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A procedure for hydrogel contact lens base curve verification

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Abstract

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A PROCEDURE FOR HYDROGEL CONTACT LENS BASE CURVE VERIFICATION

A PROCEDURE FOR HYDROGEL CONTACT LENS BASE CURVE VERIFICATION

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Preliminary (literature review and methodology)

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Introduction

Successful contact lens fitting depends to a great extent on the practicioner's ability to accurately determine the specifications of the lens, initially as a means of confirming the manufacturer's ability to produce the requested design and secondly as a means of carefully monitoring the lens changes induced as the practicioner makes various modifications to achieve the desired fit. As hydrogel lenses continue to increase in popularity and the fitter finds himself deprived of the customary modification procedures with these lenses, it becomes more important to deliver a properly fit lens at the initial dispensing. Even a carefully conducted diagnostic fitting can lead to frustration for both patient and practicioner when apparently identical prescription lenses arrive and fail to perform as expected.

The single most troublesome measurement which prevents the fitter from accurately describing the indicated trial lens, as well as verifying its alleged "twin" on delivery, is the base curve determination. Although a wide variety of measurement devices has been proposed, none have enjoyed widespread acceptance or come into common use, even though the need for an accurate measurement means can be clearly demonstrated. In addition to the previously mentioned direct benefits to diagnostic fitting, accurate base curve determination can aid us in 1) identification of stock or inventory lenses which become mixed up in handling or lose identifying labels; 2) determination of the specifications of an individual's present lenses when records are not available, to prepare for eventual loss or damage requiring replacement; 3) determining the lens changes that result from aging, heat sterilization, exposure to cleaning, preserving, and disinfecting solutions, and dehydration/rehydration cycling, and 4) demonstrating how the base curve varies as a function of lens diameter, thickness, and power so that manufacturers can more accurately predict the final lens dimensions in the hydrated state.

History

A number of methods of soft lens base curve measurement have been described in the literature, and they are found to vary widely in both complexity and degree of accuracy. Harris, et al [1] first employed templates, a series of plastic rods machined on one end to a curvature varying from 8.0

to 9.2 mm. The technique involves dropping a wetted lens onto each of the templates in turn until an alignment fit is found. Initially the series of templates provided 0.1 mm steps in radius, but is was found that differences in base curve of less than 0.3 mm could not be distinguished. The ± 0.3 mm reliability range is most likely a result of gravitational and capillary forces acting on the unstable lens in air.

The ICOR Radius Tool[2] is a second approach to measuring the base curve in air, and is designed to be attached to the keratometer forehead rest support. Surface tension is relied upon to hold the convex lens surface against the end of a hollow plastic tube, presenting the concave surface of the lens to the projection end of the keratometer. The power measurement is made using the keratometer in its usual fashion, and a conversion table is provided to convert the measurement to radius in millimeters. Although this method is the most economical and convenient of those surveyed, the irregular surface dehydration significantly upsets the quality of the lens as a reflecting surface. An accuracy of "roughly one diopter" (approximately 0.2 mm) is claimed, although experience seems to indicate that a tolerance claim of ± 0.4 mm is more in order.

Koetting[3] discusses the use of the radiuscope for measuring base curve while the soft lens is immersed in a saline bath with the concave side up. Measurement is conducted in the normal manner and the indicated radius multiplied by 1.336 to correct for the air/saline index difference. What would appear to be a straightforward technique is complicated by many shortcomings, including lens drift in the saline, surface movement of the saline disturbing optics, and a tremendous loss in percentage of reflected light. Koetting claims that efficiency is so low, even with increased illumination, that measurements of any kind are all but impossible.

Wray[4] proposed a similar use of the radiuscope that avoids the illumination problem by floating the lens on the surface of the saline pool with concave side up. Assuming that the lens hydrates normally in this position, and that the quality of the reflecting surface is not disturbed by irregular wetting or pooling, the base curve measurement would proceed as with a rigid lens.

Total saline immersion techniques seem to offer the greatest hope for accurate, repeatable base curve measurement. The Sohnges projection system[5] employs a saline cell in which the soft lens is placed convex side up. A high luminosity halogen lamp projects a highly magnified profile view of the immersed lens onto a screen where the lens curve is matched to one of a series of arcs of known radius. Loran[6] tested the Sohnges system extensively and concluded that a reliability of ± 0.1 mm could be expected. An additional benefit of this system is that accessory screens and lens supports also allow one to measure lens diameter, thickness, periphery detail, and inspect for surface quality.

