SENIOR RESEARCH PROJECT

A Study of the In Vivo Movement of the Dow-Corning Silsoft Contact Lens

Submitted By

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INTRODUCTION

The requirements of a new contact lens material are many and varied. A contact lens material must fulfill optical, physical, and physiological requirements. A few of the optical and physical requirements are high transparency to visible light, stable optical quality, reproducability, and wettability. The major physiological requirements of a contact lens material and design are chemical inertness, and physiological tolerance with adequate wearing time. It is a general opinion that a contact lens must influence the corneal metabolism as little as possible. One of the most important criterion is the oxygen requirement of the cornea. If the oxygen suppying the cornea drops below a critical level, the aerobic metabolism cannot be maintained and the corneal swelling occurs.

For many years several companies in America and Abroad have experimented with silicone elastomers as a contact lens material. The silicon rubber material has many properties which make it attractive for this purpose. The most appealing of these properties is the high oxygen transmissibility, strengh, and durability.Elastoficon A's (the generic name for the Dow-Corning Silsoft lens) chemical structure is the key to these unique combination of properties. (see figure I)

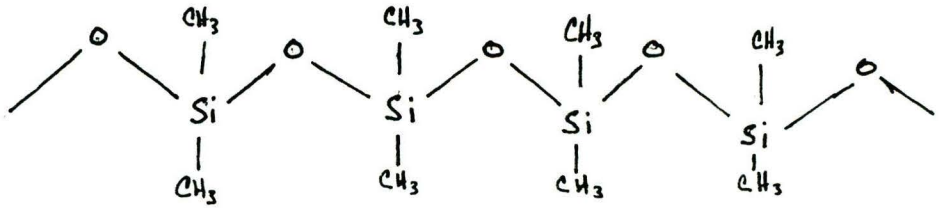

FIGURE I

As described by Fitzgerald, the structure provides for 'polymer chain motion', which in turn results in 'holes' by which oxygen and carbon dioxide are easily diffused. The polymer chains are also cross linked to give it strengh and durability. Hill has shown that silicon rubber lenses

do not result in glycogen depletion with prolonged wear as compared with hydrophilic lenses of high water content. Another chief property of silicone is it's hydrophobicity. In a contact lens, wettability of the lens surface is one of the most important properties. To retard the problem, manufacturers have to add, by grafting or ionization, surface molecules that are hydrophilic. Unfortunately, this process appears to decrease the gas permeability of the material slightly.

In many respects, silicone appears to be the ideal material for contact lenses: it's pliability results in greater comfort, it's inability to absorb water results in stable optical properties, while it's high oxygen permeability makes it a prime candidate for continuous wear. It is with this enthusiasm that silicon lenses were first introduced to the market in West Germany and Japan in 1978. Shortly after their introduction, a number of serious problems were observed among silicon lens wearers. The most outstanding and serious complication was termed sterile kerititis by Roth, et.al. In a few cases, ulcers occured in the center of the cornea. Usually these patients were asymptomatic, and their lenses had ceased moving due to a suction effect under the lens.

Fatt measured the suction power of a silicone elastomer lens by using an artificial cornea and an hydrolic manometer. His findings indicated an increase in negative pressure of 4.0mm when the lens was steepened 0.3mm to 0.5mm. When the lens is pressed onto the cornea, as during a blink, negative pressure is built up which results in suction. This suction then eliminates any tear exchange under the lens. The resulting sterile kerititis is thought to be caused by an allergic reaction to the toxic by-products of de-vitalized cells and protein substances. Therefore, even though the gas permeability property of silicone is highly sought after, it's elastic properties can lead to a

total obliteration of the tear pump under the lens. Furthermore, this condition usually results in an asymptomatic patient while the lens is in place, which may allow for the condition to worsen before the patient or doctor is made aware.

With these and other complications of silicon lenses in mind, the Ministry of Welfare in Japan suspended selling of silicon lenses in 1979. In the United States, Dow-Corning Ophthalmics has recieved FDA approval for it's Silsoft and Silcon contact lenses. The developers claim to have solved many of the problems inherent in a silicone material such as hydrophobicity, and more importantly, adherence of the lens to the cornea.

The main objective of this study is to assess the performance and movement of the Silsoft contact lens, and to determine if or when the lens would adhere to the cornea. The conditions which were varied were wearing time and base curve. By doing this, a model may be developed by which the private practitioner may avoid the possible adherence complications previously noted.

