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Abstract

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of a Gas Permeable

Contact Lens Material

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A Thesis

Presented to

The Faculty of the College of Optometry

Pacific University

In Partial Fulfillment Of the Requirements of the Degree Doctor of Optometry

By

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and

Gregory D. Scott

May, 1975

approved, Niles Roth

Introduction

In 150% Leonardo da Vinci conceived the idea of neutralizing the anterior corneal power by substituting for it a new refracting surface. His "contact lenses" assumed many forms; however, all of them contained a fluid, usually water, which was directly in contact with the eye. Leonardo's work clearly suggested the concept of corneal neutralization and replacement which is a basic function of all contact lenses. In 1887 three scientists independently developed the first contact lenses actually to be placed on human eyes. Scleral contact lenses were introduced in America around 1936 by William Feinbloom, and as recently as 1947 Kevin Touhy made the first corneal contact lenses from plastic. In recent years, contact lens technology has mushroomed. Optometry has taken the dream of correcting man's vision by direct application of a lens on the eye and made it a reality.

Scleral contact lenses were a good start, but their wearing time was limited and their comfort was minimal. However, they maintain a position in the optometrist's armamentarium even today for such things as contact lens telescopes in low vision and correction in aphakia. If fit properly, scleral lenses do have advantages to recommend their use.

Corneal contact lenses made from polymethyl-methacrylate have been the treatment method of choice for many thousands of patients since their inception. They captured the research and development interest from scleral lenses and never relinquished it. Cosmetically, they are superior, and they are less frightening to the patient then the much larger scleral lenses. There have been many different methods of fitting corneal lenses developed over the years, and they are being used for a number of different therapeutic regimens. One school of thought

believes in prescribing a large lens, with an overall diameter approaching the size of the cornea and riding under the upper lid. These lenses can eliminate the flare and three-nine staining caused by enaller, interpalpebral aperture positioning lenses, but their wearing time may be limited. Furthermore with large lenses corneal respiration is often impaired, leading to edema and central corneal clouding, If smaller lenses are used, and if good centration and bearing can be achieved. then there are still the problems of flare, three-nine staining and spectacle blur to contend with. No matter what the lens-cornea relationship has been in fitting corneal contact lenses, some patients simply cannot seem to achieve confortable, safe full-time wear. The practitioner must always be on the alert for signs of neovascularization, edema, corneal curvature changes, staining and structural damage. Even in a well fitted, successful case the patient must be very careful to maintain a regular wearing schedule or risk the chances of an abrasion with all its possible consequences.

Of course, the benefits of polymethyl-methacrylate (PMMA) corneal contact lenses are innumerable, making the attempt to achieve a good fit worthwhile. PMMA provides strength, dimensional stability, high optical quality, light weight and adequate resistance to heat. PMMA contact lenses effer the patient good, stable visual acuities, convenience, cosmetic appeal and durability.

Within the last several years, a new contact lens material has been added to the scene: this material is hydrophilic and flexible, contrasting with PMMA's rigidity and hydrophobic properties. Flexible gel lenses, such as Bausch and Lomb's Soflens, have some advantages not offered by PMMA lenses. They have less potential for corneal trauma,

being flexible, and the adaptation period required is less than that for conventional PMMA lenses. Flexible lenses can be worn irregularly, or part-time, and they will not easily fall off the eye. Because flexible lenses tend to follow the shape of the cornea, they do not permit foreign bodies to come between the lens and the cornea as readily as do conventional lenses. Also, spectacle blur is practically nil with flexible lenses, and comfortable wear is achieved almost immediately.

The disadvantages of flexible lenses are their low tensile strength, affinity for proteinaceous deposits, and lack of firm and unchangeable optics. Also, their value in controlling myopia or achieving orthokeratologic corneal changes is questionable, whereas there is considerable evidence that PMMA provides some benefit in these areas. High degrees of corneal toricity or moderate amounts of refractive astigmatism can not usually be treated with flexible lenses because of their flexing characteristic. And the bugaboo of corneal edema still exists with flexible lens patients, although it may take forms other than those typical with PMMA contact lens patients.

Unimpaired corneal respiration, it seems, is the key to a safe, comfortable and long-wearing contact lens. Let's take a short look at what is known about this critical phenomenon. Mandell¹⁶ and many other authorities agree that the cornea gets the majority of its oxygen supply from two sources: the atmosphere via the tear layer, and the capillaries of the palpebral conjuctiva. During waking hours, when the eyes are open, the atmosphere provides the cornea with oxygen through the corneal epithelium via the tear film. The conjuctival capillaries take over when the eyes are closed. Without an adequate supply of oxygen the corneal tissues retain excess water, causing the epithelium

to increase in thickness and also become translucent. This is seen as gross edema or central corneal clouding by the contact lens practitioner, With a prolonged oxygen shortage the glycogen reserves in the epithelium are greatly reduced, leading to microcystic edema and patient discomfort. Depending on each patient's oxygen requirements, the interposition of a contact lens between the corneal epithelium and the atmospheric supply of oxygen may lead to impaired corneal respiratory functioning.

Hill and Fatt⁹ have shown the average oxygen consumption of the human cornea in vivo to be 48 microliters/cm²/hr. They claim that the oxygen tension in the corneal stroma drops to near zero in about three minutes when contact lenses are worn and oxygen intake is limited, Polse and Mandell⁵ have calculated the high and low minimum required oxygen tensions at the anterior corneal surface to be 3.3×10^8 (sec) (ml) (mmHg/cm) (ml 0_2) and 1.0 X 10^8 (sec) (ml) (mmHg/cm) (ml 0_2) respectively. Fatt, Bieber and Pye²¹ investigated the effects of a contact lens' oxygen transmissibility on corneal respiration. They concluded that the contact lens must have a transmissibility of 3.0×10^{-10} (cm^2) (ml 0₂)/(sec) (ml) (mm Hg) for an average cornea. Even though these studies demonstrate the importance of knowing what influences the delicate metabolic balance of the cornea, the values for each individual depend on many factors and unfortunately at this time cannot be measured by the average contact lens practitioner.

The question at this point is: can we look to the materials now being used in the manufacture of contact lenses to meet the requirements of those patients who are very sensitive to changes in the oxygen supply to their corneas, or who have erratic wearing schedules but cannot wear flexible lenses? And if not, what new materials should be considered

for clinical investigation? Among the materials we have to choose from are PMMA, hydrophilic gel, flexible gas-permeable silicone, and rigid gas-permeable hydrophobic plastic. Hill, Augsburger and Uriacke¹⁰, in a comparative study, used three in situ-based physiological tests to assess the efficacy of PMMA, gas-permeable rigid plastic, and silicone. All tests were conducted without the benefit of the tear pump mechanism that is active in normal contact lens wear. In the detection of a short-term oxygen debt, the maximum debt was produced by PMMA lenses. The oxygen permeable rigid lens results were approximately 1/3 to 1/2 the way toward the silicone results, which is well above the minimum oxygen level set by Polse and Mandell. The second test measured stability of epithelial thickness. Best results were produced by the silicone material, with the other materials causing large increases in ewithelial thickness. The authors speculated that this may have been due to the effects of a stagnant tear pool trapped under the lenses. The third test measured the effects of prolonged static contact lens wear on the epithelial glycogen reserves. Again PMMA was the worst offender, causing the greatest depletion. Silicone lenses caused the least depletion, with exygen permeable lenses causing quite a bit of depletion (again, perhaps, due to the stagnant tear pool under the lenses).

In another study, a Bausch and Lomb Soflens 0.29 nm thick at 35° C., as measured by Fatt⁵, permitted an oxygen tension at the anterior corneal surface of 2.6 X 10^{8} (sec) (ml) (mm Hg/cm) (ml 0_{2}). When the thickness was reduced to 0.20 mm, the oxygen tension became 1.8 X 10^{8} (sec) (ml) (mm Hg/cm) (ml 0_{2}). R.M. Hill¹¹ calculated that a hydrogel lens with a thickness of 0.01 mm should contain approximately 86% water

to have an oxygen permeability high enough to satisfy a closed eye's normal oxygen need. According to Hill, the normal oxygen consumption rate by a unit corneal surface is 7 microliters $(STP)/(cn^2hr)$.

The above evidence seems to show that an ideal contact lens should have the stability and optical characteristics of a rigid lens, the confort, wearability, and lack of corneal trauma of the flexible gel lens, and the gas permeability of the silicone lens. There is a new lens material available that may combine most of these characteristics. The gas permeable nature of this material was the primary object of our scrutiny in this study.

The most widely studied and publicized gas permeable contact lens to date is RX-56 by Rynco Scientific Corporation. Although we were not able to obtain RX-56 lenses, we will present its specifications as being somewhat representative of gas-permeable contact lenses in general.

RX-56 is an optically clear polymer that is permeable to oxygen, carbon dioxide and nitregen. It has a refractive index of 1.52, and it can be ordered in plus, minus, toric, and lenticular forms. The material is more flexible than PMMA and is hydrophobic, but it is claimed to be 30% more wettable by the manufacturer. Reich, Stahl and Ivani²¹ found RX-56 to be non-toxic and non-irritating to the eyes, nose and throat. It does not provide support for the growth of micro-organisms, and it has an extremely low tissue sensitivity. RX-56 lenses can be cleaned, wet and stored with any commercially available solution.

Using a standard gas permeability test (D 1434-64 as described in A.S.T.M. -- 25°C. at 1 atm. 0_2 and $C0_2$), Reich, Stahl and Ivani²¹ found the oxygen permeability of RX-56 to be 1960 ml/mil/100 in² /24 hrs., and the carbon dioxide permeability to be 7940 ml/mil/100 in²/24 hrs. They

reported the oxygen permeability rate to be approximately equal to 15.76 $ul/cm^2/hr$, for an average contact lens thickness of 0.15 mm., which is five times greater than the minimum oxygen consumption rate of the human corneal epithelium as determined by Jauregui and Fatt (2.8 $ul/cm^2/hr$). They also approximated the carbon dioxide rate of transmission to be 61.6 $ul/cm^2/hr$, RX-56 at 30°C, has an oxygen transmissibility of 3.75 X 10^{-10} (cm²) (ml 0₂)/(sec) (ml) (mm Hg), and a carbon dioxide transmissibility of 6.40 X 10^{-10} (cm²) (ml C0₂)/(sec) (ml) (mm Hg).

In searching the literature for clinical date on RX-56 contact lenses, we found only three studies to be available. Reich, Stahl and and Ivant²¹ fit rabbit eyes with RX-56 and PMMA contact lenses of varying sagittal depths. The authors compared the effects of fitting "on K", "steeper than X" and "flatter than K", as well as the effects of small, average, and large contact lens diameters in relation to the corneal diameters. The RX-56 eyes showed minimal staining or stippling, whereas the PMMA eyes demonstrated extensive trauma.

In another study with rabbits, Hill, Schultz and Thayer¹² measured the oxygen flux across the tear-epithelium interface at the center of the cornea following 120 second static wearing periods. They fit all their lenses "on K", with center thicknesses of 0.04 mm, 0.08 mm, 0.12 mm, 0.20 mm and 0.40 mm. They compared immediate post-wear fluxes to those produced by known oxygen-nitrogen mixtures applied to the eyes in mir-tight circumlimbal contact chambers, and then they estimated the equivalent percent of oxygen maintained under each lens. A PMMA lens of 0.20 mm thickness, used as a control, showed zero oxygen maintained under the lens. The oxygen permeable lenses of varying thicknesses exhibited the following results:

		thicknessapproximately			
0.08	mit	thicknessapproximately			
0.12	mm	thicknessapproximately			maintained
0.20	mm	thicknessapproximately			maintained
0.40	mm	thickness,approximately	3.7%	02	maintained

The authors conclude that contact lenses made of oxygen permeable material could be 0.30 mm or less in thickness and still meet the 5% oxygen requirement for rabbit corneas to keep epithelial glycogen stores intact (according to Uniacke, Hill, Greenberg and Seward) with no tear pump mechanism involved. Furthermore, the lenses could be greater than 0.30 mm thick and still meet the requirements if the tear pump activity is taken into account, according to the authors.

The most comprehensive study we found that dealt with human subjects was carried out by L.A. Reich²⁰ who fit one hundred eyes with RK-55 lenses. The patients were between the ages of 14 and 85; 42 were myopic, 9 were aphakic, and 2 were hyperopic. Of the 53 participants, 33 were previous PMMA contact lens wearers and 20 were new contact lens wearers. Some of the previous PMMA wearers were successful and some were not, Reich designed the lenses used so that they would be expected to produce a "tight" fit with PMMA lenses. If the corneal toricity was less than 1,00D., the lenses were 0,25D, to 0.50D, steeper than K, and 1f the corneal toricity was greater than 1.00D. the base curves were steeper yet. The optical zone widths and overall diameters of the lenses were larger than those of small, apical clearance PMMA lenses, ranging from 6.8mm to 8.4mm and 8.5mm to 10.0mm, respectively. All minus lenses used had center thicknesses of 0.10mm to 0.20mm, The author fit the lenses so as to insure that there was a good tear flow under the lenses, making the oxygen permeability factor a contributor to, rather than a provider of, the total oxygen supply needed for corneal respiration,

Reich reported that the previous PNMA wearers experienced increased comfort for lenger periods of uninterrupted wear, no thredness, and no red eyes. Also, no spectacle blue was experienced despite the length of the wearing schedule. He also noted rapid adaptation, lack of next morning symptoms, and no adverse reactions from varied wearing schedules on successive days. Reich's objective exams showed little change in postwear K readings regardless of wearing time, unchanged post-wear spectacle refractions, and no spectacle blue. The slit lamp examinations revealed only mild occasional 3-9 punctate staining in those patients wearing relatively small lenses. In all other instances the corneas were clear, showing no signs of central corneal clouding, edema, staining, corneal injection or neovascularization at the limbus.

The data we have presented on the RX-56 lens seems to indicate a definite potential for gas permeable lenses. The flow of optometric technology is moving toward contact lens materials that can satisfy physiological and biological requirements of human corneas not previously possible. Dreams are becoming realities. Dr. J.B. Goldberg, in "Biomicroscopy for Contact Lens Practice," page 51, states that "contact lenses are foreign bodies which may produce corneal physiological changes by causing trauma, by altering corneal metabolism, and by changing the levels of sensation and oxygen tension. These possibilities are eliminated when contact lens design variables are compatible with all of the factors which are related to the maintenance of corneal transparency." In our study, we hope to contribute to the development and use of a material that will further advance the optometric utilization of contact lenses as a primary therapeutic agent.

Experimental Design

Eight males and two females from the student body of Pacific University College of Optometry were selected as the subjects for our study. Their ages ranged from twenty to twenty-seven; nine were myopic and one was hyperopic, corneal toricity varied from none to 1.87D and corneal radii ranged from 7.90mm to 7.36mm (42.75 D, to 45.87 D.). Nine of the subjects had never worn contact lenses previously, and one subject had worn contact lenses for a very short time several years prior to the study. All were highly motivated to successfully wear contact lenses.

Our preliminary examination¹⁶ consisted of a thorough case history, a subjective refraction, visual acuities with and without spectacles, keratometry, and a biomicroscopic inspection with and without fluorescein. Other applicable findings were also noted and recorded, such as lid tension, blink rate and quality, tear quality and quantity, and necessary physical dimensions of cornea and fissure. All the subjects were evaluated as potentially successfully contact lens wearers, and were judged to be free from any pathology, anomaly, or defect that would be a contra-indication to their participation in the study.

Comparing the physiological effects of gas permeable contact lenses to those of PMMA contact lenses would be a monumental undertaking if attempted without a specific goal in mind. Therefore, our study, was limited to a comparison of the subjective symptoms and objective signs associated with gas permeable and PMMA contact lenses during the initial stages of adaptation. For simplicity and adequate control, one sye of each subject was fitted with a gas permeable lens and the other eye with a PMMA lens. In other words, each subject was his own control. To prevent experimental bias, the assignment of the type of lens to each eye was completed in a random manner by an outside person. Thus, due to the double blind design, neither the subjects nor the examiners knew what kind of lens was on an eye.

In order to insure that lens permeability would be the major factor under investigation, we designed the lenses for optimum fit and wearability. The Wesley-Jessen PEK fitting system provided us with a vehicle that would satisfy this criterion, as well as eliminating any subjective fitting preferences or variables inherent in any other fitting philosophy. In this way, we hoped to be able to attribute any differences in the subjective symptoms and objective signs between the two types of lenses to the differences in their permeability.

All of the PMMA lenses were computer-designed and manufactured by Wesley-Jessen. The permeable lenses were ordered from Guaranteed Contact Lenses of Arizona, Inc., and were manufactured to the same computerdesigned specifications as the PMMA lenses.

Upon receiving the lenses, the subjects were taught insertion, removal, centering and care of the lenses. All performed these tasks satisfactorily. The techniques for handling the lenses were chosen to be easily learned and readily regimented, and were those that are commonly used in contact lens practice. Care and cleaning of the lenses required that special methods be used, because the gas permeable lenses were noted to be difficult to clean and aspeticize. The specifics of the care program were as follows:

insertion....wash hands with soap, wash fingers with Glose Up toothpaste (red), rub lens for a few seconds with toothpaste, rinse lens until squeaky clean, wet lens with Soaclens, place on eye.

removal....wash hands with soap, wash fingers with toothpaste, rub lens for a few seconds with toothpaste, rinse lens until squeaky clean, soak lens in hydrogen peroxide for a maximum of 30 to 60 seconds, rinse lens well with tap water, soak in Soaclens overnight.

We discovered as the study progressed that the toothpaste should only be used to clean the lenses at night before storing them in the scaking solution. If used during the day, the toothpaste remained on the lenses and some subjects experienced a severe burning and redness that lasted for fifteen or twenty minutes after insertion. Due to this problem, our final two subjects followed a modified care schedule.

We divided the subjects into three groups, with four subjects in each of the first two groups and two subjects in the last one. Due to time limitations, the final two subjects were observed for only two days, whereas the eight subjects in the first two groups were each observed for a period of three days. The wearing schedule for those in the first two groups was six hours the first day, eight hours the second day, and ten hours the third day. The examinations took place at three and six hours the first day, five and eight hours the second day, and seven and ten hours the third day. The final two patients were examined at three and six hours the first day, and seven and ten hours the second day. Though this accelerated wearing schedule may seem out of the ordinary, it was designed to elicit maximum symptomatology and accentuate the differences between the permeable and the PMMA lenses.

Each examination consisted of a thorough case history, visual acuities with the contact lenses on, a subjective refraction over the contact lenses, fluorescein evaluation of each lens fit, a complete biomicroscopic evaluation, and keratometry. Also, biomicroscope pictures were taken to record visible objective signs and to show the progression

of any limbal vascular changes. The final examination of each day included a careful inspection of the contact lenses, including determination of base curve. A standardized form was used for all examinations (see appendix B).

To attain a continuous record of the subject's subjective symptoms during the course of the wearing time, a comfort scale was designed based on one published by Dr. Joe Breger. The subjects were instructed to rate the comfort of their contact lenses every two hours by encoding responses on the comfort scale. We stressed to the subjects the necessity of being aware of differences between their eyes. A copy of the comfort scale is included in appendix C.

In order to better evaluate the corneal curvature changes that occurred from contact lens wear, and the quality of the lens-cornea relationships, final PEK pictures were taken and analyzed by the computer. These topographical outlines can possibly detail the minute central and peripheral changes in corneal eccentricity more accurately than can the keratometer, which measures only the central cornea.

Results

We will present a short case summary for each of our ten patients in order to demonstrate the individual differences exhibited in the findings. Following this we will generalize the results into an overview of the differences between the eyes wearing gas permeable lenses and the eyes wearing PMMA lenses.

Patient 1

W.F. was a 24 year old male who had never worn contact lenses. He was myopic with a diopter of anisometropia. His corneas were very nearly spherical. On the comfort scales, W.F. rated the permeable and PMMA

eyes the same for the first two days of contact lens wear, and then rated the permeable eye as slightly more comfortable on the third day. He reported a bad cold on the first day, and stated that it may have influenced his finds. In his comments he consistently reported the permeable eye as being the most comfortable. (See table 1-a and graph 1). (Note: symptom nine was renumbered to be symptom two, for greater continuity, in graphs 1 through 10. Thus, symptom two became symptom 3, symptom 3 became symptom 4, etc. Symptoms 1 and 10 remained the same.)

In the examinations, W.F. reported some lid discomfort, some corneal discomfort, gritty, sandy feeling, dryness, and haloes. The permeable eye was reported as being generally more comfortable than the PMMA eye with respect to the above symptoms. The permeable eye was noted to be blurred much of the time, but the over-refractions indicated that the permeable lens was over-plussed. The patient's lids were observed to be slightly swollen during contact lens wear with the permeable eye being less so. (See table 1). Also, he reported no spectacle blur with the permeable eye, but one and one-half hours of blur with the ' PMMA eye, after lens removal on the first and second days of wear,

Fluorescein evaluation of the lens fits showed both to have moderate apical clearance, good centration, and adequate tear exchange. The right and left eyes had similar fits. Biomicroscopy revealed no central corneal clouding in the permeable eye, and progressively severe clouding in the PMMA eye. (See table 12). Staining was variable over time, but was usually worse in the permeable eye. (See table 13).

Keratometry showed the flat meridians (K_f) of each eye steepened with contact lens wear-the PMMA eye showed consistently more steepening than the permeable eye. The steep meridians (K_s) followed the same

pattern of steepening. (See table 14 and graph 11). The keratometer mires were clear and regular throughout the study.

Patient 2

B.H., a 25 year old male, wore contact lenses for one and one-half years about five years ago. He was a myopic astigmat with no anisometropia. His corneas showed almost two diopters of toricity. His comfort scales rated the PMMA eye as being somewhat more comfortable than the permeable eye, with both eyes becoming more comfortable with increasing contact lens wear. (See table 1-a and graph 2).

In the examinations, B.H. reported slight lid discomfort on all three days, and corneal pain at the end of the second and third days. The permeable eye was rated as being worse for these symptoms. He also reported a gritty and sandy feeling, scratchiness, redness, and photophobia. Again the permeable eye was thought to be the least comfortable On the final day, B.H. reported that both eyes ached, with the PMMA eye being more painful. All other comments gave the edge to the PMMA eye. Good acuities were attained with both lenses. The over-refractions were very close to plano throughout the examinations (see table 3).

Fluorescein evaluation of the lens fits showed both lenses to have moderate apical clearance and adequate tear exchange. Both lenses rode slightly inferior to the central cornea, with the PMMA also lens riding temporally. The right and left eyes had similar fits overall. Biomicroscopy revealed less central corneal clouding in the permeable eye, (see table 12), but more staining in the permeable eye (see table 13). The clouding disappeared in both eyes by the final day, whereas the staining was constant throughout the entire period of wear.

Keratometric findings revealed that the flat (K_f) and steep (K_g) meridians of both eyes flattened to some extent and remained flatter than normal during the course of the study. The permeable K_f 's flattened to a lesser extent that the PMMA, as was the case with the permeable K_g 's also. (See table 14 and graph 12). The keratometer mires were slightly distorted for the PMMA eye in one examination.

Patient 3

S.H., a 26 year old female, had never worn contact lenses. She was myopic with no anisometropia or astigmatism. Her corneas showed a slight amount of toricity. The comfort scale revealed a highly varying degree of comfort for both eyes, with the permeable eye being generally the most comfortable. The final hours of wear for each day showed a marked difference between the right and left eyes, with the permeable eye again being more comfortable. (See table 1-a and graph 3).

S.H.'s examinations revealed more subjective symptoms on the first and third days of the wearing time. The symptoms most often reported were corneal discomfort, a gritty and sandy feeling, and blurred, hazy vision. All except blur were experienced most by the PMMA eye. Both lenses were slightly over-plussed, however the acuity changes and overrefractions did not vary in a regular pattern. The patient often reported her acuity with the permeable eye as not being as sharp as the PMMA eye. (See table 4). Also spectacle blur after lens removal was reported to be much worse with the PMMA eye than with the permeable eye.

Fluorescein evaluation of the lens fits showed moderate apical clearance, adequate tear exchange, and good centration for both lenses. The permeable lens centered better than the PMMA lens in the last two examinations. Both left and right eyes had similar fits, however, Bio-

microscopic investigations revealed fairly extensive central corneal clouding in the PMMA eye, while the permeable eye showed little or no clouding. This was a constant situation during the course of the wearing time. (See table 12). Staining was slightly heavier in the permeable eye, but by the last day the difference was negligible. (See table 13).

The keratometer revealed a large amount of flattening of the flat meridian (K_f) of the permeable eye the first day, and then a leveling off to a slight amount of flattening. The K_f of the PMMA eye steepened more and more with time, leveling off the final day of wear. The K_g of the permeable eye fluctuated irregularly around its original value, while the K_g of the PMMA eye steepened a moderate amount the first day, and then gradually resumed its original curvature. (See table 14 and graph 13). Slight distortion of the keratometer mires was noted during one examination.

Patient 4

W.H., a 27 year old male, had never worn contact lenses. He was a myopic astigmat with a one and one-half diopter anisometropia. His corneas showed a slight amount of toricity. His comfort scale ratings showed the largest difference in comfort during the first day of wear, with the permeable eye being the most comfortable. The second day showed the PMMA eye to be the most comfortable, but by the third day the permeable eye had again become the most comfortable. The final rating placed both eyes at the same degree of comfort. The overall trend for both eyes indicated that both types of lenses became more comfortable as wearing time increased. (See table 1-b and graph 4). W.H. commented the first day about the amount of lid pain present in the PMMA eye. He had

many complaints of burning and stinging immediately after insertion due to toothpaste remaining on the lenses.

W.H.'s examinations revealed lid pain in the PMMA eye. He also reported lid discomfort, itching, haloes, and blurred, hazy vision. These were all more prevalent in the PMMA eye. Most of W.H.'s symptoms had disappeared by the third day of wear. The gas permeable lens was very much over-plussed, accounting for the blur in that eye. (See table 5).

