5-1998

An evaluation of manufacturing inconsistencies of rigid gas permeable contact lenses

Trevor Cleveland
Pacific University

Joel Casey
Pacific University

Robert Fleckenstein
Pacific University

An evaluation of manufacturing inconsistencies of rigid gas permeable contact lenses

Abstract

It is very important that rigid gas permeable lenses be manufactured to the specifications requested by the practitioner. Precise determination of the parameters of rigid gas permeable lenses by the practitioner is a futile exercise if the lens that is received from the lab differs from that which was ordered. Twenty-four rigid gas permeable lenses ordered from four different labs were verified and their parameters compared to what was ordered. The edges of the lenses were also subjectively graded. Although no significant variability was found between labs, a considerable amount of lenses studied had one or more parameter that was significantly different than those ordered. Also, seventy one percent of lenses ordered failed to meet ANSI Standards for one or more of the specified parameters. Thus, it is beneficial to the practitioner to verify all incoming lenses to ultimately save doctor time, the time of the patient, and to increase the ratio of first-time successful fits.

Degree Type

Thesis

Degree Name

Master of Science in Vision Science

Committee Chair

Patrick Caroline

Keywords

rigid (gas permeable) contact lenses, lens parameters, consistency, verification, ansi standards

Subject Categories

Optometry

An Evaluation of Manufacturing Inconsistencies of Rigid Gas Permeable Contact Lenses

by

TREVOR CLEVELAND

JOEL CASEY

and

ROBERT FLECKENSTEIN

A thesis submitted to the faculty of Pacific University College of Optometry
Forest Grove, Oregon
for the degree of Doctor of Optometry
May, 1998

Advisor:

Patrick Caroline, C.O.T., F.C.L.S.A.

AUTHORS

(In Alphabetical Order)

Joel Casey

Trevor Cleveland

Robert Fleckenstein

ADVISOR

Patrick Caroline, C.O.T., F.C.L.S.A.

ABOUT THE AUTHORS...

JOEL CASEY

Joel Casey is in his fourth year of Optometry School at Pacific University. His projected date of commencement is May, 1998. He completed three years of Kinesiology at Simon Fraser University before receiving a Bachelor of Science in Visual Science from Pacific University in 1996. Joel is applying for a residency position in ocular disease. He likes to sleep.

TREVOR CLEVELAND

Trevor Cleveland graduated in 1994 with a Bachelor of Science degree in biology from Bemidji State University- Bemidji, Minnesota. He is currently in his fourth year of Optometry School and will graduate in May 1998. Future plans include practicing in and enjoying the state of Oregon while avoiding pediatrics.

ROBERT FLECKENSTEIN

Robert Fleckenstein graduated from the University of Alaska at Anchorage in 1993 with a Bachelor of Science degree in Biological Sciences. He is currently in his fourth year of Optometry School at Pacific University and will graduate in 1998. He is an avid participator in outdoor activities and hopes to return to Alaska to practice Optometry and climb things.

ABSTRACT

It is very important that rigid gas permeable lenses be manufactured to the specifications requested by the practitioner. Precise determination of the parameters of rigid gas permeable lenses by the practitioner is a futile exercise if the lens that is received from the lab differs from that which was ordered. Twenty-four rigid gas permeable lenses ordered from four different labs were verified and their parameters compared to what was ordered. The edges of the lenses were also subjectively graded. Although no significant variability was found between labs, a considerable amount of lenses studied had one or more parameter that was significantly different than those ordered. Also, seventy one percent of lenses ordered failed to meet ANSI Standards for one or more of the specified parameters. Thus, it is beneficial to the practitioner to verify all incoming lenses to ultimately save doctor time, the time of the patient, and to increase the ratio of first-time successful fits.

Key Words: rigid(gas permeable) contact lenses, lens parameters, consistency, verification, ANSI standards

INTRODUCTION

The fitting of rigid gas permeable contact lenses is a very meticulous process for an eyecare practitioner, and a proper fit is essential for patient comfort and eye health. Consequently, considerable time and effort on the part of the practitioner is utilized to ensure a proper contact lens fit. Several variables such as lens base curve, overall diameter, back vertex power, edge design, center thickness, optic zone diameter, and peripheral curve blends may require alteration to assure a proper lens for a patient. Some of these parameters can be modified by a practitioner, but many lens properties can only be changed in an optical lab by skilled technicians. Often times an entirely new lens must be manufactured by the lab if alterations to a lens are not possible. It is imperative that all variables stay unchanged from one lens to the next for consistent and successful fitting to be achieved.

