College of Optometry                    Theses, Dissertations and Capstone Projects

3-10-1984

# A clinical evaluation of the Dow Corning silcon contact lens

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## Abstract

A clinical evaluation was made of the Dow Corning SILCON lens. Designed to be optically clear and stable, it also has the highest 0xygen permeability of all other rigid lenses presently available. Physiological difficulties with the lens such as its non-wetting surface accounted for most of the initial fitting failures. The first fit success of fourteen eyes was twenty-nine percent. This increased to seventy percent after one lens reorder and after a second reorder success was achieved for all patients. The base curves of all the lenses were verified before dispensing and at the last progress exam. Some changes were found, but they were statistically insignificant at the .01 level. The findings also showed changes that suggested increased corneal thickness with initial wear and a subsequent decrease in thickness as wearing time increased.

## Degree Type

Thesis

## Degree Name

Master of Science in Vision Science

## Committee Chair

Don C. West

## Subject Categories

Optometry

A CLINICAL EVALUATION

OF THE

DOW CORNING SILCON CONTACT LENS

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March 10, 1984

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Midterm Grade

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Final Grade

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## ACKNOWLEDGEMENTS

## ABSTRACT

A clinical evaluation was made of the Dow Corning SILCON lens. Designed to be optically clear and stable, it also has the highest oxygen permeability of all other rigid lenses presently available. Physiological difficulties with the lens such as its non-wetting surface accounted for most of the initial fitting failures. The first fit success of fourteen eyes was twenty-nine percent. This increased to seventy percent after one lens reorder and after a second reorder success was achieved for all patients.

The base curves of all the lenses were verified before dispensing and at the last progress exam. Some changes were found, but they were statistically insignificant at the .01 level. The findings also showed changes that suggested increased corneal thickness with initial wear and a subsequent decrease in thickness as wearing time increased.

## INTRODUCTION

The Dow Corning SILCON lens is of a 100% silicone resin polymer. Approved on October 26, 1981, the lens has an advantage over the other present lenses in terms of high oxygen permeability.

The nature of the silicone polymer allows increased gas flow to the cornea. The factors considered here contributing to increased permeability include a non-polar methyl group freely rotating around the silicon atom and an increased distance between silicon atoms (compared to the carbon-carbon distance in Poly-2 hydroxethyl methacrylate - PHEMA), both of which offer less resistance to permeability of gases compared to PHEMA. In addition to increased permeability, silicone absorbs practically no water, resulting in stable optical properties.[1] Silicone also exhibits stable dimensional characteristics although it is subject to polymer degradation.[2] Thus in these respects, silicone appears to be the ideal material for contact lenses.

Studies have shown that with the SILCON lens, patients are free of corneal edema, significant keratometer changes and spectacle blur. Johnson notes particularly his refitting success of the silicone lens for patients having problems with poor oxygen transmission and/or poor wettability with other lenses.[3] Thomas found the silicon lenses valuable due to its wettability characteristic. The lens wetted well on many problem cases including non-blinkers and partial blinkers.[4] Fontana cites the flexibility of wear between this lens and spectacles. He notes lack of keratometer changes, the clarity of the mires in post keratometry findings and a post refraction of 20/20.[5] Recent literature also suggests that corneal vascularization caused by corneal anoxia recedes if refit with a well-designed silicon lens.[6]

The present lens design is available in base curves ranging from 7.25 to 8.23 in .04 mm steps. The diameters are 8.8 and 9.4 mm with a center thickness of .12 mm. Presently power ranges are available in minus powers only. The refractive index of the material is 1.52.

A major limitation of the SILCON contact lens is its hydrophilic surface. Any attempt to modify or polish the lenses will remove this surface and expose the hydrophobic matrix of the lens. With a non-wetting surface, patients will report blurry vision and discomfort.[7]

This clinical evaluation looks at four major areas which include the durability, corneal changes, fitting characteristics and the performance of the lens. The durability of the lens surface will be evaluated by the wettability of the lens. The lens will also be carefully assessed for any changes in the base curve and how different solutions perform with it. Corneal thickness changes will be monitored by use of a pachometer. The performance of the tricurve design will be evaluated in terms of visual acuity, masking of refractive cylinder, subjective comments and the fluorescein pattern.

# METHODS

Patients entered in this study were persons desiring contact lenses from the general population of the Pacific University College of Optometry Clinic. The requirements were: 1) persons with no ocular pathologic condition or dry eyes (tear break-up time of less than ten seconds), 2) persons not presently using any ocular medications, including over-the-counter medications, 3) pre-presbyopic myopic persons with less than six diopters (D) of refractive error, 4) persons with no more than 2.00 D of corneal toricity or 1.50 D of refractive astigmatism, 5) persons with no general binocular dysfunctions, 6) persons with a minimum of 20/20 spectacle correction, 7) no previous contact lens wear (exceptions made for subjects who have not worn contact lenses for the last six months, and exhibit stable keratometric and refractive findings), 8) persons available for six months, 9) persons willing to be fitted with rigid gas permeable lenses, and 10) persons who have acceptable hygiene and are willing to report for the necessary examinations and pachometry measurements.

Ten patients were initially selected from the previous criteria and informed of the nature of the study. Of these patients, six were female and four were male. Their ages ranged from twenty to thirty-three years. Six of the patients had previously either worn hard or soft contact lenses. There were several different reasons why these patients had discontinued their previous wearing of contact lenses. They included discomfort, unsuccessful physiological adaptation, and the loss of their previous contact lenses. Patients were myopic and their spherical refractive errors ranged

from 0.75 D to 4.50 D. Their cylindrical refractive errors ranged
from plano to 1.50 D. A summary of the subject characteristics
is given in Table One.

Each patient signed an informed consent form and contact lens
fitting agreement approved by the Pacific University Institutional
Review Board. The informed consent form described and listed the
risks and benefits of the study.

The patient's initial examination included a standard Pacific
University visual examination, with special attention to biomicro-
scopy in evaluating BUT, anterior segment health, and horizontal
iris diameter. Central and peripheral keratometry findings were also
included.

The patients were then fitted using a trial lens procedure.
The Morrison diagnostic set was used and the initial base curve
was selected according to the SILCON recommended fitting procedure.
The Morrison diagnostic set parameters and the SILCON fitting
procedures are given in Tables 2 and 3. The optic zone diameter of
the lens was determined by the Moss table. These characteristics
are shown in Table 4.

The patients were then evaluated based on the fluorescein pattern, lens centration and performance, visual acuity with over-refraction and keratometry readings.

With respect to the fluorescein pattern, the contact lens was observed for 1) 1 mm movement in the vertical meridian, 2) centration in the primary gaze, 3) no staining, and 4) reference line - lacrimal line fitting criterion.

