Spring 1979

Testing the wearability of the N&N Menicon soft contact lens

Steven M. Wells  
Pacific University

Michael J. Sato  
Pacific University

Duane R. Beckwith  
Pacific University

Thomas Y. Fong  
Pacific University

Recommended Citation
Wells, Steven M.; Sato, Michael J.; Beckwith, Duane R.; and Fong, Thomas Y., "Testing the wearability of the N&N Menicon soft contact lens" (1979). College of Optometry. 552.  
https://commons.pacificu.edu/opt/552

This Thesis is brought to you for free and open access by the Theses, Dissertations and Capstone Projects at CommonKnowledge. It has been accepted for inclusion in College of Optometry by an authorized administrator of CommonKnowledge. For more information, please contact CommonKnowledge@pacificu.edu.
Testing the wearability of the N&N Menicon soft contact lens

Abstract
Forty-four patients were fit with N & N Menicon Soft Contact Lenses for future approval of the lenses by the Food and Drug Administration. Eighteen patients utilized chemical sterilization (Burton Parsons Flexol) and nineteen used heat (Meniconilizer). Seven patients were released from the study for personal reasons. No patients were discontinued from lens wear due to objective or subjective symptoms. Twenty patients were monitored and decreases in tear pH, tear flow, and tear break up time were noted at the end of six months wear. Anterior segment photographs were taken on twenty-three patients to document any changes in limbal vascularization and only minimal changes were found. We found the N & N lenses to be excellent, particularly in achieving visual acuity and in ease of patient handling.

Degree Type
Thesis

Degree Name
Master of Science in Vision Science

Committee Chair
Stephen Dippel

Subject Categories
Optometry
Testing the Wearability of the N & N
Menicon Soft Contact Lens

by
Steven M. Wells
Michael J. Sato
Duane R. Beckwith
Thomas Y. Fong

Submitted in Partial Fulfillment of the
Requirements for the Degree of Doctor of Optometry

Spring 1979
# TABLE OF CONTENTS

Acknowledgements ................................................ i
Abstract ...................................................................... 1
Objective ..................................................................... 2
General ........................................................................ 2
Methods ...................................................................... 4
Procedure
   A. Trial Fitting ..................................................... 6
   B. Lens Dispensing ................................................. 8
   C. First Follow-up .................................................. 9
   D. Follow-up Examinations ..................................... 9
Photography .................................................................. 10
Fee Schedule ................................................................ 12
Results ....................................................................... 13
Discussion .................................................................... 20
Appendix I ................................................................... 26
Appendix II ................................................................. 27
Appendix III ............................................................... 28
Appendix IV ............................................................... 29
Appendix V .................................................................. 30
Appendix VI ............................................................... 31
Appendix VII ............................................................. 32
Appendix VIII ........................................................... 33
Appendix IX ............................................................... 34
Appendix X ............................................................... 35
Appendix XI .............................................................. 36
Appendix XII ............................................................ 39
Appendix XIII ........................................................... 50
Bibliography ............................................................ 55
We would like to extend our appreciation to the patients who took part in this study, and to Beta Sigma Kappa, the Oregon Optometric Association, and the Pacific University Contact Lens Research Fund for financial assistance.

A special thanks goes to our advisor, Dr. Stephen Dippel, for his guidance and encouragement and to Brian Grudem and Dale Graf for their help during the project.

We would also like to give warm thanks to Betty Rea for her help and understanding throughout the study, and to Kelly Rea who graciously did all of our typing.
ABSTRACT

Forty-four patients were fit with N & N Menicon Soft Contact Lenses for future approval of the lenses by the Food and Drug Administration. Eighteen patients utilized chemical sterilization (Burton Parsons Flexol) and nineteen used heat (Meniconilizer). Seven patients were released from the study for personal reasons. No patients were discontinued from lens wear due to objective or subjective symptoms. Twenty patients were monitored and decreases in tear pH, tear flow, and tear break up time were noted at the end of six months wear. Anterior segment photographs were taken on twenty-three patients to document any changes in limbal vascularization and only minimal changes were found. We found the N & N lenses to be excellent, particularly in achieving visual acuity and in ease of patient handling.
OBJECTIVE

The purpose of this study was to determine the wearability and fitting characteristics of the Menicon N & N Soft Contact Lens on patients over a period of six months. We also determined the effect of the N & N Soft Contact Lens on tear pH, tear flow, and tear break up time. In addition, we monitored the effects of the lens on limbal vascularization and on the upper and lower tarsal conjunctiva. Two systems of disinfection, heat and chemical, were used to determine differences in patient acceptance or wearability of the lens.

GENERAL

The Menicon N & N Soft Contact Lens is a lathe cut hydrogel lens based on 70% 2-Hydroxyethyl Methacrylate (HEMA) by weight in a saline solution. It has a lower water content (30%) than most currently available soft lenses which Menicon claims makes this lens more durable and easier to handle. It has a visible light transmission of greater than 90% with a refractive index of 1.45. The standard overall diameters are 12.5mm and 13.0mm. Minus lenses are available in powers ranging from plano to -25.00 diopters and above, in base curves from 7.6mm to 9.0mm of radius, and in center thicknesses from 0.22mm to 0.14mm. The bevel width on minus lenses is 0.039mm. (See Appendix I) Each 12.5 diameter lens is marked on the front surface with the base curve and overall diameter which is helpful in identification and in determining if the lens is inside out.

A previous study on the Menicon N & N Soft Lens by Phillips revealed that on a population of seventy-five patients the lenses showed good physiological responses, comfort,
durability, visual acuity, and quality control. Most patients found the lenses easy to handle and no lenses were split or torn during the twelve month study.26

Grosvenor, in a study of the Menicon N & N Soft Lens, reported a flattening of the corneal curvature in both meridians during the first six weeks of wear. This was accompanied by a decrease in myopia. After the six week period, corneal curvature steepened and myopia increased and both leveled off to approximately their pre-fitting status.10

In this study, we worked as an investigative team for the N & N Menicon Company for the possible FDA approval of their Menicon lens for use in the United States. Forty-four patients were fit with minus lenses. Also included were several other evaluations over a six month period after dispensing of the lenses. Patient selection was of a random nature, but we stayed within the recommended boundaries set aside in the N & N patient guidelines.30,26
METHODS

I. General

Certain methods and protocol as required by the Federal Food and Drug Administration were used in this study. Nineteen patients used chemical sterilization (Burton Parsons Flexol) and eighteen patients used heat sterilization (Meniconilizer). Evaluation forms furnished by the N & N Menicon Company were filled out after each patient visit. There were separate forms for the initial patient visit, dispensing of the lenses, and for the progress evaluation. These forms included general physical data of the lenses and their fitting characteristics. (Appendices II, III and IV).

We also kept our own recording forms on each patient which consisted of the data required by N & N plus measurements on tear pH, tear break up time, and tear flow, which were taken during the trial fitting and close out visits on twenty patients.

Physiological changes of the upper and lower eyelids and of limbal vascularization on twenty-three patients were documented using N & N criterion by anterior segment photography (See Appendix XI) on color slide film (See photography section page #50). Photographs were taken at monthly intervals throughout the six month study unless individual abnormal conditions suggested they be done more frequently. Anterior segment photography and measurements of tear pH, tear flow, and tear break up time were taken in that order with a five minute time span between each procedure.
Tear pH was determined by the use of pH Hydrion Paper Strips (manufactured by Micro Essential Laboratories) calibrated to the nearest 0.2 pH unit. Measurements were taken by retracting the lower eyelid and touching the strip to the lower tarsal conjunctiva.

Tear flow was measured by the Schirmer Tear Test following the procedure outlined by Halberg and Berens. The test was conducted under one drop of a topical anesthetic (Benoxinate 0.4% or proparacaine 0.5%) for five minutes and recorded in millimeters.

Tear break up time was determined using sterile sodium fluorescein strips in the method described by Lemp and Hammil. A break up time of greater than 15 seconds was recorded as 15 seconds.

