5-1992

A comparison between nomogram versus trial fitting of rigid gas permeable contact lenses

Joel T. Postma
Pacific University

Amy M. Postma
Pacific University

A comparison between nomogram versus trial fitting of rigid gas permeable contact lenses

Abstract

To determine the differences between prescribing a trial fitted versus a nomogram (System 10™) selected rigid gas permeable contact lens, 42 subjects were fit with one lens design on one eye and the other lens design on the opposite eye. Subjective responses for comfort and vision, objective signs of central corneal clouding, conjunctival injection, post keratometry readings, 3-9 staining, over refraction, post refraction and lens position were ranked and assigned to success levels for each eye. Subjects were evaluated at 1 week, 1 month, and 3 months. The first fit success rates were 92% for the trial fit and 86% for the nomogram fit. The trial fit lens attained significantly better outcomes in individual categories of comfort and over refraction. It was noted that the lens diameters differed significantly and a large percentage of both types of lenses benefited from a slight blend and edge modification. Although trial fitting remains the method of highest success, nomogram fitting (using System 10™) appears consistent enough to consider it an option for certain practice situations .

Degree Type

Dissertation

Degree Name

Master of Science in Vision Science

Committee Chair

Cristina M. Schnider

Keywords

nomogram, trial fit, empirical fit, rigid gas permeable contact lenses

Subject Categories

Optometry

A COMPARISON BETWEEN NOMOGRAM VERSUS TRIAL FITTING OF RIGID GAS PERMEABLE CONTACT LENSES

by

JOEL T. POSTMA, O.D.
AMY M. POSTMA, O.D.

A thesis submitted to the faculty of the
College of Optometry
Pacific University
Forest Grove, Oregon
for the degree of
Masters in Clinical Optometric Management
May, 1992

Advisors:
Cristina M. Schnider, O.D.
A. Richard Reinke, O.D.
Nada J. Lingel, O.D.

A COMPARISON BETWEEN NOMOGRAM VERSUS TRIAL FITTING OF RIGID GAS PERMEABLE CONTACT LENSES

AMY M. POSTMA, O.D.

JOEL T. POSTMA, O.D.

Place: Pacific University, Forest Grove, OR

Approved:

CRISTINA M. SCHNIDER, O.D., Chair — Date 4/15/92

A. RICHARD REINKE, O.D. — Date 4/15/92

NADA J. LINGEL, O.D. — Date 4/15/92

BIO PAGE

Joel T. Postma received his B. S. degree in 1978 and O. D. degree in 1980 from Pacific University, College of Optometry. He is a fellow of the American Academy of Optometry and a Major in the U. S. Army. After completing his Master's program, he will return to optometric practice with the U. S. Army in Frankfurt, Germany.

Amy M. Postma received her B. S. degree in 1978 and O. D. degree in 1980 from Pacific University, College of Optometry. She is a fellow of the American Academy of Optometry and a Major in the U. S. Army. After completing her Master's program, she will return to optometric practice with the U. S. Army in Frankfurt, Germany.

ABSTRACT

To determine the differences between prescribing a trial fitted versus a nomogram (System 10™) selected rigid gas permeable contact lens, 42 subjects were fit with one lens design on one eye and the other lens design on the opposite eye. Subjective responses for comfort and vision, objective signs of central corneal clouding, conjunctival injection, post keratometry readings, 3-9 staining, over refraction, post refraction and lens position were ranked and assigned to success levels for each eye. Subjects were evaluated at 1 week, 1 month, and 3 months. The first fit success rates were 92% for the trial fit and 86% for the nomogram fit. The trial fit lens attained significantly better outcomes in individual categories of comfort and over refraction. It was noted that the lens diameters differed significantly and a large percentage of both types of lenses benefited from a slight blend and edge modification. Although trial fitting remains the method of highest success, nomogram fitting (using System 10™) appears consistent enough to consider it an option for certain practice situations.

KEY WORDS: Nomogram, Trial fit, Empirical fit, Rigid gas permeable contact lenses

INTRODUCTION

With the completion and success of the Operation Desert Storm campaign, acclaim for technological advances that aided in the Armed Services victory was heightened. One of these technological advances of interest to optometrists is the use of contact lenses by Army aviators. Army aviators in the Persian Gulf who wore contact lenses felt they performed better with contacts than with glasses. They cited better peripheral vision and reported they preferred their vision with contacts over glasses.[1] These aviators wore disposable soft lenses; however, rigid gas permeable (RGP) lenses were also available to them.

In a study conducted on 620 Apache aviators who were fit with contact lenses, 90% of subjects were fit with soft disposable or flexible wear and 10% with RGP extended wear.[2] Contact lenses are an authorized item of issue for some personnel in all three branches of service. Interest in contact lenses for military personnel has increased significantly due to the events in the Persian Gulf, and it is expected that even more personnel will be authorized to wear them while performing their official duties. Fitting techniques for RGP lenses would thus be of interest to a military optometrist who may encounter some unusual circumstances in his practice such as the need for expediency and lack of resources to provide traditional contact lens services.

With the concern over soft lens problems during the mid to late 80's and the introduction of new and better RGP lens materials, trends indicate that RGP fitting is on the rise.[3] There is however a large group of clinicians with the 'RGP avoidance syndrome' described by Schnider[4] that may need to rediscover how to fit RGPs. These practitioners, and in fact all other practitioners, have a myriad, and at times intimidating array of prescribing methods from which to choose.

The argument is held by some contact lens providers that in order to successfully prescribe a rigid gas permeable lens, trial fitting must be used to obtain a lens cornea relationship that will result in an optimum contact lens fit.[5,6] In the Bennett et al. study, patients who were trial fitted had more confidence and motivation in the RGP fitting process than those who were not.[5]

There are others who believe a lens can be fit successfully initially without trial fitting through the use of a fitting nomogram (e.g., providing refractive status, keratometry readings and lid aperture size to the laboratory or calculating lens parameters in office). In a survey of practitioners by Maruna et al.[3], only 56% of respondents reported trial fitting a lens. Of the remaining 44%, 30% determined the lens parameters by calculation and 14% let the lab determine the lens parameters. Many practitioners feel they are too busy, have insufficient volume to justify a diagnostic fitting set, or do not want to hassle with rigid gas permeable lenses. Those desiring help with RGP fitting can find many companies providing contact lens fitting services to the eye practitioner utilizing refraction, corneal curvature and other ocular measurements.

