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An evaluation of clinical and patient acceptance of the Dow Corning silicon hard resin contact lenses

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An evaluation of clinical and patient acceptance of the Dow Corning silicon hard resin contact lenses

Abstract

The purpose of this study was to determine the clinical and patient acceptance of the Dow Corning SILCON hard resin lens. Ten subjects were initially used for this study. After three months of wear, the lenses showed superior wettability, consistent visual acuities, and no clinically significant edema. Subjective patient comfort was good with a few intermittent reports of a scratchy or itchy feeling of the eyes. These symptoms were found to be relieved by a thorough recleaning of the lenses.

Because of the lens surface alteration, these lenses cannot be modified or polished. This created a problem with turn around time for lenses that needed to be refit or modified.

Degree Type

Thesis

Degree Name

Master of Science in Vision Science

Committee Chair

Don C. West

Subject Categories

Optometry

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FOREST GROVE, OREGON

AN EVALUATION OF CLINICAL
AND PATIENT ACCEPTANCE OF THE
DOW CORNING SILCON HARD RESIN CONTACT LENS

by

Dale Tosland

Kathy Wan

Larry Wan

Pacific University
College of Optometry
March 1983

Advisor

Don C. West, O.D.

Don C. West

We would like to thank Don C. West, O.D. for his help and clinical supervision during the fitting and follow-up examinations of these patients. Also we extend a very special thanks to Dow Corning Ophthalmics Inc. for supplying the materials to make this study possible.

The purpose of this study was to determine the clinical and patient acceptance of the Dow Corning SILCON hard resin lens. Ten subjects were initially used for this study. After three months of wear, the lenses showed superior wettability, consistent visual acuities, and no clinically significant edema. Subjective patient comfort was good with a few intermittent reports of a scratchy or itchy feeling of the eyes. These symptoms were found to be relieved by a thorough recleaning of the lenses.

Because of the lens surface alteration, these lenses cannot be modified or polished. This created a problem with turn around time for lenses that needed to be refit or modified.

SILCON (Silificon A) contact lenses are made from a specially formulated 100% silicone polymer. Silicone, by its inherent chemical nature is a very hydrophobic material.^{1,2,3,4,5,6,7} Dow Corning Ophthalmics Inc. has developed a process of rendering the surface of the SILCON lens more wettable. This process involves a chemical alteration which forms hydroxyl groups on the surface of the lens.¹ Thus the lens surface becomes hydrophilic while the inside of the lens remains hydrophobic. It is important to note that the wettability of the surface of the SILCON contact lens is not due to a layer of a different substance or coating. Instead the chemistry of the outermost portion of the silicone material is changed to increase its affinity for water.¹

It is the intent of this study to evaluate the clinical and patient acceptance of the Dow Corning SILCON hard resin lens.

The SILCON lens may not be modified by cutting or polishing the surface because these types of procedures will remove the hydrophilic surface, and expose the hydrophobic matrix of the lens.

METHODOLOGY

A) Patient Selection

Subjects chosen for this study were from the general pre-presbyopic population with the following criteria:

- 1) Myopic patients only.

- 2) No major binocular problems present.
- 3) Minimum of 20/20 distance acuity with the right and left eyes through the spectacle correction.
- 4) No evidence of active ocular pathology or dry eye as determined by tear break up time (B.U.T.).
- 5) No history of ocular disease.
- 6) No ocular medications being taken.
- 7) No greater than 2.00 diopters of corneal astigmatism as determined by central keratometry readings.
- 8) Visual acuity, corrected by contact lenses acceptable to the subject and the examiner (Snellen 20/20).
- 9) Attempts were made to select patients having nearly identical parameters for both eyes. Former contact lens wearers were acceptable provided that a stable refraction after discontinuation of lens wear had been determined.

B) Patient Numbers

Ten patients were initially used for this study.

C) Baseline Data

Before any lenses were placed on the eye, the patient was required to pass all of the following tests without any contraindications:

- 1) Complete 21 point examination to include keratometry, ophthalmoscopy, and tonometry.

- 2) Slit lamp evaluation.
 - 3) Tear break up time.
- D) Fitting Procedure

Lenses were fit according to the manufacturer's suggested methods for using diagnostic lenses.

1) Lens Diameters

All lenses have an 8.8 diameter with a 7.6 optic zone.