Fluorescein evaluation of the lens fits showed moderate apical clearance, good tear exchange, and good centering for both lenses. Both lenses had similar fits. The biomicroscopic examinations revealed very little central corneal clouding with either lens. (See table 12). Staining was slight and occurred equally in both eyes, with no differences over time. (See table 13).

Keratometry revealed that the permeable eye's flat meridian (K_f) varied slightly around the original value. The PMMA eye's K_f steepened moderately and remained their during the entire study. The steep meridian (K_s) of the permeable eye steepened by a moderate amount the first day and then decreased to a slight amount by the final examination. The K_s of the PMMA eye flattened slightly the first day and then returned to its original value by the last day. (See table 14 and graph 14).

Patient 5

G.L., a 20 year old male, had never worn contact lenses. He was myopic with no anisometropia or astignatism. His corneas showed a very slight amount of toricity. The comfort scale ratings showed almost equivalent comfort for each eye. The ratings did not improve very much from the first day to the last day of wear. He was bothered several times by burning, stinging and redness on insertion of the permeable

lens. This was probably due to toothpaste residues on the lenses. (See table 1-b and graph 5).

G.L.'s examinations revealed a high degree of subjective symptoms throughout each of the three days of wear. He reported lid discomfort, a gritty and sandy feeling, redness, dryness, photophobia, haloes, and blurred, hazy vision. The lid sensation was the same for both eyes, while all the others were less prevalent for the permeable eye. (See table 6). The permeable eye was over-plussed, giving reduced acuities and a constant blur. The over-refractions consistently supported this fact. G.L. also reported more spectacle blur after lens removal with the permeable eye than with the PMMA eye.

Fluorescein evaluation of the lens fits showed moderate apical clearance, good tear exchange, and good centering for the permeable lens. The PMMA lens, on the other hand, showed a parallel fit with good tear exchange and good centering. The PMMA lens also showed some possible intermediate bearing areas after a blink. In the blomicroscope investigations, much more central corneal clouding was seen in the PMMA eye than in the permeable eye. The PMMA eye's clouding was dense and covered a large area of the cornea, whereas the permeable eye's clouding was very hazy and diffuse when it was present. (See table 12). The permeable eye exhibited extensive and almost constant staining throughout the wearing time, whereas the PMMA eye had only slight staining limited to the peripheral cornea. (See table 13).

Keratometry revealed that the flat meridian (K_{f}) of the permeable eye varied slightly around the original value, whereas the K_{f} of the PMMA eye steepened moderately the first day and remained at that level throughout the three days of wear. The steep meridian (K_{g}) of the permeable eye

steepened slightly over the first two days, and then went moderately steeper the final day. The K_s of the PMMA eye flattened slightly over the first two days, and then jumped to a moderately steep value for the final day, flattening slightly in the final examination. (See table 14 and graph 15). The keratometer mires showed a slight distortion for the PMMA eye, and medium distortion for the permeable eye, throughout the course of the lens wear.

Patient 6

L.R., a 24 year old male, had never worn contact lenses. He was myopic with no anisometropia and no astigmatism. His corneas had slight to moderate toricity. He showed no differences at all between the permeable eye and the PMMA eye in his comfort scale ratings. Both stayed at a constant, fairly comfortable level for the entire fitting time. The main complaint was lid discomfort, which stayed constant. The patient did complain of more blur with the gas permeable eye after removal on the second day of wear. (See table 1-b and graph 6).

L.R.'s examinations showed his subjective complaints to be similar on each day of the three days of contact lens wear. The major complaints were lid discomfort, a gritty and sandy feelings, scratchiness, redness, photophobia, haloes, and blurred, hazy vision. The incidence of these symptoms was less in the permeable eye for lid discomfort, a gritty and sandy feeling, scratchiness, and haloes. The patient reported more blur for the permeable eye than for the PMMA eye. (See table 7). The overrefractions showed a residual astignatism for the permeable eye, whereas the PMMA eye's over-refraction showed a plano spherical equivalent. Subjectively, the patient reported the permeable eye to be less clear, especially after a blink. He also noted more lid irritation with the PMMA

lens. Spectacle blur after lens removal was noted for both eyes at times.

Fluorescein evaluation of the lens fits showed a large amount of apical clearance, adequate tear exchange, and good centering for the permeable lens. The PMMA lens showed a moderate amount of apical clearance, good tear exchange, and temporal and inferior corneal placement. The lens fits were definitely not equal. Biomicroscopic examination revealed slight to moderate central corneal clouding in the PMMA eye, and very slight to no clouding in the permeable eye. The PMMA eye became progressively worse as wearing time increased. (See table 12). Staining was seen more on the first and last days for both eyes, with the permeable eye having less than the PMMA eye at all times. The staining was never more than a moderate amount peripherally in the PMMA eye. (See table 13).

Keratometry revealed that the flat meridian (K_f) of the permeable eye flattened by a large amount during the first day of wear, returning to a more moderate level by the end of the third day. The K_f of the PMMA eye steepened slightly during the first day of wear, and then reversed to a moderate amount of flattening by the end of the wearing time. The steep meridian (K_g) of the permeable eye varied by a moderate amount on either side of the original value, ending up with no change from the original value at the end of the study. The PMMA eye's K_g flattened by a large amount of flattening throughout the rest of the wearing time. (See table 14 and graph 16). The keratometer mires were slightly distorted at the end of each day for the permeable eye.

Patient 7

E.R., a female of age 23, had never worn contact lenses. She was hyperopic with no anisometropia or astigmatism. Her corneas had slight toricity. Her comfort ratings show a constant difference between the permeable and PMMA eyes, with the permeable eye being more comfortable. Overall comfort of both eyes improved with increased wearing time. (See table 1-c and graph ?).

E.R.'s examinations showed more subjective complaints on the first and third day of contact lens wear. Her major complaints were lid discomfort, itching, scratchiness, redness, tearing, photophobia, haloes, and blurred, hazy vision. All these symptoms occurred more often and to a greater extent in the PMMA eye, which also was reported to have corneal discomfort on the first day of wear. (See table 8). E.R. reported the PMMA lens as always feeling more uncomfortable, and as being scratchy and irritating in comparison to the permeable lens. Although her acuities remained constant throughout the study, the over-refractions were variable and erratic. No spectacle blur after lens removal was reported.

Fluorescein evaluation of the lens fits showed moderate apical clearance, good tear exchange, and good centering for both lenses. The fits were judged to be of comparable quality. Biomicroscopic examination revealed no central corneal clouding in the permeable eye until the final day, when a moderate amount was seen. The PMMA eye exhibited a moderate amount of clouding at all times, with the PMMA eye usually having more than the permeable eye. The staining in both eyes decreased with increased wearing time. (See table 13).

Keratometry revealed that the corneal curvatures in all meridians of both eyes remained very close to their original values. (See table

14 and graph 17). The keratometer mires remained clear and regular for every examination.

Patient 8

M.H., a 26 year old male, had never worn contact lenses. He was a myopic astigmat with no anisometropia. His corneas had a moderate amount of toricity. His comfort scale evaluations showed that both lenses were equally uncomfortable for the first two days of wear. Throughout most of the third day both lenses were equally comfortable except at the end of the wearing time when they both became very uncomfortable. (See table 1-c and graph 8).

M.H.'s examinations showed that the subjective symptoms became progressively less with increased wearing time. The major complaints were lid discomfort, stinging, and redness. Stinging occurred only in the PMMA eye, whereas the others were reported in both eyes equally. (See table 9). The patient reported flare for both eyes throughout the study, with the greater incidence in the PMMA eye. M.H.'s acuities were variable for the permeable eye, and the over-refractions were also variable.

Fluorescein evaluation of the lens fits showed moderate apical clearance and adequate tear exchange for both lenses. The permeable lens centered well, while the PMMA lens rode slightly inferior and temporal. The lens fits were judged to be close but not equal, with the difference being only in the centering characteristics. Biomicroscopic evaluation revealed irregular incidence of slight central corneal clouding in the permeable eye. The PMMA eye demonstrated a fairly constant level of slight to moderate clouding throughout the course of the study. (See table 12). The staining became progressively worse in the permeable eye with increased wearing time, while it remained at a constant low

level in the FMMA eye. Both eyes showed only peripheral staining the first two days, but the permeable eye showed some central staining as well on the final day of wear. (See table 13). Spectacle blur after lens removal was reported for both eyes equally.

Keratometry revealed a trend toward flattening in all meridians of both eyes. The steep meridians of each eye showed the greatest flattening, with the PMMA eye flattening more than the permeable eye. (See table 14 and graph 18). The keratometer mires were slightly distorted for both eyes at times, with the PMMA eye showing a greater amount.

Patient 9

T.K., 2 21 year old male, had never worn contact lenses. He was a myopic astigmat with no anisometropia. His corneas had a moderate amount of toricity. Due to time limitations, T.K. could only participate in the study for two days, so the wearing schedule was modified to achieve ten hours wear in two days. The comfort scale ratings showed a marked increase in comfort, as wearing time increased, for both eyes equally. The last part of the final day showed a preference for the permeable lens. (See table 1-d and graph 9). The patient reported that both eyes were very itchy, with the PMMA eye being more itchy than the permeable eye.

T.K.'s examinations showed fewer subjective symptoms on the final day of lens wear. The major complaints were lid discomfort, itching, redness, tearing, photophobia, and haloes. The first day both eyes, were reported to be equal with respect to these symptoms. The final day showed the permeable eye to have less lid discomfort, less itching, less redness, and fewer haloes than the PMMA eye. (See table 10). The patient reported the permeable eye as feeling generally more comfortable, although both eyes felt pretty good. The acuities were fairly constant

throughout the study, and the over-refractions were also constant and stable. No spectacle blur after lens removal was reported.

Fluorescein evaluation of the lens fits showed moderate apical clearance, good centering, and occasional intermediate bearing areas for both lenses. The fits were judged to be equal. The biomicroscope examinations revealed very slight central corneal clouding in the permeable eye during the first day of wear, which decreased to no clouding by the end of the study. The PMMA eye had moderate clouding during the first day's examinations, which increased to a more severe form by the end of the study. (See table 12). Staining was in evidence in both eyes the first day of wear, while the final day showed more staining in the PMMA eye. All the staining was slight to moderate and was limited to the peripheral corneal areas. (See table 13).

Keratometry revealed a trend toward steepening in all meridians of both eyes on the final day of lens wear. The flat meridian (K_f) of the PMMA eye steepened much more than any other meridian, with the steep meridian (K_s) of the PMMA eye steepening almost as much. (See table 14 and graph 19). The keratometer mires were very slightly distorted for both eyes, with the PMMA eye showing distortion more often.

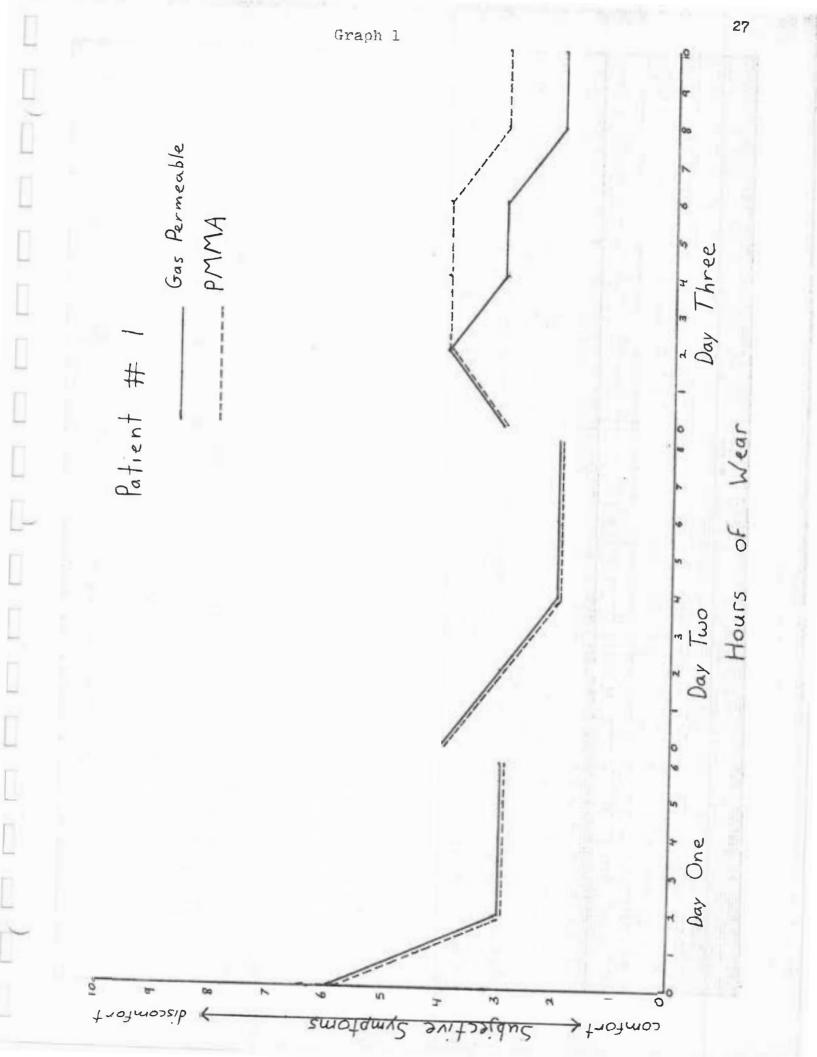
Patient 10

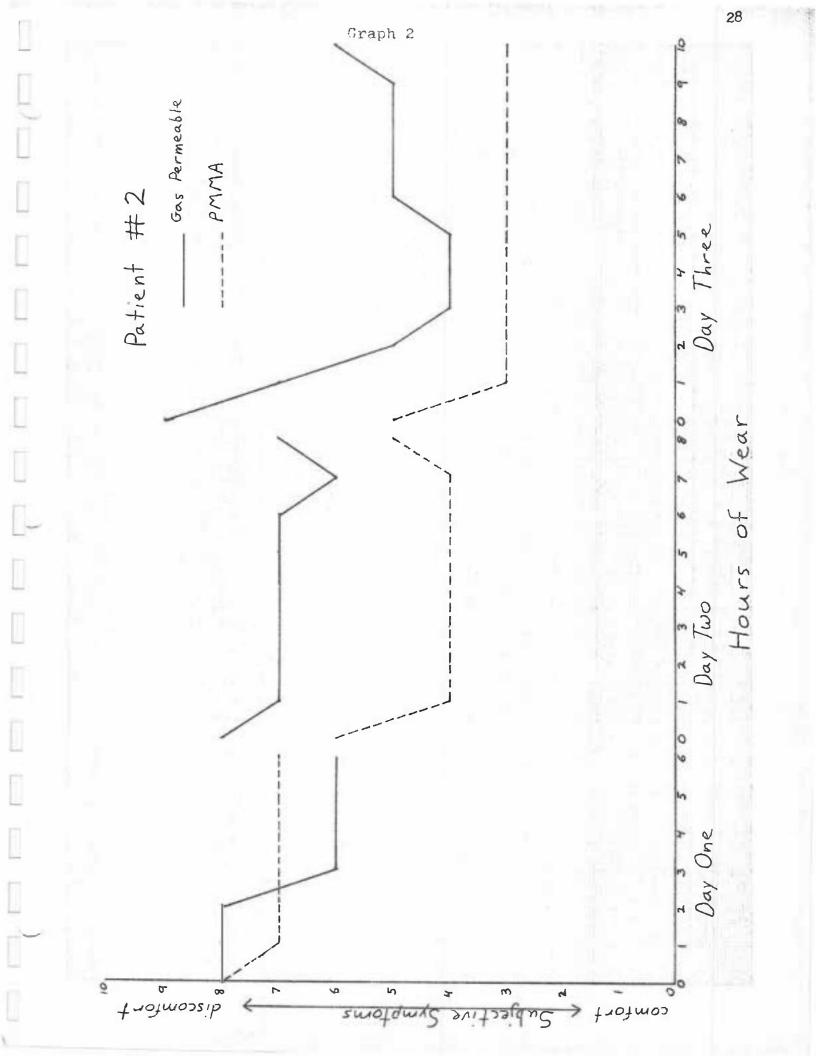
L.S., a 21 year old male, had never worn contact lenses. He was a myopic astigmat with no anisometropia. His corneas were nearly spherical. As with T.K., this patient was on a wearing schedule that permitted ten hours of wear in two days. His comfort scale ratings showed the permeable eye to be considerably more comfortable than the PMMA eye throughout the entire wearing time. Both eyes remained at about the same levels of comfort over time. (See table 1-d and graph 10).

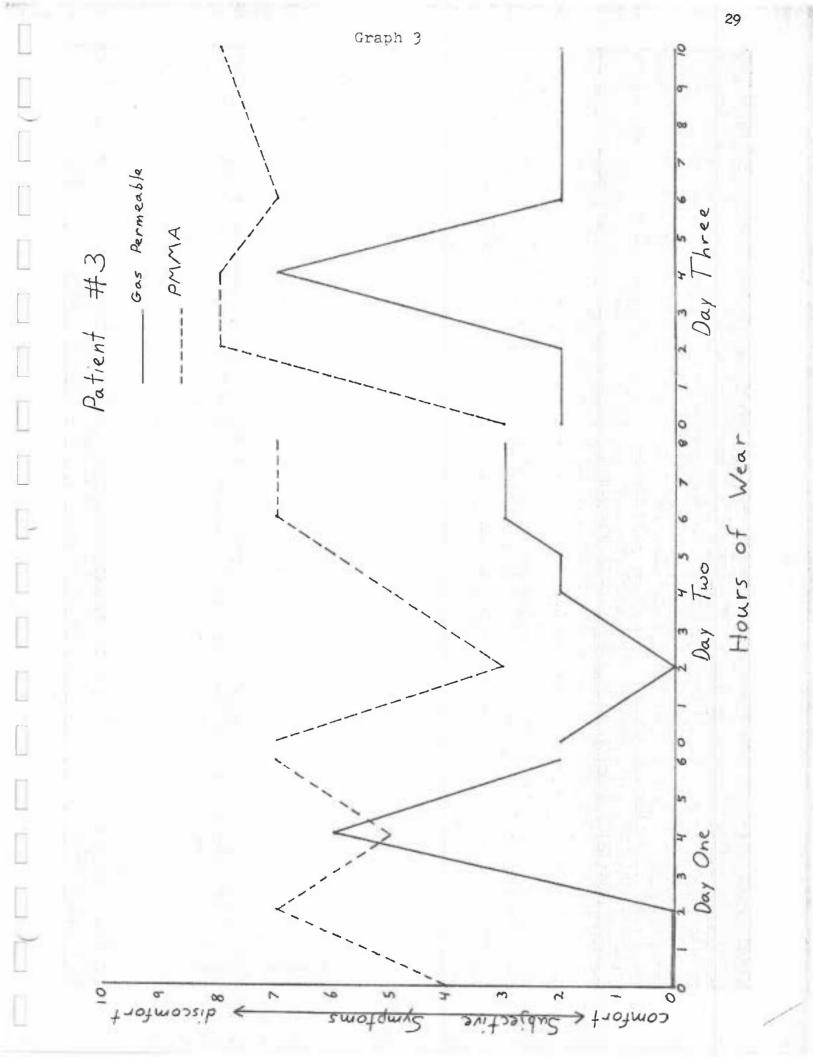
L.S.'s examinations showed a constant level of subjective symptoms during the two days of lens wear. The major complaints were lid discomfort, itching, redness, tearing, and blurred, hazy vision. The permeable eye had less incidence of lid discomfort and itching, but more incidence of blurred, hazy vision. (See table 11). The patient reported the permeable eye as feeling better than the PMMA eye overall. The acuities became progressively better with increased wearing time, but never reached an optimum level. The over-refractions showed that both eyes were overplussed by about the same amount, but the PMMA eye had the worst acuity.

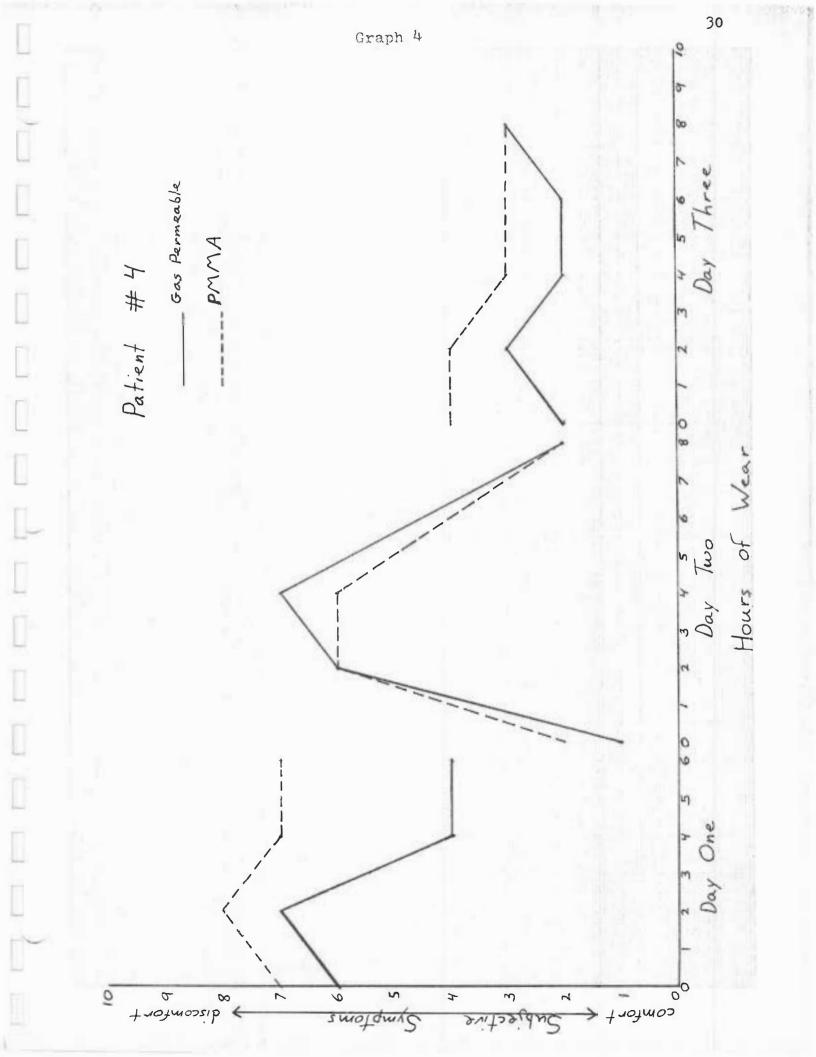
Fluorescein evaluation of the lens fits showed the permeable lens to have a better fit than the PMMA lens. The permeable lens had moderate apical clearance, adequate centering, and adequate tear exchange. The PMMA lens had inadequate apical clearance, centered poorly (low and temporal), and adequate tear exchange. The fits were definitely not equal. The biomicroscope examinations revealed slight central corneal clouding in the permeable eye the first day, which decreased to no clouding by the end of the study. The FMMA eye had moderate clouding in evidence at all examination times during the study. (See table 12). In general, the PMMA eye demonstrated a greater degree of staining than the permeable eye. However, at one point in day two the permeable eye had extensive peripheral and central stippling in evidence. This subsided by the end of the wearing time. (See table 13). No spectacle blur was reported.

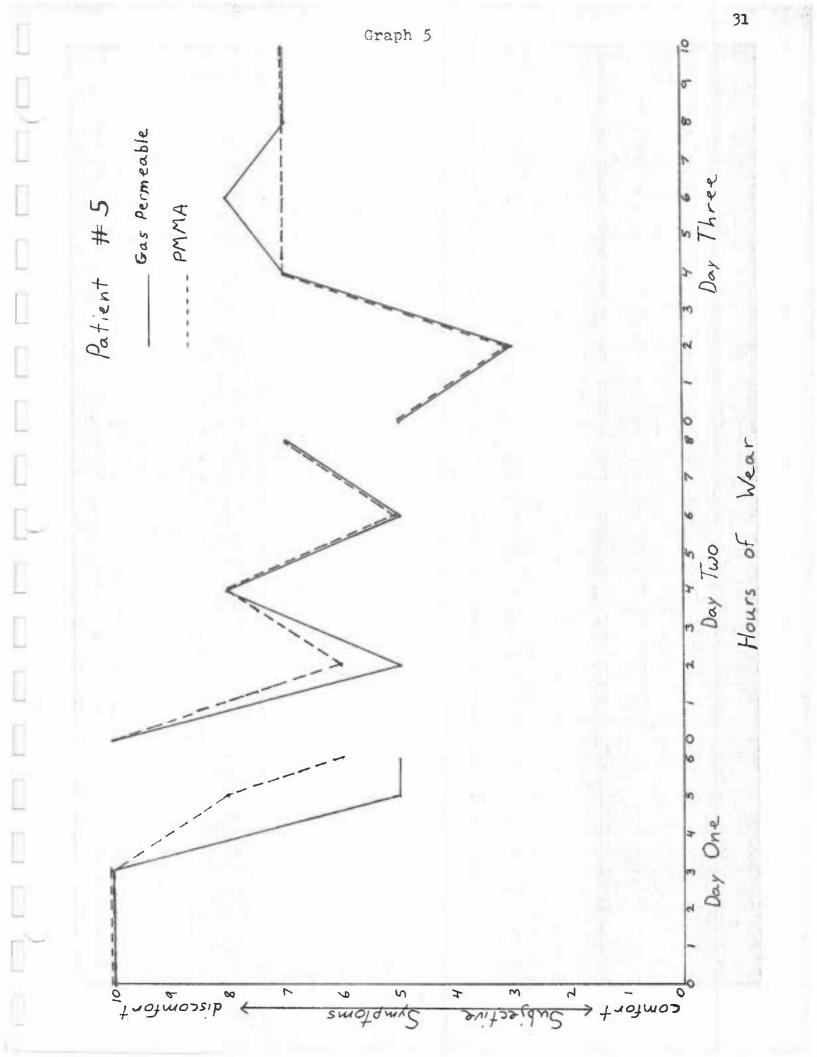
Keratometry revealed flattening of all meridians with increased wearing time, leveling off during the second day. The flat meridian (K_f) of the permeable eye flattened the least, while the K_f of the PMMA eye flattened the most. (See table 14 and graph 20). The keratometer mires had slight distortion for the permeable eye at the last examination of the wearing time.

