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The Boston equalens: A clinical evaluation for wear

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The Boston equalens: A clinical evaluation for wear

Abstract

Recent advances in gas permeable contact lens materials have accounted for their successful use in extended wear. In this study, 18 subjects were fitted with the Boston Equalens, a new silicon/acrylate lens which is combined with a fluorinated monomer. The subjects wore one lens as a daily wear contact lens and the other lens as an extended wear contact lens for a period of 90 days. Four patients successfully completed the 90 days of extended wear and five patients completed between 30 and 90 days of extended wear. No significant differences of corneal curvature, refractive error, corrected visual acuity, or subjective responses were noted between the daily wear eye and the extended wear eye. Also there were no reports of lens adhesion on any of the subjects' eyes.

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Committee Chair

James E. Peterson

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THE BOSTON EQUALENS:
A CLINICAL EVALUATION FOR EXTENDED WEAR

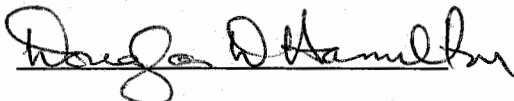
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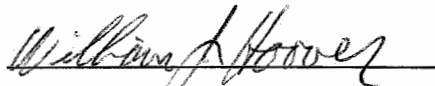
Douglas D. Hamilton
William J. Hoover
Stephen C. Sternitzky
Dr. James E. Peterson

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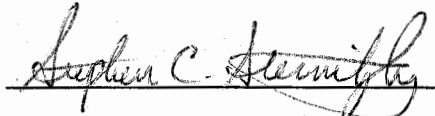
The Boston Equalens: A Clinical Evaluation for Extended Wear



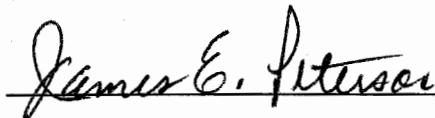
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ABOUT THE AUTHORS:

Douglas D. Hamilton is a 1976 graduate from the Georgia Institute of Technology with a Bachelor of Chemical Engineering degree. He co-authored an optics review for National Boards and is a member of the American Academy of Optometry and the AOSA.

William J. Hoover graduated from Pennsylvania State University in 1975 with a Bachelor of Science degree in Geology. Further education prior to entering Pacific University included studies in biology and chemistry at Mesa College, Colorado in 1982. Present memberships include AOSA, BSK, AOA, AOA contact lens section, and the Colorado Optometric Association. Post-graduate plans have not been finalized.

Stephen C. Sternitzky is a 1979 graduate from the University of Wisconsin-Madison with a Bachelor of Science degree in Zoology.

All three authors are 1987 graduates from Pacific University College of Optometry.

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ABSTRACT

Recent advances in gas permeable contact lens materials have accounted for their successful use in extended wear. In this study, 18 subjects were fitted with the Boston Equalens, a new silicon/acrylate lens which is combined with a fluorinated monomer. The subjects wore one lens as a daily wear contact lens and the other lens as an extended wear contact lens for a period of 90 days. Four patients successfully completed the 90 days of extended wear and five patients completed between 30 and 90 days of extended wear. No significant differences of corneal curvature, refractive error, corrected visual acuity, or subjective responses were noted between the daily wear eye and the extended wear eye. Also there were no reports of lens adhesion on any of the subjects' eyes.

INTRODUCTION

Extended wear of contact lenses has been investigated since the early days of contact lens technology. Extended wear conditions create an increased physiological and mechanical stress to the cornea and surrounding tissue. Important considerations of extended wear include greater corneal oxygen requirements created by hypoxic closed lid conditions, as well as efficient metabolic waste removal from beneath the contact lens. Until recently, only hydrogel lens materials could supply adequate oxygen to the cornea, allowing safe extended wear. These lenses, which are highly permeable, supply oxygen to the cornea through the lens itself rather than by a tear pump mechanism as with rigid lenses [1]. The oxygen supplied to the cornea during sleeping hours is supplied mainly by the conjunctival blood vessels of the lids and limbal structures. Extended wear (EW) hydrogel materials supply sufficient oxygen from the lid to the cornea to prevent excessive corneal edema during overnight wear. Efficient removal of metabolic waste products from beneath the lens, depends mainly upon the cornea to lens fit, amount of lens movement, and individual patient metabolism. Although movement of hydrogel lenses does occur, it may be limited and

sporadic, especially during sleeping hours. This may prevent adequate removal of waste products from beneath the lens possibly creating further complications. Inadequate lens movement and waste accumulation can create significant complications as a result of extended wear. These include conjunctival injection and edema, corneal edema, neovascularization, epithelial microcysts, ulcers, keratitis, GPC, and corneal endothelial problems [2]. Although extended wear of hydrogel lenses has been very popular [3,4,5,6], the incidence of serious complications has directed attention towards gas permeable rigid materials as a more advantageous extended wear product [6-16].

PMMA lenses have been worn successfully for extended wear [17], usually by aphakic patients with reduced corneal oxygen demands resulting from surgery. Generally these lenses are not used for EW due to their low permeability [18].

Gas permeable lenses offer an attractive alternative since oxygen is supplied to the cornea by both a tear pump mechanism (lens movement) and direct transmission through the lens [2,19,20]. These rigid lenses also remove metabolic waste products from beneath the lens very efficiently since the lenses are smaller (less cornea is covered) and an excellent tear pump is present. Successful EW of relatively low oxygen permeable materials has been documented [21,22,23]. New research has suggested specific oxygen levels needed by the cornea to prevent higher than normal amounts of edema during overnight wear [24,25,26]. Within the last several years new materials, which have a much higher oxygen transmissibility (Dk/L) have been developed to provide sufficient oxygen to the cornea than was previously possible with earlier gas permeable materials. Research efforts have been directed at developing a material which is both highly permeable and also deposit resistant. Other advantages of gas permeable lenses over hydrogel lenses include increased visual acuity, correction of higher amounts of astigmatism, longer lens life, decreased care time for the lenses, easier handling, a wider range of fitting applications, fewer allergic responses, and little interference with ocular medications [27-34].

