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Reliability of the soft lens analyzer in measuring the base curve of thin hydrogel lenses

Abstract

Posterior curve measurements were performed on 18 separate lenses by means of the Hydro-Vue Soft Lens Analyzer. 20 measurements were made per lens to determine this instruments ability to provide accurate and reproducible data. Six lens manufacturers were represented with three different powers used from each company. It was found that no significant difference existed between lens manufacturers in their ability to provide reproducible base curve data. Likewise, variance in measurements could not be related to the power of the lens. When our findings were compared to the base curve stated on the vial it was seen that a significant discrepancy occurred in 2 cases, thus demonstrating a need for a tool the clinician can use to monitor his fitting variables.

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William Preston

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FITZES
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McCartney,
MA

RELIABILITY OF THE SOFT LENS ANALYZER IN
MEASURING THE BASE CURVE OF THIN HYDROGEL LENSES

Myles A. McCartney
James R. Gutfleisch
William Preston O.D.

February/1981

PACIFIC UNIVERSITY COLLEGE OF OPTOMETRY

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for without their help this study could not have been done:

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Randy McDonald
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Pacific University College of Optometry and
Portland Optometric Clinic for facilities and
necessary materials

ABSTRACT

Posterior curve measurements were performed on 18 separate lenses by means of the Hydro-Vue Soft Lens Analyzer. 20 measurements were made per lens to determine this instruments ability to provide accurate and reproducible data. Six lens manufacturers were represented with three different powers used from each company.

It was found that no significant difference existed between lens manufacturers in their ability to provide reproducible base curve data. Likewise, variance in measurements could not be related to the power of the lens. When our findings were compared to the base curve stated on the vial it was **seen** that a significant discrepancy occurred in 2 cases, thus demonstrating a need for a tool the clinician can use to monitor his fitting variables.

TABLE OF CONTENTS

Acknowledgements II

Abstract III

Introduction 5

Methodology 8

Figures 1,2,&3 10

Data 11-22

Figure 4 23

Discussion 24

Bibliography 29

INTRODUCTION

One of the significant problems in fitting soft contact lenses is the verification of parameters, base curve being particularly difficult. Most clinicians have experienced the problem of ordering a duplicate replacement lens, only to find the fitting characteristics and performance substantially different than the original. It has been seen that two lenses marked as being identical can be quite different with regards to base curve.¹ Soft lenses have also been shown to change vital parameters in the course of their use by the patient.² This could be attributed to many possible factors of which may include pH and tonicity of the storage solution.^{3,4}

It would be a great advantage to clinicians to have a reliable tool to measure base curves, thus assuring quality control and more predictability in their fitting regimen. In recent years many methods have been proposed for just such a purpose.^{4,5,6,7,8,9,10,11} When discrepancies of 0.3 to 0.9mm in base curve radius occur, significant differences in lens performance result.¹² We feel, however, that all too often the major emphasis is placed on the accuracy (validity) and less on reproducibility (reliability) of the instrument-

ation. How a lens performs and the physiological response it induces in the patient is a function of many factors. We would be wrong to expect a 60% H₂O content lens to behave the same as a 30% H₂O content lens having the same posterior radius. Likewise, overall diameter, center thickness, and chemical structure would all have their influence on the final outcome. As clinicians then, a practical goal should be to understand the characteristics of the limited brands of lenses we use and combine this information with reproducible base curve data to give us predictability of performance during our fitting procedures.

The purpose of this paper is to determine if modern soft thin lenses lend themselves to accurate and repeatable measurements of base curve radius using the Hydro-Vue Soft Lens Analyzer. The goal of this study is therefore to answer the following questions:

1. How do the various lens manufacturers compare with one another in providing reproducible base curve information using this instrument?

2. How does the base curve data obtained by the Soft Lens Analyzer compare with that which the manufacturer states on the vial?

3. Does the power of the soft thin lens affect the repeatability of measurements?

METHODOLOGY

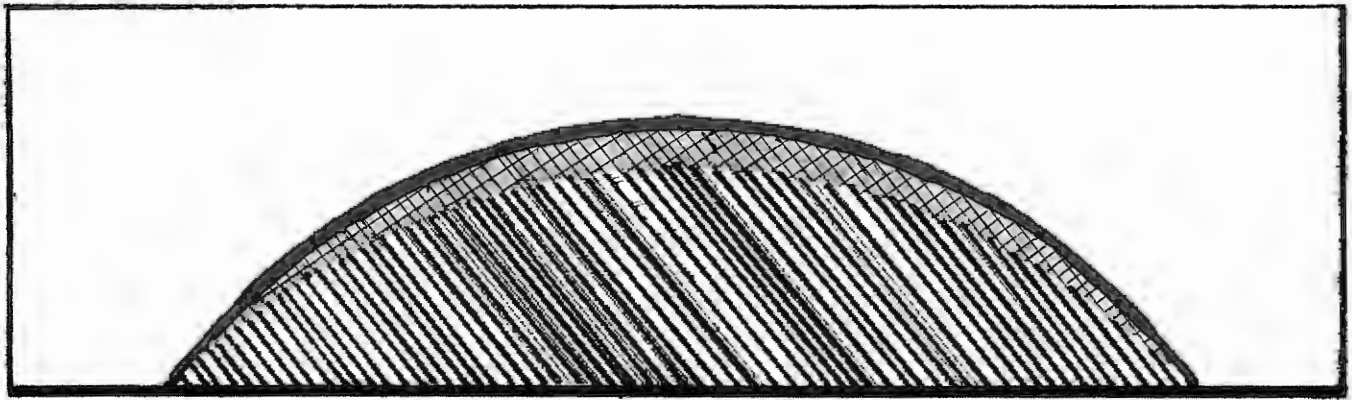
The Soft Lens Analyzer measures base curve radius using templates of known radius combined with a projection system. The lens to be measured is placed in a water cell and laid to rest upon a spherical surface. One then views a profile of the lens-template relationship on the projection screen and determines if the lens is steep, flat, or in alignment with the template of known radius of curvature. If for example a lens is judged too steep it is then placed upon a template of smaller radius and a new evaluation is made. This process is continued until an alignment relationship is noted or the lens is judged to have a base curve in between two successive templates (steep relative to one & flat relative to the other). Templates are available in 0.2mm increments. The sensitivity of this measuring system is thus judged to be 0.1mm.