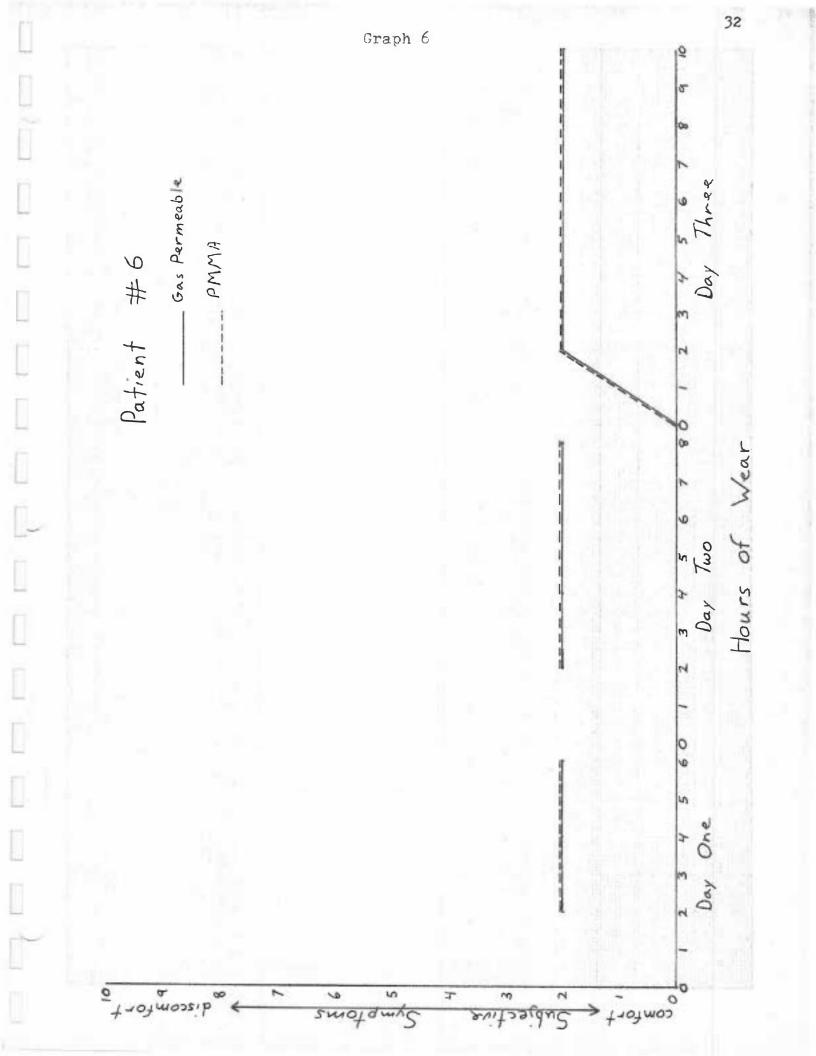


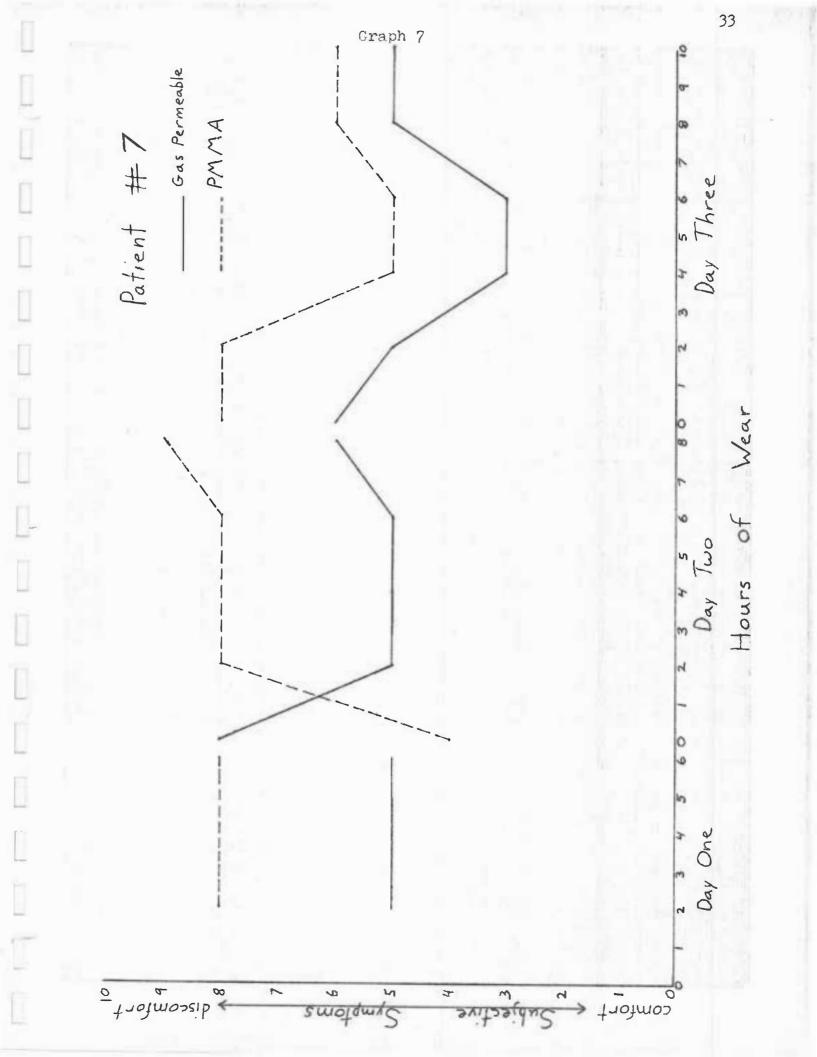


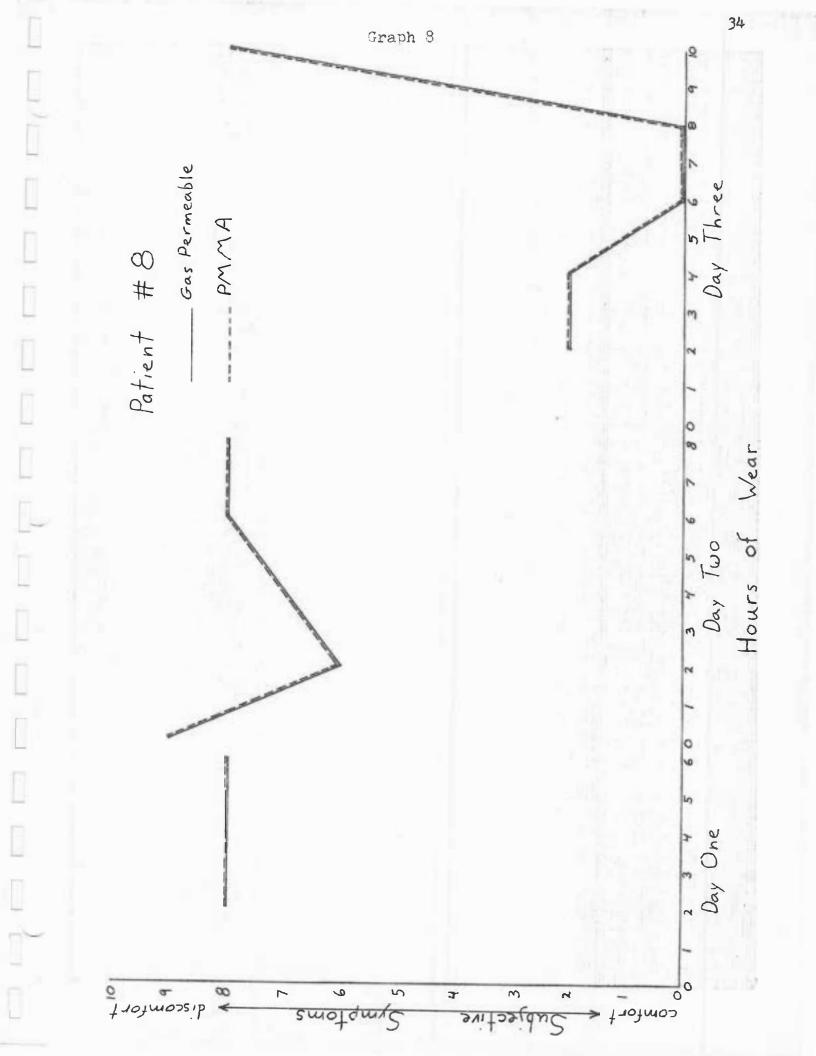


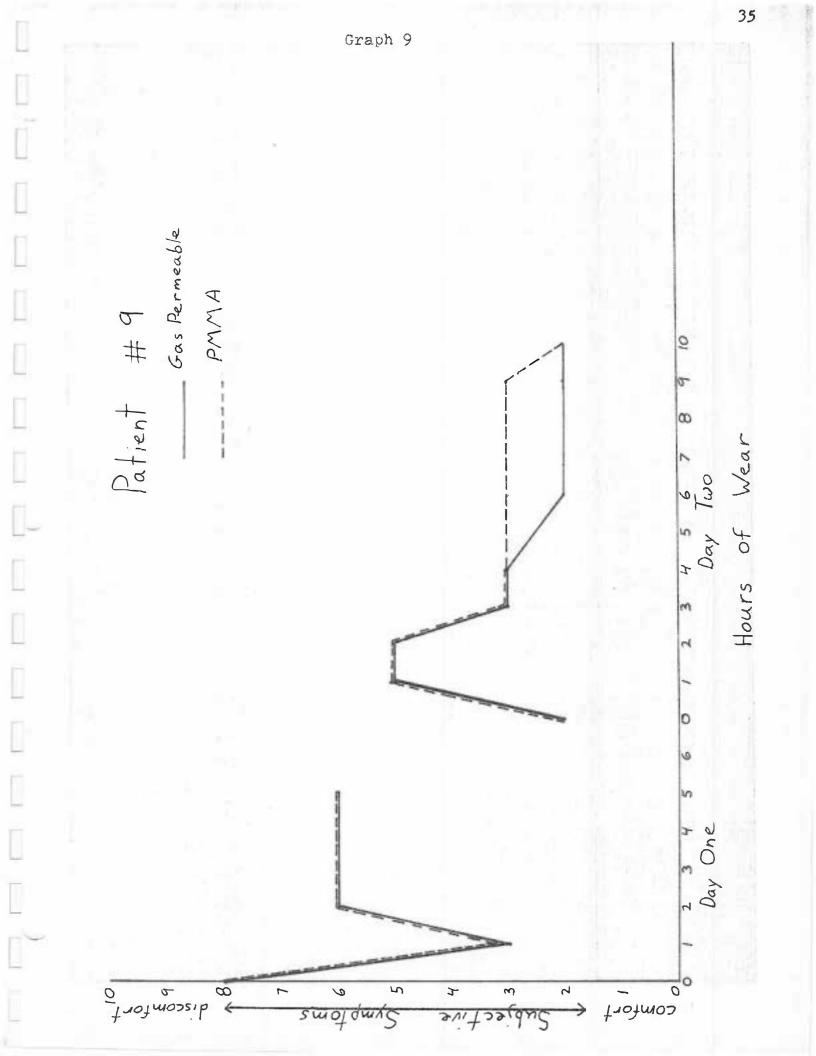


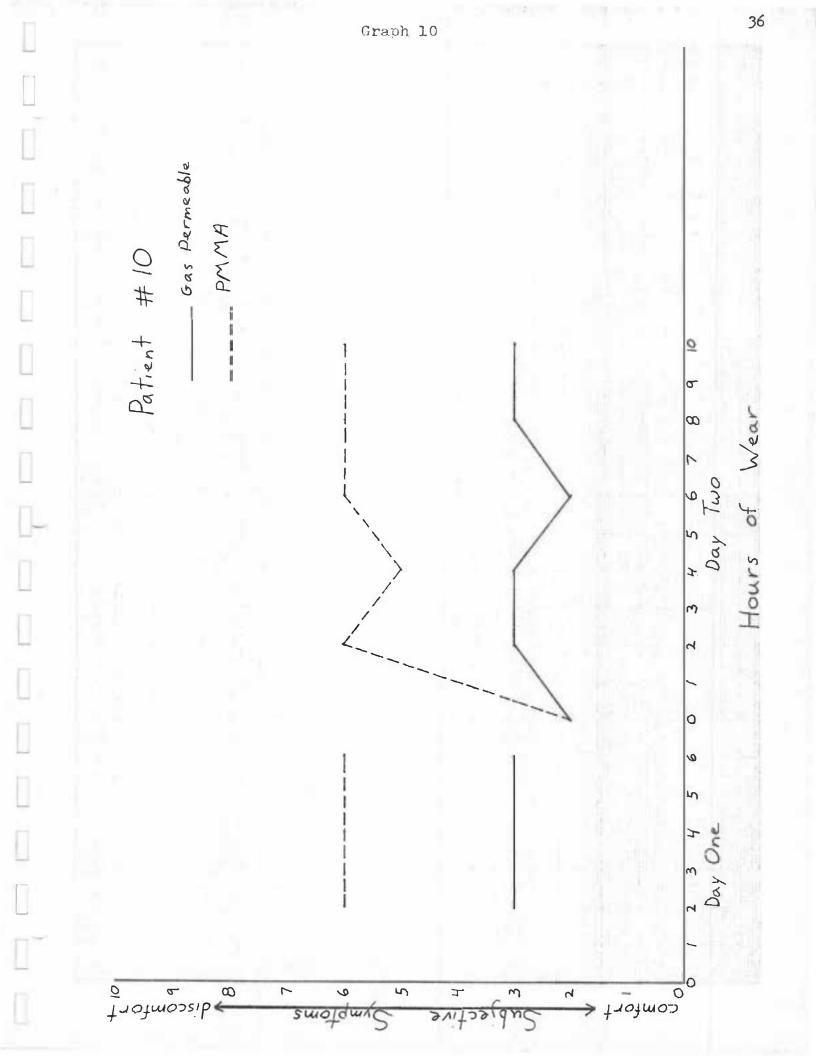












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	PATIEN	ONE	PATIEN	T TWO	PATIENT THREE		
	Permeable	PMMA	Permeable	PMMA	Permeable	PMMA	
DAY 1							
Insertion Mour 1	5	5	7	7	0	3	
2	2	2	7 7 5 2,5	6 6 6	0	6	
3 4 5 6	2	2	2,5	6	5	4	
Post-	0	0	5	6	1	6	
Removal	0	0					
DAY 2	5						
Pre-	0	0					
Insertion Insertion	0 3	0 3	7 6	5	1	6	
Hour 1 2	2	3	6 5-6	53333334	0	2	
345	1	2	5-6 5-6))) (1	4	
5 6 7	1	1	6	200	2	5 6	
7 8 Post-	1	1	5 6	4	2	6	
Removal	0	1					
DAY 3							
Pre- Insertion	0	0					
Insertion Hour 1	2	0 2	7 - 8 6	4	1	2	
2	3	3	4 3	2 2	1	7	
4	2	3	4 3 3 3 4	2 2	6	7	
3 4 5 6 7 8 9 10	2	3	4	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	1	6	
8	1	2 2	4 4 5	2	2 K. C		
Post- Removal	0	2	2	2	1	7	
VOID AST	U	+					

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	PATIEN	FOUR	PATIEN	NT FIVE	PATIEN	T SIX
	Permeable	PMMA	Permeable	PMMA	Permeable	PMMA
DAY 1						
Insertion Hour 1	5	6	8,10	8,10		
2	6	7	5,7,10	5,7,10	1,9	1,9
3 4 5 6	3	6	2,4	2,5,7	1	1
Post=	3	6	4	5	1	1
Removal						
DAY 2						
Pre- Insertion Insertion	0 9	9 1	1 5,10	1 5,10		a
Hour 1 2	5	5	4	5	1	1
3 4 5 6 7	6	5	7,9	7,9	1	1
56			4	4	1	1
8	1	1	6	6	1	1
Post- Removal			0	0	0	0
DAY 3						
Pre- Insertion Insertion	1,9	3	0 4	0 4	0 0	0
1 nour 1 2	2	3	2	2	1,9	1,9
4	1	2	6	6	1	1
6	1	2	7	6	1	1
Hour 1 2 3 4 5 6 7 8 9	2	2	6	6	1	1
10 Post-			6	6	1,9	1,9
Removal					9	9

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	PADIENS	SIGNION	PATIENT	EIGHT	
	Permeable	PMMA	Permeable	PMMA	
DAY 1					
Insertion Hour 1					
	1,4	1,7	7	7	
2 3 4 5 6	1,4	1.7	7	7	
6 Post-	1,4	1,7	7	7.9	
Removal			0	4	
DAY 2					
Pre-					
Insertion	1,9	1,9	0	•	
Insertion	1,7	1,3	0	0 8	
Hour 1	± • /	1.0	8	0	
	1,4	1,7	5	5	
4	2,4	1,7			
2 3 4 5 6 7 8	2.4	2,7	7	7	
8 Post-	1,5	1,8	7	7.9	
Removal	1	0	1	1	
DAY 3					
Pre-					
Insertion			0	0	
Insertion Hour 1	1.5	1,7			
2	2,4	1,7	1	1	
45	0-2	2,4	1	1	
3 4 5 6 7 8	2	2,4	0	0	
9	2,4	2,5	0	0	
10 Post-	1,4	1,5	7	7	
Removal					

	PATIENT	NINE	PATIENT	TEN
	Permeable	FMMA	Permeable	PMMA
DAY 1				
Insertion Hour 1 2 3	25	7 2 5	2	5
2 3 4 5 6	5	5	2	5 5
Post- Removal	0	0		2
DAY 2				
Pre- Insertion	15		Av Sed	
Insertion Hour 1 2	1 2-4 4	1 2-4 4	1 2	1 5
3 4 5	2 2	2 2	2	4
3 4 5 6 7 8 9	1	2	1 2	5 5
9 10 Post-	1	2 1	2	5
Removal				

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Patient # 1

Perm PMMA

Pain (lid)

SUBJECTIVE SYMPTOMS REPORTED IN CASE HISTORIES

Pain (cornea)	Perm PMMA				1			
Discomfort (lid)	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX						
Discomfort (cornea)	Pefin PMMA		1971				**********	1
Burning	Perm PMMA				Sector 2		 	
Hot	Perm PMMA			19 - L		-		
Itching	Perm PMMA							
Gritty, sandy	Perm PMMA	XXXXXXXXXXXXXXX			00000000000000000	000000000000000000000000000000000000000	000000000000000000000000000000000000000	*****
Stinging	Perm PMMA	·						
Scratchy	Perm PMMA							
Redness	Perm PMMA			-				
Dryness	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX			000000000000	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXX	*****
Tearing	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX						
Photophobia	Perm PMYA				1.5.1.5			
Haloes	Perm PMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX				*****	******	*******
Elurred, hazy vision	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX					XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Other	Perm PYYA	***********			Contraction of the second s		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
		3 Hours	6 Hours		5 Hours	8 Hours	7 Hours	10 Hours
		DAY O	NE		DAY	TWO	DAY TI	HREE

Table

#2

		3 Hours DAY (6 Hours	5 Hours DAY	8 Hours	7 Hours 10 Hours DAY THREE
)ther	Perm PMMA	XXXXXXXXXXXX	2000000000			
Elurred, hazy vision	Perm Pyya					
Haloes	Perm PMMA					
Photophobia	Perm PMKA			XXXXXXXXXXXX XXXXXXXXXXXXXX		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Tearing	Perm PMMA	******	XXXXXXXXXXXX			
Dryness	Perm PMA					
Redness	Perm Pi21A		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX			XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Scratchy	Perm PMMA		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Stinging	Рега Рима					
Gritty, sandy	Perm PMMA				XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
Itching	Perm PMMA				XXXXXXXXXXXXX	
Hot	Perm PMMA					
Burning	Perm PMMA			100 100 100	10.16.76	
Discomfort (cornea)	Perm PMMA					
Discomfort (lid)	Perm PMMA					
Pain (cornea)	Perm PMMA				XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Pain (lid)	Perm PMMA					

Patient # 2

SUBJECTIVE SYMPTOMS REPORTED IN CASE HISTORIES

Table #3

Patient # 3

SUBJECTIVE SYMPTOMS REPORTED IN CASE HISTORIES

- 43

		3 Hours	6 Hours	5 Hours	8 Hours	7 Hours	10 Hours
)ther	Perm PMMA	00000000000000	XXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXX	00000000000000000000000000000000000000	000000000000000000000000000000000000000
Elurred, hazy vision	Perm PMMA	XXXXXXXXXXXX			XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Haloes	Perm PMMA	00000000000000	XXXXXXXXXXX XXXXXXXXXXX				000000000000000000000000000000000000000
Photophobia	Porm PMMA		See 2				
Tearing	Form PMMA					XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
Dryness	Perm PMMA		000000000000000000000000000000000000000				
Redness	Perm PMMA	_				XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
Scratchy	Perm PMMA					000000000000000000000000000000000000000	
Stinging	Perm PMMA					0000000000 X XXXXXXXXX	
Gritty, sandy	Perm PMMA					000000000000000000000000000000000000000	
Itching	Perm						
Hot	Pere PMMA	000000000000000000000000000000000000000	00000000000000000	1			
Burning	Perm Phone						
Discomfort (cornea)	Pefm PMMA		000000000000000000000000000000000000000			XXXXXXXXXXX	
Discomfort (lid)	Perm PMMA				1		
Pain (cornea)	Perm PMMA						
Pain (lid)	Perm PMMA		1. A.		1. ····		

		DAY O	NE	DAY 7	WO	DAY TI	HREE
		3 Hours	6 Hours	5 Hours	8 Hours	7 Hours	10 Hours
)th er	Perm PMY.A						
Elurred, hazy vision	Perm PMMA			XXXXXXXXXXXX		000000000000000000000000000000000000000	
Haloes	Perm PMMA	00000000000000000	XXXXXXXXXXX	000000000000000000000000000000000000000		000000000000000000000000000000000000000	000000000000
Photophobia	Perm PMYA		CXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXX		
Tearing	Perm PMMA	XXXXXXXXXXX XXXXXXXXXX		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Dryness	Perm PMMA						
Redness	Perm PMMA		1		000000000000000000000000000000000000000	0000000000	
Scratchy	Perm PMMA						
Stinging	Perm PMMA						
Gritty, sandy	Perm PMMA			XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Itching	Perm PMMA		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	000000000000000000000000000000000000000		
Hot	Perm PMMA	• • • • • • • • • • • • • • • • • • •	0000000000	Cost of the second			
Burning	Perm PMMA	371.122	1		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		
Discomfort (cornea)	Perm PMMA						
Discomfort (lid)	Perm PMMA	XXXXXXXXXXXX	000000000000000000		000000000000000000000000000000000000000		
Pain (cornea)	Perm PMMA						
Pain (lid)	Perm PMMA		00000000000	100			

Patient # 4

SUBJECTIVE SYMPTOMS REPORTED IN CASE HISTORIES

		DAY C	INE	DAY 1	IWO	DAY T	HREE
		3 Hours	6 Hours	5 Hours	8 Hours	7 Hours	10 Hours
)ther	Perm PMMA						
Elurred, hazy vision	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
faloes	Perm PMYA	*****		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	TOM USE STATE OF A STOCK STOCK
Photophobia	Perm PMYA	1		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX		XXXXXXXXXXX XXXXXXXXXX
Tearing	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX			
Dryness	Perm PMMA			XXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	X X X X X X X X X X X X X X X X X X X
Redness	Perm PMMA			00000000000000		and the second sec	****
Scratchy	Perm PMMA		XXXXXXXXXXXX XXXXXXXXXXXX		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		
Stinging	Perm PMMA	•					
Gritty, sandy	Perm PMMA						**************************************
Itching	Perm				XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		XXXXXXXXXXXXX XXXXXXXXXXXX
Hot	Perm PMMA	1 2 2 3					
Burning	Perm PMMA	199.42	1,1,165				
Discomfort (cornea)	Perm PMMA			2			*****
Discomfort (lid)	Perm PMMA				XXXXXXXXXXXXX		****
Pain (cornea)	Perm PMMA						
Pain (lid)	Perm PMMA	00000000000					1

Patient # 5

SUBJECTIVE SYMPTOMS REPORTED IN CASE HISTORIES

Table #6

		DAY C	NE	DAY		DAY TH	REE
	T L'ALAN	3 Hours	6 Hours	5 Hours	8 Hours	7 Hours	10 Hours
)ther	Perm PMMA						000000000000000000000000000000000000000
Elurred, hazy vision	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		XXXXXXXXXXXX		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
laloes	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
Photophobia	Perm PMMA			XXXXXXXXXXX XXXXXXXXXXXXXX		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
Tearing	Perm PMMA			XXXXXXXXXXXX XXXXXXXXXXX			XXXXXXXXXXXXX XXXXXXXXXXXXX
Dryness	Perm PMMA	000000000000000000000000000000000000000	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX				
Redness	Perm PMMA		XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX			**************************************
Scratchy	Perm PMMA	000000000000000000000000000000000000000	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXX		XXXXXXXXXXXXXX XXXXXXXXXXXXX
Stinging	Perm PMMA	1 .					XXXXXXXXXXXX XXXXXXXXXXXX
Gritty, sandy	Perm PMMA		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX			***********	XXXXXXXXXXXXX
Itching	Perm PMMA						****
Hot	Perm PMMA						
Burning	Perm PMMA		100000		1. 6. S 2.	and and a state of the	
Discomfort (cornea)	Perm PMMA						
Discomfort (lid)	Perm PMMA		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	Construction of the second			1
Pain (cornea)	Perm PMMA		10 (a 14				
Pain (lid)	Perm PMMA			R. C.			