However, these lenses are not without drawbacks. Possible complications include lens adhesion to the cornea, lens dislocation, flare, changes in corneal curvature, protein accumulation, corneal staining, ptosis, increased initial fitting time, and

increased adaptation time for the patient [20,27,29,35-40]. A number of cases of successful extended wear using the new highly permeable rigid lenses have been documented in the literature [35-45]. These lenses offer a new hope in finding an optically efficient and physiologically compatible material for extended wear contact lenses.

EXPERIMENTAL DESIGN

This clinical investigation involved extended wear use of the Boston Equalens, a new highly permeable rigid lens material, which utilizes a fluorinated monomer combined in a silicon/acrylate base. This material offers both a very high transmissibility as well as excellent wettability characteristics [46], two factors not usually inherent together in other materials.

This investigation was designed to monitor any physiological or refractive changes resulting from extended wear use of the Boston Equalens. Physical properties of the Equalens are as follows:

BOSTON EQUALENS PROPERTIES

Oxygen Permeability *	71×10^{-11} (35°C)
Oxygen Transmissibility	50.7×10^{-11} (Avg.)
Index of Refraction	1.439
Specific Gravity	1.18
Hardness (Rockwell R)	111

* $(\text{cm}^2/\text{sec})(\text{ml O}_2/\text{ml} \times \text{mm Hg})$

The subject population for this study consisted of 7 male and 11 female subjects, a total of 18. The mean age was 25 with a range of 18 to 33 years. There were 6 previous hydrogel contact lens wearers, 6 previous gas permeable contact lens wearers, and 6 subjects had no previous contact lens experience. No subjects had worn PMMA lenses for at least two years prior to the start of the project. The patient population spherical refractive error ranged from -.50 D to -5.75 D. The refractive cylinder ranged from 0.0 D to 2.00 D. All subjects had with the rule astigmatism.

Refractive parameters of those patients who completed the 90 day EW schedule are shown below.

Refractive Parameters
(90 day EW patients)

<u>Refraction (diopters)</u>	<u>#of eyes</u>	<u>Mean</u>	<u>Range</u>
Spherical	8	-3.44	-1.75 to -5.75
Cylindrical	8	-0.44	0.0 to -1.00
<u>Corneal Curvature</u>			
Horizontal K		43.42	40.75 to 45.12
Corneal Toricity (ΔK)		1.00	0.62 to 1.75

All patients were screened for the presence of ocular disease or any contraindicated ocular or systemic drug therapy. One subject who completed the full 90 day extended wear schedule had previous indication of conjunctival papillary hypertrophy (GPC grade II).

The study was designed to have each subject wear the Equalens on each eye, one of which was randomly chosen for extended wear, the other to function as a daily control. Prior to diagnostic fitting each patient was given a complete refractive and ocular health examination. Each patient was required to wear both lenses on a daily wear basis for at least one week. The time required for adequate adaptation to the lenses varied among patients. The wearing schedule for the first week of daily wear was as follows:

<u>DAY</u>	<u>WEARING TIME</u>
1	4-8 hours
2	6-10
3	8-14
4	10-15
5	12-all waking hours
6	all waking hours

Once 12-14 hours of daily wear was established the patient was started on extended wear with one eye. Progress exams were done on day 1 of daily wear (DW), day 7 DW, day 1 EW, and on days 7,14,30,60, and 90 of EW. These exams were scheduled for evenings after a minimum of 6-8 hours of wearing time.

The cleaning regimen utilized the Boston cleaning, conditioning, and reconditioning

solutions, as described in Appendix 1. The reconditioning drops were used as needed during the day and also before and after sleeping hours to facilitate cleaning and rewetting of the EW lens. Patients were instructed to use Allergan Softlens enzymatic cleaner at least once a week. This required that the EW lens be left off the eye overnight.

The fitting procedure varied according to the chosen lens diameter, but central alignment, slight apical clearance or mild apical bearing were maintained. In addition, all fits demonstrated adequate movement of the lenses with blinking. The range of diameters fit was 8.0 mm to 9.5 mm, with center thickness maintained at a .12mm to .18mm range. Thicker lenses were used for higher amounts of astigmatism as well as lower minus powered lenses. The lens specifications used by the subjects that completed 90 days of extended wear are summarized:

LENS PARAMETERS

	<u>Mean</u>	<u>Range</u>
Base Curve (mm)	7.63	7.4 to 8.1
O.A.D.	8.8	8.2 to 9.0
O.Z.	7.6	6.8 to 7.8
C.T.	.14	.14
Power (diopters)	-4.00	-2.00 to -6.50

There was no difference between DW and EW fitting techniques. Progress exams consisted of measurement of both refractive and physiological changes of the DW and EW eyes. Refractive measurements included visual acuity, sphero-cylinder over-refraction, lens-off-refraction and keratometry. Central corneal curvature was measured within 10 minutes of lens removal using standard calibrated keratometers. Refractions and visual acuities were quantified using standard phoropter procedures with standard room illumination (10-15 footcandles) and projection charts. Cornea-scope photographs were taken before and after the study to monitor possible corneal distortion. Physiological changes which were graded (using biomicroscopy) included edema, neovascularization, injection, GPC, and fluorescein staining. Subjective symptoms such as blur, flare, photophobia, itching, burning, tearing, dryness, halos,

diplopia, lens dislocation, and adhesion were recorded at each visit.