The answer to the question of whether there is a difference between trial fitting versus nomogram selections, could benefit a practitioner both in the military and civilian sector of optometric practice.

METHODOLOGY

Subjects

Subjects were selected from the general population seeking care at the Pacific University Family Vision Center. Ages ranged from 16 to 43 with a mean age of 29. There were 16 male and 21 female subjects. The distribution of gender and age groups are shown in Figure 1. Refractive errors ranged from plano to -8.25 diopters with refractive astigmatism of less than 1.75 diopters. A complete optometric examination was conducted prior to consideration for the study. Eligible subjects had similar ocular characteristics between their two eyes (refractive power, corneal curvature) and needed to be free of ocular or systemic diseases which contraindicated rigid contact lens wear. A written informed consent was obtained from each subject prior to the study (enclosure 1). Subjects were either current soft lens wearers or persons having no history of contact lens wear within the last 6 months.

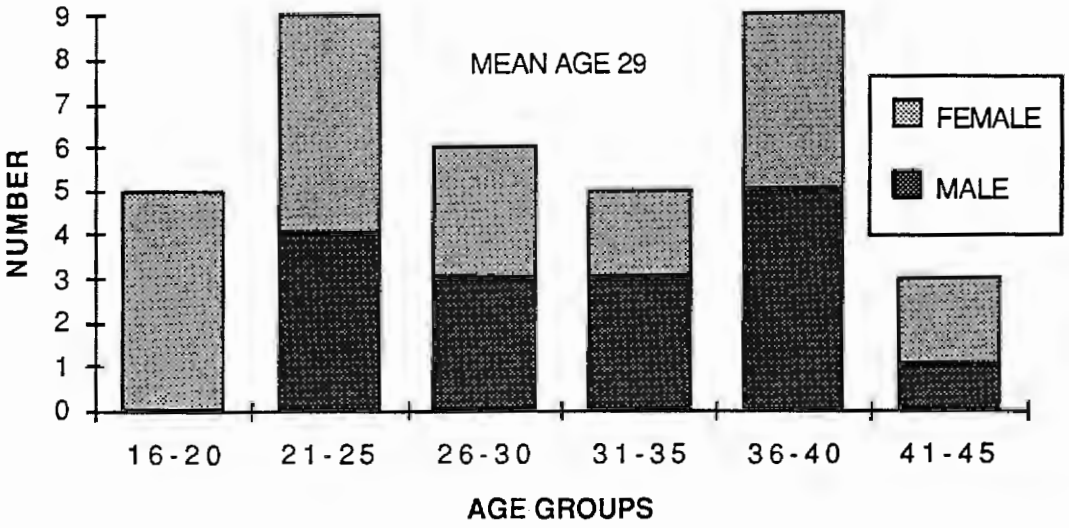

Figure 1: Age group ranges and gender distribution.

Lenses

The RGP lenses used in the study were of the fluorosilicone acrylate family (Fluoroperm 30, Paragon Optical). Early assessments of the Fluoroperm 30 have been generally favorable. Lens stability is sufficiently managed by lens thickness and design. Reported advantages of the material appear physiologically and physically significant in the areas of oxygen permeability, cleanliness and comfort.[7,8]

Procedures

Twenty-one subjects were trial fitted by each investigator with a standard design RGP. The investigators were military optometrists with 10 years of contact lens fitting experience. Base curve, diameter and peripheral curves were tailored to each individual's eyes using Bennett's fitting guide to obtain optimal centration, movement and bearing characteristics.[9] A pair of lenses were ordered according to the fitter's specifications from Valley Contax, Eugene, Oregon, who manufactured the lenses in the Fluoroperm 30 material. The requested ocular parameters (keratometry readings, spectacle refraction and aperture size) for the same patient were supplied to Lens Mode, Millburn, New Jersey, for their analysis. A pair of lenses from the Fluoroperm 30 material were supplied according to Lens Mode's System 10™

design that mathematically coordinates curvature, diameter and sagittal depth. Both pairs of lenses were inspected and verified upon receipt. Each investigator randomized one lens from each design to each eye of their subjects. The subjects were then turned over to the other investigator for follow up. Neither patient nor follow-up investigator was aware of which eye was wearing which design.

Lenses were dispensed with appropriate lens care instructions for wear. All subjects started with the Alcon Soaclens System RGP starter kit without use of the enzyme tablets. Several subjects did require different systems due to allergic reactions to thimerosal. The enzymatic process was added to a few of the subject's cleaning regimens due to problems with protein build up.

Evaluations were conducted following 1 week, 1 month and 3 months of lens wear. Each visit included an evaluation of patient satisfaction, where subjects were asked to grade vision and comfort (enclosure 2). Contact lens performance was evaluated by fluorescein pattern, lens position, refractive status and anterior segment ocular health. Injection, central corneal clouding, 3-9 desiccation, over refraction, post refraction changes, keratometry changes and lens position were used in the objective evaluation (enclosure 3). A five point grading scale was used for both subjective symptoms and objective signs. The scales were anchored descriptively; e.g., where 1 was very comfortable--can't tell the lens is on, to 5 intolerable--not able to wear the lens for more than 1 hour. Modifications of the peripheral blends and edges were performed as indicated on both lens designs to improve comfort.

Data Analysis

The investigator's professional judgment was used to determine the rankings in the grading scales. The data were ranked, summed and assigned to a success level. The success level was determined by the worst score across all variables (Table 1). For example, a subject could have a 1 in all categories, but if he/she had a 5 in comfort, they were considered a level 5, not successful. Some subjects could have one of two scores that were so similar that the investigators judged them to be essentially in the same level. For example, in the category of comfort, a subject could judge a lens to be a one, very comfortable, can't tell the lens is on, or a

two, comfortable, occassional lens sensation. They were still considered a level one, very successful (See enclosure 2). Another example is the category of central corneal clouding. A rank of 4 was central corneal clouding with distinct borders, area of clouding visible against iris in a dimly lighted room and a rank of 5 was dense clouding, visible in normal room lighting(See enclosure 3). Either rank in the investigators opinion would have indicated a fit at level 5, not successful. The data were entered in a database management package on the Macintosh computer and analyzed by non-parametric statistics for matched pairs (Wilcoxon signed-ranks statistic and chi square). An alpha level of .05 was used to determine significance.

