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Clinical comparison of flat versus alignment fitting philosophies

Abstract

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**CLINICAL COMPARISON
OF
FLAT VERSUS ALIGNMENT
FITTING PHILOSOPHIES**

By

**Diana M. Wahl
Renee D. Allison
Liza T. Garhofer**

**A thesis submitted to the faculty of the
College of Optometry
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Forest Grove, Oregon
for the degree of
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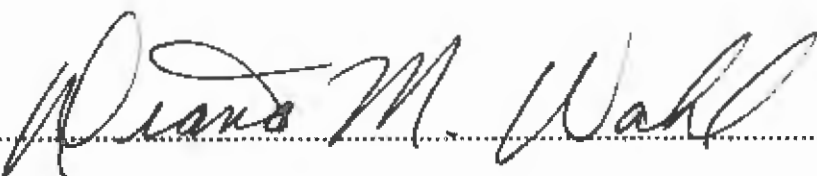
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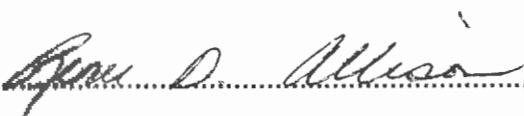
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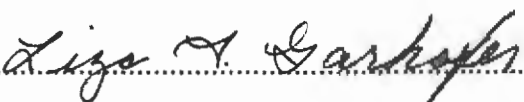
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ABSTRACT

A clinical study of twenty-three subjects was conducted to compare corneal changes and patient responses observed with flat versus alignment fitting philosophies. Corneal changes were assessed by comparison of initial and endpoint data gathered on refractive status, corneal curvature, and corneal staining. The subjective response to lens comfort was also monitored. Corneas fitted with lenses on alignment showed statistically less change in corneal astigmatism, visual acuity, and staining than lenses fitted flat.

Key Words: Rigid gas-permeable contact lens, RGP, Boston RXD, Fitting philosophy.

INTRODUCTION

Since the advent of contact lenses, researchers have attempted to minimize corneal trauma and increase patient comfort by altering the materials, size, and the shape of the lens. Improvements in oxygen transmission obtained with higher DK materials and improvements in polymers which allow thinner lens designs, leave shape as a major factor effecting corneal changes and comfort. ¹

The corneal epithelium is dependent on the pre-corneal tear film for its oxygen supply. ² Minimum corneal oxygen demand ranges from 2-5%, but PMMA only allows between 1-3% of oxygen to reach the cornea if tear exchange is accomplished. ³ PMMA lenses relied on a tear pump to replace oxygen and tears under the lens, but the apical clearance observed with the steep base curves required for centration often resulted in tear stagnation and lack of oxygen exchange. Central corneal edema and microcysts were commonly observed consequences of oxygen deprivation caused by PMMA and early gas permeable rigid lenses. ⁴ Corneal deformation and steepening with an associated increase in myopia and spectacle blur were also effects observed with small, steep lenses. ⁵ Spectacle blur, the subjective observation of decreased vision while wearing spectacles following contact lens wear, resulted secondary to corneal molding or edema. ⁶ Loss of corneal sensation and resultant reduced blink reflex can also occur following corneal edema, and corneal

hypoxia can also lead to more serious consequences such as neovascularization of the normally avascular tissue. 7,8

PMMA lenses were often fitted with small diameters to reduce hypoxia secondary to the lack of oxygen permeability of the polymethylmethacrylate material. Steep base curves were required to achieve centration and reduce the flare observed with small optical zones. The small interpalpebral lens also created patient discomfort and adaptation problems due to contact between the upper lid and the lens edge during blinking. 9 The rigid lens wearer may adopt an incomplete blinking pattern to minimize the sensation of the lid contacting the lens edge, and as a consequence develop peripheral corneal desiccation from the incomplete spread of tear film. This desiccation of the peripheral cornea is also known as three and nine o'clock staining and can progress to the formation of dellen. 10

Sarver used infra-red light to study the blink responses of subjects wearing a lens on only one eye. He found that peripheral staining occurred on the eye without a lens and concluded that the lens worn on one eye had altered the blink rate and lid closure of the eye without the lens. 11 Others speculate that the gap created between the lens edge and the cornea may restrict the spread of the tear film causing desiccation. 12 Blinking exercises are recommended by many practitioners to eliminate corneal drying. 13

