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A clinical evaluation of extended wear contact lenses

Abstract

A clinical evaluation of extended wear contact lenses

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A CLINICAL EVALUATION OF
EXTENDED WEAR CONTACT LENSES

By

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Robert D. Lunde

Kevin M. Moore

In Partial Fulfillment of the Requirements for
the Doctor of Optometry Degree
Pacific University College of Optometry

Dr. Don C. West, Advisor

March 1984

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WEST BEND, OREGON

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A CLINICAL EVALUATION OF
EXTENDED WEAR CONTACT LENSES

Everyday an increasing number of patients are seeing practitioners with a desire to wear the lenses that can be "left in overnight." They are convinced that successful extended wear of contact lenses is easy when in actuality it involves a complicated process. This process includes patient motivation, proper contact lens material, successful contact lens fit compatible to the eye's physiology for full-time wear, and strict patient management.

The production of a lens that allows continuous wear without significant compromise to the patient has reached a high technical level. The high water content lens and super thin design have made possible the approval of contact lenses for continuous wear. Laboratory tests have shown these lenses allow sufficient oxygen transmission to prevent corneal hypoxia during extended closed eye environmental conditions.

Although these designs and materials have been approved for continuous wear, certain problems may develop. Phillips cites the following list of pathology associated with extended wear lenses:¹

1. Neovascularization -- superficial, noninfective, and stromal.
2. Superficial edema with Descemetes folds.
3. Endothelial edema and necrosis.
4. Anterior uveitis.
5. Follicular conjunctivitis.
6. Keratoconjunctivitis.
7. Infiltration of fibroblasts, white cells and lipids.
 - a. superficial, stromal, and with vessels.
8. Chronic superficial keratopathy.
9. Stromal lysis with marginal degeneration
10. Hypertropic epithelial reaction.
11. Corneal abscess.

He states these problems associated with the extended wear lenses take much longer to resolve; up to weeks or months longer than the same problems

not associated with soft contact lenses.

One reason some of these problems develop is due to deposits of material on the lens surface.² Cordrey proposes the following mechanism in the development of follicular conjunctivitis of extended wear lenses:³

The papillae are a result of an autoimmune reaction by the eye to protein absorbed onto the surface of the lens. The tear fluid proteins are altered geometrically, not structurally, upon coming into contact with the polymer structure.

He also states that his data shows that protein accumulation is a function of the fit of the lens, each type of lens being different. This autoimmune response should only be clinically significant with patients who have a predisposition to sensitified reactions.

Since the cleansing of lenses is an important part of lens care, the effects of long term wear without daily lens cleaning must be considered. Fowler and Allansmith⁴ compared the surface of extended wear lenses that weren't cleaned to those that were cleaned daily. The non-cleaned lenses showed a smooth, completely covered surface with no bare areas. The thickness of the coating varied with 2 microns being the average thickness. There were some areas that showed fresh deposits of a granular mucus-like material. Enmeshed in the coating were bacteria-like forms. The daily cleaned lenses also showed some coating, but the coating was not continuous and much thinner. They concluded that in the first few minutes of wear, cells and mucus adhere to the lens surface and layers are then added onto the initial one. Daily cleaning with occasional enzyming would not remove all of the deposits. This study provided valuable insight on the effect of coating to oxygen transmissibility of the lens. This must be considered as a reason for unsuccessful continuous wear.

Phillips⁵ reported two general types of deposits seen on extended wear lenses. One was a general diffuse, denatured proteinaceous layer or

areas that was common to all types of hydrogel lenses. The second type consisted of small areas of white spots. In their study, 10% of the extended wear patients experienced these spots. If they were removed, they usually left pits in the lenses that resulted in replacement of 50% of the lenses. More white spot deposits were seen in poor blinkers, dry eyes and loose fitting Permalens. He described these white spots as being composite structures built up of layers of different materials, probably from extraocular gland secretions.

Stein and Slatt⁶ reviewed the performance of 46 extended wear patients and found lens deposits to be the major problem. Their overall success rate was greater than 60%. They concluded that extended wear lenses of less than 60% water produced too many acute and chronic problems and greater than 60% water content produced no acute reactions. In direct opposition to Stein and Slatt's conclusion, Cordrey⁷ states that there is no evidence yet to suggest extended wear lenses contribute to disease, although he adds it is possible that patient error will have more serious consequences than daily wear.