Another saline immersion system, designed by Sagan[7], utilizes the lens base curve as a spherical mirror which brings to a focus an incident light beam from a coherent source. By linking the focusing mechanism with a measuring dial, a reading that can be related to the radius in millimeters is achieved. Sagan measured a series of rigid lenses both with his device and with a radiuscope, and found that his measurements were reliable to within ± 0.1mm.

This survey of present and proposed methods of soft lens base curve measurement is not intended to be comprehensive, but rather to illustrate that the profession has yet to adopt a common direction in the matter of base curve verification. While certain independent investigators have demonstrated the capability of measuring base curve with an accuracy of ± 0.1 mm, there appears to be little cooperative effort between manufacturers and practicioners toward adoption of a standardized lens verification scheme.

Method

The measurement system to be presented here, designed as an attachment to the Bausch & Lomb keratometer, was apparently first used by Chaston[8] in a similar form, although the methods were developed independently and took different physical forms. Adapting the keratometer to this kind of purpose is advantageous because it is a widely used instrument and perhaps offers the best prospect for a standardized measuring system. A saline cell is employed for its clear advantage in the areas of lens support free of distortion, uniform hydration, and maintenance of a smooth reflecting surface.

In its present form, the device consists of two pieces, a 45 degree first surface mirror positioned so as to deflect the mires pattern vertically, and a small saline vessel with a flat glass bottom which can be quickly clipped into place on the headrest supports of the keratometer. Figure 1 illustrates how the mires pattern is delivered to the concave lens surface, and also depicts the return path of the reflected image. The mirror assembly is mounted directly to and moves with the keratometer body, while the lens holder remains fixed as earlier described. This arrangement allows one to use the keratometer controls for position and

