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LETTER TO THE EDITOR

THE VALIDITY OF DETERMINING THE HYDROGEL LENS THICKNESS FROM THE SWELL FACTOR

(Received 31 *January* 1982)

It is well established that the thickness of a hydrogel contact lens is a significant parameter both in terms of fitting (Mertz *et al.*, 1979; Killpatrick, 1980) and oxygen transmissibility (Hill, 1975). It is acknowledged that the average thickness is clinically significant with respect to gas transmission and the edge thickness relates primarily to comfort and peripheral corneal anoxia. In practice however one is generally concerned with the centre thickness, because it is more easily measured and can be checked in air using a conventional radiuscope (Harris *et al.*, 1973; Paramore and Wechsler, 1979; Wechsler and Paramore, 1978). A tolerance better than ± 0.05 mm (wet) as recommended by the British Standards Institute (BSI) in 1978 may readily be achieved (see Table 1).

Table 1. Tolerances suggested by various authors for the hydrated centre thickness of hydrogel contact lenses

British Standards Institution (1978)	± 0.05 mm
Pearson (1980)	± 0.02 mm
Barr and Lowther (1977)	± 0.01 mm
Paramore and Wechsler (1979)	± 0.01 mm
Loran et al (1981)	± 0.008 mm

These figures, with the exception of the BSI ones, are based on the reliability of radiuscope checking, and are the SDs of repeated independent measurements on single lenses.

One might, then, enquire if this important parameter is normally verified in practice. In an attempt to answer this question a modest survey covering 10 eminent practitioners and 10 contact lens laboratories was undertaken in 1979 by the authors. The results showed that none of the practitioners checked the centre thickness. The replies from the laboratories are given in Table 2 from which it can be seen that:

(a) Six out of 10 laboratories specified the centre thickness.

(b) Eight out of 10 checked the dry or xerogel thickness. One laboratory produced its lenses by spin-casting and therefore this measurement was inapplicable.

(c) Seven laboratories checked the hydrated or wet centre thickness.

(d) One laboratory checked neither the wet nor the dry centre thickness.

If this, albeit small, survey is truly representative then it might be expected that 30% of patients could be wearing lenses for which the hydrated centre thickness had not been verified and one in 10 could be wearing lenses for which this parameter had not been checked—wet or dry.

It is instructive to consider the consequence of ordering a thin 38% Polyhema hydrogel lens (0.06 mm) with its hydrated centre thickness specified according to a tolerance of ± 0.05 mm, the maximum at present allowed by BS 5562 (1978). A range of centre

Table 2. Quality control of hydrogel contact lens thickness by 10 laboratories

Laboratory	Is the centre thickness specified?	Is the xerogel or dry centre thickness measured?	Precision claimed by laboratory ± mm	Is B.S.I. tolerance of ± 0.02 mm claimed?	Is the hydrated or wet centre thickness measured?	Precision claimed by laboratory ± mm	Is B.S.I. tolerance of ±0.05 mm claimed?
A*	YES	NO	NONE	NO	YES	0.001	YES
B	YES	YES	0.01	YES	YES	0.02	YES
C	NO	YES	0.005	YES	NO	NONE	NO
D	YES	YES	0.01	YES	YES	0.01	YES
E	YES	YES	0.01	YES	NO	NONE	NO
F	YES	YES	0.02	YES	YES	0.02	YES
G	YES	YES	0.02	YES	YES	0.025	YES
H	NO	YES	0.02	YES	YES	0.02	YES
I	NO	YES	0.05	NO	YES	0.05	YES
J	NO	NO	NONE	NO	NO	NONE	NO

*Spin-casting.

thickness from 0.01 to 0.11 mm would then be considered tolerable. Translating these figures into their oxygen equivalent (Hill, 1975) we obtain a range of oxygen equivalent from 2 to *16%*. Clearly, while the centre thickness variation would appear tolerable, the resulting oxygen equivalent variation would seem quite unacceptable. This obviously suggests that the BSI tolerances may be too large.

Paramore and Wechsler (1979) have examined the differences between specified and measured hydrated centre thicknesses. They obtained a mean difference of 0.022 mm with 184 lenses. On a sample of 131 hydrogel lenses, Barr and Lowther (1977) determined that *45%* were outside a tolerance of ± 0.02 mm.

