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A clinical evaluation of the CIBA bisoft and the Bausch & Lomb P.A.1 bifocal soft contact lenses

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A clinical evaluation of the CIBA bisoft and the Bausch & Lomb P.A.1 bifocal soft contact lenses

Abstract

This study attempted to answer the following questions: Is there a difference between the Ciba BISOFT and the Bausch and Lomb P.A.1 bifocal soft contact lenses in providing an acceptable correction? What limitations are presented to the presbyopic contact lens patient? A literature review has failed to reveal a comparison study dealing with the performance of these lenses. Even though the visual acuity obtainable in the majority of subjects was 20/20, persistent complaints of glare, flare, double vision, and poor night vision limited these lens designs. Due to optics involved and the resultant reduction in acuity, these lenses may be best suited only for occasional use rather than full time wear. This LS obviously dependent on the patient's visual demands.

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A CLINICAL EVALUATION OF THE
CIBA BISOFT AND THE BAUSCH & LOMB P.A.1
BIFOCAL SOFT CONTACT LENSES

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SUBMITTED TO THE FACULTY OF
PACIFIC UNIVERSITY COLLEGE OF OPTOMETRY
FOR PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE
DOCTOR OF OPTOMETRY

SPRING 1984

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ABSTRACT

This study attempted to answer the following questions: Is there a difference between the Ciba BISOFT and the Bausch and Lomb P.A.1 bifocal soft contact lenses in providing an acceptable correction? What limitations are presented to the presbyopic contact lens patient? A literature review has failed to reveal a comparison study dealing with the performance of these lenses.

Even though the visual acuity obtainable in the majority of subjects was 20/20, persistent complaints of glare, flare, double vision, and poor night vision limited these lens designs. Due to optics involved and the resultant reduction in acuity, these lenses may be best suited only for occasional use rather than full time wear. This is obviously dependent on the patient's visual demands.

INTRODUCTION

The scope of this paper will deal with the designs by Bausch and Lomb (P.A.1) and Ciba (BISOFT). Appendix A lists a comparative analysis of their characteristics. The major differences in the two lens designs is how the reading addition is generated, the available near powers, and base curves.

Background

Bausch and Lomb and Ciba's bifocal design can be found in Figure 1A and 1B. It can be shown that the Bausch and Lomb gradually increases in near power (progressive addition), while the Ciba BISOFT has two distinctive power zones (simultaneous vision design).

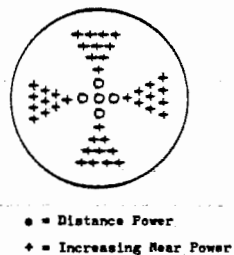


Figure 1A
Bausch & Lomb Bifocal Design

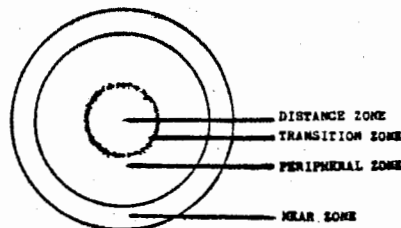


Figure 1B
Ciba Vision Bifocal Design

Literature Review - Bausch and Lomb P.A.1

A clinical evaluation of the Bausch and Lomb bifocal, by Caffery,¹ et al., revealed an overall success rate of 59 percent. The range of visual acuity at distance and near for the successful patients was from 20/20 to 20/60 with an average of 20/30. This study showed that

reading spectacles may still be necessary for long periods of close work. It was stated that this type of bifocal contact lens would allow visual functioning at intermediate and close distances such as reading menus, looking up information in a telephone directory, etc., without having to put glasses on.

Literature Review - Ciba BISOFT

In a study comparing Ciba BISOFT's to spectacles, by Lowther,² et al., the following areas were investigated: visual acuity, stereopsis, visual fields, night vision, and effects of glare. Even though no difference was found in any of these areas, distance visual acuity was equivalent to that of spectacles, but near visual acuity was slightly decreased, but still approximately 20/20 (mean acuity level). Advantages found with the Ciba BISOFT lenses were increased fields with contacts versus spectacles, and a range of clear vision; whereas, the lenses acted as a multifocal system. (This increase in fields is contrary to the results found in the study by Peterson and McDonell, in which horizontal motion and form fields were studied.³) The disadvantages found were flare, to which the subjects were able to adapt after an initial blurring of acuity upon dispensing. The patient acceptance in this study was more than 80 percent.

