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IE OPTICS OF REFRACTIVE KERATOPLASTY EMPLOYING HYDROGEL IMPLANTS

P. W. CHURMS, M. SC., F. B. O. A. [1]

Glasgow, Escocia

INTRODUCTION

The accurate optics of refractive keratoplasty employing either donated corneal implants to the stroma or the removal of corneal material by cryolathing, has been dealt with by Littmann (1970).

In recent experiments Mester, Heimig and Dardenne (1976) held that the use of a plastics hydrogel (HEMA) lenticule gave surgical results of ametropia correction (in rabbits) in close agreement with those predicted by Littmann's simplified theory.

In existing techniques (eg Barraquer, 1970), variables affecting corneal storage and the poorly quantifiable mechanisms of corneal dynamics have contra-indicated the use of anything better than refined approximations of optical formulae. However, if hydrogel implants prove to be clinically viable in human recipients then the problems presently associated with the highly variable response of human donor material to storage and freezing will be eliminated. The presumably increased reliability and accuracy of results will then justify the use of accurate formulations.

Mester et al, assumed that the hydrogel material was optically similar to the recipient corneal stroma, and hence by the use of optical theory simplified in that respect, they sought to predict the results of surgery.

This study presents the optical theory of the two-component cornea-hydrogel system and compares its predictions with those of the single-

1 Department of opthalmic optics, Glasgow college of technology.

component system in which the hydrogel implant is considered to possess the optical properties of the corneal stroma. The experimental data of Mester et al, is then briefly discussed with reference to this comparative theory.

THEORY

The surgical modifications made to the cornea are shown in Fig. 1. The cornea is sectioned using a microkeratome so that the excised disc has concentric anterior and posterior radii of curvature. An implant is placed on the corneal bed and the excised disc is replaced and sutured. The result is a decreased anterior corneal radius of curvature and a radius dependent increase in corneal thickness. The forward movement of the anterior corneal vertex requires that a corresponding compensation is applied to the anterior corneal radius to account for its change in **effective** power.

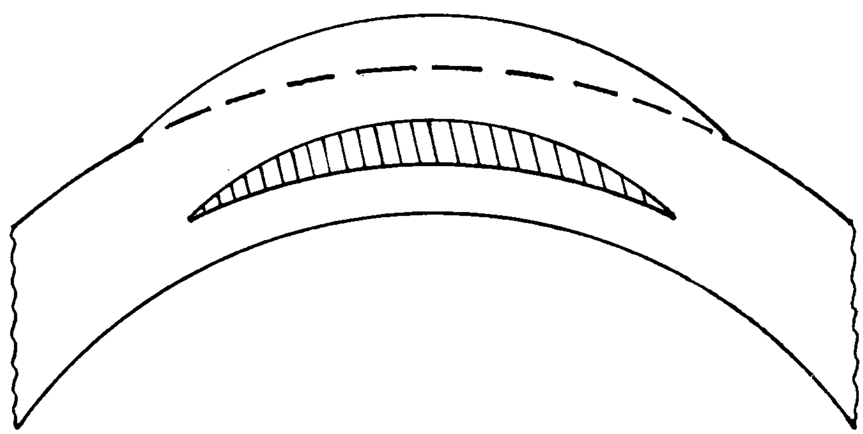

FIGURE 1

The technique of keratophakia: The shaded area represents the implanted lenticule.

Representing the optical components in Fig. 2, the necessary relationships can be derived by using standard vergence techniques.