Trial lenses received from the N & N Menicon Company were stored in sterile saline. All diagnostic lenses were stored in Burton Parsons Flexol throughout the six month study. Prior to and following each trial fitting of a patient, the lenses were cleaned with Burton Parsons Preflex and rinsed with Burton Parsons Normol.

Upon entering this research study, each patient was required to sign an Informed Consent Form stating that he was aware that he was participating in a new drug study, and that he had been advised of the potential hazards, complications, and adverse reactions which may be associated with the wearing of this investigational soft contact lens. (See Appendix IX)
At the close-out visit, each patient received an insurance application for N & N Menicon Soft Lenses and a letter of thanks for their cooperation in the research study. The letter also contained information concerning their lens prescription and on obtaining follow-up visual care. (Appendix X)

PROCEDURE

A. Trial Fitting

Prior to trial lens fitting, each patient was required to have a visual examination conducted by a student intern at the Forest Grove or Portland Clinics of the Pacific University College of Optometry.

On the day of the initial fitting, corneal cylinder readings were taken using an American Optical CLC Ophthalmometer. The palpebral aperture size, horizontal visible iris diameter, and pupil size under normal room illumination were also recorded. As suggested by the N & N Fitting Manual, a trial lens three diopters flatter than the average ophthalmometer reading with a 12.5mm diameter was the first lens placed upon the eye. If the horizontal visible iris diameter was larger than 11.5mm, a 13.0mm diopter lens was used. In all cases, the smallest size lens which had ample movement and covered the limbus was the lens of choice. If the patients distance refractive correction was between -0.25 diopters and -6.00 diopters, the -3.00 diopter trial set was used. If the distance correction was more than -6.00 diopters, the -10.00 diopter trial lens set was used.2

When putting the trial lens on the eye, the patient was requested to look down and the lens was placed half on the
sclera and half on the cornea. The bubble trapped beneath the lens was observed as the patient slowly looked up without blinking. If the bubble escaped quickly from beneath the lens, it was an indication that the lens was too flat. If the bubble was trapped beneath the lens, a steep fit was suggested.

Once the lens was on the eye, the patient was allowed to adapt to the lens for five minutes. After this adjustment period, the lens was checked for centering, movement, lag on upward gaze, and lens position on downward gaze according to the following criteria. On centering, the lens should cover the limbus in all areas when in the primary position of gaze. Movement should be one to two millimeters. On upward gaze the lens should lag one to two millimeters and be pulled over the limbus in the 6 o'clock position with the blink. On downward gaze the lens should be two to three millimeters above the limbus in the 12 o'clock position. If the initial trial lens did not fit these criteria, the appropriate lens with a base curve 0.2mm flatter or steeper was then placed upon the eye and evaluated.

When the proper fitting lens was on the eye, ophthalmometer readings were taken over the lenses and the clarity of the mires noted. If the mires cleared after the blink and then became blurred, it suggested a flat fit. If the mires blurred after the blink and then became clear, the fit was judged to be steep.

A spherical over-refraction was then done and the visual acuity through the over-refraction recorded. The blink test was performed and the crispness of the retinoscopy reflex
checked to evaluate the quality of the lens fit. The trial lenses were then removed and anterior segment photographs followed by measurements of tear pH, tear flow, and tear break up time were done. The lenses of the proper size and power were then ordered.

B. Lens Dispensing

The lenses were dispensed about one week after the trial fitting visit. Verbal and written instructions on lens insertion and removal were given to each patient. The method of lens sterilization to be used was explained.

Once the lenses were on the patient's eyes, visual acuity, a sphero-cylinder over-refraction, and the blink test were done. The lenses were also checked for movement and centering.

Instructions given to the patients stressed hygienic care and proper cleaning of the lenses. They were told to note any unusual sensations with the lenses or changes in visual acuity and under what circumstances they occurred. They were also told that their lenses may have to be replaced if their current lenses were not fitting satisfactorily as evaluated with objective and subjective techniques. They were reminded to follow the wearing schedule provided them and to report any unusual discomfort or problems with the lenses. The wearing schedule was as follows:
C. First Follow-up Examination

After the lenses were dispensed, the patient was seen for the first check-up in approximately one week. At this time, any subjective and objective symptoms were noted. Visual acuity through the lenses, sphero-cylinder over-refraction, movement, and centering were recorded. The lenses were then removed and a biomicroscopic evaluation was made for the presence of edema, staining, vascularization, and injection. These were recorded according to the grading system provided by the N & N Menicon Company. (See Appendix IV)

The lenses were examined through the biomicroscope for the presence of surface deposits or damage. If deemed necessary, the patient was given Enzymatic Contact Lens Cleaning Tablets to use, following the procedure explained in the N & N Menicon Research Proposal Protocol for Phase III.

D. Follow-up Examinations

The second check-up visit (fourth visit overall) took place approximately three weeks after the time the lenses were dispensed. The procedure was the same as was conducted.
during the first check-up with the addition of anterior segment photographs. (See photography supplement below.)

The following visits took place at monthly intervals for the remainder of the six month study with the procedure the same as the second check-up visit. (See Appendix IV) The close-out visit also included measurements of tear pH, tear flow, and tear break up time. The close-out form was included in each patient's permanent record.

PHOTOGRAPHY

Anterior segment photographs were taken to monitor any physiological changes taking place while wearing the N & N Soft Contact Lens. The following pictures were taken during the dispensing visit and on each follow-up visit: superior perilimbal, inferior perilimbal, horizontal perilimbal (3-9 area), lower lid, upper lid, and OD and OS lens profiles.

For this study we used a hand held system combined with extension tubes. The apparatus consisted of a Pentax MX camera back, a standard 50mm f1.7 lens, extension tubes (36mm, 20mm, and 12mm), a 2X tele-converter, Vivitar Model 102 flash, and a bracket. We used Eastman Type 5247 film made by Kodak.

A 2:1 magnification ratio was used to take the pictures of the perilimbal areas and the eyelids. For the lens profile pictures we used 1:1 magnification.

As suggested by Puckett and Nelson the following magnification ratios were used. 1:1 ratio - camera back, 36mm extension tube, 2X tele-converter, 12mm extension tube, and 50mm lens. For a 2:1 magnification ratio, the apparatus
consisted of camera back, 36mm extension tube, 2X tele-converter, 12mm extension tube, 20mm extension tube, and 50mm lens.

The flash was mounted under the front part of the camera. The bracket was attached to the tripod socket on the camera and the flash was attached to the bracket with a hot shoe adapter. The flash was electrically connected to the camera by means of a PC cord.

With magnification ratios of 1:1 and 2:1 the working distance between the camera and the eye was 15cm and 7cm, respectively. Due to this close working distance a small flash was needed. Therefore, the modification of black masking tape to cover half of the flash was used to reduce the intensity of the flash. For dark colored irises, an eighth inch more of the flash was exposed.

For all the anterior segment photographs a chin rest was used which helped eliminate head movements by the patient.

For the lens profile pictures, the patient was asked to take two complete blinks and look straight into the camera. The upper and lower eyelids were pulled back and the lens was allowed to fall into its static position.

The superior perilimbal photographs were taken with the patient's eyes directed toward the bottom of the camera lens (6 o'clock position). The upper lid was then retracted to expose the superior portion of the globe.

For photographs of the inferior perilimbal area, the camera was rotated so the flash was on top. The patient was asked to look at the top portion of the camera lens (12 o'clock position) and the lower lid was retracted.
The horizontal perilimbal picture was taken with the flash on the bottom of the camera. The patient was asked to look straight into the camera (primary gaze) and the upper and lower eyelids were pulled apart.

The camera was rotated again for the lower lid picture. The patient looked at the ceiling and the lower lid was pulled down to expose the lower palpebral and bulbar conjunctiva.

