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A clinical evaluation of extended wear contact lenses

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Abstract

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A CLINICAL EVALUATION OF EXTENDED WEAR CONTACT LENSES

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A CLINICAL EVALUATION OF EXTENDED WEAR CONTACT LENSES

For many people, the ideal soft lens would be one that could be placed on the eye for indefinite period of time without a need for concern. Although achieving this may sound quite simple, with the many recent advances in the soft contact lens field, in actuality, the solution is quite complex. A lens that is to be worn for extended periods of time must present all of the favorable characteristics of limited wear lenses plus each characteristic must stand up over time. The lenses must be comfortable and, at the same time, durable. Vision must be clear and constant over time and, most importantly, any potential risks to the health of the eye must be completely minimized, if not eliminated.

One of the most vital parameters that must be met in extended wear contact lenses is a supply of oxygen to the cornea in sufficient quantities to support all of the necessary metabolic processes. There are three ways in which the cornea obtains its all important supply of oxygen: from the air via the tears, from the aqueous humor and from the limbus. Two-thirds of the oxygen supply under open-eye conditions comes from the atmosphere. Therefore, under closed eye conditions encountered during sleep the overall oxygen supply to the cornea is cut to approximately one-third of that available when the eyes are open due to the fact that the major source of oxygen is now the palpebral conjunctival vessels.[1,2] During closed eye conditions there is also an increase in corneal temperature (93^{o} as compared to 88.5^{o} for the open eye) which leads to additional oxygen consumption.[3] It therefore becomes apparent that out of necessity, any extended wear lens, in order to be successful, should not

interfere with the oxygen supply reaching the cornea under the already reduced state found in closed eye conditions.

One of the primary concerns of the reduced oxygen supply to the cornea in extended wear has been the resultant corneal thickness changes.

Schoessler and Barr monitored the corneal thickness changes in eight myopic patients who wore extended wear lenses continuously for eighteen months. They found that corneal thickness reaches a peak increase after one week and then gradually declines. After several months of continuous wear the average thickness returned to near baseline levels with the first month being the critical period in terms of maximum edema formation. They also found that there was variability in the response of patients. Some exhibited chronic edema with no complaints and some demonstrated corneal thinning. The thinning did not appear until after nine months, indicating that this may be a long-term effect. They also found striae present in almost all cases where the corneal swelling was greater than 5%.[4]

In the study of Sorensen and Corydon the central corneal thickness of 38 normal myopes was observed after fitting with extended wear lenses. They found a thickness increase of 4-6% after the 24 hours adaptation period. The thickness increase gradually declined to 2.5 - 3.1% after six months. During sleep, the central corneal thickness increased 9%. They also found that, whereas the normal cornea returned to its daytime value in half to one hour, the cornea covered by the contact lens reached a steady state after three to four hours.[5]

Sarver, Baggett, Harris and Louis also examined the corneal edema resulting from hydrogel lenses being worn under closed-eye conditions.

This study compared the amount of edema that developed when patients wore one daily wear lens, with the edema that developed when they wore three lens types designed for extended wear. The daily wear lens was the B & L U_3 series. The extended wear lenses were the Cooper Permalens, Hydrocurve II 55 lens, and the Sauflon PW lens. The authors found that the five subjects developed only small amounts of edema under open-eye conditions. However, under closed-eye conditions none of the lenses transmitted enough oxygen to prevent the development of significant amounts of corneal edema when worn for three-hour periods.[6]

In an extensive survey, Stark and Martin evaluated the long term effects in 106 patients who had been fit in England with Permalens for extended wear myopia correction. The duration of extended wear use ranged from four to eight years. Visual acuity was 20/40 or better in 95% of the 207 eyes fitted. The authors found that corneal neovascularization, when encountered (approximately 8.7% of the time), was mild and did not reduce the visual acuity. They also found no cases of infectious corneal ulcer or scarring or of permanent visual loss from use of the extended wear lens. The authors, therefore concluded that, in selected patients, the use of extended wear lenses seems to be a viable procedure for the correction of myopia.[7]