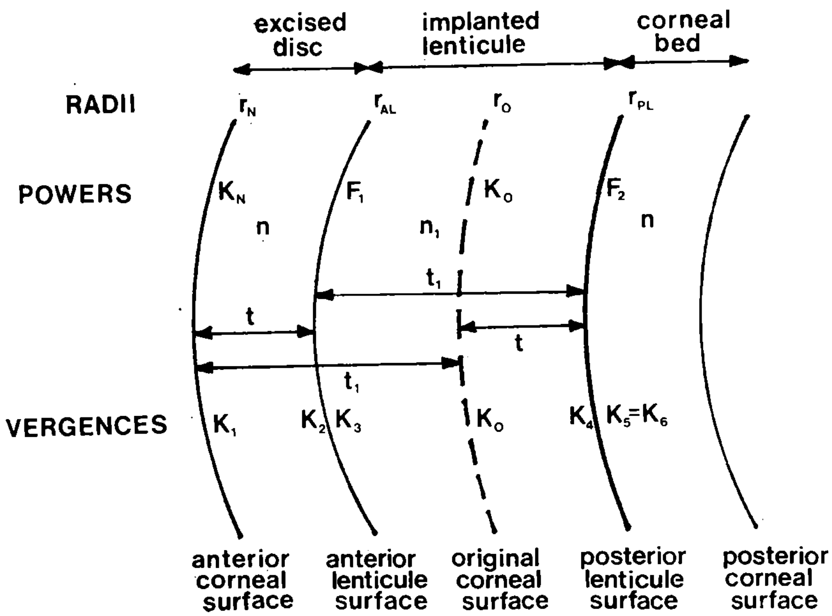

FIGURE 2

The main optical components of the cornea-implant system represented schematically with vergences included. Symbols are explained in the text.

The following symbols are used:

A = ocular refraction before surgery.

r_O = original radius of curvature of the anterior corneal surface.

K_O = original power of the anterior corneal surface.

r_N = new radius of curvature of anterior corneal surface, post-operative.

S_O = Sagitta of original anterior corneal surface.

S_N = Sagitta of new anterior corneal surface.

d_1 = diameter over which S_O and S_N are measured.

r_{PL} = radius of curvature of posterior lenticule surface (implanted).

r_{AL} = radius of curvature of anterior lenticule surface (implanted).

S_{PL} = sagitta of posterior lenticule surface.

S_{AL} = sagitta of anterior lenticule surface.

d_2 = diameter of implanted lenticule.

F_1 = power of anterior cornea-implant interface.

F_2 = power of posterior cornea-implant interface.

K_1 = vergence just within anterior corneal surface.

K_2 = vergence just anterior to anterior cornea-implant interface.

K_3 = vergence just posterior to anterior cornea-implant interface.

K_4 = vergence just anterior to posterior cornea-implant interface.

K_5 = vergence just posterior to posterior cornea-implant interface.

K_6 = vergence just posterior to posterior cornea-implant interface. (in stroma) before surgery and with the ametropia corrected.

t = central thickness of excised disc.

t_1 = central thickness of implanted lenticule.

e = edge thickness of implanted lenticule.

n = refractive index of corneal stroma (1.376).

n_1 = refractive index of implanted lenticule.

Powers and vergences are expressed in dioptres and distances in millimetres. All vergence values correspond to an initial incident vergence of zero ie parallel incident light.

If the cornea is no subject to a thickness change during surgery then the new anterior surface power is given by:

$K_N = K_o + A$, which gives an <u>effective</u> power (vergence K_6) just within the corneal bed of:

$$K_6 = \frac{1}{\dfrac{1}{K_o + A} - \dfrac{t}{n1000}} \qquad \text{.................} \quad 1$$

The final system which includes the lenticule must mimic this vergence just within the corneal bed hence:

$$K_6 = K_5 \qquad \text{.................} \quad 2$$

The following relationships follow from Fig. 2:

$$K_2 = \frac{1}{\frac{1}{K_N} - \frac{t}{n1000}} \qquad \text{.........} \quad 3$$

and

$$K_3 = K_2 + F_1 \qquad \text{.........} \quad 4$$

and

$$K_4 = \frac{1}{\frac{1}{K_3} - \frac{t_1}{n_1 1000}} \qquad \text{.........} \quad 5$$

and

$$K_5 = K_4 + F_2 \qquad \text{.........} \quad 6$$

Given pre-determined lenticule parameters the correction applied to the cornea is found from equations 3, 4, 5 and 6 where the value of KN in equation 3, is determined from the given anterior radius of curvature of the lenticule in its implanted position.