The reference line/lacrimal line (RL/LL) fitting criterion is a technique to quantify a contact lens fit in terms of apical touch, clearance and alignment. A thin cobalt blue optical section is placed on the central portion of the contact lens. The bio-microscope is set in high magnification and set at an angle approximately sixty degrees from the illumination system. With fluorescein, the RL and LL will be seen as two thin green lines, separated by a dark space. The RL represents the pre-lens tear film on the anterior contact lens surface. The dark space represents the contact lens thickness while the LL represents the tear layer between the contact lens and the cornea. It is important not to confuse the LL with the dimmer green hue which is the optic section of the cornea.

If the contact lens base curve is fitting so that the RL has the same thickness as the LL, this is an approximate alignment fit or a 1.0 ratio. An apical clearance would have a RL/LL ratio less than 1.0. If the RL/LL is greater than 1.0, this is assumed to represent apical touch.

This method can also be used to detect 1) bearing zones, 2) evaluate the blend, 3) observe the shape of the tear reservoir, and 4) evaluate the tear meniscus of the edge of the contact lens.

The initial fitting of the RL/LL included apical clearance,

with the RL/LL ratio in the range of 1/2 to 1/4, and a smooth
transition from the optic zone to the peripheral tear reservoir.

All of the lenses were ordered in a tricurve design (See
Table 5). This was done to help eliminate the bearing restrictions
that were seen with the Morrison diagnostic lenses. The lens power
was determined by over-refraction calculation.

The lenses were verified and pachometry readings were taken
prior to dispensing. The pachometer used was the Digital Computer
Model II RK from Dicon Ophthalmic Instruments. Following the
initial findings, a second set of measurements were taken after each
subject achieved six hours of continuous contact lens wear. The
final set of measurements were taken at six hours once the patient
achieved maximum wearing time. The pachometer was calibrated
before each set of measurements and only one clinician took the reading,
eliminating interclinician variability. The readings were taken
at the central cornea and at positions approximately three mm
from the center, in the superior, inferior, medial and lateral
directions. At each position, five readings were taken and the
mean, standard deviation, and ranges were recorded. The readings
for these measurements were kept below a 0.02 mm standard deviation
level.

At the time of dispensing, visual acuity with contact lenses,
an over-refraction and a biomicroscopic examination evaluating the
RL/LL, lens performance and staining was performed. The patients
were next instructed in lens care. Recommended solutions were
used for the lenses, these are listed in Table 6. Where the patients
experienced substantial coating or wetting problems the solutions
were changed.

Several progress exams were performed on each patient. The first progress exam immediately followed four hours of lens wear on the day following dispensing. The second progress exam took place one week after dispensing. The third progress exam was three weeks after the initial dispensing. Subsequent progress exams were then made after two months and four months of total wear. Variances in the above schedule resulted when lenses needed to be refit and/or reordered.

The progress exams performed included patient's subjective comments, wearing time, visual acuity with lenses on, over-refraction and biomicroscopic examination with fluorescein to evaluate the RL/LL, the lens performance and the lens surface for build-up, drying and scratches. Pachometry was done immediately after lens removal and spectacle refraction and keratometry readings subsequently followed.

## TABLE ONE - SUBJECT CHARACTERISTICS

Sex:  Female - 6
       Male  - 4

Age (years):

    Mean - 24.50
    S.D. -  4.25
    Range- 20-33

Contact Lens Experience:

    Previous wear - 6
    No previous wear - 4

Spectacle Correction - based on 14 eyes:

    Spherical Refractive Power:

    Mean    2.49 D
    S.D.    1.21 D
    Range   0.75-4.50 D

    Cylindrical Refractive Power:

    Mean    0.54 D
    S.D.    0.45 D
    Range   PL - 1.50 D

    Cylindrical Axis:

| | |
|---|---|
| WTR cylinder (within 30 of horizontal axis) | 10 |
| ATR cylinder (within 30 of vertical axis) | 0 |
| Oblique cylinder (between 30 - 60 , and 120 - 150 ) | 2 |
| No cylindrical component | 2 |

Corneal Curvature:

    Flattest Keratometric Reading:

    Mean    43.96
    S.D.    2.15
    Range   39.25 - 47.25

## TABLE 2

### MORRISON DIAGNOSTIC SET PARAMETERS

Base Curve Range:   7.02 to 9.57 mm

Peripheral Curve Radius = Optic Zone Radius + 1.0 mm

Blend Radius = Optic Zone Diameter + 0.5 mm

$$\frac{\text{Overall Diameter} - \text{Optic Zone Diameter}}{2} = \begin{array}{l}\text{Peripheral Curve Width} + \\ \text{Blend Width}\end{array}$$

PCW = 0.3 mm
Blend = 0.2

## TABLE 3

### DOW CORNING TABLE FOR BASE CURVE SELECTION

| Amount of Corneal Toricity | Base Curve |
|---|---|
| 0 to 1.00 D | Within 0.25 D (0.05 mm) of the flatter K |
| 1.12 to 2.00 D | 0.50 D (0.10 mm) steeper than K |
| 2.12 to 3.00 D | 1.00 D (0.20 mm) steeper than K |

## TABLE 4

### MOSS TABLE

| Flattest K reading | Optic Zone Diameter (in mm) |
|---|---|
| 38.00 - 40.00 | 8.0 |
| 40.12 - 42.00 | 7.5 |
| 42.12 - 44.00 | 7.0 |
| 44 and above | 6.5 |

## TABLE 5

### TRICURVE DESIGN

| | WIDTH | RADIUS |
|---|---|---|
| Peripheral Curve | 0.3 | base curve + 3.0 mm |
| Intermediate Curve | 0.2 | base curve + 1.5 mm |
| Blend | 0.1 | base curve + 0.7 mm |

TABLE 6

MANUFACTURER RECOMMENDED SOLUTIONS

FOR THE DOW CORNING SILCON LENS

Wetting Solutions:

CLERZ (CLERZ 2)
HYPOTEARS

Soaking Solutions:

SOACLENS
ALLERGAN Wetting & Soaking Solution

Cleaning Solutions:

PLIAGEL
LOBOB

Enzymatic Cleaners:

ALLERGAN Enzymatic Cleaner

## RESULTS

During the course of the study, ten subjects were fit with the silicone lens. At the close of the study, seven subjects (70%) were wearing their lenses. Of the unsuccessful cases, two subjects were dropped because of failure to return for the progress exams. The other was dropped because of poor tolerance to the lens.