Extended wear also presents other problems which, although they do not predominate, do deserve mention. One of the most common problems in extended wear is the increased incidence of lens replacement. Due to the very fact that they are to be used for extended wear, the lenses must be made either ultra thin or with a very high water content. Either choice results in decreased durability of the lens.[8,9] Deposits forming on the lens can also be a nuisance and have been reported in 5 to 33% of

extended wear patients.[10] The most serious problem of lens coating is from inorganic deposits (mainly calcium phosphate) and denatured protein deposits. An additional problem can be the deposition of immuno globulins which can lead to antigen - antibody reactions. All these coating substances act to further reduce oxygen transmissibility.[11] Other problems that may be observed are perilimbal injection, vertical striae, epithelial or stromal hazing, microcystic edema, and alterations of the endothelium.[12,13]

Patient selection is also a key to successfully fitting extended wear lenses and requires more criteria than for the normal daily-wear patient. Any possibility of pathology must be completely ruled out. It is extremely important for the patient to realize that an unusual amount of time and effort may be required in order to obtain satisfactory results. They must understand that it may take several fitting sessions before they can "take their lenses home." It is also vital that the patient understands the need for and be willing to cooperate in a substantially larger number of post-fitting progress examinations than is required in normal daily wear.[14,15]

As extended wear lenses and manufacturers continue to develop new and better products, extended wear will very likely become more common. The purpose of this study was, therefore, to evaluate and monitor the ocular effects of extended wear contact lenses and to gain some insight into the advantages and disadvantages therein.

METHOD OF EVALUATION

Optometry students and/or their spouses comprised the subject pool for this project. They were selected to participate based on criteria which would normally be used in a clinical setting to determine if a patient is a likely candidate for extended wear lenses. The criteria are based on:

(1) Phakic eyes only

(2) 20/30 or better with correction

(3) 2.00 D of astigmatism or less

(4) No evidence of lid infection, no structural abnormalities of lids, no conjunctival abnormalities or infection, including papillary hypertrophy or cobblestoning. A cornea free of scars, edema, staining, vascularization, infiltrates, vertical striae or opacities when examined by the slit lamp.

(5) Tear break-up-time (B.U.T.) of 10 secs. or greater

(6) Past medical history

(7) Allergies

(8) Personal hygiene

(9) Cooperation

(10) Comprehension

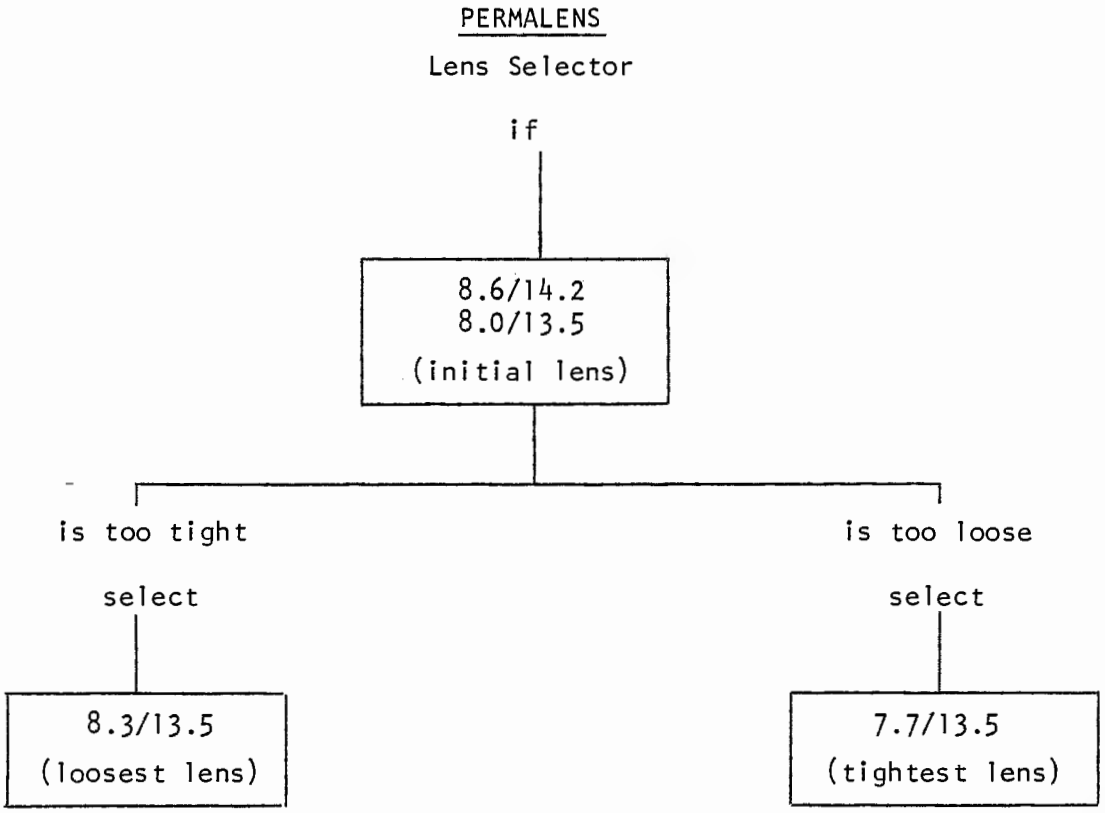
(11) Success as daily wear contact lens patient