Patient # 6

SUBJECTIVE SYMPTOMS REPORTED IN CASE HISTORIES

Patient # 7

DAY ONE

SUBJECTIVE SYMPTOMS REPORTED IN CASE HISTORIES

DAY TWO

Pain (lid)	Perm PMMA			122			
Pain (cornea)	Perm PMMA		farmer -				
Discomfort (lid)	Perm PMMA	*****	XXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	00000000000000000	*******
Discomfort (cornea)	Perm PMMA	0000000000000	000000000000000000000000000000000000000				
Burning	Perm PMMA		000000000000000000000000000000000000000				1
Hot	Perm PMMA		000000000000000000000000000000000000000		14 M		XXXXXXXXXXXX
Itching	Perm PMMA		******			XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
Gritty, sandy	Perm PMMA						
Stinging	Perm PMMA						
Scratchy	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX			XXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX
Redness	Perm PMMA		0000000000000	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	1	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	00000000000000000
Dryness	Perm PMMA				000000000000000000000000000000000000000	XXXXXXXXXXX 0000000000	
Tearing	Perm PMMA			XXXXXXXXXXX	00000000000	000000000000000000000000000000000000000	
Photophobia	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	42	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
Haloes	Perm PMMA	000000000000000000		000000000000000000000000000000000000000			XXXXXXXXXXXX XXXXXXXXXXXX
Elurred, hazy vision	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	X0000000000000000000000000000000000000	000000000000000000000000000000000000000		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXX XXXXXXXXXXX
)ther	Perm					********	

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DAY THREE

		DAY (ONE	DAY	TWO	DAY TI	HREE
	100	3 Hours	6 Hours	5 Hours	8 Hours	7 Hours	10 Hours
Other	Perm PMMA					-	
Elurred, hazy vision	Perm PMMA				XXXXXXXXXXXX		
Haloes	Perm PMMA	XXXXXXXXXXXX					
Photophobia	Perm PMMA						
Tearing	Perm PMMA			XXXXXXXXXXX			
Dryness	Perm PMMA						XXXXXXXXXXXX XXXXXXXXXXXX
Redness	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX			XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		************** *****
Scratchy	Perm PMMA		XXXXXXXXXXX 00000000000				
Stinging	Perm PMMA		00000000000	000000000000000000000000000000000000000	000000000000000000000000000000000000000	1. 1. 1. 1.	
Gritty, sandy	Perm PMMA				000000000000000000000000000000000000000		XXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXX
Itching	Perm PMMA						-
Hot	Perm PMMA		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	1000			
Burning	Perm PMMA				and the second	a	-
Discomfort (cornea)	Perm PMMA						
Discomfort (lid)	Perm PMMA				CCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCC		XXXXXXXXXXX
Pain (cornea)	Perm PMMA						
Pain (lid)	Perm PMMA						

Patient # 8

SUBJECTIVE SYMPTOMS REPORTED IN CASE HISTORIES

Patient # 9

SUBJECTIVE SYMPTOMS REPORTED IN CASE HISTORIES

		DAY (DNE			DAY T	ଜପ
		3 Hours	6 Hours	5 Hours	8 Hours	7 Hours	10 Hours
)ther	Perm PMMA		1.2			000000000000000000000000000000000000000	
Blurred, hazy vision	Perm PMMA	XXXXXXXXXXX					
Haloes	Perm PMMA		****			XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX XXXXXXXXXXXX
Photophobia	Perm PMMA		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		1971	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	- /
Tearing	Perm PMMA	XXXXXXXXXXX	XXXXXXXXXXXX XXXXXXXXXXXX				XXXXXXXXXXXX XXXXXXXXXXX
Dryness	Perm PMMA						
Redness	Perm PMMA		XXXXXXXXXXXX				*********
Scratchy	Perm PMMA						
Stinging	Perm PMMA	*					
Gritty, sandy	Perm PMMA						
Itching	Perm PMMA			14315			00000000000000000000000000000000000000
Hot	Perm PMMA						
Burning	Perm PMMA	1.000		1.	1.		
Discomfort (cornea)	Pefe PMMA						
Discomfort (lid)	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX					
Pain (cornea)	Perm PMMA						

Perm

PMMA

Pain (lid)

-

Pain (lid)	Perm PMMA								
Pain (cornea)	Perm PMMA								
Discomfort (lid)	Perm PMMA						XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		
Discomfort (cornea)	Реги РМКА								
Burning	Perm PMMA								
Hot	Perm PMMA								
Itching	Porte PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX							
Gritty, sandy	Perm PMMA								
Stinging	Perm PMMA				1				
Scratchy	Perm PMMA								
Redness	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		2				XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
Dryness	Perm PMMA						-		
Tearing	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX					XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		
Photophobia	Perm PMMA	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX					XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX		
Haloes	Perm PMMA								
Elurred, hazy vision	Perm FMMA		XXXXXXXXXXXX				******		
)ther	Реги РУУА								
		3 Hours	6 Hours		5 Hours	8 Hours	7 Hours	10 Hours	

Patient # 10

SUBJECTIVE SYMPTOMS REPORTED IN CASE HISTORIES

Table #11

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General Overview

We found the patient comfort scales to be very valuable in charting the flow of subjective symptoms during the daily wearing times. Most of the patients were able to complete the scale every two hours with little inconvenience. Doing this also made it easier for the subjects to be aware of the differences between their right and left eyes at the examination times. Overall, four out of the ten patients scaled the permeable lens as being more comfortable than the PMMA lens during the wearing time. Five of the ten patients scaled the permeable and PMMA lenses as being equally comfortable. And one out of the ten patients preferred the PMMA lens to the permeable lens for comfort.

We broke down the patient comfort scale into the percent occurrence of each symptom over time for the permeable and PMMA eyes. Looking at the most commonly occurring symptoms, we found that the less severe symptoms occurred more frequently for the permeable eyes, and the more severe symptoms occurred more frequently for the PMMA eyes, on the whole. However, over time, there does not seem to be a predictable relationship between the type of lens worn and the severity of a particular symptom. See graphs 28 through 38 for more detailed information. The most consistently reported symptom for both types of lenses, on the comfort scales was "awareness", followed by "light to medium awareness" for the permeable lens and "medium foreign body feeling can tolerate but annoying" for the PMMA lens.

In the case history portion of each examination, we elicited a differential report of subjective symptoms from each patient. This was done to find out which of the commonly heard adaptational complaints in contact lens practice would be associated with gas permeable lenses as compared

to PMMA lenses, as well as to determine which type of lens was the most comfortable overall. In order to more easily understand the results, we selected the seven most frequently reported symptoms from the examination case histories. Of the seven symptoms, five were typically associated with the wearing of both kinds of lenses (using the number of times reported as the significant factor). These five symptoms were lid discomfort, itching, gritty and sandy feeling, tearing and photophobia. In other words, of all the symptoms reportedly experienced by our patients, these five were reported to about the same extent for both permeable and PMMA lenses. Two symptoms were more frequently reported for the PMMA lenses than for the permeable lenses. These were redness and haloes. The permeable lenses, therefore, had pretty much the same types of adaptational symptoms associated with them as did the PMMA lenses, with the exception of redness and haloes. All the other subjective symptoms that were experienced by the patients and reported to us in their examination case histories were of significantly less frequency than the seven mentioned above. They also followed the same trend, however,

As mentioned in the introduction, one of the most significant factors indicating the need for a gas permeable lens is the requirement for maintaining an adequate oxygen supply to the cornea, thereby allowing proper corneal metabolism and reducing the incidence of edema, or central corneal clouding. This study was designed to detect the occurrence of edema by both objective and subjective means. The primary objective method used was the biomicroscope. We also made use of the acuities and over-refractions as additional checks, while subjective checks for edema were included in the comfort scales and in the examination case histories. The results of the latter data were presented in the individual case sum-

maries, and we will discuss their correlations in the "discussion" section of this report. The results of the biomicroscope examinations showed a very significant difference between the permeable and the PMMA contact lenses. Using a rating scale for central corneal clouding based on one designed by Dr. Maurice Poster,¹⁸ we calculated and plotted the mean values over time for the permeable lenses and for the PMMA lenses. These values represent a gradation in the severity of the central corneal clouding, and are explained on the page preceding graph 21, where the data is plotted. This graph is only meant to illustrate the comparison between the two types of lenses, and cannot be relied upon to provide accurate numerical values. For individual statistics, see table 12.

As can be seen from graph 21, throughout the total hours of lens wear the permeable lenses resulted in a significantly lower incidence of central corneal clouding as compared to the PMMA lenses. Also, the permeable lenses showed a less severe gradation of clouding than did the PMMA lenses. The greatest disparity between the two types of lenses occurred at the end of the second and third days of lens wear. In fact, nine of the ten patients in the study showed much less severe central corneal clouding for the gas permeable lenses than for the PMMA lenses. One patient had equal clouding for both types of lenses.

Corneal staining was also coded according to a scale based on one by Dr. Maurice Poster¹⁸. The values were graphed in the same manner as were the central corneal clouding values, and can be found in graph 22. The mean values show a greater severity of staining for the permeable lenses on each of the three days of contact lens wear. However, the difference between the permeable and FMMA lenses is not as great as that for central corneal clouding. Five of the ten patients in the study

showed less severe staining for the PMMA lenses. Three patients showed less severe staining for the permeable lenses, and two patients showed equally severe staining for both types of lenses. Individual statistics for corneal staining can be found in table 13.

In order to evaluate any adverse physiological effects resulting from either the lens materials or errors in the design of the lenses, we utilized both the keratometer and the PEK. Keratometry was performed at every examination, whereas PEK photographs for analysis were taken at the beginning of the study, prior to lens wear, and after the lenses were removed on the final day. The keratometer measures central corneal curvatures, and the PEK measures changes in overall corneal topography, and provides an eccentricity value for each meridian. In graph 23 and table 15, the mean keratometric corneal curvature changes are plotted. The mean dioptric change over time was not significant for the flat meridians (K_{f}) or the steep meridians (K_{s}) of either the permeable eye or the PMMA eye. All mean curvature changes were less than 0.25 diopter. In other words, neither lens material caused significant change in the mean corneal curvatures as measured by the keratometer. However, it may be noted that the mean K_{f} of the corneas wearing the permeable lenses flattened, whereas the mean K_{f} of the corneas wearing PMMA lenses steepened. Also, there were less individual variations over time for the mean K_{f} of the corneas wearing permeable lenses as compared with all the other meridians. The mean K_{f} of the corneas wearing PMMA lenses had the greatest individual variations over time. (See graph 24, 25, 26, 27).

According to Borish, in a study done by Black, the error inherent in keratometry readings is plus or minus 0.25 diopter. Using this as a criterion, three of ten patients' mean K_{f} values for eyes wearing permeable

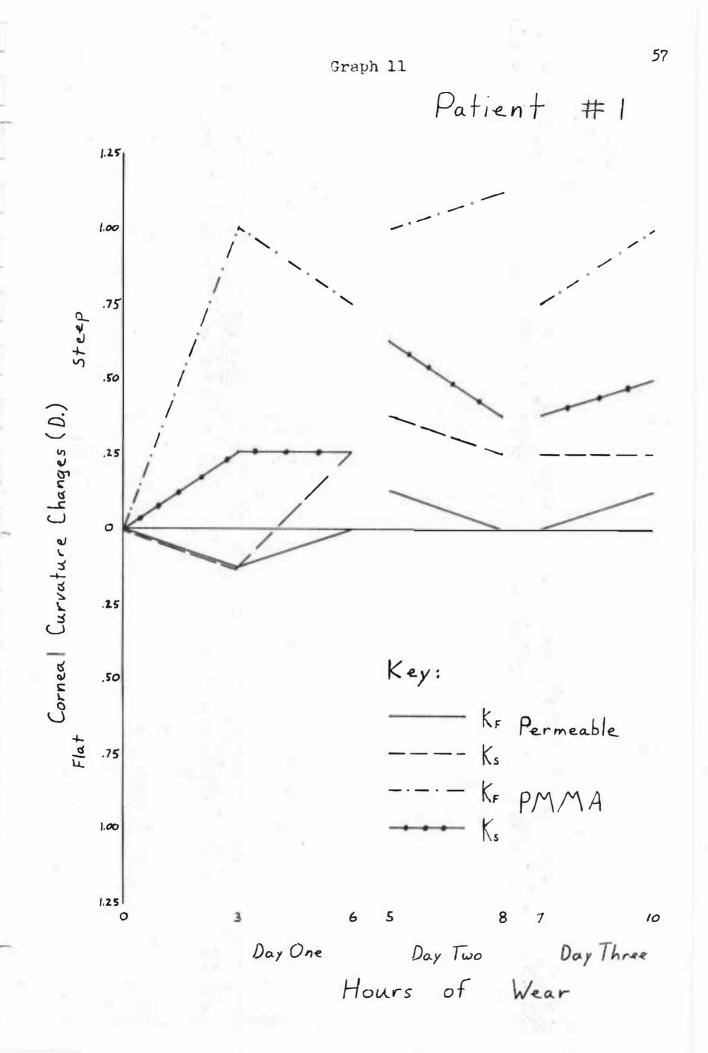
lenses flattened by a significant amount, whereas in no case did the mean K_f of eyes wearing permeable lenses steepen. Looking at the mean K_f values for eyes wearing PMMA lenses, two patients showed flattening and five patients showed steepening. For eyes wearing permeable lenses, the mean K_s values of two patients flattened, and the mean K_s values of three patients steepened. On the other hand, the mean K_s values of four eyes wearing PMMA lenses flattened, whereas the mean K_s values of three eyes wearing PMMA lenses steepened. (See table 14). Thus, the mean K_f values for eyes wearing permeable lenses were the least affected by lens wear.

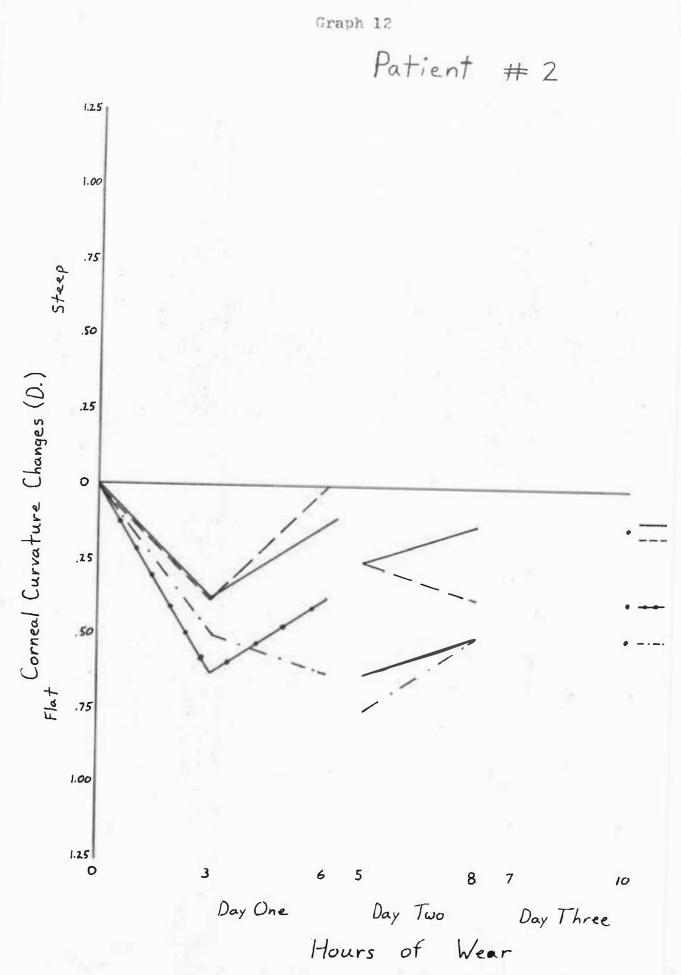
In analyzing the PEK data, we compared the pre-wear shape factors with the post-wear shape factors. The shape factor is a measure of the eccentricity of the cornea, with a 0.00 shape factor being a circle and a 1.00 shape factor being a parabola. Shape factors between 0.00 and 1.00 indicate elliptical variations. We found no particular correlation between the type of lens worn and the direction of change in the shape factor (or eccentricity). This held true when comparing the pre-wear and post-wear data for each meridian for each patient, and also when comparing the flat meridians of each patient and the steep meridians of each patient, According to Wesley-Jessen, Inc., clinical studies indicate that shape factors for typical corneas range between 0.10 and 0.50 with an average of 0.25. Using these ranges, we again compared pre-wear and post-wear data to detect changes from normal to abnormal, or vice versa. We found that for the flattest meridians of eyes wearing permeable lenses. nine of the ten patients were initially within normal limits in their prewear readings; of the nine, only two changed to values outside normal limits, with both becoming less eccentric (shape factors became lower in value). The patient whose flattest meridian started out outside of nor-

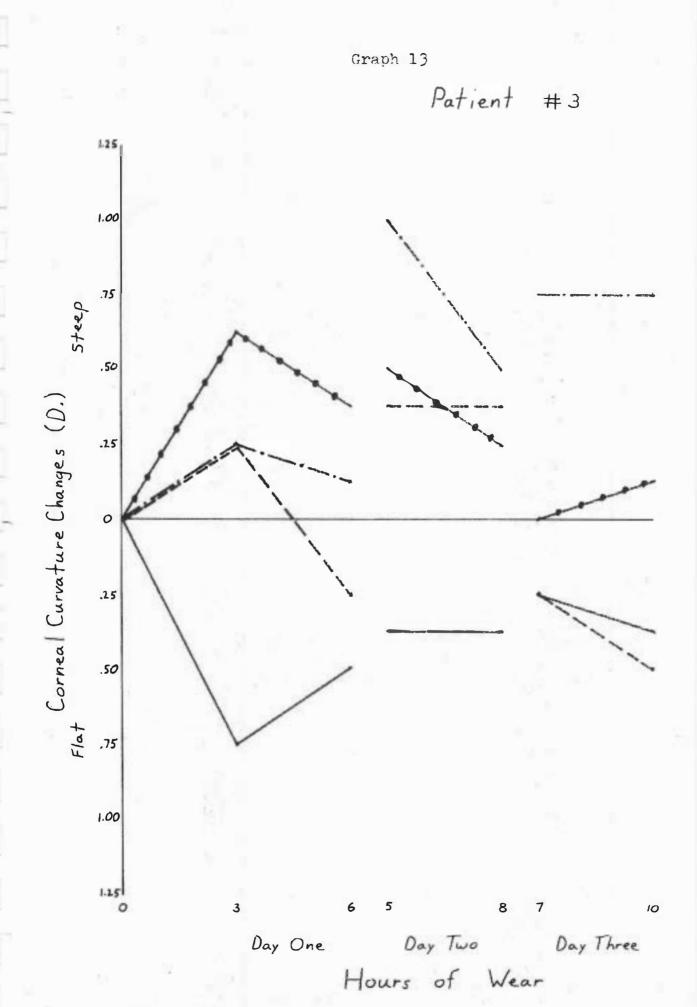
mal limits. For the flattest meridians of eyes wearing PMMA lenses, we found all ten patients to be initially within normal limits in their prewear readings; of the ten, six changed to values outside normal limits, with four becoming less eccentric and two becoming more eccentric. Looking at the steepest meridians of eyes wearing both types of lenses, all ten patients started out within normal limits in their pre-wear readings. Of the eyes wearing permeable lenses only two steep meridians changed, and only one steep meridian changed that was wearing a PMMA lens. All three became more eccentric after wearing contact lenses, independent of the lens material. (See table 16 and appendices F 1-10).

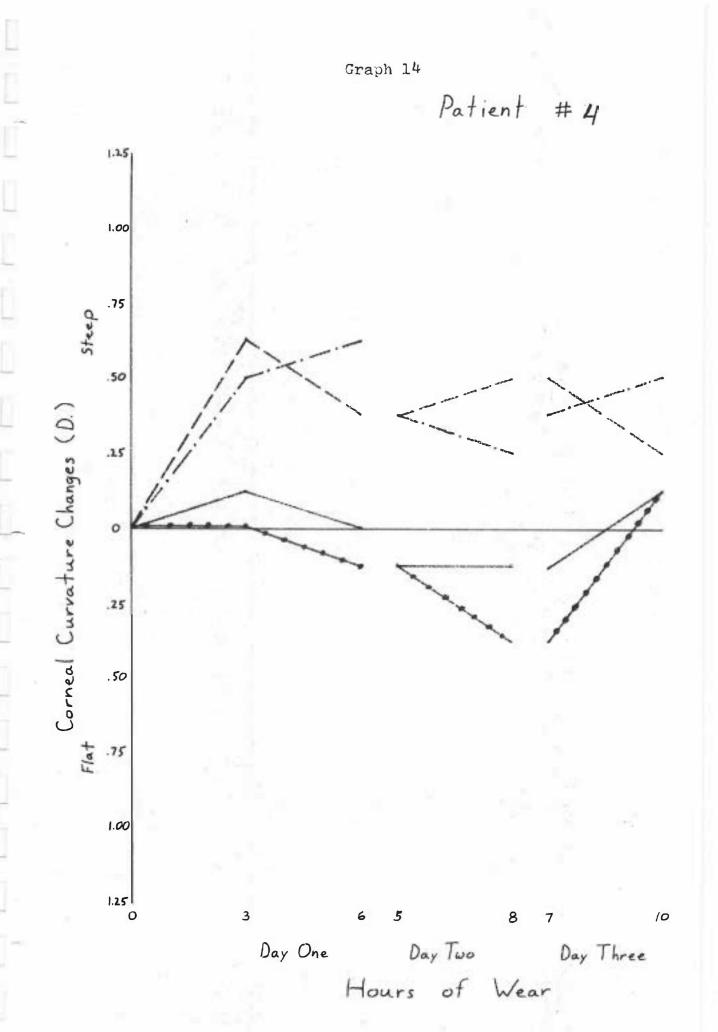
It is a clinically proven fact that the base curves of contact lenses may vary when transferred from a dry state to a hydrated state. Because of this, we measured the base curves of all of our lenses at the end of each wearing day. We found, that almost all of the lenses either flattened over time, or remained the same. Computing the mean change, we found that eight of the ten permeable lenses flattened and the other two remained the same. All ten of the PMMA lenses flattened during the course of the study. The PMMA lenses flattened much more than the permeable lenses over time, changing by .07 mm (mean change) compared to the permeable lenses mean change of .02 mm. (See table 17).

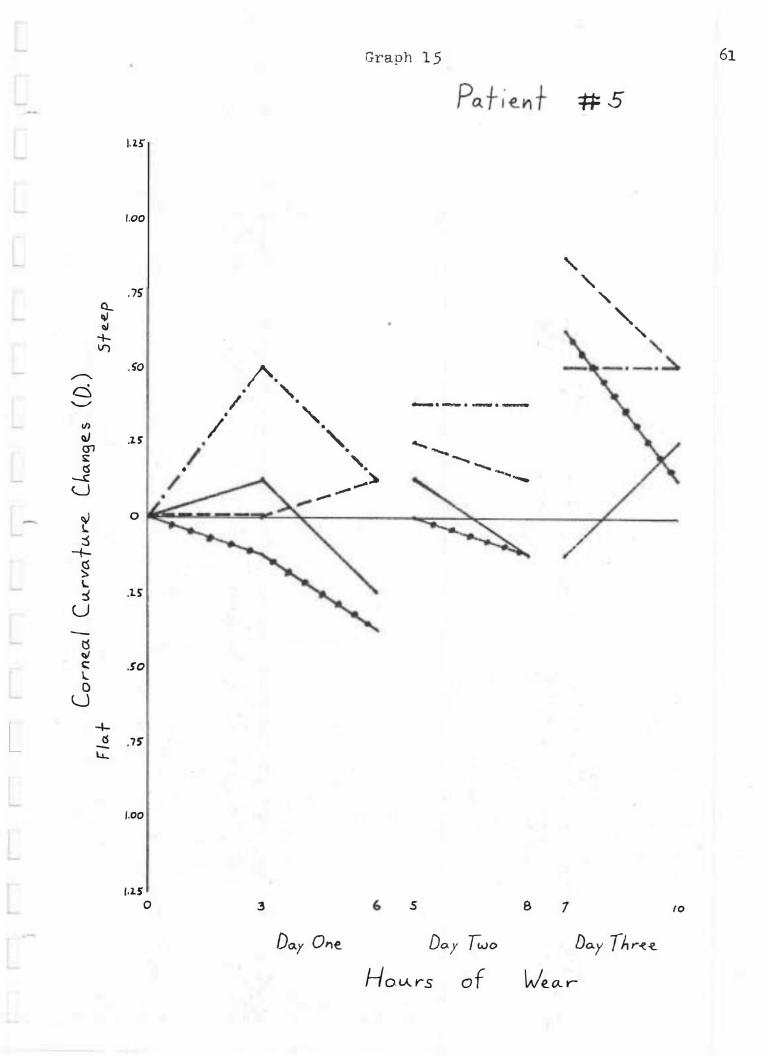
During the biomicroscopic examinations we photographed vascular changes at the limbus, as well as examples of central corneal clouding and stippling. For the limbal vessel differences between the two types of lenses, see the attached slide series. These slides also include the differences in central corneal clouding and stippling.

