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CLINICAL INVESTIGATION OF THE WEARABILITY OF THE

BAUSCH AND LOMB LOW PLUS SOFLENS

by

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INVESTIGATION OF THE WEARABILITY OF THE B&L LOW PLUS SOFLENS

INTRODUCTION

The Bausch and Lomb Soflens has been available in the United States since 1971.[1] However, until recently, fitting was restricted to the myopic or high hyperopic individual. It was not until the early part of 1974 that the Soflens was made available to the low or moderate degree hyperope. This is a study report of the investigation of the clinical aspects in the fitting of the Low Plus Bausch and Lomb Soflens.

PROCEDURE

It was initially intended that the patient selection be from the optometry student body since appointments and examinations would be easier for these patients. With the lack of hyperopes available for study, however, patients were also taken from the public. Each patient wishing to be part of the study underwent the following tests and evaluations: corneal measurements, fissure dimensions, blink rate, lid tension, pupil size measurements, a complete analytical examination, visual fields, tonometry, central and peripheral keratometer readings, a complete biomicroscopic examination and exterior eye photography. Individuals considered for the study were limited to those hyperopes falling in the range of +0.25 to +6.00 diopters of hyperopia, having no active pathological conditions, and not currently taking any ocular medication. Motivation, reliability, and hygenic habits were also evaluated and considered very strongly in the patient selection. Individuals meeting the above criteria were then initially fitted with the Soflens.

The lens of first choice was based on the refractive data of that patient, where the marked power was equal to the spherical component of the patient's refractive error.[2] The lens was then placed on the patient's eye, and he was allowed to wear the lens for approximately twenty minutes before an evaluation of the fit of the lens was made. At the end of that time, the following data was gathered: Visual acuity, keratometry readings over the lenses for an evaluation of lens distortion while it was on the eye, centering, lag, over-refraction, and a check on lens wetting.[3] If, at this time, the over-refraction indicated a need for a change in lens power, this change was made. If the lens appeared to be centering well and the power was correct, the patient was then instructed on the proper care and handling of the Soflens. This included insertion and removal training, distinguishing a properly oriented lens from an inverted lens, cleaning, ascepticizing and storage,[4] and the wearing schedule for the following week. Before the patient left the clinic, the lenses were verified[5] and the patient was instructed to return for his first progress evaluation after wearing the lenses for four hours.

The cleaning procedure for the Soflens patients was as follows. The only chemical solution used was 0.9% saline. Patients were instructed to clean the lenses immediately after removal by placing then in the palm of the hand and rubbing with the index finger. After rinsing the lenses, they were placed in the ascepticizing unit and sterilized for no less than twenty minutes.

At the end of the first four hours of wear the patient was examined and the following determinations were made: visual acuity, centering, lag, keratometer readings over the lenses, over-refrac-

tion, keratometer readings after lens removal, and an extensive biomicroscopic examination. During the biomicroscopic examination, a check on the location and concentration of conjunctival injection and corneal edema was made. Special attention was also given to the circumcorneal blood vessels in order to detect any engorgement of the vessels or their infringement onto the cornea. The lenses were then removed and fluorescein was used to locate any corneal epithelial erosion. The patient was then instructed not to wear the lenses for the remainder of the day so as to prevent the Soflens from being affected by the remaining fluorescein. After removal of the lenses, they were inspected under a microscope and any lenses suspected to be defective were replaced.

Patients exhibiting good adaptive signs at this point were put on a wearing schedule of four hours the first day, and then increased their wear by one hour per day up to a maximum of eight hours per day of continuous wear. At one week after dispensing, the patient's progress was again evaluated, using the same techniques just mentioned. Again, if progress was satisfactory, he was told to continue adding one hour per day up to full time wear and another progress evaluation was done one week later. Subsequent progress evaluations were then done at four weeks, twelve weeks, and before releasing the successful patient for full time wear (usually 24 weeks).

RESULTS

Determining the qualifications for a successful fit was difficult since both patient responses to the lenses and desires of patients varied greatly. It was found, however, that in all cases but one, the objective signs found in the examinations and subjective comments brought forth by the patient were in agreement, and thus

helped to identify the patient as either successful or unsuccessful. In the one exception, the objective signs of mild corneal erosion and moderate injection warranted a classification as unsuccessful even though the patient's report of the lenses was satisfactory and he desired to wear them full time.