Phillips⁸ broke down the possible consequences of red eye in the extended wear lenses:

- 1) The rate of epithelial breakdown was greater than the re-generation rate due to anoxia or poor fitting lenses.
- 2) Deposits on the lenses.
- 3) Cell debris trapped behind the lens creating a toxin-antibody response.
- 4) Conjunctivitis-like reaction due to pathogens trapped by mucus adhesions.

One and/or several of these may contribute to unsuccessful extended wear.

In Dreyer's⁹ study on 167 extended wear myopes, his success rate was 69%. There was no sex difference and no dependence on previous contact

lens experience. All subjects were over 20 years old having between 1.50 to 5.00 D myopia with less than 1 D of corneal astigmatism. The highest rate of discontinuation was found before three months and the percentage of discontinuance was diminished by half in the last three months. The major reason for discontinuation of lens wear was diagnosed as conjunctivitis, which was significantly more common than expected in the general population.

Most of the studies reviewed showed the average lens life to be between 5 to 7 months. Loss of lens was the number one reason for replacement with lens deposits being a close second. All of the studies reviewed concluded with extended wear lenses being safe for a selected population, but they also present greater risk to the patient and doctor over daily wear lenses.

The studies cited by Tiller, Snapp, and McMurray¹⁰ addressed the clinical significance of changes in corneal thickness, corneal neovascularization and lens replacement due to lens deposits associated with extended wear. With the information provided by the studies cited above and by Tiller, et al, this study will further pursue the clinical evaluation of extended wear lenses.

METHOD OF EVALUATION

The method of evaluation for the continuation of the Tiller, et al,¹¹ study are the same as the original study. They will be repeated here to facilitate reference to the tables. The same standards and methods of clinical examination were performed also. The tables that follow were repeated from the original study.¹²

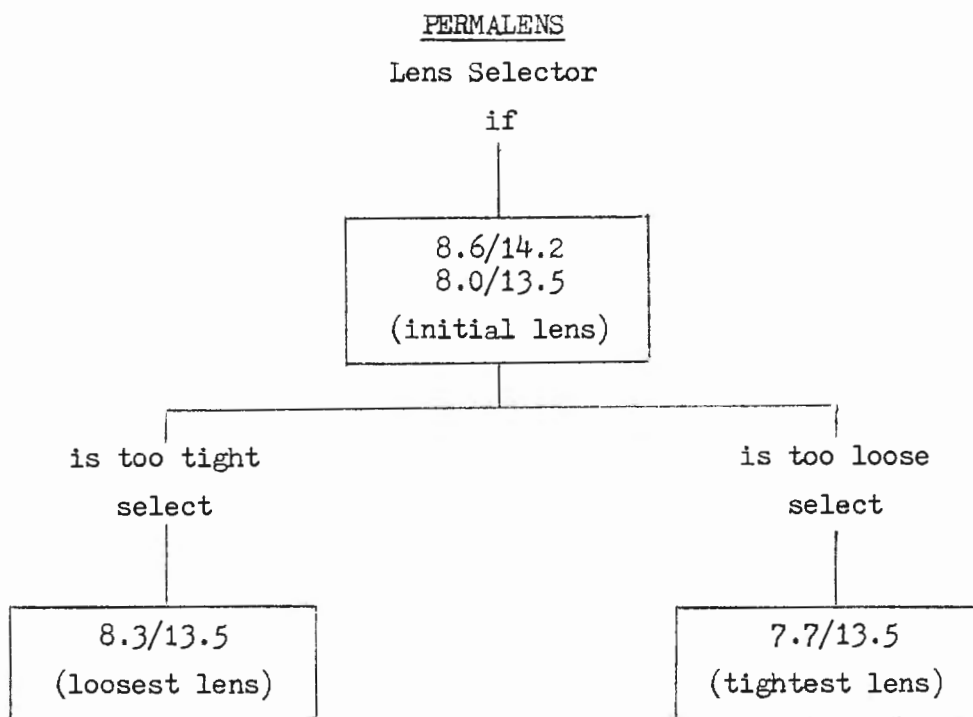
METHOD OF EVALUATION

The subjects for this project were comprised of Pacific University Optometry students and/or their spouses. Selection was based on criteria that would normally be utilized in a clinical setting to determine the likelihood of success for extended wear contact lenses. The criteria are as follows:

- (1) Phakic eyes only.
- (2) Best correction of 20/30 or better.
- (3) Astigmatism of 2.00 D or less.
- (4) No evidence of structural abnormalities of the lids or lid infection, no conjunctival abnormalities or infection, including papillary hypertrophy or cobblestoning. A cornea with no scars, edema, staining, vascularization, infiltrates, vertical striae, or opacities under slit lamp evaluation.
- (5) Tear break-up-time (B.U.T.) of 10 seconds or greater.
- (6) Past medical history.
- (7) Allergies.
- (8) Personal hygiene.
- (9) Cooperation.
- (10) Comprehension.
- (11) Success as a daily wear contact lens patient.
- (12) Patient environment.