The effective ametropia corrected is then determined by re-arranging equation 1 so that:

$$A = \frac{1}{\frac{1}{K_6} + \frac{t}{n1000}} - K_o \qquad \text{.............} \quad 7$$

The original corneal power is found using the general lens formula

$$\text{ie} \quad K_o = \frac{(n - 1)1000}{r_o} \qquad \text{.............} \quad 8$$

Since the radius of curvature of the corneal bed is $(r_o - t)$, F_2 can similarly be found thus :

$$F_2 = \frac{(n - n_1)1000}{r_o - t} = \frac{(n - n_1)1000}{r_{PL}} \quad \ldots\ldots 9$$

F1 can be determined by employing the radius of curvature of the first cornea-implant interface. Assuming that the radii of curvature of the excised disc remain concentric (see later) then the interface radius must take the value of the new anterior radius minus the excised disc thickness.

Hence $r_{AL} = r_N - t$

$$\text{and} \quad F_1 = \frac{(n_1 - n)1000}{r_N - t} = \frac{(n_1 - n)1000}{r_{AL}} \quad \ldots\ldots\ldots 10$$

The calculation of overall thickness increase is problematical. The implant central thickness if not directly known, is given by the difference in sagitta between its anterior and posterior radii plus its edge thickness. Employing the accurate sagitta formula:

$$t_1 = r_N - r_o - \left((r_N - t)^2 - (d_2/2)^2\right)^{0.5} + \left((r_o - t)^2 - (d_2/2)^2\right)^{0.5} + e \quad \ldots\ldots 11$$

If the implant thickness is given, then its anterior radius is given by :

$$r_{AL} = \frac{(S_{PL} + t_1 - e)^2 + (d_2/2)^2}{2(S_{PL} + t_1 - e)} \quad \ldots\ldots\ldots\ldots\ldots 12$$

When its posterior radius r_{PL} aligns with the corneal bed radius.

However, the assuption often made, that an overall thickness increase of t1 (central implant thickness) takes place, is irreconciliable with the assumption that the new anterior corneal radius of curvature remains concentric with the anterior lenticule radius over the **same area of cornea.** If thickness increase is related to the anterior corneal surface pre and post-operatively, then the thickness increase (c) is given by:

$$c = S_N - S_o + e$$

$$= r_N - r_o - (r_N^{\,2} - (d_1/2)^2)^{0.5}$$

$$+ (r_o^{\,2} - (d_1/2)^2)^{0.5} + e \ldots\ldots\ldots\ldots \quad 13$$

Clearly, if $d_1 = d_2$ then $c \neq t_1$

Thus, the change in anterior corneal curvature occurs over a different area than that of the corneal bed **or**, if the changes take place over this same area then there must be some dynamic change in t and/or t1. Indeed, the total effect may be a combination of changes in area of surgical effect and thickness changes.

These problems indicate the necessity of monitoring the corneal topography and thickness before and after surgery. In the process of calculation the overall thickness increase will be interdependent with t, t1, e and the area (indirectly diameter d1) over which the correction of ametropia is obtained. Such calculations can be made iteratively, to indicate the dimensions necessary in the lenticule to correct a given ametropia. The present discussion however, is limited to a consideration of the refractive effects of various lenticules of predetermined values. The problem of thickness and area effects will be resolved by assuming that there is no axial compression or expansion of the optical components and that the radii of the excised disc remain concentric throughout the operation. The area over which refractive changes are induced is then automatically determined, and it will be of interest to note the difference between the diameter of the modified area and that of the lenticule.

Hence, to calculate the diameter of the area modified on the anterior corneal surface we have, from equation 13:

$$d_1 = 2(r_N^{\,2} - (r_N - r_o - t_1 + e$$

$$+ (r_o^{\,2} - (d_1/2)^2)^{0.5})^2)^{0.5} \quad \ldots\ldots\ldots\ldots \quad 14$$

Where the thickness increase t1 is substitued from equation 11 and d1 is found by iteration.

The ametropia for which the surgical correction would be desired was calculated using the following parameter values:

n = 1.376.

n_1 = 1436 (HEMA implant) and 1.376 (Stromal implant).

t = 0.30, 0.25, 0.20, and 0.15 mm.

t_1 = 0.10, 0.15 and 0.20 mm.

r_o = 7.00, 7.80 and 8.60 mm.

e = Zero (Knife-edge lenticule).

d_2 = 4, 6 and 8 mm.

RESULTS

The effects of the various parameters in determining the refractive change in the eye are shown in Figs. 3 - 6.