Our survey indicated that, of the nine laboratories supplying lathe-cut hydrogel lenses, eight measured the dry thickness, no doubt assuming one could accurately predict the hydrated centre thickness from the linear swell factor where:

$$\text{Linear swell (\%)} = \frac{L_G}{L_P} \times 100 = \left(\frac{V_G}{V_P}\right)^{\frac{1}{3}} \times 100 \text{ (Gee, 1980),}$$

where L_G is the linear dimension of the hydrated polymer, L_P is the linear dimension of the dehydrated polymer, V_G is the volume of the hydrated polymer, and V_P is the volume of the dehydrated polymer.

In order to determine the validity of this assumption, seven test lenses were ordered by the authors to a specification of C Hyd l/8.30:13.0/plano, with requested centre thicknesses ranging from 0.03 to 0.20 mm and water contents from 38 to 70%, as shown in Table 3. It is accepted that powered lenses may not necessarily swell in a linear fashion

but for practical reasons it was decided to restrict our sample to piano lenses. The two participating laboratories were asked to carefully control the ambient variables, and to accurately measure the dry (but not the hydrated) centre thickness, in order to predict the hydrated centre thickness from a known linear swell. The laboratories were aware of the nature of the project—that the hydrated centre thickness would be checked by the authors and the results published.

When they were received from the laboratories, the centre thickness of each hydrated lens was measured 25 times using a radiuscope and a bisurfaced hydrogel lens platform (Wechsler and Paramore, 1978; Paramore and Wechsler, 1979). The radiuscope was calibrated against precision feeler gauges which ranged in thickness from 0.05 to 0.25 mm and was found to be essentially unbiased and free from systematic error. The average reliability achieved was ± 0.009 mm, suggesting an average SE of the means of ± 0.002 mm. As Table 3 shows, the reliabilities achieved for individual lenses varied from ± 0.005 to ± 0.010 mm. From the specified and measured centre thicknesses given it can be seen that all lenses were within the recommended BSI tolerance of ± 0.05 mm, all within ± 0.02 mm and six out of seven within ± 0.01 mm. These results suggest that providing ambient variables such as humidity and temperature are carefully controlled during manufacture then the hydrated centre thickness can be predicted with reasonable certainty from the dry state.

Table 3. Details of the seven lenses ordered for the study

lens	material	water content	centre thickness in mm			reliability of measurement
			predicted	measured	difference	
1	P.Hema	38%	0.03	0.040	+0.010	0.0054
2	P.Hema	38%	0.05	0.048	−0.002	0.0087
3	P.Hema	38%	0.10	0.102	+0.002	0.0087
4	P.Hema	38%	0.15	0.156	−0.006	0.0087
5	P.Hema	38%	0.216	0.227	+0.011	0.0080
6	Sauflon	55%	0.20	0.200	−0.000	0.010
7	Sauflon	70%	0.20	0.218	−0.002	0.010

The lenses were ordered to an identical specification of C Hyd l/8.30:13.00/plano. The predicted thicknesses were those specified by the manufacturer based on swell. Each measured thickness was the mean of 25 separate measurements carried out by the authors (SD given in the reliability column).

The Working Party of International Standards is currently considering draft tolerances for contact lenses (BSI, 1981; Ruben, 1982). It recommends that measuring instruments should have a precision of half the tolerance limits for a relevant test and suggests a tolerance of ± 0.02 for stated hydrated centre thickness below 0.20 mm. As illustrated in Table 3, both our results and those of previous investigators substantiate that these tolerances are practical and realistic and may be achieved in air using conventional instrumentation. We are unable to comment, however, either on tolerances for centre thicknesses substantially greater than 0.20 mm or for powered lenses, as neither were included in our study.

It is our opinion that the centre thickness of hydrogel contact lenses should be routinely checked by the laboratory in the dry state and preferably hydrated at least on a sample basis. However, it is the ultimate responsibility of the practitioner to determine that the

thickness of the hydrogel lenses which he prescribes is within acceptable tolerances. The centre thickness is readily verified but our future attention should now be directed towards both the edge and average thickness where development of different and more sophisticated instrumentation is necessary.

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