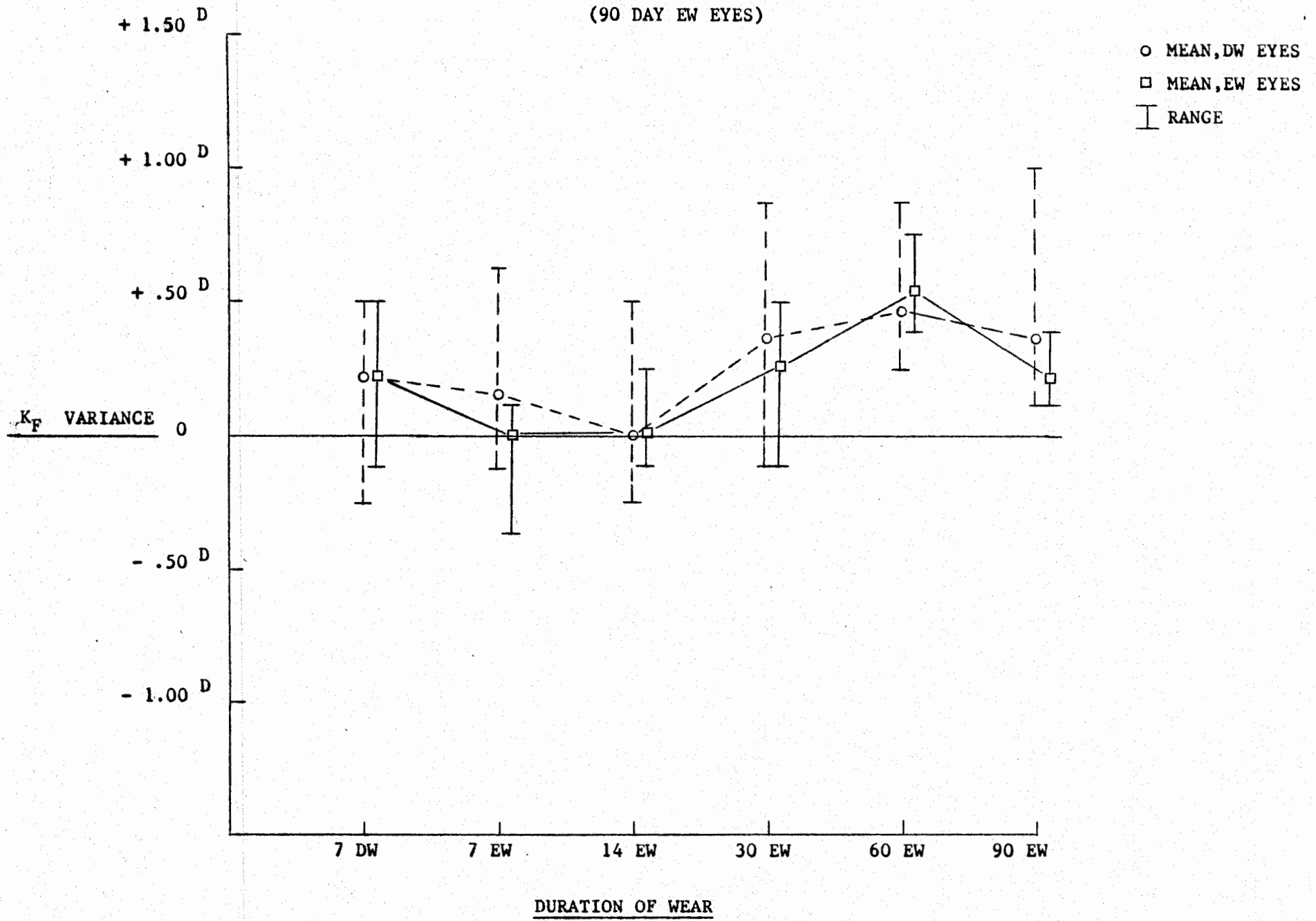
RESULTS

Refractive characteristics as well as length of EW, reason for withdrawal and adverse physiological changes are listed for all 18 subjects in appendix 2. Four of the subjects completed 90 days of EW; 5 others completed at least 30 days of EW. However all 5 of these chose to discontinue EW prior to finishing the full 90 days of EW. Individual data (and composite data) for changes in flattest corneal meridian (K_f), changes in principal meridians (ΔK), and changes in lens off refraction (spherical equivalent) for the DW and EW eyes of the four 90 day EW subjects are listed in appendices 3-7. Composite graphs showing mean variance and ranges in these measured parameters for the four 90 day EW subjects are shown on the following pages.

The flattest corneal meridian steepened .37 D for the four DW eyes and .22 D for the EW eyes. This difference between DW and EW is not clinically significant. The change in K_f of approximately .25 D may reflect methods of lens fitting or variations between clinicians' measurements. The ΔK measurements increased .28 D for EW and decreased .31 D for DW. The steepening of K_f in both DW and EW 90 day eyes correlates with changes in the spherical equivalent refractions. Both the DW and EW eyes required an increase in minus power: -.34 D mean for DW and -.53 D for EW. Analysis of corneoscope photographs after the EW period showed no indication of excessive corneal distortion. Throughout the study the corrected visual acuity with and without the contact lenses was 20/20 in both the DW and EW eyes. Although there appears to be little change between DW and EW, tests for statistical significance of the measured parameters are invalid due to only 4 subjects successfully completing the 90 days of EW.

Reasons for withdrawal from the study are listed below.

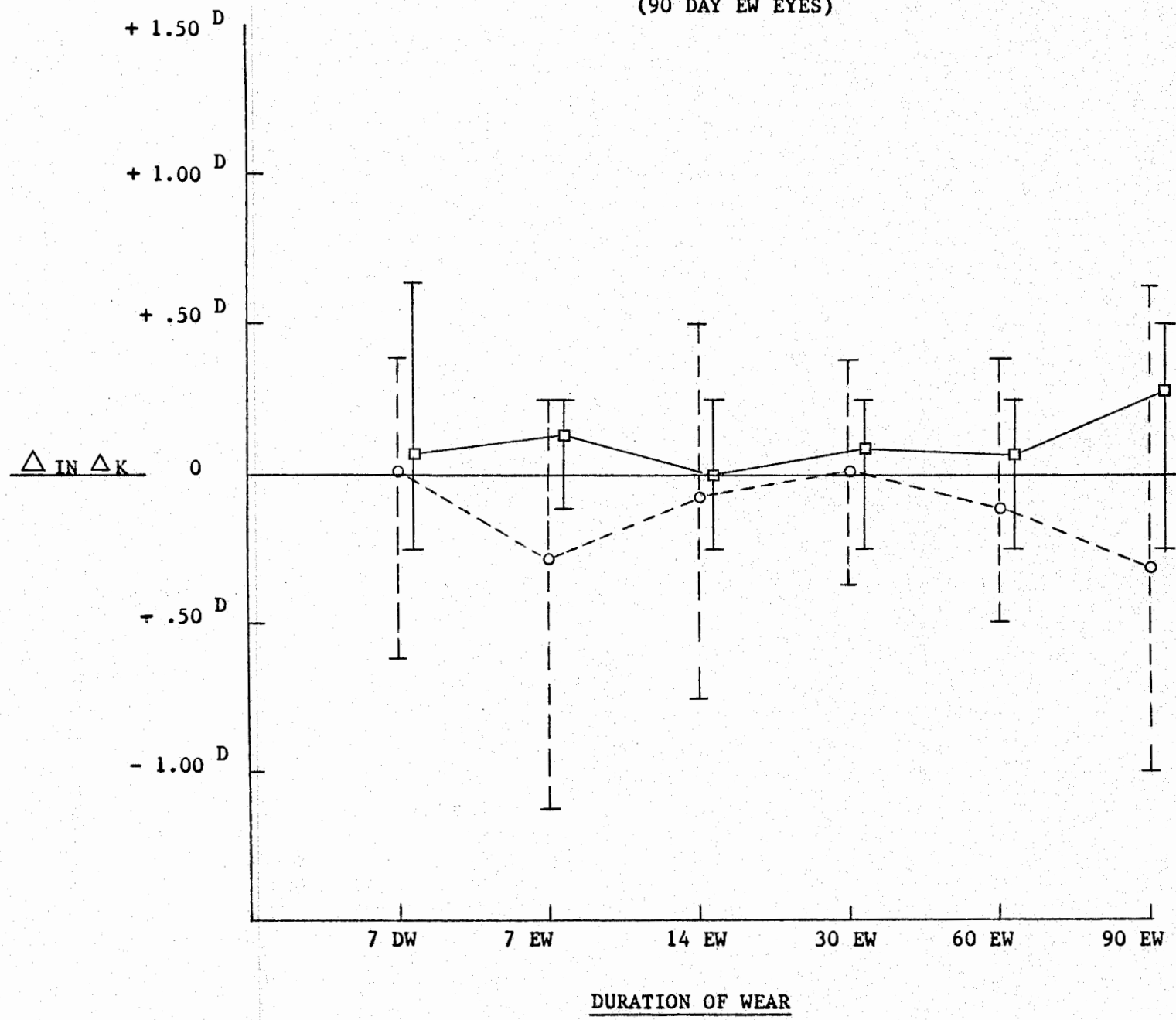
COMPOSITE DATA
(90 DAY EW EYES)



