never report them to their physicians.

In more severe stages of GPC, patients may complain of mild blurring of vision after hours of wearing the lens (from deposits on the lens and not corneal edema), readily apparent excess mucus, and movement of the lens on blinking.

In advanced stages of GPC, patients cannot tolerate the foreign body sensation of pain associated with wearing the contact lens. Sheets or strings of mucus are present, sufficient sometimes to glue the eyes shut on waking in the morning. At this stage, the lenses are visibly clouded by mucus soon after they are inserted. Abnormal amounts of deposits on the soft lenses are a constant feature of the syndrome. Deposits on the lens are most easily seen by drying the lens slightly and looking through it against a light. Although some asymptomatic wearers of soft contact lenses may also produce heavy deposits on their soft lenses, all symptomatic wearers do.

Usually patients report the symptoms of GPC long before the appearance of definitive clinical signs. Furthermore, patients vary widely in how much ocular discomfort they will tolerate from various degrees of GPC. Some patients may continue wearing their soft contact lenses despite scores of giant papillae covering both upper tarsal plates. Other patients may stop wearing their soft contact lenses because of the itching and increased mucus, although the only definitive sign of GPC is conjunctival thickening. Such patients will complain of lens intolerance even though no giant papillae are apparent.

Early in the clinical stage of GPC, the normally small papillae become obscured by more elevated ones. Small normal papillae do not enlarge to become giant papillae; new abnormal papillae begin to grow from the substructure of the deep conjunctival or tarsal area. At this point there is a generalized thickening of the conjunctiva. The conjunctiva has a translucent rather than transparent appearance, and the vasculature of the plate becomes more visible. The conjunctiva may appear hyperemic. In the more aggravated stage of GPC, the conjunctiva loses translucency to become more opaque (due to cellular infiltration), and it is possible to observe the earliest demar cations of macropapillae (0.3 to 1.0 millimeters) or giant papillae (1.0 millimeters or greater).

As the disorder progresses, giant papillae increase in size and elevation. The surface flattens to produce a mushroom appearance devoid of remnants of the small papillary pattern. As the number and size of giant papillae increase, they may almost completely cover zones 1 and 2 with papillae ranging in size from 0.6 to 1.75 millimeters in diameter, with most approximately 0.75 to 1.0 millimeters in diameter.

Papillae and follicles resemble each other in some respects, and both are signs of active inflammation in the palperbral conjunctiva. Giant papillae are distinguished from follicles, however, by the presence of blood vessels in the centers of the follicles as well as around the edges. Follicles are more commonly observed in the inferior palpebral conjunctiva and the inferior fornix. Papillae are more commonly observed in the upper palpebral conjunctiva. The side walls of papillae are often perpendicular to the plane of the tarsal plate and not pyramidal-like follicles. Papillae may have white heads resembling scars. These white, scar-like areas usually regress as the papillae regress. Some patients with GPC may have Horner-Trantas dots (Meisler et al., 1980). A network of fine dilated blood vessels may be observed in GPC. The disease may also be confined to the limbus in some patients, with no infiltration of the lid.

## TREATMENT OF GPC

The goal of treatment is to allow the GPC patient to continue wearing contact lenses or to tolerate an ocular prosthesis with the benefit of the most effective and least obtrusive therapeutic program (Molinari, 1982). Nonetheless, the treatment of GPC is complex, requires carefully sequenced clinical divisions, and can be both tedious and expensive for the patient and the physician.

Six conditions favor the development or exacerbation of GPC: increased deposits on the lenses, increased time per day that lenses are worn, use of lenses consistently for months or years, individual reactivity to wearing a particular lens type, larger lens and therefore broader area of adhering antigenic material, and genetic constitution of the patient.

The treatment of GPC depends on three therapeutic strategies: teaching the patient to clean the lens, finding the best tolerated lens, and treating the conjunctival inflammation.

## Cleaning the Lens

### Lens Care

Patients must clean the lens thoroughly, preferably using cleaning agents that are free of preservatives (e.g., thimersol). The lens should be rinsed and stored in fresh saline. Cold disinfecting solutions preserved with chlorhexidine should not be used.

Three methods of sterilizing the lens are currently available: cold disinfection, heat disinfection, and treatment with hydrogen peroxide. In cold disinfection the lenses remain overnight in the unheated disinfecting solution. Heat disinfection is effective, but the heat bakes the deposits on the surface of the lens. Hydrogen peroxide treatment depends on the disinfecting power of hydrogen peroxide, which is then neutralized by contact with a platinum disc. Of the three commercially available methods, treatment with hydrogen peroxide seems to be the best tolerated by the inflamed or potentially inflamed conjunctiva.

### Deposits

Patients should clean their lenses with a proteolytic enzyme at least once a week. For some patients daily cleaning with a proteolytic enzyme is recommended. Of the two enzyme preparations on the market—the proteolytic enzyme papain and a pancreatic enzyme containing lipases and proteolytic enzymes—the papain enzymatic cleaner seems to be more effective in removing deposits and quieting the GPC.

## Type of Contact Lens

### Lens of the Same Design

In many patients GPC can be controlled by reestablishing good cleaning practices, a new lens of the same design, and replacing the contact lenses every 6 to 12 months. The patient should then be instructed to clean the lens thoroughly and to use enzymatic cleaning as described above.

### Lens of a Different Design

If proper care and cleaning of the lens and regular replacement do not resolve the GPC, a new contact lens of a different design should be prescribed. A lens of a different design and a polymer different from the one worn when the GPC developed (i.e., change manufacturers) should be prescribed.

A lens of a lower water content also can be prescribed. We have initial evidence that non-hydroxyethylmethacrylate (HEMA) lenses may be better tolerated by patients with GPC than HEMA-containing lenses. Patients should be instructed to clean the new lens following the procedure described above.

### Lenses of Different Design for Each Eye

A third maneuver in discovering a tolerable lens design is to prescribe lenses of different design for each eye. For example, one might prescribe a Hydrocurve lens for one eye and a CSI for the other, avoiding the polymer and design that had been associated with exacerbation of the GPC.

### Rigid Gas-Permeable Lens

A fourth option is to prescribe a rigid gas-permeable (RGP) lens rather than a soft (hydrogel) lens. RGP lenses are smaller and thus have less surface to hold deposits. The edge of a gas-permeable lens can be reshaped to be less traumatic to the conjunctiva. Finally, deposits are more easily removed from RGP lenses than from hydrogel lenses.

## The Conjunctiva

### Irrigation

GPC patients can often tolerate their lenses if they irrigate the conjunctiva with unpreserved saline two or three times a day.

### Withdrawal of Lenses

Contact lenses must be withdrawn under certain pathologic conditions: (1) staining of the tops of the giant papillae when fluorescein is introduced to the tear film, (2) heavy mucus observed on the papillary conjunctiva, (3) significant tarsal hyperemia, and (4) increased lens movement (decentering of the lens) when the patient blinks. Lenses should not be reintroduced until the patient has been free of symptoms for 3 to 5 days and the hyperentia has resolved.

Partial resolution of certain signs is acceptable. For example, the large papillae need not decrease in size, but they must be completely healed (as disclosed by failure of fluorescein to stain the tops of the papillae). Itching and heavy mucous production must be resolved.

## Cromolyn Sodium

If GPC symptoms recur after this hygienic program has been followed, cromolyn sodium 4 percent ophthalmic solution may be applied four times daily. Cromolyn sodium may be applied with the contact lens in place. We have found no difficulty in using benzalkonium chloride preserved cromolyn sodium solution while the contact lens is being worn.

Donshik and colleagues (1984) carried out a carefully controlled study of the effects of changing various lens parameters and the use of topical cromolyn sodium in the treatment of patients with GPC. Of one group of patients (N = 22), 17 GPC patients (77 percent) found relief by being fitted with new lenses of a different type, but 5 patients suffered a recurrence of symptoms within an average of less than 6 months. Of a second group of patients (N = 17) refitted with the same type of lens, 11 GPC patients (65%) were relieved of symptoms, but 6 patients suffered a recurrence of symptoms. A group of the patients for whom hygienic measures failed to give relief (N = 9) was treated with 2 percent cromolyn sodium. Of this group of difficult cases, 7 patients (78 percent) were relieved of symptoms when treated with cromolyn sodium and were able to resume wearing their contact lenses. The average follow-up period was 7.7 months (range of 5–12 months). The authors reported that there had not been any adverse effect from cromolyn sodium on the contact lens.

Matter et al. (1984) reported the results of a 6-week, double-blind, placebo-controlled study of cromolyn sodium in the treatment of contact-lens-associated GPC in 37 actively symptomatic GPC patients. The authors reported the clinical and statistical ($p < .05$) superiority of cromolyn sodium over placebo in relieving the dryness, grittiness, and abnormal lens movement associated with GPC. Clinical signs were likewise improved after treatment with cromolyn sodium. Cromolyn sodium reduced hyperemia in the bulbar conjunctiva and upper and lower tarsal conjunctiva, diffuse infiltration and size of palpillae in the upper tarsal conjunctiva, and mucous production in the lower tarsal conjunctiva and fornix.

In addition to the effectiveness of cromolyn sodium in the treatment of active GPC, its safety makes it valuable as a drug for treating the earliest signs of disease and as a prophylactic agent. We have found it useful in the very early stages of GPC. Cromolyn sodium is also helpful in resolving early (stage 1) symptoms of GPC—increased mucous production and mild itching without giant papillae forming in the upper tarsal conjunctiva. It is not effective, however, in the treatment of the final stages of GPC. However, it is well worth considering use of it as a daily drop to prevent emergence of symptoms in a high-risk, high-need patient.

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# Endothelial Effects from Contact Lens Wear

John P. Schoessler

Let me preface my remarks by saying that I too will address a risk associated with contact lens wear. It is a long-term risk and does not apply to an immediate concern for pilot performance during a mission. I consider those concerns to be the distracting and debilitating influences, such as unstable acuity, discomfort, and dislodging of the appliance. Putting contact lens risks into perspective, they are probably nothing like the risk of climbing into a high-tech aircraft and riding it multiple times the speed of sound.

I believe attitude in performance of any task counts for much. If there is a perceived advantage in the wearing of contact lenses versus spectacles when piloting an aircraft because of the "freedom" afforded the pilot in terms of not having spectacles "hanging on the face," I guarantee that it will result in better performance—directly measurable or not.

Nevertheless, just as in the civilian community, military personnel about to be fitted with contact lenses must be apprised of the immediate and long-term risks of contact lens wear, so that wearers will not return saying: "I didn't know contact lenses might cause corneal ulcers" or "You didn't tell me about 'Agent Contact Lens'."

With this in mind, let me tell you about one long-term effect of contact lens wear.

An unexpected revelation in recent years has been that contact lens events at the anterior surface (or epithelial layer) of the cornea produce effects at the back surface (or endothelial layer). The endothelial cells line the back of the cornea as a single monolayer.

Because of the importance of the role of the corneal endothelium in controlling corneal hydration, there has been interest in studying the consequences of contact lens wear on this layer. There is a tendency for the corneal stroma to swell and absorb water, but this is normally held in check by the front and back corneal barriers—the epithelium and endothelium. In addition, the endothelium is responsible for actively transporting water out of the stroma to maintain partial stroma dehydration. The importance of the endothelial layer is readily seen. Any major breakdown in its function as a barrier or pump will produce uncontrolled corneal swelling, loss of corneal transparency, and bullous kertopathy. The application of certain contact lens designs to the cornea places stress on the system, since the anterior hypoxic environment allows buildup of lactate in the stroma, which in turn draws water in from the aqueous. The corneal endothelium then must counteract this extra hydrating force.

The normal corneal endothelium of a person who is a nonuser of contact lenses consists of a fairly regular mosaic pattern of cells. The majority are six-sided. The sizes of the cells are nearly the same, with larger cells tending to be about three to four times the area of the smallest cells for young adults. Figure 1 shows the normal endothelial cell pattern in a 24-year-old male who has never worn contact lenses.

The endothelial cell density in the normal population has been extensively studied. The corneal endothelial cell density declines slowly over the life of an individual but never reaches a critical level of compromise. A cell density of about 2,800 cells per square millimeter is considered average. The cell density is apparently higher among persons of Japanese descent. These relationships are illustrated in Figure 2 in terms of mean cell area (1/density).

Generally, corneal endothelial effects from contact lens wear can be divided into two categories: transient (or "blebs") and long-term (or pleomorphic).

## TRANSIENT ENDOTHELIAL CHANGES FROM CONTACT LENSES

Endothelial "blebs" were first described by Zantos and Holden (1977). These dark areas in the endothelial mosaic pattern are maximally observed 25–30 minutes after placing a hard or soft lens of low oxygen transmissibility on an eye previously unadapted to contact lens wear. The blebs gradually fade away as contact lens wear continues past 2 hours.

If the contact lens is removed at the peak of the bleb response, the mosaic returns to normal within minutes (Figure 3). Subjects vary markedly in the number of blebs produced.

The appearance of corneal endothelial blebs has been noted not only with contact lens wear but also with lid closure, nitrogen goggles, and carbon dioxide environment. The apparent cause for the dark areas is a bulging of the posterior cell membrane of certain endothelial cells, causing a disruption of the specularly reflected light.

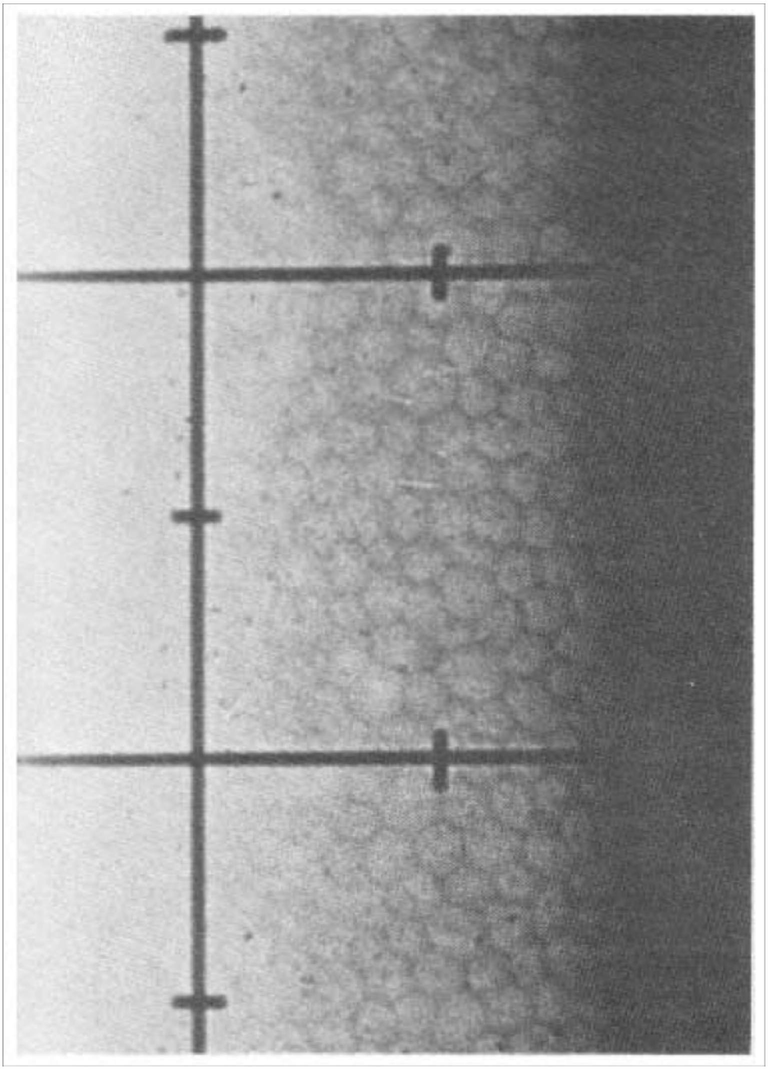

Figure 1
Endothelial cell pattern of a 24-year-old nonuser of contact lenses. SOURCE: Schoessler (1988).

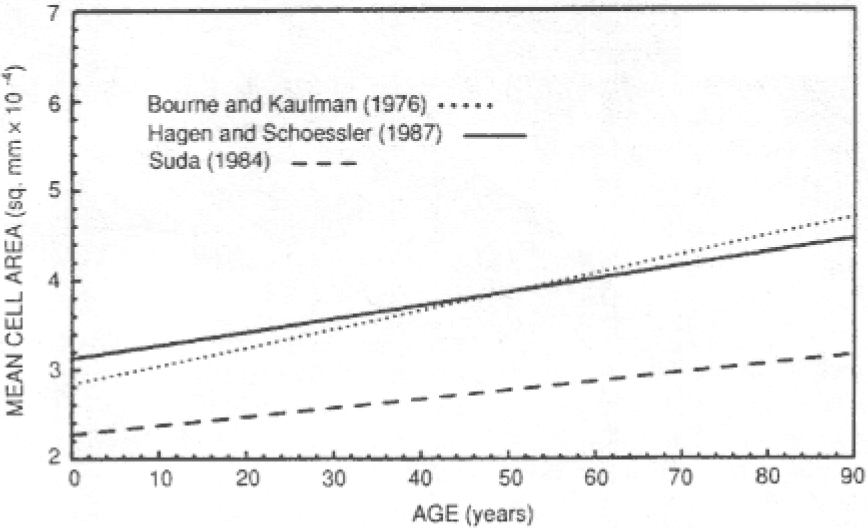

Figure 2
Mean endothelial cell area versus subject age. SOURCE: Schoessler (1988).