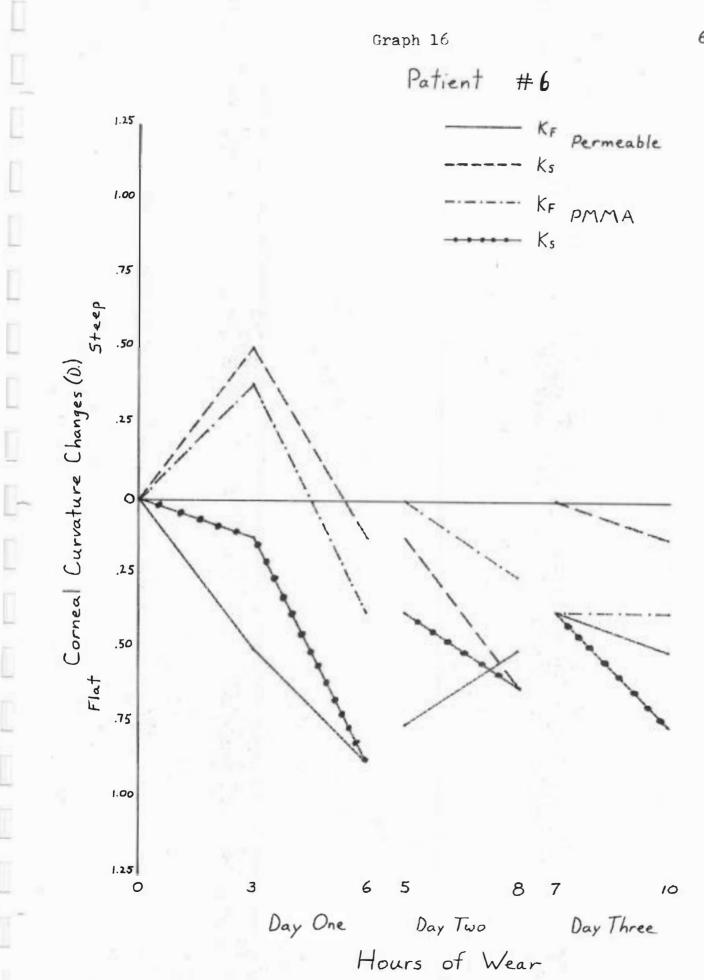


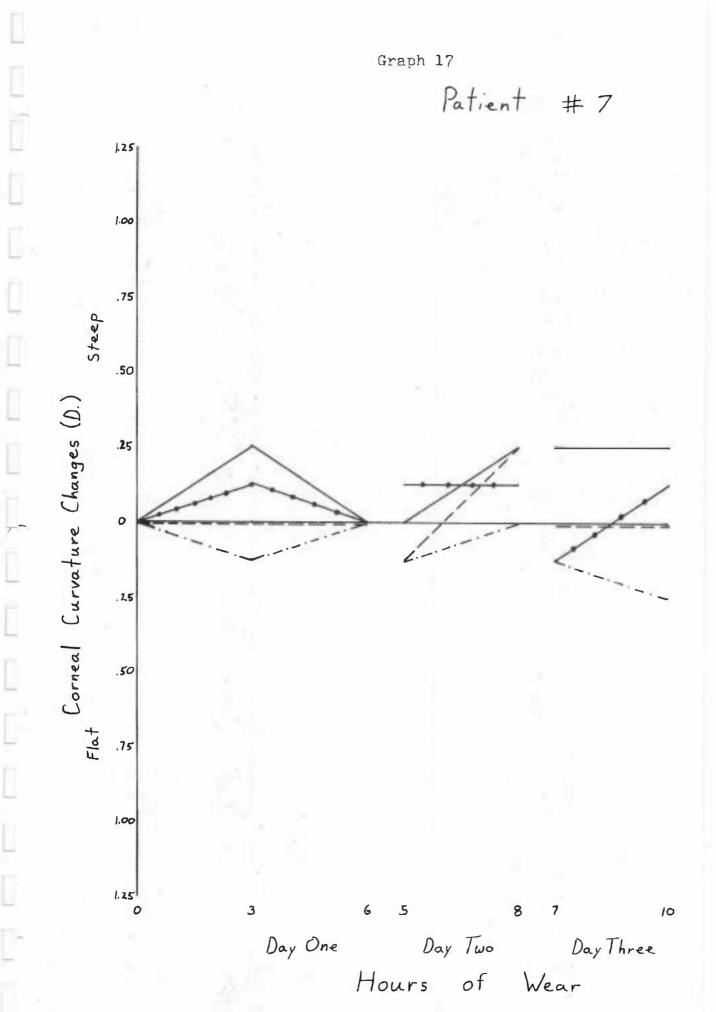


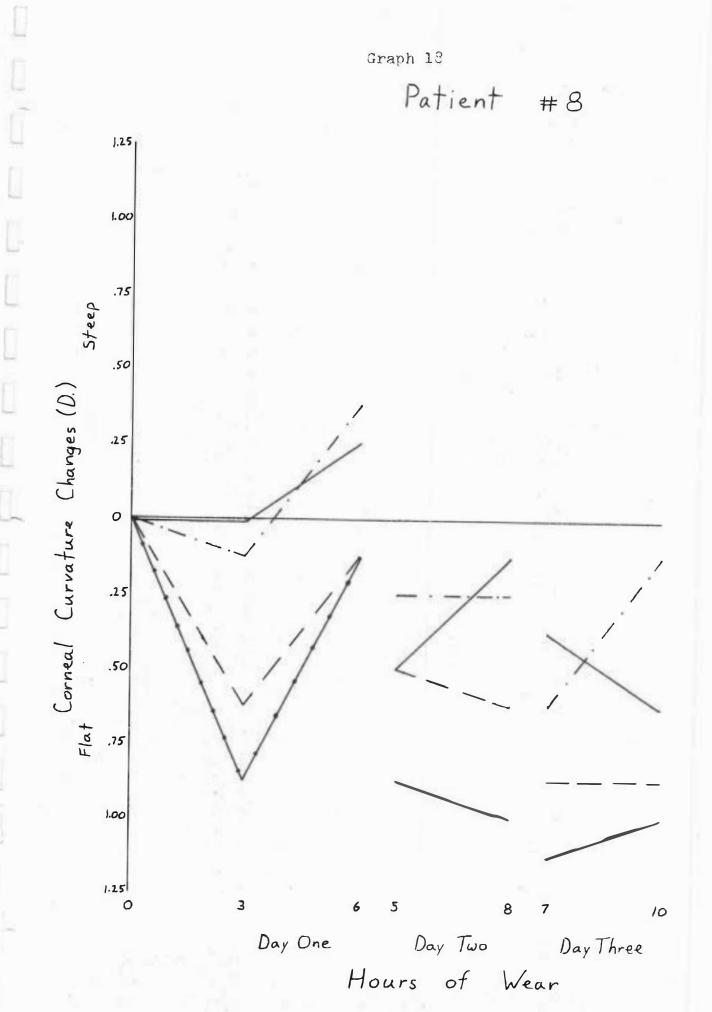


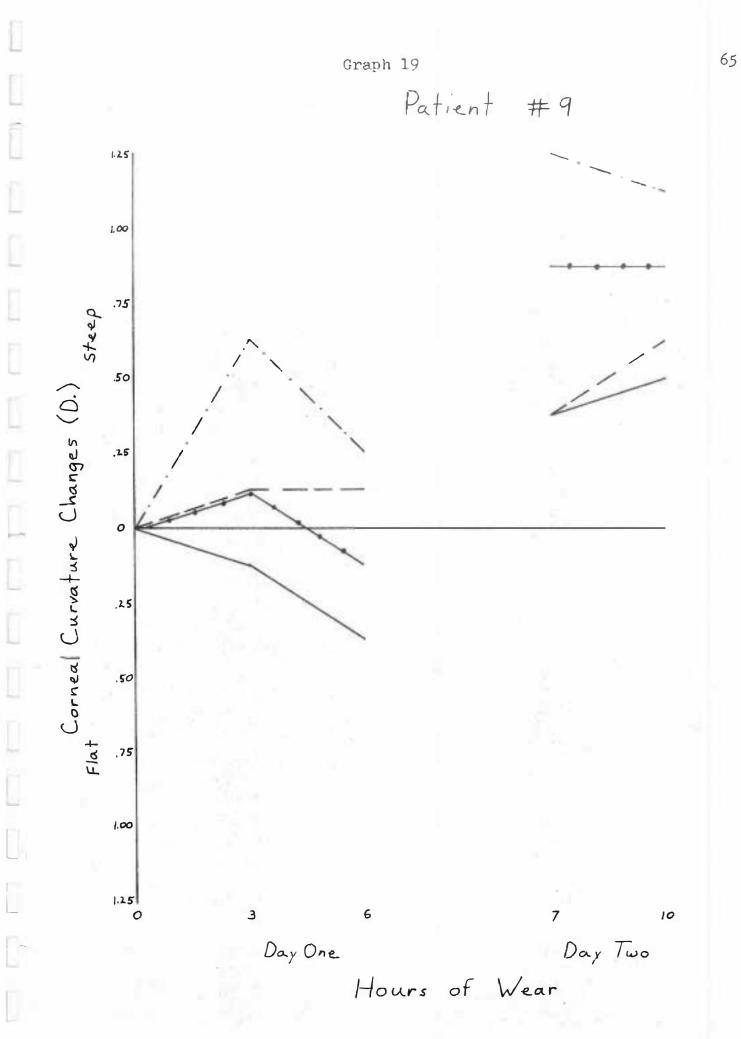


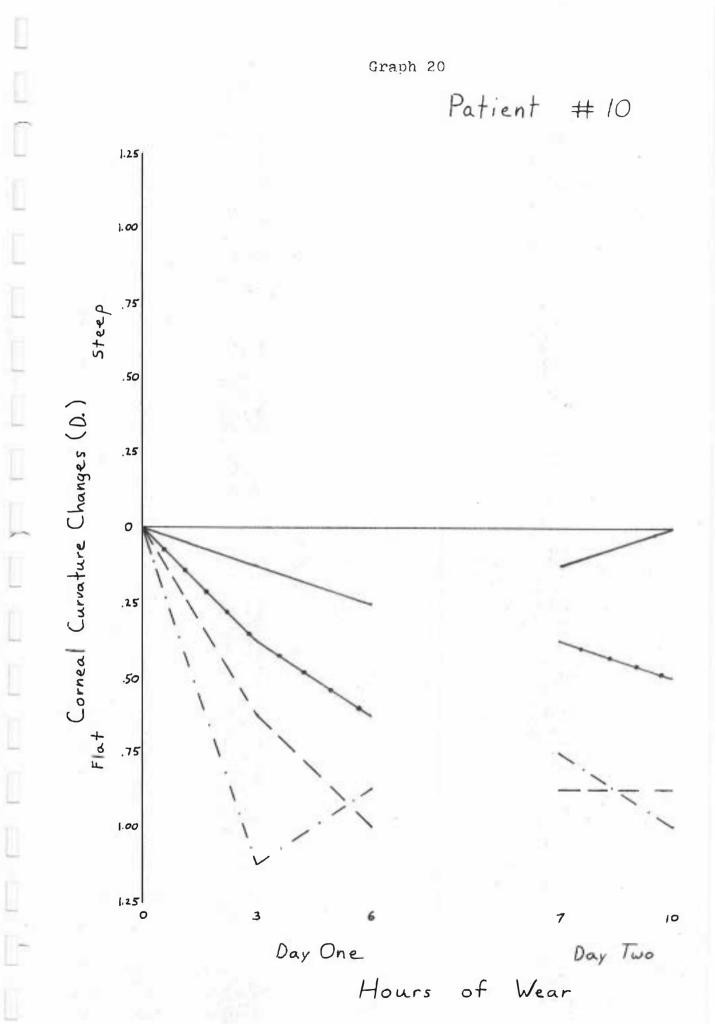








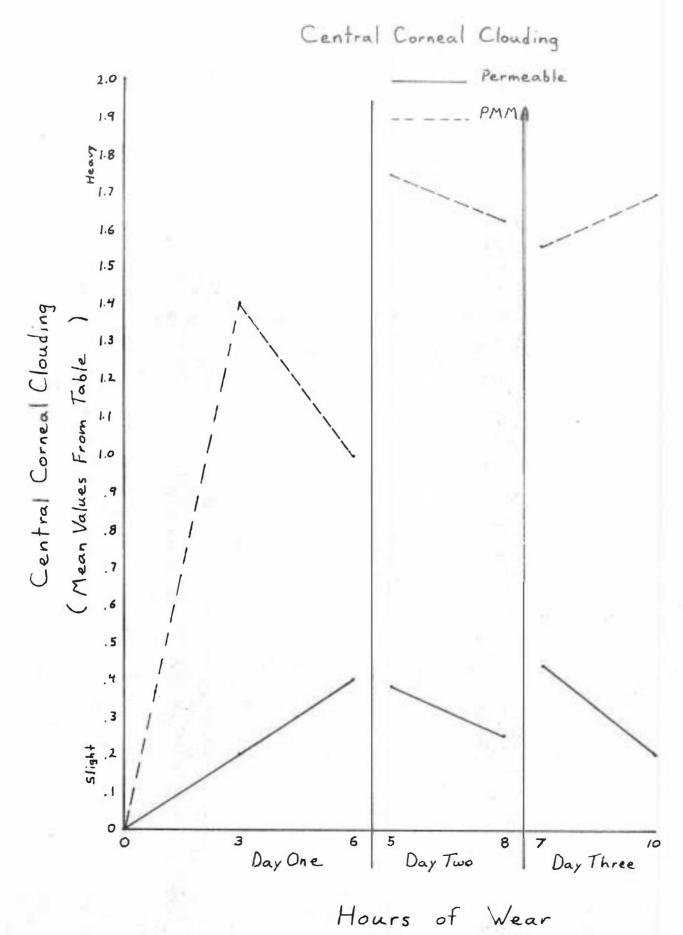




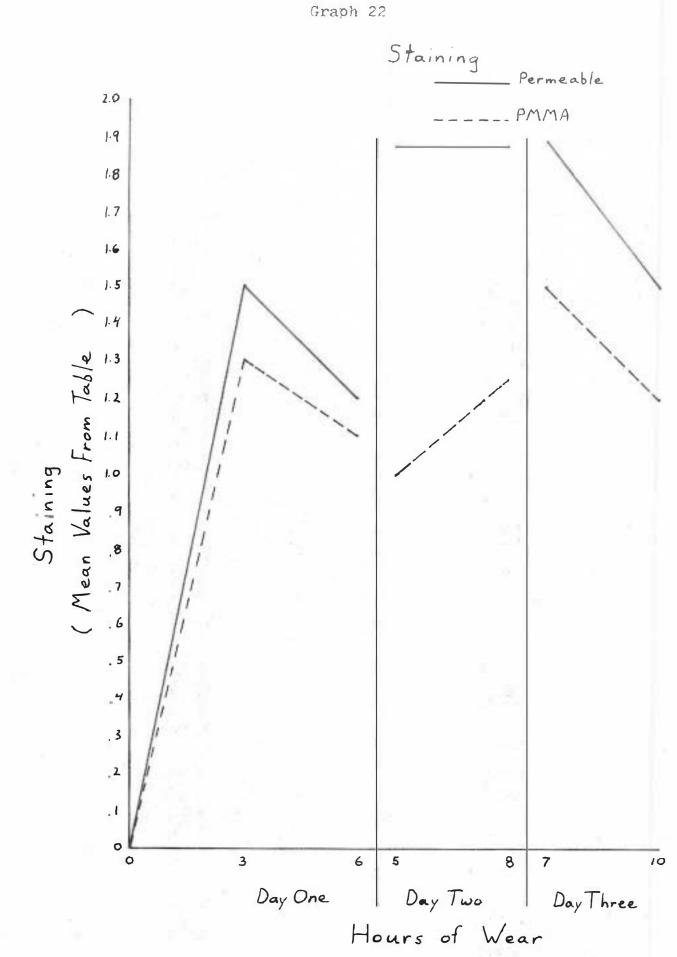
Graph 21

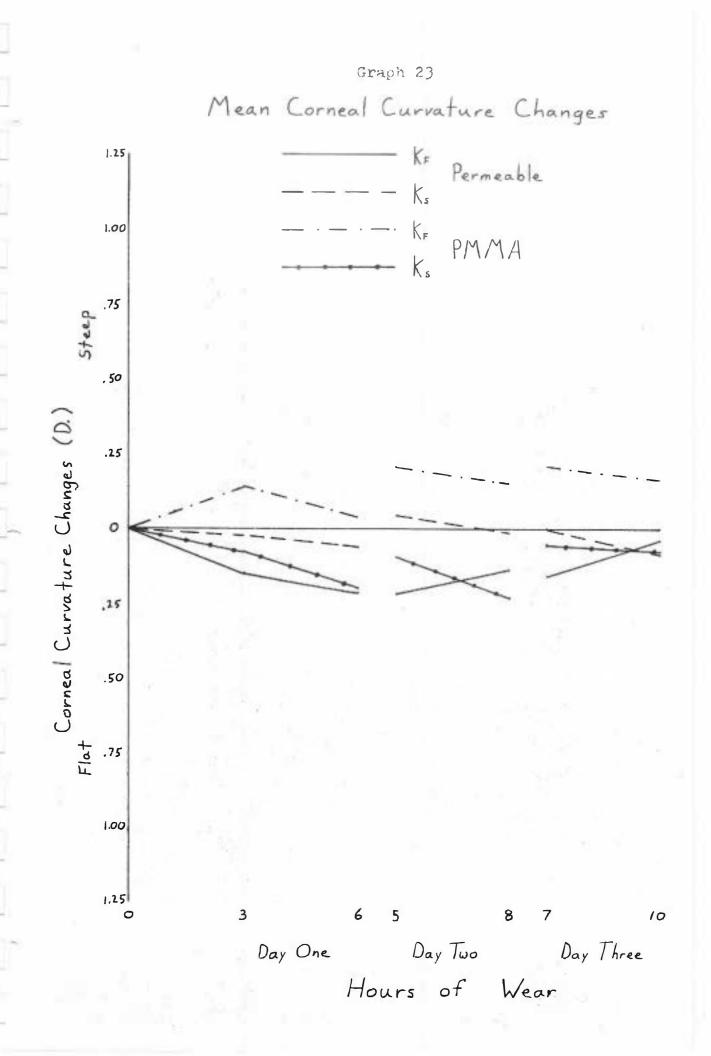
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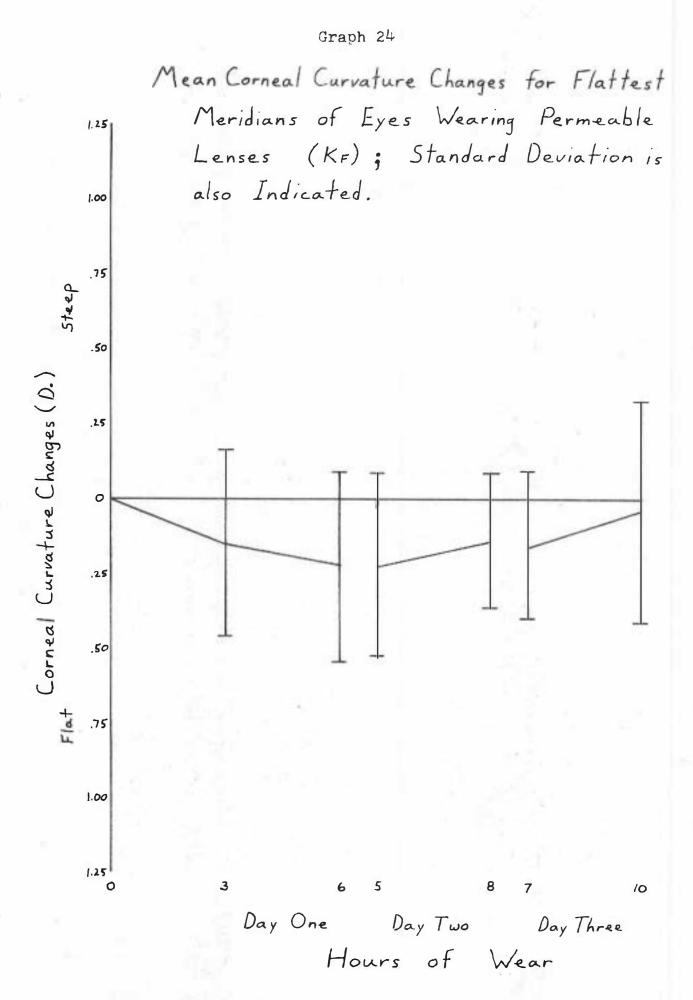
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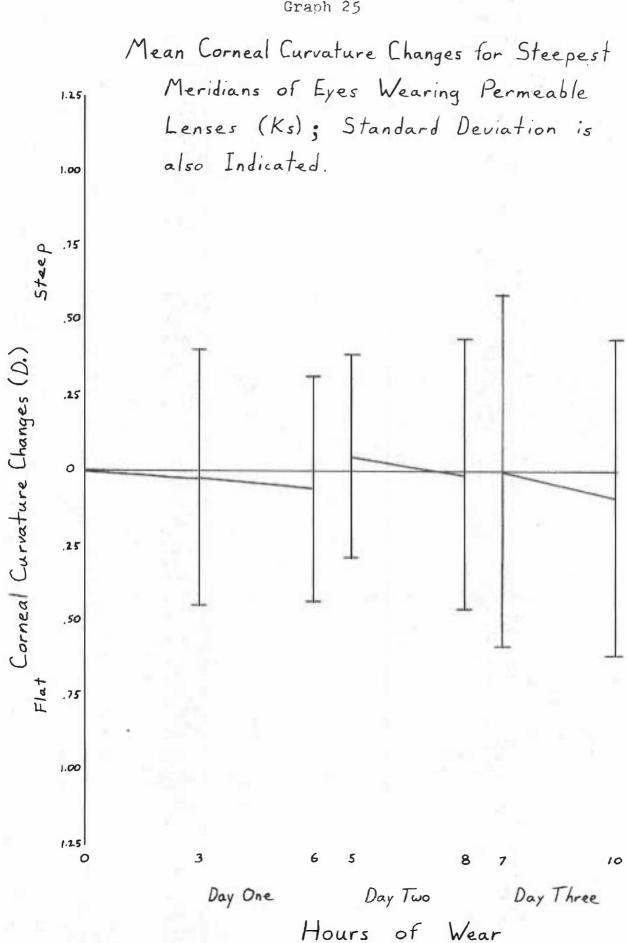


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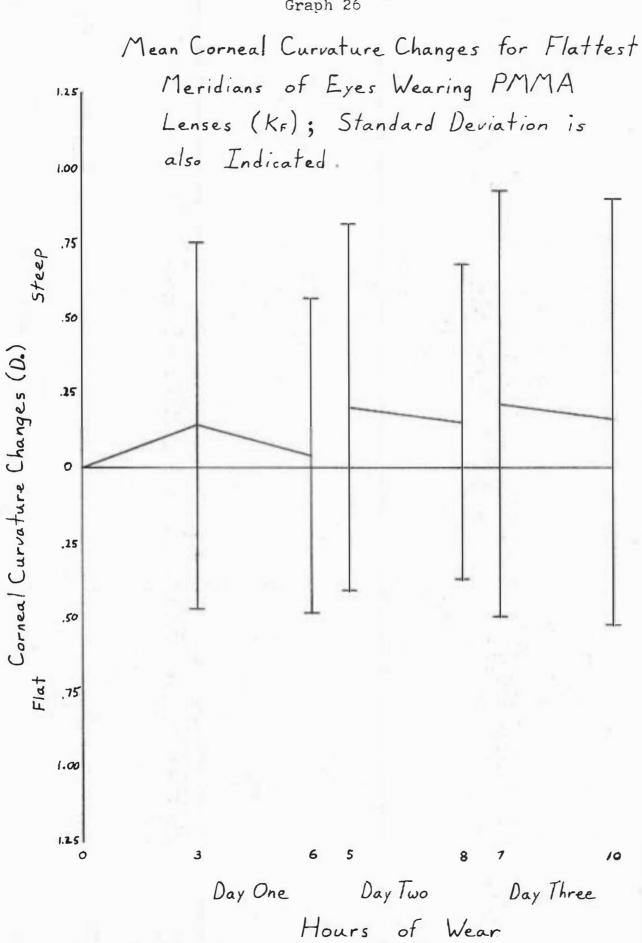




