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AN ASSESSMENT OF THE EFFECTS OF ERROR IN REFRACTIVE KERATOPLASTY

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Introduction

Keratophakia is the surgical correction of aphakia by the insertion of a correctly powered positive lenticule into the corneal stroma [1].

The extent to which errors of measurement and manufacture of the lenticule may influence the accuracy and reliability of the correction of ametropia is of obvious clinical significance. Littmann [2], has discussed the effects of some errors of measurement that may occur in keratophakia employing donated stromal lenticules. However, in treating the cornea-implant combination as an optical system consisting of two discrete units with either matching or disparate refractive indices, it is possible to calculate the effects of error from faulty production of the lenticule in addition to those due to faults of measurement. The optics employed [3, 4], is distinct from previous theory not only in this two component treatment, but also because lenticule design is optimised to achieve a minimum thickness implant. Thus, an error in measurement of even a single parameter at the outset, will result in additional unwanted refractive changes induced by the compensatory design shifts dictated by the design scheme in its search for the thinnest implant. Clearly, there may be complex interactions between the design elements. An analysis of these refractive effects is the purpose of this study.

Method

Because the optical theory is optimised and parameters interact in a complex way, the simple expedient of differentiating each parameter singly with respect to the dioptric power of the new corneal surface is no longer practicable. The method employed here is in two parts. Firstly, errors due to initial measurement error are deduced by designing the optimum lenticule based on this incorrect measurement, and then determining its dioptric effect upon the eye. Secondly, errors due to manufacture are found by designing the perfect lenticule and then, assuming one of its parameters is faulty in manufacture, its refractive effects in this state are calculated.

Since the technique of keratophakia is most commonly used to correct aphakia, the corneal parameters of the uncorrected eye have been assigned values roughly in the normal range for an emmetrope, as indicated in the firts column of Table A. The two types of error which occur are assigned with notional values. Thus, the initial value of the original anterior corneal radius is considered to have extremes at ± 0.02 mm. from its true value. The range chosen represents the best standard deviation that might be achieved with careful and practised use of the keratometer but in caution, it is emphasised that in this study this is taken as a measure of accuracy rather than reliability. In reality, systematic errors induced by assigning the aspherical cornea with a spherical radius of curvature probably exceed these limits. However, it seems more meaningful at this stage to express errors of correction in relation to typical reliability limits and hence gain some impression of the dioptric changes that might be expected within the limits of instrumentation used. Hence, lathing limits are nominally considered to be within ± 0.02 mm. of the intended value. Since two surfaces are effectively lathed on the lenticule, and since the posterior surface bens to match the corneal bed surface, then the error is taken as a total of ± 0.04 mm. on the anterior lenticule surface. In each case, the correcting lenticule was calculated using the optimising computer program [4], to give a real dioptric accuracy of correction to within ± 0.00005 D. Effects of the degraded lenticules were found using a program specially written for this purpose. Having determined the effects of each error in isolation they are then considered to act together. All parameter errors giving, for example, positive refractive change errors in *isolation*, are combined in a single instance to give a total interactive effect. These total effects are then compared with the simple sum of the errors obtained in isolation, thus indicating the presence, and to some extent, the degree of interaction when several individual errors occur together in a single case.

Results

TABLE A

Table A summarises the main results. Mostly, these are self explanatory, but attention should be drawn to certain interesting points.

Errors in lenticule anterior radius seem high when compared to those caused by measurement errors in original anterior corneal radius, even when account is taken of the fact that the limiting range of the former is double that of the latter. This can be explained in the following way: Considering the firts row of the data table, this represents an underestimation in measurement of 0.02 mm., ie the pre-operative anterior corneal radius is taken incorrectly as 7.78 mm. This error leads to a corresponding underestimation of the corneal bed radius which, for an excised disc thickness of 0.25 mm. would be 7.53 mm. instead of 7.55 mm. Thus, the posterior surface of the lenticule is assigned a radius of 7.53 mm. and the anterior surface is assigned with a shorter radius than would have been given if the initial measurement had been correct. When this lenticule is placed on the eye with an actual corneal bed radius of 7.75 mm. it flexes and flattens and the anterior lenticule radius is increased by approximately 0.02 mm. (which for the present data, is accurately calculated by assuming that for small degrees of flexure, the lenticule central thickness and the difference between its anterior and posterior surface sagittae remain constant). The overall flattening of the lenticule results in a corresponding effect upon the anterior corneal radius, being dictated by the assumption that the anterior and posterior excised disc radii remain concentric throughout the whole procedure. It will be seen that the total dioptric effect is almost a balancing of the initial steepening and subsequent flattening effects. In contrast, an error in the cryolathing of the lenticule, the design of which has been based on correct initial parameters, is fully manifested at the anterior corneal surface. For similar reasons, the lenticule refractive index has a greater effect (whether its value is 1.376 or 1.436), than the corneal refractive index.

The fourth row of the table relates to overall thickness errors in the lenticule, ie the error is constant from centre to edge. Tickness errors which are not constant result in a change in anterior lenticule radius and can be referred to in that section of the data. Comparing the summed isolated errors and the sum of errors acting together, it is seen that the former leads to an underestimation of positive dioptric error. There is a danger, in taking all same sign errors together in the fashion of this analysis, of shrouding certain effects. This is because two or more of the individual factors may act to counterbalance each other. However, that there is interaction is evident, although the effects are small.