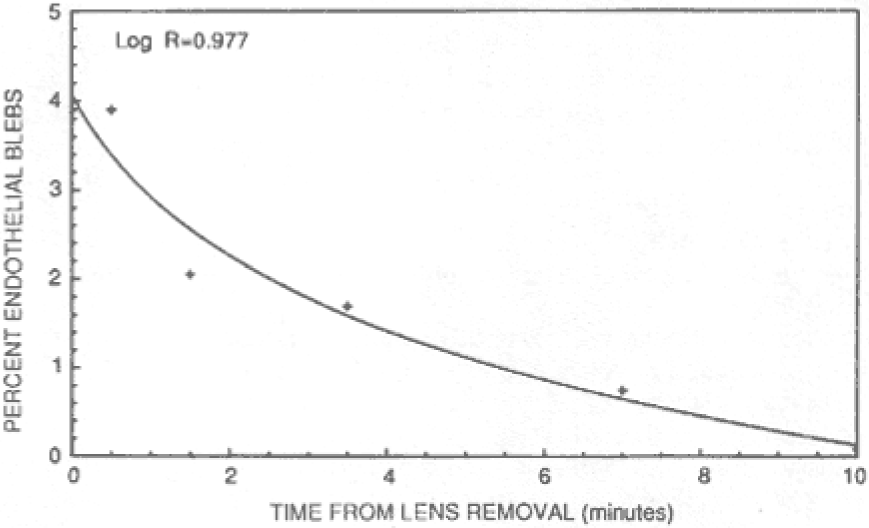

Figure 3
Recovery of the "bleb response" to contact lenses. SOURCE: Schoessler (1988).

This effect on the endothelium is said to be mediated by a pH change in the corneal tissue initiated by the corneal hypoxia. The significance of the bleb response and its wide quantitative variation among nonusers of contact lenses is not well understood. In any event, as this phenomenon is studied, it seems probable that the corneal endothelial bleb response to contact lenses will be found to bear some relationship to the viability of corneal endothelial cells.

## LONG-TERM ENDOTHELIAL CHANGES FROM CONTACT LENSES

Endothelial changes over time are usually quantified not only by cell density but also by the amount of polymegethism and the percentage of hexagonal cells. Endothelial cell measures are (1) cell density (cells/square millimeter), (2) polymegethism (coefficient of variation of mean cell area), and (3) pleomorphism (percentage hexagonal cells).

### Endothelial Cell Density

Contact lens wear apparently does not affect endothelial cell density. The literature overwhelmingly supports the view that there is no loss of endothelial cells even over long periods of wear.

### Endothelial Polymegethism

Contact-lens-induced polymegethous corneal endothelial changes are characterized by marked endothelial cell size variation (Schoessler and Woloschak, 1981). Such cell size variation has been noted to occur gradually with age, but not to the extent or suddenness with which it appears in contact lens wearers. Examples of corneal endothelial polymegethism in long-term contact lens wearers are seen in Figure 4.

Endothelial cell polymegethism is characterized by the development of many cells that are smaller than normal and by the development of cells much larger than normal.

Corneal endothelial cell area distributions for long-term contact lens wearers differ from those of nonusers of contact lenses. A comparison of cell area distributions for contact wearers and a sex-and age-matched control group of nonwearers is shown in Figure 5.

The coefficient of variation (standard deviation divided by the mean) of endothelial cell area is the generally accepted measure of endothelial polymegethism. For nonusers of contact lenses in the age range of 20–30, the coefficient of variation of endothelial cell area is generally about 24 per

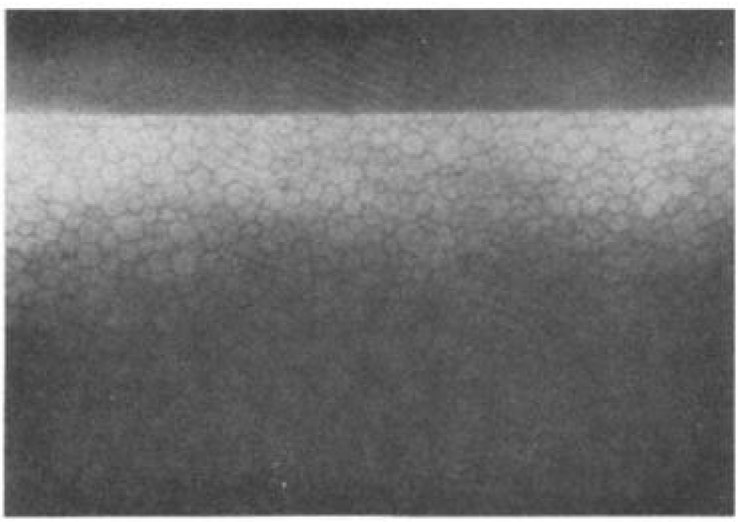

Figure 4
Contact-lens-induced corneal endothelial polymegethism.

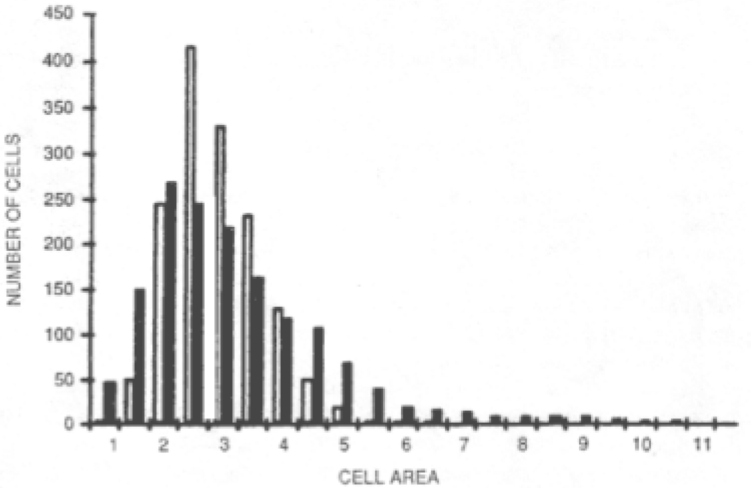

Figure 5
Endothelial cell area distributions for contact lens wearers and age- and sex-matched controls. The abscissa is the cell area × 10 millimeters. SOURCE: Mandell (1988).

cent. For the same age range, contact lens wearers may show coefficients of variation for endothelial cell area that may approach 60 percent or greater.

Endothelial cell polymegethism has been noted with polymethylmethacrylate (PMMA) wear (Schoessler and Woloschak, 1981; Stocker and Schoessler, 1985), in hydrogel daily (MacRae et al., 1986) and extended wear (Schoessler, 1983), in rigid gas-permeable daily (Woloschak, 1983) and extended wear (Orsborn and Schoessler, 1988), and with continued eye closure (Schoessler and Orsborn, 1987). Endothelial cell polymegethism has not been found in persons wearing silicone elastomer for daily and extended wear (Schoessler et al., 1984).

### Cell Pleomorphism

As endothelial cells become larger or smaller as a result of contact lens wear, they also tend to deviate from the normal hexagonal pattern. Larger cells tend to have more than six sides, while smaller cells are often pentagonal. The numbers of hexagonal cells are generally reduced to about 50–60 percent of the endothelial mosaic.

In addition, the endothelium of eyes exposed to long-term contact lens wear is often characterized by irregularly shaped cells. Examples of such cells are noted in Figure 6. Such extreme changes in cell morphology have generally not been described for the normally aging patient.

Endothelial cell photographs from contact lens wearers may also reveal cells that appear thick or "swollen." These cells seem to project out of the mosaic pattern and are mostly noted in persons who have worn PMMA contact lenses for long periods of time. Examples of this phenomenon are seen in Figure 6.

## DISCUSSION

It is obvious that corneal endothelial cells respond both immediately and chronically to corneal hypoxia. Prolonged contact-lens-induced hypoxia causes: no change in endothelial cell density, increased endothelial polymegethism, decreased numbers of hexagonal cells, increased numbers of irregular cells, unevenness of endothelial mosaic pattern, and decreased cell functional capacity. The implications of these phenomena are not completely clear, although some trends are becoming evident.

The significance of polymegethous and pleomorphic cell changes lies in the notion that they are correlated with loss of endothelial cell function. It is not apparent whether the barrier function or pump mechanism of the endothelium, or both, is altered. Conner and Zagrod (1986) suggest several mechanisms by which the endothelial barrier and pump functions may be altered by contact lens wear. One suggestion is that ATP levels and altered calcium homeostasis may be responsible for contact-lens-induced endothelial polymegethism. In addition, other suggestions as to the actual agent involved in producing the cell changes include pH shift and lactate or carbon dioxide buildup. Some investigators postulate that the barrier function of the endothelial layer is faulty by reason of aberrated cells with altered interdigitations producing an ineffective barrier (Rao et al., 1984).

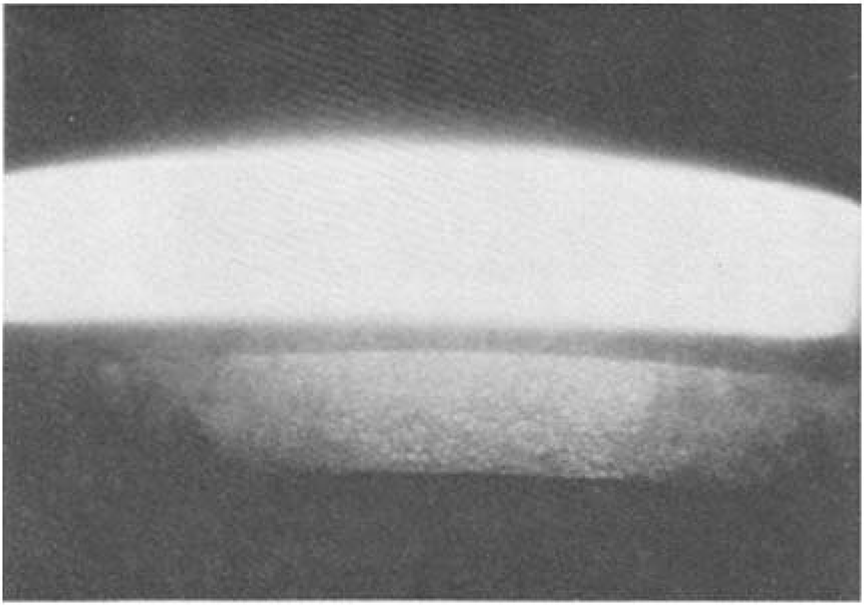

Figure 6
Endothelium of a long-term contact lens wearer. The mosaic demonstrates irregular and "swollen" cells.

Rao and co-workers (1979, 1984) have shown that persons with corneal endothelial polymegethism are at greater risk for corneal swelling complications following surgery for (IOL) implantation. The implication is that contact lens wear may alter endothelial cells sufficiently to impair their ability to allow the cornea to regain normal deturgescence following severe corneal stress, such as that from IOL surgery. This conclusion reemphasizes the need for development of contact lens materials with high oxygen permeability. Lens design becomes a key factor also for providing maximum oxygen transmissibility. This would include the use of thinner rigid bitoric lenses for patients with moderate corneal astigmatism instead of rigid spherical back curve lenses designed with increased center thickness to prevent lens flexure. The development of endothelial polymegethism may also be responsible for the "corneal exhaustion syndrome," whereby persons who have worn

PMMA lenses for many years suddenly find they are not able to tolerate them anymore.

Complete recovery from significant endothelial polymegethism is apparently not possible. Only slight recovery from contact-lens-induced endothelial polymegethism has been noted following cessation of contact lens wear or after switching to lenses of significantly higher oxygen transmissibility. The development of contact-lens-induced endothelial polymegethous cell changes is the indirect result of corneal hypoxia and is related to contact lens oxygen transmissibility, contact lens design, hours of contact lens wear, and type of wear (daily or extended).

It is certain that contact lens events at the front of the cornea affect the status of the important endothelial layer. For the majority of the present contact-lens-wearing population, this may mean an increased risk of corneal swelling complications or other problems following high corneal stress such as corneal surgery. One must be concerned not only with the reported results of cataract/IOL surgery but also with potential long-term problems associated with radial keratomy procedures on corneas with polymegethous endothelial cells.

Furthermore, a recent case study by Roth (1986) reports the observation of an apparent spontaneous bullous kertopathy resulting from pleomorphic endothelial changes induced by long-term PMMA and soft contact lens wear. This could possibly indicate that a contact lens environment alone is enough of a stress factor to cause corneal decompensation in some persons with abnormal endothelial cells. It is obvious that this topic will be the focus of much research for some time to come. At present, measures to reduce the probability of contact-lens-induced endothelial changes include using contact lens materials with the highest oxygen transmissibility and advising patients to use daily-wear lenses during waking hours only.

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# CONTACT LENSES AND THE EYE: PRACTICAL CONSIDERATIONS IN EVERYDAY AND MILITARY LIFE

# Corneal Effects of Extreme Environments: Considerations for Pilots Wearing Contact Lenses

Joshua E. Josephson

A review of the literature revealed several areas of concern that may be applicable for considering the ocular risks of military pilots wearing contact lenses in various extreme environments. However, there were a few limitations to the implications or interpretations of these reports in the literature. Many of the studies did not use controls. In addition, others involved animal experiments without human follow-up.

## WIND FORCE

Gauvreau's (1976) study of free-fall-jumping parachutists fitted with soft lenses revealed that, when lenses were blown off the eye, corneal epithelial punctate staining and temporarily reduced visual acuity occurred.

## ULTRAVIOLET RADIATION AT HIGH ALTITUDES

Increased ultraviolet radiation is a risk at higher altitudes. The effects of ultraviolet radiation are primarily a long-term risk. Ocular protection may be achieved by wearing a visor or by wearing ultraviolet-absorbing contact lenses, which are available in both hard and soft lens materials. Because a soft lens covers the diameter of all of the cornea, limbus, and a portion of the bulbar conjunctiva, it is more protective than the smaller hard lens.

## CLIMATE EXTREMES

### Heat

Brennan and Girvin (1985) tested subjects wearing soft contact lenses for 1 hour in an environment where the temperature was kept at 50°C, the relative humidity was 20 percent, and the wind speed was 1.5 meters per second$^{-1}$. They found no significant subjective or objective changes in vision or comfort.

Lovsund et al. (1979) investigated temperature changes in contact lenses on rabbit eyes when directly exposed to radiation from infrared heaters. When the rabbit eyes were kept open, the lenses tended to dry on the eye. When rabbits wearing soft lenses were exposed to radiation from certain types of welding (such as manual metal arc, tungsten inert gas, and metal inert gas), a great increase in contact lens temperature was noticed, especially with manual metal arc welding. It should be noted that the rabbits did not have the ability to turn away from the stimulus and that their blink rate is significantly less than that of humans. Although these experiments provide information, the situations may not be a realistic representation of the human situation. They may be even less representative of cockpit environment.

### Cold

Socks (1982, 1983) examined the effects of extreme cold on the eyes of rabbits wearing contact lenses. One eye of each rabbit was fitted with a hard contact lens, while the other eye served as the control. The rabbits were then exposed to a temperature of -28.9°C with winds up to 78 miles per hour for 3 hours. Throughout the cold exposures no permanent harmful effects were produced. Minor epithelial damage, which cleared within a few hours after exposure, was detected in three animals. Socks suggested that contact lenses may be acceptable in an extremely cold environment and may protect the eye from wind-driven ice and snow.

### Increased Humidity

The average comfortable indoor humidity is between 35 and 45 percent. An increase in ambient humidity has been reported to have no significant effect on vision or ocular response (Eng et al., 1982).

### Decreased Humidity

Brennan and Girvin (1985) reduced relative humidity to 21 percent and found that it had no significant effect on vision or ocular health. Eng (1979), using a survey of flight attendants on commercial aircraft, where the ambient relative humidity is in the range of between 7 and 11 percent, related that 50 percent of the flight attendants reported significant discomfort within 2 hours of takeoff and that 85 percent reported significant discomfort after 5 hours. Jagerman (1973) and Corboy (1980), ophthalmologists at hospital emergency rooms near airports, have encountered a conspicuous frequency of corneal epithelial damage and edema in lens wearers who had just completed long nonstop high-altitude flights. They have anecdotally associated these problems with the dry cabin environments.

Zantos et al. (1986) observed subjects wearing high-water-content hydrogel lenses of various thicknesses in normal-and low-humidity environments. In low-humidity environments, some subjects developed a localized central or inferior central epithelial breakdown. This was particularly noted with very thin extended-wear lenses. Others have observed similar effects with very thin hydrogel lenses (Holden et al., 1986; McNally et al., 1987).

Low humidity and moving air that induces evaporation from the lens surface have been implicated as the cause of central and inferior central keratitis associated with soft lens wear, especially with thin extended-wear lens.

## EFFECTS OF ALTITUDE ON THE CORNEA

Two studies that investigated the effects of reduced atmospheric pressure on subjects wearing contact lenses showed significant adverse ocular effects. All other studies reported minimal adverse ocular effects.

Hapnes (1980), working with 38.5 percent hydroxyethylmethacrylate (HEMA) lenses worn by subjects in a low-pressure chamber, decreased the atmospheric pressure "fairly rapidly" to an altitude equivalent to 18,000 feet for a partial pressure of oxygen of 80 mmHg. Ambient temperature was maintained at 21°C and the relative humidity 42 percent (an unrealistically high figure for any useful investigation of a high-altitude cabin environment). Air circulation was "below draught" conditions. After 3 hours all subjects developed debris in the tear film, and three to five subjects experienced ocular irritation in both eyes. After 4 hours one subject had significant discomfort, pronounced ciliary injection, photophobia, and abundant lacrimation. At this point the test monitors were obligated to temporarily stop the test. Hapnes found that there was no change in corneal thickness in these subjects; however, visual acuity was reduced from one to three lines in 6 out of 10 eyes. There was no change in visual acuity in 4 eyes.

Castren (1984) tested subjects in a hypobaric chamber at an atmospheric pressure equivalent to 13,000 feet. The relative humidity varied between 42 and 64 percent. This humidity was unrealistically high for the investigation of a cabin environment. All soft lens wearers developed injection. Corneal "erosions" were observed in 4 eyes and stromal "opacities" in 10 eyes. Fluorescein staining was "pathological" in 4 out of 14 eyes.