For the upper eyelid photograph the camera was again rotated so the flash was on the bottom of the camera. The patient was asked to look down and the upper lid was everted and pressed against the frontal bone to prevent the patient from blinking. The eyelid was returned to its normal position by pulling the upper lid forward allowing the tarsal plate to fall into place.

**Fee Schedule**

In this study the fee schedule was $100. per patient, which we feel provided economic incentive. This included the initial examination, follow-up evaluations, one pair of N & N Menicon Soft Contact Lenses, and solutions and equipment for the handling and sterilization of the lenses for the six month period. If any lenses could not be worn within the first month after dispensing, they were replaced at no extra cost to the patient. Also, any lens which was damaged during the dispensing visit was replaced free of charge.

After the dispensing visit, the patient was charged material cost ($25.) for any lenses he lost or damaged.
RESULTS

A total of forty-four patients were initially fit in this study, but seven were closed out early due to personal reasons. However, all seven of these patients reported good comfort and 20/20 or better acuity before leaving the study. Of the thirty-seven remaining patients, twelve were males and twenty-five were females. All of these patients have been wearing their lenses for at least four months at this time.

Patient ages ranged from 14 years to 68 years with an average age of 27 years. The median age was 23 years. The average amount of initial corneal astigmatism, as measured by the ophthalmometer, was 0.93 diopters with a range from 0.00 D to 2.12 D. Our patients were fit an average of 2.41 diopters flatter than the flattest ophthalmometer reading. Of the 37 patients, only two had visual acuities poorer than 20/20 while 19 patients had better than 20/20 acuity. The average wearing time of the lenses was 13.5 hours per day with a range from 8 to 16 hours.

Initially 18 of the patients used the chemical disinfection system (Burton Parsons Flexol) and 19 used heat sterilization (Meniconilizer). Seven patients were switched from chemical to heat sterilization because of follicle formation.

Twelve (32.4%) of the 37 patients developed lens deposits and were given enzymatic cleaner to use in cleaning their lenses.

Nineteen patients were found to have slight staining of not more than grade 4, edema of not more than grade 1, or
foreign body tracks of grade 3. (See Appendix XI for grading classifications). Eighteen patients had none of these problems.

There were 37 lens changes during the course of the study. Ten lenses were changed because of fitting characteristics, 5 were changed because of defective lenses, 3 were changed because of loss, and 18 were changed because of power. (See Appendix XII) Of the power changes, 13 were changed to increase the minus power, and 5 were changed to reduce the minus power.

The following figures are the results of photodocumentation of slit lamp observations of 23 patients (46 eyes). These figures are in the areas of conjunctival injection, corneal vascularization, and the occurrence of follicle formation of the upper and lower eyelids. The classifications were recorded according to the N & N guidebook. (See Appendix XI)

Photographs of the peri-limbal bulbar conjunctiva revealed the following in the area of injection (See Table 1):

-----Superior:

----15 eyes (33%) showed no change in classification from the pre-fitting photographs.

----31 eyes (67%) demonstrated a change from the pre-fitting data, 9 of these eyes changed from grade 0 to grade 1, and 22 eyes changed from grade 0 to grade 2.

-----Inferior:

----25 eyes (54%) showed no changes in classification.
---21 eyes (46%) showed grade classification changes, 18 eyes of which went from grade 0 to grade 1, and 3 eyes that went from grade 0 to grade 2.

---Horizontal:

---21 eyes (46%) showed no classification changes throughout the study.

---25 (54%) showed changes, 21 eyes changed from grade 0 to grade 1 and 4 eyes which changed from grade 0 to grade 2.

Photographs taken to document changes in corneal vascularization in the upper and lower quadrants of the cornea as well as the horizontal (3-9) meridian revealed:

---Superior:

---40 eyes (87%) showed no corneal vascularization.

---6 eyes (13%) showed corneal vascularization during the study, none of which exceeded 1.5mm.

---The Inferior and Horizontal (3-9) quadrants revealed no corneal vascularization.

Of the 46 eyes that were photographed to document upper and lower eyelid changes, 34 eyes (74%) showed no changes from the pre-fitting photographs. The other 12 eyes (26%) showed changes labelled as follicle formation not seen at the pre-fitting stage (See Table 2). All the changes occurred in the upper eyelid.
INJECTION

<table>
<thead>
<tr>
<th>LIMBAL AREA</th>
<th>EYES REMAINING STABLE</th>
<th>EYES SHOWING GRADING CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>GRADE 0 TO 1</td>
</tr>
<tr>
<td>SUPERIOR</td>
<td>15</td>
<td>9</td>
</tr>
<tr>
<td>INFERIOR</td>
<td>25</td>
<td>18</td>
</tr>
<tr>
<td>HORIZONTAL</td>
<td>21</td>
<td>21</td>
</tr>
</tbody>
</table>

Table 1

UPPER-PALPEBRAL FOLLICLE FORMATION

<table>
<thead>
<tr>
<th></th>
<th>NO CHANGE</th>
<th>FOLLICLES</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>CHEMICAL</td>
<td>HEAT</td>
</tr>
<tr>
<td>INITIALLY</td>
<td>33 EYES</td>
<td>4 EYES</td>
<td>12 EYES</td>
</tr>
<tr>
<td>6 MONTHS</td>
<td>17 EYES</td>
<td>18 EYES</td>
<td>14 EYES</td>
</tr>
</tbody>
</table>

Table 2
PERILIMBAL
CONJUNCTIVAL
INJECTION

Fig. 1
CORNEAL VASCULARIZATION

Fig. 2

SUPERIOR

INFERIOR

HORIZONTAL

NO CHANGE
GRADE INCREASE

NO CHANGE
GRADE INCREASE

NO CHANGE
GRADE INCREASE

100%

87%
13%

100%

0%

100%

0%
Fig. 3
DISCUSSION

In this study, we found the N & N Menicon Lens to be acceptable in the areas of patient comfort, refractive error correction, and physiological considerations as previously reported by Phillips. 26

Eighteen of the patients in this study had not worn contact lenses before, and the remainder were previous hard (17) or soft (2) contact lens wearers. None of the patients had problems handling the lenses and all could adequately insert and remove the lenses after the initial visit.

Our average lens fit of 2.41 diopters flatter than the flattest ophthalmometer reading compared favorable to the 2.50 diopters value obtained by Grosvenor. 10

The N & N lens has shown, as with other soft lenses, that it may contribute to decreases in tear pH, tear flow, tear break up, and to minimal vessel growths. 14, 18, 17, 4

These changes may also contribute to an increase in lens deposits in some people, necessitating use of enzymatic cleaner.

In our patients, we found a lower baseline tear pH reading (7.12) than the 7.46 open eye pH reported by Hill and Carney. 13 This could be due to the fact that we made our measurements with pH paper strips while Hill and Carney used a closed chamber micro-electrode maintained at a constant temperature of 36°C. The decrease in pH we observed could also be due to effects of the lens on tear viscosity or tear flow. These results indicate further study is needed in this area.
The 1.1% decrease we found in tear flow was considerably lower than the 15% decrease reported by Kline and DeLuca with the Bausch and Lomb Soflens.\textsuperscript{17} This difference could possibly be due to the use of a topical anesthetic in our study.

The 18.5% decline we observed in tear break up time after six months of wear was much less than the 54% decrease shown by Kline and DeLuca.\textsuperscript{17} Also, our average initial tear break up time of 13.14 seconds was higher than the 11.24 seconds obtained by Kline and DeLuca in their study.

A possible explanation for the reason our measurements of tear pH, tear flow, and break up time differed from those previously reported was that they were performed following the taking of anterior segment photographs.