Twenty measurements of base curve were performed on each soft thin lens used in this study. Six different manufacturer's lenses were examined. In addition, three different powers consisting of low minus, moderate minus, and high minus were evaluated from each manufacturer. We therefore performed a total of 360 separate determinations of base curve on the

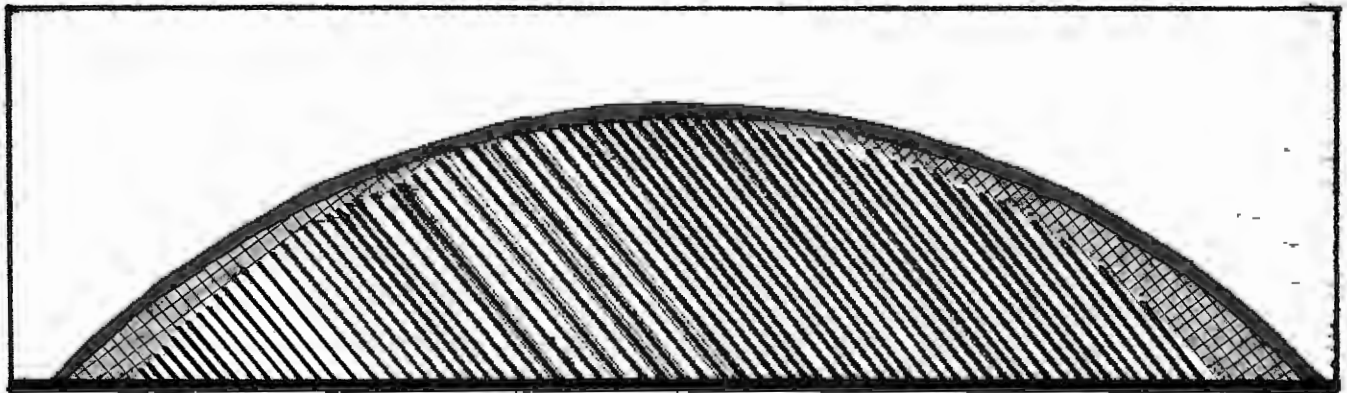
Soft Lens Analyzer. We felt that twenty measurements per lens were necessary in order to obtain a statistically significant insight on variance using this instrument. The lenses studied in this experiment were as follows:

1. Aquaflex (Super-thin)
2. Hydro-Marc (Ultra-thin SM Series)
3. Hydrocurve II (Ultra-thin)
4. American Hydron .06 (Ultra-thin)
5. B&L (U4 Series)
6. American Optical (AO-Thin)

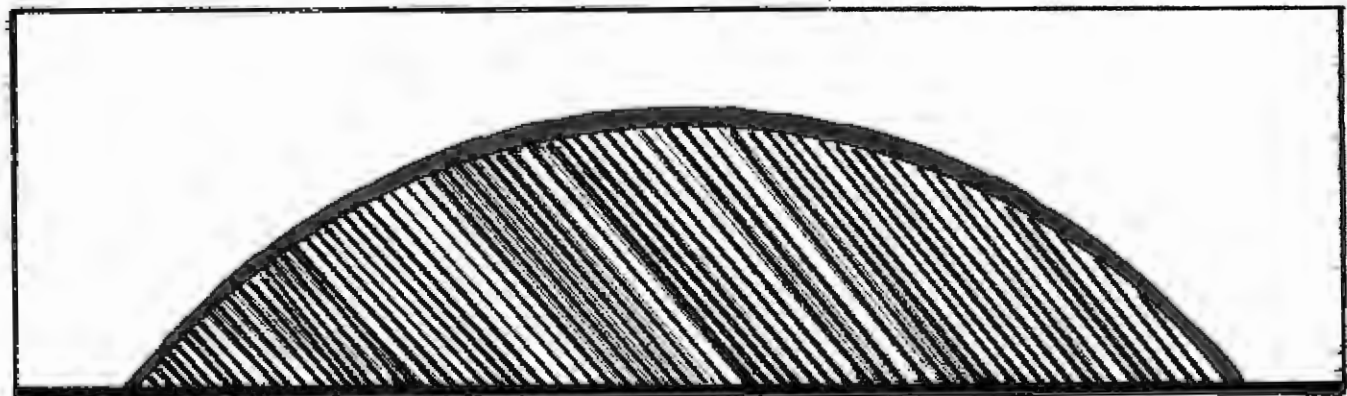
In order to avoid any bias on the part of the person making the measurement, a lens was randomly presented for analysis without that person being aware of neither manufacturer nor power. The investigator was asked to estimate the base curve to the nearest 0.1mm. Once a base curve determination was made the lens was returned to a second investigator who recorded the result and presented a new lens. This process continued until all lenses were measured twenty times. One investigator performed all 360 measurements in order to prevent unwanted clinician to clinician variance. Once all the data was collected mean, range, and standard deviation were determined for the measurements performed on each individual lens.



. FIGURE 1 (Steep Relationship)



. FIGURE 2 (Flat Relationship)



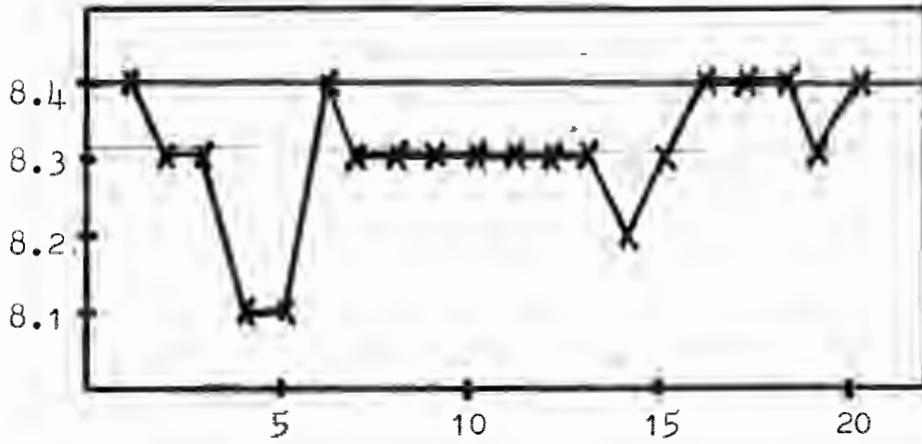
. FIGURE 3 (Alignment Relationship)

AQUAFLEX (SUPER-THIN)

