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Abstract
The objective of this research project was to study and photodocument the fitting of the Silsight contact lens. Criteria for the photodocumentation were to be supplied by the sponsoring company, Dow Corning Ophthalmics. It was also our intent to investigate corneal changes which may have been incurred by the contact lens user study. At the time this project was begun, the Silsight contact lens was FDA approved and available to the general public.

Degree Type
Thesis

A STUDY AND PHOTODOCUMENTATION OF THE LENS-CORNEA FITTING RELATIONSHIP OF THE SILSIGHT LENS

Presented to
The Faculty of the College of Optometry
Pacific University

In Partial Fulfillment of the Requirements
for Doctor of Optometry Degree

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MAY 1985

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Acknowledgements

We would first like to thank Dr. Don West for generously sharing both his expertise and his time on countless Tuesday evenings. Thanks also to Dean Reinke for helping out when Dr. West was gone.

A special thanks to Gerard Gibbons for many hours spent in video taping, and to Robert Gibbs for his assistance with audio and editing.

And lastly, thanks to all our Pacific friends who gave considerable time as subjects for this project.

ABSTRACT

The objective of this research project was to study and photodocument the fitting of the Silsight contact lens. Criteria for the photodocumentation were to be supplied by the sponsoring company, Dow Corning Ophthalmics. It was also our intent to investigate corneal changes which may have been incurred by the contact lens under study. At the time this project was begun, the Silsight contact lens was FDA approved and available to the general public.

Introduction

Fifteen subjects were interviewed and examined as perspective subjects. Of this group, six were able to be fit with Silsight lenses. Three of these were chosen as representative of median, steep, and flat corneas for the purpose of filming. Photodocumentation was to demonstrate various examples of lens fit as previously determined by Dow Corning. Each of the three patients chosen was given an optimum fit as defined by clinical standards, a steep fit, and a flat fit.

All six of the subjects chosen were to be monitored for corneal changes that might have occurred as a result of wearing the Silsight contact lens. This was to be accomplished by a series of complete progress exams including a complete refraction, keratometry, photokeratoscopy, and biomicroscopy evaluation and photos.

Unfortunately, in March 1985 Dow Corning Ophthalmics was dissolved by the parent company, Dow Corning inc., causing some obvious problems for this project. For one thing, in the pre-shutdown "panic" communications with Dow Corning became very difficult, and we were never able to obtain criteria on which to base our photodocumentation. We ended up by drawing on Dr. West's knowledge and experience to set up criteria of our own.

Another drawback was that several hundred dollars which had previously been promised for video, photokeratoscope, and slit lamp photo film never did materialize.

Company officials claimed that the major reason for the failure was that in spite of excellent optical characteristics, the lenses were not comfortable. We indeed found this to be true. Of the six subjects fit, only two were still wearing the lenses by the first progress exam even though all had been encouraged to do so. Of the remaining two, one lasted a week and one a month before they too gave it up. All six stated that it was because of the discomfort factor.

Thus, even if our funding had come through, a meaningful longitudinal study would have been very difficult, at least with this particular group of subjects.

The photodocumentation, then, is the major thrust of this project. The video is self explanatory. Based on the criteria established by Dr. West and the researchers involved, a variety of fits are evaluated on corneas of median, steep, and flat curvatures. This tape, "A Study and Photodocumentation of the Lens-Cornea Fitting Relationship of the Silsight Contact Lens", is on file in the Learning Resources Center in the College of Optometry.

A Photodocumentation of the Lens-Cornea

Relationship in Fitting the Silsight Contact Lens

(Audio transcript)

The Silsight contact lens is constructed with a lenticular anterior surface and a tricurve posterior surface. The secondary and peripheral curves provide lens positioning and fluid exchange. It comes in an 11.3mm diameter, with base curves ranging from 7.3 to 8.5.

The lens is made from a highly elastic silicone polymer and has unique fitting characteristics which are different from both hard and gel type lenses. In making the visual inspection for a proper fit there four important things to consider.

These are movement, centering, standard flourescein pattern evaluations, and estimation of the lacrimal line/reference line ratio. We will further define these criteria as we look at a number of examples involving flat, median, and steep corneas. In each case we'll determine whether or not the lens is properly fit based on our checklist.

We begin with an example of a good fit on a cornea of median steepness. The first thing to consider is movement and centration. Although the lens is extremely oxygen permeable, movement is still essential for the removeable of metabolic by-products and cellular debris from underneath the lens. Allowing about fifteen minutes for the lens to settle, the movement should be about the same or slightly less than a hard lens and more than a gel lens. This is typically about one or two mm. It is better

initially to have as much movement as possible without excessive decentration or discomfort, as movement sometimes decreases slightly in the first forty eight hours.

In a good fit the lens may be centered superiorally or superior temporally under the upper lid. Any of these variations are acceptable as long as clear, consistent vision is obtained.

A flourescein examination is done at this point to ensure that tears are able to get behind the lens.