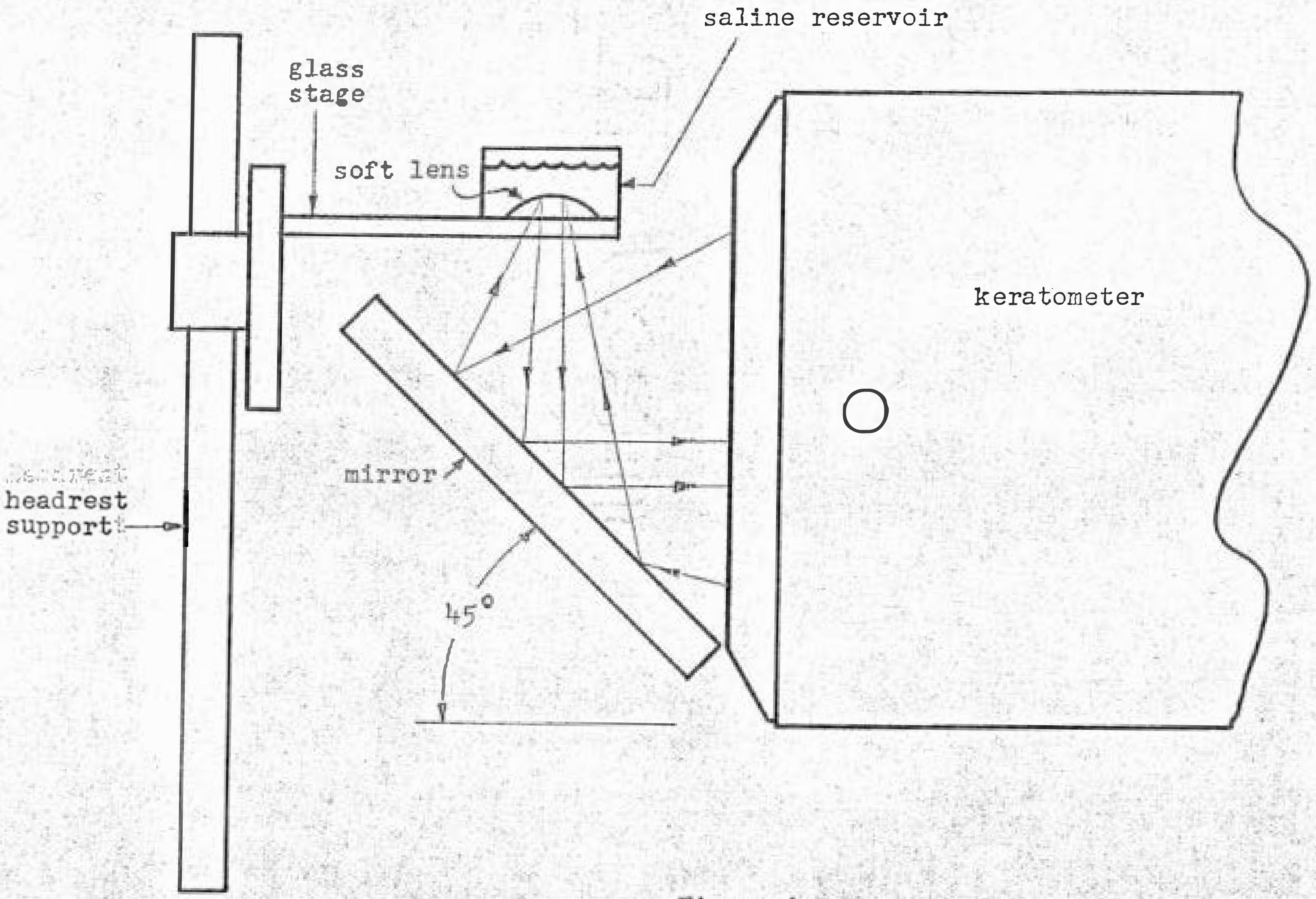

saline reservoir
glass stage
soft lens
keratometer
mirror
headrest support
45°

Figure 1

8

focus without disturbing the critical mirror position in front of the keratometer.

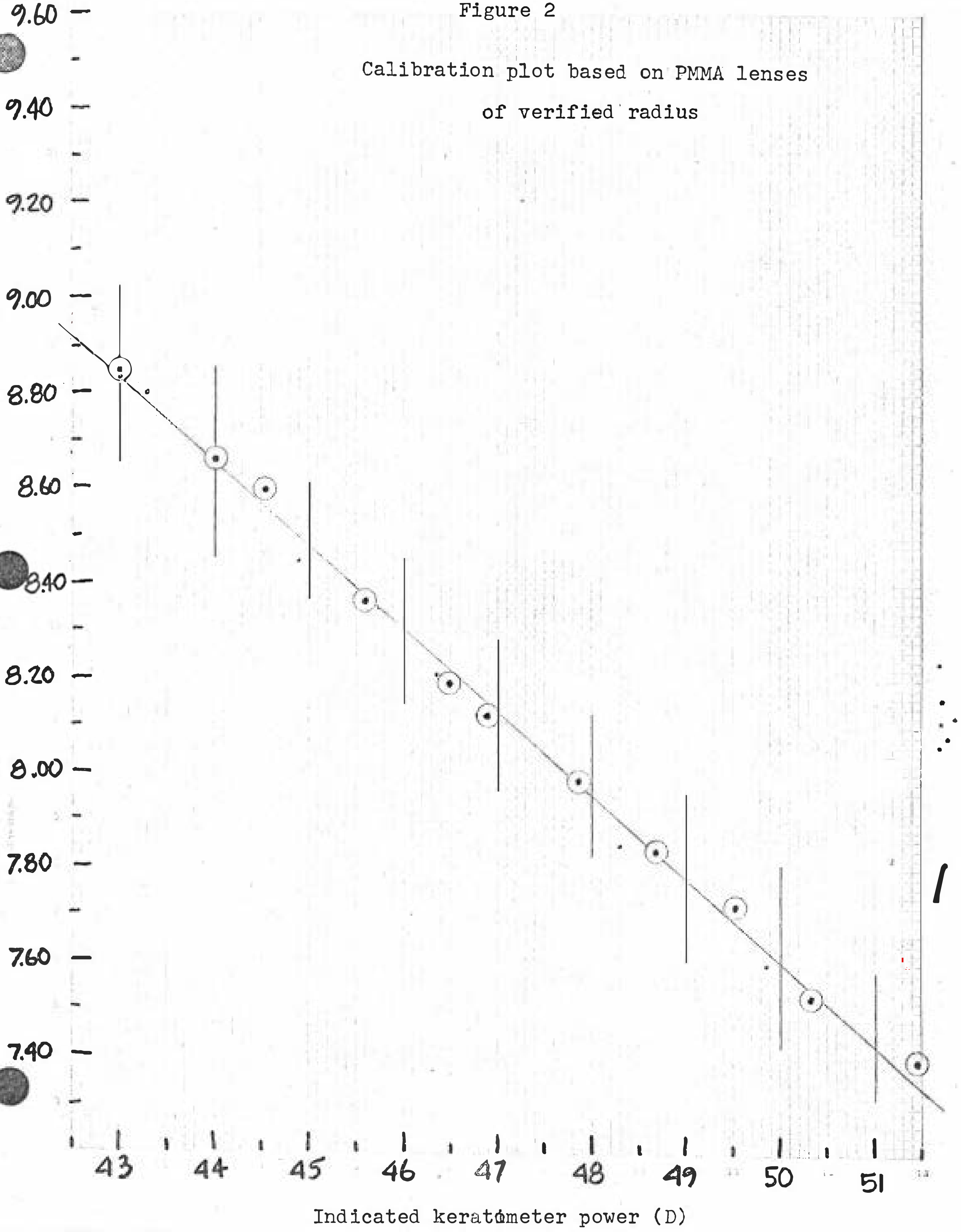
Because the lens is now surrounded by a medium other than air, the instrument must be recalibrated by measuring a series of known, rigid concave surfaces under identical conditions of saline immersion. In addition, it is found that a + 1.50 D lens must be fitted to the keratometer aperture in the manner of a range extender lens. With this lens in place, the instrument can be calibrated to measure concave surfaces (in saline) ranging from 7.40 mm to 10.0 mm in radius.