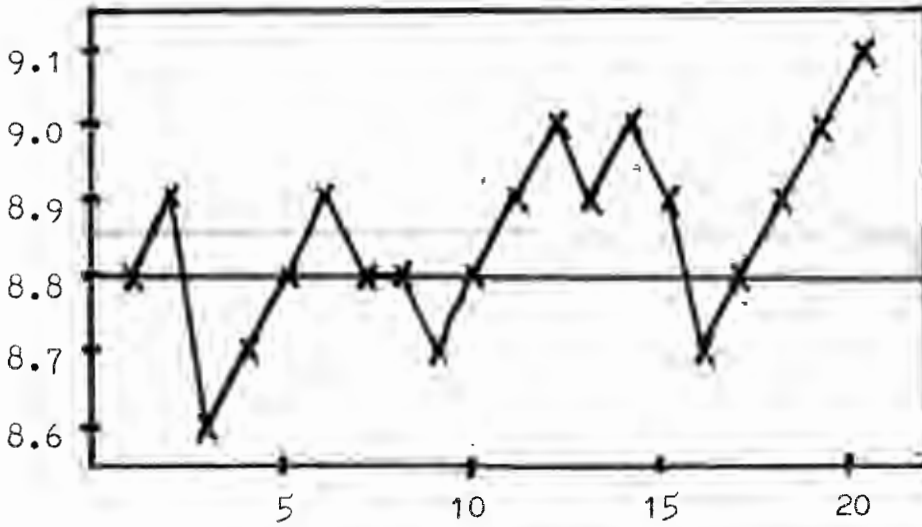
Lot #	1575-18	1664-13	1642-23
Diameter	13.8 mm	13.8 mm	13.8 mm
Power	-1.75 D	-2.50 D	-6.00 D
Base Curve	8.4 mm	8.8 mm	8.8 mm
1)	8.4	8.8	9.1
2)	8.3	8.9	9.2
3)	8.3	8.6	9.0
4)	8.1	8.7	9.2
5)	8.1	8.8	9.2
6)	8.4	8.9	9.2
7)	8.3	8.8	9.1
8)	8.3	8.8	9.1
9)	8.3	8.7	9.1
10)	8.3	8.8	9.1
11)	8.3	8.9	9.1
12)	8.3	9.0	9.3
13)	8.3	8.9	9.2
14)	8.2	9.0	9.2
15)	8.3	8.9	9.1
16)	8.4	8.7	9.1
17)	8.4	8.8	9.1
18)	8.4	8.9	9.2
19)	8.3	9.0	9.1
20)	8.4	9.1	9.1
MEAN	8.31	8.85	9.14
RANGE	(8.1-8.4)	(8.6-9.1)	(9.0-9.3)
STAND. DEV.	0.089	0.124	0.068

Aquaflex (Super-thin)

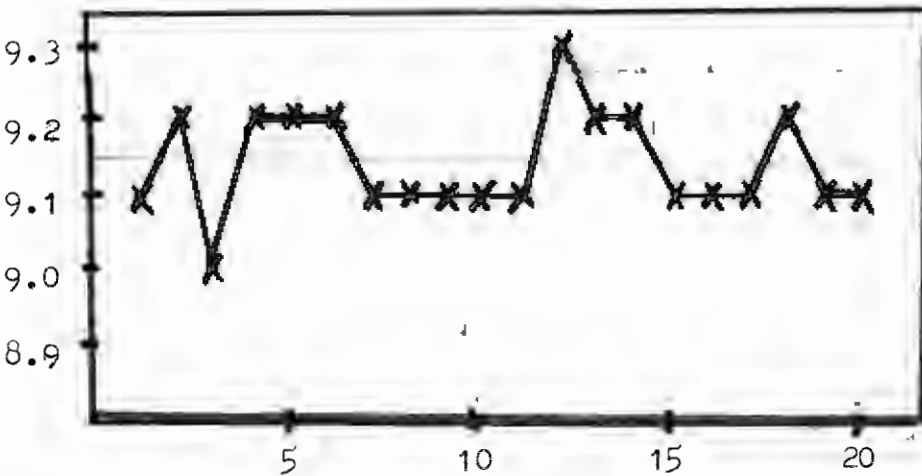
Base
Curve
Radius
(mm)





Base
Curve
Radius
(mm)



Base
Curve
Radius
(mm)



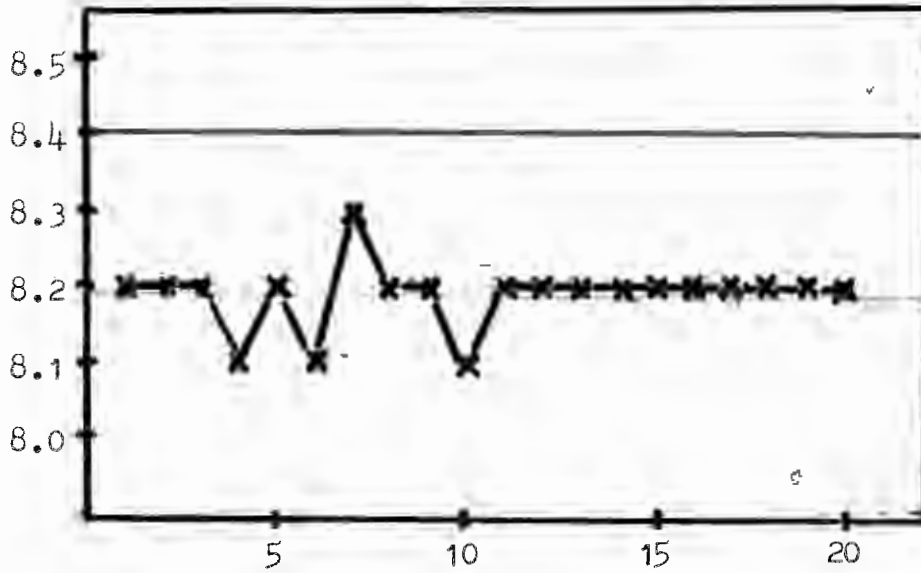
MEAN 
VIAL BC 

HYDRO-MARC (ULTRA-THIN SM SERIES)

Lot #	480092	38430469	30430441
Diameter	14.0 mm	14.0 mm	14.0 mm
Power	-1.25 D	-2.50 D	-4.00 D
Base Curve	8.4 mm	8.4 mm	8.4 mm
1)	8.2	8.4	8.2
2)	8.2	8.5	8.4
3)	8.2	8.8	8.3
4)	8.1	8.4	8.4
5)	8.2	8.5	8.4
6)	8.1	8.6	8.4
7)	8.3	8.5	8.4
8)	8.2	8.4	8.3
9)	8.2	8.6	8.4
10)	8.1	8.5	8.3
11)	8.2	8.4	8.4
12)	8.2	8.5	8.3
13)	8.2	8.4	8.5
14)	8.2	8.5	8.5
15)	8.2	8.5	8.4
16)	8.2	8.5	8.4
17)	8.2	8.5	8.4
18)	8.2	8.5	8.5
19)	8.2	8.4	8.5
20)	8.2	8.5	8.4
MEAN	8.19	8.50	8.39
RANGE	(8.1-8.3)	(8.4-8.8)	(8.2-8.5)
STAND.DEV.	0.045	0.095	0.079