For a good fit we expect minimum central tear film flourescence, bearing in the intermediate zone, and moderate edge lift as evidenced by the peripheral flourescein pattern.

We adjust the slitlamp for observation of the lacrimal line/ reference line by placing the illumination system in clickstop, and moving the biomicroscope out to about eighty degrees. The lacrimal line refers to the tear layer beneath the lens, and the reference line to the tear layer above the lens. These lines have the appearance of railroad tracks, with the darker contact lens in between. If the ratio of lacrimal line over reference line is from 1.1 up to 1.4, there is adequate apical clearance and the fit is acceptable. This finding is used in conjunction with the others to make an overall appraisal. In this case, all findings indicate a successful fit.

The next example shows the same eye with a 7.5 mm lens which is too steep. In such a case there will be insufficient movement or no movement at all as the patient blinks, and the lens will usually be well centered.

Examination of the flourescein pattern shows apical clearance, but there is a lack of continuous flourescein/tear film behind the lens. There is also little or no flourescence at the periphery indicating insufficient edge lift.

And lastly, we see a lacrimal line/reference line ratio of approximately 1.5 to 1, giving final confirmation that the lens is indeed too steep for this cornea.

To demonstrate the signs of a flat fit, we again have the same eye, but now with a lens of 8.3mm base curve. In this case we see excessive movement. The lens is also sinking and will not stay properly centered. When the problem is severe enough the lens will be repeatedly displaced off the cornea.

Evaulation of the flourescein pattern shows a lack of continuous flourescein/tear film behind the lens, and also an excessive amount of edge standoff.

Our loose fit diagnosis is further confirmed by a lacrimal line/reference line ratio of less than 1 to 1.

We will now see how these same criteria are applied if the cornea is either steeper or flatter than the norm.
Our first example shows a proper fit for a cornea 1.5 diopters steeper than in the previous example. Before instilling flourescein we notice that there is good centration and about 2 mm movement at each blink.

The flourescein pattern gives evidence of a continuous flourescein/tear film beneath the lens, minimal central flourescence, minimum intermediate zone bearing, and adequate peripheral clearance.

And our final check shows an acceptable lacrimal line/reference line ratio of approximately 1.4 to 1.

With an 8.3 mm lens on this same cornea, we have another good example of a flat fit. Notice how the lens droops and will not center, as well as the excessive movement. We can expect vision to be variable and unstable in such a case.

As expected, there is excessive edge lift and no continuous flourescein/tear film underneath the lens. Notice too the edge rippling or scalloping which is another indication of a loosely fit lens.

The lacrimal line/reference line ratio is about .8 to 1. Another sign that the lens is too flat.

Lastly, we look at a flatter cornea of 40.5 diopters. In demonstrating a correct fit we have both good centration and the proper amount of movement with the blink.

The flourescein pattern shows good apical clearance, minimal intermediate zone bearing, and moderate edge lift. (The interpalpebral staining visible here is due to a longstanding case of lagophthalmos).

And the lacrimal line/reference line ratio is estimated at 1.3 to 1 indicating optimal apical clearance.

With a steep lens on this same eye, we notice that the lens is well centered, but there is insufficient movement with the blink.

The flourescein pattern shows central pooling with no continouos flourescein/tear film under the lens and insufficient flourescein at the peripheral curve indicating little or no edge standoff.

The lacrimal line/reference line ratio is at least 1.5 to 1, indicating excessive apical clearance.

We've seen then that the same four criteria can be used over a wide range of corneal curvatures to appraise the lens/cornea relationship when fitting the Silsight silicone lens. Once again these are:

- 1 to 2 mm of movement on the blink.
- A lens that centers or is slightly superior temporal.
- A good flourescein pattern as evidenced by a continuous flourescein tear film under the lens, minimal central flourescence, minimal intermediate zone bearing, and moderate peripheral clearance.
- And lastly, a lacrimal line/reference line ratio anywhere from 1.1 to 1 on the flat side up to 1.4 to 1 on the steep side.

When considered along with the subjective responses of the patient such as comfort and visual stability, meeting these criteria is an excellent indication of a properly fitted Silsight lens.

APPENDIX I

TO: IRB

RE: Senior Thesis

I. TITLE

A Study and Photodocumentation of the Lens-Cornea Fitting Relationship of the Silsight Contact Lens.

II. ABSTRACT

The objective of this research is to study and photodocument the fitting of the Silsight contact lens. Criteria for the photodocumentation will be supplied by the sponsoring company, Dow Corning Ophthalmics. It is also intented for the researchers to investigate corneal changes which may have been incurred by the contact lens under study. The Silsight contact lens is FDA approved and available to the general public.

III. LOCATION

Pacific University College of Optometry will be the location for all the work and research of this project.