2) Centration

Desirable lens fit was centration in the primary position of gaze. Korb style fit with adequate movement was also acceptable.

E) Movement

Movement of approximately 1 mm in the vertical meridian was desirable. Fluorescein examination should indicate alignment to light central pooling, light intermediate bearing, and light to moderate peripheral clearance.

F) Lens Power Determination

Power determination was accomplished by over-refraction with lenses in both eyes.

G) Wearing Schedule

Basic four plus-one wearing schedule.

Example: day one, 4 hours

day two, 5 hours

day three, 6 hours

up to 8 hours wear until second progress exam.

Eventually wearing time will work up to all waking hours.

H) Cleaning Procedures

All subjects are to follow Dow Corning patient guide of two solution chemical system for cleaning. This involves PREFLEX and FLEX-CARE. Lenses are also cleaned with Allergan enzymatic tablets once a week.

I) Progress Examination Schedule

At least four hours of lens wear was required before each progress examination.

1st follow-up exam: one day after lenses dispensed.

2nd follow-up exam: after one week.

3rd follow-up exam: after three weeks.

Subsequent follow-up exams every two months.

J) Difficulties With Full Time Wear

Lenses not satisfying the necessary criteria for full time wear were reordered with appropriate explanation as to the nature of the difficulties encountered.

Ten subjects were accepted from those screened for this study. Of this ten, eight achieved the fitting criteria required for subsequent evaluation; four of whom were females and four males. At the time of this writing, one of the subjects is still in the process of achieving full wear, and the remaining subject was dropped because of a severe case of poison oak. Refer to Tables 1 and 2 for the distribution of age, sex, previous contact lens wearers and mean refractive error.

Screening of the subjects took place in the summer of 1982, and at that time baseline data were obtained which consisted of a routine visual examination. Contact lens work-up included keratometry, slit lamp evaluation, tear break-up time and corneoscope pictures. From this data including a diagnostic lens evaluation, Dow Corning SILCON contact lenses were prescribed.

Lenses were dispensed in October 1982 and progress evaluations were made on a regular basis as described in the methodology until February 1983. Over this period all of the lenses met the fitting criteria established by Sarver et al. and the anterior surface of each contact lens wetted in a consistent uniform manner.

Daily lens care and cleansing were recommended as per the package insert with each prescription i.e. Preflex after the lens was removed, and disinfection and overnight storage using Flexcare. A weekly cleaning using Allergan's enzymatic tablet was added to the above care system.

One subject developed a slight allergic reaction i.e. #1 injection to the initial solution regimen and was therefore switched to Allergan's "Two Chemical" system with Lobob as the lens cleaner.

Since Dow Corning was unable to provide a flat piece of "treated" material, lens wettability was not assessed by the determination of the wetting angle. In lieu of this and in order to better replicate clinical procedures available to the professional, subjective comfort, slit lamp evaluation of the anterior lens surface together with the tear break-up time was used to judge the wettability of this surface. It has been suggested by Dow Corning that any erosion of the treated surface or any contamination thereon would decrease the tear break-up time on that surface.

Stock lens design seriously limited the fitting of the SILCON lens. Of the total number of subjects accepted, only two were identified as achieving the best fit using the stock lens design. The remaining subjects required alterations to this basic design, most frequently adding an intermediate curve to alleviate what appeared to be severe bearing restrictions at the edge of the peripheral curve. This basic tricurve design was as follows:

	radius	width
blending	base curve + 0.7 mm	0.1 mm
intermediate curve	base curve + 1.5 mm	0.2 mm
peripheral curve	base curve + 3.0 mm	0.3 mm

All lenses were fit using an overall diameter of 8.8 mm and an optic zone diameter of 7.6 mm. This standardized lens design was chosen to minimize the variables among subjects. Refer to Table 3 for specific lens parameters for each patient. The tricurve design achieved better centering and provided a lens/corneal relationship which was judged as alignment for four of the subjects and slight apical clearance in the remaining five. This was assessed by using

slit lamp observation utilizing a narrow optic section. The thickness of the tear layer under the contact lens (lacrima line) compared to the tear layer over the anterior surface of the contact lens (reference line) was evaluated. If the lacrima line equaled the thickness of the reference line, this gave an indication of alignment fit. If the lacrima line was thicker (plus lacrima line) this indicated apical clearance and if the lacrima line was thinner (minus lacrima line) this would indicate apical touch. The slight apical clearance was the initial goal for all the subjects, but repeated efforts to achieve this through shorter base curves failed. Any lens which produced any discomfort and/or poor visual acuity, since there was no modification possible, had to be reordered.