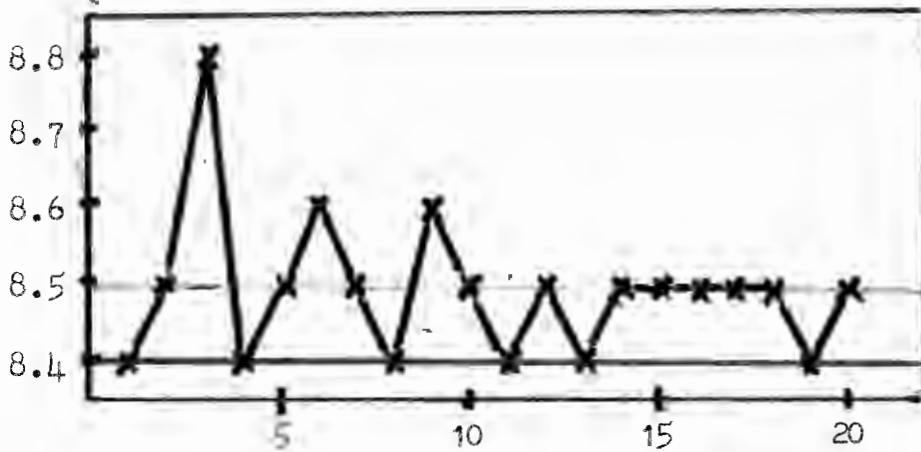
Hydro-Marc (Ultra-thin SM Series)

Base
Curve
Radius
(mm)



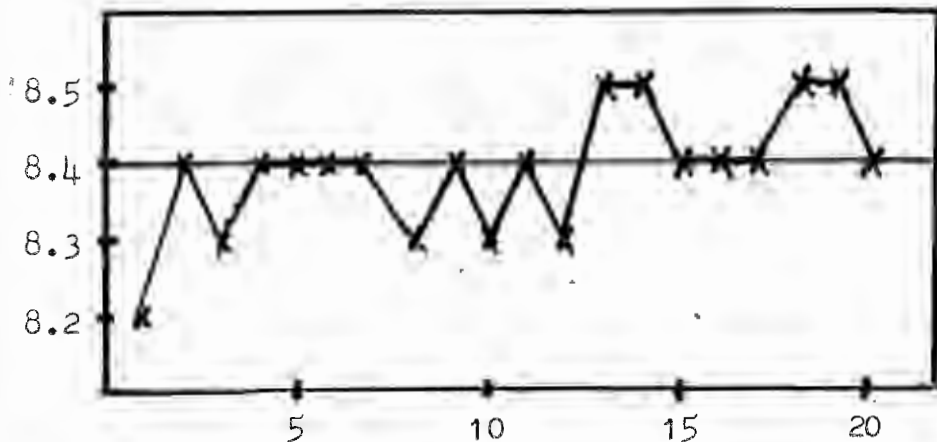
(-1.25 D)

Base
Curve
Radius
(mm)



(-2.50 D)

Base
Curve
Radius
(mm)



(-4.00 D)

MEAN

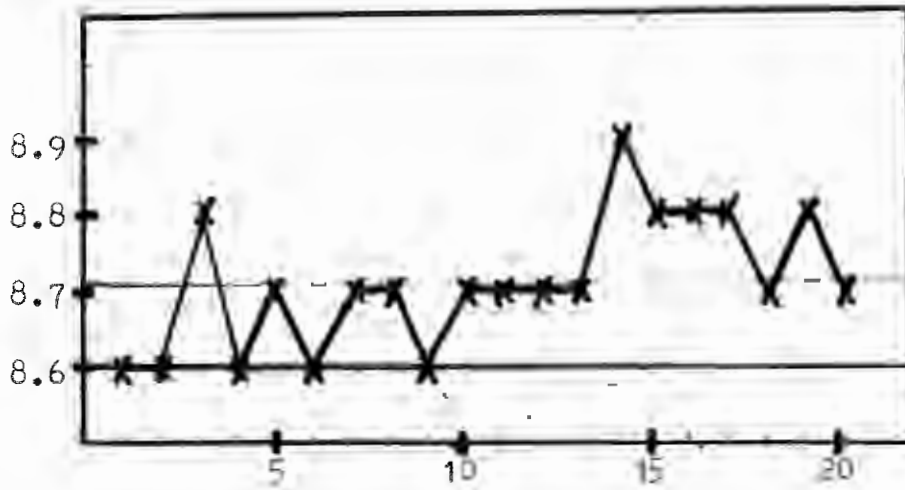
VIAL BC 

HYDROCURVE II (ULTRA-THIN)

lot #	IMWT-461	IODX-816	IOTT-55
Diameter	13.5 mm	13.5 mm	15.5 mm
Power	-0.75 D	-3.00 D	-6.00 D
Base Curve	8.6 mm	8.3 mm	9.5 mm
1)	8.6	8.5	9.5
2)	8.6	8.3	9.7
3)	8.8	8.2	9.4
4)	8.6	8.1	9.5
5)	8.7	8.3	9.4
6)	8.6	8.2	9.6
7)	8.7	8.3	9.5
8)	8.7	8.3	9.6
9)	8.6	8.4	9.6
10)	8.7	8.3	9.5
11)	8.7	8.3	9.7
12)	8.7	8.3	9.7
13)	8.7	8.3	9.7
14)	8.9	8.1	9.8
15)	8.8	8.2	9.7
16)	8.8	8.3	9.5
17)	8.8	8.4	9.7
18)	8.7	8.2	9.7
19)	8.8	8.2	9.7
20)	8.7	8.2	9.6
MEAN	8.71	8.27	9.61
RANGE	(8.6-8.9)	(8.1-8.5)	(9.4-9.8)
STAND.DEV.	0.085	0.098	0.115