COMPOSITE DATA

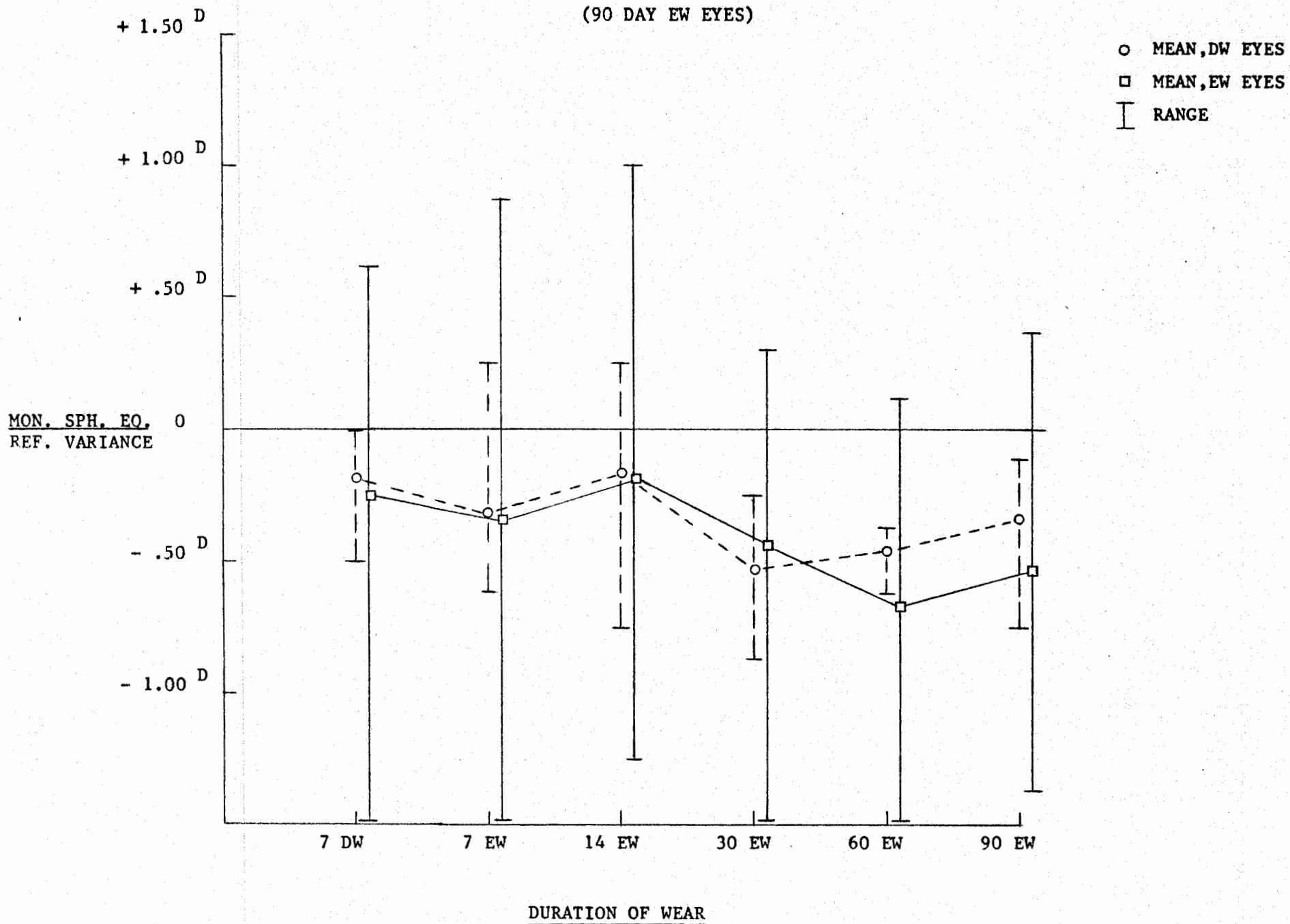
(90 DAY EW EYES)

- MEAN, DW EYES
- MEAN, EW EYES
- ┆ RANGE



COMPOSITE DATA

(90 DAY EW EYES)



<u>REASON FOR WITHDRAWAL</u>	<u>NUMBER OF SUBJECTS</u>
Poor motivation	6
Subject moved	3
Lost or broken lenses	2
Eye injury	1
Meibomianitis	1
Work environment conflict	<u>1</u>
total	14

Although it is often difficult to select motivated EW patients, important factors include personality, life style, working environment and previous contact lens experience. The two cases of withdrawal from the study because of eye injury and meimbomianitis were not related to the contact lens wear. In those patients who were not previous rigid contact lens wearers, there appeared to be a definite psychological factor to leaving this type of lens on overnight. Other patients often did not want to take the DW lens off at night because the lenses were so comfortable. The degree of comfort appeared mostly dependent upon an optimum lens to corneal relationship.

