PHYSIOLOGICAL CONSIDERATIONS IN THE CORRECTION OF APHAKIA BY SOFT CONTACT LENSES

by

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ABSTRACT

The history of cataract and its treatment is outlined. The number of cataract extractions per year in the United Kingdom is given with a discussion on the need for a good post-cataract (aphakic) optical correction. The unwanted optical effects of high plus spectacle lenses are contrasted with these optical effects in contact or intra-ocular lens form.

The handling problem of daily worn contact lenses by the (mostly) elderly population and the surgical problems of intra-ocular lens implants are discussed with the advantages of the good optical correction by the soft lens coupled with the ability for rapid removal should clinical problems arise.

The areas of measurement studied in this thesis are the temperature difference between the room and the eye, and the effect of these differences on the intensive properties of water content, refractive index, and permeability of soft lens materials and the extensive properties or dimensional changes in back and front radii of high plus lenses.

Another area of measurement studied is the effect on back vertex power of high plus lenses on 'bending' from the form of the lens in the bottle to the shape of the lens on the eye.

The last area of measurement recorded is the oxygen tension at the anterior corneal surface of the aphakic and phakic eye.

Visual acuity standards are given with respect to spectacles and various back radii fittings of high plus soft lensesand the hypothesis given that high plus soft lenses should be fitted with a particular back radius to achieve the highest standard of visual acuity.

Finally, this thesis gives a new method of fitting high plus soft lensesusing the traditional high plus PMMA fitting set as a diagnostic aid. The transposition of these PMMA parameters to the parameters of the soft lens on the eye and to the soft lens to be ordered from the manufacturers is given by taking into account the effects of heat and 'bending' on the parameters of high plus soft lenses. These calculations are summarised graphically.

CHAPTER 1

INTRODUCTION

Introduction

(1) Cataract, Aphakia and its Correction

Cataract or opaqueness of the crystalline lens is the most common form of blindness but is a reversible form of blindness because easily it can be cured by removal of the opaque lens.

Every year in the United Kingdom there are some 38,000 cataract extractions carried out in National Health Service hospitals. Three-quarters of these patients are over 65 years of age (DHSS et al 1981).

Because the human eye has a power of about +60.00D and its crystalline lens contributes about 30% of this power, some form of man-made optical correction is necessary if the crystalline lens is removed, to allow the rays of light to focus on the retina and so enable the brain to interpret visual stimuli without difficulty.

An eye without a crystalline lens is called an aphakic eye (a = without, phakos = lens). If the lens from only one eye is removed then the patient is said to be unilaterally aphakic. If both crystalline lenses have been removed, the patient is bilaterally aphakic.

The eye without a lens in the unilateral aphakic patient could be corrected by a high plus spectacle lens. In this case, three unwanted effects would be present, magnification of the corrected image in the aphakic eye is greater than the magnification of the image on that retina before the cataract extraction. As a result, judgement of distance by the brain of images received from that eye is confused. A second optical effect for the unilateral aphakic patient is the unequal image magnifications now presented to both eyes. This large inequality of image size prevents fusion of the images. Finally, there is the prismatic effect of high plus spectacles where the peripheral visual field is constricted which results in disorientation of the patient. In the case of the bilateral aphakic patient, spatial distortion and prismatic effects are present in the same manner as for the unilateral aphakic patient but binocular vision can usually be regained because retinal images are relatively similar in size.

There are two other well-known forms of correction for aphakia that reduce the magnification of the image, allowing fusion of the images in the aphakic and phakic eyes and diminish the constriction in the peripheral visual field. One form is by an intra-ocular lens implant and the other is by a contact lens.

At this time, intra-ocular lens implants have a greater risk of eye infection due to surgery than the more straightforward cataract extraction.

Correction of aphakia by contact lenses eliminates problems of surgery involved in the insertion of intra-ocular lenses. But if the contact lens is worn on a daily wear basis, it must be inserted and removed from the eye each morning and evening. However, because the majority of aphakic patients are elderly, there is often a problem of the inability or unwillingness to learn and apply the techniques of insertion and removal of the contact lens.

The extended wear soft lens should answer the problems just outlined. Optically it is acceptable because spectacle magnification and peripheral field constrictions are minimal and as the patient keeps the appliance on the eye at all times during the day and night, there will not be the problems associated with handling the contact lens.

There have been clinical studies of the fitting of the aphakic eye with daily and extended wear lenses (Lobascher et al 1974, Chaston 1979, Morris 1979) but none to date has described the factors influencing the design of the optimum lens for extended wear for the aphakic patient.

(2) The 'Best Form' High Plus Soft Contact Lens

It is the object of this thesis to introduce the concept of the optimum or 'best form' high plus soft contact lens. The design of such a lens requires detailed knowledge of the inter-relationship of the intensive properties of the soft contact lens materials and the influence of stress on the extensive properties of the contact lens itself.

This thesis gives the relationship of the intensive properties of soft contact lens materials, such as refractive index, water content and permeability with change in temperature. Also given is the change in the extensive properties such as the change in linear dimensions of back and front radius of high plus contact lenses in an unstressed condition as a change from room (20^{o}C) to eye (35^{o}C) temperature. The change in back and front radii when the soft lens is stressed by constraints on the eye also is given and its difference noted from the unstressed high plus soft lens change at the eye's temperature.

(3) <u>The PMMA Dome Model</u>

An innovation presented in this thesis is the use of a PMMA dome to represent the eye onto which the soft contact lens was draped and its surface radii measured. The results of the change in radii from the soft lens vial to the dome were compared to the change in radii of the high plus soft lens on the eye as observed in the clinic.

This thesis presents data which relates oxygen flux to a cornea to the oxygen transmissibility of the soft contact lens used in extended wear. When combined with previously found data of oxygen tension needed at the corneal surface to prevent excessive corneal swelling, this thesis provides the information needed to calculate oxygen transmissibility required to overcome excessive corneal oedema in extended contact lens wear.

CHAPTER II

CATARACT & APHAKIA

Catarct and aphakia

(1) The Human Crystalline Lens

The human crystalline lens contributes about 30% of the refractive power of the eye; so should it be missing or removed, a lens of between +10 and +20 dioptres will be needed in front of the cornea or an intra-ocular lens of about +17 to +24 dioptres in the pupillary region. Rarely is there a congenital absence of the crystalline lens. As a rule, aphakia is the result of removal or displacement of the crystalline lens because of lenticular opacities interfering with vision or trauma dislocating the lens from the pupil area.

(2) Cataracts

Lenticular opacities are called cataracts and technically any lenticular opacity is a cataract. Many people have congenital lenticular opacities which do not interfere with vision or do not interfere enough with vision to warrant removal of the crystalline lens. Cataracts are the most common cause of visual disability and blindness but if the retina is not damaged, vision can be restored by removal of the lens. There are congenital and developmental cataracts and cataracts associated with disease, diet deficiency, trauma and toxins, but by far the most common cataract is the senile cataract occurring during middle age or later.

(3) Metabolism of the Crystalline Lens

Knowledge of the metabolism of the crystalline lens is not yet sufficient to give with certainty the aetiology of the cataract. What is known is that usually loss of transparency is due, in the first place, to the swelling between the fibroid colloid system of the crystalline lens. Water accumulates between the lens fibres and the crystalline lens then swells. This swelling produces a diffraction effect with its subsequent irregular refractive condition. Increased water leads to a swelling of the lens and this has the effect of producing myopia. This swelling is reversible and therefore the refractive condition alters. The patient usually complains of monocular diplopia rather than a diminution of visual acuity at this stage. The other stage in cataract is an irreversible chemical change when the proteins become coagulated and insoluble and there is a loss of transparency of the tissue. At this stage visual acuity falls.

The condition and treatment for cataract has been known for some 4,000 years and probably further (Duke Elder 1969). The disease and treatment were known to the Sumerians of Mesopotamia, the Ancient Egyptians, Greeks and Romans and the Hindus. Early techniques of cataract removal were known as couching or reclination.

(4) The Techniques of Cataract Extraction - An Historical Perspective

Most early couching techniques involved the use of one sharp instrument both to pierce the sclera and depress the lens, so clearing the pupillary zone from the opacified crystalline lens and allowing light to fall upon the retina again. The Hindus were the earliest recorded people to use two instruments, first a sharp one to pierce the sclera and then a blunt one to depress the lens. Experience showed there were less complications with the use of a blunt instrument to depress the lens and in time this became the accustomed method.

Couching prevailed all over the world when cataract surgery was performed until the 17th Century. Stephan Blankaart of Holland, it is said, was the first to remove the cataractous lens from the eye and not just the pupillary zone, but it was not until the 18th Century that this technique was in general use. Jaques Daviel in 1748 made the first planned removal of the cataract from the inside of the eye. Otto Becker (1828 - 1890) who held the chair of Ophthalmology at Heidleberg was the first to consolidate knowledge of the history of cataract and its method of treatment. With the advent of the slit-lamp microscope, Alfred Vogt of Zurich accurately observed the cataractous lens and laid the foundations for modern knowledge of cataract surgery.

The method of cataract extraction depends upon the type of cataract present. On patients under 40 where the lens mass is soft, some form of extra-capsular extraction is usually performed. This method removes the anterior lens capsule and scoops out the cataract. For those over 50 years of age, when the nucleus of the lens is hard, intracapsular extraction techniques are used. The lens is ruptured from the zonule and the lens and capsule are removed from the eye.

Duke Elder (1969) states that 65% of persons in the 5th decade of life and 96% of persons over 60 have some form of lenticular opacities, and that one per 2,000 persons over 20 present themselves for cataract surgery. Operations for cataract are more numerous than for any other ophthalmological condition.

It is estimated that in the United Kingdom there is only a 4% complication rate after cataract surgery and the majority of patients leave hospital from 5 - 15 days after surgery. Subsequent aftercare is given in the ophthalmic outpatients' department.

CHAPTER III

THE CASE FOR EXTENDED WEAR SOFT CONTACT LENSES FOR APHAKIA

The case for the extended wear soft contact lens for aphakia

(1) Optical Corrections for Aphakia

Aphakia is now for many patients just a refractive condition needing optical correction. Cataract surgery is commonplace and the techniques have been refined to the point where complications are at a minimum. In many cases the optical correction can be prescribed and dispensed by an optometrist without the need for supervision by the ophthalmologist.