METHODS

Subjects were selected from the Pacific University College of Optometry clinic population. A complete visual analysis was performed, and the subjects were found to be acceptable contact lens candidates. Table 1 is a summary of our study population.

Table 1			
STUDY POPULATION:			
Patients enrolled	10	SEX: Male	4
Patients completed		Female	6
B & L portion	8	AGE: 40 to 60 years	
Ciba portion	7	*15 years	
(1 patient discontinued after the B & L portion)			
Patients in progress	2		
DISCONTINUED PATIENTS:			
Unsatisfactory			
visual results	1		
Physiological	0		

*Accommodative Esotrope

Both types of lenses were evaluated using a standard follow-up schedule including three progress evaluations. At each evaluation, an over refraction was performed in and out of phoropter. Distance ophthalmoscopy was used to evaluate centration of the distance zone of the Ciba lenses. Retinoscope reflex clarity, slit lamp evaluation, and keratometry with the lenses on (looking for clear mires, free of distortion) helped to determine proper fit.

RESULTS

Bausch and Lomb P.A.1

With the single base curve option, the movement of the lenses varied from subject to subject depending on the power needed and the corneal curvature. The fitting guide recommends movement of 0.5 mm for best results with this contact lens design. The subjects with 0.5 to 1.0 mm movement exhibited the more stable visual acuities, near and far, and had the least subjective complaints. There was no direct correlation found between keratometry values and the movement observed. There was a general stabilization and slight tightening of the lenses as the

wearing period progressed. No lenses were reordered due to inadequate movement, edge standoff, circumlimbal injection, limbal vascular changes, or irregular keratometry readings. On two of the subjects, the lenses exhibited tight fitting characteristics based on movement. There was no blanching of the conjunctival vessels on either patient, and no edema observed. Based upon these observations and a stable refraction, these subjects completed this portion of the study without change in lens parameters or wearing schedule.

The fitting guide on the Bausch and Lomb lens recommends the power prescribed to be -0.50 to -1.00 diopters more minus than the habitual distance spectacle prescription. During the diagnostic fitting, the initial near acuities were compromised with this power. More plus was tried to bring up the near acuities without degrading the distance acuities past 20/25. The dioptric difference between the contact lenses ordered and the spherical equivalent distance spectacle prescriptions are listed in Table 2. (All Bausch and Lomb data is based on the 8 subjects who have completed this portion of the study.)

Table 2	
NUMBER	CHANGE
2	+0.75
3	+0.50
1	0.00
1	-0.25
1	-0.50

It should be noted, at the time of dispensing, that in 87.5 percent or seven of the subjects, the over refraction would result in a power change that would put the BVA in the range of -0.50 to -1.00 diopters over the spectacle prescription. This was in agreement with the fitting

guide; however, it caused a reduction in near acuities. The power ordered was the more plus power in most cases.

The acuities at the time of dispensing and final progress examinations are listed in Table 3.

Table 3				
DISPENSING EXAM			FINAL PROGRESS EXAM	
Acuity	Distance	Near	Distance	Near
20/15	-	-	3	-
20/20	6	2	3	4
20/25	2	-	2	-
20/30	-	5	-	2
20/40	-	1	-	-
20/50+	-	-	-	2

The subjects with minimal cylinder correction showed no subjective residual cylinder in the over-refraction. The subject with the greater cylinder correction showed an over-refraction of -0.50 OD and -0.75 OS for the residual cylinder component. There was a partial amount of masking effect from the contact lenses. The subjects' refractive profiles and differential characteristics are listed in Table 4.

Table 4	
<u>KERATOMETRY (FLATTEST):</u> Range 39.87 to 44.75	<u>REFRACTIVE CYLINDER:</u> Spherical (5) Astigmatic (5) Range -0.25 to -1.00 D
<u>REFRACTIVE SPHERE:</u> Hyperope (5) Range +0.75 to +1.75 D Myopes (5) Range -0.50 to -2.25 D *-3.25	<u>PUPIL SIZE:</u> Bright Illumination Range 2.0 to 4.5 mm Dim Illumination Range 3.0 to 6.0 mm
<u>READING ADDITION:</u> Range +1.25 to +2.50 D	

*Accommodative Esotrope

Improvement in acuities was observed during the adaptation period. Distance visual acuity improved in 50 percent or four of the subjects and 37.5 percent or three of the subjects acuity remained stable. Near visual acuities improved in 25 percent or two of the subjects, decreased in 25 percent or two of the subjects, and remained stable in 50 percent or four of the subjects.