A small circular defect (less than 1.0 mm diameter) was found on the anterior surface of 20% of the lenses. Dow Corning attributed these to a problem with quality control. Where these were dispensed subjects failed to report any awareness of such a defect. Three months of wear where the cleaning regimen was used daily produced no noticeable change in the dimensions of this defect. This assessment was made using a slit lamp and recorded using a video tape.

Photodocumentation of the fluorescein patterns failed to record significant information, however a video tape recording of the anterior lacrima line and the lacrima lens proved to be worthy of the effort and provides a significantly new avenue for determining the apical relationship of the base curve.

In addition to the circular defects, small dry areas of less than 1 mm in diameter were found after four weeks of lens wear on

four lenses and these were accompanied by patient symptomology of an "itchy" feeling of the eyes. Refer to Table 4 for a profile of patient symptoms. These problems were remedied by thoroughly re-cleaning the lens. It was found that the SILCON lens seemed to have an affinity for contaminants which may accumulate on the lens surface. This necessitated a more frequent cleaning regimen which was, by itself, a viable solution to the problem.

Slit lamp evaluation of the SILCON lens showed consistent biocompatibility with the corneal physiology. Not a single patient rejected the lens material. No clinically significant edema or spectacle blur was reported or observed. One patient exhibited diffuse punctate staining the day after dispensing. This staining was due to make-up trapped under the lens. Throughout the follow-up care, no improvement of personal hygiene and lens care was demonstrated by the patient which required discontinuation of contact lens wear.

Visual acuities remained stable for all patients during the course of this study. Every patient obtained a visual acuity of 20/20 or better with each eye.

After the three month period, a general trend of corneal flattening took place. Post fit corneoscope readings using the "K" ring or third ring on the comparator showed an average flattening of .81 D for the sixteen eyes, and this included three eyes which steepened or stayed the same. The range of corneal changes shown by the corneoscope photographs varied from .87 D steepening to 2.37 D flattening. The three photographs which gave readings of 1.87 D or greater of corneal flattening were considered invalid due to poor

or blurred pre or post fit corneoscope photographs resulting from experimenter error. Post-keratometry readings showed the same trend of corneal flattening, but to a less variable degree. Only one of the sixteen eyes showed slight steepening of .185 D well within experimenter error. Corneal flattening averaged .37 D with a range of 0 to 1.25 D (refer to Table 5).

It was noted in the data collected that there was no significant difference in corneal flattening between the patients fit with slight apical clearance versus alignment fit (.35 D vs. .40 D). The standard deviation was much smaller for patients fit with alignment fit (S.D. of .17) compared to those fit with apical clearance (S.D. of .41). Keratometry findings and corneoscope photographs gave no indications of corneal distortion by way of distorted mires or reflections.

One disadvantage of the SILCON lens was not being able to modify or polish it. Turn around time on a refit or a modification such as a power change or intermediate curve change for a custom ordered lens was a problem. The surface treatment procedure which rendered the SILCON lens surface hydrophilic is not a renewable process after modification. If a lens becomes scratched to the point that wettability becomes a problem, the manufacturer suggests reordering a new lens.

All clinical results point to a lens material having excellent gas permeable properties. Dow Corning Ophthalmics published a DK value for the SILCON lens as 18.1×10^{-10} . This value is 22% greater than its closest competitor. See Table 6 for comparison of clinical parameters regarding DK values and wetting angle.

In summary, the success of the SILCON lens with the patient was based on the following:

1. No significant change in surface wettability of new versus worn lens as determined by slit lamp evaluation and video recordings.
2. No recurrent dry spots in the same area on the lens after three months of wear as determined by slit lamp evaluation and video recordings. Recurrent dry spots or recurrent non-wetting spots would indicate lens surface erosion of the treated surface, surface contamination or surface damage which would decrease the effectiveness of wettability and therefore patient comfort.
3. No significant change in tear break-up time (B.U.T.) on the anterior surface of the lens. If there was a significant change this would indicate an erosion of the treated surface or surface contamination.
4. No change or enlargement in circular defects as noted earlier. This was documented on video tape and in the case records.
5. A decrease in subjective complaints over time.
6. No alteration of the lens surface characteristics from scratches caused by the mechanical pressures of cleaning the lens.