Eng et al. (1978) tested subjects wearing Bausch and Lomb soft lenses at 20,000 feet and 30,000 feet and found no change in visual acuity, refraction, or keratometry. At the conclusion of their study the subjects reported that their eyes felt tired and dry but that there was no severe ocular discomfort.

Flynn et al. (1985) observed polymethylmethacrylate (PMMA) rigid lens wearers up to 40,000 feet and found that 66 percent of eyes showed central bubbles, primarily at altitudes greater than 18,000 feet. Two subjects with large bubbles were subjectively aware of blurry vision. Rigid gas-permeable lens wearers were tested to a maximum of 25,000 feet. Central bubbles were found in 2 out of 10 eyes, particularly at 20,000 feet. These bubbles dissipated rapidly. All subjects had bubbles under the edge of the contact lens, which cleared rapidly with blinking. There were no adverse effects on vision or comfort, and the epithelium was unaffected. Soft lens wearers were also tested, and 33 percent had bubbles up to 25,000 feet. However, the bubbles were present at the limbus only and dissipated over several minutes. There were no adverse effects on the central cornea or on vision. The occurrence of subcontact lens bubble formation and the duration of bubbles may be related to the gas transmissibility of the contact lens. In the case of rigid contact lens a further variable may be the affectivity of the lens design in blink-induced tear pumping.

Flynn et al. (1988) examined subjects fitted with low-, medium-, and high-water-content soft lenses and with spectacles worn in a hypobaric chamber. The temperature was maintained at 21 to 25°C. Simulating a fighter-attack-reconnaissance (FAR) aircraft cabin environment, subjects breathed supplemental oxygen through oro-nasal masks. The relative humidity was maintained at 40 to 50 percent (this was too high to accurately represent the FAR aircraft cabin environment). Atmospheric pressure was varied from 8,000 feet for 30 minutes to 25,000 feet for 30 minutes, at a simulated ascent of 5,000 feet per minute. Descent was 5,000 feet per minute with stops at each 5,000 foot level. There were no changes in visual acuity or subjective vision over time. There were no physiological changes from base line or in the ability to wear soft lenses. Flynn et al. also simulated a tanker-transport-bomber (TTB) aircraft cabin environment. The relative humidity was first maintained at 50 percent at ground level and then at 5 percent at ground level. Subjects were then observed at 10,000 feet, and the relative humidity was first maintained at 50 percent and then 5 percent. Visual acuities were 20/20 or better throughout the flight simulation. Although visual acuity fluctuations occurred 19 times in 6 of 8 soft lens wearers and 12 times in 4 of 8 subjects wearing spectacles, these were not considered to be significant and could not be attributed to the con atmospheric pressure. A reduction in contrast sensitivity in subjects wearing contact lenses compared with subjects wearing spectacles was reported only at the highest spatial frequency. However, contrast sensitivity of the subjects wearing contact lenses after 4 hours was not statisti cally different from base line. There was an increase in corneal staining at high altitudes and in dry environments. There was no significant difference in response between the low-water-content and high-water-content lens wearers, especially at the 50 percent relative humidity level. There were no subjective visual changes in all environments tested.

The physiological stress on the cornea presented by such signs as tear debris, conjunctiva injection, and corneal epithelial staining was greater at higher altitudes with contact lens wear. Flynn et al. (1988) suggested that any conjunctival or corneal staining may be the result of low atmospheric pressure, although other factors such as "dry air" may play a role. The results of this study confirm that the physiological response of the cornea to soft lens wear is subject to higher levels of stress at altitude than at ground level. However, the higher stress levels occurred without measurable visual degradation or significant adverse ocular effects. Therefore, the authors suggested that, although the exposure was limited and prolonged repeated exposures combined with additional aircraft environmental factors may hypothetically severely affect the physiological response of the cornea to adversely affect vision, soft contact lenses can be worn while flying.

Brennan and Girvin (1985) simulated military situations with subjects wearing Snowflex 50 percent water content contact lenses and Scanlens 75 percent water content contact lenses. The first altitude simulations were at 12,000 feet. There were no physiological changes or changes in contrast sensitivity at this altitude. All subjects achieved satisfactory visual acuity; however, two had minor decreases in visual acuity that were not considered to be significant. There was a minimal increase in flare and edema that produced no significant adverse visual effects. An atmospheric pressure of 27,000 feet was then simulated. At this level 16 of 17 subjects had satisfactory visual acuity. There was no change in contrast sensitivity. Subjects were also tested with rapid decompression of 6,500 feet per second. All subjects had satisfactory visual acuity, although there was a minor reduction in visual acuity in two subjects. No bubble formation was observed. There was no increase in flare and no changes in contrast sensitivity. Brennan and Girvin also tested the effects of an aircrew respirator worn by subjects in this situation. Air flow was directed across the eyes at a rate of 50 liters per minute for 2 hours. There were no changes in visual acuity or contrast sensitivity. There was a minor insignificant increase in flare after 2 hours. In summary, Brennan and Girvin found that in all instances the visual performance and ocular response of the aircrew wearing contact lenses did not differ significantly from that of spectacle wearers and was not degraded significantly by any of the environmental stresses of the study. In addition, there was no difference in performance between a 75 percent water content lens and a 50 percent one.

Forgie (1981) examined subjects wearing soft contact lenses in a hypobaric chamber with atmospheric pressure equivalent to 25,000 feet over a period of 2.5 hours. He observed no significant changes in vision or corneal thickness. There were no subcontact lens gas bubbles observed at any time. After 6 hours of testing at 10,000 feet, there were no significant changes in the vision of the test subjects and no gas bubbles were observed under the lenses at any time. Minor changes were noted in tear film debris in both controls and in lens wearers. There was no clear evidence that the tear debris increased significantly as the runs progressed. After 6 hours at 10,000 feet, there was no fluorescein staining in the four control eyes. In the 18 test eyes, 3 showed no staining, 11 showed absolutely minimal staining, 2 showed minimal staining and 2 showed mild staining. The tear film was sampled at 2, 4, and 6 hours into the run. The epithelial cells, the polymorphonuclear leukocytes and the lymphocytes were identified, counted, and compared with samples taken of the tear film prior to the 6-hour run. The results were evaluated statistically and found to be so widely variable that there were no significant differences observed in the lens wearers and the controls at any time between the beginning and the end of the experiment. Forgie concluded that in the situations tested there was no problem sufficient to significantly interfere with aircraft control or visual acuities. He concluded that selected aircrew can wear soft lenses and operate without any problems in a wide variety of military aircraft.

## IMPRESSIONS OF PREVIOUS RESEARCH AND RECOMMENDATIONS

From the available studies it would seem likely that aircraft pilots can wear soft and hard lenses in FAR and TTB aircraft cabin environments with minimal risk of ocular or visual complications. However, the errors in the test parameters —such as 40 percent more or humidity when the typical relative humidity in a cabin environment is much lower, lack of controls in some studies, and conflicting results—make it advisable that further controlled testing be completed. Such testing should represent both real and simulated environments. Although visual acuity (Snellen) was monitored in many studies, more sensitive high-and low-contrast log acuity tests may be needed. The protocols should be reviewed and approved by a panel of experts prior to the initiation of the studies.

Better controls of lens materials and physical parameters are needed to correlate the results of necessary future studies. Lens water content should be monitored on the eye with an Atago device using the method recommended by Efron. The thickness of lenses should be standardized for soft lens studies, and four thicknesses should be used: 0.035, 0.07, 0.12, and 0.15 millimeters. If any subjects wear toric lenses, other variables also must be controlled, such as the design used to control meridional orientation.

All testing should be performed on three classes of designs and in two water contents (38 and 55 percent): thin zone torics, back toric, prism ballast, and front toric prism ballast. In addition, if testing prism ballast designs are tested, two wedge designs require testing: 0.75 and 2.0 .

For rigid lens testing, two standard diameters should be used: 8.7 millimeter and 9.5 millimeter; thicknesses of 0.08 and 0.17 millimeters should be considered. Also, prescriptions of +4.00, -2.00, -6.00 diopters; low oxygen permeable (24 percent $\times 10^{-11}$); and high oxygen permeable ($70 \times 10^{-11}$) materials should be used.

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# Effect of Aircraft Cabin Altitude and Humidity on Oxygen Tension under Soft and Hard Gas-Permeable Contact Lenses

Melvin R. O'Neal

The uninitiated reader on contact lenses may wish to start with an encyclopedia overview of contact lens types and lens wear modalities and complications (O'Neal, 1988). The primary source of oxygen to the cornea is from ambient air. Contact lenses decrease the amount of oxygen getting to the corneal surface. Below a critical oxygen level, debated to be between 40 and 75 mmHg, corneal hypoxia occurs and the cornea swells (Mandell and Farrell, 1980; Holden et al., 1984). The adverse military flying environment includes aircraft cabin pressure that is decreased from normal sea level and cabin humidity that is usually much lower than normal. This cabin environment is shown to result in calculated oxygen levels under contact lenses that may be substantially reduced from normal and thus needs consideration.

## MILITARY AIRCRAFT CABIN PRESSURIZATION

At sea level the ambient air pressure is about 760 mmHg (14.7 psi); however, the ambient pressure rapidly decreases as altitude increases (Spells, 1965). U.S. Air Force aviation can be divided into two basic aircraft cabin pressurization schedules (Heimbach and Sheffield, 1985). Both are isobaric-differential pressurization systems in which cabin pressurization begins as the aircraft ascends through 5,000–8,000 feet, and then the isobaric function maintains this pressure until a preset pressure differential (psid) is reached between the ambient and cabin pressures. This psid is then maintained with continued ascent, and the resulting cabin pressure can be written as: ambient psi + psid = cabin psi.

The typical cabin pressurization schedule for fighter-attack-reconnaissance (FAR) aircraft is shown in Figure 1. For FAR aircraft the cabin may be unpressurized to about 8,000 feet (10.9 psi); then cabin pressure is held at this altitude until a preset pressure differential of 5.0 psid is reached at 23,000 feet (5.9 psi). This 5.0 psid is then maintained as aircraft altitude increases. Thus, at an altitude of 30,000 feet (4.4 psi) the FAR cabin altitude is 12,000 feet (9.4 psi), and at 39,000 feet (3.0 psi) the FAR cabin altitude is about 16,000 feet (8.0 psi). For Tanker-Transport-Bomber (TTB) aircraft, the cabin is held near sea level until the preset pressure differential, usually 8.6 psid, is reached at 23,000 feet (14.7-8.6 = 6.1 psi). At an altitude of 43,000 feet (2.3 psi) the TTB cabin altitude is about 8,000 feet (10.9 psi). Military aircraft routinely fly in the 30,000 to 45,000-foot altitude range, thus, cabin altitudes will frequently be between 8,000 feet (565 mmHg pressure) to 16,000 feet (412 mmHg pressure).

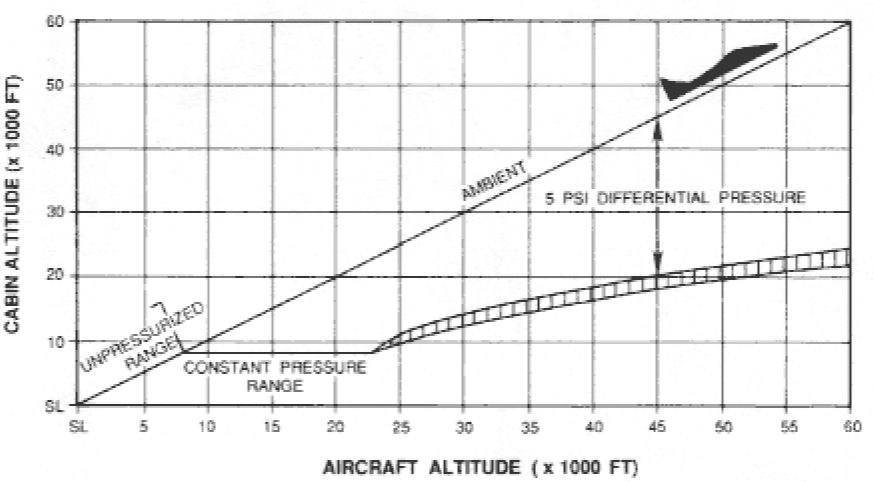

Figure 1
Typical cabin pressurization schedule for fighter aircraft.

## CABIN ENVIRONMENT AND CONTACT LENSES

Oxygen makes up about 21 percent of air at any altitude, and thus oxygen pressure is also reduced at higher altitudes. At sea level the partial pressure of oxygen ($PO_2$) is 159 mmHg (760 mmHg × 0.21), but it is 118 mmHg $PO_2$ (565 mmHg × 0.21) at the 8,000-foot cabin altitude and only 86 mmHg $PO_2$ (412 mmHg × 0.21) at the 16,000-foot cabin altitude (see Figure 2). The amount of oxygen passing through contact lenses is directly related to the $PO_2$ or "driving force" of oxygen in the air (Fatt, 1978). At higher altitudes the oxygen under a contact lens must therefore be lower. In addition, lower humidity is known to result in partial dehydration of soft lenses (Andrasko and Schoessler, 1980). Since oxygen passes through the fluid phase of a soft lens (Fatt, 1978), any water loss will decrease the oxygen transmission of the lens. Also, virtually no tear exchange occurs under soft lenses (Polse, 1979), and thus the oxygen under these lenses is due only to diffusion through the lens. Conversely, hard gas-permeable (HGP) lenses do not dehydrate and have the added benefit of the "pumping" of oxygenated tears under the lens during blinking (Fatt and Lin, 1976). This tear exchange increases the level of oxygen under HGP lenses by about 7–15 mmHg $PO_2$ above the amount from diffusion (Efron and Carney, 1983; Fatt and Liu, 1984).

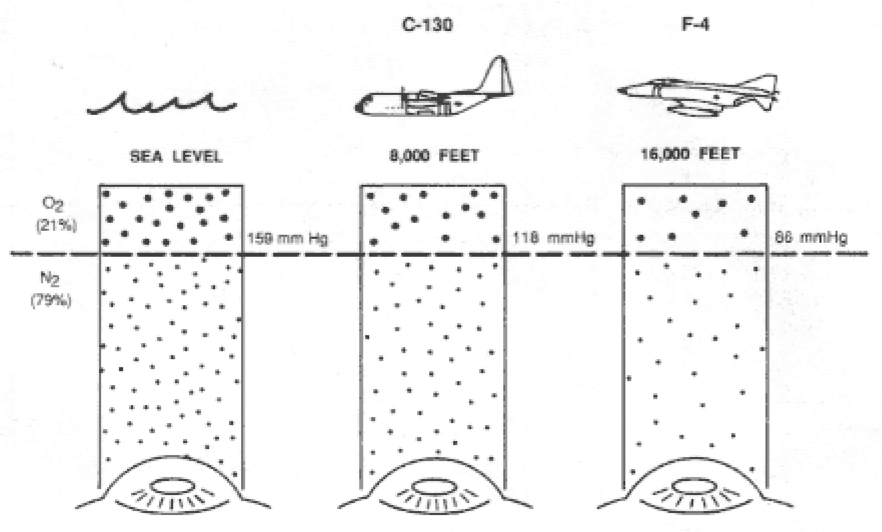

Figure 2
Comparison of oxygen tension in ambient air at three altitudes.

A number of studies in altitude chambers and aircraft have assessed the subjective, visual, and corneal responses to contact lenses at aviation altitudes and low humidity levels (Eng et al., 1978, 1982; Brennan and Girvin, 1985; Flynn et al., 1986; Dennis et al., 1988). In general, they report only minimal corneal surface abnormality, variable subjective irritation, and little or no effect on visual acuity. However, there have apparently been no studies to assess the corneal swelling response in these environments. Although marked corneal edema would be necessary to affect the parameters measured, moderate corneal swelling may still occur. This may be important to the military aviator, since repeated corneal edema has been implicated in the cause of a number of corneal complications, such as epithelial microcysts, during extended contact lens wear (Weissman and Mondino, 1985; Polse et al., 1987).

## PROPOSED "ACCEPTABLE" CORNEAL SWELLING/ MINIMUM OXYGEN LEVEL

Published findings allow an attempt to derive an "acceptable" oxygen level under a contact lens. Holden and Mertz (1984) suggested that a contact lens with an oxygen transmissibility (Dk/L) of about $35 \times 10^{-9}$ worn during sleep causes an allowable amount of corneal swelling for most individuals to return to normal corneal thickness the following day. The results of Poise et al. (1987) show that this Dk/L level reduces corneal complications during extended wear. These studies found approximately 8 percent corneal swelling with this Dk/L, which is about twice the 4 percent swelling that occurs normally each night during sleep in individuals not wearing lenses (Mertz, 1980). Adopting such a 2× normal swelling criterion would seem prudent. Repeated high levels of overnight corneal swelling appear to not only adversely affect the corneal epithelium but also to induce morphological changes in the cornea endothelium (Schoessler, 1983). These morphological changes may have an effect on endothelial ability to maintain normal corneal hydration (O'Neal and Polse, 1986), of which the long-term effects on corneal health have not been determined. The minimum oxygen level under a lens occurs during the critical closed-eye period of extended wear when the ambient oxygen pressure from the palpebral conjunctiva is decreased to only 55 mmHg $PO_2$ (Efron and Carney, 1979). A contact lens with a Dk/L of $35 \times 10^{-9}$ has a calculated oxygen tension under the lens during eye closure of about 25 mmHg $PO_2$—the proposed "acceptable" minimum oxygen level.