Once the subjects had satisfied the above criteria, a standard refraction, keratometry, and pachometry was performed by one of the three examiners. Following this, a trial fitting of Permalens and Hydrocurve II extended wear contact lenses was done.

The lenses were fitted by the examiners incorporating the fitter's guidelines provided by the manufacturers. The fitting method for Permalens is basically the same as for other hydrophilic lenses, except that the loosest fitting lens that provides comfort and centration is used. The initial trial lens should have a base curve of 8.00 mm. Following a two to four hour initial wearing period, a preliminary assessment of the lens performance was done. At the 24-hour visit, the amount of lens tightening was determined and if a lens change was necessary, a change was made based on the following criteria:



The fitting guide manufactured by Hydrocurve II suggest beginning with a lens with an overall diameter (O.A.D.) approximately 1.50 mm larger than the horizontal visible iris diameter (H.V.I.D.). The customary starting lens is the 8.8 mm/14.5 lens. The manufacturer also suggests that the lens fit as loosely as possible and still remain stable on the eye.

The final lens chosen was then permitted to equilibrate for a period of approximately 15 minutes. At this time, the best corrected visual acuity was determined and the quality of the retinoscopic reflex was evaluated. To determine if a lens fit too tightly or too loosely, the following criteria was utilized:

A lens that is too tight may demonstrate:

- A distorted retinoscopic reflex.
- Bubbles trapped beneath the lens.
- Circumcorneal injection.
- A foreign body sensation.

A lens that is too loose may demonstrate:

- Bubbles at the edge of the lens.
- Excessive lens movement.
- Lens decentration.
- Edge stand-off.

The suggested fitting guide of the manufacturers was followed unless the appraisal of the examiners or an advisor deemed it necessary to make changes.

Once the lens was considered satisfactory for extended wear, an examination was done prior to the overnight wear, and the subject was directed to sleep with the lens in place and return the following morning for a follow-up examination. The scheduled visits were then performed utilizing the following schedule:

- (1) The day following the first overnight wear.
- (2) Three days after overnight wear.
- (3) One week (five to seven days) after first overnight wear.
- (4) Two weeks following visit no. 2 (three weeks post-fitting).

- (5) One month following visit no. 3 (seven weeks post-fitting).
- (6) Three months following visit no. 4 (nineteen weeks post-fitting).
- (7) Every three months thereafter.

Any unscheduled visits and data taken were also recorded.

Once extended wear had been established, a chemical disinfection system was utilized on a weekly basis. The examiners explained the cleaning process and stressed the importance of the procedure. In addition, the examiners demonstrated to the subjects how to look for opacities or tears in the lens.

The lens cleaning method included scrubbing with Pliagel upon lens removal, after which the lenses were subjected to the Barnes-Hind, Soft-Mate cleaning kit on a weekly basis. B & L enzymatic treatment was also used after the cleaning regimen. Following the enzymatic treatment the lenses were cleaned with Pliagel and then rinsed thoroughly with Allergan preserved saline before the lenses were reinserted. Allergan disinfecting solution was recommended for any long term storage of the lenses. Clerz was recommended as the solution of choice for lubricating and rewetting the lenses while in the eyes, and was used a minimum of every morning and evening. A second choice of Lens-Wet was used as a rewetting agent.

Patients were instructed to remove the lenses every week for cleaning. This regimen appeared to keep the lenses cleaner and more comfortable due to greater permeability and wettability.

During absences of periods greater than one month, subjects were advised to see their private practitioner for observation and report the findings on a form provided to them. The forms are displayed on pages 23 and 24.