A practitioner may think she is receiving a lens that matches the ordered parameters, but in reality the lens received may be quite different. This makes proper fitting a difficult task. These lens parameters have direct influence on how a certain lens performs on a patient's eye. For example, an inadequate edge design can result in lid awareness, foreign body sensation, excessive or unpredictable lens movement, 3 and 9 staining, and peripheral abrasions.[1] The wrong lens diameter can affect stability. An unexpected base curve will alter the lens-cornea relationship. Inaccurate center thickness can affect the weight of the lens or consequently affect edge thickness, which can both lead to reduced patient comfort. An unexpected back vertex power can cause numerous complaints with vision and comfort.

In addition to "quantifiable" lens parameters, careful examination of lens edge characteristics is an especially important, yet often overlooked step for doctors. A variety of lens materials and lack of ANSI standards make a consistent edge shape and thickness difficult to attain even from a single lab, yet the shape and quality of the contact lens edge is of utmost importance in providing a comfortable and properly fitting contact lens.[2,3] Our edge evaluation looked at three areas or "zones" of the lens edge. The anterior zone is the area in contact with the upper lid during a blink. Its function is to taper the lens periphery and reduce interaction between the lid and lens. The posterior zone is on the backside of the lens and is responsible for bringing the edge away from the cornea to allow free lens movement, centering of the lens, fresh tear flow, and ease of lens removal. The lens apex is the junction between the anterior and posterior zones. This area must be well rounded to minimize lens awareness.[4]

Although advancements have been made in the production of rigid gas permeable lenses by means of computer lathes, many characteristics of the lens are still hand-altered, such as blending and edging. This human factor allows for variance and may contribute to the final lens product being very different from that intended. Regardless of practitioner bias and differences in lens edge philosophies, inconsistent edging and non-verification by the practitioner will result in frustration. Research from previous studies as well as discussions with experienced clinicians support our contention that the rigid lens you receive from the lab may vary from the lens that you ordered.[5,6]

Our goal with this study was to support our hypothesis by ordering twenty four lenses of different parameters from four different labs located in the Pacific Northwest. These lenses were verified and statistical comparisons were made between the ordered and received parameters. Analysis was also performed to determine variability between labs.

METHODS

Twenty four rigid gas permeable (RGP) contact lenses were verified and compared to the parameters that were ordered. The lenses used in this study were ordered for Casey Eye Institute from four different labs in the Pacific Northwest region. For the sake of anonymity the labs will be referred to as labs A, B, C, and D. The following parameters were verified: back vertex power (BVP), base curve (BC), center thickness (CT), overall diameter (OAD), and edge design.

To ensure quality of measurement, all twenty-four lenses were measured three times by the same reseacher on three different sets of equipment. Standard operating procedures were implemented for the equipment by following the instructions given to the reseachers by Pacific University faculty in various classes as well as techniques gleaned from *Clinical Contact Lens Practice* by Edward S. Bennett. The average of these three readings was then assumed to be the reading for that parameter for statistical analysis. Optic zone diameter and overall diameter were measured using 7x PEAK scopes. Back vertex powers were verified using Marco, model 101 lensometers. A Reichert, model 11200 radiuscope was used to measure base curves and identify possible warpage. Edge design and condition was also assessed using a Reichert, model 11200 radiuscope used as a modified dissecting scope. Edge photographs were taken through this modified dissecting scope using a Polaroid *Microcam* microscope camera on Polaroid 339 film.

Center thickness was determined using a Neitz-CG, model 671117 micrometer. Results for each parameter were recorded and statistically compared to the parameters that were specified while ordering the lenses. Variability between the four labs was tested using a factorial design analysis of variance (ANOVA).[7] In addition, lenses were compared to the American National Standards for Hard Contact Lenses (ANSI) for the parameters of back vertex power, base curve, overall diameter, and center thickness.

Not all parameters could be evaluated with mathematical comparisons and statistical analysis. Since there are no ANSI standards for the edges of rigid gas permeable contact lenses, a subjective analysis was performed comparing the edges we received to what we deemed as adequately constructed according to our adopted grading scale. Each edge was analyzed in three areas or "zones": anterior zone, apex, and posterior zone (appendix).[1] All lens edges were compared to the "ideal edge" having a smooth, contoured profile of the anterior zone, a slight regression of the posterior zone away from the cornea, and a well rounded apex. As the edges were carefully examined and photographed, each of the three zones were separately evaluated as adequate, inadequate, or excessive. An 'inadequate' or 'excessive' determination in any area deemed the edge unacceptable. All three areas must be 'adequate' for the edge to be acceptable. Again, all edge characteristics were unspecified and left to the lab's discretion.