We found a 0.20 diopter change in the flattest ophthalmometer reading after six months of lens wear which is similar to the change shown previously by Grosvenor\textsuperscript{10} and by Lebow and Goldberg.\textsuperscript{22}

None of our patients showed arcuate staining after six months of wear compared to the 38.5% reported by Kline and DeLuca with Bausch and Lomb Lenses.\textsuperscript{19} However, one patient did develop an inferior corneal arcuate stain after one week of lens wear which disappeared when a smaller diameter lens was used. Also, 50% of our patients had pitting stain which is more than the 32% found with Hydrocurve thin series lenses by Kline and DeLuca.\textsuperscript{18}

Four patients (3 females and 1 male) had lenses which developed a non-removable greyish color. These lenses were
replaced and the discolored lenses sent back to the N & N Menicon Company for analysis. All four patients were using heat sterilization. At this time the cause of the discoloration is not known, but possibly it was caused by poor patient handling or a foreign contaminant reacting with the heat from the disinfesting unit. This is similar to the occurrence of lens contamination reported by Porter.28 No lens discoloration occurred with the chemical disinfection system in this study.

The average initial pH measurement was 7.12 which decreased 1.8% to 6.99 after six months of lens wear. This change was significant at the 0.025 level. The Schirmer Tear Test showed a 1.1% decrease from a baseline average of 23.47 mm to a six month measurement of 22.45 mm. This change was not significant at the 0.1 level. The average initial breakup time was 13.14 seconds. This decreased 18.5% to 10.71 seconds at the end of the study. This change was highly significant at the 0.005 level. The average flattest ophthalmometer reading showed a 0.20 diopter decrease (0.46%) from 43.54 D to 43.34 D. This non-significant (0.1 level) change is within the measurement error of the ophthalmometer.

In terms of documenting conjunctival injection with anterior segment photography, most of our patients demonstrated minimal amounts of injection (grades 0 and 1 respectively). Those eyes that were listed as having severe vessel injection (grade 2) by N & N's criterion may be subject to variation since no specific criterion other than subjective speculation could be used. This would tend to leave a wide area between
grades 0 and 2, since the definitions of minimal and severe was not clearly defined. Better methods of classifying slit lamp findings would be useful for future studies of this nature. If specific criterion were standardized, findings could be better correlated and measured, and not be as subject to variations. In all cases concerning injection, none of them, in our opinion, was of an extreme nature as to warrant our removing the lenses from the patient and closing them out of the study.

In one of the cases, a patient had neglected to remove his lenses and had fallen asleep while taking a sauna. He came to us with severely injected and dilated conjunctiva (grade 2). We removed the lenses from the patient and monitored his condition. Within a few days the injection had subsided (grade 1) and the lenses were returned. The patient has worn the lenses comfortably since that time and regressed back to the pre-fitting stage. (grade 0)

The photographs of our study reported that the highest prevalence of injection occurred in the upper peri-limbal quadrant of the cornea. This was also true in the case of corneal vascularization with the only examples documented in the study appearing in the upper quadrant of the cornea. In one instance, the patient was a myope of -11.50 diopters. She was a trial fit with -3.00 diopter lenses and when her lenses arrived they tended to position high. On following visits, her lenses did not change their fitting characteristics and subsequently, she started showing upper corneal injection and vascularization. New lenses were ordered with a steeper base
curve and the lenses then centered better on the eyes. With the wearing of these lenses, there was a noticeable lessening of the injection and vascularization.

In this instance, the injection and vascularization could be attributed to a high riding lens, but we were not able to find the same with the other cases. This could be due to the fact that this example was not the average case since this patient was a high myope and a previous contact lens wearer. Correlations in this area may want to be included in future studies.

The photographs taken to monitor changes of the eyelids showed no changes in the lower eyelid. Of the 33 eyes that were reported to have no changes in the upper eyelid, from the pre-fitting photographs, 16 of those eyes exhibited conjunctival follicles as described by Allensmith\textsuperscript{1} at the pre-fitting stage which did not show any changes throughout the study. Six of those eight patients were on the heat disinfection system of lens sterilization. Of the eight patients that did exhibit follicle formation not characteristic at the pre-fitting stage, seven were using the chemical disinfection system. The one patient using the heat disinfection system exhibited follicle formation which occurred on just one eye.

The preceding data may suggest some kind of reaction of the eye to the chemicals in cold storage systems of soft lens sterilization, as suggested by Spring.\textsuperscript{31} In addition, of the eight patients using heat sterilization who had follicles present prior to lens wear, only two showed any further
follicular formation.

The patients initially using chemical sterilization that acquired the follicles were switched to heat. They are currently being monitored to determine if the follicle formation will persist. Further studies to determine the exact causes of the follicles are needed, but from the data gathered from our study, these people may not have to be precluded from soft lens wear if they are put on heat sterilization methods of disinfecting the lenses. It is also interesting to note that of the eight patients showing follicles at the onset of the study, only two were previous contact lens wearers.

The documentation of slit lamp findings by use of anterior segment photogaphy was used in this study. Further studies using photography techniques may be found useful for retaining permanent visual records during contact lens wear to monitor any changes which may occur. The photographs taken during this study are being donated to the Pacific University College of Optometry.

Compared to other soft contact lenses we have worked with, we found the Menicon N & N Soft Contact Lens to be equal or superior, especially in the areas of visual acuity, ease of handling, and the masking of corneal astigmatism. These advantages may be attributed to the relatively low water content (30%) of the lens. Further studies are warranted.
APPENDIX I

MINUS LENS PARAMETERS
MINUS SERIES

12.5 TO 13.0 DIAMETER

11.0 To 15.0 Available On Special Order In Increments Of Five

Lens Dimensions (Hydrated In Saline Solution)

Optical Zone  
8mm on 12.5
9mm on 13.0

BASE CURVES

Bevel Width .039mm

Center Thickness .22 to .14

POWERS

<table>
<thead>
<tr>
<th>Power</th>
<th>Thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plano To -1.00</td>
<td>.22</td>
</tr>
<tr>
<td>-1.24 To -1.75</td>
<td>.20</td>
</tr>
<tr>
<td>-2.00 To -2.75</td>
<td>.18</td>
</tr>
<tr>
<td>-3.00 To -4.25</td>
<td>.16</td>
</tr>
<tr>
<td>-4.50 To -5.25</td>
<td>.15</td>
</tr>
<tr>
<td>-5.50 To -25.00 and Above</td>
<td>.14</td>
</tr>
</tbody>
</table>
APPENDIX II

N & N MENICON
INITIAL VISIT EXAMINATION FORM
CORNEAL CONTACT LENSES FOR NON-DISEASED EYES
CLINICAL EVALUATION PROGRAM INITIAL VISIT

<table>
<thead>
<tr>
<th>Doctor</th>
<th>No.</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td></td>
<td>Age</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mo. Day Yr.</td>
</tr>
<tr>
<td>Address</td>
<td>Last</td>
<td>First</td>
</tr>
</tbody>
</table>

MARITAL STATUS: Single | Married | Divorced | Widowed
RACE: Caucasian | Negro | Mongolian

OCCUPATION: (Check One)
- Inspection on close machine work
- Driver of mobile equipment
- Machine operator
- Laborer
- Mechanics and skilled tradesmen
- Other, list

MOTIVATION FOR CONTACTS: (Check One)
- Cosmetic
- Inconvenience of Glasses
- Sports and recreation
- Occupation
- Frame Allergy
- Increased visual acuity
- Aniseikonia
- Aphakic
- Medical
- Specify

TONOMETER READINGS
OD: ____________________
OS: ____________________

PREVIOUS CONTACT LENS WEARER
OD: Yes | No
OS: Successful | Unsuccessful

OCULAR EXAMINATION
RIGHT
Uncorrected Vision 20/00
Corrected Vision [20/00] X
Keratometer reading X

LEFT
Uncorrected Vision 20/00
Corrected Vision [20/00] X
Keratometer reading X

SLIT LAMP EXAMINATION
RIGH
- Lids
- Conjunctiva
- Limbus
- Cornea
- A.C.

LEFT
- Lids
- Conjunctiva
- Limbus
- Cornea
- A.C.

