The Efficacy of Verifying the Base Curve of Hydrogel Contact Lenses

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Contact lenses can only be manufactured and prescribed as accurately as they can be checked, and frustration arises if supposedly duplicate lenses perform differently in situ. Such difference may arise because of inadequate quality control in the manufacturing process or in the final verification of lens parameters.

It appears there are no official recommended standards and, somewhat surprisingly, the FDA does not appear to stipulate tolerances for the parameters of soft lenses used in clinical trials. [1-4] Drafts of standards for public comment are now available,[4-6] and the suggested tolerance for the base curve of a lens immersed in liquid varies from ±0.05 mm (Australian standards draft) to ±0.10 mm (British standards draft). The purpose of this study was to determine the reliability of several instruments available to the authors and also to determine if these suggested tolerances for the back central optic radius (base curve) of a hydrogel lens are realistic.

Procedure

A trial lens of unknown base curve was selected at random. The lens was made of hydroxyethyl methacrylate; it had 40 per cent water absorption, a pH value of 7.20, a refractive index of 1.50 when dehydrated, and a center thickness of 0.14mm. It was semiscleral. The base curve was then measured 25 times by one of the authors (DL) on each of the following instruments:

(1) *The Carl Zeiss (Oberkochen) ophthalmometer* [7-11] uses keratometry to measure the base curve of a soft lens mounted convex-side-up in a liquid cell. The mire images are reflected by a mounted prism cell into the telescope, and the resultant reading is multiplied by the refractive index of the saline. A compensation factor of about 0.03 mm is added to compensate for the convex calibration of the instrument.

(2) *The Nissel ultraradiuscope*[11] is basically a Drysdale microscope with a sealed objective lens directly immersed into a liquid cell in which the lens is centered concave-side-up. As the light only travels through a single medium, a direct reading is possible, although a high-luminosity bulb is necessary to compensate for the light lost by reflection.

(3) *The wet cell gauge (Contact Lens Manufacturing, Ltd.)*[11] is a magnified vertex depth gauge that permits the approximate determination of the base curve of an immersed lens.

(4) *The Wohlk microspherometer* [11] also uses sagometry to measure the primary sag of the lens mounted in air on a holding ring. The reading is taken from a clock dial calibrated to read the base curve at a point where the probe just touches the back surface of the lens.

(5) *The Soehnges control and protecttion system*[11,12] projects the profile of a lens immersed in fluid at a previously calibrated distance onto a screen containing graduated annuli that may be adjusted vertically until alignment is achieved.

The recommended tolerance for the base curve of a hard corneal lens is ±0.02mm.[5, 6, 13] For comparison, the base curve of a hard corneal lens was measured 25 consecutive times with a conventional radiuscope. Table 1 shows that the specified base curve was 7.35mm, the measured base curve was 7.37 mm, and the standard deviation of ±0.03 was slightly greater than the recommended tolerance. While measuring the base curve of a soft lens in a liquid, the lens was immersed in normal saline and the ambient temperature controlled to 5C. While using the microspherometer the lens was immersed after every five measurements to avoid dehydration errors.

Results

The mean, standard deviation, and range of base curve measurements for each sample of 25 observations are shown in Table 1. The steepest readings in this instance were obtained with the ultraradiuscope and the flattest with the ophthalmometer. The difference between the two was 0.10mm.

The reliability or precision of an instrument may be specified in terms of the standard deviation of the readings carried out on a single lens if representative. This is referred to as the standard error of measurement and gives us an estimate of the bounds within which 68.26 per cent of the readings should lie if we make the reasonable assumption that the underlying measurement errors are normally distributed. Also assuming that the instruments give relatively unbiased readings, we can find the percentage of readings for each instrument that should be within the Australian and British standards drafts. These are also given in Table 1.

According to our estimates, all the instruments except the Wohlk microspherometer had standard errors of measurement that were within the British standards draft tolerance of ±0.10 mm, although sampling error prevents us from being completely unequivocal on the CLM wet cell gauge. With the exception of the Nissel ultraradiuscope (and possibly the Zeiss ophthalmometer), however, none were

TABLE 1

The base curve of a hydrogel lens measured by five instruments.*

	Sample statistics (N = 25)			Readings expected within standard tolerances		
Instrument	Mean (mm)	SD (mm)	Range (mm)	Australian (0.05)† (percent)	British (0.10)† (percent)	British (0.02) hard lenses† (percent)
Ultraradiuscope	7.25	0.023	0.10	91-100	100	
Zeiss ophthalmometer	7.35	0.051	0.26	56-82	88-99	
Soehnges projection system	7.35	0.076	0.30	40-64	70-93	
CLM wet cell gauge	7.29	0.096	0.35	32-53	58-85	
Wohlk microspherometer	7.35	0.17	0.60	18-33	35-59	
American Optical radiuscope‡	7.37	0.030	0.26			40-64

*The instruments have been assumed to be essentially unbiased, the standard deviations have been taken as estimates of the standard errors of measurement, and instrument errors have been assumed to be normally distributed.