## APPROACH

A calculational approach is used to assess the possibility of corneal hypoxia with contact lenses during military flight operations. The oxygen levels of both soft and HGP contact lenses are calculated for sea level, two cabin altitudes, and different humidities. Given the assumptions involved in the calculations, the oxygen levels determined, although probably close, may not be the actual values. However, these calculated oxygen levels allow relative comparisons between lenses under military cabin environments and can also be compared to the proposed "acceptable" oxygen level. The calculations suggest that corneal hypoxic conditions could occur, particularly with soft lenses, that may approach the hypoxia that occurs during night wear. The resulting corneal edema may be high in some cases; however, the actual amount of corneal edema needs to be measured. Regardless, the maximum corneal edema and frequency of swelling to be allowed remain debatable.

## CALCULATION OF OXYGEN TENSION UNDER CONTACT LENSES

### General Equation

Equations and values of the empirical constants for calculating oxygen tension under a gas-permeable contact lens without the presence of tear pumping have been given by Fatt and St. Helen (1971). The contact lens and cornea are considered to be tightly joined, and the oxygen flux through the lens, $j_{cl}$, is taken to equal the oxygen flux, $j_{c}$, into the cornea. From $j_{cl} = Dk/L\ (P_a\text{-P})$ and $j_c = aP^{1/2}$, setting these equal and rearranging gives the useful equation: $Dk/L = aP^{1/2}/(P_a\text{-P})$, where $Dk/L$ is the lens oxygen transmissibility, $a$ the empirical constant $0.24 \times 10^{-6}$ ml $O_2$/cm$^2$ × sec × (mmHg)$^{1/2}$, $P_a$ the ambient oxygen tension at lens surface, and P the oxygen tension at the corneal surface.

The condition of little or no tear pumping applies to all soft contact lens wear (Polse, 1979) and for hard lenses worn during eye closure (O'Neal et al., 1984; Benjamin and Rasmussen, 1985). Using this equation, the relationship between lens oxygen transmissibility and calculated oxygen tension under a contact lens is shown in Figure 3 for soft lens open-eye wear at sea level and at cabin altitudes of 8,000 and 16,000 feet. Also shown, for comparison, is the low oxygen tension under the lens calculated for the

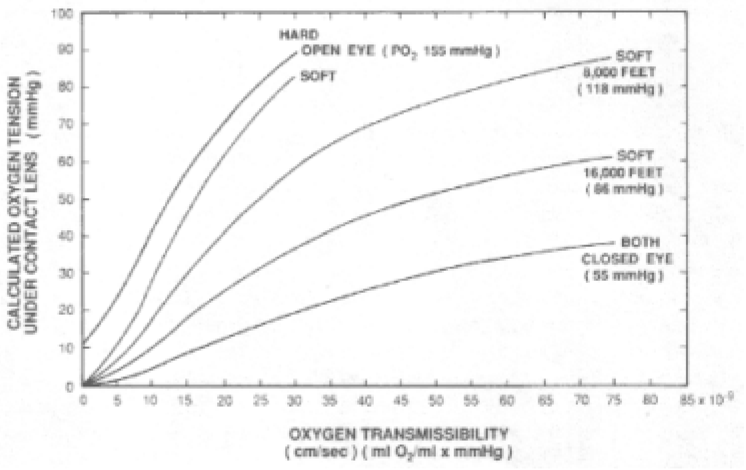

Figure 3
Calculated oxygen tension under soft and hard gas-permeable lenses over a range of lens oxygen transmissibility for the open eye at three altitudes and for the closed eye.

critical closed-eye overnight period of extended wear. The upper curve in Figure 3 shows the higher level of oxygen due to tear exchange under hard versus soft lenses during open-eye wear.

## Effect of Humidity on Soft Lens Oxygen Transmission

Since oxygen passes through the fluid phase of a soft lens, the diffusion (D) and solubility (k) of oxygen in the lens are related to the amount of water in the lens (Fatt, 1978). Fatt and Chaston (1982a) derived the relationship between the oxygen permeability (Dk) and percent water content (% $H_2O$) of a soft lens at eye temperature as, $Dk = 2.00 \times 10^{-11} \exp (0.0411 \times \% H_2O)$. Lower humidity results in partial dehydration of soft lenses; and Fatt and Chaston (1982b), using the data of Andrasko and Schoessler (1980), have listed the effect of lower humidity on various soft lens parameters, including percent water content and lens thickness. Using data in their Table 4, the oxygen transmissibility (Dk/L) of the soft lens in the vial, the Dk/L during normal wear, and the Dk/L at a low 18 percent relative humidity were calculated and are listed in Table 1 for two frequently used water content soft lenses, 55 percent and 71 percent $H_2O$ soft lenses having 0.09- and 0.21-millimeter average lens thicknesses, respectively.

The ambient oxygen transmissibility during normal wear is lower than the vial Dk/L by 11.3 percent and 14.2 percent for the 55 percent and 71 percent $H_2O$ lenses, respectively. This decrease in oxygen transmissibility becomes substantial under low (18%) humidity, with the ambient Dk/L now

TABLE 1 Effect of Humidity on Soft Lens Oxygen Transmission

| Humidity Level | % $H_2O$ | Lmm( L/L) | Cal Dk[a] | Cal Dk/L[b] |
|---|---|---|---|---|
| 55 % $H_2O$ Lens | | | | |
| Vial | 55 | 0.090 (1.00) | 19.2 | 21.3 |
| Normal | 51 | 0.086 (0.96) | 16.2 | 18.9 |
| 18% | 47 | 0.085 (0.94) | 13.8 | 16.3 |
| 71% $H_2O$ Lens | | | | |
| Vial | 71 | 0.210 (1.00) | 37.0 | 17.6 |
| Normal | 66 | 0.200 (0.95) | 30.1 | 15.1 |
| 18% | 58 | 0.183 (0.87) | 21.7 | 11.9 |

[a] $\times 10^{-11}$ (cm$^2$/sec)(ml $O_2$/ml × mmHg); $Dk = 2.00 \times 10^{-11} \exp (0.441 \times \% H_2O)$.

[b] $\times 10^{-9}$ (cm/sec)(ml $O_2$/ml × mmHg).

SOURCE: Fatt and Chaston (1982, Table 4).

much lower than the vial Dk/L by 23.5 percent and 32.4 percent for these lenses, respectively.

### Effect of Humidity/Altitude on Oxygen Tension under Soft Lenses

The aircraft cabin environment includes both lower humidity and cabin pressure that is decreased from normal sea level. Aircraft cabin humidity is frequently between a very low 5 to 10 percent relative humidity. Although data on lens changes are not available for these very low humidities, the low 18 percent humidity data noted above shows a dramatic effect on lens oxygen transmissibility. Using the calculated Dk/L in Table 1, the calculated oxygen tension under 55 percent and 71 percent $H_2O$ soft lenses in the vial, during normal wear, and at 18 percent relative humidity is shown in Table 2 for sea level and for cabin altitudes of 8,000 and 16,000 feet.

At sea level the calculated oxygen under the lens is higher for the 55 percent versus the 71 percent $H_2O$ lens by 11 mmHg $PO_2$ (23.4%) during normal wear and is 17 mmHg $PO_2$ (51.5%) higher in low 18 percent humidity. More significant for aircrew, the calculated $PO_2$ is 52.4 percent and 66.7 percent higher for the 55 percent versus the 71 percent $H_2O$ lens at low 18 percent humidity at cabin altitudes of 8,000 feet and 16,000 feet, respectively. As a comparison, for the 16,000-foot altitude and low-humidity aircraft cabin, the oxygen tension under the 71 percent $H_2O$ lens approaches the very low oxygen level calculated for soft lenses during overnight closed-eye wear.

TABLE 2 Effect of Humidity/Altitude on Oxygen Tension Under Soft Lens

| | | | Calculated $O_2$ Tension (mmHg) at: | | |
|---|---|---|---|---|---|
| Humidity Level | % $H_2O$ | Calculated Dk/L[a] | Sea Level | Cabin at 8,000 ft | Cabin at 16,000 ft |
| 55% $H_2O$ Lens | | | | | |
| Vial | 55 | 21.2 | 62 | 42 | 25 |
| Normal | 51 | 18.9 | 58 | 38 | 23 |
| 18% | 47 | 16.3 | 50 | 32 | 20 |
| 71% $H_2O$ Lens | | | | | |
| Vial | 71 | 17.6 | 58 | 38 | 23 |
| Normal | 66 | 15.1 | 47 | 30 | 18 |
| 18% | 58 | 11.9 | 33 | 21 | 12 |

[a] $\times 10^{-9}$ (cm/sec)(ml $O_2$/ml × mmHg).

## Effect of Altitude on Oxygen Tension under HGP Lenses

During open-eye wear of hard gas-permeable (HGP) contact lenses, tear exchange with blinking increases the oxygen level under the lens. Efron and Carney (1983), using the equivalent oxygen percentage (EOP) polarographic sensor technique, reported an average increase of about 2 percent $O_2$ (15 mmHg $PO_2$) under hard lenses with blinking. The time-averaged oxygen tension under hard contact lenses has been computed by Fatt and Liu (1984). The upper curve in Figure 3, as adapted from their Figure 2, indicates approximately a 7- to 12-mmHg $PO_2$ (1–1.5 percent $O_2$) higher level of oxygen under hard versus soft lenses during open-eye wear. Also, their equations show that the additional oxygen due to blinking is related to the ambient oxygen tension in the air.

To derive the additional level of oxygen under hard lenses at the lower ambient oxygen tensions found in the aircraft cockpit, the ambient $PO_2$ was multiplied by 0.075 (7.5%). This factor seems appropriate, since it is equivalent to 1.5 percent $O_2$ (11.5 mmHg $PO_2$) at sea level (i.e., 1.5 percent of 760 mmHg), which is in the middle of the range between the calculated and EOP techniques noted above. The additional oxygen under hard lenses due to blinking was thus taken to be 9.0 mmHg $PO_2$ (118 mmHg × 0.075) at 8,000-foot and 6.5 mmHg $PO_2$ (86 mmHg × 0.075) at 16,000-foot cabin altitude. The calculated oxygen tension under HGP lenses having oxygen transmissibilities from $20 \times 10^{-9}$ to $40 \times 10^{-9}$ (cm/sec)(ml $O_2$/ml × mmHg) is shown in Table 3 for sea level and for 8,000- and 16,000-foot cabin altitudes.

The oxygen tension under a medium ($30 \times 10^{-9}$ Dk/L) oxygen transmissibility HGP lens is much higher than that for soft lenses (89 vs. 58 mmHg $PO_2$) even at sea level alone. For the low 18 percent humidity condition, when the soft lens partially dehydrates and the hard lens does not, the calculated oxygen tension under the hard lens is two to three times that

TABLE 3 Effect of Altitude on Oxygen Tension Under HGP Lens

| | Calculated Oxygen Tension (mmHg) at: | | |
|---|---|---|---|
| Lens DK/L[a] | Sea Level | Cabin at 8,000 ft | Cabin at 16,000 ft |
| 20 | 70 | 49 | 31 |
| 25 | 80 | 59 | 37 |
| 30 | 89 | 67 | 43 |
| 35 | 97 | 74 | 48 |
| 40 | 105 | 80 | 52 |

NOTE: $PO_2$ added for tear exchange = 0.075 × ambient $PO_2$.
[a] $\times 10^{-9}$ (cm/sec)(ml $O_2$/ml × mmHg).

under soft lenses at all cabin altitudes. The oxygen tension under HGP lenses appears to be enough to prevent most corneal swelling, even for the low ($20 \times 10^{-9}$ Dk/L) oxygen transmissibility HGP lens at the 16,000-foot cabin altitude.

## DISCUSSION AND RECOMMENDATIONS

The calculated oxygen tension under 55 percent $H_2O$ content soft lenses is about 1 1/2 times higher than that for 71 percent $H_2O$ lenses under all conditions and is particularly noteworthy for the low-humidity, high-altitude conditions found in the aircraft cockpit. For the low-humidity environment, the medium-water-content lens was calculated to be above the proposed minimum oxygen level of 25 mmHg $PO_2$ at the 8,000-foot altitude but not at 16,000 feet; however, the high-water-content lens would not meet this minimum oxygen level at either altitude. Indeed, for the 16,000-foot cabin environment, the 71 percent $H_2O$ lens is calculated to have the very low oxygen level that is found during closed-eye overnight wear.

These calculations suggest that high-water-content soft lenses may not be the best choice, at least from an oxygen standpoint, for wear in the military aircraft cabin environment. Lens dehydration in low humidity also affects soft lens parameters and fit and may complicate the use of soft lenses by aircrew. It should be stressed that the oxygen levels presented are for a low 18 percent humidity. The aircraft cabin frequently has a very low 5–10 percent humidity that would result in even lower oxygen levels and greater corneal hypoxia.

The calculated oxygen levels under soft lenses further suggest that normal everyday extended wear of soft contact lenses may not be a viable choice for military aircrew. The low oxygen level during overnight soft lens wear results in a substantial amount of corneal swelling in most individuals. In normal soft lens extended wear the cornea deswells the following day, although usually not completely (Holden and Mertz, 1984). However, during flight the lower oxygen under the lens could cause corneal swelling and affect its recovery in both FAR and TTB aircrew. Thus, significant amounts of corneal swelling could be present not only at night but also during daytime flight and would be further compounded for those aircrew flying many hours in a day, particularly TTB aircrew.

Corneal swelling may be related to a number of corneal complications seen during extended wear, including epithelial microcysts and nonreversible changes in endothelial morphology (i.e., polymegethism) and may predispose the cornea to some of the other complications seen in extended wear. The added burden of corneal edema during the daytime may result in a higher incidence of corneal complications during extended wear in military aircrew. Notwithstanding the oxygen question during flight, it is intuitive that the probability of complications increases as a function of years of extended wear. If the military adopts everyday extended wear for aircrew, it can be expected that a number of pilots will be grounded due to complications from long-term extended wear, many of whom will be lost just when they become fully trained and reach their peak. It would seem wiser to maintain corneal health with daily wear (nighttime removal) and switch to extended wear when necessary. This would allow aircrew members to wear contact lenses over a greater number of years and help preserve this important resource.

HGP contact lenses are calculated to have much greater levels of oxygen under the lens in the aircraft cabin environment than any soft lens. HGP lenses would generally have much more oxygen under the lens than the proposed minimum oxygen level at both cabin altitudes. This higher oxygen level occurs because HGP lenses do not dehydrate in low humidity, as soft lenses do, and they get additional oxygen under the lens from the tear exchange that occurs with blinking, which does not occur with soft lenses. Importantly, HGP lenses can be made with much higher oxygen transmissiblity and thus have much greater levels of oxygen under the lens at all times, particularly during overnight closed-eye wear. Corneal deswelling the day after overnight wear is much more rapid and much more complete, returning almost to normal, with HGP lens versus soft lens extended wear (see Figure 3 of O'Neal, 1988). This rapid corneal recovery may be a critical factor in the much lower incidence of some of the corneal complications that occur during extended wear (Polse et al., 1987).

The advantages of HGP lenses for use by military aircrew would seem obvious considering oxygen alone. Also, vision with hard lenses is generally better than with soft lenses, even more so for those with astigmatism. Preliminary results of a centrifuge study indicate that the new HGP lenses remain centered on the eye even under high G forces. However, concern has been voiced about the possibility of foreign bodies under hard lenses and discomfort under dry conditions. Foreign bodies may not be the problem some imagine since anecdotal comments from a number of NASA astronauts indicate no problems during T-38 training flights and even during microgravity while on-orbit when there is substantial dust floating in the shuttle. Irritation with dry eye during low humidity may be a problem for some individuals, but this will also be the case when soft lens dehydration causes a tighter-fitting and less comfortable lens.

The U.S. Navy has for years allowed nonpilots to wear contact lenses, and many of them must be wearing HGP lenses. If there had been any significant problem with this lens type, it would be known; however, no such problems have been documented. Some individuals need soft lenses and some need HGP lenses to obtain the best vision and fit, and successful contact lens fitting will not occur without trying both lens types. The

USAF should continue research into the use of HGP lenses in the FAR environment and could initially obtain data on in-flight wear by rear-seat aircrew using such lenses.

In summary, (1) high-water-content soft lenses, at least from an oxygen standpoint, may not be the best choice for use in the cockpit environment; (2) long-term normal extended wear will most likely lead to grounding of some aircrew due to increased corneal compromise over length of wear and is advised against; (3) flexible wear in which daily wear is used to preserve corneal health over many years of wear and extended wear when necessary is recommended; (4) HGP lenses have already been used successfully by pilots in fighter aircraft and would improve vision and corneal oxygen supply; and (5) continued laboratory and field study of HGP lens wear by aircrew is necessary.

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# Ocular Occupational Health Concerns: Considerations for Pilots Wearing Contact Lenses

Joshua E. Josephson

There are several occupational health concerns that may be directly or indirectly related to the environment of a military pilot.

## THE BAILOUT AND WIND BLAST

Gauvreau's (1976) study of free-fall-jumping parachutists fitted with soft lenses revealed that corneal epithelial punctate staining and temporarily reduced visual acuity resulted when lenses were blown off the eye.

## FACIAL PERSPIRATION

Sweat is an uncomfortable occupational problem. It is a concern for people who wear soft and hard lenes and for nonusers. Sweat dripping into the eyes can not only be uncomfortable but can also disturb the lens wearer's vision. A lens wearer can be distracted by excessive blinking or the desire to keep wiping their face or eyes with their hands. This may be a significant concern for the fighter-attack-reconnaissance aircraft pilot in combat. It may also be more of a long-term problem for the soft lens wearer, if the sweat is absorbed by the lens. Distraction and sensory interference have accounted for aircraft incidents (Billings and Reynard, 1984).

## OCULAR RISKS OF PROLONGED EXTENDED WEAR: NEOVASCULARIZATION

Extended wear may be an advantage if the pilot is on an operation or in time of war. A pilot must be ready to "scramble" and may have no time for lens insertion.