Korb advocates using a large diameter lens, very flat base curve, and specially designed edge which curves toward the lid to attain a superior, lid-attached fit. This method enables the lens to glide over the cornea with the lid during blinking which decreases interaction

between the upper lid and lens edge and therefore does not inhibit blinking. Korb stresses the importance of blinking in maintaining corneal wetting and reducing peripheral staining.¹³ Bennett, in a 12 month study on extended wear rigid gas-permeable lenses, found one-third less incidence of corneal desiccation with superior riding lenses as interpalpebral lenses. Schnider agrees with the under-lid philosophy, but prefers an alignment fit to reduce bearing areas which disturb the mucin layer and prevent adequate tear exchange.¹⁴

Studies utilizing PMMA materials found central corneal edema and thickening occurred with all fitting methods. In a retrospective study, Brannen analyzed three fitting philosophies; alignment, flat or steep and found that large, flat lenses created the least amount of peripheral corneal staining with PMMA lenses. He further concluded that central corneal edema was reduced, but not eliminated by utilizing a flat fitting method.¹⁵ Barr and Schoessler found that lenses fit 1D flatter than the patients' flattest corneal meridian induced the least amount of corneal thickening as measured with pachometry. Although the flat lens was found to cause less edematous change, they do not advocate this fitting method due to increased corneal astigmatism with long-term wear.¹⁶ Hage determined that lenses fit with base curves equal to the subjects flattest corneal meridian caused more corneal thickening than those lenses fit flatter than K. He believes that flat lenses permit a greater amount of oxygen to reach the cornea and the mechanical effect of the lens riding on the cornea has little effect.¹⁷

The advent of gas permeable polymers eliminated many of the problems originally observed with PMMA lenses. The oxygen permeability of the new materials allowed the lenses to be fit larger and the

subsequent increase of the optical zone reduced the need for centration and therefore steep base curves. Studies using early gas-permeable materials showed that corneal oxygen demands could be maintained without a tear pump due to oxygen permeability of the material.¹⁸ Finnemore and Korb compared the incidence of corneal edema found with PMMA and an early gas-permeable polymer and determined that 96% of PMMA wearers had significant corneal edema, while only 16% of gas-permeable wearers showed any edematous changes.¹⁹ Further advances in gas-permeable polymers with increased oxygen permeability have practically eliminated the incidence of central corneal edema. Sevigny monitored the corneas of Boston lens wearers with computerized pachometry following 12 hour wearing periods and found no statistically significant levels of corneal edema.²⁰

There are many opinions as to which fitting method creates the least corneal insult and the greatest patient comfort. There are still those who believe in the small, steep interpalpebral fitting philosophy once popular with PMMA, but they are in the minority.²¹ The majority of researchers advocate an alignment or flat fitting philosophy. Many studies have been conducted using PMMA to determine the relationship between contact lens fitting philosophy and corneal contour changes, but few have been completed using rigid gas-permeable materials. In early studies of PMMA, Rengstorff found that all subjects experienced between 0.5D and 1D corneal steepening following an 8 hour wearing period regardless of whether they were fit with lenses on K, flat, or steep. He found the steepening to be greater in the horizontal meridian and both meridians flattened slightly following contact lens removal.²² The flattening trend continued over time and remained an

average of 0.57D flatter than original readings in the horizontal meridian, inducing with-the-rule astigmatism. ²³ He believes corneal changes cannot be attributed to the shape of the lens. ²² Saks also observed initial corneal steepening followed by flattening over time and further reported that almost all cases resulted in an apical clearance fit, regardless of the initial fitting method used. ²⁴ Goldberg and Misage completed studies with similar results. ^{25,26}

Carney believes that corneal shape changes may be caused by both uneven corneal thickness resulting from decreased oxygen and by mechanical forces which mold the cornea. He found marked flattening or steepening occurred with flat or steep lenses respectively in an oxygen rich environment. But, in an oxygen deprived environment, both flat and steep lenses caused corneal steepening secondary to central corneal thickening. ²⁷