Ciba BISOFT

Nine of the ten subjects that started the study continued to the second half; two subjects are still in progress and their results will not be reported.

The Ciba lenses showed good coverage and adequate centration on all subjects. Two subjects had lenses that had a lag of 1.0 to 2.0 mm initially, but as the wearing period continued the lenses centered better and the lag was reduced. A fairly uniform amount of movement was seen throughout the subjects, because of the ability to vary the base curves. There were no lenses that were reordered, after initial dispensing, due to inadequate movement, edge standoff, circumlimbal injection, limbal vascular changes, or changes in keratometry readings.

The differences between the powers ordered and the spherical equivalent distance spectacle prescription are listed in Table 5. Refer to Table 4 for subject refractive profile and characteristics. (All Ciba data is based on the 7 subjects who have completed this portion of the study.)

Table 5	
NUMBER	CHANGE
2	+0.25
2	0.00
2	-0.25
1	-0.50

Near acuities were able to be improved without changing the distance power, because of the ability to vary the near add powers. The acuities at the time of dispensing and final progress examination are listed in Table 6.

Table 6				
DISPENSING EXAM			FINAL PROGRESS EXAM	
Acuity	Distance	Near	Distance	Near
20/15	1	-	4	-
20/20	4	3	2	4
20/25	1	-	1	-
20/30	1	3	-	2
20/40	-	1	-	1
20/50+	-	-	-	-

*Two subjects still in progress.

Distance visual acuity improved in 57 percent or four of the subjects, and 43 percent or three of the subjects' acuity remained stable. Near visual acuities improved in 29 percent or two of the subjects, 57 percent or four subjects remained stable, and decreased in 14 percent or 1 subject.

With both sets of lenses, all subjects were able to reach a wearing time of not less than twelve hours. There were no reports of discomfort that might have been caused by the contact lenses. Keratometric findings were found to remain stable on all subjects, from the dispensing exam to the end of the lens wearing period. There were no tight fitting characteristics experienced by any of the subjects. Patients comfort was found to be equal with both the Bausch and Lomb P.A.1 and the Ciba BISOFT. There were no fluctuations noted in the maximum wearing time achievable with both sets of lenses.

The centering of the optic zones with either lens design was found

to be a major factor in obtaining maximum visual efficiency. Distance ophthalmoscopy is an important technique in assessing the alignment of the Ciba BISOFT. See Figures 2A and 2B for a diagrammatic view of proper and improper alignment as seen through the ophthalmoscope at a distance.

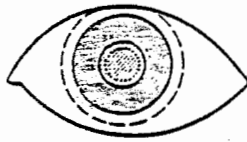


Figure 2A
Proper Lens Alignment as Seen Through the Ophthalmoscope

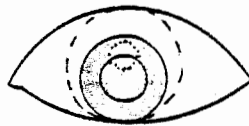


Figure 2B
Improper Lens Alignment as Seen Through the Ophthalmoscope

SUBJECTIVE EVALUATION

A questionnaire was given to each subject at the final progress evaluation of each set of lenses. The subjects were asked to subjectively evaluate each set of lenses in the following categories:

- I Driving at night
- II Driving during the day
- III Light sensitivity
- IV Various every day visual tasks
- V General consumer questions

Table 7 compares the average of the overall subjective evaluation of the Bausch and Lomb P.A.1 and the Ciba BISOFT lenses. Categories I-IV are the total representation of questions asked in each area. These questions can be found in Appendix D. The questions in Category V could not be averaged, since they are general questions and non-related. Table 7

illustrates that the subjects favored the overall performance of the Bausch and Lomb P.A.1 as compared to the Ciba BISOFT. An influencing factor may have been the order of fitting and time period involved in the evaluation of the two sets of lenses.