Table 1	
Subject Characteristics	
Sex	
Females	4
Males	4
Age	
Mean	23.2
S.D.	2.7
Range	19-28
Previous lens wearers	6

Table 2	
Refractive Error	
Sphere	
Mean	-2.75
S.D.	1.62
Range	-1.00 to -5.50
Cylinder	
Mean	-.54
S.D.	.45
Range	plano to -1.50

Table 3

Contact Lens Parameters

Subject	B.C.	Blend	Intermediate curve	Peripheral curve	OAD	CT	Power
1. J.W.							
OD	7.99	8.70/.1	9.50/.2	11.00/.3	8.80	.12	-2.00
OS	7.99	8.70/.1	9.50/.2	11.00/.3	8.80	.12	-2.50
2. J.K.							
OD	7.20			8.40/.6	8.80	.12	-2.25
OS	7.10			8.30/.6	8.80	.12	-2.25
3. C.B.							
OD	8.03	8.70/.1	9.00/.2	10.50/.3	8.80	.12	-2.00
OS	7.94	8.65/.1	9.00/.2	10.50/.3	8.80	.12	-2.25
4. R.B.							
OD	8.03	8.70/.1	9.50/.2	11.00/.3	8.80	.12	-0.75
OS	7.94	8.60/.1	9.40/.2	11.00/.3	8.80	.12	-1.00
5. L.W.							
OD	7.63	8.30/.1	8.63/.2	10.13/.3	8.80	.12	-4.25
OS	7.59	8.24/.1	8.53/.2	10.04/.3	8.80	.12	-4.00
6. D.N.							
OD	7.79	8.50/.1	9.30/.2	10.80/.3	8.80	.12	-2.75
OS	7.65	8.40/.1	9.20/.2	10.70/.3	8.80	.12	-3.00
7. D.K.							
OD	7.45	8.20/.1	9.00/.2	10.50/.3	8.80	.12	-1.75
OS	7.38	8.10/.1	8.90/.2	10.40/.3	8.80	.12	-2.25
8. P.S.							
OD	7.75			8.96/.6	8.80	.12	-4.50
OS	7.75			8.96/.6	8.80	.12	-4.75
9. R.C.							
OD	7.84	8.50/.1	9.35/.2	10.85/.3	8.80	.12	-5.00
OS	7.58	8.30/.1	9.10/.2	10.60/.3	8.80	.12	-6.50