TABLE B

In relation to the ocular refraction, there is an increase in dioptric error with the degree of ametropia. Table B, shows that when the dioptric error is expressed as a percentage of the total refractive change intended, then it decreases with increasing ametropia. The table also shows the general effect of initial corneal radius of curvature for those eyes which are essentially ametropic before cataract surgery. A point of importance not accounted for in the compilation of Table B, is that as optical surfaces decrease in curvature and become more powerful, then the keratometric and lathing accuracies decrease. Therefore, in practice, the figures may be expected to be somewhat greater.

In conclusion it should be said that even the total errors encountered in the present data are much less than those met in practice, perhaps emphasising the difficulties of reliably freezing and lathing a flexible substance. The systematic errors referred to earlier are doubtless to blame in some instances and clearly, the restriction of these is the domain of the individual surgical unit. Possibly the greater errors in practice result from the two well established assumptions basic to the optical theory. These are, firstly, the proposition that central keratometric readings and corneal refractive power are closely related and secondly, the belief that the excised corneal disc flexes such that its radii of curvature remain concentric and spherical when it is replaced on the implanted lenticule. The general validity of these assumptions has been adequately demonstrated by experiment and surgery. It is suggested however, that further progress in determining their exactness can be assessed only by investigating the relationship between the pre- and post-operative refractive and aberrational performance of the total visual area of the cornea and the corneal contour, using methods which are now becoming available.

PARAMETERS	ERROR	LENTICULE INDEX	OCULAR REFRACTION + 10.00DS DIOPTRIC ERROR	OCULAR REFRACTION + 15.00DS DIOPTRIC ERROR	OCULAR REFRACTION + 20.00DS DIOPTRIC ERROR
Original Corneal Anterior Surface Radius (=7.80 mm)	- 0.02	1.376	+ 0.007	+ 0.011	+ 0.016
		1.436	+ 0.006	+ 0.010	+ 0.014
	+ 0.02	1.376	- 0.007	- 0.011	- 0.015
		1.436	- 0.006	- 0.010	- 0.014
Lenticule Anterior Surface Radius	- 0.04	1.376	+ 0.377	+ 0.448	+ 0.527
		1.436	+ 0.419	+ 0.489	+ 0.565
(Calculated)	+ 0.04	1.376	- 0.372	- 0.441	- 0.518
		1.436	- 0.413	- 0.482	- 0.556
Excised Corneal Disc Thickness	- 0.05	1.376	- 0.157	- 0.247	- 0.344
		1.436	- 0.139	- 0.219	- 0.304
(= 0.25 mm)	+ 0.05	1.376	+ 0.161	+ 0.253	+ 0.354
		1.436	+ 0.142	+ 0.224	+ 0.311
Lenticule Thickness	- 0.05	1.376	+ 0.123	+ 0.145	+ 0.169
		1.436	+ 0.152	+ 0.176	+ 0.202
(Edge = 0.10 mm)	+ 0.05	1.376	- 0.123	- 0.145	- 0.169
		1.436	- 0.152	- 0.175	- 0.201
Corneal Refractive Index	+ 0.005	1.376	- 0.007	- 0.011	- 0.015
		1.436	- 0.006	- 0.009	- 0.013
(= 1.376)	+ 0.005	1.376	+ 0.007	+ 0.011	+ 0.015
		1.436	+ 0.006	+ 0.009	+ 0.013
Lenticule Refractive Index	- 0.005	1.376	+ 0.148	+ 0.222	+ 0.298
		1.436	+ 0.126	+ 0.190	+ 0.254
(1.376 and 1.436)	+ 0.005	1.376	- 0.144	- 0.216	- 0.289
		1.436	- 0.123	- 0.185	- 0.248
TOTALLED ERRORS For each ocular refraction, left column is sum of isolated errors, right column is total of combined errors	+ve	1.376	+ 0.82 + 0.84	+ 1.09 + 1.12	+ 1.38 + 1.42
		1.436	+ 0.85 + 0.87	+ 1.10 + 1.13	+ 1.36 + 1.40
	-ve	1.376	- 0.81 - 0.79	- 1.07 - 1.04	- 1.35 - 1.31
		1.436	- 0.84 - 0.82	- 1.08 - 1.05	- 1.34 - 1.30

T A B L A A

Showing the dioptric error caused by error in measurement or production of parameter values. A positive dioptric error indicates an over correction of the ametropia. For each parameter, both positive and negative errors are shown and, for each of these, two values of refractive index are considered. The error value in the second column is added to the corresponding nominal parameter value stated in the firts column to give the parameter value used in the calculation. The lenticule thickness change is considered to be constant at the centre and edge of the lenticule.

		AMETROPIA (OCULAR REFRACTION)		
		+ 10.00DS	+ 15.00DS	+ 20.00DS
		% ERROR	% ERROR	% ERROR
Initial Corneal Anterior Radius of Curvature (mm)	7.40	9.45	8.07	7.47
	7.80	8.74	7.52	6.99
	8.20	8.14	7.05	6.58

TABLE B

Showing the variation of total positive errors with original corneal radius of curvature as a percentage of the ametropia to be corrected. Parameters have the nominal values stated in Table A, and the lenticule has a refractive index. of 1.436.

SUMMARY

The effects of measurement and lathing errors in an optimised system of keratophakia are tabulated in dioptric form. It is shown that these interact in a complex manner and that in general, errors in lenticule production are likely to have greater effects than do similar errors in initial measurement of the aphakic eye. Because of the small magnitude of these errors, it is suggested that future attention should be increasingly directed towards assessing the exactness of the basic assumptions on which the theory is classically founded.

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