	B&L			Ciba		
	Excel	Good	Bad	Excel	Good	Bad
I Driving at night	12.5%	57.5%	30.0%	3.12%	65.6%	31.3%
II Driving during the day	17.5	67.5	15.0	12.5	62.5	25.0
III Light sensitivity	3.33	93.3	3.33	0	75.0	25.0
IV Various every day visual tasks	47.8	38.9	13.3	13.9	56.7	29.2
Total %	20.3%	64.3%	15.4%	7.4%	65.0%	27.6%

B&L based on 10 subjects. Ciba based on 8 subjects.
For a total breakdown of each category see Appendix C.

Certain surveyed areas revealed that three or more subjects (30 percent or greater) reported limitations in the use of these lenses:

Ciba and B & L	Reading road signs at night Affects of headlights Magazines
B & L Only	Affects of street lights at night Direct sunlight
Ciba Only	Reading road signs during daylight Newspaper, telephone directory

There was no change in Donder's amplitude, near point of convergence, phorias or ductions noted between the subject's responses while wearing spectacles or either set of contact lenses.

CONCLUSION

One problem that was encountered during the study was that there was not a set method to standardize the evaluation of lens movement or

centration of the power zones. A new Ciba fitting guide was introduced in September, 1983 after all of the subjects lenses had been ordered and dispensed. This new fitting guide states that a useful technique for evaluation of lens performance is distance ophthalmoscopy or streak/spot retinoscopy. Distance, near, and transition zones can be easily evaluated for proper pupillary centration. This becomes particularly important for the patient with an eccentrically located pupil. This may be one of the factors in causing the ghost images or double vision experienced with this lens design. It is felt that the recommended movement of 0.5 mm is necessary in order to reduce the possibilities of these visual effects.

The investigators clinical experience in fitting these two sets of lenses has led to the development of a suggested fitting guide for the practitioner's future use of this simultaneous vision lens design. Appendix B lists the suggested guidelines for patient expectations, 20/25 blur evaluation, and the diagnostic lens evaluation.

At the time of the final progress examination, the visual acuities obtainable with the Bausch and Lomb ranged from 20/15 to 20/25 at a distance, and 20/20 to 20/50+ at near. The final acuities obtainable with the Ciba ranged from 20/15 to 20/25 at distance, and 20/20 to 20/40 at near. Figure 3A and 3B demonstrates the correlation of distance and near visual acuities obtainable for each set of lenses.

Figure 3A

A correlation
between
distance and
near visual
acuity with
Bausch and
Lomb P.A.1

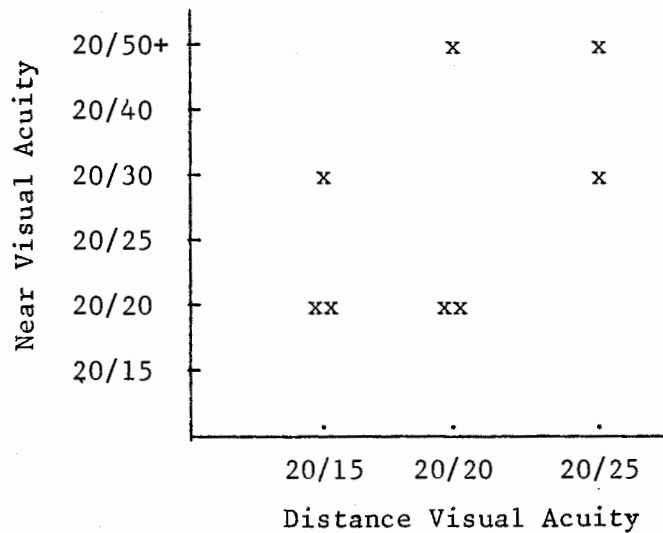
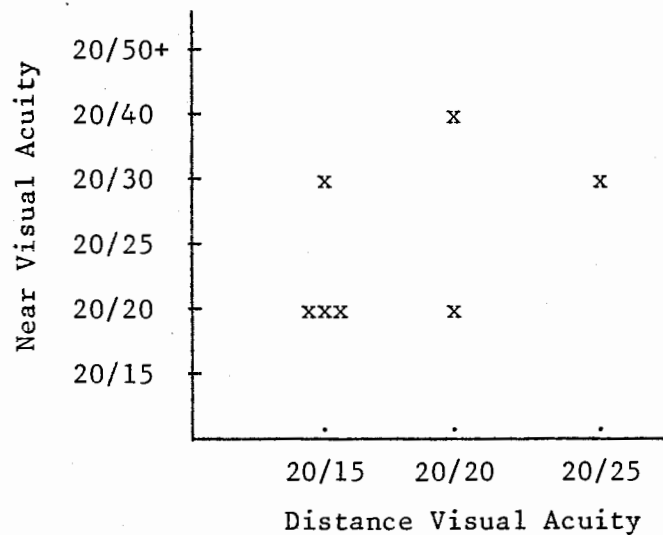