The main objectively observed responses to the lenses are summarized below. The primary responses were flourescein staining (3-9 and 6 o'clock) and injection. Corneal staining generally reflected a need for edge redesign and was improved by modification. Conjunctival injection was usually low grade and moderately diffuse in both the DW and EW eyes. There were also two cases of low grade GPC which presented during the study. In both cases the subjects showed a higher than normal protein content in their tears. Two patients who had evidence of low grade GPC prior to the study continued to exhibit signs but with no further proliferation. There were no complaints of itching with the four successful subjects. Other symptoms (blur, dryness) were relieved with increased frequency of cleaning and enzyming. Trace amounts of edema were noted in several subjects and one case of slight limbal blood vessel enchroachment (less than 1.5 mm into the cornea) was recorded. There were no differences in the corneal responses between the DW and EW eyes. However, several subjects did experience a slight amount of discharge in the EW eye upon awakening. The discharge usually occured at the beginning of EW and decreased with time.

ADVERSE OBSERVED RESPONSES

<u>Type</u>	<u>Grade</u>	<u># of DW eyes</u>	<u># of EW eyes</u>
Staining	Trace - 2+	8	8
Injection	Trace - 1+	4	4
GPC	Trace - 2+	4	4
Edema	Trace	2	2
Neovascularization	Trace	1	1
Discharge	Trace	0	4

The main subjective complaints to wearing the Equalens were dryness and flare. Dryness responses and observed 3-9 staining were generally reduced by lens modification. Patients with complaints of dryness exhibited either increased tear protein, 3-9 staining, or lens deposits. Increased use of reconditioning drops as well as enzyming generally improved the patients' subjective comments. Complaints of flare at night were evident with smaller lenses and larger pupils. Flare complaints were alleviated by fitting larger diameter lenses and reducing peripheral curve widths, allowing for a larger optic zone and less peripheral distortion. Most complaints from the patients were relieved by lens modification or more frequent use of reconditioning drops, cleaning, or enzyming. There was one case of lens dislocation early in the EW schedule. There were no reports of lens adhesion to the cornea or conjunctiva. Several lenses which were in the low minus power range developed serrated or chipped edges as a result of wear, cleaning, handling, or modification. Due to the brittleness of the lens material, they must be handled and modified carefully. Also, lens adhesions and flexure should be reduced by fitting base curves close to K_f and maintaining adequate center thickness.

DISCUSSION

Although only 4 subjects completed 90 days of EW of the Boston Equalens, no contraindications to extended wear were seen. Other subjects did not complete the 90 days of EW because of poor motivation or relocation. There were no complications which precluded 15 of the total 18 subjects from completing the 90 day EW schedule.

The other three subjects had complications, although not due to the wear of the contact lenses, which prevented them from finishing the study. Several subjects chose to go back to daily wear since they saw no advantage to overnight wear. There were no serious problems with corneal edema, neovascularization, GPC, ptosis, lens dislocation or adhesion. Central corneal curvature changes were minimal and a stable refractive status was maintained in both the DW and EW eyes. Other recent studies have not defined any adverse responses of corneal thickness, curvature, or endothelial characteristics from extended wear use of gas permeable lenses. Future studies should include long term (3-5 years) analysis of ocular responses to extended wear of these rigid lenses.

CONCLUSIONS

Gas permeable contact lenses appear to be a solution to the problems seen in extended wear use of hydrogel lenses. Successful extended wear of RGP lenses depends upon maintenance of a clean wettable lens as well as an optimum lens to cornea relationship, including edge design. The Boston Equalens is an excellent material supplying high oxygen transmissibility and wettability allowing for potential successful extended wear.

APPENDIX 1

CONTACT LENS CARE

CLEANING:

1. Wash hands with mild soap.
2. Completely cover lens with several drops of the Boston Cleaner in the palm of your hand.
3. For 20 seconds allow the lens to soak and then rub the lens gently for 10 seconds with your finger.
4. Rinse off thoroughly with fresh tap water.

STORAGE:

1. After cleaning lens, place lens in storage case.
2. Fill storage case with the Boston Conditioning Solution.
3. Soak for at least 4 hours (or overnight) before wearing.

INSERTION:

1. After removing the lens from the storage case, dip briefly in fresh tap water, if desired, and insert.
2. If lenses are removed temporarily, rub several drops of the Boston Conditioning Solution on both surfaces of the lens prior to insertion.
3. Rinse interior of storage case and completely replace the Boston Conditioning Solution every day.

REWETTING SOLUTION:

1. Use 1 to 3 drops as needed. Blink firmly at least 6 times after use.
2. With extended wear lenses use 1 to 3 drops before going to bed and upon awakening. Blink firmly at least 6 times after use.

MONITORING EYE HEALTH: TO BE CHECKED EVERY MORNING.

1. Look good -- eyes look good and healthy.
2. Feel good--eyes feel good.
3. See good--vision is clear and sharp through each eye.

IF YOU HAVE ANY CONCERNS OR QUESTIONS ABOUT WEARING THE LENS REMOVE IT IMMEDIATELY. THEN CALL AND WE WILL SEE YOU IMMEDIATELY IF NEEDED OR WILL ANSWER YOUR QUESTIONS REGARDLESS OF THE TIME. YOUR CONTINUED GOOD EYE HEALTH IS OUR CONCERN.