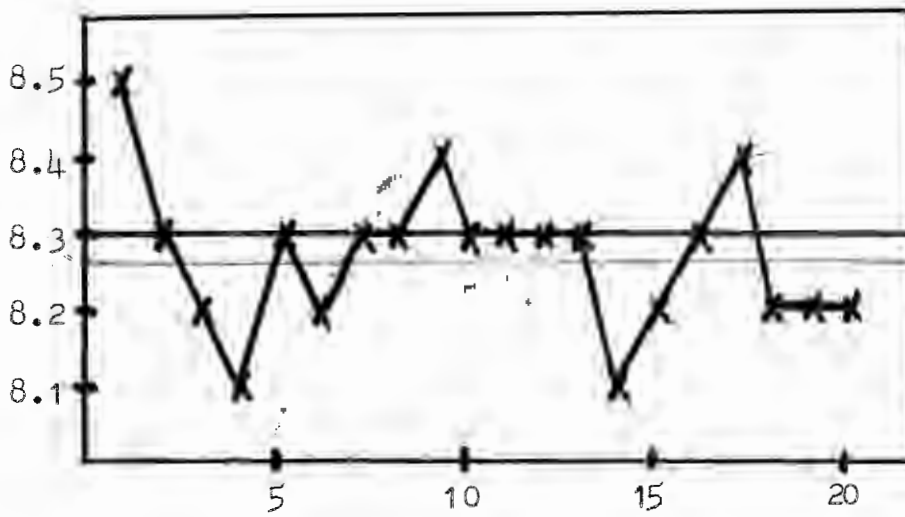
Hydrocurve II (Ultra-thin)

Base
Curve
Radius
(mm)



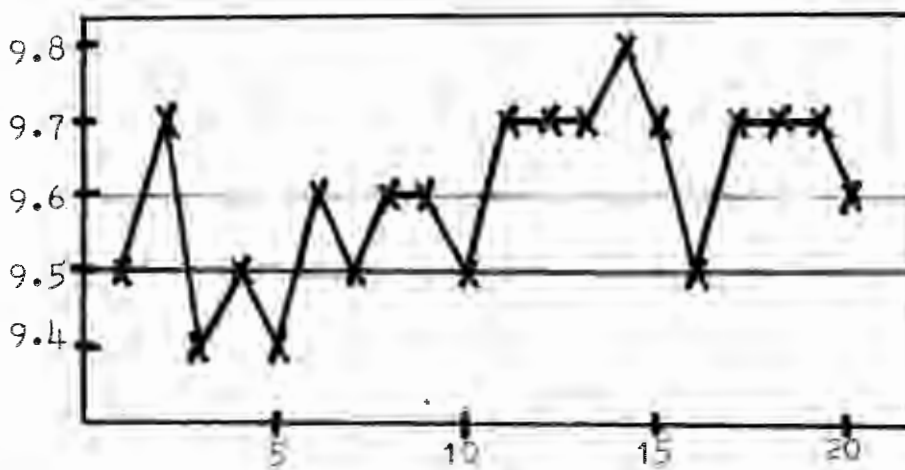
(-0.75 D)

Base
Curve
Radius
(mm)



(-3.00 D)

Base
Curve
Radius
(mm)



(-6.00 D)

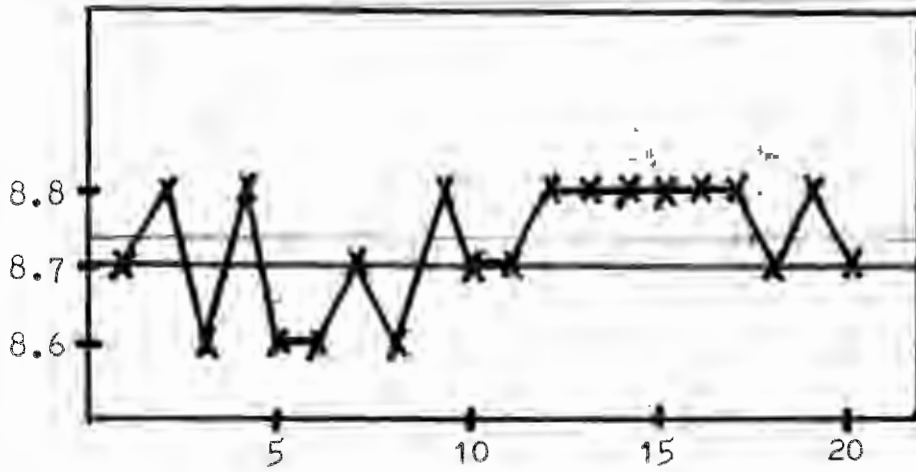
MEAN —
VIAL BC —

AMERICAN HYDRON .06 (ULTRA-THIN)

Lot #	A 100324	A 100266	A 100234
Diameter	14.0 mm	14.0 mm	14.0 mm
Power	-1.50 D	-3.00 D	-4.50 D
Base Curve	8.7 mm	9.0 mm	8.7 mm
1)	8.7	9.0	8.9
2)	8.8	8.9	8.8
3)	8.6	8.9	8.9
4)	8.8	9.2	9.2
5)	8.6	9.2	8.7
6)	8.6	9.3	9.1
7)	8.7	9.1	9.0
8)	8.6	9.1	9.1
9)	8.8	9.0	9.0
10)	8.7	9.1	8.8
11)	8.7	9.2	9.0
12)	8.8	9.4	9.0
13)	8.8	9.0	9.0
14)	8.8	9.0	8.9
15)	8.8	9.1	9.0
16)	8.8	9.2	8.9
17)	8.8	9.3	9.0
18)	8.7	9.4	9.0
19)	8.8	9.2	8.9
20)	8.7	9.2	9.0
MEAN	8.73	9.14	8.96
RANGE	(8.6-8.8)	(8.9-9.4)	(8.7-9.2)
STAND. DEV.	0.080	0.147	0.114

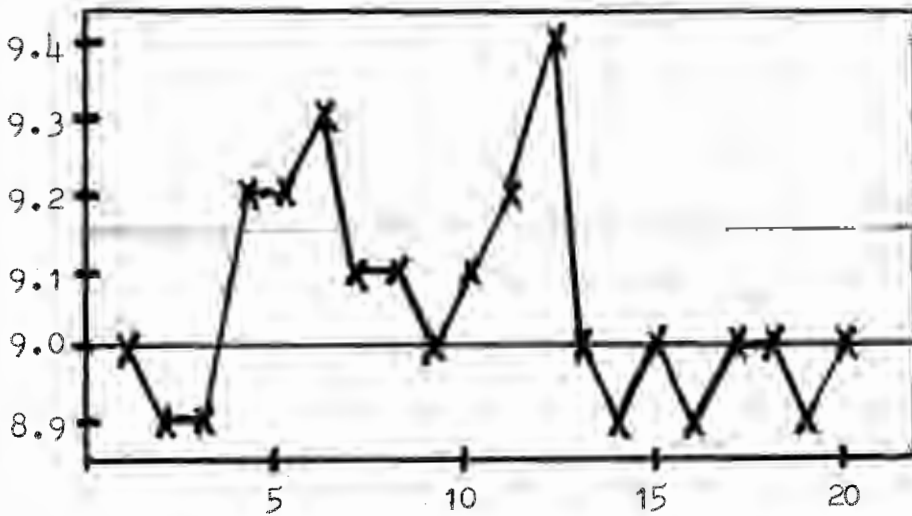
American Hydron .06 (Ultra-thin)