Optical corrections for aphakia can be by spectacles made of glass or plastics; by hard contact lenses of polymethlymethacrylate (PMMA), cellulose acetate butyrate (CAB); or copolymers of silicone and methyl methacrylate such as Polycon; by soft contact lenses with a range of water contents from 38% to 78%; by silicone rubber lenses with hydrophilic coating or by glass or plastic intra-ocular lenses. All of these devices for providing the refractive correction have advantages and disadvantages.

(a) Spectacles

Spectacle lenses have the advantage that they are easy to use. They can be removed from their case and placed on the face without much difficulty by most patients who need high plus corrections.

Spectacle prescriptions for aphakia can be dispensed in glass or plastic with full aperture or reduced aperture (lenticular) lenses. In full aperture high plus power lenses, the main difficulty arises from their weight and their bulbous appearance. No advantage is derived from the use of high index glass which saves centre thickness but may increase weight. Plastic lenses save weight but the range of prescriptions is limited and they are more susceptible to scratching than is glass. The cosmetic appearance of high plus plastic spectacle lenses gives an even greater bulbous appearance than the corresponding glass prescription.

To cut down the weight and reduce the bulbous appearance of high plus lenses of glass or plastics, reduced aperture lenses are available.

High plus spectacles have two main optical disadvantages - a large spectacle magnification giving rise to increased retinal image size and large prismatic effects giving rise to restrictions in the peripheral field of vision. For patients with bilateral aphakia, the enlarged retinal image size gives spatial disorientation The unilateral aphakic patient cannot be corrected by a high plus lens placed in front of the aphakic eye while the other, phakic, eye needs no or a very low power correction. The disparity of retinal image sizes is then too great for the brain to fuse the images and so binocular vision is not regained after cataract surgery. The usual method of prescribing spectacles for the unilateral aphakic patient is by assessing the useful vision or visual acuity in the phakic eye. If the visual acuity in this case is less than 6/18, the eye is given a balance lens but if it is higher than 6/18 (even if the aphakic eye has a visual acuity as high as 6/6 after correction), many practitioners take the view that it is advantageous to the patient to be corrected for distance with the phakic correction and a balance lens used in front of the aphakic eye. The enlargement of the retinal image size giving rise to spatial disorientationand the prismatic effect restricting the visual field, are not present in this method of prescribing. The prismatic effect restricting the field is not troublesome in close work such as reading because the visual field needed for reading is so much smaller than all the visual fields produced by lenticulated high plus lenses. The magnification provided by the high plus reading lens may well be beneficial to the elderly patient with failing vision. It can be seen that spectacles for the unilateral aphakic patient rarely give binocular vision.

This can be regained only with the refractive correction offered by contact lenses or intra-ocular lenses.

(b) Other Forms of Optical Correction

Contact lenses and intra-ocular lenses have the advantage that the spectacle magnification is reduced. With the small magnification produced by the contact lens or the intra-ocular lens, the brain usually can fuse the phakic and aphakic retinal images. Binocular vision can thus be regained after removal of the cataract. For the bilateral aphakic patient, the reduction of the spectacle magnification gives less spatial distortion. The reduction in the visual field is absent and the patient has almost as much visual field as in the pre-aphakic eye.

(i) The Hard Daily Wear Lens

The hard contact lenses prescribed for daily wear are PMMA, CAB, Polycon and other oxygen transmissive materials. Contact lenses should allow the cornea to acquire oxygen for metabolism. None of these materials has enough oxygen transmissibility in centre thickness needed for aphakia, to allow significant oxygen transport through the lens, so that all contact lenses made of these materials must have enough edge lift to allow oxygen for the cornea's metabolism to be transported via tear flow under the lens.

Most contact lens practitioners familiar with fitting contact lenses to patients with aphakia find that hard contact lenses are easy to fit. Well-designed lenses have adequate edge lift to provide good tear flow beneath the lens and the lenticular front optic keeps the weight and thickness of the lens to a minimum.

The main problem with hard contact lenses is that they must be inserted and removed daily and it is this practice which is often the limiting factor to success. When the patient is elderly and manual dexterity is failing, the enthusiasm or the ability to cope with hard contact lenses for daily wear is often missing.

Soft contact lenses for daily wear present the same problem of coping by the aphakic patient with insertion and removal. Daily wear soft contact lenses have the advantage that they are more comfortable to wear than the hard contact lenses but their insertion and removal is often as difficult, with the added problem that they tear or break more easily than the other daily wear lenses. In addition, the storage and cleaning regime for daily wear soft lenses, be it heat disinfection or chemical disinfection, is more complicated and expensive than hard lens regimens. Silicone rubber, a hydrophobic contact lens material with high enough oxygen permeability to have high oxygen transmissibility in high plus contact lenses, is coated with a hydrophilic material to allow comfortable wear but this coating soon wears off and there is then a build-up of tear components, such as mucin, on the lens surface. For this reason the lens must be removed at least once a week for cleaning. If the patient has to learn to do this for the once-a-week cleaning, it may as well be done on a daily basis and if so, the same problems may apply to silicone rubber contact lenses as to all the other daily wear lenses, that is the inability to handle, clean and store the lenses properly.

(ii) <u>The Intra-ocular Lens</u>

Intra- ocular lenses are still not popular in the United Kingdom. Out of some 38,000 cataract extractions per year performed through the National Health Service in England and Wales, only about 1% of patients have intra-ocular lenses inserted. (DHSS et al 1981). In the United States of America there were some 500,000 cataract extractions in 1980 (Choyce 1981) and the proportion of intra-ocular lenses inserted into aphakic eyes was 35%. Results indicate that there are still problems of techniques to be resolved by the surgeons as well as problems of poorly-designed lenses which may be made of impure materials. Other problems of the use of intra-ocular lenses have been attributed to residue left by the method of ethylene oxide sterilisation. The Food and Drug Administration (FDA) in the USA treats intra-ocular lenses as devices which need to be regulated. In the United Kingdom there is as yet no such regulation.

Optically, intra-ocular lenses afford the same if not a better answer than contact lenses to removal of the crystalline lens because the intra-ocular lens is placed very nearly in the same position as the patient's previous own crystalline lens and it may well be that once the problems of surgical techniques, sterility and design have been resolved, intra-ocular lenses will supersede extended wear contact lenses. At the moment, intra-ocular lenses are not regarded as trouble free.

(iii) <u>The Soft Contact Lens for Extended Wear</u>

The last option in contact lens correction is the extended wear soft contact lens. A contact lens that can be left on the eye of the patient with aphakia for, say, one to three months without interference would be a boon to the patient whose ability to handle and disinfect the lens is low.

CHAPTER IV

OPTICAL CORRECTION OF APHAKIA BY SPECTACLES AND SOFT CONTACT LENSES

Optical Correction of Aphakia by Spectacles and Soft Contact Lenses

(1) Introduction

Spectacles lenses for aphakia produce a change in retinal image size due to their high plus power, thickness and form. For patients with bilateral aphakia this produces spatial distortion. With unilateral aphakia the spatial distortion is outweighed by the suppression of the image in the aphakic eye because of the brain's lack of ability to fuse two vastly different retinal image sizes.

(2) Spectacle magnification

Spectacle magnification has two factors, the power factor P and the shape factor S. For distance vision for spectacle lenses the power factor is given:-

$$P = \frac{1}{1-aF'_v} \qquad \text{(IV.1)}$$

Where F'_v is the back vertex power of the spectacle lens and a is the positive distance in metres from the back vertex of the lens to the entrance pupil of the eye. High plus lenses should be dispensed with the back vertex distance as short as possible to reduce power magnification and increase the field of view. Back vertex distances of high plus spectacle lenses are usually in the region of 15 mm, while corresponding back vertex distance of the contact lens is taken to be 3 mm. From equation (IV.1) it can be seen that the shorter the back vertex distance for a given power the smaller the power magnification will be.

TABLE IV.3

SPECTACLE MAGNIFICATION OF HIGH PLUS SPECTACLE AND SOFT CONTACT LENSES

SPECTACLE LENS BVP (D)	TOTAL SPECTACLE LENS MAGNIFICATION FOR				TOTAL SPECTACLE MAGNIFICATION OF SOFT CONTACT LENS MATERIALS OF DIFFERING % WATER CONTENTS				
	GLASS		PLASTIC						
	FULL APERTURE	REDUCED APERTURE	FULL APERTURE	REDUCED APERTURE	40	50	60	70	80
+10.00	1.23	1.20	1.25	1.21	1.04	1.04	1.04	1.04	1.05
+12.00	1.31	1.24	1.30	1.25	1.05	1.05	1.05	1.06	1.06
+14.00	1.34	1.28	1.34	1.29	1.06	1.06	1.07	1.07	1.07
+16.00	1.41	1.33	1.41	1.35	1.07	1.08	1.08	1.08	1.09
+18.00	1.46	1.37	1.47	1.40	1.09	1.09	1.09	1.10	1.10
+20.00	1.51	1.42	1.51	1.51	1.10	1.10	1.10	1.11	1.12

TABLE (IV.3)

TABLE IV.2

Contact Lens BVP (D)	Water Content % Centre Thickness t(mm) Front Surface Power F_1 (D)										Shape Factor(S) for different water content materials %					Power Factor (P)
	40		50		60		70		80							
	t	F_1	t	F_1	t	F_1	t	F_1	t	F_1	40	50	60	70	80	a = 3 mm
+11.36	.21	65.77	.23	63.61	.27	61.42	.33	59.05	.40	56.81	1.01	1.01	1.01	1.01	1.02	1.03
+14.02	.23	68.22	.26	66.09	.31	63.83	.38	61.49	.47	59.17	1.01	1.01	1.01	1.02	1.02	1.04
+16.83	.23	70.97	.29	68.78	.35	66.45	.43	64.03	.53	61.73	1.01	1.01	1.02	1.02	1.02	1.05
+19.80	.27	73.83	.32	71.45	.38	69.28	.47	66.78	.60	64.30	1.01	1.02	1.02	1.02	1.03	1.06
+22.96	.29	76.79	.35	74.47	.42	72.11	.51	69.66	.66	67.09	1.02	1.02	1.02	1.03	1.03	1.07
+26.32	.31	79.85	.38	77.61	.45	75.19	.55	72.66	.73	70.00	1.02	1.02	1.02	1.03	1.04	1.08