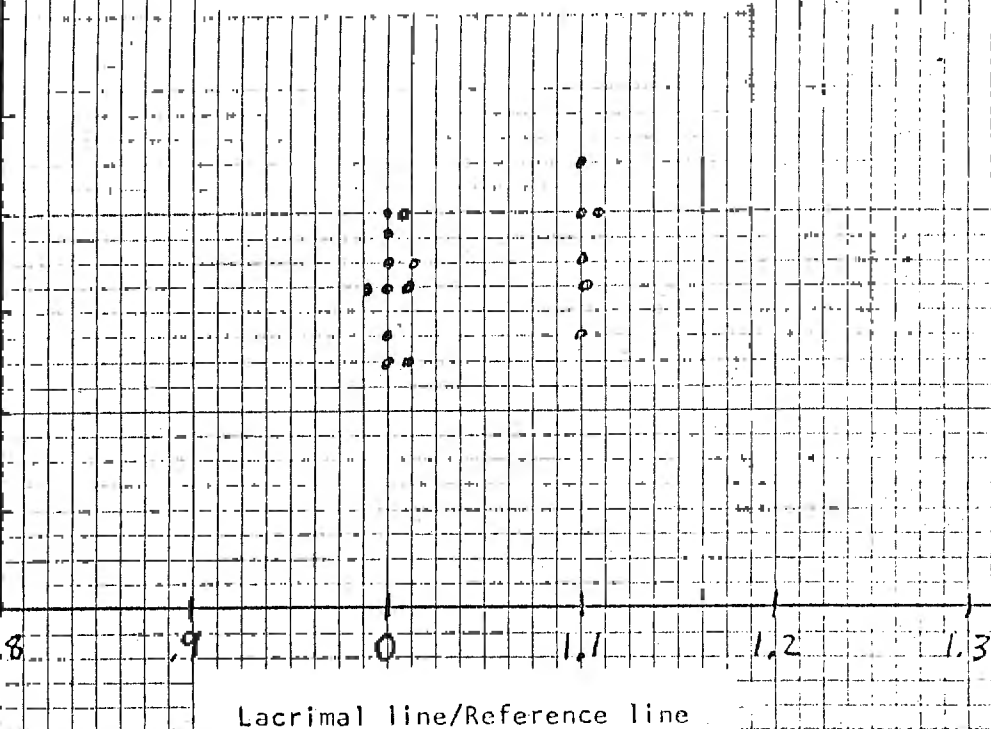
Table 4

Summary of Progress Examinations

	1 day after dispensing	1 week after dispensing	4 weeks after dispensing	3 months after dispensing
L.W.	no subjective complaints	slight conjunctival injection	slight conjunctival injection	slight conjunctival injection - chemical system changed. some dryness & discomfort after 14 hours of wear.
L.K.	diffuse punctate staining OU < grade 1	slight 3-9 staining, foreign body tracks OU from makeup < grade 1	superficial foreign body tracks OU	superficial punctate keratitis OU due to poor insertion & removal techniques & personal hygiene grade 1-2. Lenses taken away for 1 week.
L.B.	patient did not show for progress exam	Slight discomfort after 4 hrs. of wear	subjective complaint of intermittent scratchy feeling	vision & comfort good.
R.B.	slight itchiness at end of 4 hours	left lens lost	subjective complaint of dry itchy eyes	comfort improved tremendously.
L.W.	vertical foreign body tracks OS	no subjective complaints	comfort good, no staining	comfort & vision good, no dry spots.
D.M.	slight inferior punctate staining OU	central punctate staining OU < grade 1	central punctate staining OU < grade 1 wetting solution recommended	comfort okay - patient has dry eyes tear B.U.T. seven seconds.
P.S.	subjective complaint of dry scratchy eyes 3-9 staining < grade 1	no complaints slit lamp showed dry spots OU on lenses	patient gone on vacation	no complaints, no dry spots on lenses.
R.C.	slight itchiness reported	no complaints	no complaints	wearing time increased if lenses were recleaned after 1st four hours of wear.

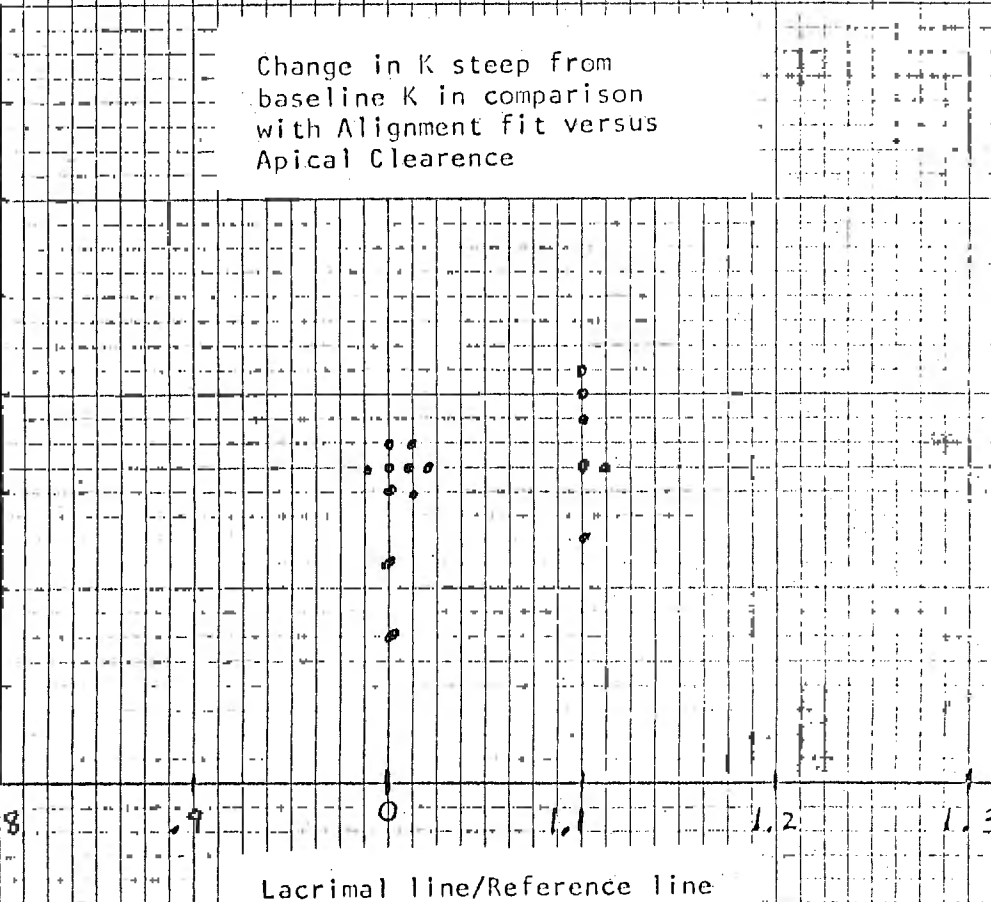
Change in K flat from
baseline K in comparison
with Alignment fit versus
Apical Clearance