The clinical parameters utilized by the examiners were as follows:

1. Wearing time: In this category, the number of hours of comfortable wear achieved were scaled as follows:

Grade	No. of Days or Hours
0	7 days (maximum)
1	4-6 days
2	1-3 days
3	14-24 hours
4	7-14 hours
5	1-6 hours
6	0 hours

2. Incidence of Edema: In this category, any incidence of edema was noted and graded utilizing the following scale:

Grade	Appearance
0	No observable edema
1	Very light density; no defined borders; no stain
2	Light density; some definition of borders; no stain
3	Medium density; borders defined beginning epithelial breakdown
4	Somewhat dense; borders well defined; epithelial breakdown with light staining
5	Dense; localized or generalized; edematous corneal lines; epithelial breakdown and staining
6	Very dense; generalized breakdown with heavy staining; dimple veiling

3. Presence of Staining: The following scale was used in grading the extent of staining:

Grade	Appearance
0	No observable stain
1	Very light; diffuse; countable
2	Light; diffuse; not easily countable
3	Moderate; diffuse; not countable; some stipples
4	Somewhat dense; some clumping; stippling; some punctate
5	Dense; clumping; stippling; punctate; beginning vascular changes
6	Very dense; clumping; heavy stippling; punctate; definite vascular changes

4. Injection: Both conjunctival and perilimbal injection was considered utilizing the following scales as guidelines:

Conjunctival injection:

Grade	Appearance
0	None
1	Very light conjunctival injection; no chemosis
2	Light conjunctival injection; no chemosis
3	Moderate conjunctival injection; no chemosis
4	Moderate conjunctival injection; moderate chemosis
5	Severe conjunctival injection; chemosis

Perilimbal injection: (following page)

Grade	Appearance
0	None
1	Mild congestion and dilation of limbal vessels (which was not characteristic of the prefitting condition)
2	Moderate congestion and dilation of the normal limbal vessels
3	Severe congestion and dilation of the normal limbal vessels
4	Severe congestion and dilation of the normal limbal vessels with new vessel growth 4 mm onto the cornea
5	Neovascularization 1 mm

5. Subjective Comfort: Comfort was rated by the patient on a scale from 0 to 10, with 0 being no discomfort (i.e., maximum comfort) and 10 being minimum comfort.
6. Visual Acuity: Visual acuity was taken utilizing the Snellen scale of visual efficiency, which expresses the visual acuity as a fraction.
7. Patient Appearance: The appearance of the patient was subjectively rated by the examiner on a scale of 0 to 10, where 0 is normal appearance and 10 is an obviously "abnormal" appearance (i.e., head tipped back, excessive blinking, squinting).
8. Over Refraction: Over refractions were done on all of the patients and the findings were recorded. The findings (in diopters) were then ranked according to the following scale:

(see following page)

Grade	Diopters
0	0
1	.25
2	.50 to .75
3	1.00 to 1.25
4	1.50 to 1.75
5	2.00 to 2.50
6	2.50

9. Tear Break-Up-Time: The tear break-up-times were observed and noted in the records. The information was ranked according to the following scale:

Grade	Time in Seconds
0	30 sec
1	25 to 30 sec
2	15 to 25 sec
3	10 to 15 sec
4	5 to 10 sec
5	0 to 5 sec (abrasion)

10. Changes in Corneal Thickness: Information for this section was obtained utilizing a pachometer. The data was then ranked using the following scale:

Grade	Amount of Change (in mm)
0	0 mm
1	.01 mm
2	.02 mm
3	.03 mm
4	.04 mm
5	.05 mm
6	.06 mm
7	.07 mm or greater

RESULTS

These results represent the continuation of the Tiller, et al,¹³ thesis from February 11, 1983. Similarities may exist in the format of these results to enable easier comparisons between the two parts of this study. Since February 11, 1983, 16 patients were involved either as continuing patients or as new patients. Three patients could not be accepted into the project because a proper fit could not be obtained. The remaining thirteen patients were fit with the best lens regardless of lens manufacturer; eight were fitted with Hydrocurve II-55%, four with Permalens, and one with Hydrocurve II-torics.

All patients successfully fit were able to attain 20/20 visual acuity at the time fo lens dispensing.

Slit lamp evaluation was performed at each follow-up exam. The results of this evaluation are in Table I. The data shows that on 84% of all visits, there was no edema or minimal edema. However, there were two patients where significant edema was present and they were subsequently withdrawn from extended wear. One patient developed moderate edema (grade IV) by the third day of extended wear. The other patient developed grade III edema after becoming pregnant. If no physiological changes occurred during the study such as pregnancy, those who demonstrated edema either decreased by one week or was not a successful extended wear candidate.

The results of corneal staining are presented in Table F. This provided valuable information regarding corneal adaptation to continuous coverage by a contact lens. Once again, the majority of visits show minimal staining but where significant staining occurred, removal from lens wear was warranted. One other patient who became pregnant after several months of extended wear developed moderate staining. Two patients

were never able to wear lenses past 3 days because of moderate staining. One other patient developed a subepithelial infiltrate after several months of wear. He discontinued lens wear and did not continue after resolution of the subepithelial infiltrate.