DeRubeis found no evidence of change in the horizontal meridian following a one month wearing period of Boston II gas-permeable contact lenses fit on alignment although the vertical meridian flattened by an average of 0.31 D. At the end of three months, the researchers found that horizontal and vertical meridians had returned to pre-fitting readings and therefore they conclude that gas-permeable contact lenses have no statistically significant effect on corneal curvature. ²⁸ Sevigny used an ON K fitting philosophy with Boston lenses to monitor the corneal curvature of 50 subjects over a three month interval. He found no statistically significant change in the horizontal meridian had occurred following 12 hour wearing periods. ²⁰ These findings imply the corneal steepening found in studies of PMMA was secondary to edema and

subsequent thickening alone, but this does not explain the long term flattening observed nor the corneal astigmatism induced with PMMA.

Refractive changes have been determined to depend on the fitting philosophy used and the length of time the lenses are worn. Many rigid lens wearers report decreased visual acuity with spectacles and variability in refraction is often found. Fanti evaluated visual acuity and refractive changes in 186 subjects using silicone lenses and a flat fitting philosophy. He found an increase in visual acuity with rigid lenses and a mean refractive shift of 0.19D toward hyperopia. A corresponding 0.05mm flattening of the cornea was also documented.²⁹ Rengstorff determined that refractive changes usually involve with-the-rule astigmatism and these changes correlate with the change in keratometry readings.³⁰ Sevigny found no statistically significant refractive changes occurred with Boston gas-permeable contact lenses which were fit with an ON K base curve.²⁰

Polymer Technology, the manufacturers of Boston RXD material used in this study, recommend fitting their lenses between 0.25D to 0.75D flatter than the flattest corneal meridian as measured by keratometry for those corneas with less than 1.5D of corneal astigmatism. The fluorescein pattern recommended should show mild apical bearing or an alignment pattern and the lenses should also be designed to ride in a superior, lid attached position. Polymer Technology recommends avoiding apical pooling or clearance when fitting with RXD materials.³¹ Boston RXD material was selected for this study due to its excellent oxygen transmission and easy machineability. The inherent stability of the material allows manufacture in the thin lens designs needed to obtain the lid attached fitting without flexure and warpage.³²

MATERIALS AND METHODS

Subjects:

Twenty three subjects, solicited through direct advertisement, received complete vision examinations and were determined to be free of contraindications to contact lens wear prior to participation in the study. All subjects signed an informed consent document prior to commencing lens wear. Current soft lens wearers were accepted to participate in the study following discontinuation of lens wear for one week prior to the initial measurements. Spherical refractive error among subjects ranged from +0.50 D to -7.25 D inclusive. All subjects had less than 2.0 D of corneal astigmatism per eye and no greater than 0.75 D of difference in cylinder correction between eyes. Tear break-up time was determined to be greater than fifteen seconds per eye on all subjects. Subjects ranged in age from 19 to 43.

Lenses:

Subjects were trial fitted with one lens on alignment with the flattest corneal meridian and the opposite lens fit flatter than K. Classification of contact lens fit was determined by evaluation of fluorescein pattern observed through a biomicroscope and Wratten #12 filter as described by Bennett.³³ An alignment fit appeared as a thin even layer of fluorescein, while a flat fit showed slight apical touch. The fluorescein pattern was used to evaluate fit instead of keratometer readings alone because it allows the direct observation of lens-to-cornea alignment. The assignment of flat or alignment was random and neither the subject nor the researcher responsible for collecting

objective data knew which method was initially assigned, allowing a double masked comparison. All lenses were fit to maintain a superior-central position on the cornea and move with the lid during blinking. The rigid-gas-permeable lenses used were composed of Boston RXD, a fluoro-silicone-acrylate polymer prescribed for daily wear. All lenses were manufactured by the same laboratory in a tetracurve design with a medium blend and no modifications were made to the lenses. Diameters ranged from 9.2 mm to 9.6 mm.

Follow up:

Progress evaluations were performed at intervals of one week and one month following dispensing. Refractive status, corneal curvature, and corneal integrity were monitored at these intervals as well as subjective responses to comfort. An investigator who was not responsible for gathering initial data monitored the corneal changes to allow a masked study. Lenses were re-measured following one month of wear to verify base curve stability.