In fitting these seven subjects with the silicone lens, there were several problems encountered in obtaining a satisfactory fit. The major problem encountered with the silicone material was its wettability. Of the fourteen lenses, only four (29%) were wetting successfully after the initial dispensing. Nine of the ten lenses were not wetting well, and the other had a bad edge. Of these lenses that had to be re-ordered, six (60%) did not need another re-order. With one re-order, seventy-one percent of the lenses were wetting successfully. A second re-order was needed to achieve 100% success in wearing the SILCON lens. At the end of the study, the lenses were gathered to check if any parameter changes had occured with wearing. There was a tendency for the base curve to flatten, the mean being 0.02 mm with a standard deviation of 0.02. This change was not statistically significant using the student's t-test.

Pachometer findings showed significant corneal thickness changes with lens wear. Only twelve eyes were included in the pachometer analysis and reasons will be given in the discussion. The eyes used showed an increase in the corneal thickness from the initial zero hour reading to both the initial six hour reading and the final six hour reading. There was a decrease found in the corneal thickness from the initial six hour reading to the final six hour reading. These trends were noted in all five positions measured. See Table 7-A to 7-E for graphs of these positions.

Each graph plots the mean and range as they change over time. The student's t-test was done on the central findings to determine if there was a statistically significant change. Each of the time intervals showed a significant change at the .01 level (These are shown in Table 8). Another corneal change observed was a small flattening of the corneas. The mean flattening was 0.33 D with a S.D. of 0.60 D.

Each of the fourteen eyes were initially refracted and had the capability to see at least 20/20. Each of the fourteen lenses also gave an acuity of 20/20. An overrefraction with the lenses showed that 71.4% of the spectacle cylinder correction was masked. Thus the refractive performance of the fourteen lenses was outstanding.

## TABLE 7-A

### CENTRAL CORNEAL THICKNESS CHANGES OVER TIME
### WITH CONTACT LENS WEAR



time of corneal thickness measurements
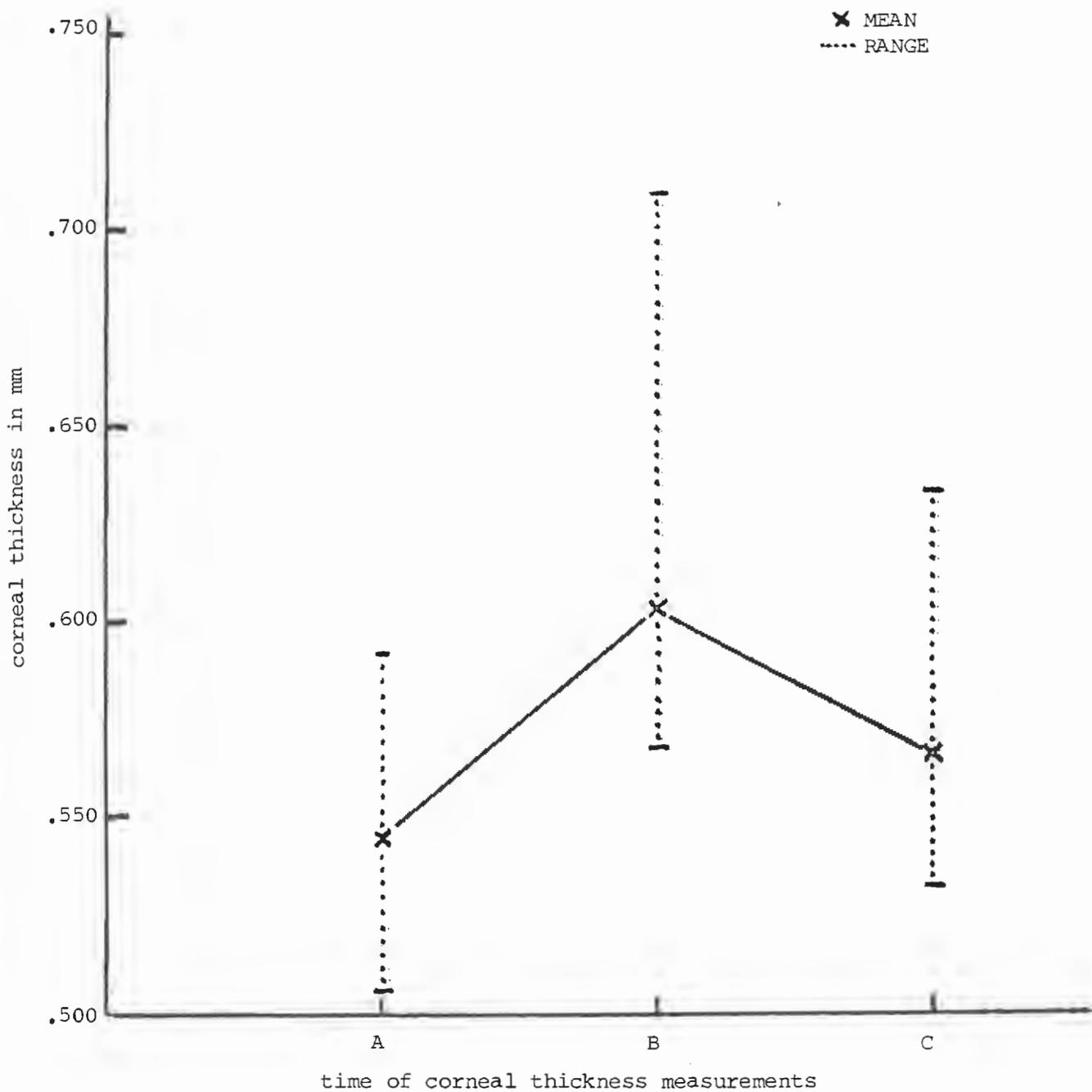
| POSITION | TIME OF PACHOMETER READING | MEAN | S.D. | RANGE |
|----------|---------------------------|------|------|-------|
| A | initial zero hour | .545 | .024 | .507-.592 |
| B | initial six hour | .604 | .048 | .568-.709 |
| C | final six hour | .567 | .030 | .533-.630 |