(Name of specific lens)_

RIGHT
- Lens Rx
- Lot No.
- Acuity Achieved 20/00

LEFT
- Lens Rx
- Lot No.
- Acuity Achieved 20/00

COMMENTS

Signature ____________________
APPENDIX III

N & N MENICON

DISPENSING VISIT EXAMINATION FORM
# CORNEAL CONTACT LENSES FOR NON-DISEASED EYES

## CLINICAL EVALUATION PROGRAM DISPENSING VISIT

<table>
<thead>
<tr>
<th>Doctor</th>
<th>No.</th>
<th>Date</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Patient</th>
<th>Last</th>
<th>First</th>
<th>Middle</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date Lenses Received from N &amp; N</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>OD</th>
<th>OS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lens Power</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Lot Number</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Acuity with Lens:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Retinoscopic Reflex Quality:</strong></td>
<td>crisp</td>
</tr>
<tr>
<td><strong>Bubbles Under Lens:</strong></td>
<td>yes</td>
</tr>
<tr>
<td><strong>Movement to Blink:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Over Refraction</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Centration:</strong></td>
<td>central</td>
</tr>
<tr>
<td></td>
<td>nasal</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Comfort:</strong></td>
<td>good</td>
</tr>
<tr>
<td><strong>Acceptable:</strong></td>
<td>yes</td>
</tr>
<tr>
<td><strong>New Lens Ordered:</strong></td>
<td>yes</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Middle</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>OS</strong></th>
<th><strong>OD</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lens Power</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Lot Number</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Acuity with Lens:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Retinoscopic Reflex Quality:</strong></td>
<td>crisp</td>
</tr>
<tr>
<td><strong>Bubbles Under Lens:</strong></td>
<td>yes</td>
</tr>
<tr>
<td><strong>Movement to Blink:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Over Refraction</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Centration:</strong></td>
<td>central</td>
</tr>
<tr>
<td></td>
<td>nasal</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Comfort:</strong></td>
<td>good</td>
</tr>
<tr>
<td><strong>Acceptable:</strong></td>
<td>yes</td>
</tr>
<tr>
<td><strong>New Lens Ordered:</strong></td>
<td>yes</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td></td>
</tr>
</tbody>
</table>

## Comments:

---

**Principal Investigator**
APPENDIX IV

N & N MENICON
FOLLOW-UP EXAMINATION FORM
**Patient Information**

- **Doctor**: 
- **No.**: 
- **Date**: 

- **Patient**: 
  - **First Name**: 
  - **Last Name**: 
  - **Visit No.**: 2nd, 3rd, 4th, 5th, Middle
  - **Initial Visit Date**: 

**Patient Symptoms**

<table>
<thead>
<tr>
<th>Right</th>
<th>Left</th>
<th>Both</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfort good</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excessive movement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excessive tearing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excessive light sensitivity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flare</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Halos</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Right</th>
<th>Left</th>
<th>Both</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain, Burning or itching</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spectacle blur</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unusual eye secretions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Awareness of lens</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excessive blink rate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Variable vision</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Ocular Examination**

- **Contact Lens Rx & Lot No.**: 
- **Visual Acuity**: 20/20 J-6
- **Over Refraction**: X
- **New Lens Rx and Lot No.**: 
- **Corrected Visual Acuity**: 20/20 J-6
- **"K" Reading**: 20/20 J-6

**Slit Lamp Examination**

- **Edema**
- **Vascularization**
- **Staining in excess of normal**
- **Injection**
- **Other Complications**
- **Iritis**

**General Information**

- **Visual acuity OU fitted with contact lenses**: 20/20
- **Jaeger acuity OU fitted with contact lenses**: J-6
- **Present wearing time**: [ ] hours
- **Lens replaced for physical reason**
  - Patient lost or misplaced
  - Bad edge
  - Bad surface quality
  - Discoloration
  - Other*
  - Enzyme Tablet used: [ ] Yes, [ ] No

**Tonimeter Readings**

- **OD**: 
- **OS**: 

**Six month check only**: 

**Patient lost to program**

- **Acuity**
- **Comfort**
- **Handling Problem**
- **Interest**
- **Pathology**
- **Other**

**Comments**

- **Signature**: 

---

*Explain in Detail*

---
APPENDIX V

AUXILLARY PROCEDURES
<table>
<thead>
<tr>
<th>Date</th>
<th>BUT</th>
<th>pH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Schirmer Test**

<table>
<thead>
<tr>
<th>Photography</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Perilimbal</td>
<td></td>
</tr>
<tr>
<td>2) Upper Lid Eversion</td>
<td></td>
</tr>
<tr>
<td>3) Lower Lid Eversion</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>BUT</th>
<th>pH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Schirmer Test**

<table>
<thead>
<tr>
<th>Photography</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Perilimbal</td>
<td></td>
</tr>
<tr>
<td>2) Upper Lid Eversion</td>
<td></td>
</tr>
<tr>
<td>3) Lower Lid Eversion</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX VI

FOLLOW-UP EVALUATION FORM
<table>
<thead>
<tr>
<th>NAME:</th>
<th>OD</th>
<th>OS</th>
<th>OD</th>
<th>OS</th>
<th>OD</th>
<th>OS</th>
<th>OD</th>
<th>OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>DATE:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EXAM #:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wearing time:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subjective Symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VA:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cyl. OR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mvt:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Centering:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Objective Signs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edema</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staining</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vascular.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kerat.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post Ref.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX VII

TRIAL FITTING FORM
<table>
<thead>
<tr>
<th>OD</th>
<th>LENS</th>
<th>Bubble Test</th>
<th>Kerat. Clarity</th>
<th>Kerat. Reading</th>
<th>Upward Gaze</th>
<th>Mvt.</th>
<th>Retina Reflex</th>
<th>O.R.</th>
<th>V.A. thru OR</th>
<th>Centering</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:

<table>
<thead>
<tr>
<th>OS</th>
<th>LENS</th>
<th>Bubble Test</th>
<th>Kerat. Clarity</th>
<th>Kerat. Reading</th>
<th>Upward Gaze</th>
<th>Mvt.</th>
<th>Retina Reflex</th>
<th>O.R.</th>
<th>V.A. thru OR</th>
<th>Centering</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:
APPENDIX VIII

CLOSE-OUT FORM
**Name:**

**Final Visit**

**Case History (on back)**

| enz. cleaner | heat or chem. | wearing time |

| Slit Lamp Evaluation |

| OD | OS |

| centration | movement | upward gaze |

<table>
<thead>
<tr>
<th>VA</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD</td>
</tr>
<tr>
<td>OS</td>
</tr>
<tr>
<td>OU</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>#7a sphere</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD</td>
</tr>
<tr>
<td>OS</td>
</tr>
<tr>
<td>OU</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>#7a cylinder</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD</td>
</tr>
<tr>
<td>OS</td>
</tr>
<tr>
<td>OU</td>
</tr>
</tbody>
</table>

| #8 | #9 | #10 | #11 |

| #13b |
| #14b | #16a | #16b |
| #15b | #17a | #17b |
| #21 |
| #20 |

**Tonometry:**

OD
OS

**Ophthalmoscopy:**

**Ophthalmometry:**

**Pictures, pH, BUT, Schirmers**
APPENDIX IX

PATIENT INFORMED CONSENT
INFORMED CONSENT

I hereby consent to the prescription and fitting by Dr. _________ of soft contact lens (es) made from hydrophilic materials. I understand that these lens (es) are investigational and that I am participating in a new-drug study. The nature, expected duration and purpose of administration of the investigational lens (es) as well as the method and means by which the lens (es) are to be administered have been explained to me. I acknowledge the receipt of written instructions for the cleaning, asepticizing, handling, care and storage of the investigational soft contact lens (es).

I have been advised of the potential hazards, complications and adverse reactions which may be associated with the wearing of the investigational soft contact lens (es). I have also been advised of the existence of alternative forms of therapy and of the beneficial effects that may come from the wearing of the investigational lens (es).