A successful fit was defined as the ability to wear the Soflens full time with no objective symptoms, no metabolic changes of the cornea and surrounding structures, and no subjective complaints. More specifically, a successful patient was one who had comfortable vision while wearing the lenses, demonstrated normal appearance, manifested visual acuity within one line of previous visual acuity with conventional contact lenses or spectacles, as well as show no injection, edema, corneal erosion, or corneal curvature changes for the amount of time he desired to wear the lenses each day.

Under the criteria thus stated, 50% of the patients initially fit with the Soflens were successful. Edema, severe injection, and corneal epithelial erosion were the most widely noticed objective signs of the unsuccessful fit. In most cases, significant inferior decentration of the lenses was believed to be the main problem. It was noted that patients who exhibited a decentered lens of two millimeters or more were rarely successful. With a decentered lens of this magnitude, the patient's ability to wear the lens was good for the first four hours. If he continued to wear the lenses longer than this four hour time period, visual acuity dropped, comfort decreased, and the typical objective signs of edema, injection, and corneal erosion were found. With the low hyperope of 1.50 diopters and less, a decentered lens of two millimeters or more resulted in unsatisfactory visual acuity. With

higher magnitudes of hyperopia, the lenses, even when decentered two millimeters inferiorly, did not affect the patient's acuity to any degree.

With the inferior positioning lenses, subjective symptoms were similar among patients. These included poor acuity, complaints that objects were hard to focus, and that the lenses made the eyes tired after wearing them three or four hours. Objective symptoms were also very similar. These included slight edema in the central-inferior region of the cornea and corneal erosion in this and other regions of the cornea. If the lens wear was continued by these patients, visible changes could be detected in the circumlimbal areas of the cornea, especially the inferior corneal-limbal junction, where there was a slight encroachment of small vessels. Patients who showed these signs were then taken off the Soflens study, dismissed for a time, and then brought back at a later date for a progress examination to see if the problems had cleared up.

Patients wearing a well-centered lens did not have the objective and subjective problems which were present in a decentered lens, especially the inferior positioning lens. It is interesting to note that in all cases where the patient demonstrated good lens centration (one millimeter or less of inferior lens decentration) success was attained. Beyond the first two weeks of adaptation, the problems of edema, corneal erosion, and circumcorneal injection, so common in the patient with a poorly centered lens, was negligible. From the table, it can be readily seen how both subjective and objective symptoms decreased in number and severity as the patient's

wearing time progressed. Normal adaptive symptoms usually lasted two weeks and consisted mainly of a slight irritation or awareness of the lens, slight hotness, and a drying of the lens.

Corneal curvature measurements taken after removal of the lenses showed insignificant changes due to the lenses. **Progress examinations showed** no significant differences between initial and post fitting curvatures, with an average being that of 0.12 diopters steeper in the flattest meridian after the lenses were worn and removed.

In comparing the results of previous hard contact lens wearers now fit with the Soflens, the results were of interest. In 33% of the patients fit with the Soflens, attempts had previously been made with conventional hard lenses which were unsuccessful. Of these, 50% were successfully fitted with the Soflens. Therefore, the Soflens may be the lens of choice with a patient having problems with the conventional hard lenses.

It is interesting to note the high correlation existing between good centering and the peripheral keratometer readings. With one exception, patients showing inferior peripheral corneal flattening of 2.00 diopters or more by the third dot on the Jessop's Disc proved to have good centering and were successful Soflens wearers. The one exception was a patient who was completely successful objectively and subjectively except that he had a complaint of asthenopia when doing near tasks, and a low refractive error (+0.75), and the lenses did not take care of his complaint so he discontinued wearing the lenses. It can be seen from the table that where peripheral corneal flattening inferiorly did not occur, the patient was usually an unsuccessful wearer.

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A final observation was that the most successful patients were those in which the posterior apical radius of the lens was 2.00 to 2.50 diopters flatter than the flattest central corneal curvature. With these patients, the adaptation time was shorter, the subjective and objective symptoms less severe, and the visual acuity better and less variable.

CONCLUSION

The Bausch and Lomb Low Plus Soflens series does offer some advantages to the moderate to low degree hyperope. A decreased adaptation time and fewer symptoms occur with the Soflens as compared to hard contact lenses. Besides almost immediate comfort to the patient, the Soflens also has another distinct advantage over the conventional hard lens, in that Soflens wearers can be part time or erratic wearers. Once the patient has demonstrated the ability to successfully wear the lens, an erratic wearing schedule is available to the patient if he so desires. Spectacle blur after lens removal is minimal, and this fact suggests another advantage over hard contact lenses.