Calibration for this study was accomplished using 12 PMMA contact lenses whose posterior radii had been verified with both Neitz and American Optical radiuscopes. Exposure time to the saline bath was so brief that hydration effects on base curve were insignificant. The resultant calibration graph, plotting indicated keratometer power in diopters against known radius of curvature is shown as Figure 2.

In theory, one should now be able to immerse a hydrogel lens in the saline cell, make a measurement in two meridians in the usual fashion, and determine base curve radius from the calibration plot. In practice, however, one finds that the mires images are so faint as to be barely readable at best, even with ambient lighting fully dimmed. The explanation lies in the Fresnel formula, which expresses the fraction of incident light reflected from a surface as

Figure 2

Calibration plot based on PMMA lenses of verified radius



$\frac{n-n'}{n+n'}$, where n and n' represent the indices of the reflecting surface and its surround. For the human cornea (n=1.3375) in air, the formula predicts that 2.1% of the incident light will be reflected. When a PMMA lens (n=1.49) is immersed in saline, the light return drops to 0.3% and the mires image is only faintly visible. Calculations for a hydrogel lens (n=1.43) in saline (n=1.336) indicate that only 0.1% of the incident light is returned to be viewed by the operator. This amounts to a 95% loss of the light normally available in human eye keratometry and explains why the light output of the instrument needs to be boosted if one is to successfully measure soft lenses in solution.

For use in a darkened room, we find that simply operating the keratometer lamp above its rated voltage sufficiently increases light output without seriously shortening lamp life. A 0-140 volt Powerstat variable step-up transformer, operated at its peak output works very well and allows a gradual increase to maximum voltage, thus extending lamp life.

Other more effective improvements can be made if one wishes to be able to make measurements in normal room light, but these will require modification of the lamp housing to accept a socket for a high output bulb. Roth[9] has suggested construction of a separate high output lamp assembly which would install on the keratometer in place of the stock item. Any high wattage installations must of course be carefully monitored to insure that excessive heat does not damage the instrument or affect its accuracy. It may be necessary to include a cooling fan in any redesign of the lamp housing, or, as Roth suggests, merely rotate the keratometer 180 degrees about its long axis, thereby locating the bulb on the top side of the instrument so that the excess heat can rise harmlessly.

Results and Discussion

The second phase of this project involved the direct application of the device previously described to clinical situations surrounding soft lens fitting. The bulk of the clinical investigation was directed to the following three areas:

a) Verification of the base curves of certain soft lenses maintained in the clinic as diagnostic sets or fitting sets.

b) Verification of the base curves of lenses as received from the manufacturer for dispensing to patients.

c) Demonstration of this system's ability to successfully identify unknown B & L Soflenses by series and power, based on measurement of the anterior and posterior radii of curvature.

Part (a) above involved base curve measurements on three separate sets of Durasoft trial lenses supplied to the clinic by Wesley-Jessen Inc. Table 1 shows the resulting data and indicates how the lenses of the minus lens trial fitting set were reorganized into a sequence of decreasing saggital depth. Table 2 shows similar data in the same format for the Durasoft prism ballast, truncated, minus lens trial set. Table 3 presents similar data for the Durasoft plus lens trial set and includes in addition a column indicating the base curves as remeasured approximately three weeks later. All measurements repeated within the range +.05 mm / -.04 mm, with the average departure only ±.02 mm from the original reading. These data supply convincing evidence of the repeatability of the system.