Patient's (or parents) signature   Dated

Doctors signature

Name of Patient (typed)

Street Address

City, State, Zip

Witness
APPENDIX X

PATIENT CLOSE-OUT LETTER
Dear

Thank you once again for participating in our research study of investigational soft lenses from N&N laboratories. Due to your participation, we have had excellent results. The expected approval of the Menicon lens is sometime in 1979.

If for any reason you desire a replacement lens (either damaged or lost), the cost will be $50.00 which when broken down is $25.00 for materials and $25.00 for service*. Once the lens becomes approved the material costs will probably double. For this reason, we recommend that you take out insurance and keep it activated.

If you have any questions or any need for a replacement lens please contact Dr. Dippel at Pacific University College of Optometry. His phone is (503) 357-6151 ext. 244.

Sincerely yours,

Stephen G. Dippel, O.D.
Staff Advisor

*Prices subject to change

Student Interns

Dana Smith
Steve Wells
Duane E. Beckwith
Brian D. Jundman
Mike Hata
Chair Torj

2043 College Way    Forest Grove, Oregon 97116    Telephone (503) 357-6151
APPENDIX XI

QUANTIFICATION
OF
SLIT LAMP OBSERVATIONS
I. **Edema**

A. None

B. Micro edema - intercellular accumulation of fluid which is limited to the epithelium and is seen only by the use of the slit lamp.

1. Slight amounts in the epithelium, seen only by retro-illumination:
   (a) Localized - over less than 50% of the cornea.  
   (b) Generalized - over more than 50% of the cornea.

2. Moderate amounts in the epithelium, seen by direct illumination:
   (a) Localized - over less than 50% of the cornea.
   (b) Generalized - over more than 50% of the cornea.

C. Gross edema - intracellular cystic accumulation of fluid, viewed by the naked eye using oblique flashlight illumination.

1. Slight case, without any stromal involvement.
   (a) Circumscribed - over less than 50% of cornea.
   (b) Generalized - over more than 50% of cornea.

2. Severe case, with stromal involvement.
   (a) Circumscribed - over less than 50% of cornea.
   (b) Generalized - over more than 50% of cornea.
II. Vascularization

A. None

B. Extension of the limbal vessels more than 1.5 mm inside limbus.
   1. Lower limbal area only. 1
   2. Upper limbal area only. 2
   3. Over the entire periphery. 3
   4. Severe (to within 1 mm of corneal apex) extensions of the limbal vessels into the clear epithelial tissue of the cornea. 4
   5. Other (explain) 5

III. Staining

A. None 0

B. Minimal, variable, peripheral stippling 1

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

D. Superficial punctate staining, centrally located 3

E. Diffuse superficial punctate staining 4

F. Epithelial dimpling associated with gas bubbles under the contact lens 5

G. Branching furrows on the epithelial surface (observed best by use of the cobalt filter and fluorescein) 6

H. Abrasions of the epithelium. Note if apparently caused by insertion and removal 7

I. Foreign body track staining 8

J. Deep corneal abrasions, ulcerations, permanent scars or other severe complications (explain) 9
APPENDIX XII

SUMMARY of PATIENT DATA
IV. Injection

A. None

B. Mild congestion and dilation of the limbal vessels which was not characteristic of the pre-fitting condition (within 1.0mm of limbus).

C. Severe congestion and dilation of the normal limbal vessels.

D. Conjunctival hyperemia due to excess lacrimation and epiphora.

V. Iritis

A. No flare or cells.

B. Minimal flare (1+).

C. Mild (2+).

D. Moderate (3+).

E. Severe (cells and flare)(4+)

VI. Other Complications

A. None

B. Adnexal changes or changes in the lacrimal or appendages of the eye.

1. Increase in mucous secretion in the tear fluid.

2. Follicular hypertrophy of the lymphoid follicles of the tarsal conjunctiva.

3. Traumatic iritis.

4. Permanent damage caused by opacity or scarring of the cornea (may or may not impair vision).

C. Other (explain)
A. Previous Contact Lens Wearer
B. Ophthalmometer Readings: readings taken from the first and last visits.
C. Wearing Time
D. Visual Acuity with Lenses
E. Base Curve of Current Lens; Diameter of Current Lens
F. Power of Current Lenses
G. Over-refraction
H. Slit Lamp Grading
I. Reasons for Lens Change
J. Enzyme Tablets

1. G.A.
   a. No
   b. 43.37/44.12 OD  43.37/43.75 OS
      43.25/44.50 OD  43.50/44.25 OS
   c. 12 hours
   d. 20/20
   e. 8.00/12.5 OD; 8.40/12.5 OS
   f. -4.25 OU
   g. +1.00 -0.75 OD  +1.00 -0.25 OS
   h. Grade 0
   i. Boiled Lenses Dry
   j. No

2. T.A.
   a. No
   b. 45.00/45.50 OD  45.00/45.25 OS
      45.25/45.62 OD  44.75/45.25 OS
   c. 12 hours
   d. 20/15
   e. 8.00/12.5 OD  8.20/12.5 OS
   f. -1.50 OD  -0.75 OS
   g. +0.25 -0.75 OD  +0.25 -0.50 OS
   h. Grade 0
   i. Steeper Base Curve on OD, Power Change OD
   j. No
3. **C.A.**
   a. Yes, unsuccessful (Soft Lenses)
   b. 44.00/44.25 OD 43.75/44.75 OS
      44.00/4450 OD 43.75/44.62 OS
   c. 10 hours
   d. 20/20
   e. 8.00/12.5
   f. -3.75 OU
   g. +0.25 sphere OD -0.25 -0.25 OS
   h. Grade 0
   i. No changes
   j. No

4. **D.A.**
   a. Yes, successful (Hard Lenses)
   b. 43.47/44.12 OD 43.00/44.00 OS
      43.75/45.50 OD 43.37/44.62 OS
   c. 16 hours
   d. 20/25
   e. 8.4/12.5 OD 8.2/12.5 OS
   f. -5.75 OD -5.00 OS
   g. -0.25 -0.25 OD +0.50 -1.25 OS
   h. Staining Grade 4 OU
   i. -5.25 OD and -4.00 OS changed to present lenses
   j. No

5. **D.B.**
   a. No
   b. 46.25/46.00 OD 46.00/46.00 OS
      42.50/42.50 OD 42.50/42.62 OS
   c. 12 hours
   d. 20/20
   e. 8.0/12.5 OU
   f. -3.75 OU
   g. plano -0.50 OD -0.25 -0.50 OS
   h. Grade 0
   i. No Changes
   j. No

6. **R.C.**
   a. Yes, successful (Hard Lenses)
   b. 39.50/41.00 OD 39.50/40.75 OS
      39.87/41.25 OD 39.75/41.00 OS
   c. 12 hours
   d. 20/15
   e. 8.60/12.5 OU
   f. -3.25 OD -3.75 OS
   g. -0.25 -0.75 OD +0.50 -0.25 OS
   h. Edema Grade 1 OU, Staining Grade 2 OU
   i. No changes
   j. No
7. C.C.
   a. No
   b. 43.50/44.75 OD 43.37/44.50 OS
      44.37/45.00 OD 43.87/44.50 OS
   c. 12 hours
   d. 20/15
   e. 8.4/13.0 OU
   f. -2.25 OD -2.00 OS
   g. plano -0.50 OD plano -0.25 OS
   h. Staining Grade 7 OU Injection Grade 1 OU
   i. Flatter base curves and inadequate movement OU
   j. No

8. F.C.
   a. Yes, successful (Hard Lenses)
   b. 44.12/44.37 OD 44.25/44.50 OS
      44.00/44.50 OD 44.25/44.50 OS
   c. 16 hours
   d. 20/15
   e. 8.00/12.5 OU
   f. -2.50 OU
   g. -0.25 OD -0.25 OD plano -0.25 OS
   h. Grade 0
   i. Steeper base curve OD Power change OD
   j. Yes