TABLE 7-B

SUPERIOR CORNEAL THICKNESS CHANGES OVER TIME
WITH CONTACT LENS WEAR



time of corneal thickness measurements
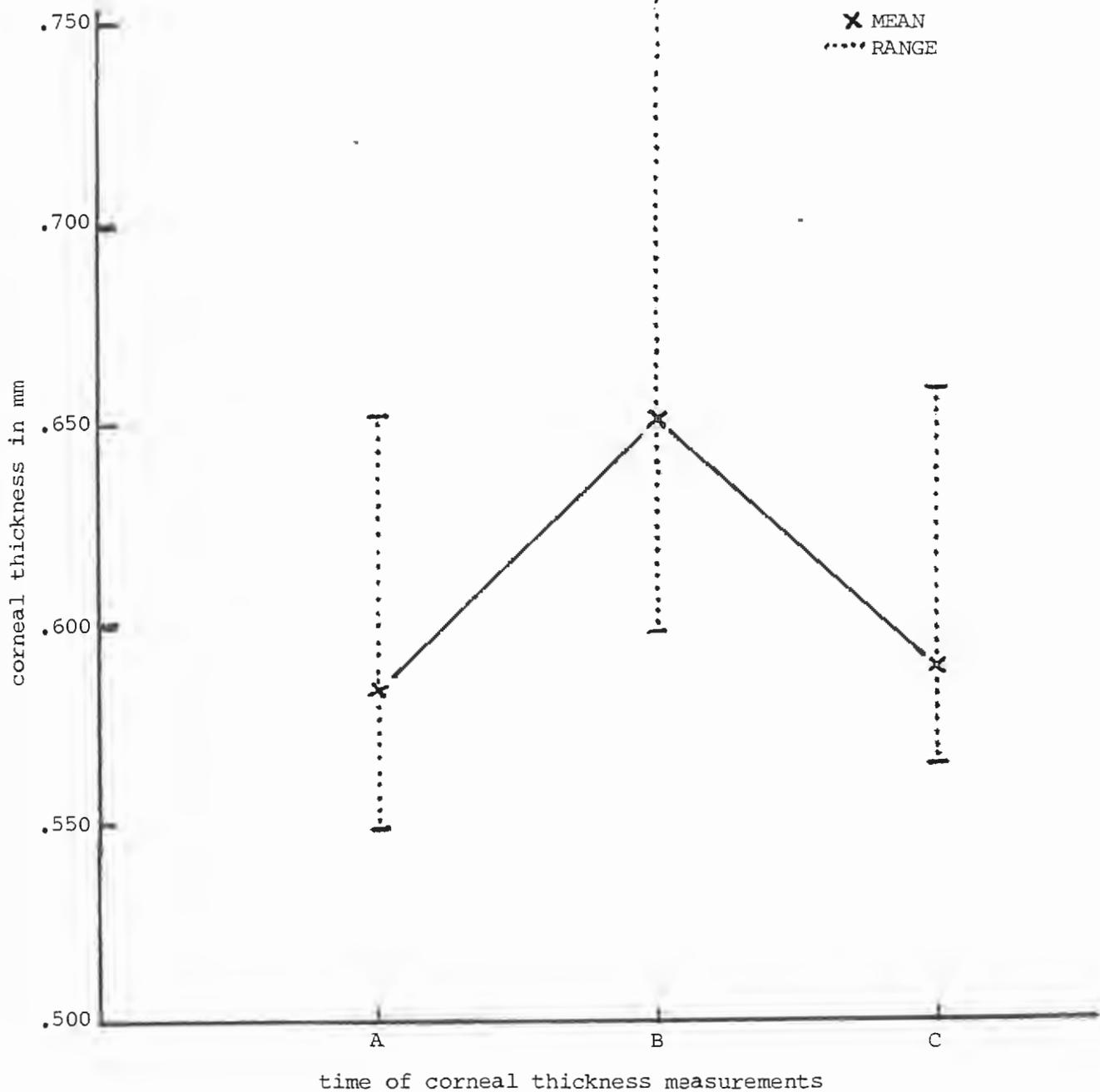
| POSITION | TIME OF PACHOMETER READING | MEAN | S.D. | RANGE |
|----------|---------------------------|------|------|-------|
| A | initial zero hour | .584 | .035 | .549-.652 |
| B | initial six hour | .651 | .052 | .599-.768 |
| C | final six hour | .589 | .021 | .565-.659 |

TABLE 7-C

INFERIOR CORNEAL THICKNESS CHANGES OVER TIME
WITH CONTACT LENS WEAR



time of corneal thickness measurements
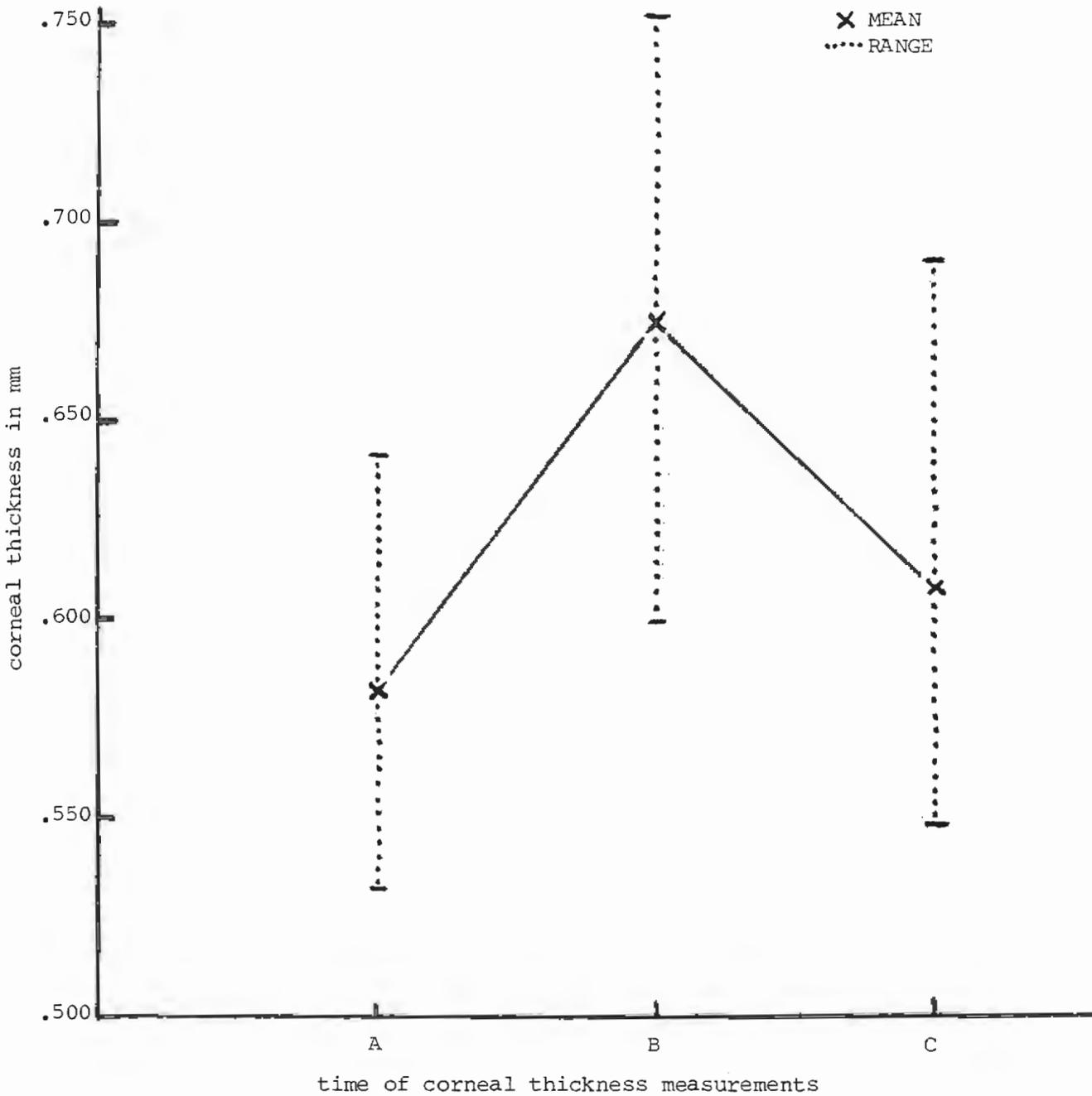
| POSITION | TIME OF PACHOMETER READING | MEAN | S.D. | RANGE |
|----------|----------------------------|------|------|----------|
| A | initial zero hour | .581 | .037 | .532-.641 |
| B | initial six hour | .665 | .053 | .599-.751 |
| C | final six hour | .608 | .040 | .548-.690 |