FLATTER in Diopters
STEEPER in Diopters



Change in K steep from
baseline K in comparison
with Alignment fit versus
Apical Clearance

FLATTER in Diopters
STEEPER in Diopters



Changes in Post Refraction
as a function of Alignment
fit versus Apical Clearance

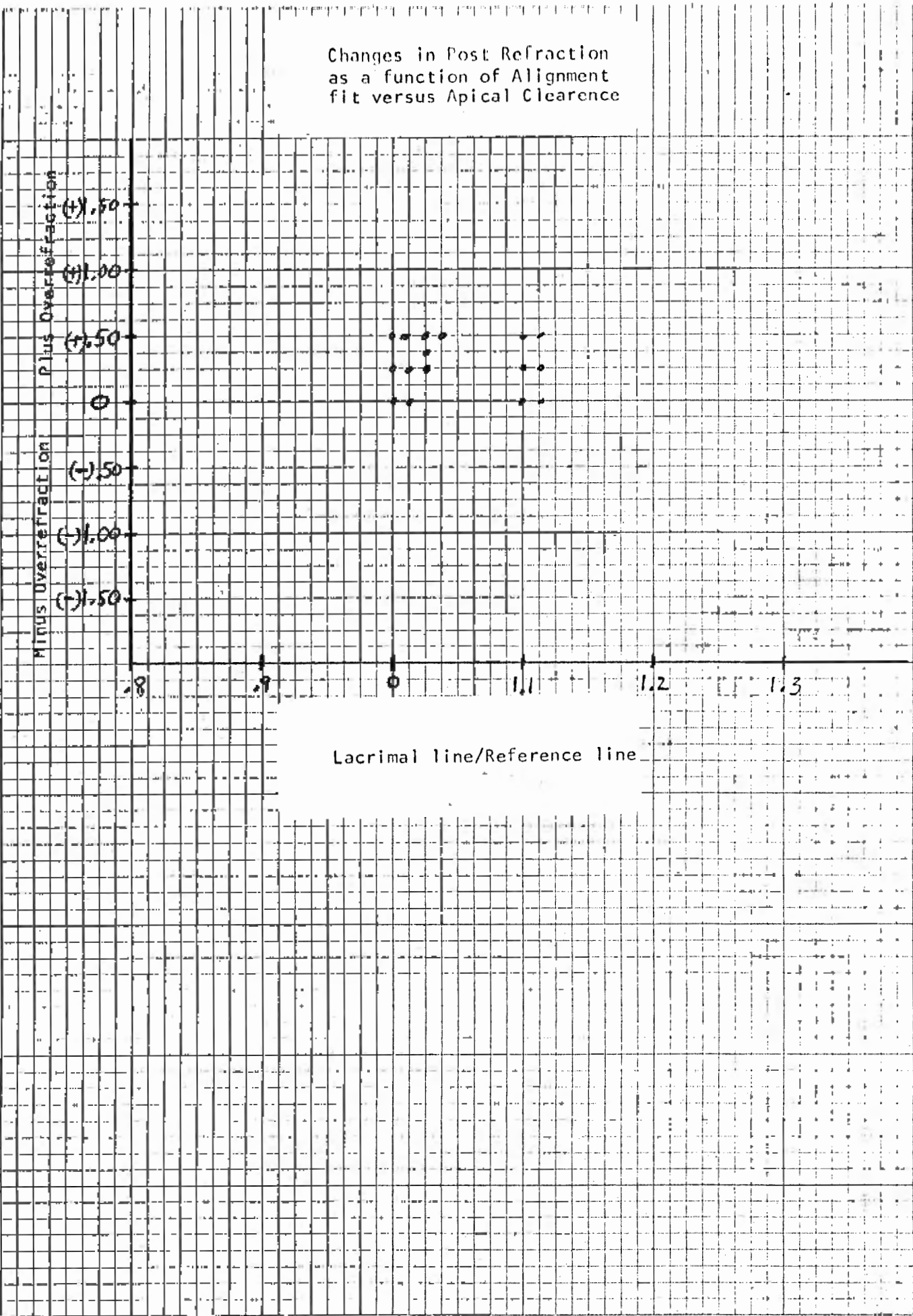


Table 5

Post-Wear Keratometry and Corneoscope Changes

Subject	Change in flat K from baseline K	Change in steep K from baseline K	Change in flat corneo- scope from baseline	Change in steep corneo- scope from baseline
1. J.W. OD	0	0.37F	2.37F*	1.87F*
OS	0.62F	0.37F	0.37F	0.62F
2. J.K. OD	0.25S	0.12S	In the process of being refit	
OS	0.25F	0		
3. C.B. OD	0.25F	0.87F	0.37F	0.75F
OS	0.75F	1.25F	0.75F	1.25F
4. R.B. OD	0	0.25F	1.25F	1.87F*
OS	0.37F	0.50F	0	0.37F
5. L.W. OD	0	0.12F	1.25F	0.87S
OS	0.62F	0.37F	0.25F	0.25S
6. D.M. OD	0.37F	0.37F	1.00F	2.62F*
OS	0.75F	0.50F	0.75F	0.87F
7. P.S. OD	0	0.75F	0.37F	0.87F
OS	0.37F	0.37F	0.62F	1.62F
8. R.C. OD	0.50F	0.25F	0.50S	0.87F
OS	0.37F	0.37F	0.25F	1.12F
Mean	0.334F	0.41F	0.65F	0.97F
S.D.	0.287	0.331	0.68	0.89

*Due to experimenter error

SILCON[®] Contact Lenses

(silafilcon A)

Laboratory data confirm superiority in clinical parameters

	SILCON [®]	Boston [†] I	Boston [†] II	Dioxyflex [†]	Optacryl [†] 60 (clear)	Paraperm [†]	Polycon [†] I	Polycon [†] II	Sil-O ₂ -Flex [†]	PMMA
Hydrophilicity* (receding contact angle)	<10	57.3±3.97	60.3±7.62	52.2±5.36	52.5±7.94	58.6±6.13	63.0±5.16	61.9±8.34	48.8±4.56	56.1±3.32