In part (b) I investigated one manufacturer's ability to demonstrate consistency in the production of lathe cut soft lenses. Of particular interest here was the <u>accuracy</u> of the bottle marking as well as the <u>range of variation</u> distributed about the mean base curve. Durasoft lens

Durasoft Minus Lens Trial Set

Lens No	Serial No.	Pwr.	Diam.	Marked B.C.	Verified B.C.
1	19450S-6072	-2.62	12.8	7.8	7.92
2	510251-5241	-2.87	12.8	7.8	7.92
3	26614-5288	-2.50	12.8	8.0	8.10
4	12933D-5269	-3.00	12.8	8.0	8.10
5	12933S-5269	-2.75	12.8	8.0	8.14
6	10201S-5269	-3.00	12.8	8.2	8.18
7	30771S-5290	-2.12	12.8	8.2	8.34
8	510272-5213	-4.37	12.8	8.4	8.44
9	7094S-5125	-1.00	12.8	8.4	8.58
10	69-5995	-4.75	12.8	8.6	8.63
11	12841S-5206	-3.37	12.8	8.6	8.75

Table 1

Durasoft Prism Ballast Minus Lens Trial Set

Lens No.	Serial No.	Pwr.	Diam.	Marked B.C.	Verified B.C.
1	18845D-6051	-3.00	12.8	8.0	7.80
2	21507D-6051	-3.00	12.8	7.8	7.84
3	18844D-6037	-3.00	12.8	7.8	7.86
4	18845S-6072	-3.00	12.8	8.4	7.92
5	21506-D	-3.00	12.8	8.0	8.00
6	21507S-6079	-3.00	12.8	8.0	8.04
7	21506-S	-3.00	12.8	8.4	8.30
8	18844S-6072	-3.00	12.8	8.6	8.46
9	18841D-6037	-3.00	12.8	8.2	8.46
10	18841S-6051	-3.00	12.8	8.2	8.51

* all lenses with 1pd BD and 1mm truncation

Table 2

Durasoft Plus Lens Trial Set

Lens No.	Serial No.	Pwr.	Diam.	Marked B.C.	Verified 12/9/76	Verified 12/28/76
1	611-51506	+3.25	12.8	7.8	7.78	7.82
2	611-48853	+3.25	12.8	7.8	8.11	8.12
3	611-50905	+3.25	12.8	8.0	8.20	8.23
4	611-50923	+2.75	12.8	8.0	7.97	7.98
5	611-51290	+3.00	12.8	8.2	8.26	8.26
6	611-51277	+3.00	12.8	8.2	8.35	8.30
7	611-50126	+3.00	12.8	8.4	8.67	8.65
8	611-50148	+3.25	12.8	8.4	8.44	8.40
9	611-51943	+2.75	12.8	8.6	8.83	8.83
10	611-51940	+2.75	12.8	8.6	8.79	8.78

Table 3

deliveries were monitored over a period of three months, and wherever possible, the base curves were verified before the lenses were dispensed to the patient. Table 4 lists the specifications of 85 lenses received and verified during the monitoring period. Figure 3 plots the marked base curve against the verified base curve and demonstrates the tendency of the Durasoft process to generally produce a flatter than desired base curve as well as a wide range of variability within each base curve group. The most marked central tendencies were demonstrated by the 8.6mm lenses, which most often measured about 8.8mm, and by the 8.2mm lenses, which tended to measure at about 8.5mm. The fact that most groups demonstrated a .4mm to .5mm range in base curve suggests that one should actually measure base curves individually rather than apply a fixed correction factor. A best fit line through the mean radius point in each lens group (indicated by the open circles in Figure 3) shows that this sample of lenses on the average measured .15mm flatter than labeled.