The original anterior corneal radius of curvature (Fig. 3) has relatively little effect upon the refractive change obtained. An increase in radius of 0.80 mm., gives and additional power change of approximately +0.50D. Also shown is the effect of lenticule refractive index. This is better seen in Fig. 4 which shows that when lenticule centre thickness is both 0.25 mm. and 0.15 mm., the dioptric modification resulting from the donor implant is approximately 15% less than that given by the equivalent hydrogel lenticule. Fig. 4 also demonstrates the relatively small effect of excised disc thickness.

Figs. 5 and 6 reveal the very marked effects of both lenticule thickness and diameter upon the power modification. In a lenticule of zero edge thickness these parameters together with lenticule refractive index, uniquely define the anterior surface radius of curvature of the lenticule and hence, the new anterior corneal radius. Lenticules of finite edge thickness will have greater anterior surface radii and will induce a smaller refractive change. The data of Mester et al, is presumably obtained with lenticules of finite edge thickness, therefore too direct a comparison between the present data and theirs is unwise. It will be noted, however, that no matter how the refractive changes are obtained, the percentage difference between those induced by stromal lenticules and those by HEMA lenticules is a practically constant at all dioptric levels.

The area of the anterior corneal surface over which curvature modification takes place is always greater than that of the lenticule. Figures not presented here show that the calculated diameter of the anterior corneal area and lenticule diameters very rarely differ by more than 5%. Considering that the increase in area is normally well outside the optic zone of the cornea and also outside the area permitted use by the limiting daylight pupil size, the refractive effects are probably of no consequence.

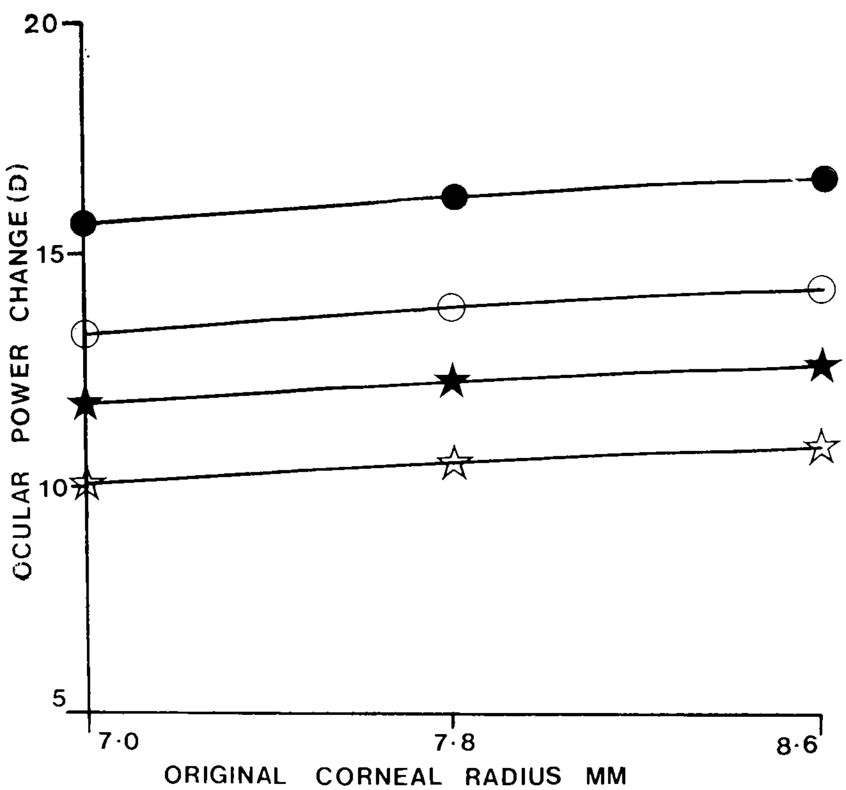

FIGURE 3

The amount of ocular power modification (effective ametropia corrected) caused by lenticules with central thicknesses of 0.15 mm (☆ ★) 0.20 mm (O ●). Filled symbols indicate a lenticule refractive index of 1.436 and open symbols an index of 1.376.