Table 1: Assignment of scores to success levels (1=best, 5=worst)

Category	LEVEL 1 Very Successful	LEVEL 2 Successful	LEVEL 3 Moderately Successful	LEVEL 4 Marginally Successful	LEVEL 5 Not Successful
Comfort	1, 2	3	3	4	5
Vision	1, 2	3	3	4	5
CCC	1	1	2	3	4, 5
3-9 stain	1	1	2	3	4, 5
Injection	1	2	2	3	4, 5
OR	1, 2	2	3	4	5
Post Ref.	1, 2	3	3	4	5
K. changes	1, 2	2	3	4	5
CL Pos.	1,2	2	3	4	5

Note: The overall success level is determined by the combination of the worst scores across all variables.

RESULTS

Of the 42 patients enrolled, 37 completed the study and 5 patients were not able to tolerate RGP wear. Neither gender or age made a difference on the success or failure rates, thus these were not intervening variables that affected the data sets.

In terms of subjective symptoms, subjects noticed that the trial fitted lens was significantly more comfortable at week 1, but no difference was noted at month 1 or month 3. The percentage of

lenses that needed edge rolling and /or blend modification to improve comfort was 30% for the trial lens and 41% for the System 10™ lens. Subjects did not notice a significant difference in vision between the two fitting methods during all examining periods.

The investigators noticed no difference in objective signs for any examining periods for central corneal clouding, injection, 3-9 desiccation staining, keratometry findings, post refraction and lens position (Figure 2).

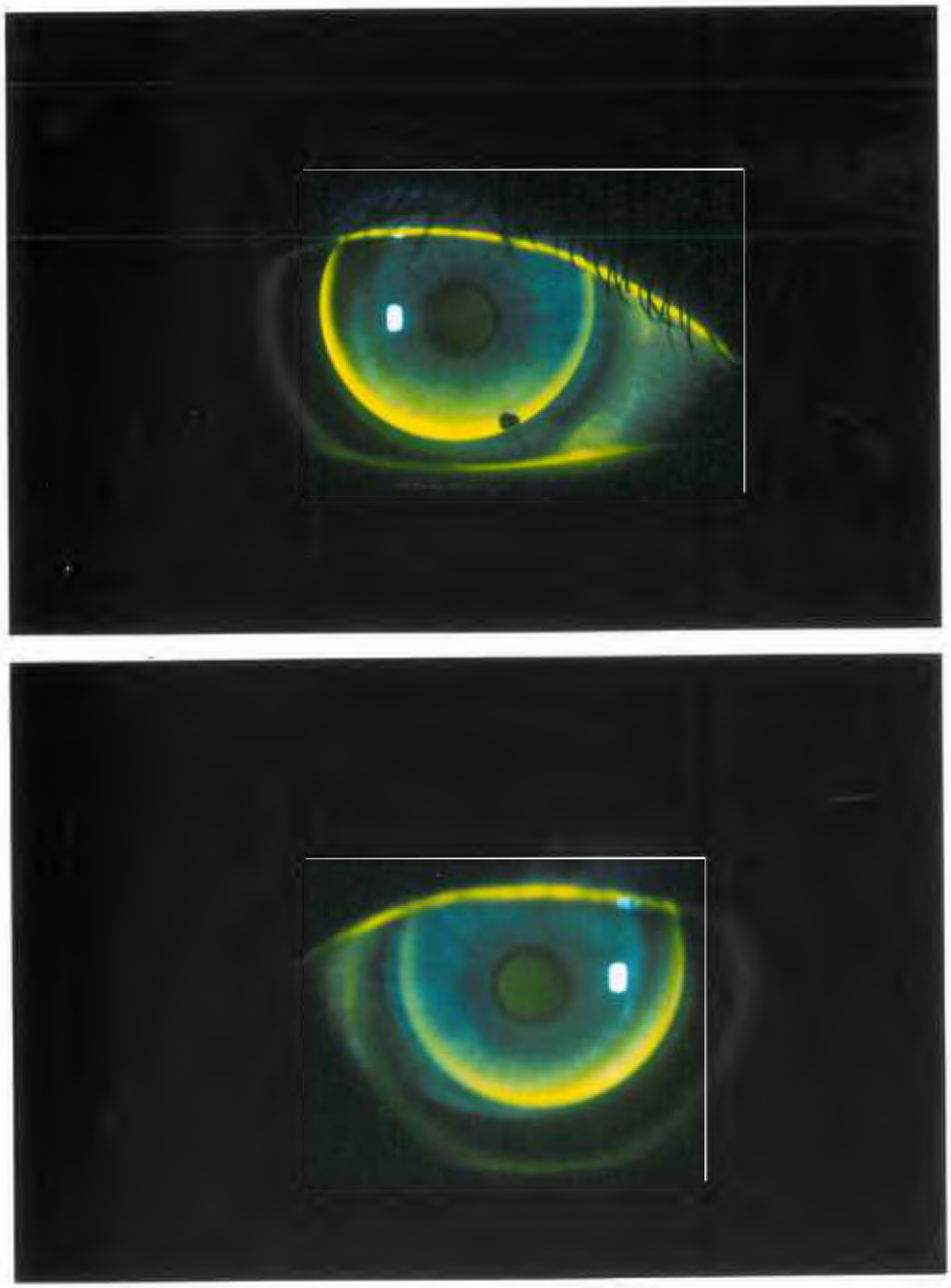

Figure 2: Nomogram (System 10™) lens right eye (top) and trial fit lens left eye (bottom). Notice that the positioning and edge lift are approximately the same between the two eyes. The black dot at the 6 o'clock position in the top picture indicates that it is the right lens. The blend of the left lens is more feathered in appearance than the right lens. Otherwise, can you tell a difference between the two fits?

Over refraction was significantly different between the two lens groups at week 1. The range of over refractions for the trial fit method was from -.25 to +.25 and from -.50 to +1.00 for the System 10™ method (Table 2).

Table 2: Over refraction range distribution and frequency.

OVER REFRACTION	TRIAL FIT		SYSTEM 10™		
	COUNT	PERCENT	COUNT	PERCENT	
-1.00	0		0		
-0.75	0		0		
-0.50	0		6	16%	
-0.25	12	32%	7	19%	
0.00	22	60%	20	54%	P=.04
0.25	3	8%	1	3%	
0.50	0		2	5%	
0.75	0		0		
1.00	0		1	3%	

The correlation difference between calculated (theoretical) versus ordered lens power of the trial fit method was .965 and System 10™ method was .977 (P=.045). See figure 3 for differences between calculated and observed powers for the two methods.