MATERIALS AND METHODS

Three patients were selected for the study. All were white females between the ages of 19 and 23, with low myopic refractive errors, and approximately equal K's in each eye. All had previously worn contact lenses. After a routine examination and evaluation of the lacrimal apparatus, related adnexa, and tear break-up time, all were fitted with the Dow-Corning Silsoft lenses. All fitting was on K, or as close as possible, and within acceptable movement and comfort criteria as specified by the manufacturer (see table I for K readings, refractive errors, and lens parameters). Patients were then instructed on care and handling and given a routine wearing schedule with follow-up appointments according to manufacturers instructions. After two weeks of normal, full time wear, testing was begun

on the lens movement. Patients were tested with a scale of base curves ranging in radius from 7.5mm - 7.7mm with a 12.5mm diameter lens, and 7.5mm - 8.3mm with a 11.3mm diameter lens.

Recording was done by means of videotaping lens movement thru a slitlamp. Our filming and recording apparatus consisted of a Nikon Zoom Photoslitlamp set at 10x power, and a Sanyo Viewfinder camera, with a Fujinin-TV 1:1.8/75 lens, mounted on a tripod. The camera was aligned to view directly thru the ocular of the slitlamp. Recording was made on a Sony (VO-2600) videocassette recorder using: Scotch UCA 60 minute color videocassette tape.

Patients were aligned in the slitlamp and then told to blink normally while watching the fixation light. Filming was done for approximately 20 seconds with each eye. Movement was filmed 15 minutes after insertion, and at four hours after insertion* (see table II).

After documenting movement we then filmed (though the slitlamp) a 10mm reticle placed in the same plane as the patients eye. The recording of the reticle was then played back on a Sony Trinitron video screen and the reticle was copied from the screen onto clear acetate. Our acetate measuring grid was then placed over the screen and used to measure movement of the contact lenses. This gave us an exact 10mm scale using the same relative magnification.

RESULTS

As can be seen in table III, the Silsoft lens movement was consistently reduced after a wearing time of four hours. Possible causes for this reduction in movement are:

1. Elasticity of the polymer which may result in a negative pressure gradient between the lens and the

* On the graphs, the initial time is recorded as '0' time for convenience, although 15 minutes was given to allow the lens to settle.

cornea, precipitated by the lids forces acting on the lens during the blink. This inturn eliminates the 'tear pump' resulting in the complications noted earlier.

2. Reduced tearing due to normal adaptation to the lens. This was partially negated by allowing a fifteen minute 'settling' period before filming.

3. Outside temperature and humidity.

4. Diurnal variations in tear production.

These factors may lead to a substantial reduction in lens movement over time. The amount of lens tightening appears to be correlated with the lens-cornea relationship, with the steeper base curve or larger diameter showing the largest reduction in movement over time. Some lenses reduced movement up to almost 2.0mm, and one lens was observed to have adhered to the cornea.

Two exceptions to this rule of decreased movement over time were lenses that were fit excessively flat. The flattness and looseness of the fit probably resulted in an increased lid sensation as the wearing time progressed. Increased lid sensation will then lead to tearing and an increased blink rate, which inturn results in increased lens movement.

DISSCUSION

In Reviewing the data, we found our best movement when fitting the lens either "on K" for slightly "flatter than K". Basically, we we felt the best fit was one that gave us maximum movement while still centering, and without sacrificing the optical or comfort criteria. The 11.3mm diameter lens was the lens of choice in fitting, and the 12.5mm diameter was only nessasary on very steep corneas, or where proper fitting could not be achieved with the 11.3mm lens (note here that corneal coverage is not required with the silsoft lens.). There was more of an adaptation period with the 11.3mm lens, this however was not a problem using a proper wearing schedule.

CONCLUSION

It appears as though the Silsoft lens can be safely used if the proper fitting proceedures are followed. However, the Silsoft lens, with the smaller diameter, produces increased lid sensation and tearing when first worn by the patient (as compared with conventional soft lenses). This results in increased lens movement which can be misleading to the clinician. The gradual alleviation of lid sensation combined with the natural elasticity of the material may lead to a physiologically comprimising situation. If the lens is fit too steeply, a marked reduction in movement over time can occur, as was demonstrated. Therefore, the practitioner should allow for adequate lens movement by careful fitting proceedures and proper follow-up evaluation. With these factors in mind, the private clinician should be able to take advantage of the many benificial properties that the silicone material offers.