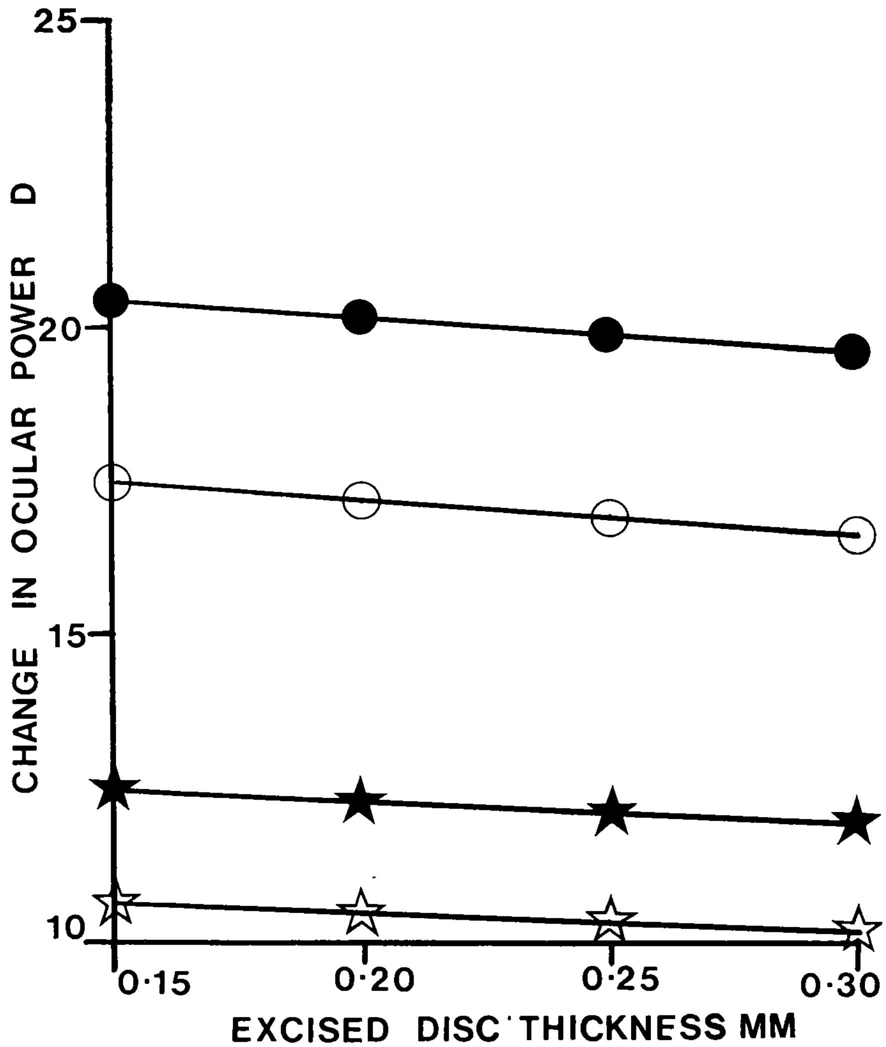

FIGURE 4

The effect upon ocular power modification of varying excised corneal disc thicknesses. Data is shown for lenticules with central thicknesses of 0.25 mm (○ ●) and 0.15 mm (☆ ★). Filled symbols indicate a lenticule index of 1.436 and open symbols an index of 1.376.