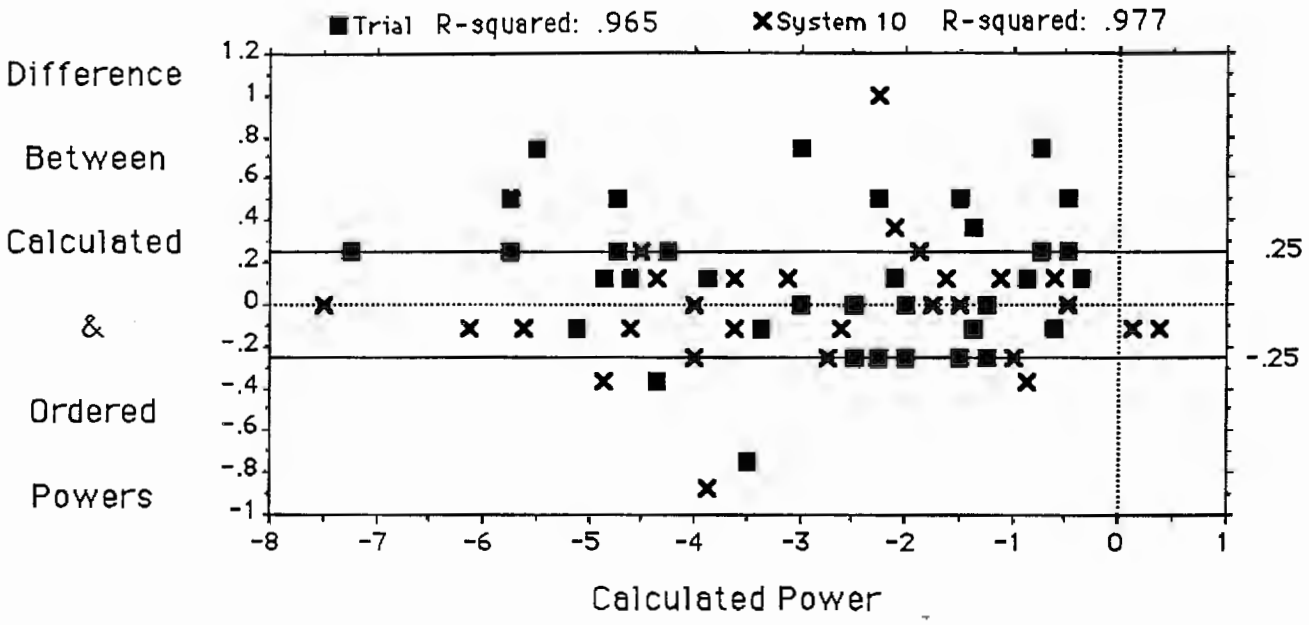

Figure 3: The correlation of the difference between the calculated and ordered powers for the trial fit and System 10™ lenses.

Other Results

The distribution of lens diameter ordered differed significantly between the two fitting groups with a chi square p value of .007. The distribution of lens diameters is illustrated in figure 4.

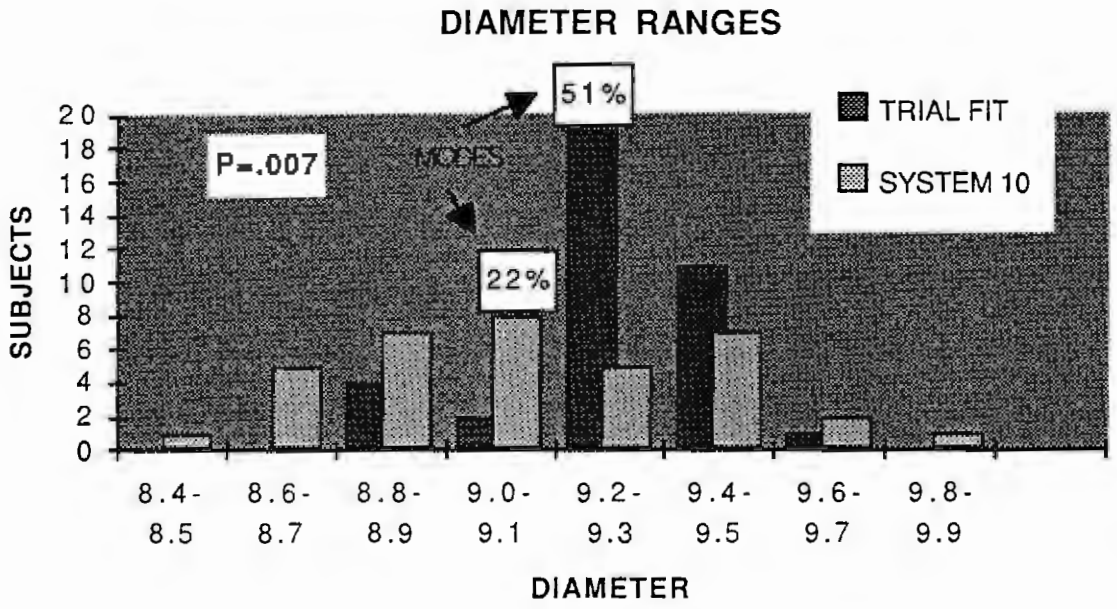

Figure 4: Diameter ranges for Trial Fit vs. System 10™.

The "first fit" success rate for the trial fit method was 92% and 86% for the System 10™ method. First fit success was defined as a subject who had attained a minimum of 8 hours of daily wear with acceptable subjective and objective findings. The subject could fall into any level, except level 5, according to the grading scales using the initial lens dispensed.

The outcomes for all examining periods were significant, with the trial fit method ranking higher than the System 10™ method. (Table 3)

Table 3: Outcome ranks for trial fit and System 10™ subjects.

	OUTCOMES				
FOLLOW UPS	SUBJECTS W/ FIRST FIT LENSES	HIGHER RANKS FOR TRIAL FITS	HIGHER RANKS FOR SYSTEM 10™	TIES	P VALUE*
WEEK 1	37	12	3	22	.01
MONTH 1	35	13	4	18	.04
MONTH 3	33	12	1	20	.02

*WILCOXON SIGNED-RANK TEST

DISCUSSION

Contact lenses are essential to ametropic personnel who need to utilize technologically sophisticated equipment for which no optical correction device has been designed. This problem is magnified in urgent situations encountered in military actions. Military optometrists occasionally are faced with situations where time, expediency and/or remoteness dictates their clinical decisions. When RGPs are indicated, a contact lens fitting nomogram for RGPs with a high first fit success rate as the System 10™ could prove useful. The major differences between the two fitting methods should be kept in mind when considering how one will ultimately prescribe RGPs.