Zuccaro et al. (1985) reported a 3 percent incidence of neovascularization with prolonged extended wear after a 5-year clinical assessment. The criterion for neovascularization was vascularization greater than 1.5 millimeters. This does not realistically represent true neovascularization as substantiated by a recent U.S. Army study (Bachman et al., 1987) performed with soldiers wearing prolonged extended-wear lenses on field maneuvers. After 3 months, at the conclusion of the study, 29 percent of the spectacle wearers had neovascularization, 60 percent of the inexperienced contact lens wearers had neovascularization, and 63 percent of the experienced wearers had neovascularization. Any observed neovascularization was included in the data.

Since pilot activities during operations or time of war are usually of short duration (a maximum of 3 days), intermittent extended wear rather than prolonged wear may be advisable, as the risk of ocular complication would be reduced. Also, although increased oxygen transmissibility of soft lenses is thought to minimize neovascularization, other factors may play a role, such as trauma or inflammatory response to retained metabolic toxic waste or static exfoliated cells (Josephson et al., 1987). Increased lens motion may be helpful in preventing vascularization.

### Ocular Risks of Extended Wear: Infection

The risk of infection is greater in individuals who wear their lenses on an extended-wear basis rather than on a daily-wear basis. The occurrence of an infection can temporarily or permanently affect visual performance. The risk of a more severe outcome is greater in remote environments or during extended maneuvers. The occurrence of an infection, even temporarily, can put a pilot on the sidelines for anywhere from a day to several weeks, depending on the severity of the infection.

## ATMOSPHERIC IRRITANTS/POLLUTANTS

### Particulate Matter (Dust), Microparticles, and Smoke

Smoke may be a related environmental hazard. Smoke can hypothetically decrease preocular tear film stability (Basu, 1977), and thus cause ocular irritation by microparticle contamination and disruption of the tear film.

The cockpit environment is highly contaminated with dust and particulate debris. Entrapment of a foreign body between the lens and eye will cause tearing and may be painful, possibly resulting in loss of control. Certainly, vision would be temporarily disrupted for at least 5 to 15 seconds, which could be a serious hazard if flying on instruments. The insult could cause superficial corneal abrasions and perhaps a later complicating infection. In addition, the lens could be displaced off the cornea or even displaced from the eye because of excessive tearing or eye rubbing in response to the irritation. These occurrences could result in reduced vision, distraction, and, possibly, loss of control of the aircraft. It would follow that the lens could be difficult to remove if there is excessive tearing and blepharospasm. This would lead to further disruption of flight control.

Pilots who wear hard contact lenses have an increased risk of entrapment of particulates between the lens and the eye compared with soft lens wearers, because, as Fatt (1969) has shown, 15–20 percent of the prelens tear volume is exchanged with each blink, when a rigid lens fits properly. However, with soft contact lenses only 1–4 percent of tear volume between the lens and eye is exchanged with each blink (Wagner et al., 1980; PoIse, 1979). Therefore, entrapment of particles between the lens and the eye is least likely for soft lens wearers, particularly those fitted with larger lens diameters. In addition, accidental lens displacement would be much less likely.

Nilsson et al. (1981, 1983) studied the effects of the mechanical trauma of airborne particles on rabbits fitted with hard and soft lenses. The animals were exposed to very hot grit particles. Although both hard and soft contact lenses protected the eye, the authors believed that industrial environments, heavily contaminated with airborne particles, are unsuitable for contact lens wear unless protection is used and the eye is fully sealed from the environment. However, prolonged sealing may result in eventual cornea hypoxia. Also, this study is an extreme condition of particulates in an immediate environment. It demonstrates that soft lenses can be worn in a dusty environment with little cornea risk. However, ocular discomfort may be expected with the accumulation of debris in the cul-de-sac and rubbing of debris by the lid over the bulbar conjunctiva.

Crosley et al. (1974) demonstrated that subjects with soft lenses were virtually free of foreign body entrapment under their lenses in dusty environments.

## Environmental Chemicals

Unfortunately, there are very few scientifically controlled studies that explore the use of contact lenses in industrial settings. There are a number of anecdotal reports in the literature, but conclusions based on scientific studies, particularly studies on humans, are difficult to find. Therefore, it is difficult to appreciate the effects of chemical contaminants in the cockpit environment without further research being done.

The effects of chemical vapor or mist/droplet pollutants in the air could vary depending on the type of lens being worn. It is likely that these contaminants would affect a hydrogel lens, a nonpermeable rigid contact lens, a rigid gas-permeable (RGP) lens (some have lipophilic surfaces), or a silicone elastomer differently. A rigid contact lens will not absorb chemical vapors or chemicals that contaminate it. It has been reported that rigid lenses will partially block a chemical splash from covering the ocular surface.

With the hydrogel lens wearer, chemical vapor can contaminate the lens and, if water soluble, can be absorbed. The effect of the contaminate would depend on the concentration, the amount of contaminate absorbed, the exposure time, the rate of elution of the sorbed chemical (the rate of release), the toxicity of the chemical, the tendency to allergic reaction to the chemical, and the severity of allergic response.

Oil mist/vapor contaminants in the air pose two risks. First, there can be reduced visual quality because of hydrophobic effects of oil on the lens surface. This would occur most readily with lipophilic surfaces, as are commonly found in silicone acrylate-base RGP materials. The second possible effect is the oil mist or vapor acting as an ocular irritant. The contaminant would disrupt the stability of the tear film and possibly irritate the ocular surface.

The use of contact lenses in environments with fumes from organic solvents or splashes of strong acids and alkalis was studied by Nilsson and Andersson (1982). They found that absorption of organic solvents, specifically trichloroethylene and xylene, by contact lens materials is not at all as dangerous as might be expected. They proposed that the contact lenses acted as a "vacuum cleaner" with the solvents. Therefore, the eyes were exposed to a lower concentration than if exposed directly without a lens in place. It should be noted that other solvents may react differently. Unfortunately, Nilsson and Andersson did not measure the concentration and rate of elution of the absorbed fumes. In addition, they did not consider the differences in possible ocular reaction with the four classes of hydrogel materials or consider lenses with various water contents. Their study was also a short-term one and did not demonstrate the effects of wearing contact lenses over a period of weeks or months.

Nilsson and Andersson also studied the effects of acids and alkalis on contact lenses worn on rabbit corneas. They considered both high-and low-water-content lenses in their study. They found that wearing soft contact lenses did not worsen the corneal damage caused by these chemicals. They evaluated the effects of a single drop of hydrochloric acid with a 40 percent concentration and one with a 20 percent concentration. They observed that soft contact lenses did not seem to worsen corneal damage and that with the acids in particular there was no significant damage even after 2 minutes of further exposure to the chemicals via the lens.

Guthrie and Seitz (1975) simulated chemical accidents to rigid contact lens wearers by instillation of 0.1 milliliters of 5 percent acetic acid, 0.5 percent butylamine, and 50 percent acetone into the eyes of rabbits. The left eye was fitted with a hard contact lens, and the right eye served as a control. The eye with the contact lens provided more protection for liquid irritant exposures than the nonprotected eye. Guthrie and Seitz believed that lid spasm caused the lens to tighten around the cornea, sealing it off under the contact lens and thus preventing further serious injury to that section of the ocular surface.

Rengstorff and Black (1974) viewed 128 documented instances of chemical irritation and physical trauma to contact lens wearers. They observed that damage often occurred to the contact lens itself, with minimal or no injury to the cornea. The authors concluded that rigid contact lenses minimized injury or protected the eyes from more serious injury.

Pitts and Lattimore (1987) describe hexanes as virtually insoluble in water and having a low affinity for the plastic material of hydrogel contact lenses. Pitts and Lattimore reported that ethyl acetate is soluble in water and therefore could be taken up by the lenses. The effect of ethyl acetate is an insidious and chronic conjunctivitis with a superficial keratitis buildup over days of exposure. The victim would experience extremely irritated eyes, and, if the fumes were also inhaled, there would be a similar response in the mucosa of the nose, throat, and even the lungs. No effect has been reported on the peripheral or central nervous systems. However, Nilsson and Andersson (1982) demonstrated that the uptake of certain solvents by hydrogel contact lenses did not exacerbate the ocular response to the chemicals compared with direct exposure of eye and that in some situations the eye was protected.

Ozone has been reported by Daubs (1957) and Van Huesden and Mans (1978) to be increased in the environment of commercial aircraft. Daubs reported ocular discomfort in both lens wearers and nonwearers when increased ozone was present. The short-and long-term ocular effects of increased ozone with soft and hard contact lens wearers are not known.

Although there have been reports that soft and hard lenses protect the eyes from chemical burns, when there is ocular irritation the difficulties with immediate removal of a soft or hard lens can pose a serious problem that can further complicate the situation. With a hard lens, eye rubbing and blepharospasm may create a situation that can make the lens very difficult to remove. Eye rubbing with hard lens wear grip could cause the lens to suction onto the ocular surface. With soft contact lenses, a change in tear tonicity can cause the lens to stick to the ocular surface, further complicating a difficult removal situation.

Another potentially significant problem may occur when an individual, without knowledge of it, is inadvertently exposed to chemical vapors or fumes. A similar risk may occur if an aware contact lens wearer is exposed to chemical vapors or fumes but does not suffer significant symptoms or remains symptom-free afterward. In these situations ocular changes may occur while the individual may continue to wear the lenses for weeks or months before a problem is actually realized or until a lens requires replacement. Studies have been performed only on the short-term effects of immediate contamination and have not focused on the possibility of the effects of chemicals at low dosages retained by hydrogel lenses and slowly eluted to the ocular environment over a period of days, weeks, or months. Williams (1986) has reported incidents of "toxic occlusion phenomena," and others have anecdotally related cases of contamination of hydrogel contact lenses without immediate obvious effects to the patient, which were thought to cause adverse ocular responses.

## Gravitational Effects

High $G_z$ forces may affect the meridional orientation and position of toric lenses. It is noteworthy that a prism made by wedge construction stabilizes the lens by the effect of lid pressure, not weight. Therefore, the term *ballast* is inappropriate. Hanks (1983) demonstrated that toric lens orientation does not change if the contact lens wearer stands on his or her head. The prism is still aligned with the lower lid by upper lid pressure, so normal gravity has no effect on lens orientation.

Forgie (1981) simulated higher than normal gravity forces in experiments with spherical soft lens wearers. Subjects were fitted with 15.0-millimeter diameter, 13.0-millimeter optic zone diameter lenses. Twelve eyes were observed under 5 $G_z$ (= 4.2 Ge) and six eyes under 6 $G_z$ (= 5.1 Ge). A lens displacement of 0.3 to 0.8 millimeters upward occurred in four eyes due to lid tightness, squeezing, and blinking and when there was a loose fit. A downward displacement of 0.1 to 3.4 millimeters occurred in 14 eyes. In this experiment displacement was insufficient to leave the pupil uncovered by the optical zone of the lens. Forgie (1981) reported isolated incidents where up to 7 $G_z$ produced no detectable loss in vision with lens slippage. However, with hard lenses there may be reason for concern for the effects of exposure on the peripheral cornea, lens adhesion after decentration or lens edge compression on the peripheral cornea or adjacent bulbar conjunctiva.

## Vibration

Brennan and Girvin (1985) found no significant effect of vibration on the visual performance of soft lens wearers compared with spectacle wearers.

## Hypoxia

The effects of a reduced oxygen environment were covered by Dr. O'Neal at this meeting. However, not mentioned was the work of Fonn (1986) on soft-lens-induced edema with three different thicknesses of polyhema lenses (38.6 percent) at high altitude.

### Dry Environments

Dry environments are frequently encountered in aircraft cabins and are known to produce ocular discomfort (Eng, 1979; Rohles, 1988), and in some soft lens wearers, a significant epithelial disruption (Holden et al., 1986; McNally et al., 1987; Orsborn and Zantos, 1988). This epithelial lesion is less frequently observed if relatively thick lenses are worn (> 0.12 millimeters). In addition, changes in lens performance may be associated with lens parameter changes that can occur if free water is lost from the hydrogel matrix (Andrasko and Schoessler, 1980). Under experimental conditions, low-humidity conditions (10 percent and 30 percent relative humidity) did not significantly affect visual acuity, refractive error, or corneal curvature in eyes wearing soft lenses and control eyes without contact lenses.

## SUMMARY

The pilot's environment may not relate directly to all of the risks described in these studies. However, these reports do provide indirect information on potential risk situations. Clearly, additional controlled studies must be performed before predictions can be made about the actual risks of contact lens wear in an aircraft cabin environment, particularly during wartime.

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# Lens Performance Considerations

Gerald E. Lowther

Contact lenses in general have advantages over spectacles: good peripheral vision, no interference when using optical instruments, no problems in the rain, no reflections from lens surfaces, no breakage while being worn, little likelihood of being knocked off, no lens fogging when going in and out of different environments, and no problems with perspiration (Crosley et al., 1974).

Considerable debate has occurred with respect to wearing contact lenses in adverse conditions such as industrial situations. Ocular trauma is one concern. Surveys and studies have generally indicated greater perceived problems than actual problems (Rengstorff and Black, 1974; Nilsson et al., 1981; Randolph and Zavon, 1987; Logar, 1987).

Subjective surveys of individuals wearing lenses in adverse conditions, including aviation, generally indicate success with and preference for contact lenses, especially hydrogel lenses (Van Norren, 1984; Crosley et al., 1974; Nilsson and Rengstorff, 1979; Bachman et al., 1987; Gilchrist, 1980). However, one must be aware that there is often bias on the part of contact lens wearers to want to continue wearing them and they thus downplay any problems.

## RIGID LENSES

### Advantages of Rigid Lenses

The oxygen transmissibility of newer rigid lens materials is greater than most hydrogel designs. Therefore, corneal edema is seldom a problem even with extended wear and should not be a major problem under low-oxygen-level conditions at higher altitudes.

The tear exchange on each blink is much greater with rigid lenses (about

10 to 15 percent per blink) than with hydrogels (less than 2 percent). Thus, metabolic waste products and cell debris are rapidly removed from under the lens.

Vision is generally sharper and more consistent with rigid lenses. Small amounts of astigmatism due to corneal toricity are corrected with spherical lenses. Toric rigid lenses give good consistent vision on highly toric corneas.

### Disadvantages of Rigid Lenses

One disadvantage of rigid lenses is loss or displacement from the cornea when the face is rubbed (i.e., by a helmet or hand). Likewise, foreign bodies can readily get under rigid lenses, causing discomfort or incapacitation (Crosley et al., 1974; Nilsson et al., 1983). A way to minimize these problems is to use large-diameter lenses. Lenses as large as 11 to 12 millimeters may be possible with the high gas-permeable materials. With these diameters it is more difficult to dislodge the lens because the lid(s) will remain over the lens edge. It is also less likely that foreign bodies will get under such lenses. Another potential answer to this and related problems is the use of haptic lenses manufactured from highly permeable materials. Foreign bodies, loss, and visual problems from lens movement would not be problems. Obviously the use of haptics would require techniques and procedures that most practitioners are not presently able to do.

The likelihood of loss or of foreign bodies getting under lenses can also be minimized by using lenses with minimal edge thickness and clearance. Axial edge lifts of less than 0.08 millimeters could be used.

Lens surface drying and front surface coatings causing blurred vision will be a problem with some individuals, especially under low-humidity conditions. Only with the development of materials with better surface properties will this problem be totally eliminated. Surface drying is often worse when a person is concentrating on a visual task, as they may not blink as frequently then. Surface drying does not seem to be as great a problem as with hydrogel lenses.

Lens flexure on toric corneas is a problem with most gas-permeable materials.

When used on an extended-wear basis there may be lens adhesion on awakening. This usually does not cause discomfort or vision problems; however, if it is persistent it could cause physiological problems. Due to that fact an adherent lens will cause temporary corneal distortion, if the lens is removed immediately following adhesion, the vision may be blurred. Proper lens design is necessary to minimize this problem.

Peripheral cornea staining is another problem with rigid lenses. It can be minimized with larger-diameter lenses, thin edges, and other design factors.

## HYDROGEL LENSES

### Advantages

A major advantage of hydrogel lenses over rigid lenses under adverse conditions is the decreased chance of lens loss or decentration. Due to the large diameter and close conformance to the eye, these lenses are worn in contact sports such as football, basketball, and hockey without lens loss. In addition, because of their size and fit, there is seldom a problem with foreign bodies getting under them (Crosley et al., 1974; Nilsson et al., 1983). Therefore, they are the lens of choice in dusty environments. By using as large a diameter as possible (e.g., 14.5 to 15.5 millimeters rather than 12.5 to 14), the chance of loss, decentration, or foreign bodies will be minimized.

Hydrogel lenses are generally more comfortable than other lens types.

There would be some concern that the fit of the lenses would change at hypobaric pressures or due to tightening of the lenses under low-humidity conditions. Studies (Polishuk and Raz, 1975; Eng et al., 1987; Tredici and Flynn, 1987) have indicated no change in lens fit or performance flight conditions and hypobaric pressures. However, low humidity in flight is most likely a problem (Eng et al., 1987).

### Disadvantages

Visual problems with hydrogel lenses due to uncorrected cylinder, surface deposits, surface distortion, and surface drying are a concern under adverse conditions where excellent and consistent vision is required. Visual performance is considered elsewhere in this volume.

Deposits and spoilage of hydrogel lenses have been a major problem with daily and extended wear. Depositing is accelerated by surface drying, increased lens water content, ionic lens materials, and improper cleaning. In addition to proper cleaning, the most feasible way to minimize this problem is frequent lens replacement. With the advent of disposable lenses this is not a major problem.