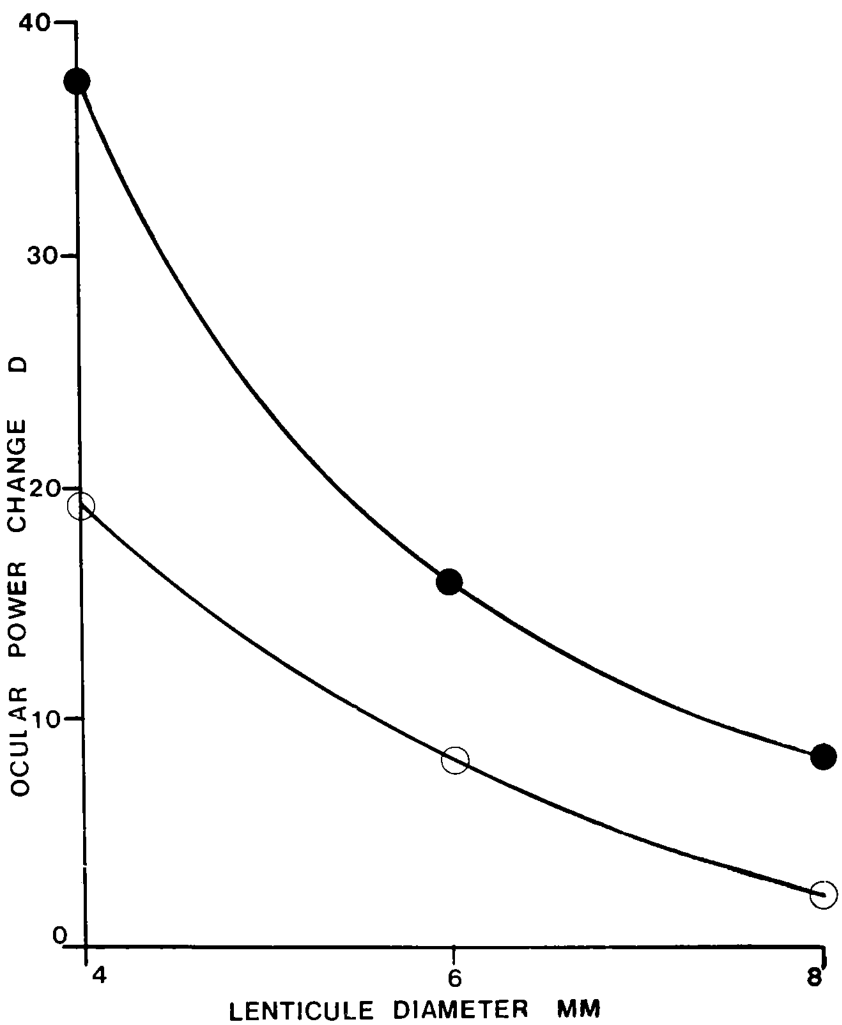

FIGURE 5

The variation of ocular power modification with lenticule diameter. The symbols ● O indicate central lenticule thicknesses of 0.20 mm and 0.10 mm respectively.