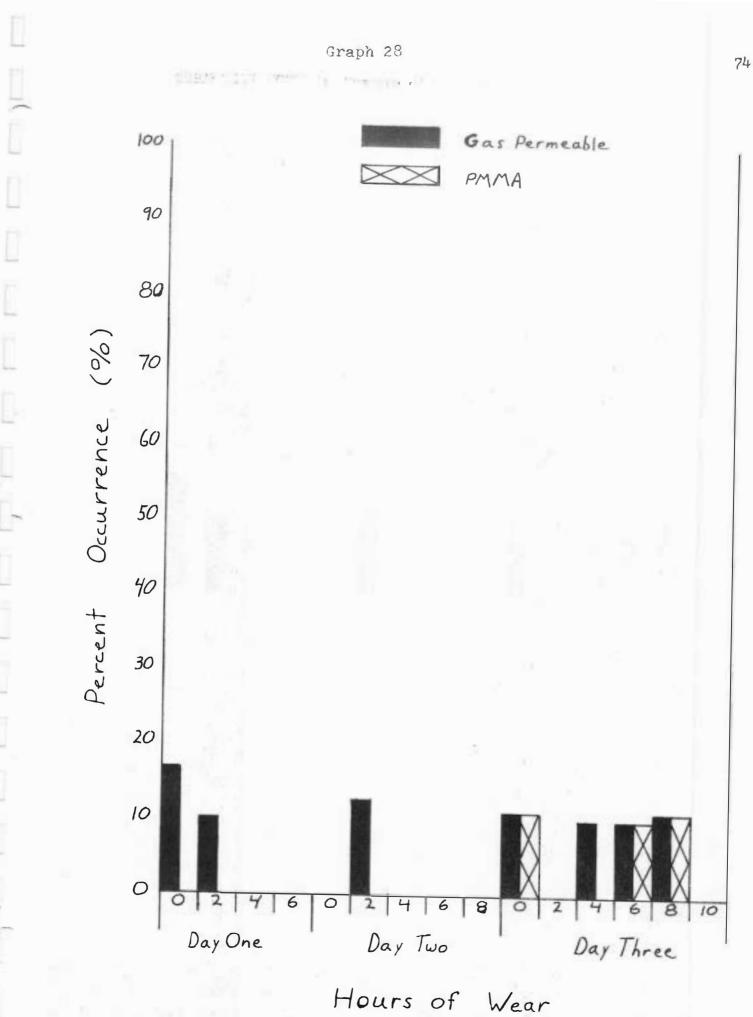


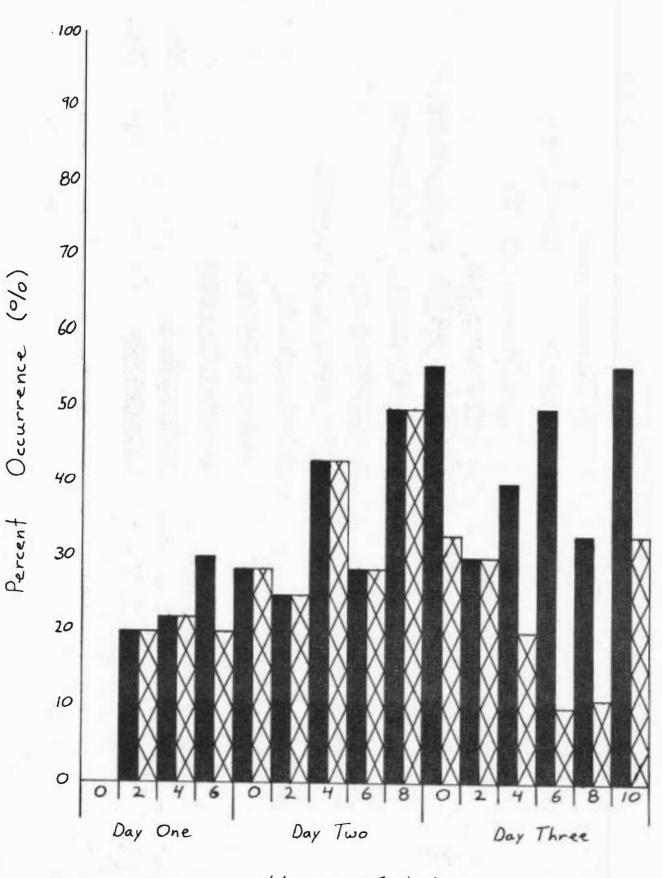


Graph 26

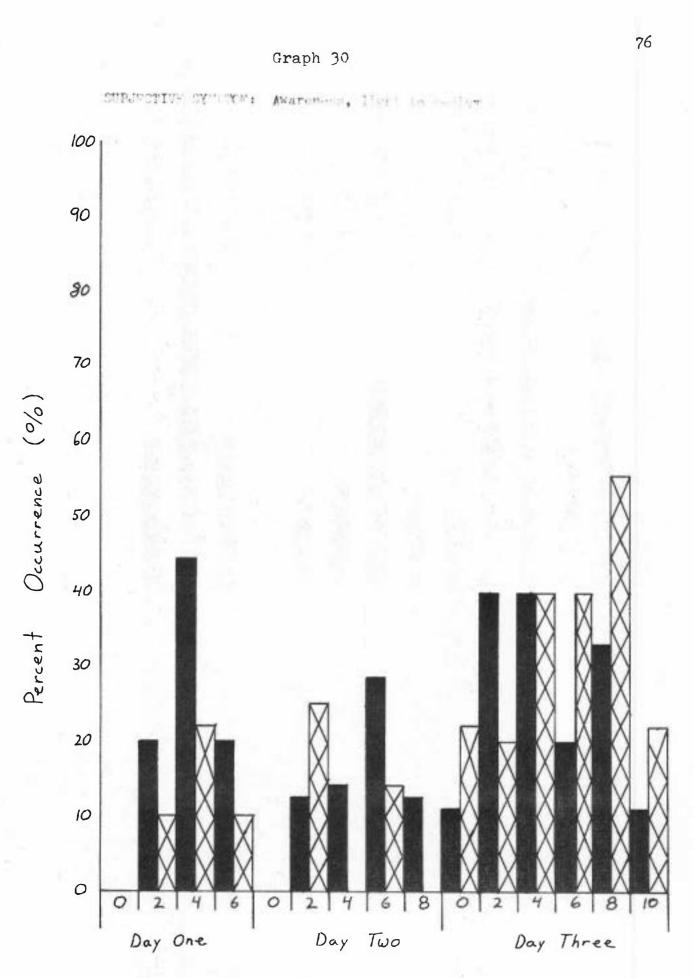


Graph 27 Mean Corneal Curvature Changes for Steepest Meridians of Eyes Wearing PMMA 1.25 Lenses (Ks); Standard Deviation is also Indicated. 1.00 Steep .75 .50 Corneal Curvature Changes (D.) .25 ο .25 .50 Flat .75 1.00 1.25 10 6 5 8 0 З 7 Day Two Day Three Day One Hours of Wear

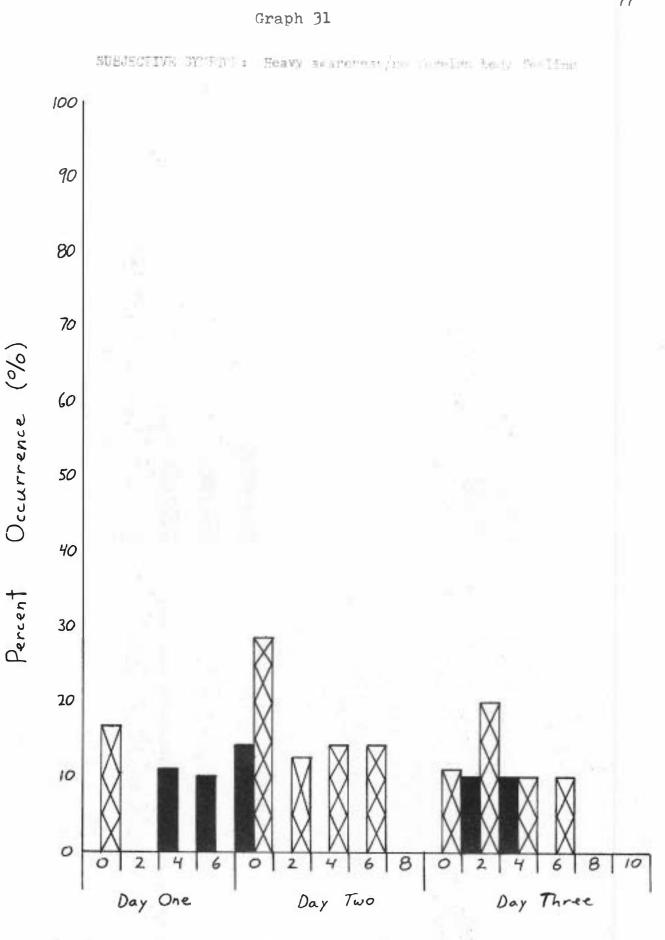




Hours of Wear



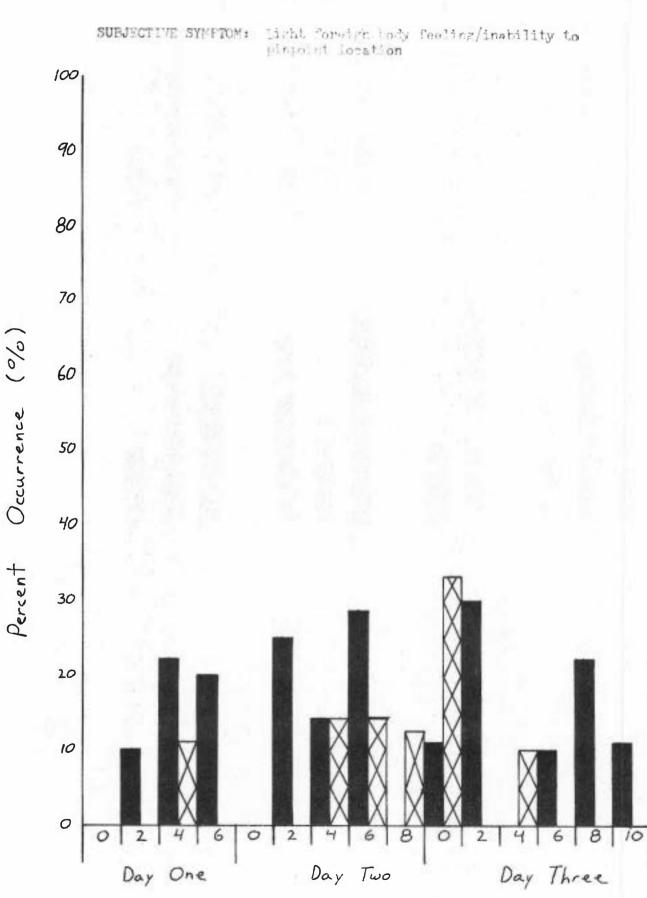
Hours of Wear



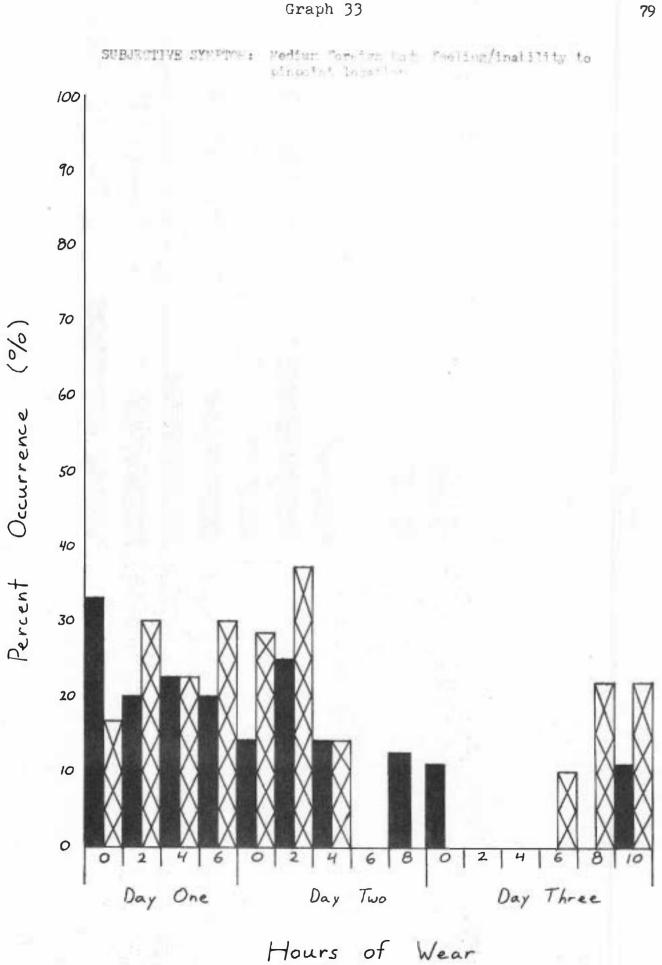
Hours

Wear

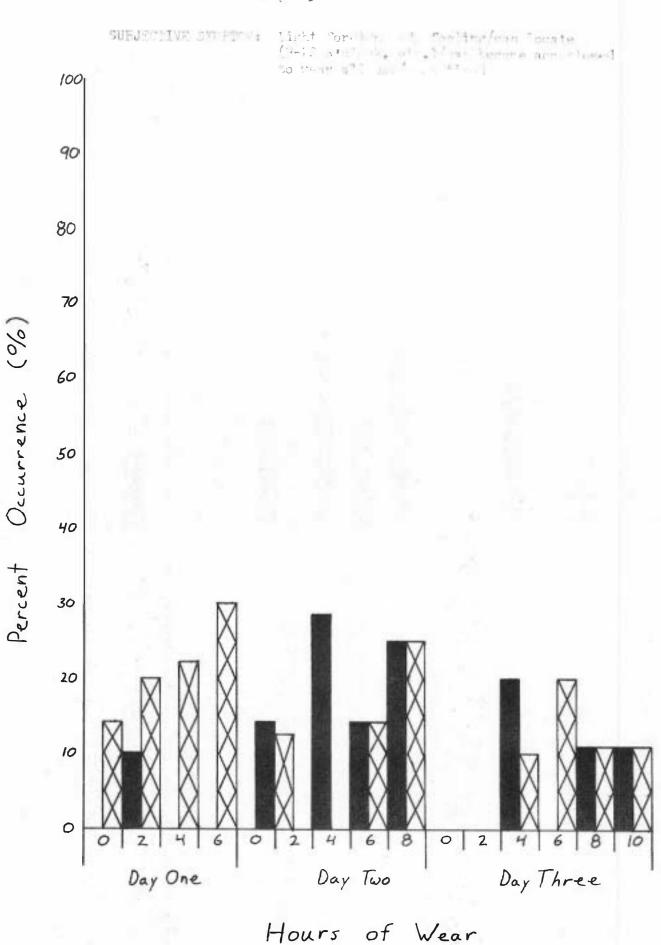
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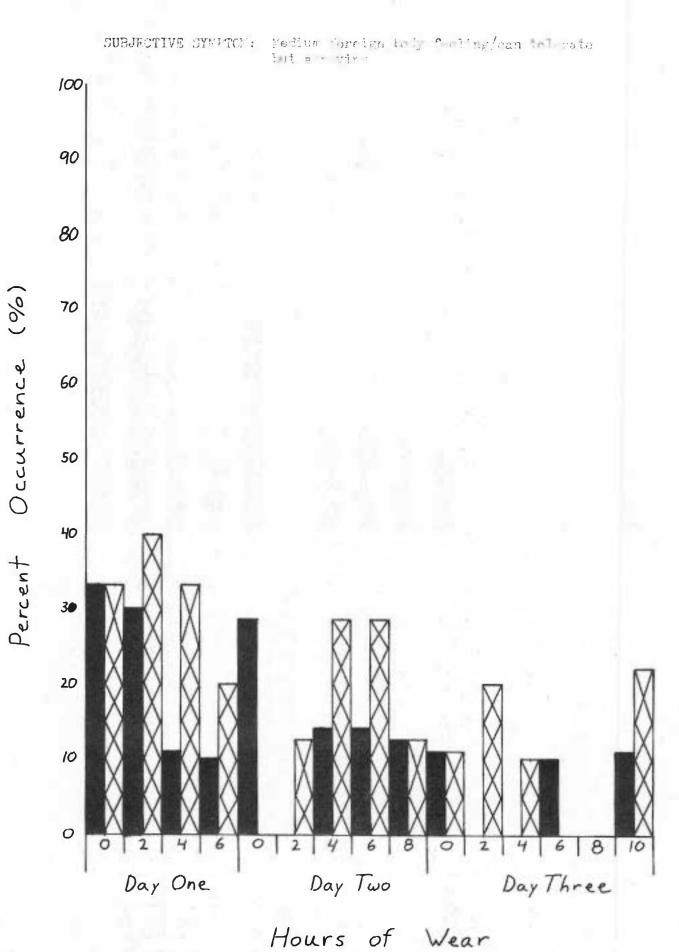
Hours of Wear



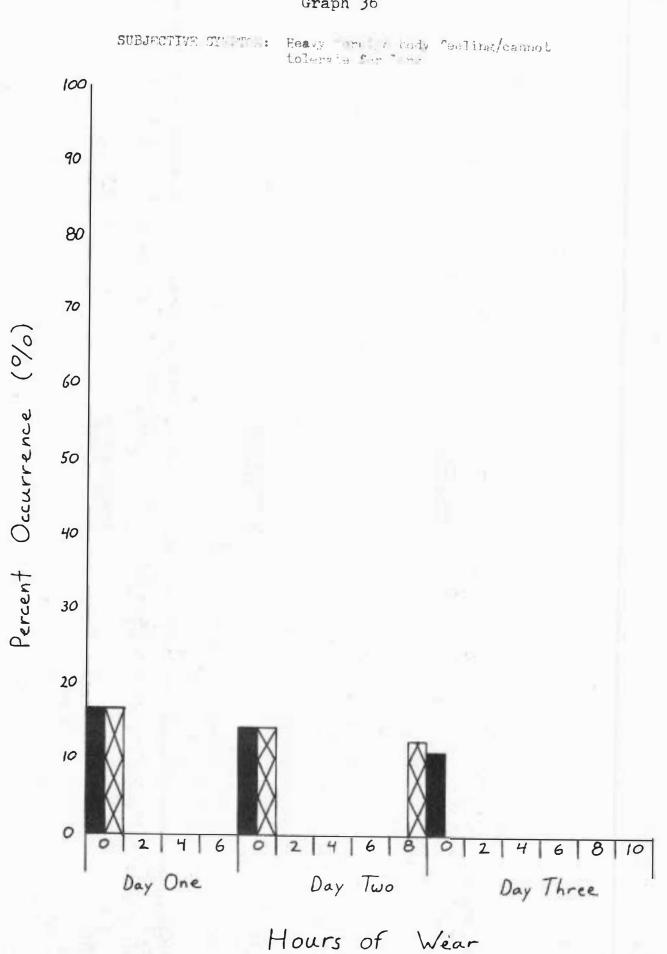
Graph 34

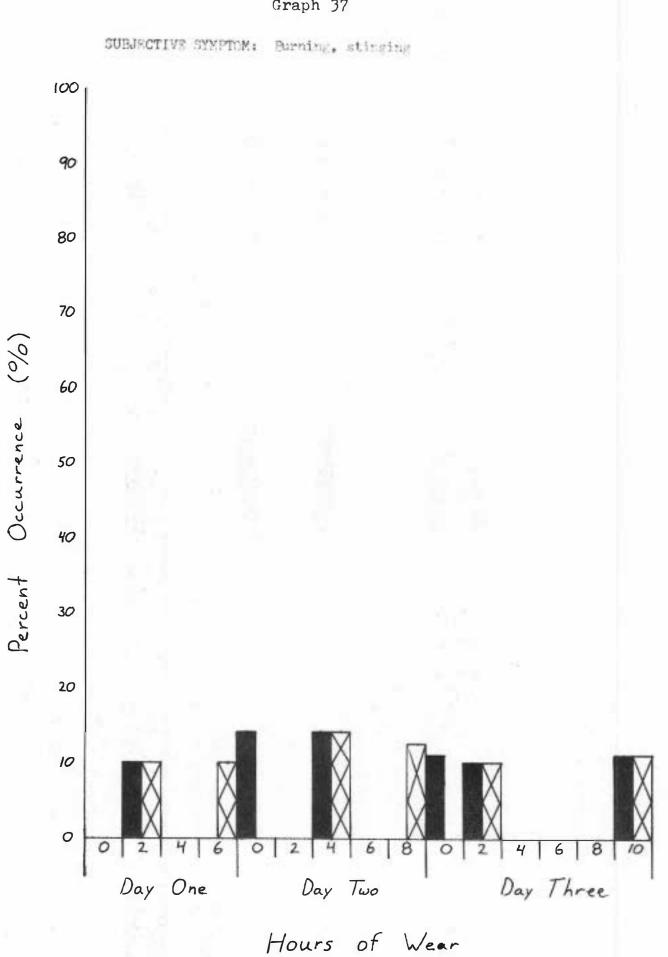


of Wear

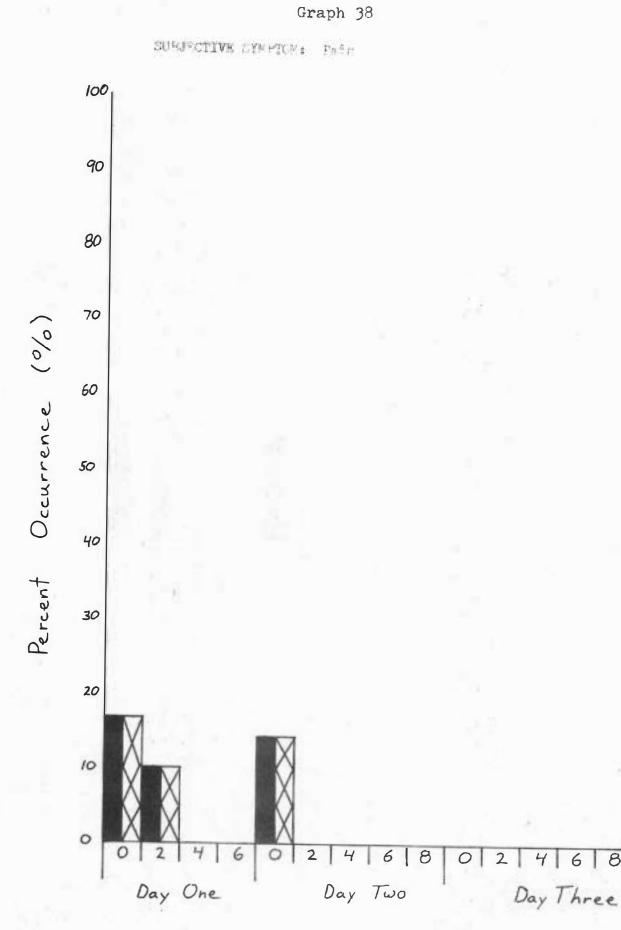


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Hours

of

Wear

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The following page shows gradations of central corneal clouding over time for each patient. The edema is scaled according to the following criteria:

0....no central corneal clouding.

- 1.....slight central corneal clouding; generalized, covering more than 50% of the cornea.
- 2....moderate central corneal clouding; localized, covering less than 50% of the cornea.
- 3....heavy central corneal clouding; localized, covering more than 50% of the cornea.

4....edematous formations or microcysts in deeper layers of the cornea.

CENTRAL CORNEAL CLOUDING

33

HOURS OF WEAR

		DAY	ONE	DAY	TWO	DAY T	HREE
201223-15	Secolar Secolar	3	6	5 1	8	7	10
	Permeable	0	0	0	0	0	C
PATIENT 1	PMMA	0	0	2	2	2	3
DAGTENG 2	Permeable	0	0	2	1		0
PATIENT 2	PMMA	2	2	2	2		0
DAGTENG 2	Permeable	0	0	0	1	0	0
PATIENT 3	PMMA	2	0	2	2	0	2
DAGTENG /	Permeable	0	1	0	0	0	0
PATIENT 4	PMMA	0	0	0	1	0	0
	Permeable	0	1	0	0	1	0
PATIENT 5	PMMA	2	2	3	3	2	2
PATIENT 6	Permeable	0	0	0	0	1	0
PATIENT O	PMMA	1	0	1	0	2	2
PATIENT 7	Permeable	0	0	0	0	1	2
PAILENI /	Pmma	2	2	2	2	2	3
PATIENT 8	Permeable	0	0	1	0	1	0
PATIENT O	PMMA	1	0	2	1	1	0
		DAT	ONE			DAY	TWO
PATIENT 9	Permeable	1	1			0	0
ALLENI 7	PMMA	2	2			3	3
PATIENT 10	Permeable	1	1			0	0
TITENT IU	PMMA	2	2	1		2	2

Table #12

The following page shows gradations of corneal staining over time for each patient. The staining is scaled according to the following criteria:

0....no staining.

1.....minimal, variable, peripheral stipple staining.

2....superficial punctate staining restricted to a peripheral location and consistent in location from examination to examination.

3.... superficial punctate staining, centrally located.

4....diffuse superficial punctate staining, both central and peripheral.

The criteria for corneal staining and for central corneal clouding were based on a classification system devised by Dr. Maurice Poster.

	STAINING		HOURS OF WEAR DAY ONE		T 10	DAY THREE	
		3	I 6	DAY 5	1 8		
	Permeable	0	0	4	4	4	2
PATIENT 1	PMMA	1	0	1	1	2	1
PATIENT 2	Permeable	2	2	2	2		2
PAILENI Z	PMMA	1	2	1	1	T	1
PATIENT 3	Permeable	3	2	1	2	1	
TATIENT J	PMMA	2	2	0	2	0	0
PATIENT 4	Permeable	0	1	1	1	0	1
FAILENI -	PMMA	0	0	1	2	1	1
PATIENT 5	Permeable	3	2	4	4	1	4
FAILENI)	PMMA	0	0	1	1	1	1
PATIENT 6	Permeable	1	1	0	0	1	2
TAILENI O	PMMA	2	2	1	1	2	2
PATIENT 7	Permeable	1	1	1	1	1	0
FAILENI /	PMMA	2	0	2	1	0	1
PATIENT 8	Permeable	2	2	2	1	4	2
	PMMA	2	1	1	1	2	1
	Permeable	2 DAY (ONE O			1 1	
PATIENT 9	PMMA	1	2	1		2	2
	Permeable	1	1			4	1
PATIENT 10	PMMA	2	2	T		2	2

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The following page shows gradations of corneal staining over time for each patient. The staining is scaled according to the following criteria:

0....no staining.

1.....minimal, variable, peripheral stipple staining.

2.....superficial punctate staining restricted to a peripheral location and consistent in location from examination to examination.

3..... superficial punctate staining, centrally located.

4....diffuse superficial punctate staining, both central and peripheral.

The criteria for corneal staining and for central corneal clouding were based on a classification system devised by Dr. Maurice Poster.

	STAINING		HOURS OF WEAP	2			
		DAY		DAY		DAY T	
	Permeable	3	6	5	8	7	10
PATIENT 1	Permeable		0	4	4	4	2
	PMMA	1	0	1	1	2	1
PATIENT 2	Permeable	2	2	2	2		2
PAILENI 2	PMMA	1	2	1	1		
DAMTENM 2	Permeable	3	2	1	2	1	0
PATIENT 3	PMMA	2	2	0	2	0	1
	Permeable	0	1	1	1	0	1
PATIENT 4	PMMA	0	0	1	2	1	1
	Permeable	3	2	4	4	1	1
PATIENT 5	FMMA	0	0	1	1	1	1
PATIENT 6	Permeable	1	1	0	0	1	2
PAILENI O	PMMA	2	2	1	1	2	2
DARTENO O	Permeable	1	1	1	1	1	(
PATIENT 7	PMMA	2	0	2	1	0	1
	Permeable	2	2	2	1	4	2
PATIENT 8	PMMA	2	1	1	1	2	1
	Permeable	DAY (ONE O			DAY 1	WO 1
PATIENT 9	PMMA	1	2		+	2	2
	Permeable	1	1			4	1
PATIENT 10		2	2			2	2

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Table # 13

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	1	PERM	TEABLE	T	PMMA			
	Kf	SD	K _s	SD	Kf	SD	K s	SI
PATIENT 1	.02	.09	.21	.17	. 94	.15	• 39	.14
PATIENT 2	20	.11	22	.16	57	.11	50	.13
PATIENT 3	44	.17	0.00	.38	. 56	.33	. 31	.23
PATIENT 4	02	.12	.44	.13	.44	.13	14	.20
PATIENT 5	0.00	.19	• 31	. 32	.39	.15	, 02	.34
PATIENT 6	58	.19	08	.36	17	.30	45	.26
PATIENT 7	.17	.13	.02	.12	10	.09	.06	.10
PATIENT 8	24	.29	60	.28	17	. 32	83	.36
PATIENT 9	.10	. 41	.31	.24	.84	. 50	.44	. 51
PATIENT 10	12	.10	84	.16	93	.16	47	.12

Corneal curvature changes for the flattest (K_f) and steepest (K_S) meridians of eyes wearing permeable and PMMA contact lenses. Standard deviation (SD) is also indicated. All values are in diopters (D.).