Dehydration of hydrogel lenses has previously received a lot of attention. It has been shown that hydrogels dehydrate rapidly with wear (Andrasko, 1982, 1983; Wechsler et al., 1983; Kohler and Flanagan, 1985). Thinner lenses lose more water than thicker ones, and higher-water-content lenses dehydrate to such an extent that water is pulled from the epithelium and epithelial damage occurs. Therefore, thin high-water-content lenses should not be used even though they have high oxygen transmission.

Lens dehydration can cause lens to "steepen," making the lens tighter, which causes vision and fitting problems (Gundel and Cohen, 1986; Fatt and Chaston, 1982; Eng et al., 1982). These changes are generally greater with high-water-content lenses but can vary with materials of the same water content (Brennan and Efron, 1987).

A study by Finnemore (reported in Lowther and Malinovsky, 1988) found that patients with marginal dry eyes and associated lens-wearing problems preferred thicker lenses (0.12 millimeters) over thinner ones (0.06 millimeters) (38 percent water lenses used). Sixty percent preferred the thicker lenses, 20 percent the thinner lenses, and 20 percent found no difference. If they were fitted with prism ballast lenses, which were even thicker in the inferior portion of the lenses, the prism lenses were preferred to the spherical thicker lenses. Seventy-three percent preferred the prism lenses, 15 percent the spherical, and 12 percent found no difference. Clinical experience has indicated that many of these patients prefer the thicker lenses. Therefore, it may be that under low humidity conditions patients will do better with thicker or spherical prism ballast lenses. Studies are required to determine this.

As previously reported, extended-wear hydrogel lenses have limited oxygen transmissibility. This can present problems if the lenses are to be worn for long time periods in low-oxygen environments, including potential ocular health problems. However, for short periods of 24 to 48 hours or less, even under low-oxygen atmospheres, this should not be a significant problem. If the lenses must be made thicker to combat the dehydration problem, the oxygen and corneal edema problems will be made worse. The answer to these problems may be the new hydrogel materials being developed, which are not dependent on just water content for oxygen transmission. However, hydrogels have been reported to perform well under extended-wear conditions for air force pilots (Nilsson and Rengstorff, 1979).

## SOFT SILICONE LENSES

A lens material that has received a lot of attention in the past and is receiving renewed attention now is the soft silicone material. This polymer is by far the highest oxygen permeable material ever used for contact lenses (Hill and Mauger, 1981). With a well-fitted silicone lens there are no oxygen-related corneal problems (LaHood et al., 1988; Sweeney and Holden, 1987). It is used extensively in pediatric aphakic patients, where extended wear is required and the lenses must be thick due to the lens powers.

There have been problems with soft silicone lenses due to discomfort, poor surface wettability, and lens adherence. Some of the problems such as comfort and lens adherence were due to the limited lens parameters (10.5- and 11.3-millimeter diameters) available. Presently new designs with diameters equivalent to hydrogel lenses (14 millimeters) are being studied (Zantos, 1988). Such diameters open the possibility for more comfortable lenses and decrease the likelihood of lens loss, displacement, and foreign bodies getting under the lenses.

Due to the fact that the lens material is relatively stiffer than hydrogels, visual acuity is generally better than hydrogels. However, they will not correct significant corneal astigmatism.

Since the material does not contain significant water, dehydration is not a problem. However, it has been reported that water moves through the lens material as water vapor.

A previous problem with silicone lenses has been lens adherence. After a period of wear, usually extended wear, the lens does not move, and if worn for sometime without movement corneal health problems occur. This nonmovement occurs with thick lenses and with lenses fitted too steep (tight). New designs will, it is hoped, overcome this problem.

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# Vision Performance with Contact Lenses

Robert B. Mandell

Visual acuity is a very complex subject in itself, even without regard to contact lens wear. I think that the primary question for us, however, is whether there is any loss in vision performance in changing from spectacles to contact lenses. This brings us to the problem of sorting out what aspects of visual performance must be considered, particularly the task involved in flight.

The first aspect that must be considered is how visual acuity is measured and defined. I shall begin by describing the various ways of defining the test parameters.

## VISUAL ACUITY MEASURES

Let us begin by considering various characteristic of contact lenses that might contribute to changes in visual acuity. Although aberrations are the primary concern, residual astigmatism, which is probably the more important aspect of contact lenses, must also be considered.

The real world has, of course, many low-contrast objects in addition to the high-contrast ones normally found on a visual acuity chart. Actually, a number of people have come up with very innovative ways of testing these low-contrast visual functions.

You may be more familiar with what is the common method of using this particular testing procedure. The test can be viewed as a variant of visual acuity testing. It incorporates a threshold testing situation in which the patient views gratings of different spatial frequencies and different contrasts. The threshold detection of these different gratings yields a contrast measure. Measuring an individual's ability to detect these gratings typically results in a plot that looks something like that shown in Figure 1.

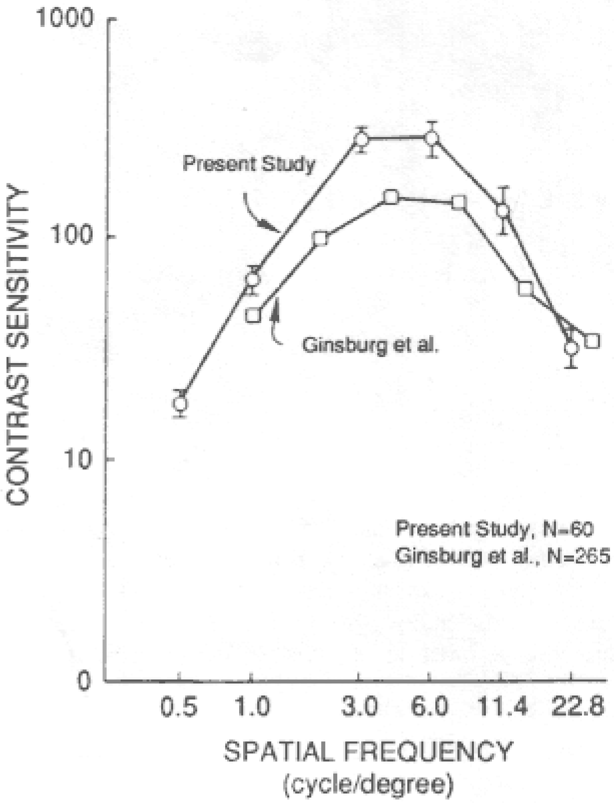

Figure 1
Mean contrast sensitivity function for 60 observers of Long and Penn (1986) and Ginsburg et al. (1984). Brackets indicate standard errors.

One of the problems in this test is the interpretation of just what is being measured when a contrast sensitivity test is performed and how the results can be transferred to our visual interpretation of the real world.

There has been a lot of discussion and a lot of disagreement about how valid the contrast sensitivity test is in terms of reproducibility. Figure 2, for example, shows the results from two runs on the same group of individuals. What exactly does a small difference in the response in this particular test mean in terms of some real interpretable measurement?

Recently, some people have tried to measure the same kind of function but by using the more traditional visual acuity testing procedures—namely, modified Snellen-type testing charts. The information obtained from these tests is in traditional terms that can be understood a little more readily than some of the results from psychophysical testing methods.

Figure 3 illustrates another new chart, designed by Bailey and Lovie. It has a number of advantages in that there are an equal number of letters per row. The sizes of the letters in the rows are determined on a basis that has some meaning in terms of graduation; it allows a simpler scaling and so forth.

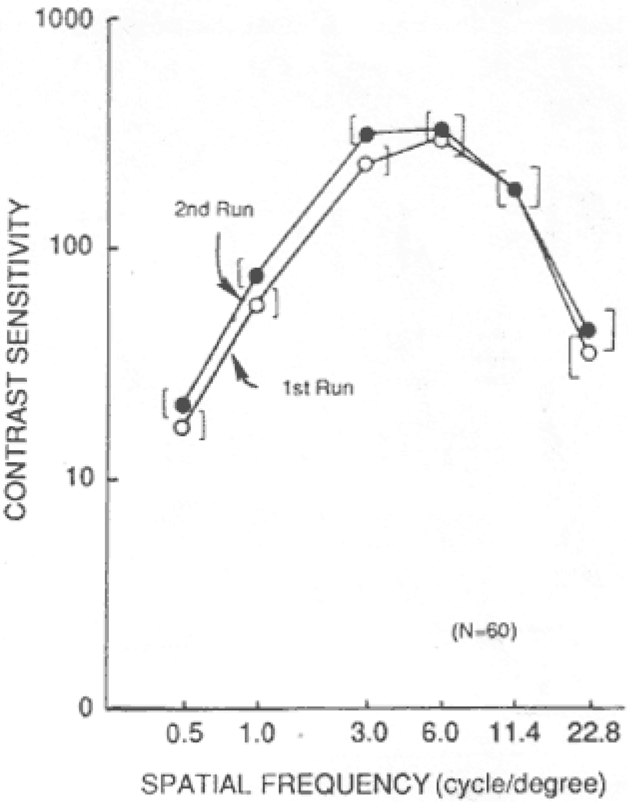

Figure 2
Mean CSF for 60 college-age observers in two separate test runs. The brackets around each date in point indicate two standard errors above and below that point. Based on data from Long and Penn (1986).

These new charts offer a number of advantages. Untrained operators can conduct the test fairly easily, and the results can be interpreted fairly simply.

## ACUITY CHANGES

Guillon and co-workers measured visual acuity changes in a group of subjects first with spectacle correction and then with contact lens correction. The group consisted of five near-ametropes who all had small amounts of astigmatism. They wore four different soft contact lenses for the test.

Figure 3
Bailey and Lovie chart for contrast sensitivity testing.

In general, there was a reduction of visual acuity with a reduction in contrast as well as a reduction in visual acuity as the luminance was reduced (Figure 4). Guillon et al. concluded that there were visual acuity differences between different contact lenses. However, conclusions of this type are often found in the literature, and they are statistically but not clinically significant.

A careful review of the literature reveals that from one study to the next there can be just about any conclusion one wants regarding the effects of contact lenses on acuity. The more recent studies show that contrast sensi tivity function is better with contact lenses than with spectacles. Other studies show just the opposite. Usually the differences between results obtained by the two forms of correction are so small that it makes no practical difference. When there is a "significant" difference between the two types of corrections—contact lenses and spectacles—it can usually be attributed to the fact that there was residual astigmatism present when the subjects were wearing contact lenses. I think that the result is very meaningful, however, in terms of what results might be anticipated with contact lenses worn by military personnel.

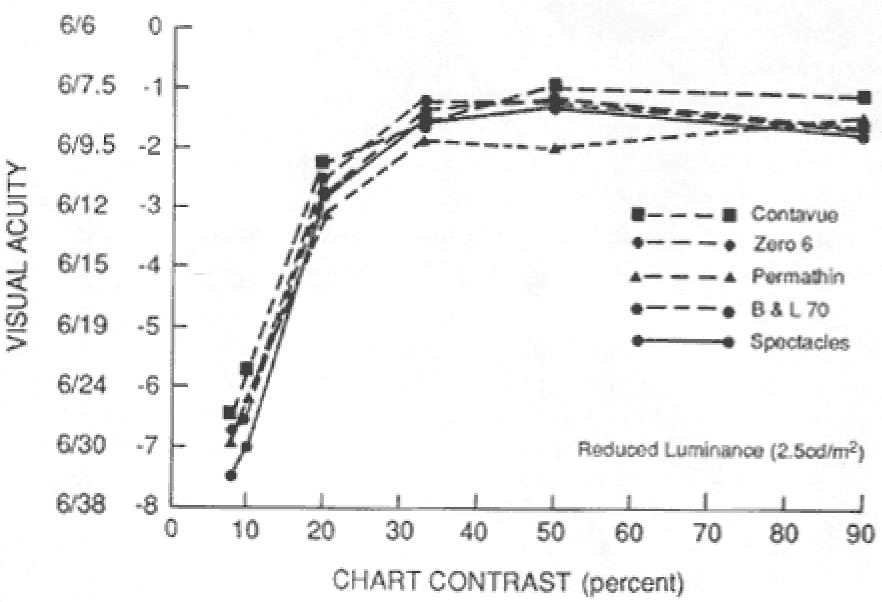

Figure 4
Visual acuity results for four contact lenses and spectacles at reduced luminance (2.5 CD/M$^2$). Based on data from Guillon et al. (1988).

## SPHERICAL ABERRATION

The aberrations that are normally encountered in the wearing of contact lens are usually not considered a serious problem. Generally speaking, spherical aberration is the only aberration considered significant.

Contact lenses are very interesting in that they offer the potential for changing the eye's spherical aberration. Some researchers have viewed this phenomenon as a possible method of improving visual acuity beyond normal or of getting "super" visual acuity. Unfortunately, there are very few experiments where this was carried out under controlled conditions.

Some contact lens manufacturers have found that certain aspherical designs produce enough spherical aberration that visual acuity is actually degraded. Most of the time this problem is not one to be concerned about because the manufacturer does not make the lens available. Unfortunately, much of the time this information has been restricted to within the organization and the data are thus never published.

## RESIDUAL ASTIGMATISM

Residual astigmatism which remains when the contact lens is in place, is a very real problem with regard to fitting military personnel with contact lenses. The task is to fit a group of subjects with an unknown distribution of refractive errors, and without knowing precisely the incidence of astigmatism. If these subjects are to be fit with soft contact lenses, there will be a significant number of people who are going to have enough residual astigmatism that it will cause a reduction in visual acuity. Even if we knew the population numbers, they would not necessarily apply to the military sample of pilots. It certainly must be recognized ahead of time that this will be a significant problem.

If you decide to fit all military personnel needing a refractive correction with soft contact lenses, there are going to be, based on the occurrence of residual astigmatism, a certain number of people who will have to have an alternative lens.

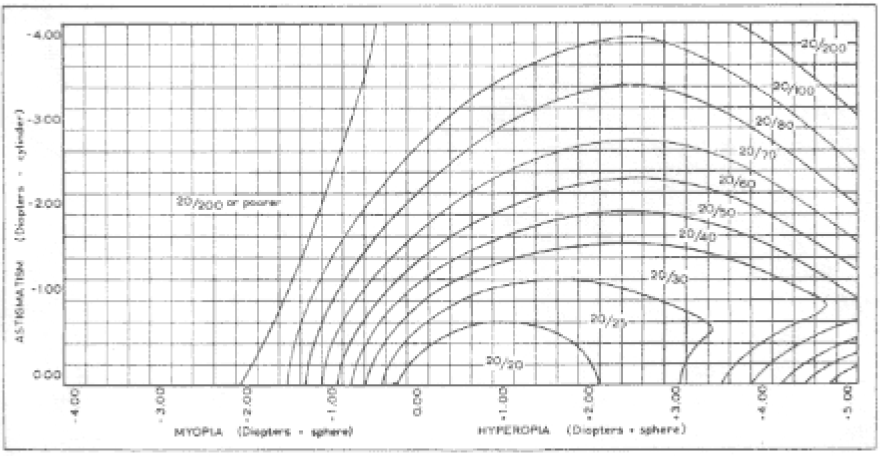

Figure 5
Relation between uncorrected astigmatism and visual acuity. Based on data from Blum et al. (1959).

Figure 5 shows the distribution of spherical refractive error against astigmatism and the amount of reduction that is to be expected in visual acuity. This information permits prediction of the amount of visual acuity loss that can be expected to occur in a certain percentage of pilots. Residual astigmatism is something that the military will have to contend with in the selection of contact lenses. It will almost have to be an individualized situation as far as fitting is concerned. For an individual who has a certain amount of astigmatism, it cannot always be predicted what type of lens will produce the best visual acuity for that person.

In conclusion, the military's policy toward contact lenses cannot really restrict the lens type to soft contact lenses and expect to provide an optimal correction for the majority of potential pilots. On the other hand, it certainly seems that the military should restrict the number of lenses to certain types. There is going to have to be a broad representation if the needs of all pilots are to be addressed.

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# An Overview of U.S. Army Aviation and Contact Lens Issues

Morris R. Lattimore, Jr.

While U.S. Army aircraft can be either fixed-or rotary-wing, this discussion will address the rotary-wing or helicopter segment of the Army aviation community. The Army's arsenal of helicopters encompasses a number of types of aircraft, each designed for a specific mission. These include cargo, observation, utility, and attack helicopters. As an institution, Army aviation has been seriously interested in contact lens wear by its ametropic pilots since the early 1970s, when it was shown that dust and debris did not cause a significant problem for soft contact lens wearers in an aviation environment (Crosley et al., 1974). However, with the soft lenses commercially available then, an unacceptable variation in visual acuity was documented.

At present, Army Regulation (AR) 40-63 prohibits contact lens wear by all aircraft crew members; the only waivers to that restriction have been associated with investigative protocols. The advent of new lens materials spurred further interest within the aviation community, leading to the development of a preliminary investigation of extended contact lens wear by a small group of volunteer aviators (Bachman, 1988). The results are in the process of being published, so only a brief summary will be supplied here.

## PRELIMINARY STUDY

In order to develop relative safety patterns in established rotary-wing systems, an initial feasibility study of contact lens wear involved volunteer ametropic aviators qualified in the UH-1H Iroquois utility helicopter and/or AH-1 Cobra attack helicopter. Forty-four volunteer subjects were fitted with six different brands of extended-wear contact lenses, including both hydrophilic and rigid gas-permeable lenses. The mean uncorrected visual acuity was 20/46, with individual acuities ranging from 20/15 to 20/200.

The extended-wear lenses were worn on a 7-day/6-night schedule. That is, after the initial fitting, the lenses were worn continuously for 7 days and 6 nights. The lenses then were removed prior to retiring on the seventh night, and were reapplied the following morning after using an appropriate disinfection and lens care regimen. Postfitting follow-up examinations were provided on day 1, day 8, and every 30 days thereafter. The study ran for 6 months with an 86 percent success rate. Six subjects withdrew from the study because of acuity problems (2) or discomfort (4).