TABLE 7-D

MEDIAL CORNEAL THICKNESS CHANGES OVER TIME
WITH CONTACT LENS WEAR
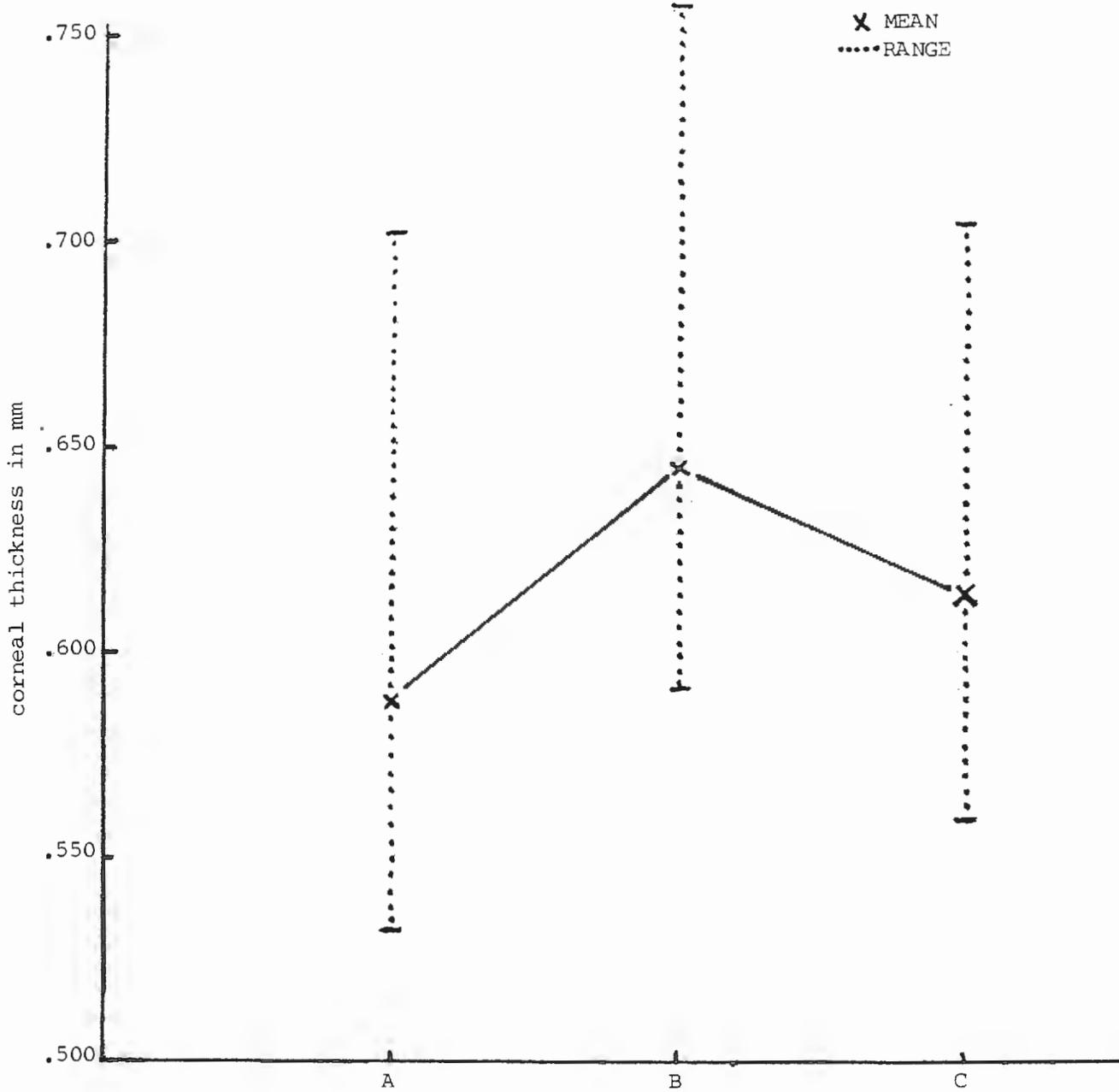


| POSITION | TIME OF PACHOMETER READING | MEAN | S.D. | RANGE |
|----------|----------------------------|------|------|-------|
| A | initial zero hour | .588 | .053 | .532-.702 |
| B | initial six hour | .645 | .051 | .591-.758 |
| C | final six hour | .615 | .040 | .559-.705 |