SPECTACLE MAGNIFICATION OF HIGH PLUS SOFT CONTACT LENSES

TABLE (IV.2)

TABLE IV.1

SPECTACLE MAGNIFICATION OF HIGH PLUS GLASS AND PLASTIC LENSES

GLASS n = 1.523 SPECTACLE BVP (D)	POWER FACTOR P (a = 15 mm)	CENTRE THICK-NESS tmm x10		FRONT SURFACE POWER F_1 (D)		SHAPE FACTOR S		SPECTACLE MAGNIFICATION S x P	
		FULL	REDUCED	FULL	REDUCED	FULL	REDUCED	FULL	REDUCED
+10.00	1.15	94	40	12.00	13.51	1.07	1.04	1.23	1.20
+12.00	1.18	118	43	14.00	16.18	1.11	1.05	1.31	1.24
+14.00	1.21	124	53	14.00	16.18	1.11	1.06	1.34	1.28
+16.00	1.24	132	53	16.00	18.75	1.14	1.07	1.41	1.33
+18.00	1.27	124	55	18.00	21.18	1.15	1.08	1.46	1.37
+20.00	1.30	134	65	18.00	21.18	1.16	1.09	1.51	1.42
PLASTIC n = 1.4985									
+10.00	1.15	116	57	11.12	12.45	1.09	1.05	1.25	1.21
+12.00	1.18	116	63	12.75	14.15	1.10	1.06	1.30	1.25
+14.00	1.21	117	70	14.14	15.88	1.11	1.07	1.34	1.29
+16.00	1.24	139	75	15.56	17.44	1.14	1.09	1.44	1.35
+18.00	1.27	142	82	17.07	19.07	1.16	1.10	1.47	1.40
+20.00	1.30	123	89	19.10	20.57	1.16	1.16	1.51	1.51

TABLE (IV.1)

For distance vision the shape factor S for spectacle and contact lenses is given by Bennett (1966) (1968) as:-

$$S = \frac{1}{1-\frac{t}{n}F_1} \qquad \text{(IV.2)}$$

Where F_1 is front surface power, t is the centre thickness in metres and n is the refractive index of the spectacle lens.

This equation shows shape factor increasing as centre thickness and front surface power increase.

Table (IV.1) shows spectacle magnification of glass and plastics full aperture and lenticular spectacle lenses from +10.00D to +20.00D mounted at a distance of 15 mm from the entrance pupil of the eye. Details of centre thickness and front surface power were given by Mr. Crockford of U.K.O. Wiseman. From the corresponding refraction at the plane of the eye, the ocular refraction (K) which is the contact lens back vertex power, and the corresponding contact lens magnifications have been calculated for soft contact lenses of various water content and are shown in table (IV.2). The criteria for refractive index is shown in chapter (VII) and best form soft lens design in chapter (XII). Table (IV.3) summarises total spectacle magnifications found in Tables (IV.1) and (IV.2).

It is easy to calculate the numerical values of ocular refraction from spectacle refraction if the back vertex distance is known, and hence calculate the contact lens back vertex power, but these numerical values for high plus lenses very rarely apply in the clinical situation. Chaston and Fatt (1980) have shown that the back vertex power of a PMMA contact lens system is only within $\pm 3.00D$ of the ocular refraction when calculated from the spectacle refraction and the back vertex distance measurement.

In unilateral aphakia binocular vision cannot be restored unless retinal image are within about 12%

The ratio of spectacle magnifications between the two eyes will be taken as the ratio of the retinal image size in the corrected aphakic eye to that of the retinal image size in the corrected phakic eye. For an object at infinity the size of the image formed by the optical system is inversely proportional to the equivalent power of the system. Hence this ratio of spectacle magnification between the two eyes of the unilateral aphakic patient can be taken to be the equivalent power of the corrected phakic eye divided by the equivalent power of the corrected aphakic eye. If the assumption is made that the phakic eye needs no correction then this spectacle magnification can be expressed as:-

$$\frac{F_p}{F_a} = \frac{F_p}{F_s + F_e - dF_sF_e} \qquad \text{(IV.3)}$$

where F_p = equivalent power of the emmetropic phakic eye

F_a = equivalent power of the corrected aphakic eye

F_s = equivalent power of spectacle lens

F_e = equivalent power of the uncorrected aphakic eye

d = distance of 2nd principal point of lens to 1st principal point of eye

Taking Gullstrands simplified schematic eye of equivalent power of +60.48D and removing the crystalline lens will reduce this power to +42.74D. A +11.30D lens placed 12 mm from the cornea now corrects this eye. The equivalent power of this system then becomes +48.24D. If the phakic eye, for example, had the equivalent power of +60.48D this will mean that the retinal image size in the aphakic eye is larger by 60.48/48.24 or 1.25 than the retinal image in the phakic eye.

When this aphakic eye is corrected by a contact lens the ocular refraction is +13.07D. If the back vertex distance is taken to be 3 mm for this system the equivalent power of the eye corrected with the contact lens becomes +54.13D. Therefore the retinal image size ratio between the two eyes is 60.48/54.19 or 1.12. The percentage increase in power spectacle magnification between the two eyes has been reduced from 1.25 or 25% to 1.12 or 12% by using the contact lens system. This 12% disparity between the retinal image sizes is within the ability of the brain to fuse the images and so regain binocular vision.

(3) <u>Prismatic effects</u>

Another problem of high plus spectacle lenses is the effect which the prismatic effect of the lenses has on the field of view. The size of the aphakic field of view when corrected by spectacles is dependent upon the power and the aperture of the lens and its distance from the entrance pupil of the eye. The larger the aperture the larger the field, but the higher the power and the greater the distance of the lens from the eye's entrance pupil the smaller the field. Beyond 6 m the field is wide enough not to be troublesome by restrictions of the field imposed by the prismatic effect of the high plus lens, and at reading distances the small field of view needed for close work of reading presents the aphakic patient corrected by a spectacle lens with few problems, but at a distance of between ½ and 3 m this reduction in field is troublesome.

This reduction in field or scotoma is called the roving ring scotoma because it rotates as the head rotates and has the disturbing effect of causing objects seen by indirect vision outside the lens to disappear and suddenly appear within the peripheral field, the so called "Jack in the Box" effect. The normal monocular visual field is, according to Reed (1960) 100° laterally 60° superiorally and 75° inferiorally. Since the concern is with the peripheral field the entrance pupil field is considered below:-

Let the semi diameter of the spectacle lens $= y$

distance of the lens to the entrance pupil (E) $= s$

distance of the lens to the image of the entrance pupil E' $= s'$

Real field of view $= 2\theta$

$$\tan\theta = \frac{y}{s}$$

$$= \frac{yS}{1000}$$

$$S = S' - F$$

$$\tan\theta = \frac{y(S' - F)}{1000}$$

FIGURE (IV.2)

Pin cushion distortion of high plus lenses

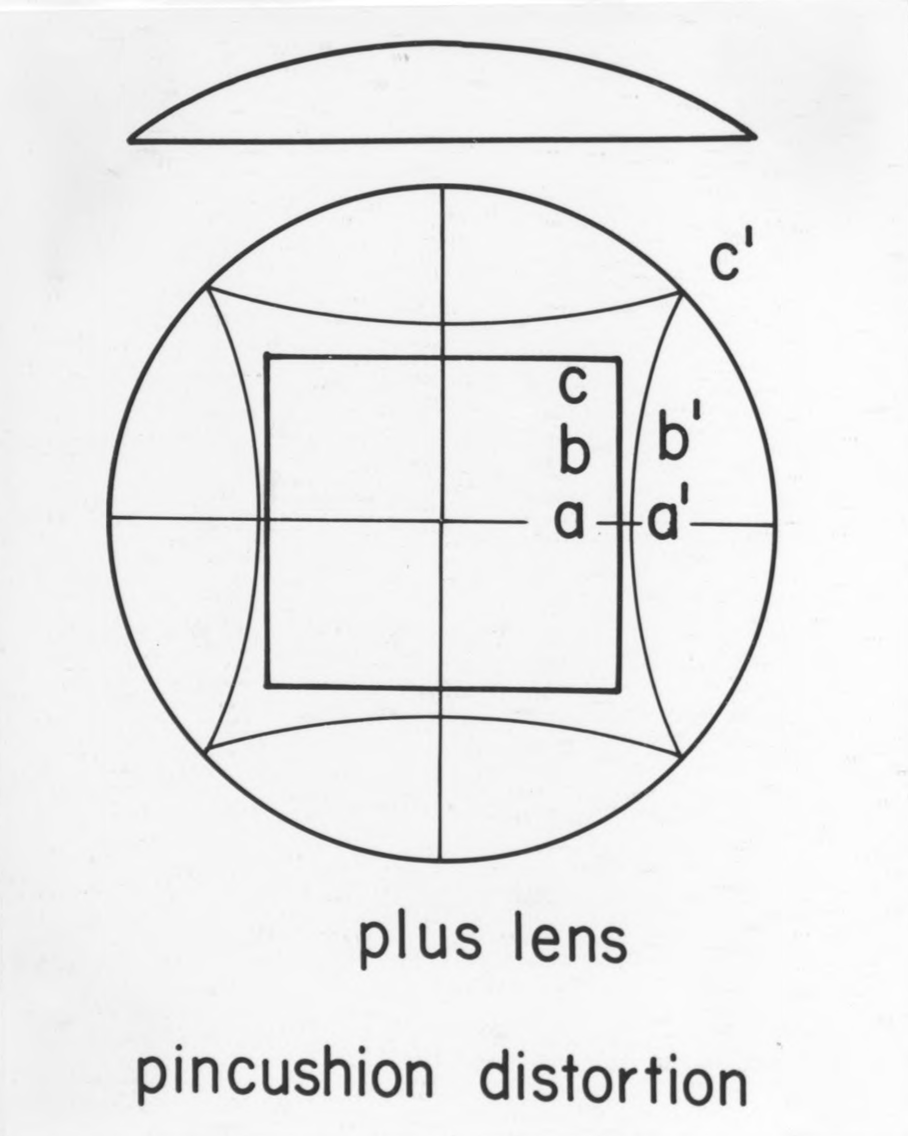


FIGURE (IV.2)