Staining was evaluated using a scale from 0-4 with 1 being minimal punctate staining and 4 coalescent staining.

Data analysis:

Objective findings, such as visual acuity, staining, and corneal curvature were analyzed with a Wilcoxon signed-rank test for non-parametric data. Subjective responses from questionnaires completed at one month progress exam were analyzed by Chi square (binomial distribution) with a significance level of $\alpha = 0.05$.

RESULTS

Table 1 summarizes the statistical analysis of all the sampled categories. Keratometry changes in the vertical meridian were greater for the flat lens group, although the aligned fit did cause minimal corneal flattening over one month of wear. Table 2 and Figures 1 & 2 depict the overall group means for keratometric changes. Flattening was also observed in the horizontal meridian for both groups but was greater in the flat lens group.

Insert Table 1 and Figures 1-2 about here

In conjunction with the corneal flattening, there was also a statistically significant change in visual acuities following lens removal with the flat fit compared to the aligned fit. Visual acuities were analyzed in decimal form based on the standard Snellen acuity chart, with 20/20 equal to 1. The eye wearing the flat lens showed a marked improvement in visual acuity. Table 3 and Figure 3 depict the mean change in visual acuity.

When considering corneal staining, the flat lens caused more staining than the aligned fit. Table 3 and Figure 4 depict the mean change in corneal staining over the one month period between the two groups.

Insert Table 3 and Figures 3-4 about here

Table 4 summarizes the observed frequency chart for all subjective data. There was no significant difference between the two fitting methods in relation to burning, redness or sandy eyes. Neither lens awareness nor lens ejection were found to be statistically significant; however, both showed strong indications of more difficulties with the flat lenses.

Insert Table 4 and Figures 5-6 about here

No evidence of corneal edema, neovascularization, or microcysts were observed with either fitting method.

Table 1

Wilcoxon signed-rank and Chi square comparison results

Categories	p-value (alpha=0.05)	Results
1. ΔK vertical	p=0.0094	This is statistically significant. The flat lens caused increased flattening of the cornea.
2. ΔK horizontal	p=0.0461	This is statistically significant. The flat lens caused corneal flattening in the vertical meridian.
3. Δ Visual Acuities	p=0.0135	This is statistically significant. Post lens wear VA's improved in the eyes fit with the flat lens.
4. Δ Staining	p=0.0351	This is statistically significant. Staining is greater with the flat lens.
5. Lens Awareness	p=0.0591	This is not statistically significant; however, the general trend suggests that lens awareness is greater with the flat lens.
6. Lens Ejection	p=0.0591	This is not statistically significant; however, the general trend suggests that lens ejection is greater with the flat lens.
7. Burning Eyes	p=0.7486	There is no statistical difference.
8. Red Eyes	p=0.7626	There is no statistical difference.
9. Sandy Eyes	p=0.5538	There is no statistical difference.
10. Spectacle Blur	p=0.7569	There is no statistical difference.
11. Lens Comfort	p=0.5492	There is no statistical difference.

Table 2

Keratometric Changes in Diopters
(Data expressed as change from baseline)

	<u>Horizontal Meridian</u>		<u>Vertical Meridian</u>	
	Aligned Fit	Flat Fit	Aligned Fit	Flat Fit
Mean*	0.12	0.296	0.467	0.82
S.D.	0.374	0.423	0.533	0.68

*The Mean is an overall group mean expressed in diopters with + = flatter, - = steeper.

Table 3

Corneal Changes
(Data expressed as change from baseline)

	<u>Visual Acuity*</u>		<u>Corneal Staining</u>	
	Aligned Fit	Flat Fit	Aligned Fit	Flat Fit
Mean	-0.02	-0.126	1.53	2.00
S.D.	0.057	0.171	0.656	1.034

*Negative changes indicate improvement in VA.

Table 4

Observed Frequency Table

(Data expressed in negative and positive responses per fit.)

		<u>Aligned Fit</u>	<u>Flat Fit</u>
Lens Awareness	yes	04	11
	no	19	12
Lens Comfort	yes	11	08
	no	12	15
Sandy Eyes	yes	09	12
	no	14	11
Red Eyes	yes	07	10
	no	16	13
Burning Eyes	yes	07	16
	no	16	07
Spectacle Blur	yes	08	08
	no	15	15
Spontaneous Ejection	yes	00	05
	no	23	18

* The data is based on subjective yes and no questions from a questionnaire. Please see Appendix A for details on the questionnaire.