DATA

Ordered Parameters

	Base Curve	Power	Diameter	Center Thickness	Design	Material
Lens 1	6.00	-12.00	8.6	0.12	Lenticular	SGP II
Lens 2	7.50	-7.00	9.5	0.12	Lenticular	SGP II
Lens 3	7.78	-2.00	9.0	0.14	Single Cut	SGP II
Lens 4	7.78	+2.00	9.0	0.25	Single Cut	SGP II
Lens 5	8.03	+14.00	9.5	0.48	Lenticular	SGP II
Lens 6	7.85/7.50	-3.00/-5.00	9.0	0.14	Bitoric	SGP II

Lab A – Verified Parameters

Lens	Back Vertex Power	Base Curve	Overall Diameter	Center Thickness
Lens 1	-12.00	6.01	8.65	0.16
Lens 2	-6.92	7.46	9.60	0.15
Lens 3	-1.83	7.76	9.05	0.16
Lens 4	2.17	7.80	8.90	0.27
Lens 5	13.91	8.06	9.60	0.50
Lens 6 (Primary PWR)	-3.12	7.90	9.00	0.16
Lens 6 (Secondary PWR)	-4.71	7.59	N/A	N/A
Lens 6 (Cylinder PWR)	1.58	N/A	N/A	N/A

Lab B – Verified Parameters

Lens	Back Vertex Power	Base Curve	Overall Diameter	Center Thickness
Lens 1	-11.92	6.00	8.60	0.12
Lens 2	-7.12	7.49	9.55	0.14
Lens 3	-2.00	7.80	9.00	0.14
Lens 4	2.12	7.76	8.90	0.26
Lens 5	14.12	8.01	9.50	0.51
Lens 6 (Primary PWR)	-3.00	7.92	9.10	0.15
Lens 6 (Secondary PWR)	-5.00	7.42	N/A	N/A
Lens 6 (Cylinder PWR)	2.00	N/A	N/A	N/A

Lab C – Verified Parameters

Lens	Back Vertex Power	Base Curve	Overall Diameter	Center Thickness
Lens 1	-11.92	5.95	8.65	0.12
Lens 2	-6.92	7.49	9.55	0.13
Lens 3	-1.96	7.76	9.10	0.16
Lens 4	2.17	7.78	9.00	0.25
Lens 5	14.08	8.02	9.50	0.46
Lens 6 (Primary PWR)	-3.00	7.86	9.00	0.13
Lens 6 (Secondary PWR)	-4.92	7.48	N/A	N/A
Lens 6 (Cylinder PWR)	1.92	N/A	N/A	N/A

Lab D – Verified Parameters

Lens	Back Vertex Power	Base Curve	Overall Diameter	Center Thickness
Lens 1	-11.75	5.95	8.50	0.12
Lens 2	-6.91	7.48	9.50	0.12
Lens 3	-2.04	7.74	9.00	0.14
Lens 4	2.08	7.79	8.90	0.22
Lens 5	14.00	7.94	9.40	0.45
Lens 6 (Primary PWR)	-2.67	7.88	9.10	0.16
Lens 6 (Secondary PWR)	-5.00	7.49	N/A	N/A
Lens 6 (Cylinder PWR)	2.33	N/A	N/A	N/A

RESULTS

A factorial design analysis of variance was utilized to determine if there was a significant variability between lenses received from each lab (Table 1). No significant variability was found between labs for the parameters of power, base curve, overall diameter, or center thickness.

Deviation of ordered from verified parameters were calculated for lenses from each lab in each parameter. These deviations were averaged and can be found in Table 3. ANSI Standards for rigid gas permeable lenses can also be found in this table.

ANSI Standards for rigid lenses are as follows: on lenses from +10.00 D to –10.00 D, deviation from ordered power should be less than or equal to 0.12 D, for lenses greater than 10.00 D the deviation must be less than or equal to 0.25 D. Base curve tolerance is +/- 0.025 mm. Overall diameter tolerance is +/- 0.05 mm. Center thickness tolerance is +/- 0.02 mm. Lenses were analyzed to determine the number from each lab did not meet ANSI Standards, the number of lenses not meeting ANSI Standards for each parameter, and the total number of lenses not meeting ANSI Standards for one or more of the specified parameters (Table 4).