TABLE IV.4

ENTRANCE PUPIL FIELD OF VIEW WITH (°)

HIGH PLUS SPECTACLE LENSES

BVP (D)	Semi Aperture y (mm) of common spectacle lens or eye sizes used in aphakic corrections					
	14	17	20	21	22	23
+10.00	76.80	87.86	97.15	99.92	102.53	105.00
+12.00	74.86	85.80	95.11	97.88	100.70	103.00
+14.00	72.80	83.68	92.98	95.70	98.41	100.92
+16.00	70.70	81.48	90.76	93.55	96.21	98.73
+18.00	68.54	79.20	88.45	91.25	93.91	96.45
+20.00	66.32	76.85	86.05	88.84	91.51	94.05

TABLE (IV.4)

FIGURE (IV.1)

Entrance pupil field of view

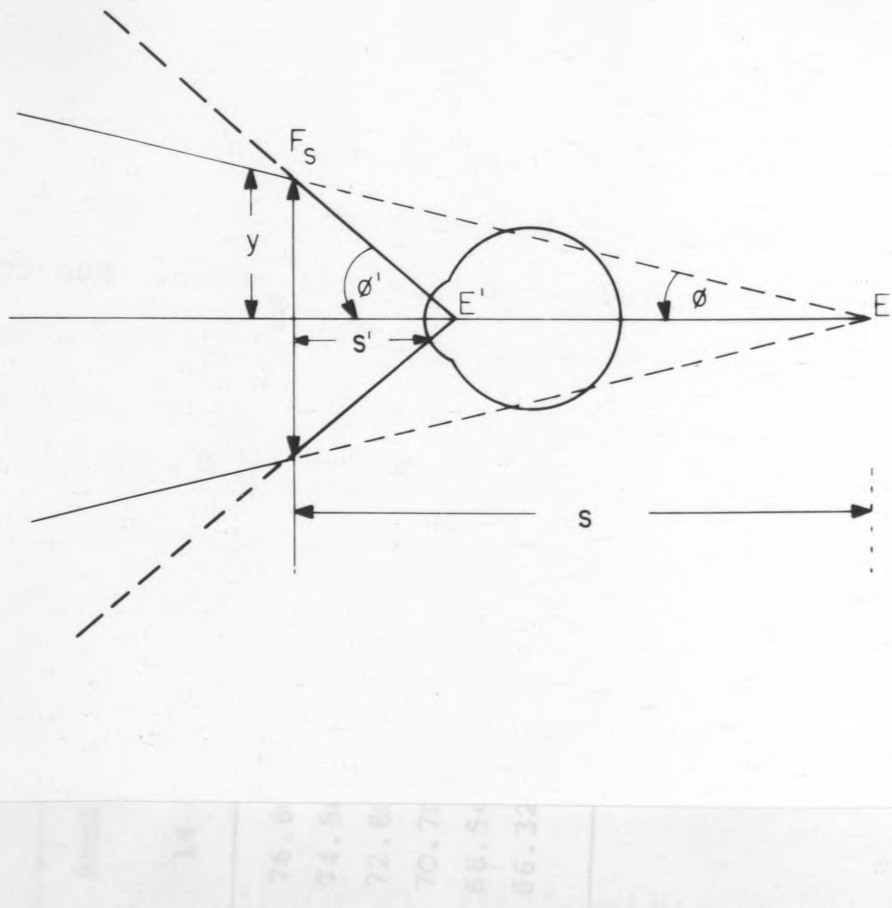


FIGURE (IV.1)

Figure (IV.1) shows the diagram for the entrance pupil field of view. Table (IV.4) shows values of the field of view of common spectacle eye sizes for lenses of back vertex powers from +10.00D to +20.00D, using a distance of 15 mm from the spectacle lens to the eye's entrance pupil.

With a soft contact lens correction for aphakia the entrance pupil field of view is the normal field of view as given by Reed (1960).

(4) Distortion

Another disconcerting effect is distortion of the image as seen through high plus spectacle lenses. Figure (IV.2) (Jalie 1977) illustrates this phenomenon. Due to the greater prismatic effect point c on the square object will be imaged further away than points a and b to give the pincushion effect as seen through high plus spectacle lenses. Prismatic effect is negligible with contact lenses because they rotate with the eye.

(5) Oblique astigmatism

Oblique astigmatism cannot be corrected for high plus lenses unless aspheric lenses are employed. Even then the spectacle correction is by no means perfect since the mean oblique error exhibited by an aspheric lens means that the subject is undercorrected by as much as 1.00D near the periphery of the field.

Difficulties also arise in translating the trial frame prescription to the final prescription. To ensure that high plus spectacles are free from errors of oblique astigmatism due to the angle of side of the trial frame, the angle of side of the final spectacle frame must be taken into consideration when the trial frame prescription is transposed to the manufacturers prescription. Because the trial contact lens occupies the same plane as the prescribed contact lens errors due to change in angle cannot occur.

(6) Chromatic aberration

The amount of chromatic aberration present in lenses is mainly a function of the material of the lens. In general the higher the refractive index the greater the dispersive power and hence dispersion, and the more the spread of coloured fringes around images - the phenomenon known as transverse chromatic aberration. Since the contact lens is normally centred on or near to the visual axis there is no or very little prismatic effect. Therefore the patient is not aware of chromatic aberration.

(7) Conclusion

The larger aperture of spectacle lenses compared with that of contact lenses produces a reduction in the field of view, poor marginal correction, and distortion of the image. These effects with soft contact lenses are negligible, since the eye corrected by a contact lens is always supposed to be looking close to the optical centre of the lens.

Soft contact lens systems like hard contact lens systems have the advantageous effect of decreasing the retinal image size found with high plus spectacle lenses and so reducing the spatial distortion in patients with bilateral aphakia. In patients with unilateral aphakia, binocular vision can be regained because of the reduction of the disparity of the retinal image size.

CHAPTER V

INTRODUCTION TO EXTENDED WEAR CONTACT LENS PROBLEMS

<u>Introduction to extended wear contact lens problems</u>

(1) <u>Introduction</u>

In extended contact lens wear there are six areas giving problems and needing investigation. The <u>first area</u> is the change in physical properties of soft lens other than dimension as the lens changes from room temperature at which it is stored, to the somewhat higher temperature of the anterior surface of the eye on which it will be placed. The <u>second area</u> needing investigation is the change in form of high plus lenses from the 'in air' dimension of the lens in the vial to the 'bent' or 'flexed' form that is taken up when the lens is placed upon the eye. High plus soft lenses change significantly in back vertex power on bending and this change has to be differentiated from the changes due to temperature differences. <u>The third area</u> needing investigaton is to find the oxygen needs of the cornea in extended contact lens wear, so that long and short term changes in the thickness and curvature of the cornea do not take place or are reduced to limits acceptable to the clinician. The <u>fourth area</u> needing investigation is the procedure for finding the dimensions of the high plus soft lens that will give the best visual acuity. Soft lenses fitted steeper than the corneal curvature do not give as high a visual acuity as lenses fitted flatter than the cornea. The <u>fifth</u> and sixth areas needing investigation are the dehydration of the soft lens and the spoilation of the lens in wear. The dehydration of the lens leads to further changes in back vertex power and spoilation leads sometimes to allergic eye responses and/or the frequent change of the soft lens for the patient.

(2) The Change in Intensive and Extensive Properties of Soft Lens Materials with Change in Temperature

It is important to know the physical changes in soft contact lens materials with temperature changes because as the soft lens is removed from the vial at a temperature of about 20°C, the lens changes as it is placed on the eye. The first task will be to determine the temperature of the anterior surfaces of the eye, such as the bulbar and palpebral conjunctival surfaces and the corneal epithelial surface. With the knowledge of the difference of the room and eye temperature, measurements of physical and dimensional changes of soft lens materials in this temperature range can be made. The changes in the physical parameters of most interest to the clinician are the change in refractive index, water content, thickness and the change in back and front radii as the lens is elevated from room to eye temperature. It is important to be able to calculate the change in back vertex power of high plus soft lenses from these changes in radii and to be able to differentiate the changes from those of 'bending' of the soft lens and/or inaccuracies in manufacturing.

(3) The 'Bending' of the Soft Lens on the Eye

The second area needing investigating is the 'bending' or 'flexing' of the soft lens upon the eye. High plus soft lenses fitted to patients with aphakia showed changes in back vertex power from the lens measurement 'in air' to that of the lens power measured on the eye (Chaston and Fatt 1980a). The amount of back vertex power change depends upon how flat or steep the soft lens has been fitted with respect to the corneal curvature. Soft lenses fitted steeper than the cornea gain more plus power in their vertex power when placed on the eye and soft lenses fitted flatter than the cornea lose plus power. As this change in back vertex power can be as much as a 3.00D loss of plus power in high plus soft lenses fitted 1 mm flatter than the corneal curvature, it is essential to be able to anticipate this change and make allowances for it when ordering from the manufacturer.

(4) <u>The Oxygen Needs of the Cornea</u>

The third area for investigation is to determine the oxygen needs of the cornea of the patient who needs high plus soft lenses. In all probability the patient will be aphakic but there will be the occasional phakic high hypermetrope who would also present for extended contact lens wear. Oxygen needs for daily wear have been determined by investigators such as Decker, Polse and Fatt (1978) by provoking the cornea into swelling and showing this swelling is a function of oxygen transmissibility of the soft lens or of oxygen tension at the cornea. Daily wear soft lenses with oxygen transmissibilities in the region of 5×10^{-9} (cm/sec) (mlO_2/ml x mm Hg) will yield an oxygen tension at the corneal surface in the region of 15 mm Hg. Although extended wear contact lenses have been used by patients for a number of years, the scientific criteria of oxygen needs of the cornea for extended wear have yet to be found.

(5) <u>The Best Fit Dimensions to Give Maximum Visual Acuity with the Soft Lens</u>

The fourth area of investigation is to determine the best fit dimensions of the back of the high plus soft contact lens that will give the maximum visual acuity. Soft lenses fitted steeper than the cornea tend to wrinkle and distort on movement when the patient blinks. This leads to an irregular astigmatic front surface is unable to be corrected by a regular astigmatic over-correction. Olsen and Sarver (1976) have shown that 38% water content spuncast lenses in the low minus range give the best visual acuity when fitted 0.3 to 0.44mm flatter than the cornea. Chaston (1979) found that high plus lenses of 75% water content fitted on average 0.3mm flatter than the cornea gave better visual acuity than 38% water content lenses fitted 1mm flatter than the cornea. It would seem that the lens should be fitted flatter than the cornea, but the question is: How much flatter?