RECOMMENDATIONS

Screening methods should include patient motivation as one of the primary factors, even though the adaptation period is much reduced over conventional contact lenses. Cleaning requirements, slight adaptation problems, and handling difficulties are a few of the reasons accounting for this. It is advised that peripheral and central keratometer readings be made on the patients before fitting, and from this a reasonably valid success prediction can be made. Also, if a lens does not center even if all indications would suggest that it should, an attempt to use

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another lens of the same power may improve the centering, due to small differences in lens constructions of supposedly identical lenses (those with same series and same marked power).[6] Finally, progress evaluations should be scheduled at least every six months after full time wear is established, so that an appropriate evaluation of any progressive changes can be made.

SUCCESSFUL PATIENTS

PATIENT	REFRAC. ERROR	POST. APICAL RAD. vs. CENT. K's	CORN. FLAT. (3rd inf. dot)	INF. LENS DECENT.	V.A.	LENS POWER	
R.R.	+2.50-0.25 x 26	2.25 D flat	2.12 D	1-2 mm.	20/15	+2.25N	
	+2.50-1.00 x 155	2.87 D flat	2.75 D	1-2 mm.	20/15	+2.25N	
A.P.	+5.25 sph.	3.50 D flat	2.00 D	2 mm.	20/15	+4.25N	
	+5.75 sph.	4.00 D flat	1.75 D	2 mm.	20/40*	+5.25N	*Amblyopic eye
E.B.	+2.00-0.50 x 60	3.00 D flat	2.00 D	.5 mm.	20/15	+1.75N	
	+1.50 sph.	2.75 D flat	1.75 D	.5 mm.	20/15	+1.50N	
M.D.	+1.00-0.50 x 100	0.12 D flat	1.37 D	.5 mm.	20/15	+0.50N	
	+0.75 sph.	0.50 D flat	1.37 D	.5 mm.	20/15	+0.50N	
J.H.	+2.00 sph.	0.37 D steep	2.00 D	3 mm.	20/15	+1.50N	
	+4.00 sph.	1.75 D flat	2.50 D	3 mm.	20/15	+3.25N	
L.B.	+1.50-0.75 x 180	1.87 D flat	1.62 D	1 mm.	20/20+	+1.25N	
	+2.50-0.75 x 180	2.12 D flat	0.62 D	1 mm.	20/20+	+1.50N	

UNSUCCESSFUL PATIENTS

PATIENT	REFRAC. ERROR	POST. APICAL RAD. vs. CENT. K's	CORN. FLAT. (3rd inf. dot)	INF. LENS DECENT.	V.A.	LENS POWER	
S.W.	pl sph						Poor acuity due to residual astigmatism through lens.
	+3.00 sph.	3.50 D flat	0.75 D	1-2 mm.	20/20	+2.50N	
J.T.	+0.50-0.25 x 95	on K	1.75 D	0 mm.	20/15	+0.50N	Lenses did not solve near complaint and were not worthwhile.
	+0.50 sph.	on K	2.00 D	0 mm.	20/15	+0.25N	
D.E.	+0.75-0.25 x 180	0.37 D flat	1.00 D	3 mm.	20/20-20/40	0.50N	
	+0.75 sph.	0.25 D flat	1.12 D	3 mm.	20/20-2-/40	0.25N	Acuity was too variable.
F.M.	+1.25-0150 x 165	2.50 D flat	2.12 D	0 mm.	20/15	+0.50N	Acuity was too variable and not as good as with spectacles
	+1.00 sph.	2.62 D flat	0.37 D	1 mm.	20/20	+0.75N	
D.M.	+2.25-0.75 x 90	1.62 D flat	0.75 D	2 mm.	20/20	+1.00N	Edema and scleral and limbal injection.
	+2.25-0.75 x 105	1.25 D flat	0.75 D	2 mm.	20/20	+1.00N	
E.B.	+3.75-0.25 x 45	5.50 D flat	0.00 D	2.5 mm.	20/50	+3.25N	Poor acuity after 4 hours due to poor centering.
	+3.75-0.50 x 105	5.75 D flat	0.75 D steep	2.5 mm.	20/50	+3.25N	

SUBJECTIVE AND OBJECTIVE SYMPTOMS OF

LOW PLUS SOFLENS PATIENTS

1 day (4 hours)

Fluctuating acuity
Feeling of dryness
No visible edema
Mild circumcorneal injection (less than
0.50 mm onto cornea)
Occasional superficial corneal erosion
Mild scleral injection