Figure 1

The Mean K Vertical Changes in Diopters

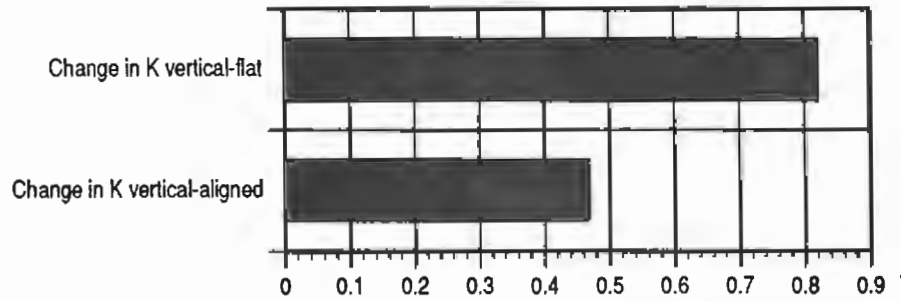


Figure 1 compares the mean difference of change in diopters between aligned and flat fit.

Figure 2

The Mean K Horizontal Changes in Diopters

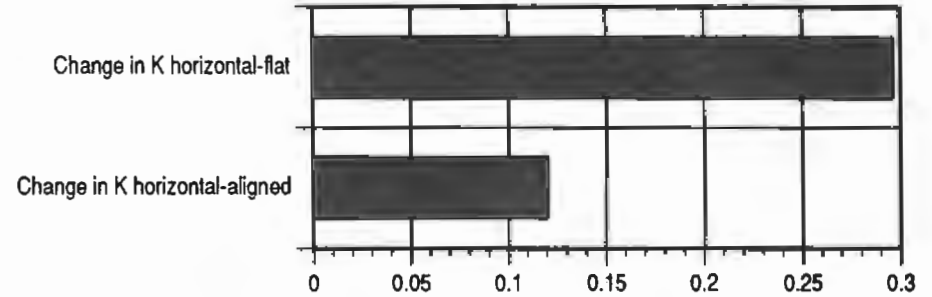


Figure 2 compares the mean keratometric changes in the horizontal meridian between the flat and aligned fit.

Figure 3

The Mean Visual Acuity Changes

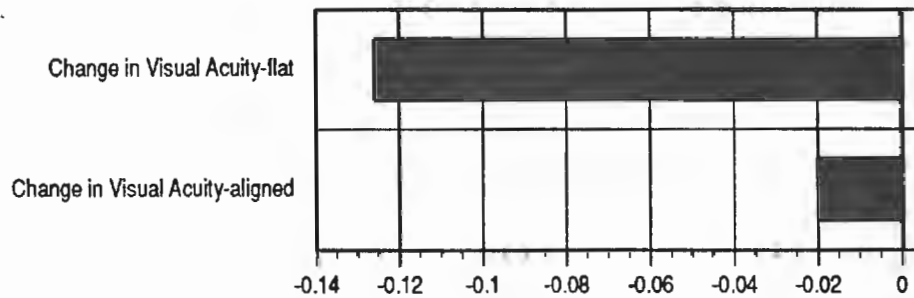


Figure 3 shows the mean change in visual acuity in each group. Negative changes indicate improved visual acuity.

Figure 4

Comparison of the Mean Staining Changes

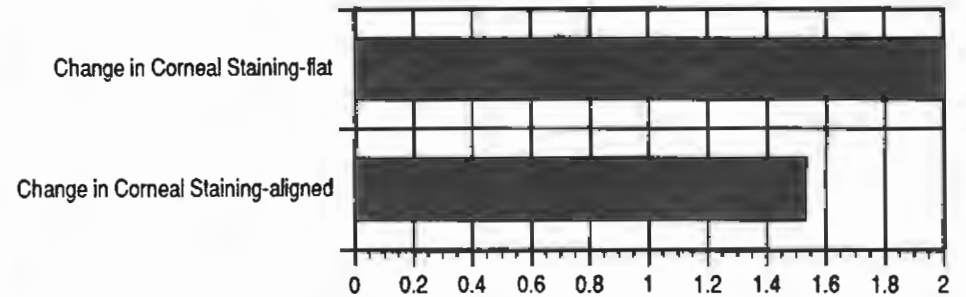


Figure 4 shows the mean change in staining over one month in each group.