(6) The Dehydration of the Soft Lens on the Eye

The fifth area needing investigation is the dehydration of the soft lens when it is worn upon the eye for extended periods of wear. With the dehydration there is a change in refractive index and a change in front radius and thus a change of back vertex power. In areas of the world with low humidity, this phenomenon occurs more frequently than in areas of high humidity. The nett effect of dehydration is the loss of plus power of the contact lens.

(7) Spoilation of the Soft Lens due to Surface Deposits

The sixth area of investigation needed is the spoilation of soft lenses giving discomfort and irritation, especially when the deposits are in the front surface and the lids rub over the deposits on blinking. Deposits and films on the back surface can lead to discomfort and corneal damage and if the deposits are large enough and placed in front of the pupil will give a reduction in visual acuity. Deposits often produce an allergic response such as giant papillary conjunctivitis and/or the red eye syndrome. However, if the deposits do none of the foregoing, it is probably because the clinician has seen them in time. Whether the lens has degenerated and given the patient trouble or whether the clinician has caught the problem in time, the nett result is the prescription of a new soft lens.

(7) Conclusion

The following chapters will deal with the effect of change of temperature on soft lens dimensions, the effects of lens bending or flexing on the eye and the accompanying change in back vertex power, the oxygen needs of the cornea for extended wear contact lenses and dimensions to give the best fit for maximum visual acuity. These data will be used to describe a 'best form' of soft contact lens for extended wear. Finally, a method will be suggested of using a high plus PMMA contact lens set as a diagnostic fitting lens and these PMMA parameters will be transposed to the required soft lens parameters to be ordered from the manufacturer.

CHAPTER VI

ROOM AND EYE TEMPERATURE DIFFERENCES

Room and eye temperature differences

(1) Introduction

In a study of dimensional changes of soft contact lenses when raised from room temperature to eye temperature, it is necessary to know the temperature of the lens in the eye. And, as the high plus soft lens has about the same central thickness as the human aphakic cornea (0.50 to 0.65 mm), it can be assumed that like the cornea (Freeman and Fatt 1973) there is only a very small temperature gradient across the soft lens and the cornea. A search of the literature revealed that such data had not been reported previously.

Measurement of temperature in living systems is difficult because the measuring device must not interfere with the living processes. Furthermore, the measuring device must not by its presence change the temperature of the system. Eye temperatures are particularly difficult to measure. Hill (1963, 1964, 65., a., b.) and his co-workers made the first attempts to measure the corneal temperature under a contact lens. They restricted themselves to scleral lenses. Their data are suspect because the temperatures they reported are probably lower than those that exist in the absence of the probe.

The temperature of a soft contact lens on the eye is difficult to measure because the probe cannot be embedded in or made part of the lens without affecting its wearibility. A solution to the problem lies in the use of a radiometric technique.

All warm bodies radiate electromagnetic energy in the infrared wavelength range. The amount of energy emitted is a function of the temperature of the surface, the nature of the surface and the temperature of the surrounding surfaces. Under controlled conditions, it is possible to calibrate a collector of infrared light so that it measures the temperature of the emitter.

Mapstone (1968) pioneered the use of an infrared collector, known as a bolometer, for measuring corneal temperature. This procedure was used here to measure the temperature of soft contact lenses on the eye. A conventional, small-bead thermistor was slipped under the closed eyelid to measure temperature of the lens in the closed eye condition.

(2) <u>Procedure</u>

The bolometer used in this study was the Dermo-Therm of Raytek Inc designed for measuring skin temperature. Reproducibility is $0.5^{o}C$ with a sensitivity of $0.25^{o}C$. The area whose temperature is measured is circular with a diameter of 4 mm when the sensor is held 2 cm from the eye. The instrument has an internal calibration that can be made moments before measuring eye temperature. In addition, an external calibration was made against a black body radiator and a water surface according to the procedure of Hamano et al (1969).

A further calibration was made by measuring the temperature of a hydroxyethyl methacrylate (HEMA) soft contact lens of 38% water content using the Dermo-Therm unit; the lens was on a brass model eye whose temperature of about 34°C was accurately known from a thermistor bead sealed in the brass near the centre of the cornea. This calibration showed that the Dermo-Therm could measure the temperature of the soft contact lens to within 0.2°C.

The sensor head, a cylinder about 8 cm in diameter and 10 cm long with a cone of apex height 4 cm at the sensing end, was fastened to the post of a Thorpe slit lamp in the position normally occupied by the microscope. When the light source in the sensor head was turned on, the observer could see a lighted spot on the cornea or lens where the measurement was being made. The subject's head was in the normal position in the slit lamp. The observer moved the sensor cone to within 1 cm of the cornea and then adjusted its position so the lighted spot was at the centre of the pupil.

The temperature of the bare cornea in the open eye was measured on a series of six subjects ranging in age from 25 - 55 years. The temperature of the contact lens in the open eye was measured on another series of 3 subjects, ranging from 20 - 55 years. In each case, the bare cornea temperature was measured and then the lens temperature a few minutes after inserting the lens in the eye. Corneal temperature was also measured after removal of the lens to show that temperature equilibrium was reached within a few minutes after either removing or inserting the lens.

To measure the temperature under the lid of a closed eye wearing a soft contact lens, the lid was closed over a thermistor probe embedded in the end of a length of 0.2 mm diameter polyethylene tubing (Yellow Springs Instrument Model 511). Temperature was read from a Yellow Springs Instrument Teletherm Model 46TUC. Measurement of the temperature under the lid was also made by a thermistor embedded in an ophthalmic conformer ring. The ring pressed the thermistor against the palpebral conjunctiva to the point of discomfort. The resultant blepharospasm yielded an under-the-lid temperature that represented an uncomfortable contact lens with frequent tight closure of the lid.

(3) Results

The bare cornea temperatures were all in the range

33° to $36^{\circ}C$ which agrees with the results reported by Mapstone (1968). The variation in bare cornea temperature from subject to subject as also reported by Mapstone made it imperative to compare contact lens and corneal temperature on the same eye.

The temperature of the soft contact lenses was never more than $0.5^{\circ}C$ below that of the bare cornea. Temperature of soft contact lenses in the open eye was in the range 34° to $35^{\circ}C$.

(4) Discussion

The temperatures reported previously are all for the front surface of the body being measured. Hamano et al (1969) showed that the temperature sensed by the type of bolometer used here is that of the tear surface. Water is almost opaque to infrared radiation; therefore such radiation originating deep in the cornea or contact lens does not reach the surface. Hamano et al (1969) showed that the normal, 7μ-thick tear layer on the cornea and contact lens will absorb 80 percent of the infrared radiation coming from below the surface, so the temperature measured by the bolometer is very close to the tear temperature. Rosenbluth and Fatt (1977) showed that the temperature of the posterior surface of the cornea is within $0.2^{\circ}C$ of that of the anterior surface;

therefore for clinical purposes the whole cornea can be considered to be at the same temperature. This situation also exists for the soft contact lens because the lens is usually thinner than the cornea and the thermal conductivity of the lens material is close to that of the cornea (Hamano 1972). The conclusion is that the temperature measurements reported here are a good representation of the corneal and soft contact lens temperature in the open eye.

The temperature in the conjunctival sac of an eye wearing a soft contact lens was 35.6°C, as measured by a thermistor probe pushed into the sac before the eye closed. When the eyelids squeezed down over an ophthalmic conformer ring, the thermistor embedded in the ring indicated that the palpebral conjunctiva temperature was 36.5°C. The increase in temperature observed during this blepharospasm probably results from increased blood flow to the conjunctival capillary bed when the lid muscles are strongly contracted.

The higher temperature of a contact lens under a closed lid - 1° to 4°C greater than in the open eye - is as expected because the vascular bed in the lid brings blood at body temperature to the palpebral conjunctiva. The combination of blood flow and thermal resistance of the tarsal plate and adjacent tissues keeps the cornea and contact lens in a closed eye near to body temperature.

This will enhance bacterial growth or other biological phenomena sensitive to temperature in the case of extended wear lenses compared with such effects in daily wear lenses.

CHAPTER VII

THE EFFECT OF HEAT ON REFRACTIVE INDEX, WATER CONTENT AND CENTRE THICKNESS OF HYDROGEL MATERIALS

The Effect of Heat on Refractive Index, Water Content and Centre Thickness of Hydrogel Materials

(1) Introduction

The effect of heating water in the range of 25^{o} to 30^{o}C is to reduce its refractive index from 1.3334 to 1.3330. (Handbook of Chemistry & Physics 1948). Therefore, if on heating a hydrogel material there is an observed increase in refractive index, this must be due to loss of water from the material because a dehydrated hydrogel has a refractive index closer to the dry material and the refractive index of dry polymers is higher than that of water. Manufacturer's data always shows a higher refractive index for the dehydrated lens material compared with the hydrated lens. If the contact lens loses water on heating, it must become thinner. Therefore, the effect of heating on refractive index and centre thickness is linked. (Fatt and Chaston 1980).