Subjective Edge Evaluation

	Lab A	Lab B	Lab C	Lab D
Lens 1	Adequate*	Adequate	*Inad. Anterior zone*	Adequate
Lens 2	Adequate	*Inad. Posterior zone*	Adequate	Adequate
Lens 3	Adequate	Adequate	Adequate	Adequate
Lens 4	Adequate	Adequate	Adequate	Adequate
Lens 5	*Inad. Ant zone*	*Inad. Posterior zone*	Adequate	*Inad. Posterior zone*
Lens 6	*Inad. Posterior zone*	*Inad. Anterior zone*	*Inad. Ant. zone*	Adequate

***Adequate = an acceptable edge design for all three zones**

Overall subjective analysis of the lens edges showed that 33% of all the lenses were unacceptable in one or more of the measured edge parameters. Interestingly, many of these inadequate designs were not from any particular lab, but rather consistent between the labs for a particular lens design. For example, lens 5 and 6 (+14D and bitoric respectively) showed poor edges in five of the six labs each were ordered (83%). A look at the consistency within a given lab showed inadequate edges as often as 50% of the time for lab B and a low as 16% for lab D. All labs showed at least one inadequate lens edge as deemed by our standards (16%). Granted this sample was small and statistical analysis to accurately predict lens-edge consistency from this study with so many variables in power and base curve would be purely academic. However, when holding all parameters equal and varying only the lab (such for lens 2), one lab does show a marked difference in subjective edge design as compared to the others for this basic myopic prescription; this is a 25% chance of an inadequate or potentially uncomfortable lens.

DISCUSSION and CONCLUSION

One of the goals of this study was to determine if there is any difference between contact lens labs when it comes to matching ordered parameters. No significant variability was found between the four labs in this study. This leads us to believe that lab precision should not be a deciding factor to a practitioner when selecting a lab to send orders. The practitioner can base this decision on other factors, such as convenience, cost, service, and personal preference.

Although there was no significant variability between labs, the mean deviations of ordered from verified lenses was surprisingly large. In other words, all four labs were consistently less than perfect. This contributes to the startling number of lenses not meeting ANSI Standards. Some may feel these standards are fairly strict. For instance, although ten lenses did not meet ANSI Standards for diameter, no lens was greater than 0.1 mm different than the ordered diameter. Will this make a significant difference when the patient in wearing the lens? Through experience, each individual practitioner should set his or her own standards depending on what he or she considers clinically significant.

The large percentage of lenses not meeting ANSI Standards leads us to believe that it would be wise for a practitioner to verify all rigid lenses before dispensing them to a patient. This would save time for the practitioner by decreasing the amount of unsuccessful lens fits and increasing patient satisfaction.

This is similarly true for edge design as well. The most consistent finding among our inadequate edges was inconsistency. For a given lens, one lab would give a good edge while another lab gave an inadequate anterior zone. Consequently a different labs error gave an lens with a poor posterior zone only solidifying the idea that a few seconds of edge verification prior to dispense may prove nothing short of invaluable. From here, each practitioner can individually decide how much variance from the "ideal" edge makes a symptomatic patient. The edge can then be simply modified or that lab simply avoided.

ACKNOWLEDGEMENTS

We would like to thank Pacific University's College of Optometry for the use of its equipment and facilities during the data collection process. Also, an integral part of this study included the faithful donation of lenses from area laboratories, which without the persistence and "sweet talking" ability of our advisor Patrick Caroline, would not have been possible. His support, suggestions, and attitude during this study proved to be invaluable. A special thank you also goes to Mr. Tim Koch of Paragon Vision Sciences for his generous monetary donation that paid for the Polaroid camera. This special camera was needed to take the in-instrument photos and will undoubtedly be used for future studies at the College of Optometry.