IV. OVERVIEW

Approximately fifteen subjects will be fit with the Silsight contact lens by Dow Corning. Photodocumentation involves the demonstration of various examples of lens fit as previously determined by Dow Corning. There are three types of contact lens fits that are to be studied; an optimum fit as defined by clinical standards, a steep fit and a loose fit. An evaluation of corneal changes that might have occurred as a result of wearing the Silsight contact lens will be accomplished be a series of complete progress exams to include: a complete refraction, monitoring changes of corneal thichness (edem) using the electronic pachometer, changes of cornea curvature using the keratometer and biomicroscopy evaluation. All aspects of patient care including supervision of patients by qualified clinical staff will be at a level equal to that provided to non-research patients receiving comparable lenses through the Pacific University College of Optometry Clinic.

V. RISKS

Risks involved are: the same for any type of first time contact lens wearer. there is a slight chance that the patient may report these symptoms:

a. lens becomes less comfortable than when first placed on the patients eye.
b. burning, itching or stinging eyes.
c. excessive watering (tearing) or unusual secretions.
d. blurred vision, decreased visual acuity may affect driving and other related activities.
e. light sensitivity (photophobia)
f. redness of the eyes.
g. dry eyes
h. slight possibility of allergic reaction to chemical disinfection solutions.

If the patient notices any of the above, he/she will be instructed to remove the lenses and check them. If the problem stops upon removal and the lenses appear undamaged, the patient will thoroughly clean,rinse, and disinfect the lenses and reinsert them.

If the problem continues or if the lenses appear damaged, immediate consultation with the investigators or advisor will be required.

VI. MONITORING

Monitoring the subjects will be in the form of follow-up examinations. The examinations will include an assessment of lens movement, centration, comfort, and fluorescein pattern. An inspection of the corneas for any irregularities will be performed using the biomicroscope. Any subjective symptoms will be solicited. Those subjects that are fit with contact lenses designated as a steep or loose fit will be restricted to a wearing time of two hours a day. The first follow-up exam will be the day after dispensing of the lenses. The second progress exam will be one week after dispensing. The third exam will be three weeks after the initial dispensing. Subsequent progress exams and aftercare will be by the normal contact lens clinic of Pacific University College of Optometry. Regular clinic fees will be charged for this aftercare.

VII. INFORMED CONSENT FORM

See attached copy of Human Subject Release Form.

VIII. DATES AND SIGNATURES

The project will run from June 1984 through January 1985

Date submitted: June 6, 1984

FACULTY ADVISOR

_____

Don C. West, O.D.

STUDENT RESEARCHERS

_____

Russell Au

_____

Roy Matsumoto

_____

Doug Olsen

_____

Joe Ryan

_____

Nelson Yoshioka

HUMAN SUBJECT RELEASE FORM

INSTITUTION

A. Title: A Study and Photodocumentation of the Lens-Cornea Fitting Relationship of the Silsight Contact Lens

B. Investigators:

Russell Au	359-5397	Roy Matsumoto	357-7495
Doug Olsen	357-0278	Joy Ryan	357-0716
Nelson Yoshioka	359-4847		

C. Advisor: Don C. West, O.D.

D. Location: Pacific University College of Optometry
Forest Grove, OR 97116

E. Date: Project will run from June 1984 through January 1985

DESCRIPTION OF PROJECT

This project is designed to clinically photodocument the fitting of the Silsight contact lens and study any physiological or refractive changes that may occur from the daily wear of this lens. The study will require a series of complete progress examinations over a four week period. After termination of the research project, aftercare will be by the normal contact lens clinic of Pacific University College of Optometry. Regular clinic fees will be charged for this aftercare.

DESCRIPTION OF RISKS

There is a 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 or other related activities)
- light sensitivity
- redness of the eye
- dry eyes
- irritation of the eye
- very slight possibility that abrasions, infections, and corneal ulcerations may occur.

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 re-insert 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 fitting characteristics of the Silsight contact lens and will eventually contribute to a better understanding of the principles involved in fitting these lenses.

COMPENSATION AND MEDICAL CARE

If you are injured in this experiment it is possible that you will not receive compensation or medical care from Pacific University, the experimenters, or any organization associated with the experiment. All reasonable care will be used to prevent injury.

ALTERNATIVES ADVANTAGEOUS TO SUBJECT

Not applicable

OFFER TO ANSWER ANY INQUIRES

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

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. If you choose to discontinue participation in this project, the lenses and supplies must be returned to the investigators.

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 _____

Address _____

City _____ State _____ Zip _____

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

Name _____ Phone _____

Address _____

_____

Photographic/Model Release

I _____ give permission to Pacific University College of Optometry to photograph me for research purposes. Such photographs may be used in association with articles, presentations or displays in which the results of various research projects are reported. No commercial use may be made of my photographs. I understand that I may be identifiable in these photographs. I am 18 years of age or older (this form is signed for me by my parent or guardian if required)

Name _____

Address _____

_____

Date _____

Signed _____

Project: A Study and Photodocumentation of the Lens-Cornea Fitting Relationship of the Silsight Contact Lens