The possibility of any neovascularization of the limbal vessels due to decreased oxygen flow to the cornea during extended wear was evaluated. All patients successfully fit showed no significant change in their limbal blood vessel pattern around the cornea. This included periods of 15 months of extended wear.

Injection of the conjunctival and perilimbal vessels (Table I) was sufficient in one patient to discontinue lens wear. This occurred after the first night of lens wear. The discomfort was associated with minimal lens movement. Otherwise, limbal and conjunctival injection was not significant with the remainder of the patients. When injection became noticeable by the patient, it usually preceded cleaning of the lenses and subsided after cleaning.

At each visit, subjective lens comfort (Table II) was rated by the patient. Incidences of severe discomfort occurred after unsuccessful lens wear in the first night. Those two patients were not successful candidates. Other reasons for decreased comfort from normal ratings were poor compliance with the cleaning regimen and decreased comfort of the lens approximately six to nine months following wear of the same lens.

Patient appearance (Table III) was also objectively recorded on a scale of zero to ten with zero being normal and ten an obvious "abnormal" appearance. Items observed were amount of injection, abnormal squinting, and frequency of blinking. Only one patient presented an obvious "abnormal" appearance and this occurred after the first night of extended wear. This

patient demonstrated moderate limbal injection, decreased tear break-up time and decreased lens comfort. He was not able to continue lens wear.

At each visit an over-refraction (Table IV) was performed. Those patients with an increased over-refraction also had other associated problems such as increased corneal thickness and edema. Two patients were removed from lens wear because of these factors. Otherwise, 81% of all findings were within plus or minus 0.75 D of the initial refraction. This was associated with no decrease on visual acuity and no lens power changes were made.

Tear break-up time (Table V) was observed and recorded at each visit. This allowed an objective observation of tear quality as the patient wore the lens for extended periods. One patient began the project with a decreased tear break-up time and was not successful in wearing the lenses. Only one patient showed decreased tear break-up time and the change occurred by the third day. It was associated with moderate corneal edema and corneal staining. Otherwise, the majority of subjects showed a fairly constant tear break-up time.

Pachometry measurements (Table VI) to evaluate corneal thickness changes was performed at each visits. Utilizing the 8% increase in corneal thickness as being of importance, criteria used by the previous examiners,¹⁴ two patients demonstrated a significant increase in corneal thickness by the third visit. Both had associated changes in their over-refraction and were removed from lens wear. Two other patients showed increased corneal thickness: one was associated with pregnancy and the other was a hard contact lens wearer put directly into extended wear.

To briefly review the results of the 16 patients:

-- Three could not be satisfactorily fit.

- Two patients experienced increased corneal thickness, decreased comfort, increased over-refraction, conjunctival injection and increased corneal staining after becoming pregnant. Prior to that time, they were successful candidates for 3 months and 9 months.
- Five patients could not progress past the first three days of extended wear for various difficulties with the lenses.
- Two patients voluntarily dismissed themselves from the project: one developed a subepithelial infiltrate and didn't want to risk reoccurrence. The other patient experienced difficulty handling the lenses.
- The previous hard contact lens wearer was returned to his hard contact lenses after demonstrating increased corneal thickness and increased over-refraction.
- Only three patients continue to safely wear their extended wear lenses.

DISCUSSION

Increased advertising of extended wear contact lenses has led to a greater public awareness that has stimulated public demand. Long term effects of these lenses have not been completely evaluated so it's to the public's benefit that a study of this nature be conducted.

A review of the literature and this study have shown a multitude of problems may be encountered. Most patients are motivated to be a successful extended wear patient. Proper patient selection however is necessary because more extensive patient cooperation is necessary. These lenses are more difficult to handle and necessitate a greater monetary obligation by the patient. These patients, some motivated by advertising, must be counseled on the possible consequences of extended wear as this study has demonstrated.

Only two lens manufacturers were utilized in this study, Hydrocurve II and Permalens. Outside practitioners may have a wider selection of lenses from which to choose. This may enable a better potential fit for a given population. The major fitting problem consisted of finding a desirable lens in order to obtain the best initial fit. This may have contributed to the poor retention of the patients in this study. Also, the patient population of optometry students and/or spouses may have been sensitive to minor changes, where a normal population might respond differently. For the above reasons, these results may prove to be an inaccurate predictor of private practice results.