REFERENCES

1. Caroline P, Norman C. RGP Edge Analysis and Modification. *Contact Lens Spectrum*, 1991 April :39-49

2. Bennet E, Henry V. Inspection and Verification of RGP Contact Lenses. In: Bennet E, Weissman B, eds. *Clinical Contact Lens Practice*. Lippencott, 1993:26

3. Morgan B. Modification. In: Bennet E, Weissman B, eds. *Clinical Contact Lens Practice*. Lippencott, 1993: 27

4. Caroline P, Hodur N, Avruskin C, Hay T. Fitting Special Design Contact Lenses. Lab Manual; Opt. 717 PUCO, 1996

5. El Hage S, Bacigalupi M. A New Method of Contact Lens Verification. *Contact Lens Spectrum*, 1992 July: 31-34

6. Unger C, Watters K. A Comparison of RGP Parameters to ANSI standards. PUCO Opt. Thesis, 1994

7. Cox P. A Handbook of Introductory Statistical Methods. 1987 pp. 91-106

FIGURES

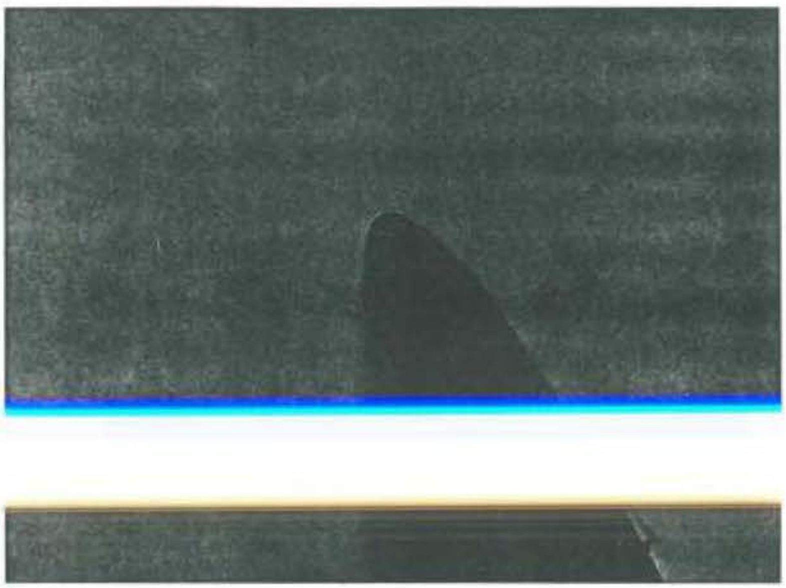


Figure 1: Preferred edge design showing well proportioned zones.

Figure 2: Edge with an inadequate posterior zone.

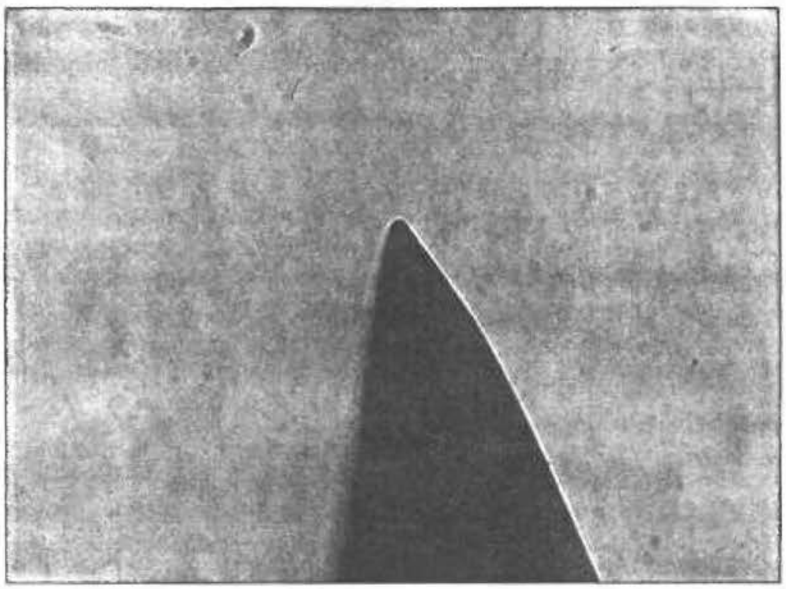


Figure 3: Edge with inadequate "sharp" anterior zone.