(12) Environment of patient

Once the subjects had been screened by the above criteria, a standard refraction, keratometry, and pachometry was performed by one of the three examiners. The examiner then determined the lens power by: (a) converting the spectable Rx to minus cylinder form; (b) adjusting the spectable Rx for vertex distance; and (c) converting to equivalant

spherical power. A trial fitting of Hydrocurve II and Permalens EW C.L. was then tried.

The examiners then fitted the lens, following the fitter's guide provided by the manufacturer. Basically the fitting method for Permalens is the same as other hydrophilic lenses, except that the loosest fitting lens which will provide comfort and concentration is utilized. The initial trial lens should have an 8.00 mm base curve. After an initial wearing period of two to four hours, a preliminary assessment of the lens performance was made. At the 24 hour visit the amount of lens tightening was then determined and if a lens change was required, it was done, based on the following criteria:



The Hydrocurve II fitting guide suggests starting with a lens with a diameter approximately 1.50 mm larger than the horizontal visible iris diameter. The usual starting lens is the 8.8 mm/14.5 lens. Hydrocurve II also suggests that the lens fit as loosely as possible and still remain stable on the eye.

Either lens was then allowed to equilibrate for approximately 15 minutes, at which time the best corrected visual acuity was obtained and the quality of the retinoscopic reflex evaluated. The following criterion was used for determining a lens which fitted too tightly or too loosely:

A lens that is too loose may exhibit:

---- Decentration

---- Edge stand-off

---- Excessive movement

---- Bubbles at edge

A lens that is too tight may cause:

---- Circumcorneal injection

---- Trapped bubble

---- Foreign body sensation

---- Distorted retinoscopic reflex

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

Once the lens had been deemed suitable for extended wear, an examination was performed prior to the overnight wear, and the subject was instructed to sleep with the lens in place. The following morning another examination was performed. The scheduled visits were then per-

formed on the following basis:

(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) Each three months thereafter

Any unscheduled visits and data taken were also recorded.

The disinfection system (chemical) was used on a weekly basis once extended wear had been established. The examiners assisted the subjects through this process and explained to them the importance of this cleaning procedure, as well as looking for any opacities or tears in the lens.

The clinical parameters which the examiners used were:

1. Wearing Time. Here, the number of hours of wear which can be comfortably 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. Here, any edema was noted and graded as per 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. This was graded on the following scale:

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. The following grading system was then employed:

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:

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

5. Subjective Comfort. The patient rated comfort on a scale of 0 to 10, where 0 is no discomfort (i.e., maximum comfort) and 10 is minimum comfort.

6. Visual Acuity. Visual acuities were taken employing the Snellen scale of visual efficiency, which expresses the visual acuity as a fraction.

7. Patient Appearance. The examiner subjectively rated the appearance of the patient on a scale of 0 to 10, where 0 is normal appearance and 10 is distinctively "abnormal" appearance (i.e., head tipped back, excessive blinking, squinting).