Part (c) of this project attempts to demonstrate that one can use these methods to determine the series of an unknown Bausch & Lomb Soflens. Since B & L publishes tables listing the anterior (mold) and posterior curves of its Soflenses, and since these vary significantly from series to series, any method of base curve measure accurate to

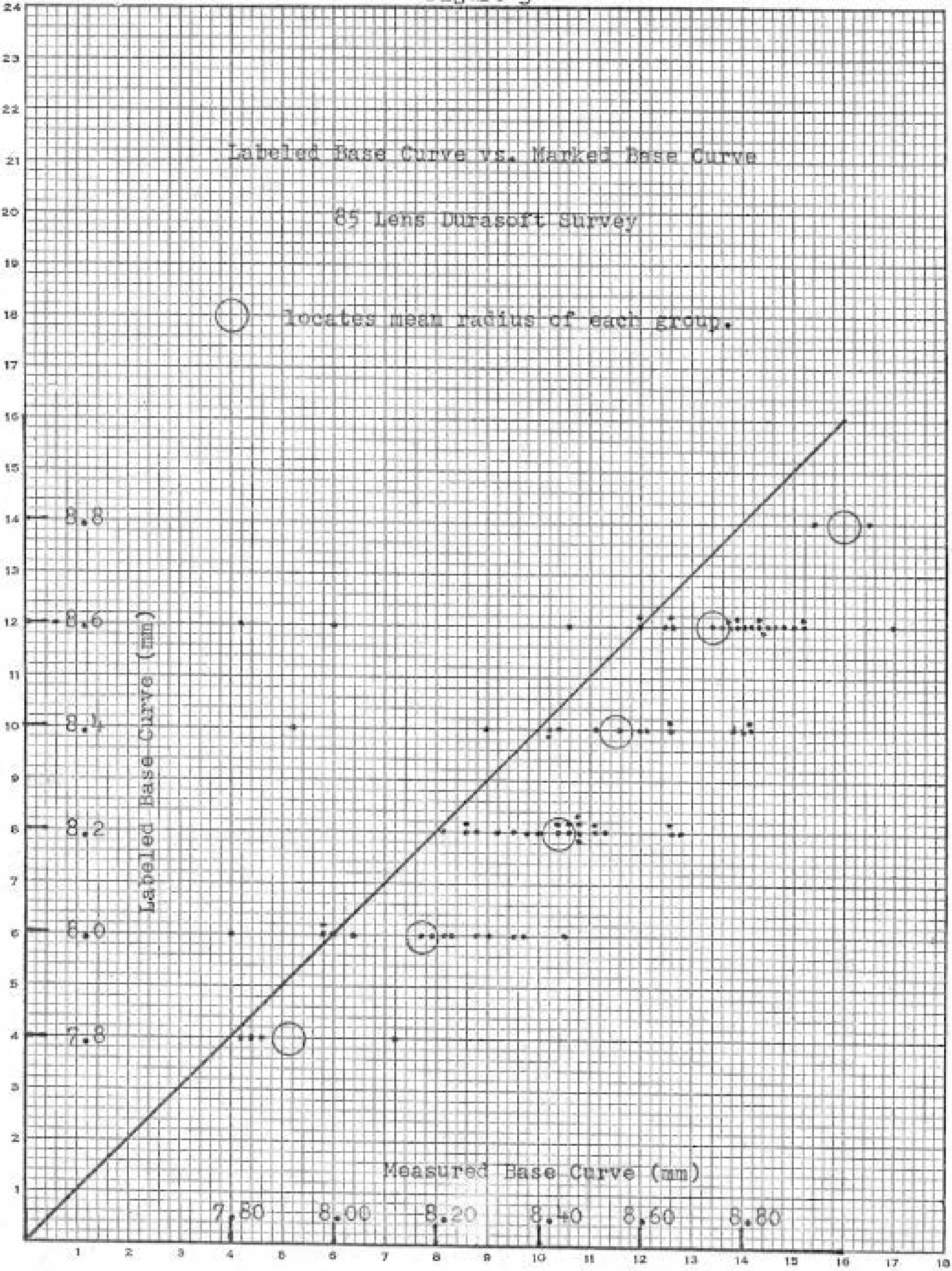
Date	S/N	Marked Base & Pwr	Measured B.C.	
10/29		8.2	8.51	
11/2		8.6/-1.12	8.92	
		8.6/-1.50	7.46	distorted
11/8	610-34494	8.6/-1.50	8.60	
	610-34495	8.6/-1.50	9.10	
11/16	610-36420	8.6/-1.12	8.85	
	611-42543	8.6/-1.50	8.79	
	611-44136	8.2/-7.00	8.44	
	611-44137	8.2/-8.00+1.25x60	8.48	
	611-44687	8.6/-3.00	8.79	
	67-5918	8.6/-2.25	7.82	
	18844D-6037	7.8/-3.00	7.86	
	21507D-6051	7.8/-3.00	7.84	
	18841S-6051	8.2/-3.00	8.51	
	21506-D	8.0/-3.00	8.00	
	18841D-6037	8.2/-3.00	8.46	
	18845S-6072	8.4/-3.00	7.92	
	21507S-6079	8.0/-300	8.04	
	18844S-6072	8.6/-3.00	8.46	
	18845D-6051	8.0/-3.00	7.80	
	21506-S	8.4/-3.00	8.30	
	69-23022	8.4/-4.25+1.50x45	8.80	
12/28	611-51506	7.8/+3.25	7.82	
	611-50905	8.0/+3.25	8.23	
	611-51277	8.2/*3.00	8.32	
	611-50126	8.4/+3.00	8.66	
	611-51940	8.6/+2.75	8.78	
	611-48853	7.8/+3.25	8.12	
	611-50923	8.0/+2.75	7.98	
	611-51290	8.2/+3.00	8.26	
	611-50148	8.4/+3.25	8.42	
	611-51943	8.6/+2.75	8.83	
12/9	611-48614	8.6/-1.25	8.86	
	611-52501	8.6/-1.50	8.74	
	611-51269	8.4/-2.00	8.66	
	611-50507	8.0/-2.00	8.35	
12/13	612-56923	8.2/-.50+.75x177	8.68	
		8.0/-1.25+1.50x105	8.37	
		8.0/-2.25+1.00x75	8.30	
		8.2/-.50+1.00x160	8.66	
		8.8/-3.00	9.05	
11/30	611-47360	8.6/*10.0	8.78	
	611-47359	8.6/+10.0	8.80	
	611-49135	8.4/-3.50+.50x80	8.81	
	67-2919	8.6/-3.75	8.00	distorted
	611-49136	8.4/-3.75+1.00x90	8.61	
	611-49067	8.6/-3,50	8.66	
	611-50156	8.6/-2.25	8.77	
	611-49616	8.6/-3.00	8.65	