Base
Curve
Radius
(mm)



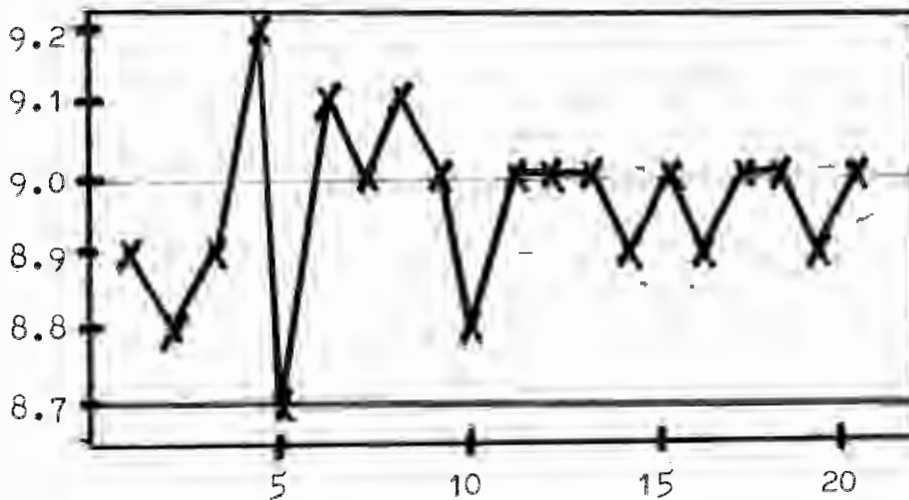
(-1.50 D)

Base
Curve
Radius
(mm)




(-3.00 D)

Base
Curve
Radius
(mm)



(-4.50 D)

MEAN 

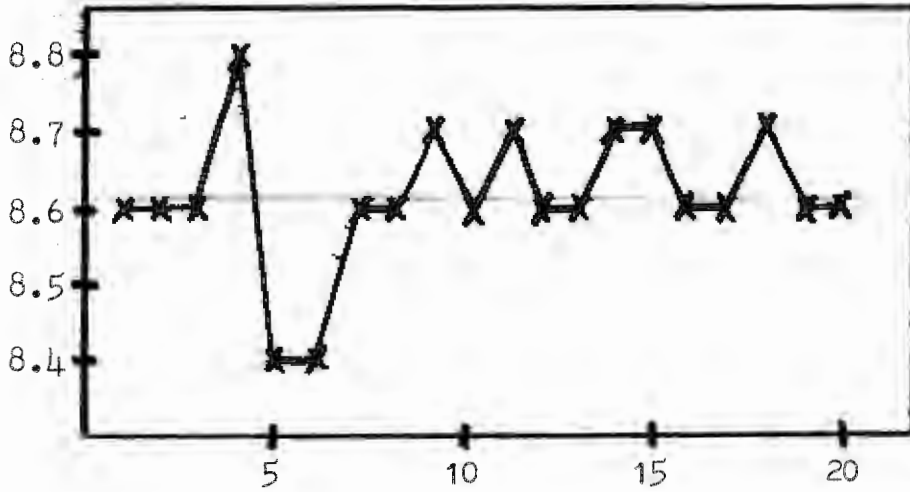
VIAL BC 

B & L (U4 SERIES)

Lot #	63855	56419	51067
Diameter	14.5 mm	14.5 mm	14.5 mm
Power	-1.00 D	-3.00 D	-7.00 D
Base Curve	Aspheric	Aspheric	Aspheric
1)	8.6	8.4	8.4
2)	8.6	8.6	8.3
3)	8.6	8.5	8.5
4)	8.8	8.6	8.5
5)	8.4	8.5	8.3
6)	8.4	8.6	8.4
7)	8.6	8.6	8.4
8)	8.6	8.5	8.4
9)	8.7	8.6	8.4
10)	8.6	8.6	8.5
11)	8.7	8.5	8.5
12)	8.6	8.5	8.5
13)	8.6	8.6	8.4
14)	8.7	8.6	8.5
15)	8.7	8.6	8.6
16)	8.6	8.5	8.5
17)	8.6	8.6	8.6
18)	8.7	8.5	8.4
19)	8.6	8.5	8.4
20)	8.6	8.6	8.5
MEAN	8.62	8.55	8.45
RANGE	(8.4-8.8)	(8.4-8.6)	(8.3-8.6)
STAND. DEV.	0.093	0.061	0.083

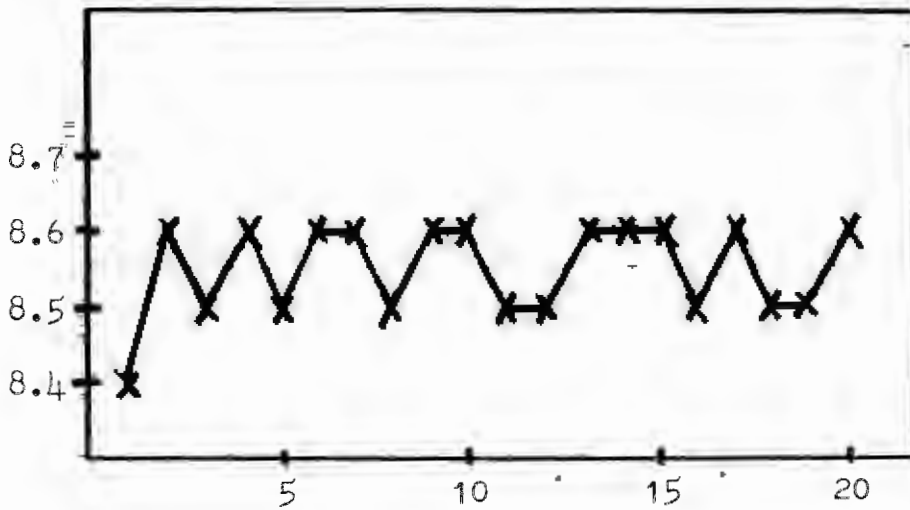
B & L (U4 Series)

Base
Curve
Radius
(mm)