			PERME	CABLE	PMMA				
		Kf	SD	Ks	SD	Kf	SD	K _s	SD
DAX 4	3 Hours	15	. 31	02	.43	.14	.62	07	.39
DAY 1	6 Hours	21	. 32	06	.38	.04	. 52	20	. 38
DAY 2	5 Hours	22	. 31	.05	. 34	.20	.61	09	. 52
DAY 2	8 Hours	14	23	02	.45	.16	. 52	23	.47
DATE 2	7 Hours	08	.25	0.00	• 59	.21	.72	05	.61
DAY 3	10 Hours	04	.36	09	. 52	.16	.71	08	.57

Mean corneal curvature changes over time for the flattest (K_f) and steepest (K_s) meridians of eyes wearing permeable and PMMA contact lenses. Standard deviation (SD) is also indicated. All values are in diopters (D_s) .

		PERME	ABLE	РИМА	
		Kf	Ka	Kf	Ks
Patient 1	Pre-wear	•25	• 31	• 31	•47
	Post-wear	•46	• 66	• 67	•73
Patient 2	Pre-wear	•18	• 31	.25	• 38
	Post-wear	•32	• 30	.03	• 20
Patient 3	Fre-wear Post-wear	•16 •34	• 37 • 21	•17 •52	.14
Patient 4	Pre-wear	•22	.09	•23	•25
	Post-wear	•19	.19	•09	•17
Patient 5	Pre-wear	.13	• 22	•15	• 31
	Post-wear	.11	• 28	•22	• 46
Patient 6	Pr e- wear Post-wear	.48 .01	.42	• 38 • 30	• 34 • 43
Patient 7	Pre-wear	•28	• 30	•22	•26
	Post-wear	•24	• 15	•08	•11
o lent ô	Pre-wear	•19	•29	•15	•21
	Post-wear	•05	•52	•26	•43
Patient 9	Pre-wear	•20	•16	.25	•14
	Fost-wear	•46	•24	1.03	•40
Fatient 10	Pre-wear	•07	•28	•21	.26
	Fost-wear	•27	•33	•15	.19

Table #16: PEK Shape Factors Including Both Pre-Wear and Fost-Wear Findings

		PER	MEABLE	_				PMMA	_	
			DAY	_				DAY	_	
	Pre.	1	2	3	Ave.	Pre.	1	_2	3	Ave.
Patient 1	7.41	7.50	7.48	7.45	7.48	7.37	7.42	7.42	7.37	7.40
Patient 2	7.56	7.64	?.55	7.61	7.60	7.60	7.74	7.70	7.69	7.71
Patient 3	7.32	7:35	7.33	7.32	7.33	7.30	7.36	7.36	7.38	7.37
Patient 4	7.57	7.56	7.62	7.60	7.59	7.64	7.70	7.72	7.71	7.71
Fatient 5	7.42	7.40	7.47	7.45	7.44	7.58	7.63	7.66	7.66	7.65
Patient 6	2.73	7.74	7.71	7.78	7.74	7.81	7.86	7.87	7.84	7.86
Fatient 7	7.26	7.26	7.32	7.33	7.30	7.32	7.30	7.36	7.37	7.34
Patient 8	7.72	7.72	7.71	7.74	2.72	7.72	7.78	7.81	7.80	7.80
Patient 9	7.50	7.43	7.50	-	7.49	7.48	7.54	7.56		7.55
Patient 10	7.46	7.49	7.50	-	7.50	7.51	7.60	7.60		7.50

Table # 17:

1

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Changes of Base Curves During The Wearing Period

Discussion

This study examined the possible differences in clinical adaptational symptoms between the conventionally used contact lens material, PMMA, and a recently developed material that could possibly satisfy the physiological and biological metabolic requirements of human corneas to a greater extent than previously believed. This material has many unique advantages, the greatest among them being its permeability to oxygen, carbon dioxide and other gasses involved in corneal metabolism. Other physical properties of this new material are its flexibility and its less hydrophobic nature, which may make gas permeable lenses less apt to cause embarrassment to the cornea and to be more easily wettable.

We chose to investigate the subjective symptoms and objective signs involved in clinically fitting gas permeable lenses. In order to make this a relevant topic for contact lens practitioners, we decided to compare the gas permeable lenses with conventional PMMA lenses; this technique, we felt, would highlight the differences and similarities between the two types of materials. To elicit the maximum difference between eyes wearing lenses made of PMMA and eyes wearing lenses made of a gas permeable material, we limited our study to the initial adaptation period, when fitting symptoms are most prevalent. To further heighten the onset and severity of the symptoms, we used an accelerated wearing schedule.

On the patient comfort scales, used to chart the daily flow of subjective symptomatology, only four out of the ten patients reported the gas permeable lenses as being generally more comfortable than the PMMA lenses. It was expected that the gas permeable lenses would have a definite advantage over the PMMA lenses in this area due to their supposedly unique properties. A contributing factor to the unexpected out-

come may have been that the different types of lenses were fabricated by different manufacturers, even though all lenses were designed to Wesley-Jessen's PEK specifications. Many physical parameters of contact lenses are highly dependent on the techniques used in their fabrication such as blend, edge contour and polish, and the care taken in duplicating the exact prescription. As can be seen in the individual case summaries presented earlier, not all patients had similar lens fits for the two different types of lenses. We judged the edges of the PMMA contact lenses to be of a superior design as compared to those of the permeable contact lenses: thus lessening the possible differences in comfort. Another contributing factor to this result may have been the philosophy behind the PEK lens design, which usually turns out small lenses with optimum apical clearance and well-designed edges. Also, all of our patients were optometry students. Even though almost all were previous non-wearers of contact lenses, many of them had completed a course in contact lens technology, and therefore were more sophisticated in evaluating the progress of their adaptation to contact lenses. Their expectations were possibly higher, causing them to be overly critical of both types of lenses. Another major contributor to this unexpected result may have been the lens care program which our patients were instructed to use. We taught them to use Close Up toothpaste as a lens cleaner before inserting their lenses during the day. The actual program should have been to use the toothpaste only at removal before putting the lenses in hydrogen peroxide and soaking them in Soaclens overnight. The toothpaste remaining on the lenses after insertion caused several patients to experience a burning and stinging reaction, accompanied by severe redness, for the first several minutes of lens wear.

The problem with the toothpaste also may have influenced the patients' responses on the examination case histories. The case histories revealed that the eyes wearing gas permeable lenses were reported to have less redness and haloes than the eyes wearing PMMA lenses. The toothpaste residues may have negated redness as a differentiating factor. However, the lesser incidence of haloes may be associated with the permeable characteristics of the lenses, as evidenced by the correlation between the occurrence of haloes and the occurrence of edema. Even though the edema was apparent in the biomicroscopic examinations, it had no great effect on the patients' acuities. In a study of longer duration, this may not have been the case.

One of the primary properties of gas permeable lenses that we wanted to investigate was the lower incidence of interference with normal corneal metabolism, resulting in a lower incidence of edema or central corneal clouding. The biomicroscopic examinations showed this property to be highly significant, with nine of the ten patients in the study experiencing much less clouding in the eyes wearing gas permeable lenses. Staining, on the other hand, showed no significant difference between the permeable and PMMA lenses. This may have been due to the problem with the toothpaste. However, the majority of the staining was three-nine stippling, which is a common objective sign when fitting small contact lenses.

The results of the keratometric and PEK investigations are selfexplanatory. The lack of a consistent pattern of corneal curvature change for most of the patients may be an indication of the good quality of the lens fits. However, what differences there were may be significant for the same reason. In other words, if lens fit was eliminated as a vari-

able, then the symptoms found were more likely caused by the difference in lens material than by anything else.

Obviously there is much more to be learned about gas permeable contact lenses before they can become a therapy of optimum use. The results of our study suggest further areas for investigation, such as the longterm effects of gas permeable contacts, their use in myopia control and orthokeratology, their usefulness in fitting problem patients with persistent edema, and their possible benefits in fitting patients with corneal pathologies. We were not able to obtain any of the manufacturer's laboratory test results on the gas permeable lens material used in the study. The chemical, physical, and physiological properties of the material must be researched and documented before extensive clinical investigation can be undertaken.

Conclusion

The goal of the study was to compare the differences in the subjective symptoms and objective signs between gas permeable and PMMA contact lenses. The significant results were that gas permeable lenses caused a lower incidence of central corneal clouding than PMMA lenses, as well as demonstrating at least the same degree of comfort as PMMA lenses. In fact, when asked which lens they actually preferred, most of our patients indicated a preference for the gas permeable lens, even though they were unaware, at the time, of which lens was the gas permeable one.

We feel that the results of this initial study will lead the way in the development and use of a contact lens material, such as the gas permeable material of which our lenses were made, that will further the profession of optometry in giving maximum visual care to our patients.

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The physical properties of RX-56 compared to polymethyl-methacrylate:

A.S.T.M. TEST			
METHODS#	PROPERTIES	RX-56	PMMA
D542	Refractive index	1.52	1.49
D638, D651	Tensile Strength, p.s.i.	5600	8190
D638		40.0-60.0	2.0-7.0
	Elongation, % 5 Tensile Modulus, 10 p.s.i.	0.5-2.0	
D638		0.5=2.0	3.5-5.0
D256	Impact Strength, ft-lb/in		
	of notch, $\frac{1}{2}x\frac{1}{2}in$, notched		
	bar IZOD Test $(\frac{1}{4}x\frac{1}{2}in.)$	3.9	4.2
D785	Hardness	112R	M-94
C177	Thermal Conductivity		
	104		
	10 ⁴ cal/sec/sq.in		
	1 ⁰ C./cm	6.4	5.0
	Resistance to heat, ^O F.	210	190
D570	Water Absorp., 24 hr.,		
	1/8in. thick, %	1.8	0.35
D635	Burning Rate; flammability,		
	in./min.	slow	0.89
D543	Effect of strong acid	decomposes	att. by high
	0	*	conc. oxidizing
			acids
D543	Effect of weak alkalies	slight	nil
D553	Effect of strong "	decomposes	attacked
D543	Effect of organic solvents		cones and esters,
	ALLECT OF OFBALLC SOLVEILS		
			lorinated hydro-
DOT (C (COM			romatic hydrocarbs.
D2167-63T	Folding endurance	250-400	none
E96-66(B)	Rate of H20 vapor	(B)	nil
	transmission $gm/100in^2/$		
	24 hr.	11.0(E)	nil
E96-66(E)	Transmissibility at 30°C.,		
	(-2) (-1 00)	10	
	(CO_2) (sec) (m1) (mm Hg)	6.40x10-10	0.02
	(sec) (mr) (mm rg)		
	(0) (cm^2) $(ml 0_2)$	3.75×10 ⁻¹⁰	0,10
	(0_2) $\frac{(Cm) (m1 0_2)}{(sec.) (m1) (mm Hg)}$	J. / JAIO	0.10
D1434-64	Permeability to gases		
	cc/100in ² /nil/24hr/atms/	$(C0_2)7940$	none
	@ 25 ⁰ C.	~	
	@ 25°G,	(0 ₂)1960	none

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Toxicological data for RX-56:

Acute oral toxicity Acute hazard by inhalation Threshold limit value

Local effects on skin

None evident

None from dust

Not determined. A dose of 500mg/kg was not lethal or toxic orally in rate. Not a primary irritant. Sensitization studies on 10 humans did not show any irritative or hyper-sensitive effects from the application of RX-56 powder in skin patches. No dermatitis effects reported in guinea pig tests. No evidence of dermatitis or other harmful effects found in people working with the resin either in production or molding.

None.

Irritation to eyes, nose, throat.

GAS PERMEABLE CONTACT LENS STUDY -- P.E. REPORT

atient	Examiner	
s. Wear	Date and Ti	
x. Hrs. Wear	_	
mfort Scale Completed		
1. How does lens feel	OD	OS
2. Pain (lid or cornea)		
3. Discomfort (lid or cornea)		
4. Burning		
5. Hot		
6. Itching		
7. Gritty, sandy		
8. Stinging		
9. Scratchy		
10. Redness		
11. Dryness		
12. Tearing		
13. Photophobia		
14. Haloes		
15. Blurred, hazy vision		-
16. Spectacle blur	8 A.	
bjective Signs: 1. Excessive blinking		
2. Insufficient blinking		
3. Squinting		
4. Swollen lids		

0U 20/ 0D 20/ 0S 20/

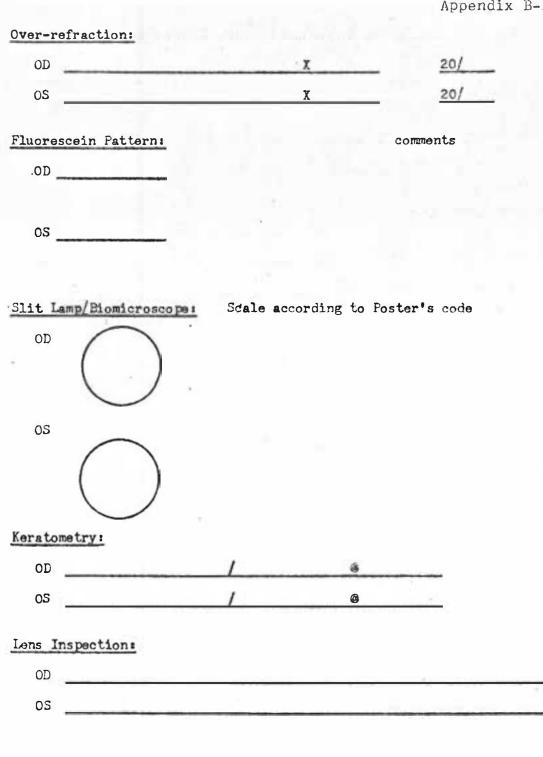
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Appendix B-2

Patient's Name:

Unaware of anything in eye Awareness		Light foreign body feeling-Can locate (9-12 o'clock, etc.)/Can become	
Light to medium awareness		accustomed to wear all day/	
	2		/
Heavy awareness/No foreign	1.0	Eyes tired	6
	2	Medium foreign body feeling/Can	
body feeling)		
Light foreign body feeling/		tolerate but annoying	7
inability to pinpoint		Heavy foreign body feeling/Cannot	
			0
location	4	tolerate for long	8
Medium foreign body feeling/		Burning, Stinging	
inability to pinpoint		Pain	10
location	5		
	1		

PLEASE RECORD APPROPRIATE CODE NUMBERS EVERY HOUR

Date	Time	Hrs. Wear	Code Numbers
	-		
<u></u>			
			1 1 2 C
			- in History and

BIOMICROSCOPE PHOTOGRAPHY SETTINGS

Subject	Type of Illumination	Mag.	Light	Light	Filter	Shutter Speed
Cornea	diffuse	1 O X	8	10 ⁰	full diffusing	1/15
Cornea	diffuse	16 - 25X	8	10 ⁰	full diffusing	1/8
Cornea	optic section	16-25 X	8	60 ⁰	partial diffusing	1
Cornea	sclerotic scatter	16-25X	8		partial diffusing	1/2
Sclera	diffuse	10X	7	10 ⁰	full diffusing	1/15
Sclera	diffuse	16 - 25x	7	10 ⁰	full diffusing	1/8
Fornix	diffuse	10X	7	10 ⁰	full diffusing	1/15
Crystalline Lens	optic section	16 x	8	60 ⁰	none	1
Fluorescein Patterns	diffuse	16 <u>x</u>	8	10 ⁰	cobalt blue	1

These settings are designed for use with the Nikon slit lamp and the Nikkormat camera, using only the internal illumination of the slit lamp. We used Kodak high-speed Ektachrome tangsten (3200 K) 35mm slide film, ASA 125, developed at ASA 320. This table was designed by Arnold Slolnik, O.D., and published in the Oregon Optometrist of March, 1973.

BIOMICROSCOPE PHOTOGRAPHS

Appendix E-1

Patient 1

Picture 14, Box 6: pre-wear, permeable eye, nasal vascularization Picture 15, Box 6: pre-wear, PMMA eye, temporal vascularization Picture 16, Box 6: pre-wear, PMMA eye, inferior vascularization Picture 17, Box 6: pre-wear, PMMA eye, nasal vascularization Picture 28, Box 7: 3 hours, permeable eye, inferior vascularization Picture 29, Box 7: 3 hours, permeable eye, nasal vascularization Picture 31, Box 7: 3 hours, PMMA eye, inferior vascularization Picture 26, Box 9: 10 hours, permeable eye, fluorescein pattern Picture 27, Box 9: 10 hours, permeable eye, fluorescein pattern Picture 28, Box 9: 10 hours, permeable eye, temporal stippling Picture 29, Box 9: 10 hours, permeable eye, temporal stippling Picture 30, Box 9: 10 hours, PMMA eye, fluorescein pattern Picture 31, Box 9: 10 hours, PMMA eye, fluorescein pattern Picture 32, Box 9: 10 hours, PMMA eye, nasal stippling Picture 33, Box 9: 10 hours, permeable eye, temporal vascularization Picture 34, Box 9: 10 hours, permeable eye, inferior vascularization Picture 35, Box 9: 10 hours, permeable eye, nasal vascularization Picture 36, Box 9: 10 hours, PMMA eye, temporal vascularization

Patient 2

Picture 34, Box 6: pre-wear, PMMA eye, inferior vascularization Picture 35, Box 6: pre-wear, PMMA eye, nasal vascularization Picture 4, Box 9: 6 hours, permeable eye, inferior vascularization Picture 7, Box 9: 6 hours, PMMA eye, inferior vascularization Picture 3, Box 10: 10 hours, permeable eye, temporal vascularization Picture 5, Box 10: 10 hours, permeable eye, inferior vascularization Picture 8, Box 10: 10 hours, PMMA eye, inferior vascularization

September 1

Patient 3

Picture 4, Box 2: pre-wear, permeable eye, temporal vascularization Picture 5, Box 2: pre-wear, permeable eye, nasal vascularization Picture 28, Box 2: 6 hours, PMMA eye, nasal vascularization Picture 28, Box 2: 6 hours, PMMA eye, nasal vascularization Picture 30, Box 2: 6 hours, permeable eye, nasal vascularization Picture 26, Box 3: 5 hours, PMMA eye, nasal vascularization Picture 27, Box 3: 5 hours, PMMA eye, inferior vascularization Picture 28, Box 3: 5 hours, permeable eye, temporal vascularization Picture 29, Box 3: 5 hours, permeable eye, nasal vascularization Picture 30, Box 3: 5 hours, permeable eye, inferior vascularization Picture 8, Box 4: 8 hours, Pmma eye, temporal vascularization Picture 9, Box 4: 8 hours, PMMA eye, nasal vascularization Picture 10, Box 4: 8 hours, PMMA eye, inferior vascularization Picture 12, Box 4: 8 hours, permeable eye, nasal vascularization Picture 13, Box 4: 8 hours, permeable eye, inferior vascularization Picture 24, Box 4: 7 hours, PMMA eye, inferior vascularization Picture 26, Box 4: 7 hours, permeable eye, nasal vascularization Picture 27, Box 4: 7 hours, permeable eye, inferior vascularization Picture 12, Box 5: 10 hours, PMMA eye, fluorescein pattern Picture 13, Box 5: 10 hours, PMMA eye, fluorescein pattern Picture 14, Box 5: 10 hours, permeable lens, fluorescein pattern Picture 15, Box 5: 10 hours, permeable lens, fluorescein pattern Picture 22, Box 5: 10 hours, PMMA eye, temporal vascularization Picture 23, Box 5: 10 hours, PMMA eye, nasal vascularization Picture 24, Box 5: 10 hours, PMMA eye, inferior vascularization Picture 25, Box 5: 10 hours, permeable eye, temporal vascularization Picture 26, Box 5: 10 hours, permeable eye, nasal vascularization Picture 27, Box 5: 10 hours, permeable eye, inferior vascularization

Patient 4

Picture 22, Box 1: pre-wear, PMMA eye, overall vascularization Picture 23, Box 1: pre-wear, PMMA eye, overall vascularization Picture 24, Box 1: pre-wear, PMMA eye, temporal vascularization Picture 25, Box 1: pre-wear, PMMA eye, nasal vascularization Picture 26, Box 1: pre-wear, PMMA eye, nasal vascularization Picture 27, Box 1: pre-wear, PMMA eye, inferior vascularization Picture 28, Box 1: pre-wear, permeable eye, overall vascularization Picture 29, Box 1: pre-wear, permeable eye, overall vascularization Picture 33, Box 1: pre-wear, permeable eye, inferior vascularization Picture 34, Box 1: pre-wear, permeable eye, inferior vascularization Picture 9, Box 2: 6 hours, permeable eye, nasal stippling Picture 10, Box 2: 6 hours, permeable eye, nasal stippling Picture 11, Box 2: 6 hours, PMMA eye, superior temporal stippling Picture 12, Box 2: 6 hours, PMMA eye, superior temporal stippling Picture 15, Box 2: 6 hours, PMMA eye, nasal stippling Picture 19, Box 3: 5 hours, PMMA eye, inferior vascularization Picture 20, Box 3: 5 hours, PMMA eye, nasal vascularization Picture 21, Box 3: 5 hours, permeable eye, temporal vascularization Picture 22, Box 3: 5 hours, permeable eye, inferior vascularization Picture 23, Box 3: 5 hours, permeable eye, nasal vascularization Picture 14, Box 4: 8 hours, PMMA eye, temporal vascularization Picture 15, Box 4: 8 hours, PMMA eye, inferior vascularization Picture 16, Box 4: 8 hours, PMMA eye, nasal vascularization Picture 17, Box 4: 8 hours, permeable eye, temporal vascularization Picture 18, Box 4: 8 hours, permeable eye, inferior vascularization Picture 19, Box 4: 8 hours, permeable eye, nasal vascularization Picture 28, Box 4: 7 hours, PMMA eye, temporal vascularization Picture 29, Box 4: 7 hours, PMMA eye, inferior vascularization Picture 30, Box 4: 7 hours, PMMA eye, nasal vascularization

Picture 31, Box 4: 7 hours, permeable eye, temporal vascularization Picture 33, Box 4: 7 hours, permeable eye, nasal vascularization Picture 8, Box 5: 10 hours, PMMA eye, fluorescein pattern Picture 9, Box 5: 10 hours, PMMA eye, fluorescein pattern Picture 10, Box 5: 10 hours, permeable eye, fluorescein pattern Picture 11, Box 5: 10 hours, permeable eye, fluorescein pattern Picture 17, Box 5: 10 hours, PMMA eye, inferior vascularization Picture 18, Box 5: 10 hours, PMMA eye, nasal vascularization Picture 20, Box 5: 10 hours, permeable eye, inferior vascularization Picture 21, Box 5: 10 hours, permeable eye, nasal vascularization Picture 11, Box 5: 10 hours, PMMA eye, nasal vascularization

Picture 18, Box 6: pre-wear, PMMA eye, temporal vascularization
Picture 19, Box 6: pre-wear, PMMA eye, inferior vascularization
Picture 23, Box 6: pre-wear, permeable eye, nasal vascularization
Picture 17, Box 7: 3 hours, permeable eye, central stippling
Picture 18, Box 7: 3 hours, permeable eye, central stippling
Picture 19, Box 7: 3 hours, permeable eye, central stippling
Picture 22, Box 7: 3 hours, permeable eye, central stippling
Picture 23, Box 7: 3 hours, PMMA eye, inferior vascularization
Picture 23, Box 7: 3 hours, PMMA eye, nasal vascularization
Picture 25, Box 7: 3 hours, permeable eye, inferior vascularization
Picture 26, Box 7: 3 hours, permeable eye, inferior vascularization
Picture 21, Box 9: 8 hours, permeable eye, inferior vascularization
Picture 24, Box 9: 8 hours, permeable eye, fluorescein pattern

Patient 6

Picture 2, Box 1: pre-wear, PMMA eye, overall vascularization Picture 3, Box 1: pre-wear, PMMA eye, overall vascularization Picture 6, Box 1: pre-wear, PMMA eye, nasal vascularization Picture 8, Box 1: pre-wear, permeable eye, overall vascularization

Picture 8, Box 3: 6 hours, PMMA eye, temporal vascularization Picture 9, Box 3: 6 hours, PMMA eye, nasal vascularization Picture 10, Box 3: 6 hours, PMMA eye, inferior vascularization Picture 11, Box 3: 6 hours, permeable eye, temporal vascularization Picture 12, Box 3: 6 hours, permeable eye, nasal vascularization Picture 13, Box 3: 6 hours, permeable eye, inferior vascularization Picture 14, Box 3: 6 hours, PMMA eye, central corneal clouding Picture 15, Box 3: 6 hours, PMMA eye, central corneal clouding Picture 16, Box 3: 6 hours, permeable eye, no central corneal clouding Picture 17, Box 3: 6 hours, permeable eye, no central corneal clouding Picture 31, Box 3: 8 hours, PMMA eye, temporal vascularization Picture 32, Box 3: 8 hours, PMMA eye, nasal vascularization Picture 33, Box 3: 8 hours, PMMA eye, inferior vascularization Picture 34, Box 3: 8 hours, permeable eye, temporal vascularization Picture 35, Box 3: 8 hours, permeable eye, nasal vascularization Picture 36, Box 3: 8 hours, permeable eye, inferior vascularization Picture 2, Box 6: 12 hours, PMMA eye, fluorescein pattern Picture 3, Box 6: 12 hours, PMMA eye, fluorescein pattern Picture 4, Box 6: 12 hours, permeable eye, fluorescein pattern Picture 5, Box 6: 12 hours, permeable eye, fluorescein pattern Picture 6, Box 6: 12 hours, PMMA eye, temporal vascularization Picture 7, Box 6: 12 hours, PMMA eye, nasal vascularization Picture 8, Box 6: 12 hours, PMMA eye, inferior vascularization