Table 4

Date	S/N	Marked Base & Pwr.	Measured B.C.
	611-45665	8.6/-3.00	8.76
	611-50311	8.6/-2.25	8.81
12/29	611-44872	8.2/-10.50	8.44
	611-42714	8.2/-10.50	8.66
	612-65424	8.2/-1.50	8.35
	612-65425	8.2/-1.50	8.48
	611-50167	8.8/-1.50	8.94
	612-63302	8.4/-4.00+3.00x180	8.56
	612-63301	8.4/-3.50+2.75x175	8.51
	612-65013	8.6/-8.00+1.25x60	8.83
	612-65012	8.6/-8.00+1.00x93	8.84
	612-61136	8.2/-3.75+1.00x174	8.48
	612-61135	8.2/-4.00+1.00x178	8.53
	612-64367	8.0/-7.25+2.25x93	8.45
	612-64387	8.2/+9.50	8.46
	612-64366	8.0/-8.00+2.00x90	8.28
	612-64386	8.4/+9.50	8.44
1/3	612-67661	8.4/+14.00	8.78
	612-67662	8.4/+14.00	8.81
	612-67607	8.2/-4.75+1.25x180	8.48
	612-67608	8.2/-4.00+1.00x180	8.28
	612-66599	8.6/-2.50	8.90
	612-66598	8.6/-2.75	8.92
1/17	7-7423	8.4/+14.00	8.60
	7-7422	8.4/*14.00	8.42
	7-7601	8.0/-10.50	7.98
	7-7600	8.0/-10.50	8.22
1/26	7-12111	8.2/-6.00+1.00x38	8.21
	7-12112	8.2/-6.75+1.00x135	8.38
	7-12083	8.2/-7.75+1.25x78	8.26
	7-12084	8.2/-7.00+1.25x76	8.40
1/31	7-15621	8.6/-3.50+.50x80	8.60
	7-15622	8.6/-3.75+1.00x90	8.66
	7-15739	8.0/-2.75	8.17
	7-15738	8.0/-2.75	8.19

Table 4 (cont'd)

Figure 3


Labeled Base Curve vs. Marked Base Curve
85 Lens Durasoft Survey
Locates mean radius of each group.
Labeled Base Curve (mm)
Measured Base Curve (mm)
8.8
8.6
8.4
8.2
8.0
7.8
7.80
8.00
8.20
8.40
8.60
8.80