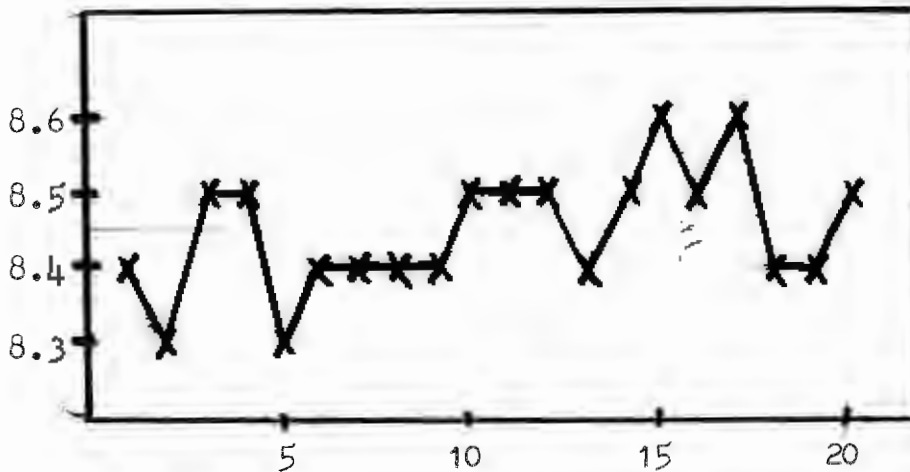
(-1.00 D)

Base
Curve
Radius
(mm)



(-3.00 D)

Base
Curve
Radius
(mm)



(-7.00 D)

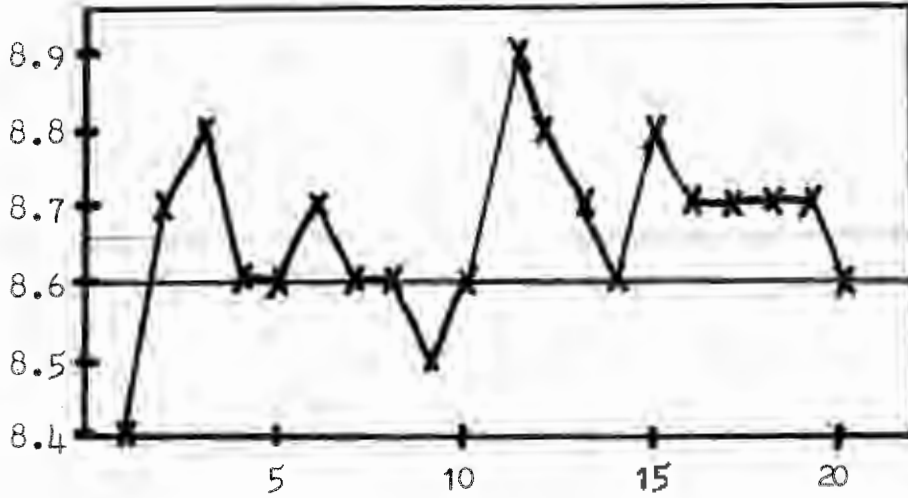
MEAN

AMERICAN OPTICAL (AO-THIN)

Lot #	1912P039	2301P020	0802P030
Diameter	13.8 mm	13.8 mm	13.8 mm
Power	-0.75 D	-2.25 D	-4.00 D
Base Curve	8.6 mm	9.0 mm	8.3 mm
1)	8.4	8.6	8.3
2)	8.7	8.5	8.3
3)	8.8	8.7	8.3
4)	8.6	8.6	8.3
5)	8.6	8.6	8.4
6)	8.7	8.6	8.2
7)	8.6	8.8	8.3
8)	8.6	8.6	8.3
9)	8.5	8.6	8.3
10)	8.6	8.7	8.3
11)	8.9	8.7	8.2
12)	8.8	8.8	8.3
13)	8.7	8.8	8.4
14)	8.6	8.7	8.2
15)	8.8	8.7	8.3
16)	8.7	8.7	8.1
17)	8.7	8.7	8.2
18)	8.7	8.7	8.4
19)	8.7	8.7	8.4
20)	8.6	8.7	8.3
MEAN	8.67	8.68	8.29
RANGE	(8.4-8.9)	(8.5-8.8)	(8.1-8.4)
STAND.DEV.	0.114	0.079	0.079

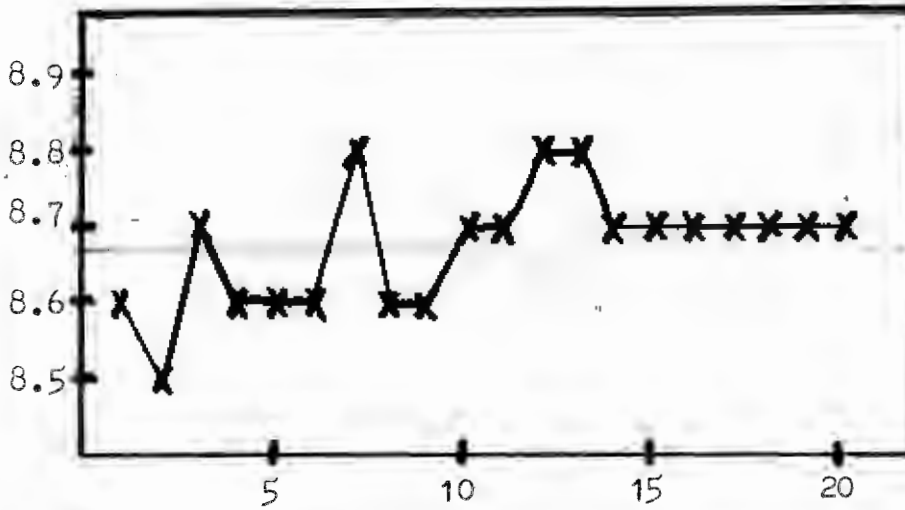
American Optical (AO-Thin)

Base
Curve
Radius
(mm)