Figure 5

Subjective Response to Lens Awareness.

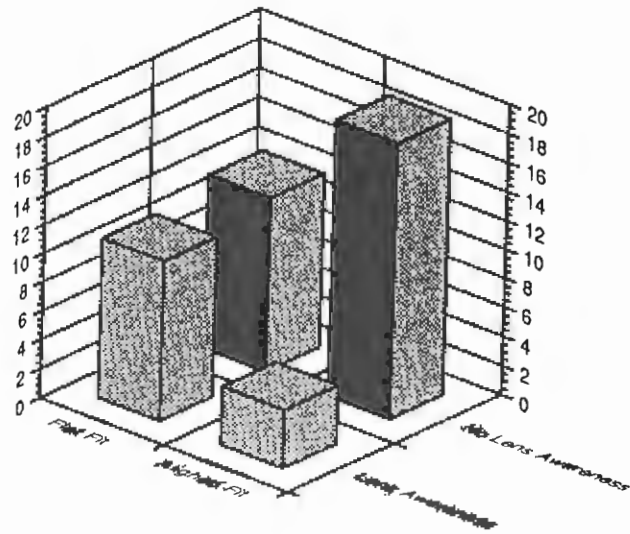


Figure 5 represents the total net positive and negative responses of the flat and aligned groups to the question relating to subjective lens awareness. See Appendix A.

Figure 6

Subjective Response to Spontaneous Ejection

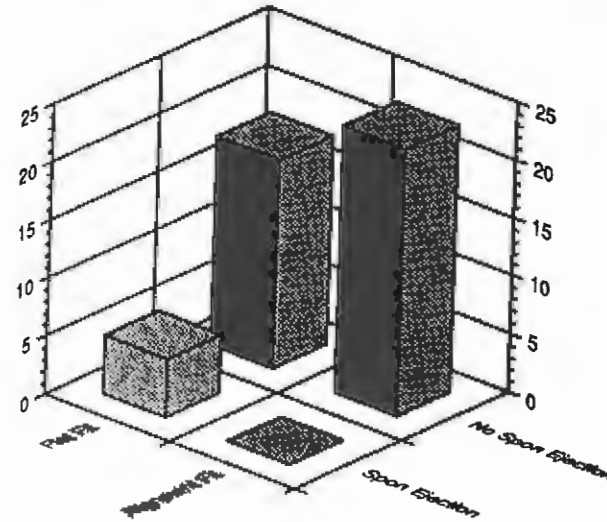


Figure 6 demonstrates the total positive and negative responses of the aligned and flat groups to the occurrence of spontaneous ejection of the lens. See Appendix A.

DISCUSSION

Two distinct fitting philosophies exist with today's rigid-gas-permeable materials: fitting ON K, or to achieve apical alignment and fitting flatter than K to enhance lid interaction. The Korb philosophy represents the extreme of the flat fit philosophies. He cites improved tear exchange, comfort, reduced staining levels, and less inhibition of blinking as advantages of this philosophy. However, this study shows that, in fact, flat fits caused increased staining, decreased comfort (manifested by lens awareness as opposed to true discomfort), increased spontaneous ejection, and most importantly changes in visual acuity and corneal curvature.

Spectacle blur is an important feedback mechanism to assist patients with monitoring their corneal health. A well fitting contact lens should cause minimal changes to corneal physiology and physical integrity. Therefore, a good spectacle RX should be dispensed prior to commencement of contact lens wear to allow the patient to observe if any visual acuity changes have occurred. If any radical changes in corneal curvature or refraction occur, the patient will be unable to wear the spectacles, and overwear of the contact lenses may occur. Therefore, the patient must be informed of the possibility of spectacle blur and advised to return to the prescribing doctor if symptoms occur. While spectacle blur should have been noticed to a significant degree with the flat lens in view of the corneal curvature changes observed, the subjects rarely reported it, which is most likely due to inadequate explanation prior to the study. Had the subjects been trained to monitor acuity monocularly,

they would likely have reported blur in the eye in which greater amounts of corneal curvature changes occurred. One subject, whose visual acuity in the flat fit eye changed from 20/200 at baseline assessment to 20/20 at one month, spontaneously observed increased acuity in one eye without correction.