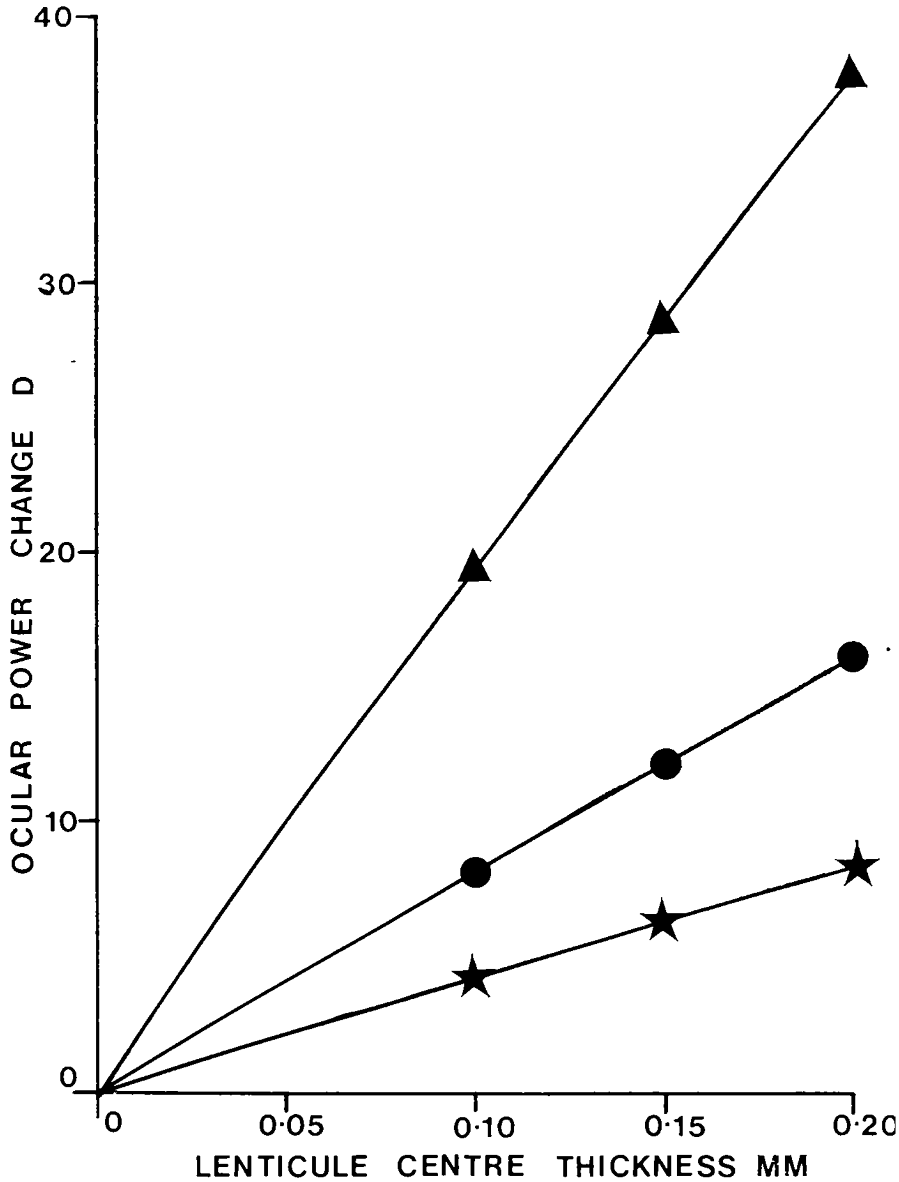

FIGURE 6

The effects of lenticule centre thickness upon the ocular power modification. Three graphs, symbols ▲ ● and ★ represent lenticule diameters of 4, 6 and 8 mm respectively.

DISCUSSION

The above analysis indicates that changes in lenticule refractive index should induce significant changes in the final refractive modification of the eye. The approximately 15% additional change in ocular power above that obtained when correction is by stromal lenticules, varies little with lenticule dimensions and excised disc thickness. Consequently, if a hydrogel lenticule is manufactured without regard to its higher refractive index (1.436) to correct an ametropia of +10.00DS, then a refractive overcorrection of some +1.50DS should occur.

The results of Mester et al, failed to show this effect. Their analytical approach was to determine the corneal power modification experimentally produced by surgery. Then using one-component optical theory, the anterior corneal radius change necessary to correct that degree of ametropia which corresponds to the power change, was calculated and compared to the clinically obtained radius. Inherent in this approach is the minor but systematic imprecision introduced when total ocular power change or effective ametropia, is equated to corneal power change. However, this taken together with the approximate 10% standard deviation of their data still is insufficient to account for any masking of a possible 15% overcorrection.

Consideration should be given to the notable departure of Mester's clinical technique from that normally applied in cases of human keratophakia. In the latter, the lenticule is designed so that its posterior surface aligns with that of the corneal bed. In the former, lenticules were standardised with a fixed posterior radius of curvature indicating that flexing of the lenticule (flattening) would be necessary in order that the posterior implant and corneal bed surfaces can be aligned. The mechanical and refractive effects of hydrogel lens flexure are of notorious contention (see eg Bennett 1976). If lenticule radii do change unpredictably in situ, then doubt must surround the calculation of total corneal power change and hence, the predicted anterior corneal radius of curvature and its ultimate comparison with experimental data. Furthermore, if it is not the cornea which distorts the lenticule, but rather the more rigid lenticule that distorts the posterior lamellae of the cornea and consequently, its posterior surface, then agáin, accurate clinical estimations of corneal power change are frustrated.

Thus, it is concluded that if optimal use is to be made of hydrogel implants then it is preferable to completely eliminate flexion. Indeed, this strategy is mandatory when employing stromal implants, specifically because of the poorly understood rheological properties of excised stromal tissue and their contributions to the whole opto-mechanical response to flexion of a lathed lenticule.

Given the relative ease with which hydrogel lenticules may be manufactured, checked and stored for long pre-operative periods, and considering the recently increased understanding of the importance of hydration and its effects in different gels; then it should be possible to greatly increase the accuracy and reliability of refractive keratoplasty.

SUMMARY

The accurate optics of keratophakia employing hydrogel lenticules is presented. It is argued that the increased refractive index of a hydrogel lenticule above that of a dimensionally equivalent stromal lenticule does have clinical significance. The influence of other parameters upon the correction of ametropia by this method are also indicated graphically.

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