Doug Hamilton	357-6573
Bill Hoover	357-9809
Steve Sternitzky	359-9562
Dr. J. Peterson	357-6151 ext. 2314

APPENDIX 2

SUBJECT DATA

SUBJECT	AGE	REFRACTIVE ERROR		PREVIOUS C.L. WEAR	LENGTH OF EW	REASON FOR WITHDRAWAL	COMPLICATIONS
		SPH. (OD/OS)	CYL. (OD/OS)				
BB	25	-1.00/-0.50	-.25/-.50	NONE	30-90 DAYS	LOST LENS	2+ 3-9 STAIN, 2+ GPC, 1+ CONJ. INJ
PF	24	-1.75/-2.00	-.25/-.25	RGP	90+	-----	1+ 3-9 STAIN
LM	29	-4.00/-4.25	-.75/-.25	HYDROGEL	0	MOTIVATION	
JM	24	-5.75/-5.25	SPH/-1.00	RGP & HYDROGEL	90+	-----	1+ CONJ INJ, 1+ GPC, 1+ NEOVASC
MM	24	-2.50/-2.50	-.50/-.50	RGP & HYDROGEL	90+	-----	1+ STAIN
DQ	21	-1.75/-2.00	SPH/SPH	HYDROGEL	30-90	MOTIVATION	1+ DISCHARGE
DD	32	-3.00/-3.50	-.25/SPH	HYDROGEL EW	0	MEIBOMIANITIS	2+ GPC
LG	21	-1.50/-1.50	-.50/-.50	HYDROGEL	30-90	BROKEN LENS	TR 3-9 STAIN, 1+ DISCHARGE
DL	27	-1.00/-1.00	-.50/-1.00	RGP	0	MOTIVATION	
FR	24	-3.25/-2.50	-.50/SPH	NONE	30-90	JOB ENVIRONMENT	2+ CONJ INJ
ES	18	-2.25/-2.00	-.25/-.75	NONE	30-90	RELOCATION	TR 3-9 STAIN
VW	21	-1.00/-2.75	SPH/SPH	HYDROGEL	0	MOTIVATION	
JC	21	-3.00/-2.75	-1.50/-1.75	RGP	<30	EYE INJURY	1+ DISCHARGE, TR 3-9 STAIN
SG	33	-3.50/-4.25	-.50/-.50	PMMA & RGP	90+	-----	2+ 3-9 STAIN
BM	22	-1.50/-1.25	-.25/SPH	HYDROGEL	<30	RELOCATION	TR CONJ INJ, 1+ DISCHARGE
TM	21	-1.25/-1.00	-.25/-.50	HYDROGEL	<30	RELOCATION	1+ DISCHARGE
JO	23	-2.25/-1.75	SPH/-.75	NONE	0	MOTIVATION	
DW	31	-1.25/-0.75	-.50/-1.25	HYDROGEL	0	MOTIVATION	

APPENDIX 3

INDIVIDUAL 90 DAY EW DATA

SUBJECT: PF
EQUALENS PARAMETERS

	OD	OS
BC	8.1 mm	8.1 mm
OAD	9.0 mm	9.0 mm
OZ	7.8 mm	7.8 mm
POWER	-2.00 D	-2.00 D
CT	0.15 mm	0.15 mm

Kf VARIANCE

EYE	Baseline Kf	Day 7 DW	Δ in Kf Day 7 EW	14 EW	30 EW	60 EW	90 EW
OD (DW)	40.87 D	-0.25D	+0.12 D	-0.12 D	+0.12 D	+0.37 D	+0.12 D
OS (EW)	40.75 D	-0.12D	+0.12 D	0	+0.25 D	+0.37 D	+0.37D

Δ K VARIANCE

EYE	Baseline Δ K	Day 7 DW	Change in Δ K Day 7 EW	14 EW	30 EW	60 EW	90 EW
OD (DW)	1.12 D	+37 D	+25 D	+50 D	+37 D	0	+62 D
OS (EW)	1.00 D	+62 D	+25 D	+25 D	+25 D	+25 D	+37 D

LENS OFF MONOCULAR SPHERICAL EQUIVALENT (MSER)

EYE	Baseline MSER	Day 7 DW	Δ in MSER Day 7 EW	14 EW	30 EW	60 EW	90 EW
OD (DW)	-1.87 D	-.12 D	-.62 D	-.12 D	-.37 D	-.37 D	-.12 D
OS (EW)	-2.12 D	-.37 D	-.62 D	-.50 D	-.37 D	-.62 D	-.87 D

APPENDIX 4

INDIVIDUAL 90 DAY EW DATA

SUBJECT: SG
EQUALENS PARAMETERS

	OD	OS
BC	7.67 mm	7.54 mm
OAD	8.2 mm	8.1 mm
OZ	6.8 mm	6.7 mm
POWER	-4.75 D	-6.50 D
CT	.14 mm	.14 mm

Kf VARIANCE

EYE	Baseline Kf	Day 7 DW	Δ in Kf				
			Day 7 EW	14 EW	30 EW	60 EW	90 EW
OD (DW)	42.75 D	+0.50 D	+0.62 D	+0.50 D	+0.87 D	+0.87 D	+1.00 D
OS (EW)	43.25 D	+0.50 D	0	+.25 D	+.37 D	+.37 D	+.12 D

Δ K VARIANCE

EYE	Baseline Δ K	Day 7 DW	Change in Δ K				
			Day 7 EW	14 EW	30 EW	60 EW	90 EW
OD (DW)	0.75 D	+.25 D	-.37 D	-.37 D	-.30 D	-.30 D	-.50 D
OS (EW)	0.75 D	0	+.12 D	0	+.25 D	+.25 D	+.50 D

LENS OFF MONOCULAR SPHERICAL EQUIVALENT (MSER)

EYE	Baseline MSER	Day 7 DW	Δ in MSER				
			Day 7 EW	14 EW	30 EW	60 EW	90 EW
OD (DW)	-4.00 D	-.50 D	-.62 D	-.75 D	-.62 D	-.62 D	-.75 D
OS (EW)	-5.00 D	-1.50 D	-1.50 D	-1.25 D	-1.50 D	-1.50 D	-1.37 D

APPENDIX 5

INDIVIDUAL 90 DAY EW DATA

SUBJECT: JM
EQUALENS PARAMETERS

	OD	OS
BC	7.45 mm	7.38 mm
OAD	9.0 mm	9.0 mm
OZ	7.8 mm	7.8 mm
POWER	-5.00 D	-4.25 D
CT	0.15 mm	0.14 mm

Kf VARIANCE

EYE	Baseline Kf	Day 7 DW	Δ in Kf Day 7 EW	14 EW	30 EW	60 EW	90 EW
OD (DW)	44.87 D	+0.25 D	-0.12 D	-0.12 D	+0.62 D	+0.37 D	+0.12 D
OS (EW)	45.00 D	+0.25 D	-0.37 D	-0.12 D	+0.50 D	+0.75 D	+0.25 D