8. Over Refraction. Over refractions were done on all patients and the findings (in diopters) recorded. This information was then ranked according to the following scale:

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. Tear break-up times were observed and recorded. The information was then ranked as follows:

Grade	Time in Seconds
0	30 sec
1	25 to 30 sec
2	15 to 20 sec
3	10 to 15 sec
4	5 to 10 sec
5	0 to 5 sec (abrasion)

10. Changes in Corneal Thickness. This information was obtained employing a pachometer. The data was then ranked as follows:

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

Of the nineteen patients on whom fittings were attempted, there were four women and fifteen men. Eleven of these were successfully fit and started in extended wear, of which three were women and eight were men. On the eight for whom a successful fit was not achieved, four were due to lack of availability of a lens with a long enough base curve radius. Four were not fit as a result of failure of adequate lens centration. Of the eleven who were successfully fit, six wore Permalens (Cooper Vision). Four wore Hydrocurve II spheres and one wore Hydrocurve II torics. An effort was made to fit an equal number of lenses from the two manufacturers.

The lens cleaning method included scrubbing with "Pliagel" upon lens removal, after which the lenses were exposed for a minimum of two hours in Barnes-Hind "Soft-Mate" cleaning kit on a weekly basis. Thorough rinsing with Allergan preserved saline before reinsertion removed the cleaning solutions. Allergan disinfecting solution was recommended for any long term (more than one night) storage of the lenses. "Clerz" was recommended as solution of choice for lubricating and rewetting the lenses while in the eyes, and was used a minimum of every morning and evening. One patient who had developed a slight allergic reaction (red eyes, itching, etc.) to the "Clerz" was given "Lens-Wet" as a rewetting agent, with no further problems.

Patients were originally instructed to remove and clean the lenses every two weeks. However, in patient follow-up care it was determined that the lenses should be cleaned at weekly intervals due to protein build-up on the lenses. This regimen seemed to keep the lenses

cleaner and more comfortable due to greater permeability and wettability.

All of the successfully fit patients had visual acuity of 20/20 or better. Six of these patients (55%) achieved an acuity of 20/15.

Seven patients were fit and started in extended wear in November, 1982, and the remaining four were fit and started in extended wear in late January or early February, 1983. All eleven patients were seen regularly and given follow-up care through February 11, 1983, at which time their care was transferred to two third-year interns, who will continue to monitor the patients in the coming year for final evaluation of long term extended wear effects and results.

This interim report is intended to cover the results and/or conclusions obtained in this project as of February 11, 1983.

Four out of our eleven patients exhibited a moderate (grade II or III) amount of edema after the first night's wear. Three of the four patients exhibited a decrease in edema to a light (grade I) amount or none by the third day (second follow-up visit) of extended wear. The fourth patient's edema continued to be moderate through the third day but had decreased to a slight amount after one week (third follow-up exam). The remaining seven patients had either slight or no edema in any of the follow-up exams. This is indicated in Table I, which shows that in 85% of the progress exams there was either slight or no edema present (grade 0 or I).

Corneal staining was evaluated with sodium fluorescein and a slit-lamp mounted cobalt blue filter and is summarized in Table I.

Two of the eleven patients were dismissed from the study primarily due to corneal staining. One of these patients suffered grade IV

staining after her first three nights of wear. The other patient was dismissed after exhibiting grade III staining after one week of overnight wear.

The other nine patients had no worse than grade II staining at any time during the wearing period. In other words, in 94% of all office visits staining of no worse than grade II was exhibited. In half of these there was no observable staining whatsoever.

The condition of the conjunctiva was determined by slit-lamp observation of the overall appearance of both the conjunctival tissue and the blood vessels. It was then graded accordingly and recorded in Table I. Three out of the eleven patients exhibited a light amount of conjunctival injection (grade II). In two of these patients the injection decreased on subsequent visits to zero or slight. The third patient continued at about the same level of injection, grade II, and no other problems were encountered. The remaining eight patients displayed either a very light amount or no conjunctival injection in any of the progress evaluations.

Only one patient of the eleven had severe (grade III) congestion and dilation (perilimbal injection) of the normal limbal vessels on the day after the first night's wear. This decreased to moderate congestion and dilation (grade II) by the third day of extended wear, which was follow-up exam No.2, but had not decreased any further in the third follow-up exam one week later. This was a contributing factor in our decision to discontinue this patient from extended wear and the project.

The remaining ten patients either had no perilimbal injection or mild congestion and dilation which then decreased to none in further follow-up exams. (Table I).

Five patients had varying amounts of neovascularization present prior to participating in this project. This pre-existing neovascularization was measured using the calibrated parallelapiped length on the slit-lamp used. The neovascularization indicated in the data relates to any progression or changes occuring as a result of extended wear. At this point in the project, neovascularization has not been a complication, however due to the nature of any soft contact lens wear, this type of problem usually does not present itself in the early periods of wear.