1 week

Occasional fluctuating acuity
Lenses feel dry at the end of wearing time
Mild circumcorneal injection (less than
0.50 mm onto cornea)
Superficial punctate corneal erosion,
especially on inferior cornea
Mild scleral injection

2 weeks

Occasional feeling of dryness, usually at
the end of wearing time
Mild circumcorneal injection (less than
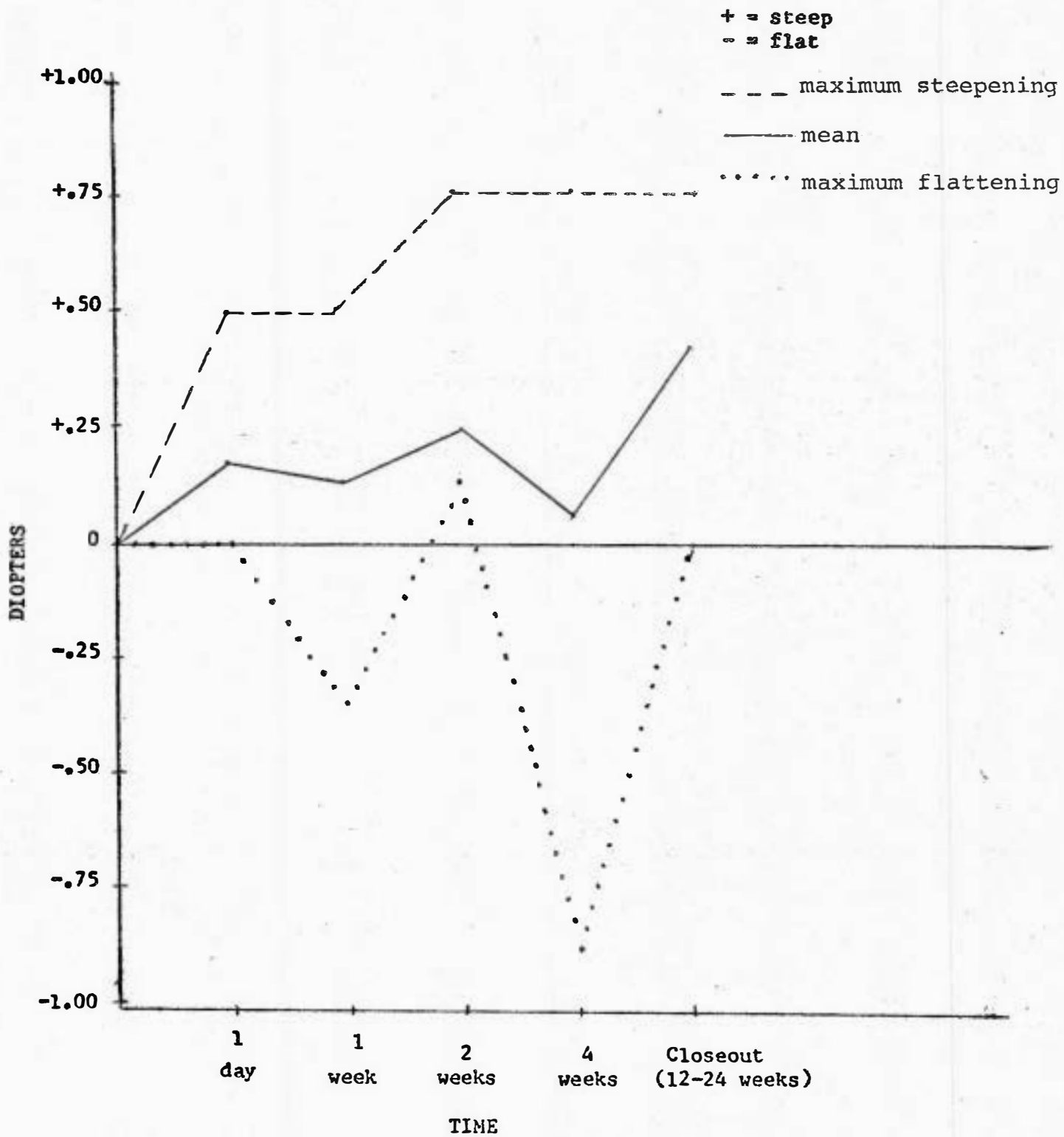at one week)
Very mild scleral injection

4 weeks

Very mild circumcorneal injection (of lesser
degree than at two weeks)

Closeout (12-24 weeks)

None

AVERAGE CHANGE IN CENTRAL "K" READING
FLATTEST MERIDIAN

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