Many problems that have arisen in this study could be minimized or eliminated in the future if the following list of suggestions could be taken into consideration:

-- There appeared to be a high degree of variability in pachometry

readings taken by each individual examiner. While each examiner's readings were internally consistent, inter-examiner readings were occasionally a problem. By limiting the number of examiners performing pachometry, an increased degree of reliability may be obtained.

- In order to keep lens deposits to a minimum, and thus maintain a relatively safe degree of oxygen transmissibility, the use of enzymatic cleansers is recommended a minimum of once every two weeks.
- In an effort to increase the number of successful fits, the examiners recommend that in the future more lenses be added to the regimen from the ever increasing extended lens wear manufacturers.
- In order to better substantiate changes in appearance of the eye, it is recommended that photodocumentation prior to the fitting of extended wear lenses be done. This would provide a graphic basis by which all of the examiners can compare future alterations of the ocular topography.
- During the study, a great deal of the torn lenses appeared to be caused by the utilization of the Barnes-Hind Hydro-Mat II cleansing unit. If insertion of the lenses into the unit was not done carefully, the lens would hang over the rim of the unit and be clipped off when closed.

CONCLUSION

At the conclusion of this portion of the study, the data indicates extended wear patients may encounter many problems. These include limbal injection, increased epithelial thickness, corneal staining indicating epithelial cell loss, lens deposits, and tear inconsistencies. These tend to require the practitioner to remove the patient from extended wear. When these problems do arise during extended wear, it would appear best to discontinue wear as they tend to worsen instead of resolve themselves. Further research would seem appropriate in clinical management of patients and in finding a more suitable contact lens material to ensure better success in extended wear.

TABLE I

Slit Lamp Examination Findings
(Percentage of Visits)

Grades	0	I	II	III	IV	V	VI
Edema	58%	26%	7%	5%	4%	0%	0%
Staining (corneal)	35%	30%	19%	11%	6%	0%	0%
Conjunctival/ Perilimbal Injection	53%	21%	22%	3%	0%	0%	0%

TABLE II

Subjective Comfort
(Percentage of Visits)

Grades	0	I	II	III	IV	V	VI	VII
Comfort	25%	19%	25%	17%	8%	2%	2%	2%

TABLE III

Patient Appearance
(Percentage of Visits)

Grades	0	I	II	III	IV	V	VI - X
	73%	16%	6%	3%	0%	2%	0%

TABLE IV

Over-Refraction
(Percentage of Visits)

Grades	0 (Plano)	I ($\pm .25D$)	II ($\pm .50-.75D$)	III ($\pm 1.0-1.25$)	IV ($\pm 1.5-1.75$)	V - VI ($\pm 2.0-2.50$)
	19%	39%	33%	7%	1%	0%

TABLE V

Tear Break-Up Time
(Percentage of Visits)

Grades	0	I	II	III	IV	V
	30 sec or	25-30 sec	15-20 sec	10-15 sec	5-10 sec	0-5 sec
% of visits	2%	18%	26%	42%	11%	2%

TABLE VI

Changes in Corneal Thickness - Pachometry
(Percentage of Visits)

Grades	0	I	II	III	IV	V	VI	VII
	0mm	.01mm	.02mm	.03mm	.04mm	.05mm	.06mm	.07mm
% of visit	8%	21%	15%	16%	11%	7%	5%	16%

Dear practitioner:

_____ is a subject
in an extended wear thesis project at Pacific University College of
Optometry. We would appreciate observation of the following parameters
to allow for continuation of the study. Attached are recording forms
with the average findings for the past three months of care. If any
questions or problems arise, please feel free to call us a collect after
5:00 pm.

Bob Lunde (503) 357-0345 Larry Johansen (503) 357-0192 Kevin Moore (503) 359-4904

Lens Parameters:

- 1) Lens Type: _____
- 2) Base Curve: _____
- 3) Lens Size: _____
- 4) Power: _____

Clinical Parameters

	3 months average	June	July	August
1) Wearing time since last cleaning:				
2) Presence of edema (0-6)				
3) Presence of staining (0-6)				
4) Injection				
5) Subjective comfort (0-10)				
6) Visual Acuity				
7) Patient Appearance				
8) Over refraction				
9) Tear break-up time				
10) Endothelial observation				
11) Lid eversion				
12) Lens movement				
13) Notes				

(Rating scale: 0 = best 10 = worst)

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