The "first fit" success rate was 92% for the trial fit versus 86% for System 10™. Although the percentage difference between the two fitting methods was minimal, the outcome findings which combined clinical data, both objective and subjective, were significant between both fitting methods for all examining periods as illustrated in Table 3. The major factors that seemed to influence the outcome in favor of the trial fit lenses were comfort and over refraction.

The difference noticed in comfort between the two fitting methods could be attributed to several factors. The System 10™ lenses had a higher percentage of lenses that needed edge/blend modifications

(see Figure 2 for difference of blend design). Another factor may be a difference in the method of fabrication between the two laboratories. It is interesting to note that both laboratories had a fairly high percentage of lenses that benefited from modification. Most modifications were done at week 1 which may explain why comfort improved for month 1 and month 3.

Comfort difference may also have been a function of lens diameter. The System 10™ design lenses tended to have smaller diameters than the trial fit lenses which may result initially in more lid sensation. Other factors affecting comfort may have been that some patients reported deficiencies in vision as 'comfort'. These patients were satisfied with the vision they obtained from each eye alone, but were not happy with the way they saw with both eyes (i.e., binocularity). This might explain why there was no significant difference noted in vision between the two fitting methods even though a significant difference in over refraction existed.

The significance in over refraction brought out a couple of interesting differences apparent between the two fitting methods. The over refraction results in Table 2 showed that the System 10™ lens values were more widely dispersed than the trial fit method. The lower correlation factor of observed versus expected values for lens power for the trial fit method or the System 10™ method was expected. We assumed that the System 10™ power calculations were based on theoretical models and therefore differences between the calculated and ordered powers would be closer to one. As illustrated by Figure 3, this appeared to be true and the differences between calculated and ordered powers for the trial lenses were more widely dispersed. Both findings confirm that the corneal topography does not always fit theoretical models.

In summary, trial fitting remains the method of choice for the best chance for RGP success. However, the use of nomograms such as the System 10™ should be a viable option to those practitioners with limited time, money and experience. If a practitioner is going to use a nomogram such as the System 10™, a more active role in selecting lens diameter might be helpful. A closer look at the peripheral curve design with the fluorescein pattern may also aid in increasing comfort of the lens. The refractive power of the contact lens may need to be fine tuned after dealing with a particular lab design and tailoring future orders to your

satisfaction. Knowledge of basic lens modification would prove useful for any type of RGP fitting. Each practitioner has to decide what first fit success rate and clinical findings are acceptable for him/her when deciding how they are going to fit a RGP lens. If the choice of whether RGP's should be incorporated into a practice relies on the decision to use a nomogram, by all means just do it!

ACKNOWLEDGMENTS

The authors would like to express their appreciation to Mr. Dan Strulowitz of Lens Mode and Mr. Steve Young of Valley Contax for manufacturing all lenses used in the study. We would also like to thank Paragon Optical and Alcon for materials and solutions supplied at no charge. This paper was written while the Dr.'s Postma were enrolled in a graduate program at the College of Optometry, Pacific University. Their participation in this program was supported by the U. S. Army. The views expressed here are those of the authors and do not necessarily reflect the positions of the Department of the Army or Department of Defense.

REFERENCES

1. News Spectrum: "Apache" pilots required to replace glasses with contact lenses. *Contact Lens Spectrum* 1991;5(6):13.

2. Military aviation use of CLs made urgent by war. *Making Contact* 1991;9(3):1,10.

3. Maruna C,Yoder M, Andrasko G: Attitudes toward RGPs among Optometrists. *Contact Lens Spectrum* 1989;4(11):25-32.

4. Schnider C: No pain, no gain. *Contact Lens Spectrum* 1990;5(7):69.

5. Bennett ES, Henry VA, Davis LJ, Kirby S: Comparing empirical and diagnostic fitting of daily wear fluoro-silicone/acrylate CLs. *Contact Lens Forum* 1989;14(3):38-44.

6. Harrison DW, Stein HA: A nomogram for fitting fluorosilicone acrylate contact lenses. *CLAO Journal* 1988;14(3):136-138.

7. Ghormley NR: The fluoroperm family-Part 2. *ICLC* 1988;15(9):274.

8. Quinn TG: Clinical Experience with Fluoroperm 30 lenses. *Contact Lens Spectrum* 1989; 4(2):63-65.

9. Bennett ES: RGP lens design and fitting. *Contact Lens Spectrum* 1990;5(9):46-53.

ENCLOSURE 1

INFORMED CONSENT DOCUMENT
Lens Mode System 10™ Clinical Trial

Institution:

A. Title	Trial fitting vs System 10™ fitting
B. Principal Investigators	Joel T. Postma, OD (690-4591 H) Amy M. Postma, OD (357-6151 #2276 M, T, F, 224-2323 W, Th)
C. Location	Portland Family Vision Center Portland Medical Center 511 SW 10th Ave Portland, Oregon 97205 (224-2323)
D. Dates of project:	January, 1991 to September, 1991

1. Description of project

This research project is designed to test the clinical performance of lenses fitted by traditional trial fitting methods compared to the System 10™ fitting method advocated by Lens Mode. Subjects will wear one lens fitted by each system and will be asked to compare the performance of each lens. Observations of on-eye lens performance and eye health will also be made by an optometrist over a 3 month period.

2. Description of risks:

All procedures performed in this study will be current, accepted clinical procedures for the fitting and management of contact lens patients. Unadapted rigid lens wearers may experience lens awareness during the adaptation period (20 minutes to 2 weeks). Small amounts of ocular redness and tearing may occur with lens wear, and there is very small risk of ocular infection and/or loss of vision with the use of daily wear contact lenses. This risk increases with non-compliance to care and follow-up schedules. Subjects who do not comply with prescribed regimens will be discontinued from the study and will be required to forfeit their lenses or lose their contact lens deposit fee. All subjects will sign an informed consent document.

3. Description of benefits:

Subjects accepted for study participation will receive complimentary lenses and care products for the duration of the study (3 months). They will receive optometric services for one year under the annual contact lens service agreement for $80. This does not include contact lens care products (i.e. contact lens solutions) after the initial 3 months. Subjects who complete the

study will be entitled to keep their study lenses. Further services can be obtained from Pacific University as a regular clinic patient with standard fees. If you prefer a different practitioner, we will be happy to forward our data concerning the study upon your written request.