## TABLE 7-E

LATERAL CORNEAL THICKNESS CHANGES OVER TIME
WITH CONTACT LENS WEAR



time of corneal thickness measurements
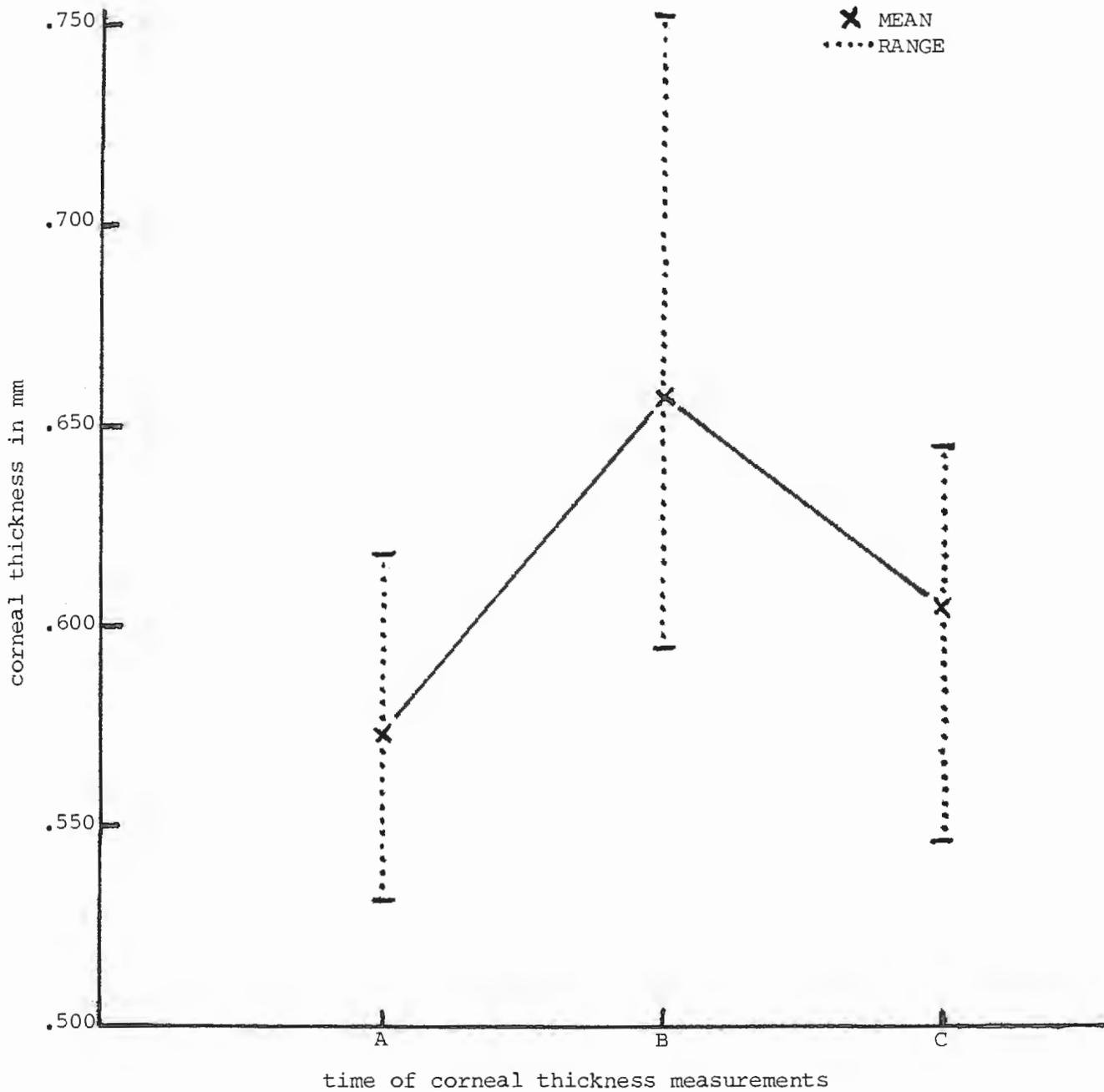
| POSITION | TIME OF PACHOMETER READING | MEAN | S.D. | RANGE |
|----------|---------------------------|------|------|-------|
| A | initial zero hour | .573 | .034 | .531-.618 |
| B | initial six hour | .658 | .057 | .595-.752 |
| C | final six hour | .606 | .035 | .547-.645 |

TABLE 8

CENTRAL CORNEAL PACHOMETER MEASUREMENTS

EVALUATION OF THEIR STATISTICAL SIGNIFICANCE

Student t-values were determined between the different time
intervals to determine if there were significant changes in the
corneal thickness.  Minus values represent increases and positive
values represent decreases in the corneal thickness during the
specified time period.

Significance Values:   .05 level   2.201
                       .01 level   3.106

| Dispensing | Initial Six Hours | Final Six Hours |
|---|---|---|

T = -6.472

K———————————————————→
significant at the .01 level

T = +5.051

K———————————————————→
significant at the .01 level

T = -4.115

K———————————————————————————→
significant at the .01 level

# DISCUSSION
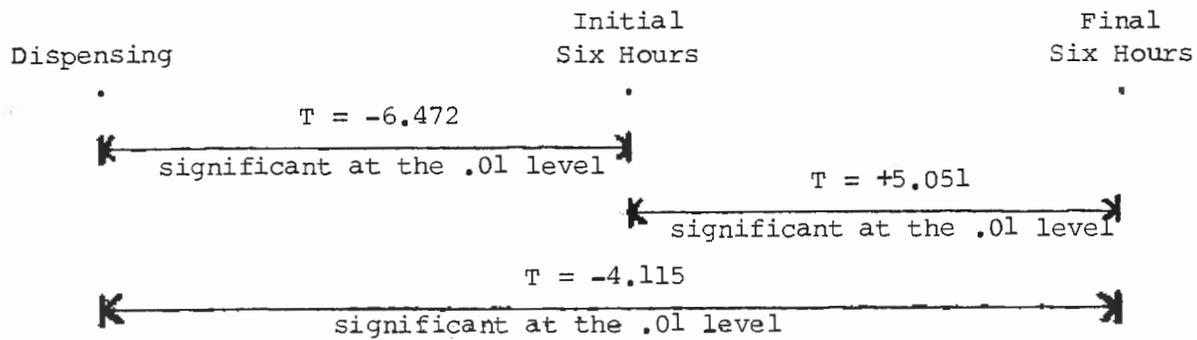
When the eye is subjected to a contact lens there is often
a compromise of the normal corneal physiology. The wearing of
contacts reduces the amount of atmospheric oxygen reaching the
cornea through the tears.

There are several factors that may reduce the presence of
atmospheric oxygen (21% at sea level) by the contact lens barrier.
These include the lens material, the fit and the design of the lens.
These factors may act independently or together to cause the atmospheric
oxygen to fall below the critical level for corneal function -
approximately two percent. This results in a disturbance to metabolism
in both the epithelium and stroma as well as endothelial changes.[8]

The SILCON lens has the best oxygen permeability (DK) and
oxygen transmissibility (DK/L) of the gas permeable lenses listed
in Appendix 1. This high oxygen permeability should minimize
any increase in corneal thickness if it is caused by a decreased
oxygen supply. Another possible cause of edema is a change in
the osmolarity of the tears. This is attributed to lid irritation
which causes reflex tearing and a change in the tonicity of the
tears. With lid adaptation the amount of reflex tearing would be
expected to decrease. Thus the osmolarity of the tears would remain
more stable with less edematous changes. With all eyes combined,
the data shows that 58 out of 60 eyes had increased from the initial
zero hour reading to the initial 6 hour reading. Thus ninety-seven
percent of the measurements had increased during that time frame.
There was good reliability in the pachometer measurements because
each measurement was the mean of five readings with a standard deviation
of 0.02 or less. This controlled the possible influence of a single
reading.