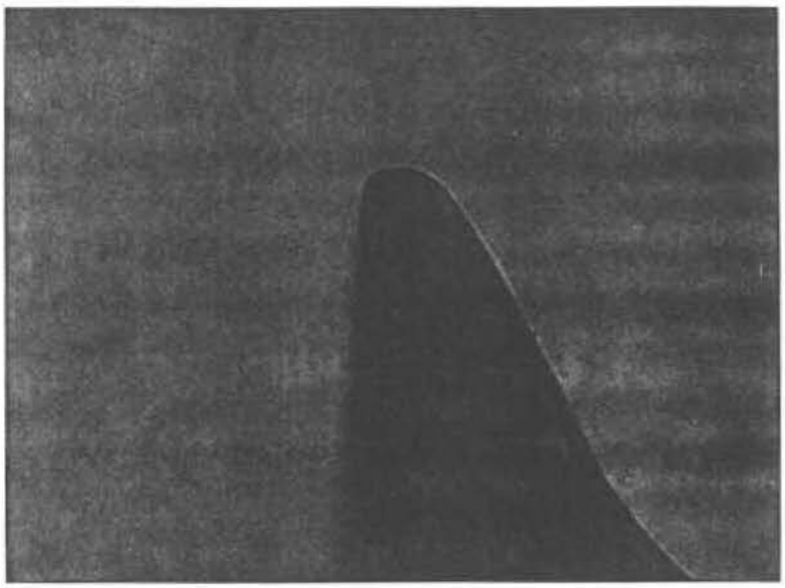


Figure 4: Thick edge with inadequate anterior and posterior zones.

TABLES

Table 1 – ANOVA Results for Variability Between Labs

Parameter	p-value
Back Vertex Power	0.1286
Base Curve	0.4760
Overall Diameter	0.4871
Center Thickness	0.1240

Significance Level: p<0.05

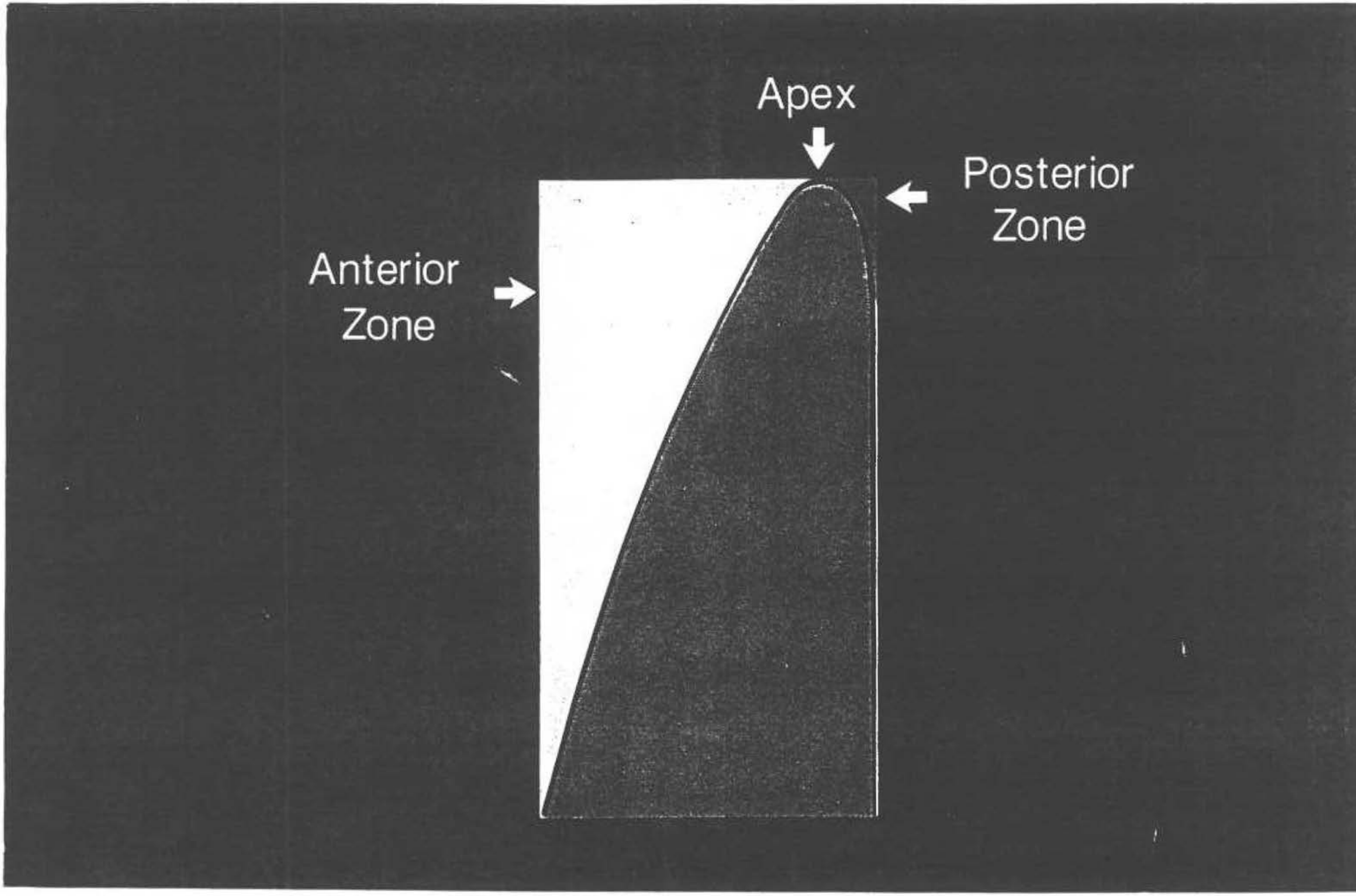
Table 2 – Mean Deviation of Verified from Ordered Parameters