4. Alternatives advantageous to subjects:

Some subjects may be better suited to soft lens wear or spectacles. Subjects not able to successfully complete the study will be given a 25% reduction on spectacles, and/or soft lens material fees. If all contact lens wear is ceased, a refund of the annual care agreement fee will be given, according to the following schedule:

Lens wear ceased at or before:	*Refund amount*
1 week follow-up	$80
1 month follow-up	$60
3 month follow-up	$40
After 3 months of lens wear	none

NOTE: No portion of the general examination fee will be refunded. Subjects who chose to continue in another type of contact lens will not receive a refund of the annual care agreement fee; however their services will be covered until their agreement expires. NO lens exchange privileges will be included for these subjects under this arrangement, except those covered by manufacturers' warranties.

5. Confidentiality of records:

Records of this project will be maintained in a confidential manner and no name-identifiable information will be released.

6. Compensation and medical care:

If you are injured in this study, it is possible that you will not receive compensation or medical care from Pacific University, the investigators, or any organization associated with the project. All responsible care will be used to prevent injury, however.

7. Offer to answer any inquiries:

The investigators will be happy to answer any questions you may have at any time during the study. If you are not satisfied with the answers you receive, please call Dr. James Peterson at 357-0442.

During your participation in this project, you are not a Pacific University clinic patient for contact lens care. All questions should be addressed to the study investigators, who will be solely responsible for any treatment (except for an emergency). It is imperative that you keep your scheduled appointments to ensure continuity of care and data collection by each investigator.

8. Freedom to withdraw:

You are free to withdraw your consent and to discontinue participation in this project at any time without prejudice to you (see also section 4).

I have read the above and understand its meaning. I am 18 years of age or over, or this form is signed for me by my parent or guardian

Printed name _____

Signed _____ Date _____

Address _____ Phone _____

City _____ State _____ Zip _____

Name and address of a person not living with you who will always know your address:

_____

_____

ENCLOSURE 2

Subjective Grading Scales

Comfort:

1. Very comfortable - can't tell the lens is on.
2. Comfortable - occasional lens sensation
3. Acceptable - mild lens sensation approximately 50% of day
4. Marginal - moderate lens sensation most of day
5. Intolerable - not able to wear lens for more that one hour

Vision:

1. Great - can see much better than with glasses.
2. Good - can see slightly better than glasses.
3. Acceptable - can see as well as glasses.
4. Marginal - see slightly worse than glasses.
5. Unacceptable - see much worse than glasses.

ENCLOSURE 3

Objective Grading Scales

Central corneal clouding (C.C.C.)

1. No C.C.C.,cornea clear.
2. Just detectable corneal haze without distinct borders.
3. Borders distinct but visible only against pupil background. light density.
4. Borders very distinct. Area of clouding visible against iris and in dimly lighted room.
5. Dense clouding. Visible in normal room lighting.

Corneal three-and-nine desiccation staining (photos will be used to clarify grading)

1. Not present.
2. Diffuse punctate staining.
3. Mild coalescence of staining.
4. Moderate coalescence.
5. Neovascularization and or opacification.

Injection

1. Not present.
2. Few conjunctival vessels dilated.
3. Mild congestion and dilation of conjunctival vessels.
4. Moderate congestion and dilation of conjunctival vessels.
5. Entire bulbar conjunctiva injected.

Over-refraction

1. Excellent Plano
2. Good +.25
3. Fair -.25-+.50
4. Marginal -.50
5. Unacceptable ≥±.75

Post refraction changes after 15 minutes

1. No change
2. Good ±.25
3. Fair ±.50
4. Marginal ±.75
5. Unacceptable ≥±1.00

Keratometry changes

1. Minimal change 0 - ±.25
2. Good ±..50 - ±.75
3. Fair ±.1.00
4. Marginal ±.1.25
5. Unacceptable ≥±1.50

Lens position

1. Optimal - centers from 2-4 with no nasal or temporal decentration.
2. Good - centers from 2-4 with slight nasal or temporal decentration.
3. Acceptable - centers from 2-4 with moderate nasal or temporal decentration but full pupillary coverage.
4. Marginal - centers from 1-2 or 4-5 with minimum pupillary coverage.
5. Not acceptable - lens decenters on eye to degree that edge bisects the pupil.

Outcome (see enclosure 3)

1. Very successful
2. Successful
3. Moderately successful
4. Marginally successful
5. Unsuccessful

ENCLOSURE 4

Outcome Criteria

Level 1 (very successful) overall grading score (<16)

comfort-grade 1 or 2
vision-grade 1 or 2
CCC-grade 1
3-9 stain-grade 1
Injection-grade 1
OR-grade 1 or 2
Post R-grade 1 or 2
K's-grade 1 or 2
Position-grade 1 or 2

Level 2 (successful) overall grading score: (<20)

comfort-grade 2 or 3
vision-grade 1-3
CCC-grade 1
3-9 stain-grade 1
Injection-grade 1 or 2
OR-grade 1 or 2
Post R-grade 1-3
K's-grade 1 or 2
Position-grade 1 or 2

Level 3 (moderately successful) overall score (<25)

comfort-grade 1-3
vision-grade 1-3
CCC-grade 1 or 2
3-9 stain grade 1 or 2
Injection-grade 1 or 2
OR-grade 1- 3
Post R-grade 1-3
K's-grade 1-3
Position-grade 1-3

Level 4 (marginally successful) overall score: (<34)

comfort-grade 1-4
vision-grade 1-4
CCC-grade 1-3
3-9 stain grade 1-3
Injection-grade 1-3
OR-grade 1-4
Post R-grade 1-4
K's-grade 1-4
Position-grade 1-4

Level 5 (unsuccessful) overall score: (>34)

any category unacceptable or intolerable on the first fit lens.
comfort grade 5
vision grade 1-5
CCC-grade 1-5
3-9 stain grade 1-5
Injection-grade 1-5
OR-grade 1-5
Post R-grade 1-5
K's grade 1-5
Position-grade 1-5

APPENDIX 1

Distribution of Gender and Significance of Pass/Fail

SEX

Bar:	Element:	Count:	Percent:	
1	MALE	16	43.243	
2	FEMALE	21	56.757	-Mode

Gender Significance for the Trial Lens

Contingency Table Analysis

Summary Statistics

DF:	1	
Total Chi-Square:	2.162	p=.1414
G Statistic:	•	
Contingency Coefficient:	.226	
Phi:	.232	
Chi-Square with continuity correction:	.736	p=.391