E-5

Patient 7

Picture 16, Box 1: pre-wear, permeable eye, inferior vascularization
Picture 17, Box 1: pre-wear, PMMA eye, temporal vascularization
Picture 21, Box 1: pre-wear, PMMA eye, inferior vascularization
Picture 1, Box 3: 6 hours, permeable eye, central corneal clouding
Picture 2, Box 3: 6 hours, permeable eye, temporal vascularization

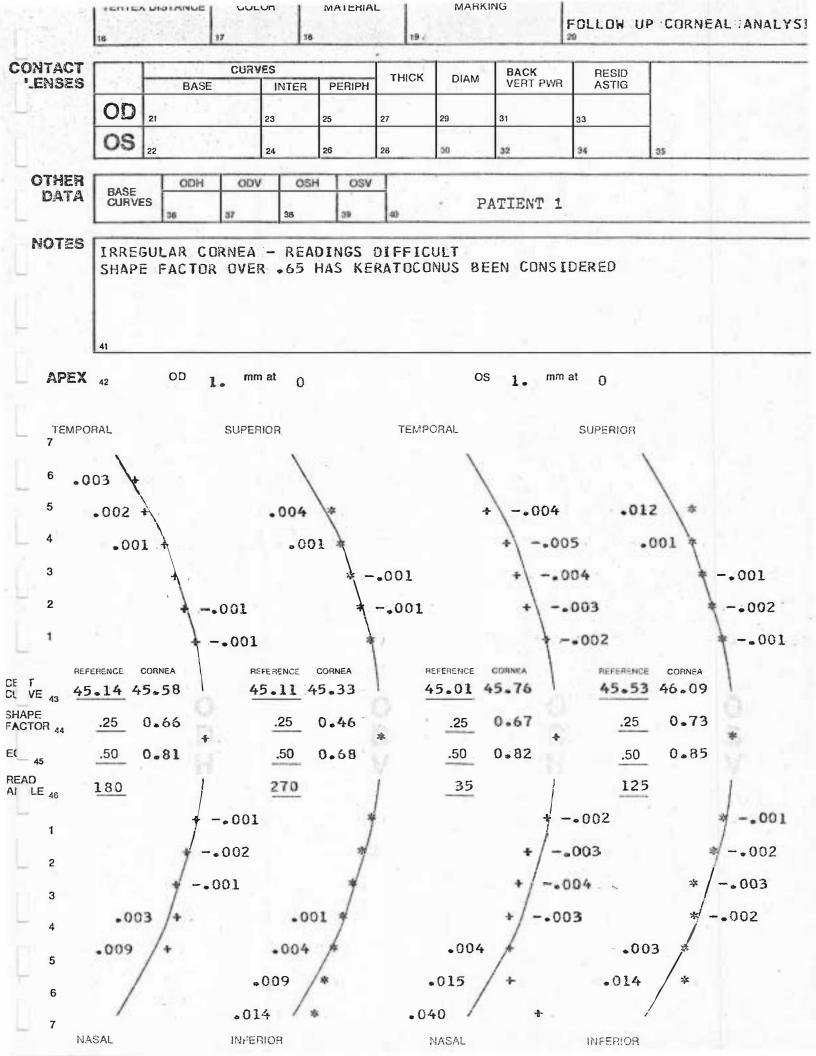
Picture 3, Box 3: 6 hours, permeable eye, inferior vascularization Picture 4, Box 3: 6 hours, permeable eye, nasal vascularization Picture 5, Box 3: 6 hours, PMMA eye, temporal vascularization Picture 6, Box 3: 6 hours, PMMA eye, inferior vascularization Picture 7, Box 3: 6 hours, PMMA eye, nasal vascularization Picture 2, Box 4: 5 hours, permeable eye, temporal vascularization Picture 3, Box 4: 5 hours, permeable eye, inferior vascularization Picture 4, Box 4: 5 hours, permeable eye, nasal vascularization Picture 6, Box 4: 5 hours, PMMA eye, inferior vascularization Picture 7, Box 4: 5 hours, PMMA eye, nasal vascularization Picture 2, Box 5: 8 hours, permeable eye, temporal vascularization Picture 3, Box 5: 8 hours, permeable eye, inferior vascularization Picture 4, Box 5: 8 hours, permeable eye, nasal vascularization Picture 5, Box 5: 8 hours, PMMA eye, temporal vascularization Picture 6, Box 5: 8 hours, PMMA eye, inferior vascularization Picture 7, Box 5: 8 hours, PMMA eye, nasal vascularization Picture 28, Box 5: 11 hours, permeable eye, fluorescein pattern Picture 29, Box 5: 11 hours, permeable eye, fluorescein pattern Picture 30, Box 5: 11 hours, PMMA eye, fluorescein pattern Picture 31, Box 5: 11 hours, PMMA eye, fluorescein pattern Picture 33, Box 5: 11 hours, permeable eye, inferior vascularization Patient 8

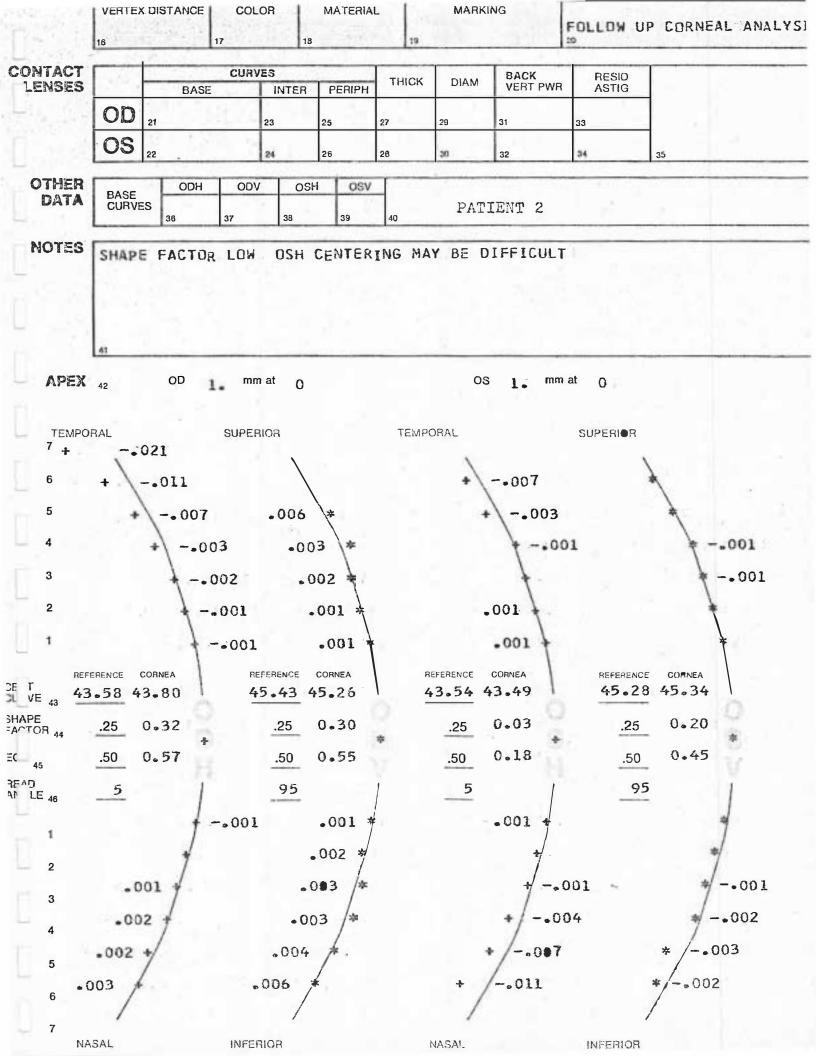
Picture 9, Box 7: pre-wear, PMMA eye, inferior vascularization Picture 10, Box 7: pre-wear, PMMA eye, nasal vascularization Picture 15, Box 9: 8 hours, permeable eye, nasal vascularization Picture 16, Box 9: 8 hours, permeable eye, inferior vascularization Picture 18, Box 9: 8 hours, PMMA eye, nasal vascularization Picture 19, Box 9: 8 hours, PMMA eye, inferior vascularization Picture 17, Box 10: 10 hours, permeable eye, stippling Picture 18, Box 10: 10 hours, permeable eye, stippling Picture 19, Box 10: 10 hours, PMMA eye, stippling

Patient 9

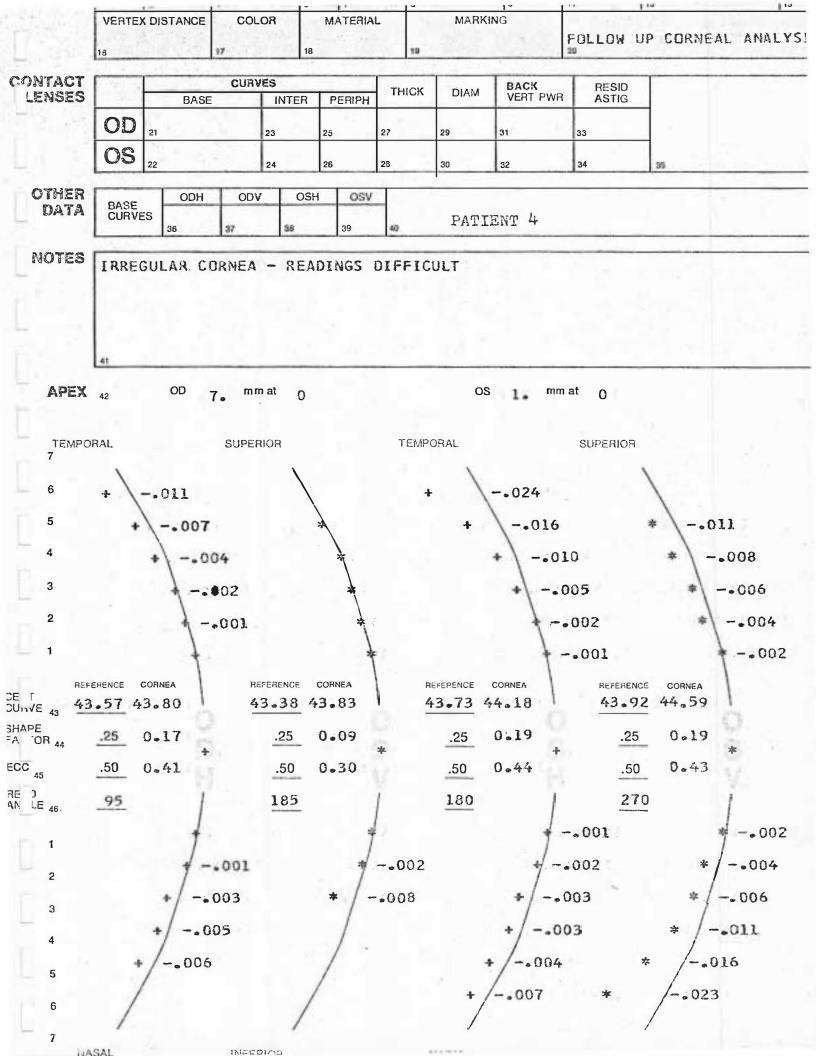
Picture 11, Box 7: pre-wear, permeable eye, temporal vascularization Picture 13, Box 7: pre-wear, permeable eye, nasal vascularization Picture 16, Box 7: pre-wear, PMMA eye, nasal vascularization Picture 26, Box 10: 6 hours, PMMA eye, central stippling Picture 36, Box 10: 6 hours, PMMA eye, temporal vascularization Picture 2, Box 11: 8 hours, PMMA eye, central corneal clouding Picture 3, Box 11: 8 hours, PMMA eye, central corneal clouding Picture 4, Box 11: 8 hours, permeable eye, no central corneal clouding Picture 5, Box 11: 8 hours, permeable eye, no central corneal clouding Picture 11, Box 11: 8 hours, permeable eye, no central corneal clouding Picture 11, Box 11: 11 hours, permeable eye, fluorescein pattern Picture 12, Box 11: 11 hours, PMMA eye, fluorescein pattern Picture 13, Box 11: 11 hours, PMMA eye, fluorescein pattern Picture 13, Box 11: 11 hours, PMMA eye, fluorescein pattern

Picture 6, Box 11: 8 hours, PMMA eye, central corneal clouding
Picture 7, Box 11: 8 hours, PMMA eye, central corneal clouding
Picture 8, Box 11: 8 hours, permeable eye, no central corneal clouding





	VERTEX	DISTANCE	COLOF	R 18	MATERIA	19	MARKI		FOLLOW U	JP CORNEAL ANALYS
CONTACT			CURVES			тніск	DIAM	BACK	RESID	
LENSES	00	BASE	-	INTER	PERIPH		Qu'nin	VERT PWR	ASTIG	
	OD	21	2:	3	25	27	29	31	33	
1.	OS	22	2	4	26	28	30	32	34	35
OTHER	BASE	ODH	ODV	OSH	OSV	_				
DATA	CURVE	ES 36	37	38	39	40		PATIENT	3	
NOTES				-		1000				
4										
n' 511	1									2011년 1월
-					21.14					1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Dr. x	41									
APEX	42	OD 1	mm a	^{it} 0			OS	1. mm :	at 0	
TEMPOR		013	SUPERIC	R		TEMPO		010	SUPERIOR	
6		008		1			1	006		
5	1	\ \			\)	<pre></pre>		
	+	007		*	100	3	+			
4		+/00	06		*/	003		100	2	•006 /*
3		+ \ (005		* -	•002		7 -00	01	.004 *
2		+\	004		+	002		+	001	.003 *
1		t.	002		ł	001		t.		.002
REFE	RENCE	CORNEA		RENGE	GORNEA	R	EFERENCE	CORNEA	REFERENC	CE CORNEA
CI VE 43 45	. 36 4	6.13	45	.92 4	6.31	1 4	5.17 4	5.34 1	46.1	6 45.71
SHAPE FACTOR 44	.25	0.52		.25	0.45		.25	0.34	.25	0.21
	.50	0.72 +		.50	0.67	*	.50	0.58	.50	0.46
RF^D Al iLE 46	5	1		95		1	5	1	9	5
1		+	002		4	001		ŧ		.002 *
		+/-	.003		*	002		*		.003
2		+/	004		*-	.002	• 0	101 + 100		.005 4
3		+/0			/	002	.00	/		.005 /*
4		/			./	002		/		/
5	+	/004			*		.005	1	•0	07 #
6	*/	001	.0	05	£		.010 /	+		
7	/			/						/
	SAL		INFERIC	RC		2	NASAL	1000	INFERIOR	



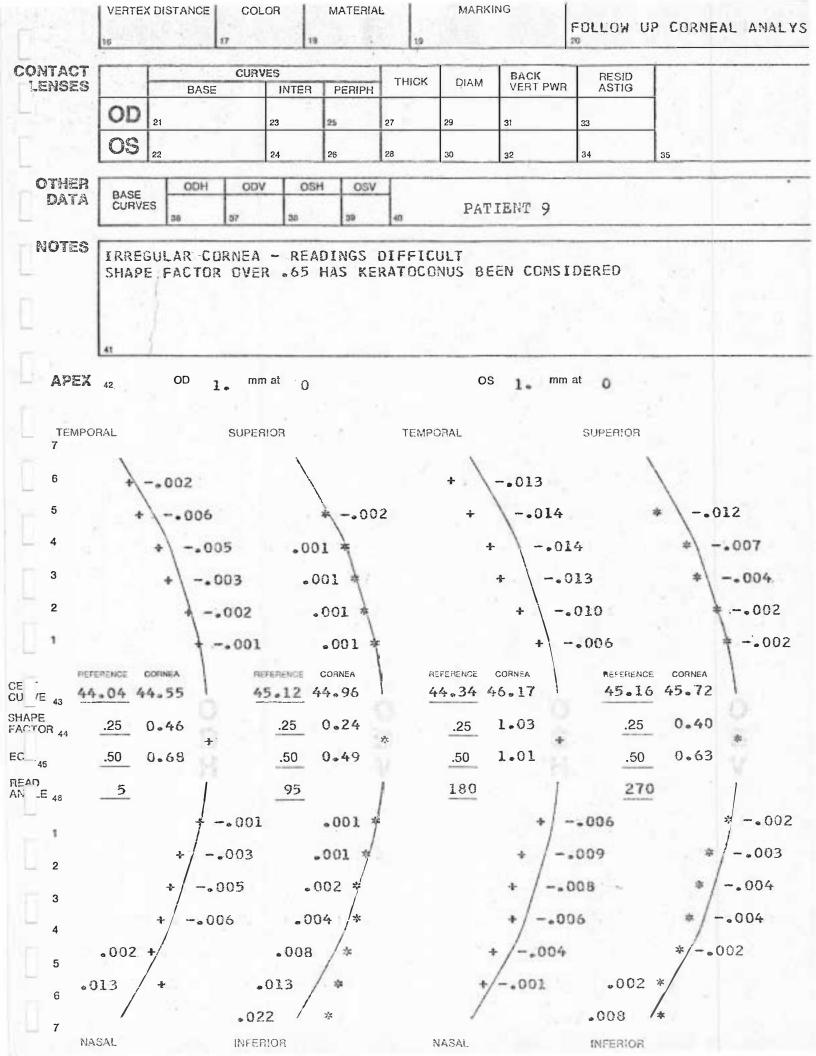
VERTEX DISTANCE	COLOR	MATERIAL	MARKING	The second second second second second
· 在外的社会	11 2 2 2	Sister W	100000000000000000000000000000000000000	FOLLOW UP CORNEAL ANALYSI
18	17	18	19	20

CONTACT		cu	RVES	-			BACK	RESID	
LENSES		BASE	INTER	PERIPH	THICK	DIAM	VERT PWR	ASTIG	
-U.	OD	21	23	25	27	29	31	33	
0.753	OS	22	24	26	28	30	32	34	35
OTHER DATA	BASE CURVE	and the second s	DV OS	SH OSV	_	ATIENT	5		
NOTES	-				1. 200	Conternio			
Ē	41								
APEX	42	OD 1.	mm at 0			OS	1. mm:	at _O	
TEMPOR		SUP	ERIOR		TEMP		609	SUPERIOR	
6	1		\backslash			1			\backslash
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5	+	004	i i i i i i i i i i i i i i i i i i i	* \00	14	+	1006	•06	04 /*
4		+\003		÷	002		+\00	5	.001
3		+ \003		* -	.001		+0	03	.001
2		+\003		4	001		<i>f</i>	001	.001
1		100	2	*	001		f		.001
OF T	•00 4	1	REFERENCE			EFERENCE		REFERIENC	CE CORNEA 5 44.34
SHAPE FATTOR 44	.25	0,46	.25	0.22	-	.25	0.28	.25	0.11
EC- 45	.50	+ 068	.50	0.47	15	.50	0.53	.50	0.33
AF LE 46	5	1	95		I	65	1	15	5
-		100	12	4	001		*		.001 #
1		1002		*	001		+		*
2		002		*/-	003	- 0	101 4		*/002
3		+/003		1	.005	-00	/		* /005
4	+	1	*	/		.005	1		* /010
5	+ /	003	*	012		.007 1	/	*	013
6	/		/			/		*	015
- 7 NAS	SAL	INF	ERIOR			NASAL		INFERIOR	

	VERTEX DI	STANCE	COLOR	MATERIA	L 19	MARKI	1	FOLLOW U	W UP CORNEAL ANALYS.		
CONTACT	F	BASE		PERIPH	тніск	DIAM	BACK VERT PWR	RESID	T		
	OD 21		23	25	27	29	31	33			
	OS 22		24	25	28	30	32	34	56		
OTHER DATA	BASE CURVES	ODH D5 3	0DV 0SF 7 38	4 OSV 29	40	PATIE	NT 6				
NOTES		ACTOR L	.0W OSH (CENTER	ING MA	Y BE D	1FFICULT				
АРЕХ ТЕМРО! 7 6	1	OD 1. s	mm at -0 UPERIOR		TEMP	OS ORAL	l. mm	at () SUPERIOR			
5 4 3 2 1	*/	004		* -	•004 -•003 -•002		010 +00 0 001 .001		001 +005 002		
CE CU_JE 43 42 SHAPE	.79 42	99	43.02 4	CORNEA 3.56 0.43		3.18 4	CORNEA 3.36	REFERENC 43 • 5	3 43.87		
FATTOR 44 EC-5 45	.25 0. .50 0.	4		0.66	*	.25 .50	08	.50			
RE D AN LE 46	5	1	95		1	5	1	9	5		
		+	001	*/	003	2	.001		*/001		
3 4 5	• 001	002 005		*/	-•004 .004 13	÷	+/00 +/012		*003		
6	SAL			004				INCEGIOD	* /005		

	16	8	17	13	-	10		1	FOLLOW UP CORNEAL ANALYSI
CUNTACT LENSES		BASE	CURVE	S INTER	PERIPH	тніск	DIAM	BACK VERT PWR	RESID
1	OD	21		9	25	27	29	34	23
	OS	22		24	26	28	30	32	34 35
OTHER		DDH	ODV	OSH	I OSV	-			
DATA	BASE CURVE		37	35	39	100	PATIEN	r 7	
NOTES	1RR60	SULAR CO	RNEA -	- REAL	DINGS	DIFFIC	ULT		
APE)		OD 1	mm a	Ū		TEMP	OS ORAL	1. mm	at O SUPERIOR
6 5 4 3	+	019 013 +00 +00		*	00	4 CO1	*	015 010 +00 +0	
CAIT	EFERENCE (5.07 4)				• 001	1	EFERENCE		002 .001 HEFERENCE CORNEA 45.93 45.95
HARE ACTOR 44		0.24			0.15	+	.25	0.08 +	.25 0.11 *
ECC_5 READ	.50 5	0.49		<u>.50</u> 95	0.39	Y	.50 165	0.28	<u>.50</u> 0.33 255 /
1		4 -	001		.001 4	-		+ -	* 001 *
2		¥	002	L.	001 *			*/	002 *
3		40	001	•0	02 1	34 14		+/0	004 */001
4		100	02	• 00	2 🚽			+/00	7 */002
5	/	*/002		.001	*		+	/011	*005
6	/			/			/		
7	IASAL		INFERI	OR			NASAL	1	INFERIOR

10.0	VERTEX DISTANCE	COLOR	MATERIA	1	MARKI			13 18
TIN	1.1.1.2.2.1.2.1.1.1		8	19		F	FOLLOW U	P CORNEAL ANALYS
	18		0					
CONTACT	BASE	CURVES INTER	PERIPH	тніск	DIAM	BACK VERT PWR	RESID ASTIG	
	OD 21	23	25	27	29	31	33	
민지원	OS 22	24	26	28	30	32	34	35
OTHER	BASE ODH	ODV OS	SH OSV	1				
DATA	CURVES 38	37 38	39	40	PAT	TIENT 8		
NOTES								
	1.15							
11 S. S. S.								
E.	41	1.00					B. B.	
APEX	42 OD 3	mm at 0			OS	1. mm:	at Q	
TEMPO	RAL	SUPERIOR		TEMPO			SUPERIOR	
	1	\		-01	1		8 B	
6	+ \007	``		•	010	+		
5	+ \004				.007	4		
4	100	2	*\	003	•00	4 *	•	.002 *
3	4 0	01	4-	.001	•0	02 {		¥
2	h	002	A			f		ŧ.
1	4.	001	.001			f		ŧ
	ERENCE CORNEA	REFERENCE	CORNEA	1		CORNEA	REFERENC	
43	.46 43.84	42.87	42.82	4	3.86 4	3.92	42.92	2 43.01
SHAPE FA OR 44	.25 0.52 +	.25	0.05	4	.25	0.43	.25	0.26
ECC 45	.50 0.72	.50	0.23		.50	0.65	.50	
RE D AN LE 46	95	185		1	90	1	180	2
1	4 -	001	.001			+		4
2	+	002	.001 *			*/		*/
	1	001	*		.0	01 +/	~	*/001
3	.002			.001	.00	2 +		*001
4	.006 /		* /00		.004	1		* /004
5	12 /+	*	006		007 \$			*006
6	/	. /	.009		/			/
- 7 NA:	SAL	INFERIOR	e V U 7		ACAL			



	VERTEX DISTANCE	COLOR	MATERIAL	MARKING	
		47	14	10	FOLLOW UP CORNEAL ANALYS
11.13	10	17	10	1.5	- 1**

CONTACT			CURVES		THICK	DIAM	BACK VERT PWR	RESID ASTIG	
An ku I U Win V	OD	BASE	INTER						
	OS	21	23	25	27	29	31	33	
L	03	22	24	26	28	30	32	34	35
OTHER DATA	BASE CURVE	S SH	ODV 05	SH OSV 39	43	PAT	TIENT 10		
NOTES									V 1
H									
-									
	41								
APEX	42	OD 1.	, mm at 0			OS	1. mm	at O	
TEMPOR 7	AL		SUPERIOR		TEMP	ORAL		SUPERIOR	
6	+ \-	011				/			001
5	*	007		*00	2	.003	1.		*003
4	3.								
		+/-•00,			004	•00	1		*\003
3		+ 01	02	* \ -	.004	•0	01 1		*002
2		+	001	*	003	•	001		*
1		4 -	.001	22	001		.001 }		*
or r		CORNEA	REFERENCE	CORNEA	1		CORNEA	REFERENC	
CU /E 43 44.	25 44	4.5/ 1	44.14		4	4.48 4		44.01	0 44.11
FACTOR 44	.25 (0 .3 3 +	.25	0.27	*	.25	0.19 +	.25	0.15
~o .	.50	0.58	.50	0.52		.50	0.43	.50	0.38
READ AN LE 48	95	1	185		1	130	1	22	0 1
1 H		4	• 00l		001	VI	.001 +		4
1		+/	002	* /	003		001 +		.001 */
<u> </u>		10		*/-	006		101 +		*
3		1	04	/					
4		1		/	.010		1		*/001
5	.003	t	24	/01	15		*/002		*/002
.00	D6 ∮		*	021		+/	006		* /005
7	/		/			/		÷	A.010
NAS	AL.	1.5	INFERIOR			NASAL		MEEDINO	1.1