Lens comfort (Table II) was subjectively judged by the patient at each visit on a scale of zero to ten, with zero being the most comfortable and ten the most uncomfortable. Since this is a purely subjective opinion by each individual patient, a grade one comfort to one patient may be a grade two or three comfort to another, nevertheless the data is of importance. In 80% of the total patient visits lens comfort was rated as a grade two or better, and comfort was rated a grade five or better in 98% of total patient visits. In only one visit was lens comfort given a rating on the lower half of the scale (grades 6-10) and this lens received a grade six rating. This patient was subsequently taken out of lens wear and the project, primarily due to pronounced corneal staining and perilimbal injection. It is also noteworthy that this patient did have moderate pinguecula on both eyes prior to lens wear and this may have been a contributing factor in lens discomfort and the other problems mentioned.

The general trend in comfort ratings seemed to be either a maintenance of original lens comfort or an improvement in the original comfort over the first week or two of wear.

Patient appearance (Table III) was graded on a scale from zero to ten, with zero being a normal appearance and ten being distinctively abnormal such as head tipped back and excessive blinking or squinting. The examiners never encountered an abnormal appearance, with the lowest rating being a grade II and 75% of all visits receiving a grade zero. Therefore, the problems contributing to an abnormal appearance were never a concern.

Over-refraction, or spherical lens required to produce best visual acuity, was also performed on every progress exam (Table IV). Thirty-three percent of the patients indicated no additional lens power was necessary, and one-half of all patients needed only plus or minus .25D to achieve best acuity. The remaining seventeen percent required between plus/minus .50D and plus/minus 1.25D to provide best subjective visual acuity. In the latter case a new lens was ordered with the same parameters but with the required power change.

Tear break-up time was also monitored at the progress exams (Table V). Only nineteen percent of the eleven patients had an actual decrease in the break-up time. The greatest decrease being from 17 seconds before fitting to only six seconds after one day of extended wear. Forty-five percent showed no change in break-up time from the point of original fit through the rest of the evaluation period. The remaining 36% actually had an increase in break-up time. One patient improved from seven seconds to twenty seconds. Another patient who became pregnant shortly after beginning the study, showed a marked improvement in break-up time, from five seconds to fifteen seconds in three weeks.

At every progress exam pachometry measurements were taken on each eye. Using an eight percent increase in corneal thickness as being

of import, it was found that two patients displayed this level of corneal thickening. One of these patients was discontinued from the project due to this and other relevant findings mentioned previously. It was discovered that the other patient was pregnant at the start of the extended wear. This patient's cornea showed thickening in progress exams one and two but then returned to baseline corneal thickness levels by the third progress exam (one week after extended wear was begun) and her corneal thickness had not changed at the fourth progress exam two weeks later.

The general trend in patients with corneal thickness changes of less than eight percent seemed to be a slight thickening at visits one and two, with a trend back towards corneal thinning at the one week progress exam and slightly fluctuating corneal thickness readings in subsequent visits (Table VI). Some of this variation could also have been attributed to examiner subjectivity in taking readings or variation due to the time of day that readings were taken, as some were taken in the morning and some in the afternoon due to patient and examiner schedules.

Three patients were dismissed from the study for various reasons which were previously referred to.

The reasons for dismissal of the first were unsatisfactory acuity due to uncorrected astigmatism and the unavailability of a toric fitting set at the time of dismissal.

The second dismissal was due to physiological reasons. This patient developed grade four epithelial staining of the cornea after the first three days of extended wear. This was in conjunction with a decreased tear break-up time. Further attempts to refit with different lens parameters were unsuccessful.

The final patient was dismissed because of grade four corneal

staining, poor subjective comfort, and continued significant corneal thickening after the first week of extended wear. This patient also exhibited transient vertical striae after the first night of wear.

DISCUSSION

This is an interim report on a research study of the fitting and evaluation of extended wear contact lenses. By the very nature of extended wear and it's potential long term effects, as referred to in the research articles listed in the references, this study will be continued over a period of one and a half years. The conclusion of this project and the final report is expected to be completed in February, 1984.