Prior to the initial contact lens fitting, the mean flying time for the subject population was 2,136 hours. Over the 6-month period of the study the mean flying time for successful contact-lens-wearing subjects was 294 hours. During the course of the study, there were no groundings for contact-lens-related reasons, and there were no aircraft incidents or accidents related to the wearing of contact lenses. Subjective performance assessments rated the contact lenses used as being superior to spectacle wear by a vast majority of the subjects for preflight (68 percent), takeoffs (83 percent), routine flight (83 percent), nap-of-the-earth flight (89 percent), night vision goggles flight (88 percent), instrument flight (88 percent), and mission-oriented protective posture IV conditions (100 percent).

Temporary discontinuances of contact lens wear were incurred by six pilots a total of nine times. Causes of discontinuance were conjunctivitis (8), abrasion (2), foreign body (2), facial trauma (1), and meibomitis (1). Again, none of the contact lens wear discontinuances led to grounding; the affected aviators merely wore their spectacles in lieu of the contact lenses. In summary, this initial feasibility study demonstrated the safe use, both in medical and flight terms, of extended-wear contact lenses by AH-1 and UH-1 pilots.

## DRIVING FORCE

Immediate interest is being directed at the AH-64 Apache attack helicopter (Figure 1). The Apache's integrated helmet and display sighting system (IHADSS) uses a virtual imaging system to provide visual input to the pilot and copilot from a closed-circuit video system. The image can be in a daytime TV mode or in an infrared-sensitive mode for night flying, with a zoom capability of up to nine times. Aviator input on the helmet display unit (HDU) is always to the right eye only. Superimposed along the periphery of the HDU are essential flight instrument readings, so the pilot can obtain enough basic information to fly the aircraft strictly from IHADSS input. The left eye remains free and unobstructed for direct viewing of the instrument panel or for visualization of the flight environment through the windscreen. Correct placement of the imaging system on the helmet is critical to efficient use. Standard flight frame spectacle wear had caused

Figure 1
AH-64 Apache attack helicopter. NOTE: The AH-64 Apache attack helicopter represents the utmost in modern air weaponry. The two-man airframe system is designed to fly in literally any weather conditions.

Figure 2
U.S. Army helmet display unit. NOTE: The HDU is positioned over the right eye; spectacle-wearing aviators have had some difficulty in obtaining proper positioning for optimal utilization.

Figure 3
U.S. Army M-48 protective mask. NOTE: The M-48 protective mask was designed specifically for the Apache system, since the preexisting M-24 protective mask was totally incompatible with HDU positioning.

some difficulty in obtaining correct placement of the system. As a result, a smaller right eyepiece was developed to minimize these difficulties, but it did not solve them (Figure 2).

Compounding the IHADSS placement dilemma has been the development of the M-43 protective mask (Figure 3), designed to protect the aviator from chemical contaminants that could be encountered in the modern battlefield. However, no accommodation was made for spectacle-wearing aviators. A proposed amendment to the protective mask consists of glue-on optics bonded

Figure 4
U.S. Army M-43 protective mask. NOTE: The M-43 protective mask does not offer an easy means of correcting refractive error; two possible options are glue-on optics and contact lens wear. Each option has its own set of advantages and disadvantages.

onto the external surface of the eye bubble. Visual complications induced by such a revision include image magnification and distortion. In addition, the peripheral HDU symbology is obscured because of a decreased field of view that stems from the increased physical distance imposed on imager placement (Figure 4). Consequently, ametropic aviators may be unable to fly the AH-64 under chemically contaminated conditions.

Contact lens wear constitutes an alternative to the M-43 glue-on optics and represents an attractive short-term solution to the aviation community. However, before even advocating contact lens wear as a viable option, the Army's medical community wishes to ensure that all potential hazards and costs are fully documented so that an informed decision can be reached.

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# Contact Lens Wear in the Aerospace Environment

Richard Dennis

Visual standards for pilot flight training have been updated in Air Force Regulation 160-43 as of October 1, 1988. Congress has mandated that 70 percent of the entering Air Force Academy cadets meet these standards. All pilot candidates entering the Reserve Officers Training Corps (ROTC) and the Officers Training School (OTS) also must meet the standards. The standards limit refractive error to no more than 2 diopters of hyperopia or 0.25 diopters of myopia. Candidates must have 20/20 acuity in both eyes with no more than 0.75-diopter astigmatism and 2 diopters of anisometropia. Candidates cannot wear contact lenses within 3 months of the entry examination or have undergone radial keratotomy.

The standards are relaxed after entry for Academy and ROTC cadets and for other Air Force personnel entering pilot training. Presently, pilot candidates are limited to 2 diopters of hyperopia and 1.50 diopters of myopia with 20/70 acuities. They are also allowed 1.50 diopters of cylinder correction. After pilot training they are limited to 3.50 diopters of hyperopia, 2.50 diopters of myopia (20/200 acuities), 2 diopters of cylinder, and 2.50 diopters of anisometropia. Refractive errors over these limits are waiverable for pilots.

## INCIDENCE OF SPECTACLE WEAR IN THE U.S. AIR FORCE

In 1980 a survey by the U.S. Air Force School of Aerospace Medicine (USAFSAM) indicated that 20 percent of the USAF pilot population and 50 percent of the navigators wore spectacles. A more recent study (September 1988) by Robert Miller at USAFSAM has shown the percentage to be even higher. Over 27 percent of the USAF pilots and 51 percent of the navigators are spectacle wearers. These percentages are distributed uniformly across the four major commands, that is, Air Training Command (ATC), Tactical Air Command (TAC), Strategic Air Command (SAC), and Military Airlift Command (MAC).

There are a number of significant problems with spectacle wear by aircrew. Spectacles are prone to fogging from a combination of body heat and aircraft air conditioners. Vision can be blurred from sweat beads streaming down the lenses, and spectacles can easily be dislodged under high $+G_z$ forces and vibrations. Another major problem is the restricted field of view with the current spectacle frame when trying to locate a peripheral target. Spectacles can be very uncomfortable when worn under a helmet on long missions, and the current frame has a tendency to create hot spots above the ears. Compatibility with life support equipment, night vision goggles, and personal protective devices has always been a problem for the spectacle wearer.

How do we solve the spectacle compatibility problem? The USAF could tighten its visual standards and eliminate waivers, but by doing so the USAF would decrease its candidate pool and possibly the quality of its candidates. With the long-term trend toward myopia, only those candidates with a reserve of hyperopia would probably remain nonspectacle wearers. Other alternatives would be to make the equipment compatible with spectacles or to design a new aircrew combat spectacle that is universally compatible. The former concept, although an arduous task, is currently being examined by Bill Woessner at USAFSAM. The most pragmatic solution to the spectacle compatibility problem may be contact lenses.

## CONTACT LENS PERFORMANCE

We have been doing research on the performance of contact lenses in the aerospace environment for several years at USAFSAM. Polymethylmethacrylate (PMMA) lenses were tested on the centrifuge and in the altitude (hypobaric) chamber in the early 1970s. They performed very poorly under the effects of acceleration ($+G_z$). At the $+6\text{-}G_z$ level, the PMMA lenses were pushed far enough down the cornea to have a significant effect on visual acuity. PMMA material is relatively heavy, with a specific gravity of 1.24, and these particular lenses were small-diameter (8.2-millimeter) tricurve lenses. PMMA lenses also performed poorly in the altitude chamber. Bubbles, which had an effect on visual acuity, formed under the lenses above 20,000 feet.

In 1982 a seven-phase program was initiated to evaluate the feasibility of soft contact lens wear in the aerospace environment. A number of centrifuge riders wearing various kinds of spherical and toric lenses were subjected to acceleration forces up to $+8\ G_z$. Because of the fitting characteristics of hydrogel lenses, the maximum decentration of the lenses, including torics, was only 2 millimeters. Visual acuity was reduced somewhat at +6 $G_z$ and +8 $G_z$, but it was also reduced during the spectacle control rides.

Subjects with soft lenses were exposed to altitudes up to 25,000 feet to see if there was any bubble formation or decrement in visual acuity. Although bubbles formed as low as 6,000 feet, they were all near the limbus and had no effect on visual acuity or corneal integrity. Explosive decompressions from 8,000 feet to 25,000 feet also failed to demonstrate any significant bubble formation or loss of corneal integrity. Visual acuity and contrast sensitivity were unaffected during 75-minute rides at 25,000 feet and 4-hour rides at 10,000 feet. However, there was an increase in corneal physiological stress during the 4-hour rides at 10,000 feet, especially when low humidity was added.

Several subjects wearing soft contact lenses were challenged with physostigmine, which was used as a chemical warfare agent simulant. The data indicated that a soft lens acts as a barrier to the chemical agent for the first hour and then as a sink as it spreads the dosage out over time.

Subjects wearing soft contact lenses from USAFSAM participated in a field study on C-130 and C-5 flights to Hawaii and the Orient. They were monitored on the flights by a slit lamp and a military vision-testing device. Although visual acuity and contrast sensitivity were again unaffected during the flights, the low relative humidity (10–15%) in the aircraft cabin may have been the reason for the increased physiological stress (tear debris, conjunctival injection, and corneal epithelial staining) on the cornea. A soft contact lens field study using TAC aircrews is an ongoing project with the USAF Tactical Air Warfare Center at Eglin Air Force Base, Florida.

## USAF CONCERNS

The USAF has several concerns with contact lens wear in the aerospace environment. A major concern is that of soft contact lens dehydration due to the low humidity of the cockpit (5–15%) and the drying effect of aircraft air conditioners. The air-conditioning systems of many high-performance aircraft create drying problems by blowing across the contact lens and cornea. Most of the crew members in the TAC field test carry rewetting drops with them. We are interested in what this group believes might be the best type of rewetting agent for our environment. Also, what might be the ideal water content for a hydrogel lens in the low-humidity/air-conditioned cockpit environment? Lastly, would rigid gas-permeable (RGP) materials offer the Air Force any advantages under these conditions?

Another concern is that of foreign body incursion under contact lenses while flying. Aircraft air conditioners are a source of particulate matter in the cockpit. As an example, the F-111's air conditioner blows out particles from the aircraft's insulation. Second, the cockpits of many high-performance aircraft are dirty, and when pulling a negative $G_z$ force, this dirt rises to the top of the canopy. This may not be a problem with soft contact lens wearers, as we have had no incidences of foreign bodies interrupting a mission during the TAC soft lens test. However, it may be enough of a problem with RGPs to lead to a two-tier system for aircrew (i.e., only soft lenses for high-performance aircraft aircrew, with RGP use limited to multiplace aircraft).

The issue of wearing contact lenses in a hypoxic environment is especially germane to the Air Force. Tanker-transport-bomber aircraft are pressurized to approximately 5,000 to 10,000 feet but have longer missions (some over 12 hours in length). Fighter-attack-reconnaissance aircraft must contend, under certain circumstances, with much higher altitudes. Routinely, high-performance aircraft are pressurized to around 10,000 feet, but under rapid decompression may be exposed to altitudes of 20,000 to 22,000 feet The Air Force is interested in determining which materials, hard and soft, have the Dk values and other characteristics to support the cornea at these altitudes for this length of time.

Another concern is the effect of wind blast on vision-correcting devices when ejecting from aircraft. This is one situation where the advantages of contact lens wear may definitely outweigh those of spectacle wear. However, we do not have any jump data on fliers wearing contact lenses. Do the Army's Golden Knights wear contact lenses during their jumps?

We also have a number of logistical concerns if contact lens wear is approved for Air Force fliers. A cleaning and disinfecting system that is simple, effective, and mobile is needed. How many more eye care professionals will have to be recruited to manage a contact lens program? How many times a year do aircrew members need to be seen? Is an annual exam sufficient? Do disposable contact lenses offer the Air Force any advantages? These are just a few of the issues that we would like the panel to help us with.

# Use of Soft Contact Lenses by Tactical Aircrews

Richard Dennis

The soft contact lens test with Tactical Air Command (TAC) is a joint operational test. Jeff Hill of the Tactical Air Warfare Center (TAWC), Eglin Air Force Base, Florida, is the project manager and is responsible for collecting and evaluating the operational data. Richard Dennis of the U.S. Air Force School of Aerospace Medicine (USAFSAM), Brooks Air Force Base, Texas, is the project coordinator of the supporting laboratory and is responsible for gathering and evaluating the medical data. Hill coordinates the day-to-day operations with participating TAC units. All contact lenses and lens solutions are ordered through USAFSAM.

Aircrews from five TAC bases are participating in the soft contact lens test. Two bases, Seymour-Johnson Air Force Base, North Carolina, and Eglin Air Force Base, Florida, are F-4 test bases. Both of these bases have hot, humid climates. Cannon Air Force Base, New Mexico, is the test base for F-111 aircraft and is considered to have a drier, more arid climate. Aircrews in F-15s are being tested at Tyndall Air Force Base, Florida, again a hot and humid climate, and at Luke Air Force Base, Arizona, a dry arid climate. F-16 aircrew are also being tested at Luke Air Force Base.

Approximately 85 subjects have volunteered for the soft lens test. Of these, 50 are pilots and 35 are weapon system officers (WSOs). WSOs are utilized in the F-4 and F-111 aircraft. A greater percentage of WSOs are spectacle wearers, as their entry visual standards are lower. The field optometrists are tasked with subject selection (from prescribed criteria), contact lens fitting and dispensing, and all follow-up exams. At multioptometrist bases one optometrist is designated to support the project.

The test was designed to incorporate the idea of flexible wear. Being conservative, we did not want to subject our crew members to extended wear. However, there may be times when they may be in a situation when overnight wear is inevitable. Consequently, we are using extended-wear lenses for daily use only. Two pairs of lenses are being dispensed to each crew member, with a third set in reserve at the optometry clinics. For those crew members who can be deployed worldwide to supplement other units, one pair of lenses and accompanying care solutions are stored in the individual's "mobility" bag.

There will be a continued reliance on spectacles as a backup system. During missions the crew members are required to carry their spectacles in their flight suits. Each subject was instructed in emergency removal of their lenses and must be able to remove both lenses within an adequate time period before being allowed to fly with them. Every subject must meet the Air Force's visual standard of 20/20 acuity in both eyes with their soft lenses.

## METHOD

For statistical purposes only two types of extended-wear soft contact lenses were used for the test. We wanted to compare a medium-water-content lens with a low-water-content lens. Hydrocurve II 55 percent spherical and toric lenses were chosen as the medium-water-content lenses, and CSI-T (38 percent) lenses were chosen to represent the low-water-content lenses. The disinfecting/cleaning system was designed to be as simple and maintenance-free as possible. Heat disinfection was not an option due to the possibility of the lack of electricity at forward basing. The AOSept peroxide system is being used along with Ultrazyme enzymatic tablets. We did have a couple of clear cylindrical cases crack under the pressure of the combination disinfection/enzyming system. These have been replaced with the sturdier opaque cases. Bausch & Lomb Sensitive Eyes preserved saline, daily cleaner, and rewetting drops are also being used.

## THE TEST PLAN

The test plan is divided into three phases. Before beginning the test, a safety-of-flight board was held at USAFSAM to review the research data and to determine if it was safe to fly with soft contact lenses. The first phase included five missions flown for each subject, one of which was a night mission, and a 1-month optometric evaluation. Following phase I, a series of safety-of-flight boards were held to evaluate the data for day and night missions in each aircraft. Phase II will end after each crew member has a total of 25 missions flown while wearing contact lenses, one mission in chemical warfare gear, and a 3-month optometric evaluation. An interim report will be forwarded to TAC after phase II is completed. Phase III will be dedicated to collection of medical data.

Phase I is already completed, while the target date for phase II completion is November 15, 1988. The final completion date of the test is scheduled to be July 5, 1989.

A complete initial evaluation was done on each entering crew member by the base optometrist. The ocular indicators also were graded during this exam and will be used as baseline measures. Visual acuities and grading of the ocular indicators with the slit lamp were measured again at the dispensing exam. The follow-up exam times are determined from the date of the dispensing exam. Each follow-up exam consists of the following tests: visual acuity with soft lenses, visual acuity with spectacles after removing the lenses, keratometry, and slit lamp grading of the ocular indicators.

We are using the following as ocular indicators: corneal edema, corneal vascularization, corneal staining with fluorescein, contact lens deposits, conjunctival injection, and any papillae formation in the upper papillary conjunctiva. The categories of the grading scale were made broad enough to ensure a high probability of the graders reaching similar conclusions. Each optometrist was given a slit lamp quantification chart to help define each category for all ocular indicators.

## TEST PROTOCOL

The aircrew postmission questionnaires are filled out by each crew member after all 25 missions. They are asked to compare soft contact lenses to spectacles (i.e., better, same, worse) for the items found in Table 1.

Other data to be collected during the soft lens test with TAC include the overall cost of lenses and solutions for the entire program and the mean individual costs for lenses and solutions. Visual acuity with spectacles upon immediate removal of the lenses is another item of concern to the Air Force that will be monitored closely. We are also monitoring DNIF (duties

TABLE 1 Questionnaire Items Analyzed Following Aircrew Use of Contact Lenses

| | |
|---|---|
| Comfort | Ability to see outside objects |
| Displacement/dislodgement | Ability to see at night |
| Fogging | Tactical air mission tasks |
| Reflections | Interference with helmet |
| Effects of vibrations | Interference with chemical defense gear |
| Peripheral vision | Interference with other flight gear |
| Ability to see cockpit displays | Ground activity visual tasks |

not including flying time) due to contact lens wear through the base flight surgeons and the number of lost or torn contact lenses.