Δ K VARIANCE

EYE	Baseline Δ K	Day 7 DW	Change in Δ K Day 7 EW	14 EW	30 EW	60 EW	90 EW
OD (DW)	0.62 D	+0.12 D	+0.12 D	+0.25 D	+0.37 D	+0.37 D	-0.37 D
OS (EW)	0.75 D	-0.25 D	+0.25 D	0	-0.25 D	-0.25 D	-0.25 D

LENS OFF MONOCULAR SPHERICAL EQUIVALENT (MSER)

EYE	Baseline MSER	Day 7 DW	Δ in MSER Day 7 EW	14 EW	30 EW	60 EW	90 EW
OD (DW)	-5.75 D	-0.12 D	+0.25 D	+0.25 D	-0.87 D	-0.37 D	-0.25 D
OS (EW)	-5.75 D	+0.62 D	+0.87 D	+1.00 D	-0.12 D	+0.12 D	+0.37 D

APPENDIX 6

INDIVIDUAL 90 DAY EW DATA

SUBJECT: MM
EQUALENS PARAMETERS

	OD	OS
BC	7.38	7.45
OAD	9.0 mm	9.0 mm
OZ	7.8 mm	7.8 mm
POWER	-2.50 D	-2.50 D
CT	0.14 mm	0.14 mm

Kf VARIANCE

EYE	Baseline Kf	Day 7 DW	Δ in Kf Day 7 EW	14 EW	30 EW	60 EW	90 EW
OD (DW)	45.12 D	+0.25 D	+0.12 D	0	-0.12 D	+0.62 D	+0.12 D
OS (EW)	44.75 D	+0.37 D	0	-0.25 D	-0.12 D	+0.25 D	+0.25 D

Δ K VARIANCE

EYE	Baseline Δ K	Day 7 DW	Change in Δ K Day 7 EW	14 EW	30 EW	60 EW	90 EW
OD (DW)	1.25 D	-0.12 D	-0.12 D	-0.25 D	+0.12 D	0	+0.50 D
OS (EW)	1.75 D	-0.62 D	-1.12 D	-0.75 D	-0.37 D	-0.50 D	-1.00 D

LENS OFF MONOCULAR SPHERICAL EQUIVALENT (MSER)

EYE	Baseline MSER	Day 7 DW	Δ in MSER Day 7 EW	14 EW	30 EW	60 EW	90 EW
OD (DW)	-2.75 D	+0.25 D	-0.12 D	0	+0.25 D	-0.62 D	-0.25 D
OS (EW)	-2.75 D	0	-0.25 D	0	-0.25 D	-0.50 D	-0.25 D

COMPOSITE 90 DAY EW DATA

Kf VARIANCE

 Δ in Kf

EYES		Day 7 DW	Day 7 EW	14 EW	30 EW	60 EW	90 EW
DW	MEAN	+0.22 D	+0.16 D	0	+0.37 D	+0.47 D	+0.37 D
	RANGE	-.25 to +.50	-.12 to +.62	-.25 to +.50	-.12 to +.87	+.25 to +.87	+.12 to +1.00
EW	MEAN	+0.22 D	0	+0.03 D	+0.26 D	+0.54 D	+0.22 D
	RANGE	-.12 to +.50	-.37 to +.12	-.12 to +.25	-.12 to +.50	+.37 to +.75	+.12 to +.37

 Δ K VARIANCEChange in Δ K

EYES		Day 7 DW	Day 7 EW	14 EW	30 EW	60 EW	90 EW
DW	MEAN	+0.03 D	-0.28 D	-0.08 D	+0.02 D	-0.11 D	-0.31 D
	RANGE	-.62 to +.38	-1.13 to +.25	-.75 to +.50	-.37 to +.37	-.50 to +.37	-1.00 to +.83
EW	MEAN	+0.07 D	+0.13 D	0	+0.09 D	+0.06 D	+0.28 D
	RANGE	-.25 to +.62	-.12 to +.25	-.25 to +.25	-.25 to +.25	-.25 to +.25	-.25 to +.50

LENS OFF MONOCULAR SPHERICAL EQUIVALENT (MSER)

 Δ in MSER

EYES		Day 7 DW	Day 7 EW	14 EW	30 EW	60 EW	90 EW
DW	MEAN	-0.19 D	-0.31 D	-0.16 D	-0.53 D	-0.47 D	-0.34 D
	RANGE	-.50 to 0.0	-.62 to +.25	-.75 to +.25	-.87 to -.25	-.62 to -.37	-.75 to -.12
EW	MEAN	-0.25 D	-0.34 D	-0.19 D	-0.44 D	-0.66 D	-0.53 D
	RANGE	-1.50 to +.62	-1.50 to +.87	-1.25 to +1.00	-1.50 to +.25	-1.50 to +.12	-1.37 to +.37

REFERENCES

1. Mandell, R.B. Contact Lens Practice, 3rd ed., 1981. Charles C. Thomas Publishing, Springfield, IL. pp. 147-160.
2. Polse, K.A. Gas permeable lens materials and design. Intern. Ophthalmol. Clinics. 1986 Spring;26(1):131-148.
3. Dangel, M. E., et al. Aphakic extended-wear contact lenses after penetrating keratoplasty. Am J Ophthalmol. 1983; 95:156-160.
4. Bradley, W., Schoessler, J. Corneal response to thick and thin hydrophilic lenses. Am J Optom Phys Opt. Jul 1979;56(7):414-421.
5. Binder, P. Myopic extended wear with the Hydrocurve II soft contact lens. Ophthalmol. 1983; 90:623-626.
6. Rengstorff, R. H., Nilsson, K. T. Long term effects of Extended wear lenses: changes in refraction, corneal curvature, and visual acuity. Am J Optom Phys Opt. Jan 1985; 62(1):66-68.
7. Zantos, S., Holden, B. Ocular changes associated with continuous wear of contact lenses. Aust J Opt. Dec 1978;61(12):418-426.
8. Coon, L. J., Miller, J. P., Meier, R. F. Overview of extended wear contact lenses. AJOA Jun 1979; 50(6):745-749.
9. Binder, P. Complications associated with extended wear of soft contact lenses. Ophthalmol. Jun 1979;86(6):1093-1101.
10. Spoor, T., Hartel, W., Wynn, P., Spoor, D. Complications of continuous-wear soft contact lenses in a non-referral population. Arch Ophthalmol. 1984;102:1312-1313.
11. Holden, B., Wertz, G., McNally, J. Corneal Swelling response to contact lenses worn under extended wear conditions. Invest Ophthalmol Vis Sci 1983;24:218-226.
12. Wallace, W. Soft contact lens associated infectious corneal ulcer. Inter Eyecare Mar 1986;2(3):171-172.
13. Wilson, L. A., Ahearn, P. G. Association of fungi with extended-wear soft contact lenses. Am J Ophthalmol Apr 15, 1986; 101(4):434-436.