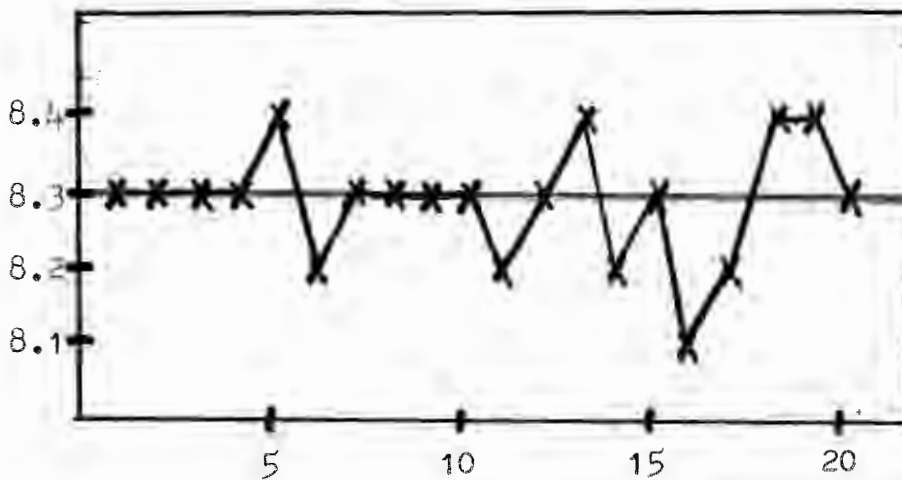
(-0.75 D)

Base
Curve
Radius
(mm)



(-2.25 D)

Base
Curve
Radius
(mm)



(-4.00 D)



MEAN 
VIAL BC 

FIGURE 4

	<u>Stand.Dev.</u>	<u>Mean</u>	<u>Stated Base Curve</u>	<u>Mean-Base Curve</u>
<u>Aquaflex</u>				
-1.75 D	0.089	8.31	8.4	-.09
-2.50 D	0.124	8.85	8.8	+.05
-6.00 D	<u>0.068</u>	9.14	8.8	<u>+.34</u>
	(Avg.) 0.094			(Avg.) .16
<u>Hydro-Marc</u>				
-1.25 D	0.045	8.19	8.4	-.21
-2.50 D	0.095	8.50	8.4	+.10
-4.00 D	<u>0.079</u>	8.39	8.4	<u>-.01</u>
	(Avg.) 0.073			(Avg.) .11
<u>Hydrocurve II</u>				
-0.75 D	0.085	8.71	8.6	+.11
-3.00 D	0.098	8.27	8.3	-.03
-6.00 D	<u>0.115</u>	9.61	9.5	<u>+.11</u>
	(Avg.) 0.099			(Avg.) .08
<u>American Hydron</u>				
-1.50 D	0.080	8.73	8.7	+.03
-3.00 D	0.147	9.14	9.0	+.14
-4.50 D	<u>0.114</u>	8.96	8.7	<u>+.26</u>
	(Avg.) 0.114			(Avg.) .14
<u>B & L (U4)</u>				
-1.00 D	0.093	8.62	?	?
-3.00 D	0.061	8.55	?	?
-7.00 D	<u>0.083</u>	8.45	?	?
	(Avg.) 0.079			
<u>A0-Thin</u>				
-0.75 D	0.114	8.67	8.6	+.07
-2.25 D	0.079	8.68	9.0	-.32
-4.00 D	<u>0.079</u>	8.29	8.3	<u>-.01</u>
	(Avg.) 0.091			(Avg.) .13

DISCUSSION

Prior to discussing the significance of our data, I feel it is important to review some basic concepts concerning the normal (Gaussian) distribution as it relates to statistical analysis. All too often researchers collect data points and plug them into a calculator to arrive at a value called the standard deviation. They then use this value to make very profound statements about individual components of their data (exp. "Item X is 2.0 standard deviations from the mean. The probability of this occurring by chance is less than 5%, therefore item X is deviant"). At first glance this appears to be a valid sequence in logic. One must remember, however, that the whole concept of standard deviation relies on the premise that the population it describes is indeed Gaussian in shape. In reality most items that are put to this type of analysis do not meet this criteria, including the data we have collected.

This is not to say that use of the standard deviation in such instances is a total waste of time. On the contrary, meaningful insight can still be gained as long as one does understand his/her limitations. In a non-normal distribution the mean \pm 1.0 standard deviation no longer contains 2/3 rds of the data points. With this acknowledgement of

our statistical limitations we now proceed with our analysis of data.

As stated earlier, one of the goals of this study was to compare the various manufacturers against one another in their ability to provide reproducible data on the Soft Lens Analyzer. One might expect that differences in lens material, process of fabrication (lathe cut vs spin cast), or H₂O content may affect this instruments ability to make measurements of base curve. The data, however, does not seem to express a significant difference in this respect. In taking averages of standard deviations it is seen that variance differs little from one brand to another. (See Figure 4) Values range from 0.073 (Hydro-Marc) to 0.114 (American Hydron). As clinicians we should thus feel equally comfortable using this instrument on a wide variety of thin lens designs.

If we compare standard deviations among the various power categories we see that this variable likewise has no significant affect on variance. Tight and loose data were noted in all power ranges.

Let us now see if this instrument is capable of giving us clinically meaningful data. If we assume that a 0.3 mm change in base curve may elicit a significant change in lens performance,¹² then any instrument we use to measure this variable should have at least this amount of sensitivity. In looking at the data we see that the largest single deviation from the mean in all 360 measurements was just that, 0.3 mm. The vast majority of base curve estimates were actually within 0.15 mm from the mean. Therefore, if a clinician were to make a single measurement he could be fairly confident that the value he receives is within the equal performance range of the true base curve of that lens.

We will now compare mean value of base curve measurements to that which is stated on the manufacturer's vial. (See Fig. 4 "Mean-Base Curve") It is seen that the average level of "error" is basically the same from one manufacturer to the next. Closer inspection reveals, however, that in two cases (Aquaflex -6.00 & AO-Thin -2.25) this discrepancy was in excess of 0.3 mm. Even though the nature of soft thin lenses allows us a great deal of play in variations of posterior surface radius, unwanted error of this magnitude may have a significant impact on performance. We do not

wish to imply that the companies mentioned are negligent in their quality control. The limited number of lenses used per manufacturer prohibits us from making any such inferences. It does point out that what the vial says is not necessarily what one gets, demonstrating a need for a tool that the clinician can use to monitor his own fitting variables.

Although this instrument has proven to give repeatable data, there are certain aspects of its clinical use that may affect measurements. The following factors arose which we feel may have influenced the data collected:

1. The ultra-thin soft lens has a tendency to slide off to one side of the template during measurements. This is especially noticeable with smaller overall diameter lenses and interferes with the ease of base curve determinations. Larger diameter lenses tend to drape over the template and stabilize more easily.
2. Higher power lenses by virtue of their construction (thin center, thicker periphery)

Can make measurements more difficult. Even when in an alignment relationship these lenses appear flat relative to the template. Very careful scrutiny is necessary to ensure a true alignment condition exists.

3. Ultra-thin lenses also seemed to have a tendency to conform to the template curvature when close to the actual base curve. The base curve while on the template may be different from its original state in a free floating solution.

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