## PRELIMINARY RESULTS

The overall subjective response to soft contact lens wear by aircrew members has been very positive. In interviews with crew members the major advantage of soft contact lens wear during operations reportedly is increased peripheral vision when "checking six" (i.e., when a pilot throws his head and eyes back to check for a target). Crew members also commented that they no longer had to worry about their spectacles fogging, slipping, causing reflections, or being blurred due to sweat beads. They reported the biggest disadvantage to be dehydration of the lenses due to the aircraft's air conditioners. Although most fliers reported better vision at night with their contact lenses, two pilots complained of inferior night vision.

No subject has been lost to the test for medical indications. Only one day of DNIF time has been reported. This was due to a corneal scratch from a fractured lens early in the test. A number of lenses have been torn during the test. This was not unexpected with our test philosophy of extended-wear lenses for daily wear and the preponderance of hard to handle low-powered lenses. Three lenses have been dislodged during flight. Two were involved with $+G_z$ loading, but they may have dislodged because of other factors. One lens was determined to be an extremely loose fitting lens, while the other was a low-powered lens (-0.25 sph CSI-T) that may have been inside out.

# Job Demands in Naval Aviation

Andrew Markovits

The U.S. Navy Medical Corps is responsible not only for the care of all naval personnel, but also for the care of all Marine Corps personnel. Marine aviation is basically tactical and helicopter not particularly different from the aviation experience of the U.S. Army and the U.S. Air Force, so attention will be directed toward how Naval aviation differs from that of the other two armed services.

Most Naval personnel receive their eye care at Naval medical facilities. People at the cutting edge of Navy work, however, are people who get their eye (and other health) care on an aircraft carrier. Fleet carriers have between 2,500 and 3,000 "ship's company" aboard, with another couple of thousand people in the carrier air group. A missile frigate plus other support vessels in the fleet add another couple thousand people. The aircraft carrier is basically the home base for medical care at sea. The medical personnel on an aircraft carrier therefore look after about 7,000 to 8,000 people.

At present, there is no one with any special eye training aboard the carriers except Navy flight surgeons. The Navy has a 6-month course in aviation medicine, 6 weeks of which is flying and 4 1/2 months is didactic. We try to include as much practical ophthalmology and refraction into this time as we can. The Navy flight surgeon is a functional, if not an expert, refractionist when he finishes our course.

Naval aviators (pilots) are not permitted to wear contact lenses at this time.[1] Class 2 aviation personnel—the so-called backseaters, tactical bombardier/navigators, radar intercept officers, and flight surgeons, and enlisted aircrew—are all allowed to wear contact lenses. About 90 percent of naval flight officers (NFOs) are ametropic, and 99 percent of them are in the backseat because of it.

Until recently we were apparently the only service that had a large group of people who have legally been wearing contact lenses, that is, the NFOs and air crewmen. In most places, unfortunately, the Navy medical care system is unable to provide lenses, either their fitting or provision.

## CARRIER OPERATIONS

Some things are specifically different about Naval aviation. Navy fliers, of course, have to land on shorter runways than most other pilots do. The carrier deck is 200 to 300 feet long with four wires to catch incoming planes. When the planes are caught, the pilots experience G forces of about 4 or 5 G's of "eyeballs out." When the planes are on the catapult shot, they have the reverse, "eyeballs in." I do not know of any particular problems with contact lenses in either case, although with glasses the possibilities are obvious.

Once the pilots are down on the deck, they are still not home free. There are all kinds of tricky maneuvers to be done on the carrier deck, which frequently is pitching and rolling. Aircraft sometimes unfortunately roll off with people aboard, and, of course, the aircraft carrier turns into the wind to make launches and recoveries. A carrier is capable of about 30 knots, and on a good day with 20 knots of wind there can be up to 40 or 50 knots of air blowing across the flight deck. There are also jet fumes, particles, etc.

If a pilot must eject, say, 100 miles from the carrier and he is in the water without his visual support, and if he is a myope, he could have a problem if he has to shine a mirror or fire a flare in the direction of a rescue aircraft.

Another task is lining up the aircraft for refueling. The refueling line connects with the tanker; the final connection must be done, of course, in a few minutes. The depth perception of the pilot in this maneuver is what everything depends on. The other matter that must be dealt with in carrier aviation is the night landing; the trick is to get yourself lined up to try to steer the airplane onto the deck. Phil Briska, whom I replaced as Chief of Ophthalmology at NAMRI, was a carrier pilot and he swears that it cannot be done on a carrier with less than 20/40 vision, whereas, if flying onto a regular airfield, it could be done with 20/70 or 20/100 uncorrected vision.

## HELICOPTER OPERATIONS

As far as helicopters go, salt spray is more likely than fresh-water spray. I do not have any particular problem with a pilot study of contact lenses

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[1] There are certain helicopter squadrons requiring the use of chemical-biological-radiological protective hoods and laser protective goggles who are now waivered, and this policy is likely to be expanded.

with helicopter and patrol bomber and maritime people. Obviously, in certain cases helicopters with optical devices and protective chemical-biological-radiological gear clearly will put pilots with contact lenses at a disadvantage, although they probably will have fewer problems than with spectacles. We are considering waivers for ametropic pilots who must use CBR protective hoods to wear contacts.

## VISUAL ACUITY

What is magic about 20/20 vision? It is my understanding that during the entire Vietnam war all air-to-air contact was initiated with visual identification because there were civilian airliners flying into Hanoi.

It simply is not true that all work is being done with black boxes, radar sets, or electrooptical devices. But look what happens: if we had a fighter up there with that airbus in the Persian Gulf, I think he would have been able to tell the difference between an airbus and a hostile F-14. (I guess we have to pick the difference between a friendly and a hostile F-14 now.)

Right now I am personally opposed to the use of contact lenses by Naval tactical aviators. The demands are a little different in Naval aviation, and, of course, there are concerns about support facilities. I do not know how we are going to get around that. I do not think that in the near future we are going to be able to put an optometrist or an ophthalmologist on every aircraft carrier to handle the problems that will arise.

# Extended-Wear Lenses: The U.S. Navy's Experience

James Socks

The submariner working in a clean environment with humidity of approximately 50 percent will have a greater choice of contact lens types than the helicopter pilot who is exposed to dust and wind. The risks associated with extended-wear contact lenses are significantly different for each group, with the latter also having the heightened probability of foreign bodies under the lens, lens displacement, and lens loss.

The high-performance jet pilot, the astronaut, and the deep-sea diver will each experience markedly different environments that will affect their ability to wear contact lenses and the performance of the lenses in those particular environments.

What drives the use of contact lenses in the military and where we are heading? Basically, it is the current regulations, the vision standards, relative to each specialty community. We have heard there is a manpower shortfall. A closer look at refractive error and the relationship of visual acuity I think will drive home the point.

The vision of our aviators, or whatever the specialty happens to be, with a little bit of myopia, begins to drop off rather dramatically and particularly when astigmatic error is included, as shown by Peters (1961) in Figure 1. The aviator, then, has a great deal of difficulty performing the assigned task.

There is, of course, the problem of man/machine interface. Machines are built without man in mind, which is a major problem. Hardware developers will build the periscopes, the night vision devices, the gas masks, and then present each to the military community and say "use it." Then somebody says, "but the man can't see." Then it comes back to us to resolve the problems.

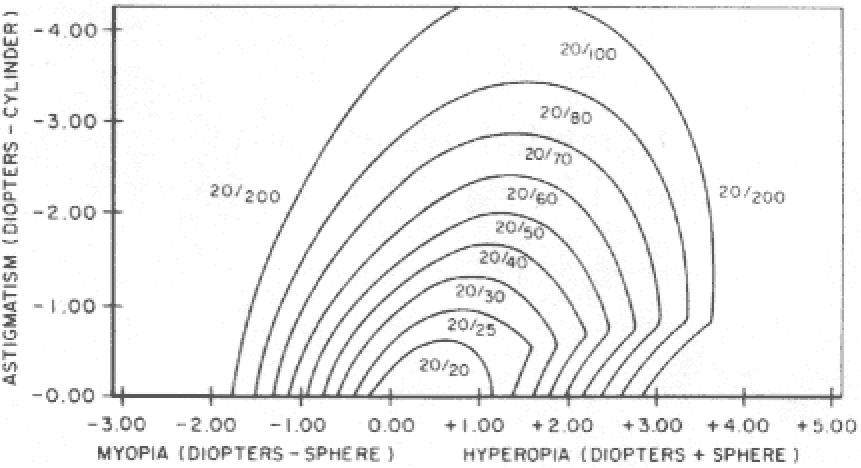

Figure 1
Level of visual acuity produced by given magnitudes of spherical and cylindrical errors (adapted from Peters, 1961).

Wearing contact lenses—be they hydrogel or rigid gas-permeable (RGP) materials—coupled with decreased humidity reduces the available oxygen to the cornea, which results in corneal swelling. Furthermore, the wearing of those lenses for an extended time results in further decrease in oxygen availability over the course of the wearing period. That results in increased swelling and a high probability of contact-lens-related complications.

In addition to the Air Force and Army's operational scenarios, we must keep in mind that special combat units operating at high mountain altitudes in the cold are exposed to a reduced partial pressure of oxygen as well as the effects of the cold. Furthermore, the U.S. Navy has given consideration to reducing the ambient partial pressure of oxygen aboard nuclear fleet ballistic missile and nuclear attack submarines in order to decrease combustibility—thus, the ever-present danger of fire that exists on submarines.

In each of these situations ocular tissues have a decreased concentration of oxygen available, and it is likely that increased insult to the cornea will result from wearing contact lenses, especially extended-wear lenses.

## COMPRESSION AND DECOMPRESSION

In studies of decompression we found that bubbles formed under hydrogel lenses during decompression (Molinari and Socks, 1987). Those bubbles left pitting of the cornea near the limbus. When we did the same decompression studies with RGP lenses in hyperbaric chambers, there was central bubbling (Socks et al., 1987). Again, that confirmed the findings of Flynn et al. (1986) that pressure changes can lead to pitting of the corneal epithelium.

The bubbles that formed underneath the lenses grew rapidly in size during the decompression, then fractured into multiple small bubbles as we reached the surface. Over a period of time, 2 to 3 hours, the dimpling disappeared. It is not known what the repeated effects of exposure in hypobaric or hyperbaric environments would have on the cornea during extended operations.

Of particular interest to us was the fact that formation of bubbles occurred from depths as shallow as 37.5 feet, which is well within the limits of the no-decompression-dive tables set by the U.S. Navy.

## EXTREME ENVIRONMENTS

Extreme cold might be experienced by mountain troops or possibly even by aviators at high altitudes. But it is unlikely that there will be a negative impact on contact lens wear (Socks, 1981, 1982), except for the fact that those environments are usually very dry. Actually, the wearing of contact lenses in extreme cold—and we are supposed to be talking about adverse environments even though we have spent most of our time speaking about the hypobaric high-altitude situation—will provide protection from wind-driven ice and snow (Kolstad and Opsahl, 1969).

The question was also raised about contaminants in the atmosphere of the cockpit and in any enclosed environment, and we have noted that many chemicals and particulate matter can be found in the submarine environment (Knight et al., 1983). Reports from submariners say that discomfort can occur at times when wearing the contact lenses aboard ship. This discomfort is often related to excess gaseous chemicals in the environment of the submarine, those that are not scrubbed out (Table 1).

I will not examine the risks of contact lens in detail because we are all aware of the specific risks of extended-wear lenses. I would like to say that the contraindications are the same for the military environment as they are for the civilian sector: inflammation, dry eye, corneal disease, and systemic disease with ocular overtones. Careful screening and patient education are absolutely vital to avoid problems during an operational situation.

Regardless of whether hydrogel or RGP lenses are used by military personnel on an extended-wear basis, they need to have spare lenses, lens care solutions that are appropriate, and access to appropriate health care professionals. Critical personnel wearing extended-wear contact lenses cannot afford to be without spare lenses during key operations. Therefore, the spare lenses must be readily available in case of loss or damage to the first pair of lenses. Disposable lenses may be an alternative.

We also need to look at the lens care systems that are available. Contact lens care systems play a vital role in the success of the contact lens wearer. For military operations simplicity is the key to compliance in the field. Storage/disinfecting solutions should possess adequate antimicrobial activity, be nonsensitizing and noncytotoxic, and have a high degree of patient acceptability. Because of limited availability of supplies and storage space in the field, it is imperative that the care regime be limited to as few components as possible and that it be simple in design and use. To this end, solutions should be multipurpose; that is, they should fill the needs of storage, soaking, disinfecting, and rinsing. The same solution might even be considered for use as a rewetting/comfort drop. Cleaners must possess adequate efficacy to rapidly remove the complex deposits that form on the lenses.

TABLE 1 Actual or Potential Sources of Contaminants in Submarine Atmospheres

| | |
|---|---|
| Human sources | Expiration (acetone, isopren, acetonitrile)<br>Other excretions (methane, $H_2O$) |
| Alimentary sources | Cooking (aldehydes)<br>Drinks (ethanol) |
| Fuels, lubricants | Leaks of diesel fuel (hydrocarbons)<br>Oils and greases (hydrocarbons, esters) |
| Materials, equipment | By emission, leak, thrown out:<br>Frigorific fluids (halons)<br>Paints, glues, cements, adhesives, sealers<br>Heat insulation (styrene)<br>Electric batteries (hydrogene, arsine, stibine)<br>Infirmary (ether, halothan)<br>Cleaning materials (ammoniac, halogenated hydrocarbons)<br>Cosmetics (esters) |
| Decomposition products | Normal (HCl, HF, CO)<br>Undersigned (HCN) |
| Indefinite | |

SOURCE: Naval Submarine Medical Research Laboratory, Special Report 83-1, June 1, 1983.

## CURRENT MILITARY EXPERIENCE WITH EXTENDED-WEAR LENSES

My comments below are based on work performed at the Naval Submarine Medical Research Laboratory in Groton, Connecticut. Keep in mind that the submariner is presented with a particular problem, the ability of the periscope operator to interface with the periscope itself because of the limitations of the optics to correct both spherical and astigmatic refractive error.

Figure 2 shows the distribution of spectacle corrections of the 154 officers and 20 enlisted men we studied. The Type 18 periscope, which is found on the Los Angeles Class 688 attack submarines, corrects to plus or minus approximately 4.5 diopters.

The entrance requirements to submarine service allow refractive spherical equivalent to plus or minus 5.5 diopters. Already the man who is at the limits is handicapped because he is 1 diopter undercorrected by the Type 18 periscope. Add to that the allowable limit on astigmatic error of 2 diopters.

It was decided that a feasibility study would be conducted. We ran this study from 1981 to 1984, primarily on fleet ballistic missile (FBM) submarine crews whose home port was Groton, Connecticut (Socks, 1985).

FBM ships may not be where the crews are home ported, and in our case in New London the ships are in the Holy Loch, Scotland. The crews leave for 3 months and relieve the opposite crew when they arrive in the Holy Loch. They go out on station for 70 days, but they are away from the base area for 3 months.

Remember 1981 was just after the first Hydrocurve and Cooper Permalenses were approved, so the materials were early-generation extended-wear materials.

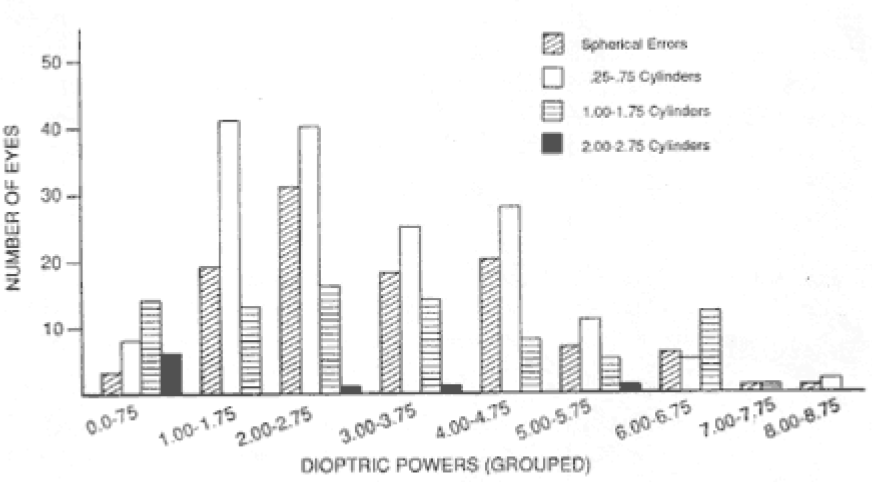

Figure 2
Distribution of spectacle corrections among submariners.

We found some problems but not very many in terms of lens replacement and tearing. These findings were not unexpected.

The other complications we found were minor, including four subjects with infiltrates and nine with minor neovascularization. Today we probably would not even put in stippling and infiltrates.

As a matter of fact, there have been no significant medical events in the time period that this program has been a fleetwide program—from about 1985, when it was initiated. In a study of submariners fit for contact lenses both under the Navy program and by non-Navy fitters, it was concluded that the risks associated with contact lens wear by submariners were low (Ulrich, 1987). Contact lenses are available at government expense to all submariners who are qualified periscope operators. The Navy will provide the care, the lenses, and the solutions. It has been a very successful program.

It has been successful, in part, because the submariners are enthusiastic; they are highly educated; they comply very strictly with the lens care instructions. I think this grows out of the Rickover era, which influenced the type of person who is accepted and trained in the nuclear submarine navy. The submariners receive regular follow-up visits; hospital corpsmen were put on the ship to ensure that they return to the clinics. We have a strong patient education program and in-depth training of Navy hospital corpsmen.

## CONCLUSION

I think contact lenses in the cockpit are inevitable. The Army, Navy, and Air Force will all have them. The equipment, the manpower, the vision standards will demand so.

We completed the pilot program and it was successful. The Air Force is doing a pilot program feasibility study, and to date it appears to be successful. I challenge the Navy air community and the Army air community and special communities within the three services to also conduct pilot programs and see what the findings are.

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