9. K.D.
   a. Yes, unsuccessful (Hard Lenses)
   b. 43.75/45.87 OD 44.37/46.00 OS
      44.50/46.00 OD 44.75/46.25 OS
   c. 14 hours
   d. 20/20
   e. 8.2/12.5 OD 8.0/12.5 OS
   f. -5.50 OU
   g. -1.50 -1.00 OD -0.50 -0.75 OS
   h. Staining Grade 4 OD Grade 7 OS
   i. No change
   j. Yes

10. M.D.
   a. Yes, successful (Hard Lenses)
   b. 45.00/46.25 OD 45.50/46.37 OS
      45.50/46.50 OD 45.75/46.50 OS
   c. 12 hours
   d. 20/15
   e. 8.8/12.5 OU
   f. -1.25 OD -1.75 OS
   g. +0.75 -0.75 OD +0.25 -0.50 OS
   h. Edema Grade 2 OU, Staining Grade 4 OU, Injection Grade 1 OU
   i. Increase power OU
   j. Yes
11. **D.D.**
   a. Yes, unsuccessful (Hard Lenses)
   b. 43.37/45.00 OD  43.12/45.37 OS
      43.50/45.00 OD  43.50/45.62 OS
   c. 16 hours
   d. 20/20
   e. 8.0/12.5 OU
   f. -2.75 OD  -3.25 OS
   g. plano OU
   h. No change
   i. Boiled lenses dry, Power change OS
   j. Yes

12. **D.E.**
   a. No
   b. 42.87/43.00 OD  42.87/43.25 OS
      42.25/42.62 OD  42.37/43.87 OS
   c. 15 hours
   d. 20/20
   e. 9.0/12.5 OU
   f. -4.50 OD  -4.00 OS
   g. +0.50 -1.00 OD  plano -0.75 OS
   h. Edema Grade 2 OU  Staining Grade 4 OU
   i. No change
   j. No

13. **J.P.**
   a. No
   b. 42.75/42.62 OD  43.50/43.00 OS
      43.00/43.12 OD  43.50/43.50 OS
   c. 16 hours
   d. 20/20
   e. 8.4/12.5 OD  8.2/12.5 OS
   f. -2.00 OD  -1.50 OS
   g. -0.25 -1.00 OD  +0.50 -0.75 OS
   h. Grade 0
   i. No changes
   j. Yes

14. **L.G.**
   a. Yes, successful (Hard Lenses)
   b. 46.00/46.12 OD  46.00/46.50 OS
      45.75/46.25 OD  45.87/46.75 OS
   c. 16 hours
   d. 20/20
   e. 8.4/12.5 OU
   f. -3.50 OD  -3.75 OS
   g. plano -0.50 OD  -0.25 sphere OS
   h. Grade 0
   i. No changes
   j. No
15. C.G.
   a. Yes, successful (Hard Lenses)
   b. 43.67/44.50 OD  43.75/45.50 OS
       43.50/45.50 OD  44.00/45.50 OS
   c. 16 hours
   d. 20/20
   e. 8.4/12.5 OU
   f. -5.00 OD  -3.00 OS
   g. +0.75 -1.25 OD  +0.75 -1.25 OS
   h. Staining grade 7 OD
   i. No change
   j. No

16. K.H.
   a. No
   b. 44.00/44.25 OD  43.87/44.50 OS
       44.12/44.62 OD  44.37/44.50 OS
   c. 12 hours
   d. 20/15
   e. 8.4/13.0 OU
   f. -1.50 OD  -1.25 OS
   g. +0.25 -0.50 OD  plano -0.25 OS
   h. Staining grade 4 OU, Injection grade 1 OU
      Foreign body removed
   i. Damaged and lost
   j. No

17. P.H.
   a. Yes, unsuccessful (Hard Lenses)
   b. 43.50/43.62 OD  42.87/43.12 OS
       43.12/43.75 OD  42.62/43.50 OS
   c. 10 hours
   d. 20/15
   e. 8.6/12.5 OU
   f. -2.50 OD  -2.00 OS
   g. plano -0.25 OD  +0.25 -0.25 OS
   h. Grade 0
   i. Increase power OD
   j. No

18. J.J.
   a. Yes, successful (Hard Lenses)
   b. 42.00/44.12 OD  42.37/43.75 OS
       40.75/42.25 OD  41.75/42.50 OS
   c. 16 hours
   d. 20/20
   e. 8.6/13.0 OU
   f. -1.50 OU
   g. plano -0.50 OD  plano -0.25 OS
   h. Grade 0
   i. Steeper base curve OU
   j. No
19. K.J.
   a. Yes, successful (Soft Lenses)
   b. 44.12/45.12 OD 43.87/45.25 OS
      43.87/45.25 OD 43.87/45.50 OS
   c. 16 hours
   d. 20/15
   e. 8.2/12.5 OU
   f. -4.50 OD -4.75 OS
   g. +0.25 -0.50 OU
   h. Grade 0
   i. Red spot on lens
   j. No

20. S.J.
   a. Yes, unsuccessful (Hard Lenses)
   b. 43.25/45.00 OD 43.00/44.00 OS
      43.87/44.87 OD 43.50/44.62 OS
   c. 15 hours
   d. 20/15
   e. 8.2/12.5 OU
   f. -1.75 OU
   g. +0.50 -0.25 OD +0.25 sphere OS
   h. Staining grade 4 OU
   i. Increase power OU
   j. Yes

21. V.K.
   a. No
   b. 42.75/43.75 OD 43.12/44.12 OS
      43.00/44.12 OD 43.50/44.00 OS
   c. 14 hours
   d. 20/15
   e. 8.2/12.5 OU
   f. -2.75 OD -2.25 OS
   g. +0.25 -0.25 OD -0.25 -0.25 OS
   h. Grade 0
   i. Lost lens
   j. Yes

22. S.L.
   a. Yes, unsuccessful (Hard Lenses)
   b. 42.00/43.75 OD 42.25/44.00 OS
      42.50/43.87 OD 42.25/44.00 OS
   c. 12 hours
   d. 20/15
   e. 8.4/12.5 OD 8.2/12.5 OS
   f. -3.25 OD -2.75 OS
   g. plano OU
   h. Vascularization grade 2 OU Staining grade 2 OU
   i. More movement needed
   j. No
23. **L.L.**
   a. Yes, unsuccessful (Hard Lenses)
   b. 45.75/45.87 OD 45.62/45.75 OS
       45.75/45.62 OD 45.75/45.62 OS
   c. 10 hours
   d. 20/25
   e. 8.6/13.0 OU
   f. -1.75 OD -2.00 OS
   g. ±0.50 -1.25 OS
   h. Grade 0
   i. Bad edge, flatter base curve
   j. No

24. **L.M.**
   a. No
   b. 44.00/44.00 OD 44.00/44.25 OS
       43.62/44.37 OD 43.50/44.37 OS
   c. 10 hours
   d. 20/15
   e. 8.4/12.5
   f. -2.00 OD -1.25 OS
   g. -0.25 -0.75 OD plano OS
   h. Staining grade 7 OU
   i. Power change OS
   j. No

25. **C.M.**
   a. No
   b. 45.12/45.37 OD 44.87/44.75 OS
       44.37/45.87 OD 44.62/45.00 OS
   c. 12 hours
   d. 20/15
   e. 8.2/13.0 OU
   f. -1.00 OD -1.25 OS
   g. plano OU
   h. Edema grade 2 OU, Staining grade 3 OU
   i. Edge stand off, wore lenses in sauna, power change OD
   j. No