During the contact lens adaptation process, the cornea of

a contact lens patient adjusts to low oxygen levels.[9] There were
56 out of 60 measurements that showed a decrease from the initial
6 hour reading to the final 6 hour reading. Thus 93% showed decreasing
edema during that time frame. This decreased edema could be part
of the corneal adaptation process. It may also be decreased due to
the decrease in reflex tearing. The final pachometer readings
also show an indication that although there was a decrease in edema
from the initial pachometer measurement, there was still some
slight edema present. There were 54 out of 60 (90%) that showed
an increase in edema from the initial zero hour to final six hour
measurements. Thus there was a high percentage of changes involved
with each time frame. There was also a statistically significant
change with each time period at a level of .01.

It should be noted that the edema that was noted with the pacho-
meter may not be clinically significant. There were no clinical
findings that suggested any of the patients were having problems
with the edema. No patients had observable edema with the biomicro-
scope or a significant change in spectacle refraction upon lens
removal. It should be kept in mind that an individuals response
to contact lenses may differ greatly from anothers, even though the
corneal features and lens design may be similar.

A patients success in adapting to contact lenses hinges on
not only his individual physiology, but also the lens design and
environmental factors. The lens designs were basically a controlled
variable and there were no statistically significant changes in the
base curves over time. One subject out of the seven wasn't included
in the pachometer findings because of the possibility of an un-
controlled environmental variable while wearing the lenses. The
subjects last set of pachometry findings had raised drastically

compared to the rest of the subjects. The subjects pachometer findings were checked once again after the uncontrolled variable was removed. The pachometer finding had decreased as was expected. Both investigators decided not to include this subjects pachometer findings to control the possibility of environmental variables.

There was a small amount of corneal flattening measured with keratometry between the initial fitting and the final progress exam. The mean was 0.33 D with a S.D. of 0.60 D. However, the findings showed 6 cases of steepening, 7 cases of flattening and one case with no change. Because of this variability no generalizations were made in regard to corneal curvature changes.

Successful fits on the initial 14 lenses were achieved with the RL/LL philosophy of 1:2 - 1:4 apical clearance. This allowed stable visual acuities to be achieved as well as provide good lens performance (sufficient movement, centration, an adequate tear reservoir and to have minimal bearing zones). A lens fit with apical touch or excessive apical clearance can produce unstable visual acuities.

Four out of the fourteen re-ordered lenses had to be replaced due to mechanical irritation from the edge. All four of these lenses were re-ordered with the same parameters and in each case the subject reported a more comfortable lens. The stock lenses were a limiting factor in fitting the SILCON lens. All lenses were ordered in a tricurve design because the SILCON lenses cannot be modified due to the surface treatment. The tricurve design was used to allow the lenses to have no major bearing zones that were seen while fitting from the bicurve Morrison Diagnostic Set. It should be noted that Dow Corning has recently come out with a stock tricurve

design lens with an overall diameter of 9.4 mm.

Of the fourteen total reorders, ten (71%) were due to the lenses poor wettability. The patients subjective complaints included blurry vision, discomfort and a foreign body sensation. Reasons for this non-wettability of the lens surface are not clear. A Dow Corning spokesperson was confronted with this high percentage of non-wetting lenses. He had no answers to our problem and stated that their total return rate is less than one percent. One possible reason may be an inadequate hydrophilization of the lens surface. If the lens surface isn't adequately hydrophilized, the hydrophobic nature of the lens is exposed creating a non-wetting area.

Another possible reason is that the subject may have a pre-lens tear film that breaks up rapidly. This exposes the lens surface to drying which can lead to lipid contamination or physiological changes. In both of these cases the lens would be difficult to keep wet. A dirty or rough surface may also cause problems in wetting. The tears need a smooth surface to be able to wet well. Any oil or contaminants on the lenses may cause a local drying spot.

Mucin has hydrophilic properties and is the tear stabilizer. A decrease in mucin will cause a rapid drying on the lens. With contact lenses most patients initially have an increase in the aqueous component of the tears. If not enough mucin is present to compensate for this increase then there may be problems in the stability of the tear film.

In all of the patients with wetting problems, attempts at solving these followed the manufacturers recommendations. Wetting agents used included Clerz and Hypotears. These both initially wetted the lenses but within 10-15 minutes the drying areas started showing up. The surfactants used included Lobob, Pliagel and Boston Lens

Cleaner. Pliagel was the best surfactant for full-time use. Though the Boston Lens Cleaner was successfully used only at times of progress exams, it was not recommended by the manufacturer because its abrasiveness may damage the lens surface. The Allergan enzymatic system was used to keep the lenses from becoming coated with proteins. Patients subjectively reported a more comfortable lens after enzyming. But upon slit lamp examination the areas of non-wettability were still present, though sometimes to a lesser degree. The last possibility of wetting the lens would be to use Miraflow in cleaning the lens. This solution is 20% isopropyl alcohol and should remove any lipid deposits on the lenses. Miraflow isn't FDA approved for these lenses and wasn't available for use. Another possible problem was the subjects blinking pattern. Partial blinking or non-blinking leads to drying because of no spreading of the mucin layer. This drying may also lead to non-wetting deposits on the surface of the lens. Partial blinkers were made aware of their condition and given some blinking exercises (see Appendix 2). Another possible reason for non-wetting could be due to the mechanical abuse of a bad edge. The bad edge may be traumatizing the goblet cell and causing it to not secrete normally.[10] Good metabolic waste drainage of the tears was observed by slit lamp examination of the tear reservoir. If all of these factors were watched and the lens was still not wetting, the authors felt that this was a good indication that the surface was compromised. **Thus new lenses were re-ordered.**

Another drawback with the SILCON lens was that they are unable to be modified or polished. Thus any blending required for removal of bearing restrictions would have to be re-ordered with the necessary

changes in parameters. This wasn't a problem though because all lenses were ordered as tricurves to help alleviate the bearing restrictions. Also any scratches causing a non-wetting area also had to be reordered. The turn-around time was actually the problem. Lenses would have to be remade and then reprocessed to be hydrophilic. The lenses can be run through and rehydrophilized but two problems are present. The first is that it is quicker and less expensive to just re-order the lens. The other problem is that all protein and lipid deposits would have to be completely removed which may be an impossible task. Thus the manufacturers suggest to consider only reordering the lenses.