Gender Significance for System 10

Contingency Table Analysis

Summary Statistics

DF:	1	
Total Chi-Square:	.988	p=.3203
G Statistic:	1.072	
Contingency Coefficient:	.152	
Phi:	.153	
Chi-Square with continuity correction:	.259	p=.6111

APPENDIX 2

Age Significance for Pass/Fail Rates for the Trial Fit

Contingency Table Analysis

Summary Statistics

DF:	5	
Total Chi-Square:	2.042	p=.8433
G Statistic:	•	
Contingency Coefficient:	.22	
Cramer's V:	.226	

Age Significance for Pass/Fail Rates for System 10

Contingency Table Analysis

Summary Statistics

DF:	5	
Total Chi-Square:	4.194	p=.5219
G Statistic:	•	
Contingency Coefficient:	.301	
Cramer's V:	.316	

APPENDIX 3

Age Groups and Statistical Analysis

Age Groups

Bar:	From: (≥)	To: (<)	Count:	Percent:
1	16	21	10	13.514
2	21	26	18	24.324
3	26	31	12	16.216
4	31	36	10	13.514
5	36	41	18	24.324
6	41	46	6	8.108

Statistical Analysis

Mean	Std. Dev.	Std. Error	Variance	Coef. Var.	Count
29.432	7.971	.927	63.536	27.082	74

Minimum	Maximum	Range	Sum	Sum Squared	Missing
16	43	27	2178	68742	31

APPENDIX 4

Diameter Chi Square and Frequency

Summary Statistics

DF:	7	
Total Chi-Square:	19.4	p=.007
G Statistic:	•	
Contingency Coefficient:	.456	
Cramer's V:	.512	

X_1 : Trial - Diam

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	8.4	8.6	0	0	
2	8.6	8.8	0	0	
3	8.8	9	4	10.811	
4	9	9.2	2	5.405	
5	9.2	9.4	19	51.351	-Mode
6	9.4	9.6	11	29.73	
7	9.6	9.8	1	2.703	
8	9.8	10	0	0	

X_2 : System 10 - Diam

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	8.4	8.6	1	2.703	
2	8.6	8.8	5	13.514	
3	8.8	9	7	18.919	
4	9	9.2	8	21.622	-Mode
5	9.2	9.4	6	16.216	
6	9.4	9.6	7	18.919	
7	9.6	9.8	2	5.405	
8	9.8	10	1	2.703	

APPENDIX 5

Over Refraction Significance and Rank Frequency at Week 1

Wilcoxon signed-rank Trial - W1/OR System 10 - W1/OR

	Number:	Σ Rank:	Mean Rank:
- Ranks	17	218.5	12.853
+ Ranks	7	81.5	11.643

note 13 cases eliminated for difference = 0.

Z	-1.957	p = .0503
Z corrected for ties	-2.083	p = .0372
# tied groups	2	

Rank Frequency for the Trial Lens

Trial - W1/OR

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	18	48.649%	-Mode
2	2	3	17	45.946%	
3	3	4	2	5.405%	
4	4	5	0	0%	
5	5	6	0	0%	

Rank Frequency for System 10

System 10 - W1/OR

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	12	32.432%	
2	2	3	20	54.054%	-Mode
3	3	4	1	2.703%	
4	4	5	3	8.108%	
5	5	6	1	2.703%	

APPENDIX 6

Over Refraction Significance and Rank Frequency at Month 1

Wilcoxon signed-rank Trial - M1/OR System 10 - M1/OR

	Number:	Σ Rank:	Mean Rank:
- Ranks	12	133	11.083
+ Ranks	8	77	9.625

note 15 cases eliminated for difference = 0.

Z	-1.045	p = .2959
Z corrected for ties	-1.114	p = .2655
# tied groups	3	

Note: 2 cases deleted with missing values.

Rank Frequency for the Trial Lens

Trial - M1/OR

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	18	51.429	-Mode
2	2	3	16	45.714	
3	3	4	1	2.857	
4	4	5	0	0	
5	5	6	0	0	

Rank Frequency for System 10

System 10 - M1/OR

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	15	41.667	
2	2	3	17	47.222	-Mode
3	3	4	0	0	
4	4	5	4	11.111	
5	5	6	0	0	

APPENDIX 7

Over Refraction Significance and Rank Frequency of Month 3

Wilcoxon signed-rank Trial - M3/OR System 10 - M3/OR

	Number:	Σ Rank:	Mean Rank:
- Ranks	12	129	10.75
+ Ranks	6	42	7

note 15 cases eliminated for difference = 0.

Z	-1.894	p = .0582
Z corrected for ties	-1.983	p = .0473
# tied groups	3	

Note: 4 cases deleted with missing values.

Rank Frequency for the Trial Lens

Trial - M3/OR

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	20	60.606%	-Mode
2	2	3	13	39.394%	
3	3	4	0	0%	
4	4	5	0	0%	
5	5	6	0	0%	

Rank Frequency for System 10

System 10 - M3/OR

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	17	51.515%	-Mode
2	2	3	9	27.273%	
3	3	4	3	9.091%	
4	4	5	4	12.121%	
5	5	6	0	0%	

APPENDIX 8

Edge/Blend Frequency and Chi Square

Trial-EDGES/BLENDS

Bar:	Element:	Count:	Percent:	
1	YES	11	29.73	
2	NO	26	70.27	-Mode

System-EDGES/BLENDS

Bar:	Element:	Count:	Percent:	
1	YES	15	40.541	
2	NO	22	59.459	-Mode

Chi Square

Contingency Table Analysis

Summary Statistics

DF:	1	
Total Chi-Square:	.949	p=.33
G Statistic:	.952	
Contingency Coefficient:	.113	
Phi:	.113	
Chi-Square with continuity correction:	.534	p=.4651

APPENDIX 9

Comfort Significance and Rank Frequency at Week 1

Wilcoxon signed-rank **Trial - W1/C** **System 10 - W1/C**

	Number:	Σ Rank:	Mean Rank:
- Ranks	17	164.5	9.676
+ Ranks	1	6.5	6.5

note 19 cases eliminated for difference = 0.