Patient		Refractive Error	K's	Base Curve	Diameter	Power
J.D.	O.D.	-1.75	45.50/ 46.25	7.5	12.5	-1.75
	O.S.	-1.75	45.00/ 46.00	7.5	12.5	-1.75
T.R.	O.D.	-1.75	41.50/ 42.37	8.1	11.3	-1.75
	O.S.	-1.75	41.25/ 42.50	8.1	11.3	-1.75
S.C.	O.D.	-1.00	42.25/ 44.25	7.9	11.3	-1.00
	O.S.	-1.25	42.37/ 44.25	7.9	11.3	-1.25

TABLE I

		7.5(11.3)	7.7(11.3)	7.9(11.3)	8.1(11.3)	8.3(11.3)
T.R.	0 hr	2.02mm	0.50mm	0.50mm	0.73mm	0.50mm
	4hr	0.10mm	0.28mm	0.30mm	0.53mm	0.15mm

		7.5(12.5)	7.7(12.5)	7.5(11.3)	7.9(11.3)
S.C.	0hr	0.13mm	0.35mm	1.32mm	0.68mm
	4hr	0.0mm	0.08mm	0.55mm	0.80mm

		7.5(12.5)	7.7(12.5)	7.9(12.5)	8.1(12.5)
J.D.	0hr	0.53mm	1.03mm	0.74mm	0.62mm
	4hr	0.02mm	0.50mm	0.08mm	0.48mm

*NOTE: '0' time is actually 15 minutes after insertion to allow for the lens to settle.

TABLE II

MOVEMENT DATA

Patient: T.R.

Lens 1, 7.55(11.3) - O.D.	0hr:	n=6, $\bar{x}$=2.02, σ_n=0.234
	4hr:	n=6, $\bar{x}$=0.1, σ_n=0.082
Lens 2, 7.7(11.3) - O.S.	0hr:	n=6, $\bar{x}$=0.5, σ_n=0.115
	4hr:	n=6, $\bar{x}$=0.28, σ_n=0.069
Lens 3, 7.9(11.3) - OD	0hr:	n=6, $\bar{x}$=0.5, σ_n=0.082
	4hr:	n=6, $\bar{x}$=0.30, σ_n=0.100
Lens 4, 8.1(11.3) - OD	0hr:	n=6, $\bar{x}$=0.733, σ_n=0.149
	4hr:	n=6, $\bar{x}$=0.533, σ_n=0.245
Lens 5, 8.3(11.3) - OS	0hr:	n=6, $\bar{x}$=0.05, σ_n=0.01
	4hr:	n=6, $\bar{x}$=0.15, σ_n=0.03

Patient: S.C.

Lens 1, 7.5(12.5) - OS	0hr:	n=6, $\bar{x}$=0.13, σ_n=0.047
	4hr:	n=6, $\bar{x}$=0.00, σ_n=0.00
Lens 2, 7.7(12.5) - OD	0hr:	n=6, $\bar{x}$=0.35, σ_n=0.05
	4hr:	n=6, $\bar{x}$=0.08, σ_n=0.06
Lens 3, 7.5(11.3) - OD	0hr:	n=6, $\bar{x}$=1.32, σ_n=0.27
	4hr:	n=6, $\bar{x}$=0.55, σ_n=0.07
Lens 4, 7.9(11.3) - OS	0hr:	n=6, $\bar{x}$=0.68, σ_n=0.18
	4hr:	n=6, $\bar{x}$=0.80, σ_n=0.15

Patient: J.D.

Lens 1, 7.5(12.5) - OS	0hr:	n=6, $\bar{x}$=0.53, σ_n=0.05
	4hr:	n=6, $\bar{x}$=0.016, σ_n=0.01
Lens 2, 7.7(12.5) - OD	0hr:	n=6, $\bar{x}$=1.03, σ_n=0.37
	4hr:	n=6, $\bar{x}$=0.50, σ_n=0.058
Lens 3, 7.9(12.5) - OD	0hr:	n=6, $\bar{x}$=0.74, σ_n=0.13
	4hr:	n=6, $\bar{x}$=0.08, σ_n=0.034
Lens 4, 8.1(12.5) - OS	0hr:	n=6, $\bar{x}$=0.62, σ_n=0.11
	4hr:	n=6, $\bar{x}$=0.48, σ_n=0.089

DIFFERENCE BETWEEN $\bar{X}_0$ and $\bar{X}_4$

Patient: T.R.

Lens 1	-1.92mm
Lens 2	-0.22mm
Lens 3	-0.20mm
Lens 4	-0.20mm
Lens 5	+0.10mm

Patient: S.C.

Lens 1	-0.13mm
Lens 2	-0.27mm
Lens 3	-0.77mm
Lens 4	+0.12mm

Patient: J.D.

Lens 1	-0.15mm
Lens 2	-0.53mm
Lens 3	-0.66mm
Lens 4	-0.14mm

NOTE: Minus values indicate that the lens tightened on the eye. While positive values indicate the lens loosened.

TABLE III

DECREASE IN MOVEMENT OVER TIME
INCREASE IN MOVEMENT OVER TIME
T.R.
S.C.
J.D.
1.92
0
.1
.2
.3
.4
.5
.6
.7
.8
.9
1.0

GRAPH I

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