This project was undertaken in an attempt to evaluate and monitor the effects of cosmetic extended wear contact lenses. With greater acceptance in the field of optometry and increased public awareness, along with Pacific University students and faculty interest in this area, it was felt this study would be beneficial in providing insights from within our own clinic as to the fitting, continuing evaluation, and long-term effects of extended wear lenses.

Experience has shown that a crucial factor in the fitting of these lenses is careful patient selection. The major factors included in this initial patient selection are proper motivation, commitment of both doctor and patient for extensive and careful follow-up care, ability by the patient to successfully handle the lenses, willingness of the patient to carefully follow the doctor's instructions, patient eye physiology, and the realization of the additional monetary obligations involved.

The major initial fitting difficulty encountered was the unavail-

ability of a lens with a base curve radius long enough to give the desired lens movement and centration. Currently, the longest base curve available is the 8.8/14.5 Hydrocurve II 55% and the 8.3/13.5 Permalens.

The limited lens parameter selection in the toric designed extended wear lenses provided additional fitting problems. A significant number of additional patients could be fit if a greater selection of lens parameters had been made available.

Corneal staining was not a significant problem with the majority of the patients. It is noteworthy that there were no complications resulting in reduced visual acuity, corneal scarring, or other manifestations at this time.

Another problem confronted, as mentioned in previous extended wear studies, was the fragility of the lens and it's susceptibility to tearing in the handling and cleaning process. This is apparently due to the relatively high water content and thin design. Tearing problems were experienced with three of the patients, two of whom had had soft lens experience.

Edema has always been felt to be a major consideration with extended wear. There was a general trend of slight to moderate edema after the initial overnight wear, which then decreased to between minimal and no edema in subsequent progress evaluations. One patient did develop edema to the degree that subsequent corneal endothelial vertical striae were noted and the patient was discontinued from lens wear.

A very encouraging finding at this stage in the project was patient comfort and appearance. The majority of patients expressed positive feedback with regards to these subjective aspects.

Excellent visual acuity (20/20 or better) was exhibited by all subjects. It should be noted, however, that the patients in this study were a select group of young optometry students and/or their spouses, and such dramatic visual acuities may not be obtained in the general population.

Conclusions drawn thus far in the study seem to indicate extended wear to be a relatively safe, viable and effective means of dealing with the cosmetic correction of refractive errors. However, indiscriminate fitting and follow-up care may create a physiologically compromised and justifiably angry patient. Therefore, the importance of a conscientious fitting regimen and extensive progress evaluations cannot be stressed enough. With these factors in mind, a practitioner can feel confident in dealing with the ever increasing popularity of the cosmetic extended wear contact lens.

Table I

Slit Lamp Examination Findings

(Percentage of Visits)

Grades:	0	I	II	III	IV	V	VI
Edema	53%	35%	10%	2%	0%	0%	0%
Staining (Corneal)	45%	25%	24%	4%	2%	0%	0%
Conjunctival Injection	51%	31%	18%	0%	0%	0%	0%
Perilimbal Injection	51%	43%	4%	2%	0%	0%	0%

Table II

Subjective Comfort

(Percentage of Visits)

Grades:	0	I	II	III	IV	V	VI
Comfort	18%	27%	35%	10%	4%	4%	2%

Table III

Patient Appearance

(Percentage of Visits)

Grades:	0	I	II	III-X
	75%	12%	13%	0%

Table IV

Over-Refraction

(Percentage of Visits, Per Eye)

Grades:	0 (Plano)	I (±.25D)	II (±.50-.75D)	III (±1.00-1.25D)	IV-VI (±1.50-2.50D)
	33%	50%	15%	2%	0%

Table V

Tear Break-Up Time

(Percentage of Visits, Per Eye)

Grades:	0 30 sec or >	I 25-30 sec	II 15-20 sec	III 10-15 sec	IV 5-10 sec	V 0-5 sec
	0%	14%	49%	29%	7%	1%

Table VI

Changes in Corneal Thickness - Pachometry

(Per Eye)

Grades:	0 0mm	I .01mm	II .02mm	III .03mm	IV .04mm	V .05mm	VI .06mm	VII .07mm
	0%	2%	4%	6%	8%	9%	11%	13%
Corneal Thickness Changes (% of Visits)	7.5%	22.5%	36%	22.5%	5%	2.5%	2.5%	1.5%

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