Figure 3B

A correlation
between
distance and
near visual
acuity with
Ciba BISOFT



Even though the visual acuity obtainable in the majority of subjects was 20/20, complaints of glare, flare, double vision, and poor night vision show limitations in the use of these lens designs. Due to the optics involved in the design of these lenses and the resultant reduction in the quality of acuity, these lenses may be best suited only for occasional use rather than full time wear. This is dependent on the patient's visual demands.

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A P P E N D I X

APPENDIX ALENS DESIGN

	CIBA	B & L
LENS DESIGN	Lathed cut Two distinct concentric visual zones	Spun cast with a sph. ant. surface and a aspherical post sur- face which has progres- sive power increments, due to radial power changes, from the cen- ter to the edge of the O.Z.
DIAMETER	13.8	13.5
B.C.	8.3, 8.6, and 8.9 (+ only)	
C.T.	Varies .07 with -3.00 .12 with +3.00	.08 to .15 - power .15 to .21 + power
DIST. POWER	-6.00 to +6.00 in .25 D steps	-6.00 to +6.00 (±5.00 .25 steps) (±5.00 to ±6.00 .50 steps)
NEAR ADDS	+1.50, +2.00, +2.50, +3.00	+1.50 nominal functional add +2.50 at 3 mm from O.C.
LIGHT TRANS.	98%	97%
H ₂ O CONTENT	37.5%	38.6%
MATERIAL	tefilcon hydrophilic polymer of hydroxyethylmethacry- late (HEMA)	polymacon 2-hydroxyethyl methacry- late

APPENDIX BSUGGESTED FITTING GUIDE

The investigators offer the following fitting recommendations for either the Bausch and Lomb P.A.1 or the Ciba BISOFT.

A. Personal Interview for Motivation and Visual Acuity

Expectations:

1. Patient's motivation has to be high to be successful. We found that the "inquisitive" patient tends to be an unsuccessful fit.
2. The patient should be aware of the possibility of decreased visual acuity. Is this sacrifice in acuity warranted for the convenience of bifocal contact lenses? The patient should be questioned about visual acuity demands for their occupation, recreational demands, and for general purposes.

B. Complete Visual Analysis

1. The fitter should be sure that the patient's prescription is within the recommended fitting guide requirements.

C. Ocular Health Evaluation

1. Ophthalmoscopy
2. Biomicroscopy

D. "20/25" Blur Evaluation

1. The patient should be blurred to approximately 20/25 at distance and near. A subjective evaluation by the patient is needed in order to assure the fitter that the patient can comfortably tolerate a possible decrease in visual acuity. It should be stressed that not all of the patients will experience this, but it is only meant as a safeguard against unsuccessful patients.

E. Diagnostic Lens Evaluation

1. Select the proper base curve for the patient (evaluate an 8.6 mm first). Bausch and Lomb utilizes only one base curve.
2. Distance ophthalmoscopy can be used to verify proper centration of the distant zone and near zone of the contact lenses (Ciba only).

- a. If poor centration is revealed, select a different base curve.
 - b. If poor centration is still prominent after selecting a different base curve, this patient may experience poor results from this type of lens.
3. The researchers feel that the lenses should not show more than 0.50 mm movement to allow adequate centration.
 - a. With this slight amount of movement, care should be taken to assure against the tight lens syndrome.
 4. The over refraction with the diagnostic lenses should be performed with a trial frame or loose trial lenses. This is due to the pin-hole effect caused by the phoropter.
 5. All exams should be performed in a well lighted room to assure maximum visual acuity.

F. Patient Counseling

1. The patient should be counseled on the possible compromise of distance and near acuity.
2. The adaptation to double vision or glare and flare may occur from 30 minutes to one month depending on the patient.
3. Demonstrate low light level effects on acuity. (Compare chart in lighted room compared to a dark room.)
4. A proper understanding of the limitations of this type of lens should be stressed to the patient during the initial evaluation (i.e. shadows around letters, halo's around objects, reduced acuity in dim illumination).