(2) The Effect of Temperature on Refractive Index and Water Content

(a) Procedure

Parallel-faced discs about 0.5mm thick were lathe cut with a diamond tool from dry hydrogel lens blanks supplied by manufacturers of the blanks. The faces were polished with hydrogel lens polish. The discs then were hydrated in sterile isotonic saline (unpreserved 0.9% sodium chloride solution) for several days at room temperature. Some discs were

TABLE (VII.1)

Refractive index of soft contact lens materials

Hydrogel Contact Lens Data

(1) Manufacturer	(2) Trade Name	(3) Polymer	(4) Manufacturer's Water Content	(5)* Refractive Index at 21°C, mean	(6)* Refractive Index at 35°C, mean	(7) Difference in means	(8)** Student's t	(9)* Refractometer water content at 21°C, %	(10)* Refractometer water content at 35°C, %	(11)*** Difference in means	(12)** Student's t
CLM London	Sauflon 85	PVP-MMA	80	1.35835	1.36800	0.00965	1.68	80	78	2.7	5.90
Duragel UK	Duragel 78.5	PVP-MMA	78.5	1.37310	1.37636	0.00320	2.56	74	73	1.8	4.09
Duragel UK	Duragel 73.5	PVP-MMA	73.5	1.37632	1.38096	0.00464	9.89	73	70	2.5	9.73
Duragel UK	Duragel 72	PVP-MMA	72	1.37209	1.37583	0.00370	11.9	75	73	2.1	8.72
Duragel UK	Duragel 60	PVP-MMA	60	1.39727	1.40375	0.00648	2.23	61	58	3.5	11.6
Global Vision UK	Permalens (UK)	HEMA-MA-PVP	72	1.36763	1.37129	0.00366	4.88	78	76	2.8	7.86
Cooper Vision (USA)	Permalens (USA)	PVP-MMA	71	1.37518	1.38183	0.00665	5.78	73	70	3.7	5.73
Smith & Nephew (UK)	Snoflex 50	HEMA	50	1.41163	1.42513	0.0135	17.7	54	48	6.4	17.1
Frontier	Hydro-Marc 43	HEMA-MMA	43	1.43479	1.43671	0.00192	4.68	43	42	0.9	4.75
Hydrocurve	Hydrocurve II	HEMA-Acrylamide-MA	45	1.43676	1.43880	0.00204	3.06	42	41	0.8	2.80
Smith & Nephew (UK)	Hydron	HEMA	38	1.43569	1.43904	0.0031	2.03	43	42	1.1	2.59

* Data are from 6 measurements on a single sample.

** For 6 correlated measurements degrees of freedom = 5, significance levels for Student's t are: 80%, t = 1.48; 90%, t = 2.02; 95%, t = 2.57; 99%, t = 4.03.

*** Difference in water content means were taken before round-off of data in columns 9 and 10.

TABLE (VII.1)

weighed dry and then again after being water saturated if the manufacturer's water content statement was ambiguous. The refractive index of each disc was measured at room temperature (21°C) in a Bausch and Lomb Abbe refractometer Model 3L. A yellow filter was fastened to the prism light entrance to give refractive indexes near the conventionally used sodium light (589 nm). Each sample was measured six times; each time the sample was returned to its vial and then replaced in the refractometer.

After the room temperature measurements were completed, all samples in their vials were placed overnight in a thermostat at 35°C. Water at 35°C from a thermostated bath was pumped around the refractometer prisms. The refractive index of each sample then was measured at 35°C by the same procedure used at room temperature.

(b) Results

Results are shown in Table (VII.1).

The observed increase in refractive index with increase in temperature is statistically significant at the 99% confidence limit or better for six out of the 11 samples tested. For one sample, the increase is significant at the 97% confidence level, another sample is significant at the 92% level and two are significant at the 80% level. Only one sample, a material of high water content, showed an increase in refractive index that was statistically

FIGURE (VII.1)

Measure of water content as a function of refractive index at 21^{O}C of soft lens materials...

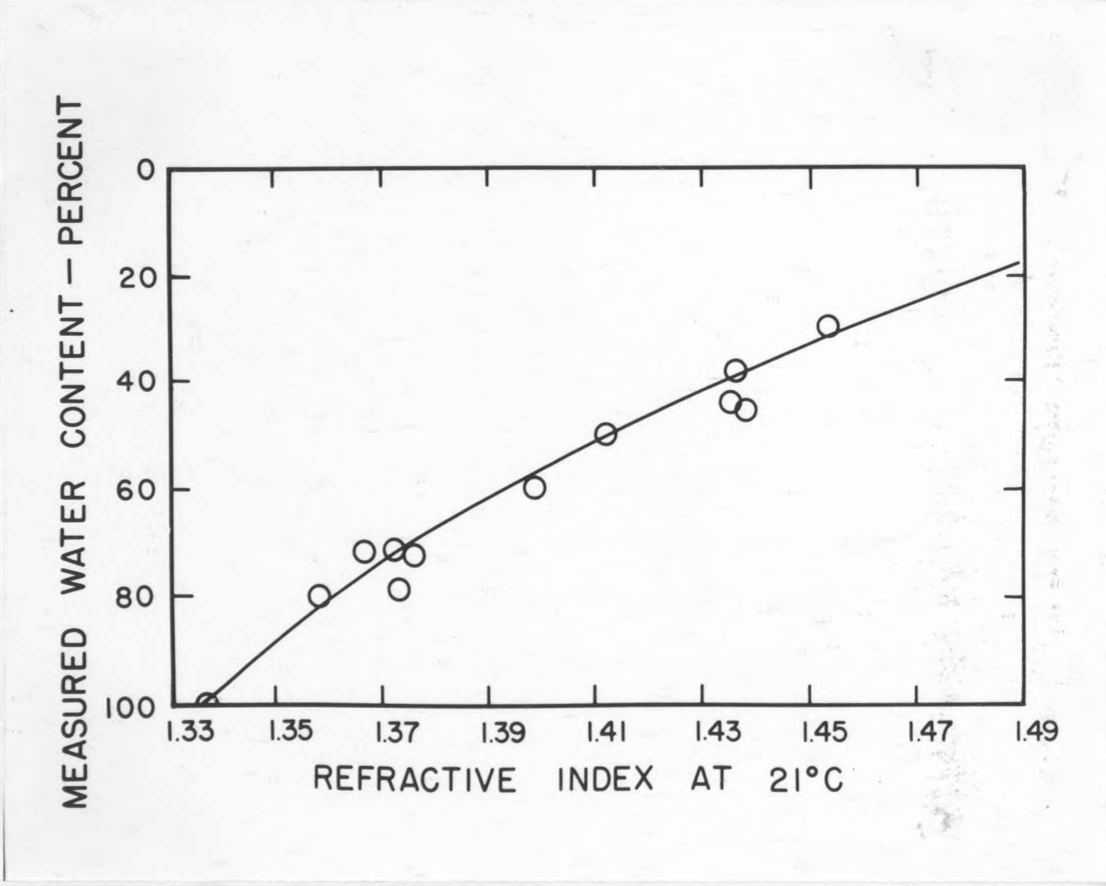


FIGURE (VII.1)

unsatisfactory.

The observed decreases in water content (as read from the refractometer solids scale) with increase in temperature are statistically significant at the 99% confidence limit for 10 out of 13 samples. For the other three, the decrease is significant at the 95% confidence level.

The water content was calculated from the solids content scale in the refractometer by subtracting from 100. Although this scale is intended to be used for simple solutions of such materials as sucrose and glucose, it appears to be applicable to hydrogels.

Figure (VII.1) shows the data points of measured refractive index plotted against manufacturer's water content. The curve was taken from the Handbook of Chemistry and Physics (1948) and shows the relationship of refractive index to water content for a simple sugar solution. If a least squares line is fitted to the data, the equation for the line is:-

$$n_{21} = 1.51331 - 1.91 \times 10^{-3} WC_{man} \qquad \text{(VII.1)}$$

where n_{21} is the measured refractive index at $21^{\circ}C$ and WC is the manufacturer's water content in percent, the correlation coefficient is -0.980. The least squares fit line for measured refractive indices at $21^{\circ}C$ and $35^{\circ}C$ as a function of water content at $21^{\circ}C$ and $35^{\circ}C$ are given by the following equations:-

FIGURE (VII.2)

Measured water content as a function of manufacturer's water content...

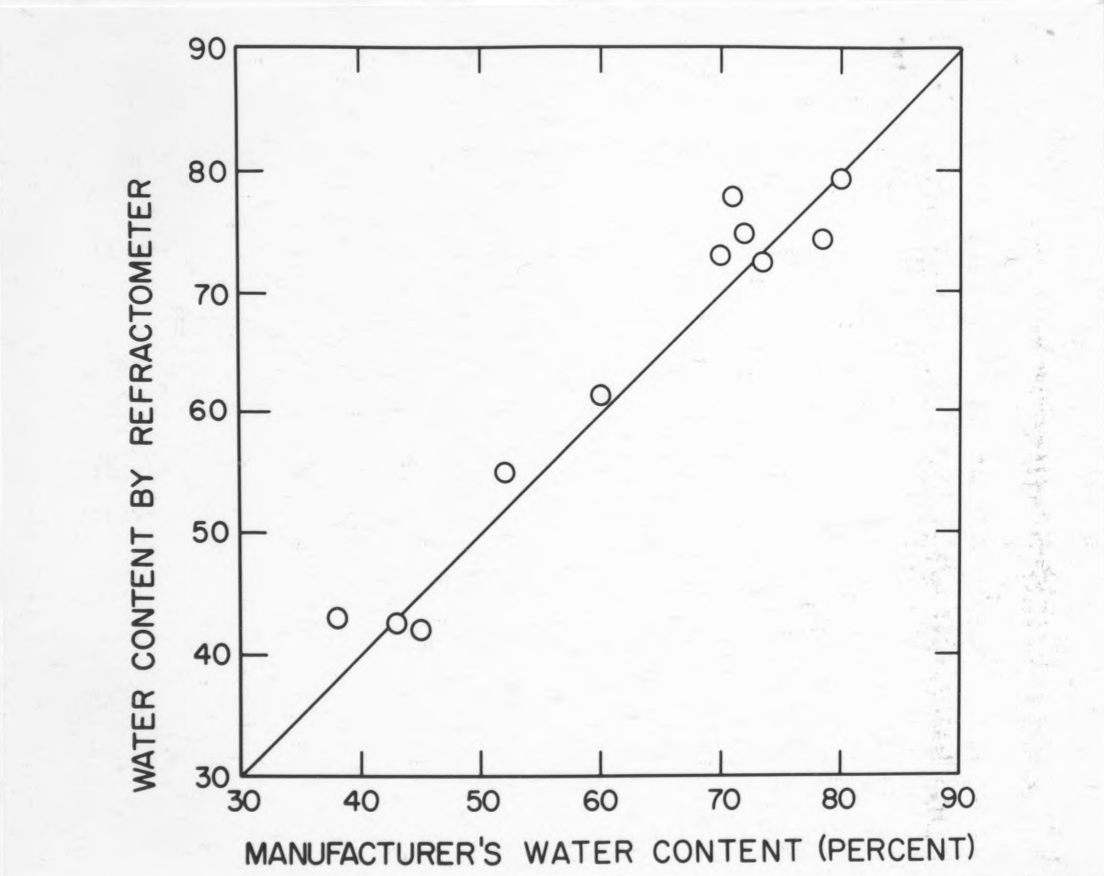


FIGURE (VII.2)

$$n_{21^{o}C} = 1.52003 - 1.98 \times 10^{-3} WC_{21^{o}C} \qquad \text{(VII.2)}$$

when the correlation coefficient is -0.999.

$$n_{35^{o}C} = 1.51932 - 1.96 \times 10^{-3} WC_{35^{o}C} \qquad \text{(VII.3)}$$

The correlation coefficient is -0.999.