Hydrophobicity† (advancing contact angle)	31.4±5.28	80.8±9.18	79.5±5.61	78.6±4.24	75.9±7.44	80.8±4.69	76.6±5.14	82.7±3.28	76.1±4.31	75.4±6.34
Oxygen permeability§ (DK x 10 ⁻¹¹)	18.1	12.0	14.8	3.3	10.8	12.9	4.5	8.8	ND [¶]	0.2
Refractive index	1.52	1.46	1.47	1.47	1.47	1.48	1.49	1.48	1.47	1.49

*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 cm²-cm/cm²-sec-mmHg. Note: Although findings are presented to one decimal place, precision is only ± 1 x 10⁻¹¹. Measurements performed at 35°C. Data from analysis by Irving Fatt, Ph.D.

¶ND= not done.

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Dow Corning Ophthalmics

(11)

INSTITUTION

- A. Title: A clinical evaluation of Dow Corning SILCON hard resin silicone contact lenses
- B. Investigators: Dale Tosland, Kathy Wan, and Larry Wan
- C. Advisor: Don C. West, O.D.
- D. Location: Pacific University, College of Optometry, Forest Grove, OR 97116
- E. Date: Project will run from April 1982 until February 1983

DESCRIPTION OF PROJECT

This project is designed to clinically evaluate the fitting of Dow Corning's SILCON contact lenses. Emphasis will be placed on the monitoring of the durability and wettability of the ionic skin surface. Evaluation will be accomplished by a series of complete progress examinations over a six month time period, with periodic progress exams over the following six months. After termination of the research project, aftercare will be by the normal contact lens clinic of Pacific University. Regular clinic fees will be charged for this aftercare.