†The 95 percent confidence limits for the number of readings expected to lie within the Australian and British standards draft for soft lenses and established British standards for hard lenses where appropriate.

‡Hard lens of similar specifications; marked base curve = 7.35.

within the Australian standards draft. It is notable that the ultraradiuscope's accuracy was comparable to that of the American Optical radiuscope, which measured a hard lens to ±0.030mm.

It should be noted that single readings often give values that are outside the Australian standards draft, as illustrated in Table *1*. The same is also true of the British standards draft, with the possible exception of the ultraradiuscope. If our statistical assumptions are reasonably valid, we expect over 99.95 per cent of its single readings to be within the standards drafts. But for other instruments it is certainly necessary to rely on more than one reading; it is a desirable precaution to always take more than one reading with any instrument. It is thought to be impractical to repeat a reading 25 times in a clinical or manufacturing situation, but assuming the lens in this study was not atypical, what would be the minimum number of readings necessary to obtain a result within the British and Australian drafted standards? Tables 2 and 3 show the number of readings required in a sample so that the mean will have the stated probability of lying within 0.10mm and 0.05mm, respectively. Since we only have estimates of the standard error of measurement for each instrument, we have given the 95 per cent confidence limits for the number of readings. Table 4 gives the comparable figures for hard contact lens measurements and the actual British standards.

It is not unreasonable to average between three and five readings; if this is accepted, most of the instruments considered have a 95 per cent probability of being within British standard draft tolerances

TABLE 2

Estimate of the number of readings required to average.*

	50 percent	68 percent	95 percent	99 percent
Ultraradiuscope	1	1	1	1
Zeiss ophthalmometer	1	1	1-2	2-3
Soehnges projection system	1	1	2-3	3-5
CLM wet cell gauge	1	1-2	3-5	5-8
Wohlk microspherometer	1-2	2-4	5-9	15-25

*This is so the sample means have the stated percentage probability of being within 0.10mm (British draft standard tolerance) of the true reading. The calculations have assumed normal distribution of errors and essentially unbiased instruments. The figures in Table 1 have been taken as estimates of the standard error of measurement of the instruments, and because these estimates are based on only 25 observations, the 95 percent confidence limits for the number of readings required have been given.

TABLE 3

Estimate of the number of readings required to average.*

	50 percent	68 percent	95 percent	99 percent
Ultraradiuscope	1	1	1-2	2
Zeiss ophthalmometer	1	1-2	3-6	6-9
Soehnges projection system	1-2	2-3	7-12	12-20
CLM wet cell gauge	2-3	3-5	11-19	19-32
Wohlk microspherometer	4-7	9-16	33-58	57-100

*This is so the sample means have the stated percentage probability of being within 0.05mm (Australian draft standard tolerance) of the true reading. The calculations have assumed normal distribution of errors and essentially unbiased instruments. The figures in Table 1 have been taken as estimates of the standard error of measurement of the instruments, and because these estimates are based on only 25 observations, the 95 percent confidence limits for the numbers of readings required have been given.

TABLE 4

Estimate of the number of readings required to average.*

	50 percent	68 percent	95 percent	99 percent
American Optical radiu-scope (hard contact lens)	1-2	2-3	7-12	11-20

*This is so the sample means have the stated percentage probability of being within 0.02mm (British standards tolerance for hard lenses). The calculations have assumed normal distribution of errors and essentially unbiased instruments. The figures in Table 1 have been taken as estimates of the standard error of measurement of the instruments, and because these estimates are based on only 25 observations, the 95 percent confidence limits for the number of readings required have been given.

and a 68 per cent probability of being within the Australian tolerances (Table 3).

Conclusion

The verification of soft contact lens parameters is a relatively new problem. There are currently no established tolerances. In formulating acceptable limits it is necessary to establish fitting criteria that should be correlated with the cost of manufacturing to the required tolerances and also with the accuracy of available checking instruments.

The back central optic radius of base curve is possibly the most important fitting parameter; paradoxically, it is probably the most difficult to check. The results of this survey suggest that with most of the instruments considered it is necessary for an average three to five readings of the base curve and that a tolerance of ±0.10 mm as suggested by the British Standards Institute is both realistic and acceptable. —

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Clinical Implications

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Accurately prescribing and replacing soft lenses depends on the practitioner's ability to measure lens parameters. If he is unable to ascertain these measurements, he suffers loss of time and frustration, and investment in large inventories becomes necessary.

The practitioner's ability to measure diameter, power, center thickness, zones, and bevels is well documented. These measurements can be easily and accurately performed in the office.

As the authors state, however, measuring the base curve is the most difficult. The Nissel wet-cell radiuscope, projection instruments, and a sagittal method (BC Tronics) are on the market today. Their costs are relatively high, and their efficacy is now being determined.

Comparisons against standards to evaluate instruments are essential; the authors have contributed to this end. — 5027 Jenkins Arcade, Pittsburgh, Pa. 15222.