# SILCON® Contact Lenses
## (silafilcon A)

# New Laboratory findings confirm superiority in critical performance areas

| | SILCON | Boston I | Boston II | Dioxyflex* | Optacryl 60 (clear) | Paraperm* | Polycon I | Polycon II | Sil-O₂-Flex* | PMMA |
|---|---|---|---|---|---|---|---|---|---|---|
| Hydrophilicity* (receding contact angle) | **1** | **6** 57.3±6.97 | **8** 60.8±7.62 | **3** 52.2±5.36 | **4** 52.4±7.94 | **7** 58.6±6.13 | **10** 63.0±5.16 | **9** 61.9±8.34 | **2** 48.8±4.56 | **5** 56.1±3.32 |
| Hydrophobicity† (advancing contact angle) | **1** 61.4±5.28 | **8** 80.4±4.18 | **7** 79.5±5.61 | **6** 78.6±4.24 | **3** 75.9±7.44 | **8** 80.8±4.69 | **5** 76.5±6.14 | **9** 82.2±9.28 | **4** 76.4±4.31 | **2** 75.4±6.34 |
| Oxygen permeability§ DK | **1** | **4** 12.0 | **2** 12.8 | **8** 8.3 | **5** 10.5 | **3** 12.9 | **7** 4.6 | **6** 8.8 | ND** | **9** 0.2 |
| Oxygen transmissibility¶ DK/L | **1** | **4** 40.0 | **2** 12.8 | **8** 8.8 | **5** 9.0 | **3** 10.8 | **7** 3.8 | **6** 6.3 | ND** | ND** |

Superimposed numbers show relative performance of various lenses. Within each clinical parameter (e.g., hydrophilicity), a number was assigned based on the relative lens performance, the number 1 denoting the best value. Lenses with identical values were awarded identical ranking scores.

*Measures how tenaciously a material will hold a film of liquid once its surface has been wetted by the liquid. The lower the angle, the more hydrophilic the material. Values are means ± standard deviation. Data from analysis by John Fitzgerald.

†Measures ability of distilled water to spread across a dry surface. The lower the angle, the less hydrophobic the material. Values are means ± standard deviation. Data from analysis by John Fitzgerald.

§Measured in $cm^3$-$cm/cm^2$-sec-mmHg
Note: Although findings are presented to one decimal place, precision is only $\pm 1 \times 10^{-11}$
Measurements performed at 35°C. Data from analysis by Irving Fatt, Ph.D.

¶Measured in $cm^3$ - $cm/cm^2$ - sec - mmHg
Note: Although findings are presented to one decimal place, precision is only $\pm 1 \times 10^{-9}$
Measurements performed at 35° C. Transmissibility analysis based on 0.12 mm lens thickness. Data from analysis by Irving Fatt, Ph.D. Additional analysis by John Fitzgerald.

**ND = not done.

## APPENDIX 2

## BLINKING EXERCISES PATIENT INSTRUCTION

1) Blink 20 times slowly and fully 2-3 times daily

2) Keep your eyes closed for a brief moment each time you blink...
long enough to utter the word "pause". (The purpose is for the
lid to wipe over the lens and bring in fresh tears.)

3) Your lids must not be squeezed tightly. To check, hold your
forefinger at the outer portion of the eye and feel that the full
and relaxed eyelid closure doesn't move the finger, whereas a
squeezing blink pulls the finger forward.

| SUBJECT | EYE | $\triangle$ FLAT K | $\triangle$ BC | SPECTACLE CYLINDER | OVER-REFRACTION CYLINDER |
|---------|-----|-----------|--------|--------------------|--------------------------|
| JP | OD | +0.25 | +0.01 | plano | plano |
|    | OS | 0.00  | 0.00  | -.25 X 060 | plano |
| KH | OD | -0.12 | 0.00  | -.75 X 005 | -.50 X 180 |
|    | OS | -0.63 | +0.01 | -.75 X 005 | plano |
| CL | OD | +0.25 | +0.04 | -100 X 175 | -.25 X 060 |
|    | OS | +0.50 | +0.06 | -.25 X 180 | plano |
| VL | OD | 0.00  | +0.01 | -100 X 165 | plano |
|    | OS | -0.25 | +0.02 | -.50 X 175 | -.25 X 090 |
| KA | OD | -0.50 | 0.00  | -100 X 180 | -.25 X 180 |
|    | OS | -0.87 | 0.00  | -150 X 175 | -.25 X 180 |
| EM | OD | -0.50 | +0.06 | -.50 X 020 | -.25 X 090 |
|    | OS | -0.25 | 0.00  | -.50 X 180 | -.25 X 180 |
| SF | OD | -1.37 | 0.00  | plano | plano |
|    | OS | -1.50 | +0.04 | -.75 X 045 | -.50 X 045 |

| SUBJECT | EYE | REORDER INFORMATION | MAX WT. | AVG WT. |
|---------|-----|---------------------|---------|---------|
|         |     |                     | (hours) |         |
| JP | OD | 1st - wettability | 6 | 6 |
|    | OS | 1st - wettability |   |   |
| KH | OD | none | 6 | 5 |
|    | OS | none |   |   |
| CL | OD | 1st - wettability | 16 | 12 |
|    | OS | 1st - wettability |    |    |
| VL | OD | 1st-wettability / 2nd-edge | 12 | 12 |
|    | OS | 1st-wettability / 2nd-edge |    |    |
| KA | OD | 1st - wettability | 6 | 5 |
|    | OS | 1st-wettability / 2nd-edge |   |   |
| EM | OD | 1st-wettability / 2nd-edge | 14 | 14 |
|    | OS | 1st - wettability |    |    |
| SF | OD | none | 6 | 5 |
|    | OS | none |   |   |

## FOOTNOTES

1) Peter Fanti and Frank J. Holly, "Silicone Contact Lens Wear I. Fitting Criteria", <u>Contact Intraocular Lens Medical Journal</u>, Oct. - Dec. 1979, pp. 150.

2) Arthur A. Birdsall, "Silicone: Material of the Future", <u>Contact Lens Forum</u>, May 1982, pp. 94.

3) Rex Ghormley, "What Makes The Silicone Lens Different", <u>Contact Lens Forum</u>, Dec. 1982, pp. 33.

4) Ibid., pp. 33.

5) Ibid., pp. 36.

6) Peter Fanti and Frank J. Holly, "Silicone Contact Lens Wear II. Clinical Experience", <u>Contact Intraocular Medical Journal</u>, Jan. - March 1980, pp. 29.

7) Birdsall, pp. 95.

8) L. Fatt, "Oxygen Transmissibility Considerations for a Hard-Soft Contact Lens Combination", <u>American Journal of Optometry And Physiological Optics</u>, October 1977, pp. 667.

9) K.A. Pole and R.B. Mandell, "Critical Oxygen Tension at the Corneal Surface", <u>Archives of Ophthalmology</u>, April 1970, pp. 506.

10) Joseph Lilley, "Contact Lens Questions and Answers", <u>Review of Optometry</u>, Ed. by Burt Dubow, February 1984, pp. 71.

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