± 0.1mm should allow one to predict the series. Table 5 lists the results of these predictions for fourteen unknown lenses selected at random and removed from their factory sealed bottles before being presented for analysis. Lens 7 was deleted since it measured 13.6mm in diameter and was originally labeled as an N series (12.5mm) lens, suggesting a mixup at the factory. Lenses 6, 8, and 9 were damaged in handling and not included in the analysis. In all ten cases of measured lenses the series was accurately predicted, and in four of the ten the power (measured in air with a vertometer) was exactly determined as well. Because of the .25mm to .30mm steps in base curve between Soflens series, an approximate power is sufficient to enable the investigator to use the PAR/AR charts to place the lens in its proper series. Small errors in power can be detected in over refraction and are deemed much less troublesome than dealing with lenses of unknown series. Thirteen of the eighteen lens surfaces measured were accurate (judged against B&L mold data) to less than .1mm, with the average departure from true radius falling at .06mm. Data is not reported for the anterior surfaces of the two high-plus lenticular lenses because the bowl radius is extremely short and cannot be measured with this apparatus.

B&L Soflens Verification

Unknown No.	Vertometer Power	Measured PAR/AR	Diam.	Nearest PAR/AR from B&L chart	Predicted Lens I.D.	Actual (label) Lens I.D.	Error
1	+4.00	9.07/8.38	13.6	8.90/8.30	+4.00F3	+4.00F3	none
2	-2.75	8.22/8.80	12.5	8.25/8.76	-2.75F	-3.00F	+.25D
3	+14.00	7.52/ --	13.6	7.50/ --	+14.00J3	+15.00J3	-1.00D
4	-.25	9.57/9.70	13.6	9.60/9.67	-.25B3	-.50B3	+.25D
5	-2.75	7.66/8.10	12.5	7.70/8.14	-2.75N	-2.75N	none
6	(damaged lens - deleted from study)						
7	(lens is 13.6 mm in diam. and cannot be an N series lens as labeled)						
8	(damaged lens - deleted from study)						
9	(damaged lens - deleted from study)						
10	+13.50	7.78/ --	13.6	7.78/ --	+13.50F3	+13.50F3	none
A	-2.50	8.49/8.99	12.5	8.60/9.08	-2.50B	-2.75B	+.25D
B	-4.00	7.74/8.38	12.5	7.80/8.44	-4.00J	-4.75J	+.75D
C	-.12	9.52/9.56	13.6	9.60/9.67	-.25B3	-.25B3	none
D	-2.75	8.06/8.62	12.5	8.25/8.74	-2.75F	-3.25F	+.50D

Table 5

Conclusion

The results obtained in the clinical application section of this study seem to indicate that the apparatus described here can indeed play an important role in the routine fitting of soft contact lenses. Certainly the hardware aspect of the system should not discourage its use, as the basic instrument (keratometer) is already close at hand for most practicioners. The modifications required can be cheaply and quickly completed by any one with average mechanical skills. Those not inclined to go through the calibration procedure with steel spheres or rigid lenses can achieve a close approximation of true radius by using a +1.25D range extender lens (for which keratometer radius conversion tables are readily available)[1]* and multiplying this corrected radius by 1.336, the refractive index of .9% saline. Results obtained by this method closely approximate those derived from the graph based on actual measurement of spheric surfaces.

Even with the technical challenge reduced to a minimum, soft lens practicioners are likely to develop widely varying opinions about the utility and practicality of adopting

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* 1. Mandell, Robert B., Contact Lens Practice, 1974, p.786.

this technique in a contemporary contact lens practice. Those dealing primarily with spun cast lenses will find that the use of a mold in lens manufacture insures a high degree of uniformity, and it would seem to be a poor use of time to routinely verify the base curves of these lenses. The procedure's greatest value to these individuals would probably be in resolving fitting problems resulting from mismarked or defective lenses, and in cases where a duplicate of an unmarked lens is desired.

Lathe cut lens manufacturing processes do not enjoy the dimensional stability or predictability inherent in the mold controlled process, primarily as a result of the inevitable variations in set-up accuracy and cutting tool condition. If the dimensional variation observed in this survey is representative of what can be expected of lathe cut lenses in general, then fitters will soon come to realize the benefits in verifying both their fitting sets <u>and</u> the patient's lenses prior to dispensing.

Only when the fitter has a complete and accurate dimensional description of every lens he places on an eye for evaluation can he bring his full diagnostic abilities to bear and methodically achieve the "best fit" in the most straightforward manner.

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