Figure (VII.2) shows the manufacturer's water content as a function of the measured water content at $21^{o}C$ and the least squares fit is given by the equation:-

$$WC_{man} = -0.82609 + 0.99438 WC_{meas\ at\ 21^{o}C} \qquad \text{(VII.4)}$$

when WC is in percent. The correlation coefficient is 0.977.

The least squares fit for the water content at $35^{o}C$ as a function of the water content at $21^{o}C$ is given by the equation:-

$$WC_{35^{o}C} = 0.98647 WC_{21^{o}C} - 1.41648 \qquad \text{(VII.5)}$$

from the data in columns 9 and 10 of Table (VII.1).

The correlation coefficient is 0.995.

And similarly, the least squares fit for the refractive index at $35^{o}C$ as a function of the refractive index at $21^{o}C$ is given by the equation:-

$$n_{35^{o}C} = 0.04070 + 0.97152 n_{21^{o}C} \qquad \text{(VII.6)}$$

from the data in columns 5 and 6 of Table (VII.1).

The correlation coefficient is 0.993.

(c) Discussion

Calculations can be made two ways to find the refractive index of a hydrogel material at $35^{o}C$ if the water content is known at $21^{o}C$. First equation (VII.2) can give the refractive index at $21^{o}C$ ($n_{21^{o}C}$). Then equation (VII.5) can be used to find the water content at $35^{o}C$ ($WC_{35^{o}C}$). This figure can be submitted in equation (VII.3) to find the refractive index at $35^{o}C$ ($n_{35^{o}C}$). But ($n_{35^{o}C}$) can be found also from equation (VII.6). If such cross calculations are made, results of the calculations after the second decimal place will not be the same. This is because the least squares fit lines do not have perfect correlation. It is best to use the equations with the highest correlation coefficient. The reduction in centre thickness upon raising the temperature of a hydrogel contact lens from room temperature to $35^{o}C$ can be calculated by assuming that upon heating a hydrogel, only water leaves the lens and thereby increases the solids content. The fractional reduction in centre thickness is a linear contraction and equals one-third of the fractional volume contraction caused by the loss of water. For example, if a cube of hydrogel material weighing 1g has 75% water content at room temperature, it will have 0.75g water and 0.25g solids. Upon raising the temperature to $35^{o}C$, the water content as measured by the refractometer or gravimetrically will be 72.5% and the solids content will be 27.5%.

However, the solids remain behind as the water leaves the cube so the cube still has 0.25g solids. For a cube that is 72.5% water and has 0.25g solids, there must be 0.659g water. The loss of water has been 0.09g. Each linear dimension of the cube has decreased by about 0.03cm. Since the hydrogel will have a density close to that of water, the cube was about 1 cm on each side at room temperature and at 35^{o}C now has a length of 0.97cm or a loss in thickness of 3%.

Equation (VII.5) was used to find the water content of the various water content hydrogels and the above calculations carried out by means of the following equation to find the percentage decrease in centre thickness when the temperature is raised from 21^{o}C to 35^{o}C:-

$$=33.3\left\{WC_{21} \times 10^{-2} - \left(\left(\frac{1 - WC_{21} \times 10^{-2}}{1-0.98647\times10^{-2}WC_{21}+1.41648\times10^{-2}} \right) - (1 - WC_{21} \times 10^{-2}) \right) \right\} \quad \text{(VII.7)}$$

The results of the calculation are shown in figure (VII.3).

Refractive index changes of hydrogels are small, ranging from 0.1% to 7% for 14^{o}C change in temperature. Take the extreme case of a hydrogel lens of 80% water and back vertex power F'_{v} of +18.00D, back radius of 8.60 mm and centre thickness of 0.50 mm.

The refractive index at 21°C given by equation (VII.2).

$$n_{21^\circ C} = 1.52003 - 1.98 \times 10^{-3} WC_{21^\circ C}$$

$$n_{21^\circ C} = 1.36163$$

The front radius r_1 can be found from:-

$$r_1 = (r_2) \times (n - 1) \times (r_2 \times F'_v - (1 - n))^{-1} + t - (t \div n)$$

$$= 6.15 \text{ mm} \qquad \text{(VII.8)}$$

The water content at 35°C can be found from equation (VII.8):-

$$WC_{35^\circ C} = 0.98647 WC_{21^\circ C} - 1.41648$$

$$= 77.50\%$$

And the refractive index at 35°C can be found from equation (VII.3):-

$$n_{35^\circ C} = 1.51932 - 1.96 \times 10^{-3} WC_{35^\circ C}$$

$$= 1.36742$$

Keeping the parameters of thickness, front and back radii constant but changing the refractive index the back vertex power F'_v at 35°C can be found from:-

$$F'_v = ((r_1 \times (n - 1)^{-1}) - (t \div n))^{-1} + ((1 - n) \div r_2) = +18.35\text{D}$$

$$\text{(VII.9)}$$

There has been an increase in power of 0.35D.

Changes of power are smaller for lenses of lower water content and/or low power. Such small changes do not

FIGURE (VII.3)

Percentage decrease in linear dimensions of a hydrogel contact lens with increase in temperature from 21^{o}C to 35^{o}C as a function of water content at 21^{o}C...

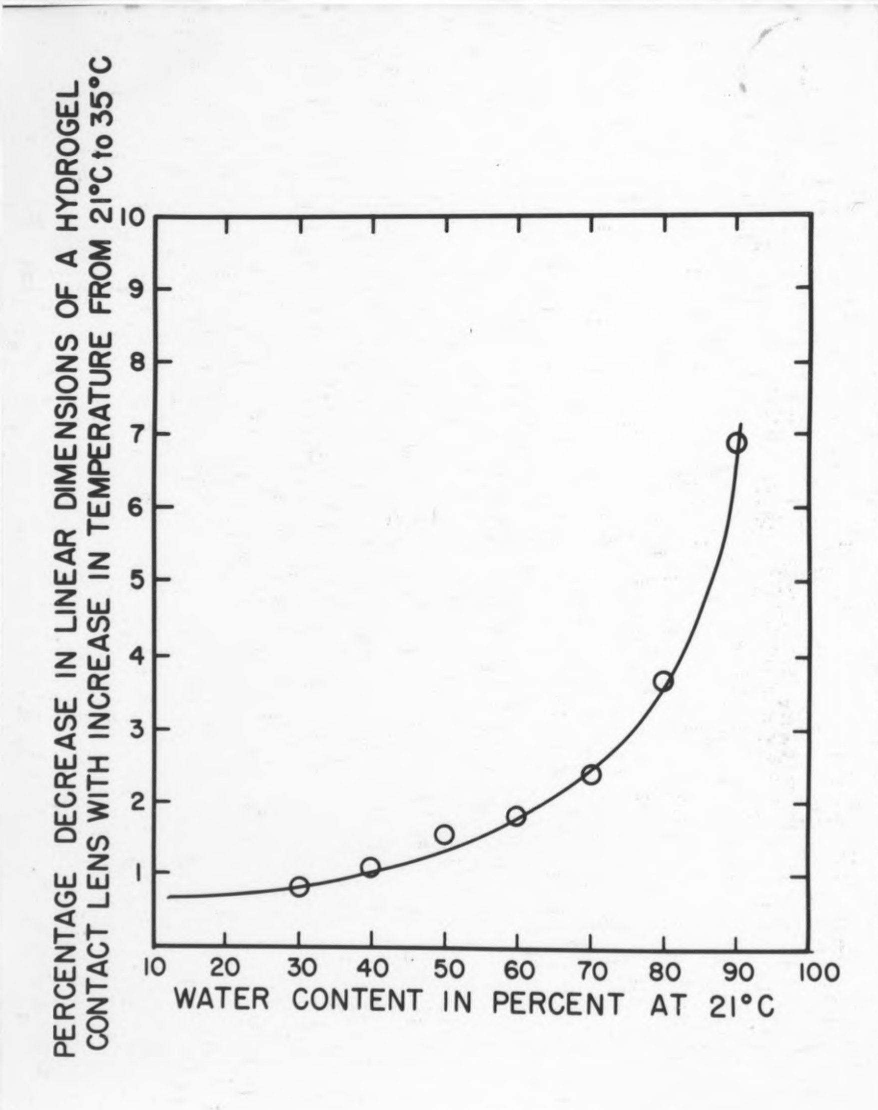


FIGURE (VII.3)

affect contact lens fitting. Therefore the effect of temperature on refractive index is not important.

(3) <u>The Effect of Temperature on Centre Thickness</u>

Reducing centre thickness as shown in figure (VII.3) will change lens power. In the extreme case of an 80% hydrogel of +18.00D back vertex power, with back radius of 8.60mm, front radius of 6.15mm and centre thickness at 21°C of 0.50 mm. The reduction in centre thickness from 21°C to 35°C is shown in figure (VII.3) as 3.7%. Therefore the centre thickness t becomes:-

$$t = 0.50 \times \frac{96.3}{100} = 0.48 \text{ mm}$$

From the back vertex power equation the new back vertex power will be +17.99D. Therefore the nett change in back vertex power from refractive index and centre thickness changes will be:-

$$+0.35 - 0.01 = 0.34\text{D}$$

Therefore the nett change is +0.34D.

(4) <u>Conclusion</u>

These changes of refractive index and centre thickness except for the extreme cases of lenses of high water content and high plus power are negligible, so that any effects of temperature on lens optics of clinical importance will be in the change in curvature of the back and front surface.