Z	-3.44	p = .0006
Z corrected for ties	-3.573	p = .0004
# tied groups	2	

Rank Frequency for the Trial Lens

Trial - W1/C

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	9	24.324	
2	2	3	19	51.351	-Mode
3	3	4	8	21.622	
4	4	5	1	2.703	
5	5	6	0	0	

Rank Frequency for System 10

System 10 - W1/C

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	4	10.811	
2	2	3	14	37.838	-Mode
3	3	4	10	27.027	
4	4	5	9	24.324	
5	5	6	0	0	

APPENDIX 10

Comfort Significance and Rank Frequency at Month 1

Wilcoxon signed-rank Trial - M1/C System 10 - M1/C

	Number:	Σ Rank:	Mean Rank:
- Ranks	9	65.5	7.278
+ Ranks	5	39.5	7.9

note 21 cases eliminated for difference = 0.

Z	-.816	p = .4144
Z corrected for ties	-.881	p = .3785
# tied groups	2	

Note: 2 cases deleted with missing values.

Rank Frequency for the Trial Lens

Trial - M1/C

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	7	20	
2	2	3	23	65.714	-Mode
3	3	4	3	8.571	
4	4	5	1	2.857	
5	5	6	1	2.857	

Rank Frequency for System 10

System 10 - M1/C

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	7	19.444	
2	2	3	19	52.778	-Mode
3	3	4	8	22.222	
4	4	5	1	2.778	
5	5	6	1	2.778	

APPENDIX 11

Comfort Significance and Rank Frequency at Month 3

Wilcoxon signed-rank Trial - M3/C System 10 - M3/C

	Number:	Σ Rank:	Mean Rank:
- Ranks	9	57	6.333
+ Ranks	3	21	7

note 21 cases eliminated for difference = 0.

Z	-1.412	p = .1579
Z corrected for ties	-1.485	p = .1376
# tied groups	2	

Note: 4 cases deleted with missing values.

Rank Frequency for the Trial Lens

Trial - M3/C

Bar:	From: (≥)	To: (<)	Count:	Percent:
1	1	2	16	48.485
2	2	3	16	48.485
3	3	4	0	0
4	4	5	1	3.03
5	5	6	0	0

Rank Frequency for System 10

System 10 - M3/C

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	12	36.364	
2	2	3	17	51.515	-Mode
3	3	4	3	9.091	
4	4	5	1	3.03	
5	5	6	0	0	

APPENDIX 12

Outcome Significance and Rank Frequency at Week 1

Wilcoxon signed-rank Trial - W1/OUT System 10 - W1/O...

	Number:	Σ Rank:	Mean Rank:
- Ranks	12	102	8.5
+ Ranks	3	18	6

note 22 cases eliminated for difference = 0.

Z	-2.385	p = .0171
Z corrected for ties	-2.499	p = .0124
# tied groups	2	

Rank Frequency for the Trial Lens

Trial - W1/OUT

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	17	45.946	-Mode
2	2	3	5	13.514	
3	3	4	9	24.324	
4	4	5	5	13.514	
5	5	6	1	2.703	

Rank Frequency for System 10

System 10 - W1/OUT

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	13	35.135	
2	2	3	6	16.216	
3	3	4	3	8.108	
4	4	5	14	37.838	-Mode
5	5	6	1	2.703	

APPENDIX 13

Outcome Significance and Rank Frequency at Month 1

Wilcoxon signed-rank Trial - M1/OUT System 10 - M1/O...

	Number:	Σ Rank:	Mean Rank:
- Ranks	13	120	9.231
+ Ranks	4	33	8.25

note 18 cases eliminated for difference = 0.

Z	-2.059	p = .0395
Z corrected for ties	-2.101	p = .0356
# tied groups	3	

Note: 2 cases deleted with missing values.

Rank Frequency for the Trial Lens

Trial - M1/OUT

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	17	48.571	-Mode
2	2	3	8	22.857	
3	3	4	6	17.143	
4	4	5	2	5.714	
5	5	6	2	5.714	

Rank Frequency for System 10

System 10 - M1/OUT

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	11	30.556	-Mode
2	2	3	9	25	
3	3	4	6	16.667	
4	4	5	7	19.444	
5	5	6	3	8.333	

APPENDIX 14

Outcome Significance and Rank Frequency at Month 3

Wilcoxon signed-rank Trial - M3/OUT System 10 - M3/O...

	Number:	Σ Rank:	Mean Rank:
- Ranks	12	80	6.667
+ Ranks	1	11	11

note 20 cases eliminated for difference = 0.

Z	-2.411	p = .0159
Z corrected for ties	-2.444	p = .0145
# tied groups	3	

Note: 4 cases deleted with missing values.

Rank Frequency for the Trial Lens

Trial - M3/OUT

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	13	39.394	-Mode
2	2	3	12	36.364	
3	3	4	7	21.212	
4	4	5	1	3.03	
5	5	6	0	0	

Rank Frequency for System 10

System 10 - M3/OUT

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	8	24.242	
2	2	3	10	30.303	-Mode
3	3	4	7	21.212	
4	4	5	7	21.212	
5	5	6	1	3.03	

APPENDIX 15

Overall Outcome Significance and Rank Frequency

Wilcoxon signed-rank Trial-Outcome System 10-Outcome

	Number:	Σ Rank:	Mean Rank:
- Ranks	13	94	7.231
+ Ranks	1	11	11

note 23 cases eliminated for difference = 0.

Z	-2.605	p = .0092
Z corrected for ties	-2.634	p = .0084
# tied groups	3	

Rank Frequency for the Trial Lens

Trial-Overall Outcome

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	14	37.838	-Mode
2	2	3	12	32.432	
3	3	4	7	18.919	
4	4	5	1	2.703	
5	5	6	3	8.108	

Rank Frequency for System 10

System 10-Overall Outcome

Bar:	From: (≥)	To: (<)	Count:	Percent:	
1	1	2	8	21.622	
2	2	3	10	27.027	-Mode
3	3	4	7	18.919	
4	4	5	7	18.919	
5	5	6	5	13.514	

APPENDIX 16

LENS CHANGES INDICATED BY GRADING SCALES

	TRIAL FIT	SYSTEM 10 FIT
DIAMETER INCREASED	3 (9.3 TO 9.65) (9.6 TO 9.9) (9.3 TO 9.6)	2 (9.1 TO 9.6) (9.5 TO 9.9)
POWER	0	2 (O.R. +1.00) (O.R. +.50)
B.C.& DIAMETER	0	1 (7.63 TO 7.55 &8.65 TO 8.8)