No significant difference in lens comfort was noted between the two fitting methods at the one month progress evaluation, however many subjects reported finding the flat lens less comfortable than the alignment lens at the end of one week. These observations are probably due to increased lid awareness during the initial adaptation period. It appears that subjects adapted to the alignment lens at a faster rate than the flat lens.

While differences in lens awareness and lens ejection were not found to be statistically significant, there is a strong trend toward the flatter fitting lens caused greater lens awareness and higher frequency of lens ejection. Of those subjects who reported the incidence of spontaneous ejection of a lens, all were determined to have occurred with the flat lens, with a total of rate of occurrence of 20%.

As anticipated, no significant differences in burning, redness, or dryness were found as these factors are usually attributed to dry eye or material factors and would likely be equal in both eyes. No changes in base curve from initial manufactured specifications were found at the one month progress evaluation, showing Boston RXD to be a highly stable polymer.

From the resultant corneal flattening observed with flat lenses and the absence of central corneal edema, we conclude that the changes are probably due to corneal molding. The corneal flattening also contributed to an increase in visual acuity in myopic subjects secondary to decreased corneal curvature and power. These findings have been well documented in previous research and show the most significant reason against utilizing a flat fitting philosophy. The ortho-K effect observed on corneal contour negates any beneficial effects on tear exchange, blinking, etc.

The statistically significant increase in peripheral corneal staining observed following flat lens wear cannot be attributed to a decreased blink rate because the contralateral eye was not effected equally. In order for this scenario to occur we would have to assume that each eye were blinking independently at different rates and amplitudes which is very unlikely. If the blink rate were reduced by either lens, both eyes would be effected and an equal amount of staining would be expected on both eyes. Although the staining is most likely explained by an increased lid-cornea gap created by the flatter lens, the researchers acknowledge that no consideration was given to the effect edge lift or peripheral curves may have contributed. Finally, it must also be mentioned that the results reported are for short-term wearing schedules and that long-term effects may be different.

In conclusion, it is our contention that alignment fitting causes less corneal molding, staining, and visual acuity changes than flat lenses and it appears that patients may adapt to the alignment lens sooner than a flat lens. Flat lenses are also contraindicated due

to the potential over-minusing effect with spectacles following lens wear. We believe all patients should receive a current pair of spectacles to monitor changes and be advised of possible side effects of lens wear if flat lenses are to be prescribed.

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Appendix A

Sample Questionnaire given at one week and one month follow-up.

PATIENT COMFORT EVALUATION

Name: _____

Date: _____

PROGRESS EXAMINATION NUMBER: 1 2 3 4

1. Please describe the comfort level of each lens INITIALLY after application.

RIGHT EYE:

LEFT EYE:

Very Comfortable _____

Very Comfortable _____

Comfortable _____

Comfortable _____

Uncomfortable _____

Uncomfortable _____

Painful _____

Painful _____

2. Please describe the comfort level of each lens at the END of the wearing period.

RIGHT EYE:

LEFT EYE:

Very Comfortable _____

Very Comfortable _____

Comfortable _____

Comfortable _____

Uncomfortable _____

Uncomfortable _____

Painful _____

Painful _____

3. Do you ever experience any of the following problems?

RIGHT EYE:

LEFT EYE:

Burning:

Burning:

morning _____

morning _____

evening _____

evening _____

All times _____

All times _____

Redness:
morning _____
evening _____
All times _____

Redness:
morning _____
evening _____
All times _____

Dry or Sandy:
morning _____
evening _____
All times _____

Dry or Sandy:
morning _____
evening _____
All times _____

4. Are you more aware of either lens during blinking?
Right eye Left eye No difference

5. Do you experience any blurring of vision while wearing glasses following contact lens wear?
Right eye Left eye No difference

6. Is one lens easier to remove than the other?
If so, which lens?

7. Does one lens tend to pop out or decenter more than the other lens?
Right eye Left eye No difference