14. Lemp, M.A., Gold, J.B. The effects of extended wear hydrophilic contact lenses on the human corneal epithelium. *Am J Ophthalmol* Mar15, 1986; 101(3):274-276.
15. Mondino, B.J., Weissman, B.A., Farb, M.D., Pettit, T.H. Corneal ulcers associated with daily-wear and extended-wear contact lenses. *Am J Ophthalmol* Jul 15, 1986; 102(1):58-65.
16. Weissman, B.A., et al. Corneal ulcers associated with extended wear soft contact lenses. *Am J Ophthalmol* 1984;97:476.
17. Welsh, R. C. Continuous use of tiny hard corneal lenses for aphakia (200 cases). *Ann Ophthalmol* 1973;5:1003-1004.
18. Nesburn, A. B. Prolonged-wear contact lenses in aphakia. *Ophthalmol* Jan 1978;85(1): 73-79.
19. Mandell, R.B. *Contact Lens Practice*, 3rd ed., 1981. Charles C. Thomas Publishing, Springfield, IL. pg. 277.
20. Osborn, G., Andrasko, G., Barr, J. RGP lenses: Daily wear vs. extended wear. *Contact Lens Spectrum* Apr 1986; 1(4):32-49.
21. Donnerfeld, E.D., Cohen, E.J., et al. Changing trends in contact lens associated corneal ulcers: an overview of 116 cases. *CLAO* Jul 1986; 12(3):145-149.
22. Benjamin, W.J., Simons, M.H. Extended wear of oxygen-permeable rigid lenses in aphakia. *Intl Cont Lens Clin.* Sep 1984;11(9):547-560.
23. Epsy, J.W. An extended wear hard contact lens in aphakia. *Annals Ophthalmol.* Mar 1979;11(3):323-327.
24. Mertz, G. Overnight swelling of the living human cornea. *JAOA* Mar 1980; 51(3):211-213.
25. Brennan, N. Current thoughts on the aetiology of ocular changes during contact lens wear. *Aust J Optom.* Jan 1985; 68(1):8-24.
26. Holden, B. A., Mertz, G. W. Critical oxygen levels to avoid corneal edema for daily and extended wear contact lenses. *Invest Ophthalmol Vis Sci.* Oct 1984;25(10):1161-1167

27. Koetting, R.A., Castellano, C.F., Nelson, D.W. Extended wear with low Dk hard gas permeables. *Cont Lens Forum*. Feb 1985;10(2):77-79.
28. Bennett, E. Hydrogel versus rigid gas permeable lense for extended wear: Criteria and differences. *AJOA* Jul 1986; 57(7):500-501.
29. Solomon, J., Snyder, R., Klein, P. A clinical experience with extended wear RGP lenses. *Cont Lens Spectrum*. Jul 1986; 1(7):49-51.
30. Hill, R.M., Brezinski, S., Flynn, W.J. The rigid 'super-permeables'. *Cont Lens Forum* Jan 1985;10(1):35-39.
31. Andrasko, G.J., Bennett, E.S. The rigid silicone/acrylates' revival. *Cont Lens Forum*. May 1985;10(5):55-63.
32. Ghormely, N.R., Bennett, E.S. Rigid extended wear: Why are they necessary? *Inter Eyecare* Jan 1986; 2(1):34-35.
33. Schwartz, C.A. The new super permeables. *Cont Lens Forum* Apr 1986;11(4):26-31.
34. Bennett, E.S., Andrasko, G. Facing the hard facts. *Rev Opt* Apr 1985; 122(4):37-44.
35. Levy, B. Rigid gas-permeable lenses for extended wear- a 1-year clinical evaluation. *Am J Optom Phy Opt*. Dec 1985; 62(12):889-894.
36. Kamiya, C. Cosmetic extended wear of oxygen permeable hard contact lenses: One year follow-up. *AJOA* Mar 1986; 57(3):182-184.
37. Zantos, S.G., Zantos, P.O. Extended wear feasibility of gas permeable hard lenses for myopes. *Int Eyecare* Jun 1985; 1(1):66-75.
38. Guillon, M. Rigid gas-permeable extended wear today. *Int Eyecare* Aug 1985; 1(3):213.
39. Kenyon, E., Polse, K.A., O'Neal, M.R. Ocular response to extended wear of hard gas-permeable lenses. *CLAO* Apr 1985;11(2):119-123.
40. Fonn, D., Holden, B.A. Extended wear of hard gas permeable contact lenses can induce ptosis. *CLAO* Apr 1986; 12(2):93-94.

41. Levy, B. The use of a gas permeable hard lens for extended wear. Am J Optom Phy Opt May 1983; 60(5):408-409.
42. Forrest, J.F., Henry, V.A., Bennett, E.S. A clinical investigation of the Paraperm EW rigid gas-permeable contact lens for cosmetic extended wear. Am J Optom Phy Opt. Oct 1984; 61(10):111P.
43. Mandell, R., Liberman, G. The Paraperm lens. Rev Opt Apr 1985;122(4):74-76.
44. Masler, W. Optacrytl K study. Cont Lens Forum Sep 1983; 8(9):21.
45. Mannis, M.J., Zadnik, K., Deutch, D. Rigid contact lens wear in the corneal transplant patient. CLAO Jan 1986;12(1):39-42.
46. Keates, R.H., Ihlenfeld, J.V., Isaacson, W.B. An introduction to fluoropolymer contact lenses: a new class of materials. CLAO Oct 1984; 10(4):332-33.