26. **C.Ne.**
   a. No
   b. 43.75/45.75 OD 43.75/45.50 OS
       44.12/46.12 OD 44.12/45.62 OS
   c. 14 hours
   d. 20/15
   e. 8.4/12.5 OU
   f. -0.75 OU
   g. plano -0.25 OD plano OS
   h. Corneal scratch OS
   i. Bad edge
   j. Yes
<table>
<thead>
<tr>
<th>No.</th>
<th>Name</th>
<th>a.</th>
<th>b.</th>
<th>c.</th>
<th>d.</th>
<th>e.</th>
<th>f.</th>
<th>g.</th>
<th>h.</th>
<th>i.</th>
<th>j.</th>
</tr>
</thead>
<tbody>
<tr>
<td>27.</td>
<td>R.M.</td>
<td>No</td>
<td>42.87/42.63 OD 42.37/42.87 OS 42.87/42.50 OD 42.37/43.12 OS</td>
<td>12 hours</td>
<td>20/20</td>
<td>8.4/12.5 OU</td>
<td>-1.00 OD -0.75 OS</td>
<td>+0.25 sphere OD +0.25 -0.25 OS</td>
<td>Grade 0</td>
<td>No change</td>
<td>Yes</td>
</tr>
<tr>
<td>28.</td>
<td>M.M.</td>
<td>No</td>
<td>43.87/44.12 OD 44.00/44.25 OS 43.75/44.75 OD 44.00/44.62 OS</td>
<td>16 hours</td>
<td>20/15</td>
<td>8.0/12.5 OU</td>
<td>-2.00 OD -2.25 OS</td>
<td>+0.25 sphere OD +0.50 sphere OS</td>
<td>Dry spots OS</td>
<td>Lost</td>
<td>Yes</td>
</tr>
<tr>
<td>29.</td>
<td>J.R.</td>
<td>No</td>
<td>44.25/45.50 OD 44.25/45.62 OS 43.87/45.25 OD 43.75/45.50 OS</td>
<td>10 hours</td>
<td>20/15</td>
<td>8.2/12.5 OD 8.0/12.5 OS</td>
<td>-1.75 OD -1.50 OS</td>
<td>-0.50 -0.25 OD -0.25 -0.50 OS</td>
<td>Edema grade 2 OU Staining grade 2 OU</td>
<td>Too little movement</td>
<td>No</td>
</tr>
<tr>
<td>30.</td>
<td>L.R.</td>
<td>No</td>
<td>41.50/43.37 OD 42.12/42.87 OS 41.50/42.25 OD 42.00/43.25 OS</td>
<td>8 hours</td>
<td>20/20</td>
<td>8.2/12.5 OD 8.0/12.5 OS</td>
<td>-1.00 OD +1.00 OS</td>
<td>-0.50 -0.50 OD -0.75 -0.75 OS</td>
<td>Edema grade 2 OU Staining grade 4 OU Injection grade 1 OU</td>
<td>Decrease power OS</td>
<td>Yes</td>
</tr>
</tbody>
</table>
31. C.S.
   a. No
   b. 43.67/44.00 OD  44.00/43.75 OS
      43.62/44.62 OD  43.25/43.75 OS
   c. 14 hour
   d. 20/20
   e. 8.2/12.5 OU
   f. -0.75 OD  -1.00 OS
   g. +0.25 -0.25 OD plano -0.75 OS
   h. vascularization grade 3 OU, Staining grade 4 OU
   i. No change
   j. No

32. L.S.
   a. No
   b. 41.25/43.25 OD  41.00/42.87 OS
      40.50/42.50 OD  40.50/41.75 OS
   c. 16 hours
   d. 20/15
   e. 8.6/12.5 OU
   f. -4.00 OU
   g. +0.25 -0.50 OD  +0.25 sphere OS
   h. Grade 0
   i. No change
   j. No

33. P.S.
   a. Yes, successful (Hard Lenses)
   b. 44.37/45.75 OD  45.12/46.12 OS
      44.87/46.25 OD  45.37/46.25 OS
   c. 16 hours
   d. 20/20
   e. 8.0/12.5 OU
   f. -3.75 OD  -1.25 OS
   g. +0.50 -0.75 OD plano OS
   h. Grade 0
   i. No Change
   j. No

34. V.S.
   a. Yes, unsuccessful (Hard Lenses)
   b. 44.12/46.25 OD  44.87/45.62 OS
      44.25/46.75 OD  44.50/46.00 OS
   c. 16 hours
   d. 20/20
   e. 8.0/12.5 OD  7.8/12.5 OS
   f. -7.00 OD  -3.25 OS
   g. plano -1.25 OD plano -0.50 OS
   h. Edema grade 1 OU, Staining grade 1 OU, Vascularization grade 1 OU
   i. Dirty lens OU, Excessive movement OS, to correct decentration OU
   j. Yes
35. **D.T.**
   a. Yes, successful (Hard Lenses)
   b. 42.37/43.12 OD  42.62/43.50 OS  
      42.50/43.25 OD  42.75/43.62 OS
   c. 12 hours
   d. 20/15
   e. 8.8/12.5 OD  8.6/12.5 OS
   f. -5.50 OD  -2.75 OS
   g. -0.25 -0.25 OD plano OS
   h. Staining OS, Foreign body removed OS
   i. Bad edge, power change OS
   j. No

36. **P.W.**
   a. Yes, unsuccessful (Hard Lenses)
   b. 42.50/43.75 OD  42.75/44.25 OS  
      42.75/44.50 OD  43.00/44.75 OS
   c. 16 hours
   d. 20/20
   e. 8.2/12.5 OU
   f. -11.50 sphere OD  -12.00 sph OS
   g. +0.50 sphere OD  +0.75 sph OS
   h. Grade 0
   i. Bad edge, decrease diameter, power change OS
   j. No

37. **A.W.**
   a. No
   b. 43.37/44.62 OD  44.12/45.25 OS  
      44.00/45.00 OD  44.00/45.37 OS
   c. 16 hours
   d. 20/15
   e. 8.0/12.5 OD  8.2/12.5 OS
   f. -3.00 OD  -1.75 OS
   g. plano -0.50 OD plano OS
   h. Grade 0
   i. Steeper base curve OD, edge lift-off OS
   j. No
Summary

Enzymatic Cleaner Used:
12 patients use 1 x week.
25 patients do not use.

Wearing Time:
1 patient wears 8 hours a day
5 " 10 " " "
11 " 12 " " "
4 " 14 " " "
2 " 15 " " "
14 " 16 " " "

Visual Acuity with Lenses:
19 patients 20/15
16 " 20/20
2 " 20/20

Slit Lamp Problems:
18 with no problems
19 with slight staining, or edema, or foreign body tracks.

K Reading:
2 patients showed a change of 1.00 or more.
35 patients showed no significant change.

Reason for Lens Changes:
Changes in base curve...............10
Loses............................... 3
Diameter.............................11
Bad Edges............................ 5
Power Changes......................18
APPENDIX XIII

ANTERIOR SEGMENT PHOTOGRAPHS
SUPERIOR PERILIMBAL AREA

Injection grade 0  Vascularization grade 0

SUPERIOR PERILIMBAL AREA

Injection grade 2  Vascularization grade 0
SUPERIOR PERILIMBAL AREA

Vascularization grade 0   Injection grade 0

SUPERIOR PERILIMBAL AREA

Vascularization grade 2   Injection grade 0
Pallidular Formation

Upper Eyelid

Normal

Upper Eyelid
INFERIOR PERILIMINAL AREA

Injection grade 1  Vascularization grade 0

HORIZONTAL PERILIMINAL AREA

Injection grade 1  Vascularization grade 0
LENS PROFILE

NORMAL

LOWER EYELID


11. Halberg, Peter; and Berens, Conrad. "Suggested Procedure for the Standardized Sterile Schirmer Tear Test." Instructions included with the sterile Schirmer Tear Strips.


16. Instructions for Wearers of N & N Menicon Contact Lenses, patient instruction handbook provided by the N & N Menicon Co.

17. Kline, Lawrence; and DeLuca, Thomas. "Effects of Gel Lens Wear on the Pre-corneal Tear Film." International Contact Lens Clinic, Vol. 21, No. 4 (Winter 1975), 56-62