APPENDIX C

SUBJECTIVE RESULTS

Totals are in percentages. Other numbers are total responses.		B&L			CIBA		
		Excel	Good	Bad	Excel	Good	Bad
I. Driving at night:	<u>Total %</u>	12.5	57.5	30.0	3.12	65.6	31.3
1. Ability to read road signs		0	7	3	0	5	3
2. Ability to read car instruments		3	7	0	1	5	2
3. Affects of oncoming headlights		1	4	5	0	5	3
4. Affects of street lights		1	5	4	0	6	2
II. Driving during the day:	<u>Total %</u>	17.5	67.5	15.0	12.5	62.5	25.0
5. Ability to read road signs		1	8	1	3	2	3
6. Ability to read car instruments		4	6	0	1	6	1
*7. Affects of oncoming headlights		2	8	0	0	6	2
8. Direct sunlight while driving (without sunglasses)		0	5	5	0	6	2
III. Light sensitivity:	<u>Total %</u>	3.33	93.3	3.33	0	75.0	25.0
9. Adaptation of going from dark area to bright area		0	10	0	0	7	1
10. Adaptation of going from bright area to dark area		1	9	0	0	6	2
11. Effects of plano sunglasses during outside activities (rate your vision)		0	9	1	0	5	3

* Question #7 was asked due to day time weather conditions in Oregon.

Totals are in percentages. Other numbers are total responses.		B&L			CIBA			
		Excel	Good	Bad	Excel	Good	Bad	
IV.	Rate the following visual demands as compared to your glasses:	<u>Total %</u>	47.8	38.9	13.3	13.9	56.9	29.2
	12. newspaper		5	5	0	0	5	3
	13. telephone directory		5	3	2	1	4	3
	14. T.V.		3	6	1	1	6	1
	15. typewriter		4	5	1	1	5	2
	16. comparing prices in grocery store		5	5	0	1	5	2
	17. eating		5	5	0	3	4	1
	18. reading menus		6	2	2	1	5	2
	19. magazines/books		5	1	4	1	3	4
	20. Overall, how do you compare these C.L. to your glasses?		5	3	2	1	4	3
V.	General Questions:		<u>Yes</u>	<u>No</u>		<u>Yes</u>	<u>No</u>	
	21. Would you wear these lenses everyday full time?		6	4		3	5	
	22. Would you wear these lenses everyday part time?		7	3		5	3	
	23. Would you wear these lenses intermittently?		6	4		6	2	
	24. Would you suggest to a friend to be evaluated to wear this type of lens?		10	0		6	2	
	25. Assuming the normal fitting price of \$450.00, would you consider these lenses?		4	6		0	8	
	26. If you lost a lens, would you replace it for a \$100.00 fee?		7	3		2	6	

APPENDIX DSUBJECTIVE QUESTIONNAIRE FOR
FOR BAUSCH AND LOMB P.A.1 AND CIBA BISOFT

- I. Driving at night:
1. Ability to read road signs
 2. Ability to read car instruments
 3. Affects of oncoming headlights
 4. Affects of street lights
- II. Driving during the day:
5. Ability to read road signs
 6. Ability to read car instruments
 7. Affects of oncoming headlights
 8. Direct sunlight while driving (without sunglasses)
- III. Light sensitivity:
9. Adaptation of going from a dark area to a bright area, as compared to glasses
 10. Adaptation of going from a bright area to a dark area, as compared to glasses
 11. If you have prescription sunglasses, answer the following question: If you wore plano sunglasses over your contact lenses (as compared to glasses) during outside activities, rate your vision
- IV. Rate the following visual demands as compared to glasses:
12. newspaper
 13. telephone directory
 14. T.V.
 15. typewriter
 16. comparing prices in a grocery store
 17. eating
 18. reading menus
 19. magazines/books
 20. Overall, how do you compare these contact lenses to your glasses?
- V. General Questions:
21. Would you wear these lenses everyday full time?
 22. Would you wear these lenses everyday part time?
 23. Would you wear these lenses intermittently?
 24. Would you suggest to a friend to be evaluated to wear this type of lenses?
 25. Assuming the normal fitting price of \$450.00, would you consider these lenses?
 26. If you lost a lens, would you replace it for a \$100.00 fee?