Parameter	Lab A	Lab B	Lab C	Lab D	ANSI Standards
Back Vertex Power	0.17	0.06	0.08	0.14	+/-0.12
Base Curve	0.037	0.031	0.016	0.036	+/-0.025
Overall Diameter	0.07	0.04	0.03	0.07	+/-0.05
Center Thickness	0.025	0.012	0.010	0.013	+/-0.02

Table 3 – Lenses Outside ANSI Standards

Parameter	Lab A	Lab B	Lab C	Lab D	Total Lenses of each Parameter
Back Vertex Power	3	0	1	1	5
Base Curve	3	1	1	4	9
Overall Diameter	3	2	1	4	10
Center Thickness	2	1	0	2	5
Total Lenses from each Lab*	6	3	3	5	**17**

*Each lens is only counted once


Apex
Posterior
Zone
Anterior
Zone

American National Standards for Hard Contact Lenses

Prescription Requirements for Corneal Lenses

(All measurements are made in air with lenses in an air-dried state.)

Parameter	Tolerance	Parameter	Tolerance
Diameter	± 0.05 mm	Cylinder axis	± 5°
Posterior optic zone diameter		Toric base curve radii	
Light blend	± 0.1 mm	Δr 0 to 0.20 mm	± 0.02 mm (Note 3)
Medium or heavy blend	± 0.2 mm	Δr 0.21 to 0.40 mm	± 0.03 mm
Posterior central curve (base curve) radius	± 0.025 mm	Δr 0.41 to 0.60 mm	± 0.05 mm
		Δr > 0.60 mm	± 0.07 mm
Posterior secondary, intermediate, or peripheral curve width		Bifocal refractive power addition	± 0.25 D (Note 2)
		Bifocal segment height	− 0.1 mm to + 0.2 mm
Light blend	± 0.05 mm	Center thickness	less than ± 0.02 mm (Note 4)
Medium or heavy blend	± 0.10 mm		
Posterior secondary, intermediate, or peripheral curve radius	± 0.1 mm	Edges	As specified
		Anterior peripheral curve radius	± 0.2 mm
Refractive power		Anterior optic zone diameter	± 0.1 mm
+ 10.00 D to − 10.00 D	± 0.12 D (Notes 1, 2, 3)	Optical quality and surface quality	No bubbles, striae, waves, inhomogenieties, crazing, pits, scratches, chips, lathe marks, or stone marks
More than ± 10.00 D	± 0.25 D		
Prism power (measured from the geometric center)			
If lens power is:			
± 10.00 D to − 10.00 D	± 0.25Δ	Color	Pigment inert and uniformly distributed
More than ± 10.00 D	± 0.50Δ		
Cylinder power			
less than 2.00 D	± 0.25 D		
2.00 D to 4.00 D	± 0.37 D		
greater than 4.00 D	± 0.50 D		

NOTE 1: If the lens base curve and power errors are cumulative (that is, base curve and lens power errors both add plus power or both add minus power to the refractive correction) the cumulative error shall not exceed 0.25 D.

NOTE 2: The cumulative errors in power between the right and left lenses shall not exceed 0.25 D.

NOTE 3: Symbols used are as follows:

- D = diopters
- Δ = Prism diopters
- Δr = difference between radii of principal meridians

NOTE 4: The algabraic differences in thickness error between right and left lenses shall not exceed 0.02 mm.