DESCRIPTION OF RISKS

There is slight possibility of the following problems:

- lens becomes less comfortable than when first placed on the wearer's eye
- burning, itching, or stinging of the eyes
- excessive watering of the eyes
- blurred vision (reduced visual acuity may affect driving and other related activities)
- light sensitivity
- redness of the eyes
- dry eyes
- irritations of the eye
- very slight possibility that the following may occur - abrasions, infections, and corneal ulcerations

If you notice any of the above, you should remove the lenses and check them. If the problem stops upon removal and the lenses appear undamaged, you should thoroughly clean, rinse, and disinfect the lenses and reinsert them. If the problem continues or if the lenses appear to be damaged, immediate consultation with the investigators or the advisor will be required.

DESCRIPTION OF BENEFITS

This study will serve to increase the basic understanding of the durability and biocompatibility of the Dow Corning SILCON contact lens, and will eventually contribute to a better understanding of the practical application of the ionic skin to future generations of contact lenses.

COMPENSATION AND MEDICAL CARE

All aspects of patient care including supervision of patients by qualified college staff will be at a level at least equal to that provided to non-research patients receiving comparable lenses through the Pacific University College of Optometry Clinic system.

ALTERNATIVE ADVANTAGES TO THE SUBJECTS

Contact lens material fees, and basic examination fees will be waived.

OFFER TO ANSWER ANY INQUIRIES

The investigators will be glad to answer any questions that you may have at any time during the course of the experiment.

FREEDOM TO WITHDRAW

You are free to withdraw your consent and to discontinue participation in this project or activity at any time without prejudice to you.

I HAVE READ THE ABOVE AND UNDERSTAND THE PROJECT AND RISKS. I AM 18 YEARS OF AGE OR OLDER.

Printed Name: _____ Date: _____

Signed Name: _____ Phone (Home) _____

Address: _____ (business) _____

Name and address of a person not living with you who will always know your address:

Name: _____ Phone: _____

Address: _____

PACIFIC UNIVERSITY
COLLEGE OF OPTOMETRY CLINICS
CONTACT LENS FITTING AGREEMENT

(20)

IN ORDER TO SERVE YOU, THE FOLLOWING INFORMATION IS AN UNDERSTANDING BETWEEN YOU AND THE COLLEGE OF OPTOMETRY CLINICS.

This is a teaching institution, therefore, reduced professional fees are charged for services. You must understand that more time and visits will be required than would normally be needed in a private practitioner's office. This is to provide for comparison findings, close faculty supervision, and teaching. Your contact lens fees consist of the following components:

- a. BASIC EXAMINATION - A complete vision analysis to determine your correction and your ocular health. (NOT REFUNDABLE.)
- b. CONTACT LENS DIAGNOSTIC EXAMINATION - An evaluation of your eyes to determine which type of contact lens would best suit you. (NOT REFUNDABLE.)
- c. CONTACT LENS TREATMENT SERVICE - Includes all follow-up exams for the prescribed time, contact lens dispensing, and instruction of lens care.
- d. CONTACT LENS LABORATORY MATERIALS - Normally this fee includes your lens. If you qualify for the SILCON lens, the fee for the lenses will be waived, but a deposit will be collected at the time for dispensing. Total deposit will be \$60.00. This deposit will be refunded upon completion of the research project.

In summary: 1st: day following dispensing
2nd: one week
3rd: three weeks
4th: two months
5th: four months
6th: six months*

At the end of this research the patient's aftercare will be by the normal contact lens clinic of Pacific University College of Optometry. Regular clinic fees will be charged for this aftercare.

If you should decide to withdraw at any time, the full deposit will be refunded when lens material is returned. Exam fee and diagnostic exam fee cannot be refunded.

In Summary:	Basic Exam	\$ _____
	Diagnostic Exam and Treatment Service	\$ _____
	Lens Deposit	\$ _____
	TOTAL	\$ _____
		\$60.00 (REFUNDABLE)

Name Printed: _____ Date: _____

Signed: _____ Investigator
or Advisor: _____

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