CHAPTER VIII

THE EFFECTS OF HEAT ON BACK AND FRONT RADIUS OF HIGH PLUS SOFT CONTACT LENSES

The Effects of Heat on Back and Front Radius of High Plus Soft Contact Lenses

(1) Introduction

Soft contact lenses made of hydrogel materials lose water upon heating. The loss of water causes a change in front and back radii of these lenses. Two experiments were performed, one to find the change in back radius of high plus hydrogel contact lenses and the other to find the change in front radius of these lenses.

(2) The Change in Back Radius with Temperature

(a) Procedure

Twenty-nine high plus lenses of water contents between 38% and 78% were measured in the range 20°C to 37°C in the cell described by Chaston (1978).

The contact lens was submerged in isotonic saline while under examination by a Haag-Streit keratometer with modified mire boxes. The mire pattern was replaced by a solid sheet of metal with a central hole about 2 mm in diameter. The two small bulbs in each of the mire boxes were replaced by one 6V, 6W automobile light bulb placed directly behind the central hole. Small lighted dots were seen on the lens surface when viewed through the telescope. The keratometer was adjusted until the left and right dots were superimposed and the radius was then read from the instrument scale.

FIGURE (VIII.1)

Keratometer reading on PMMA surfaces
in water as a function of
radiuscope reading in air

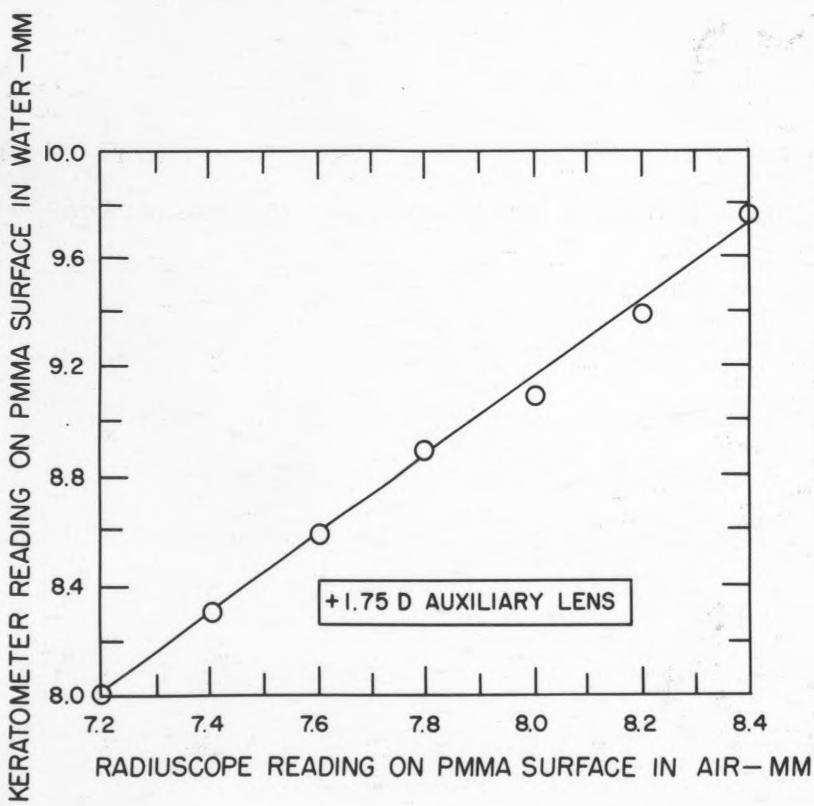


FIGURE (VIII.1)

For some lenses the dots could not be superimposed within the scale adjustment possible on the Haag-Streit instrument. In these cases, an auxiliary lens was placed in front of the telescope objective. The adjustable telescope eyepiece was kept at a fixed position for all readings.

As explained by Chaston (1978) the keratometer is designed to measure radius of a surface in air. Recalibration of the instrument is necessary for the measurement of submerged surfaces in saline with the use of auxiliary lenses in front of the telescope objective. Recalibration was made by measuring a set of PMMA buttons with concave hemispherical surfaces with the AO radiuscope and then measuring these same surfaces in saline with the keratometer with the auxiliary lens in front of the telescope objective. The radiuscope was previously calibrated with polished steel balls whose diameter was measured to 0.003 mm by a machinist's micrometer. Figure (VIII.1) is an example of the recalibration of the keratometer, in this case for a +1.75D lens in front of the telescope. The straight line was fitted by the least squares method and the equation is:-

$$r = 0.69K + 1.68 \qquad \text{(VIII.1)}$$

where r is the radius of the surface in mm and K is the keratometer reading in mm.

The temperature of the isotonic saline solution bathing the contact lens in the cell was increased slowly by exposing the solution surface to a 100W light bulb, in a reflector, placed about 10cm above the cell. Temperature was monitored by a calibrated thermistor bead sealed into the inner wall of the cell. The thermistor resistance was read out on a Sinclair Model PDM35 digital voltohmmeter.

In most cases, readings of back radius as a function of temperature were made as the saline solution cooled from 37°C to room temperature. This cooling period, 30 to 60 minutes, was sufficiently slow to allow the lens to maintain the same temperature as the surrounding solution. In a few cases, the readings were taken over the temperature increase portion of the cycle by turning off the light bulb and covering the cell, thereby allowing it to remain at constant temperature, within +2°C, for 5 to 10 minutes. These data were in agreement with those taken during the cooling cycle.

The effect of water temperature on the keratometer reading was determined to be negligible by observing in the keratometer telescope the dots formed by a polished concave aluminium surface of radius of curvature 8.47mm as the water temperature was increased from 20°C to 37°C. Over this temperature range, the keratometer reading changed by no more than 0.01mm - well within the reproducibility of a

TABLE (VIII.2)

Steepening in back radius of high plus soft lenses with increase in temperature from 20 to 35°C with respect to percentage water content...

Water Content %	Temperature Coefficients $\Delta r_2 / \Delta T^{\circ}C$	Approximate steepening Room to eye temperature (mm)
38	-0.015	0.20
60	-0.034	0.50
71	-0.043	0.60
78	-0.074	0.70

The temperature coefficients of expansion of soft lens materials and their approximate steepening from room to eye temperature as found by the direct measurement of back radius.

FIGURE (VIII.2)

Steepening in back radius of high plus soft lenses with increase in temperature from 20 to 35^{O}C with respect to percentage water content

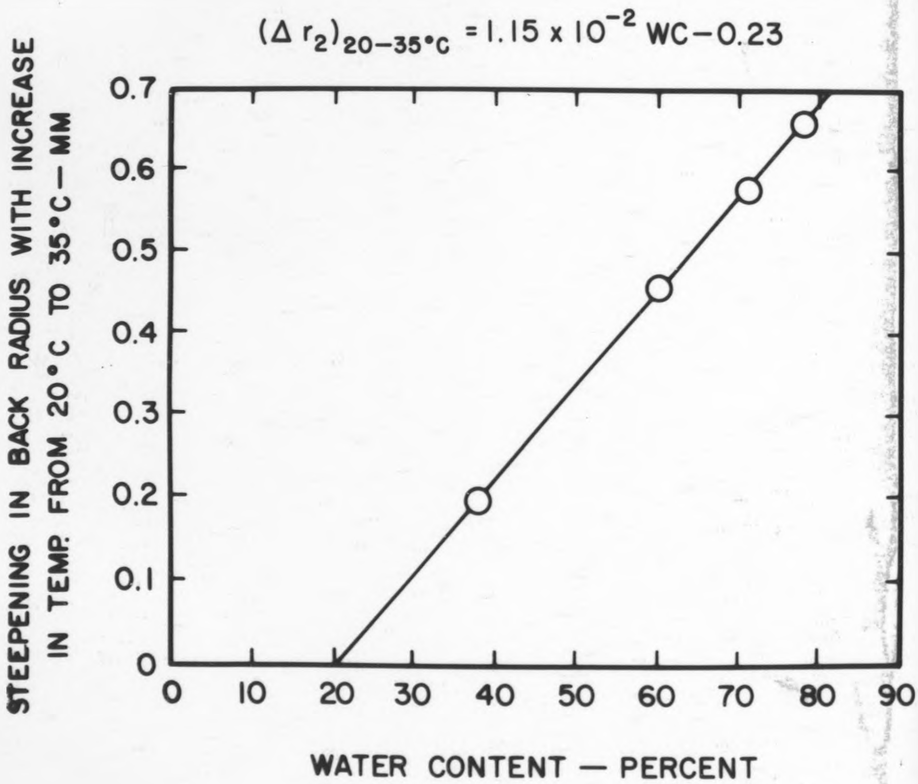


TABLE (VIII.1) cont...

LENS MATERIAL	WATER CONTENT %	GIVEN BACK RADIUS (mm) r_2	GIVEN BACK VERTEX POWER (D) F'_v	CHANGE IN BACK RADIUS (mm) Δr_2	THROUGH ^{o}C	$\Delta r_2 / \Delta T^{o}C$	MEAN $\frac{\Delta r_2}{\Delta T^{o}C}$	MEAN CHANGE IN BACK RADIUS FROM 20 to 35^{o}C (mm)
*PVP PMMA DURAGEL 78	78	8.10	+13.50	-0.69	15.00	-0.046		
*PVP PMMA DURAGEL 78	78	8.10	+13.50	-0.93	15.00	-0.062		
*PVP PMMA DURAGEL 78	78	8.70	+13.00	-0.77	15.00	-0.051		
PVP PMMA DURAGEL 78	78	8.40	+16.00	-0.63	8.5	-0.074	-0.074	-0.69
PVP PMMA DURAGEL 78	78	8.80	+18.00	-0.37	8.5	-0.044		
PVP PMMA DURAGEL 78	78	8.00	+15.50	-0.35	8.5	-0.041		
PVP PMMA DURAGEL 78	78	8.30	+13.00	-0.16	8.5	-0.019		
PVP PMMA DURAGEL 78	78	8.70	+18.00	-0.46	8.5	-0.054		

* - Denotes data taken from "The Influence of Temperature on the Base Curve of High Plus Soft Contact Lenses" (Table 3) Int Contact Lens Clinic (1981) January/February 1 43 p.49.

TABLE (VIII.1) cont.

TABLE (VIII.1) cont...

LENS MATERIAL	WATER CONTENT %	GIVEN BACK RADIUS (mm) r_2	GIVEN BACK VERTEX POWER (D) F'_v	CHANGE IN BACK RADIUS (mm) Δr_2	THROUGH ^oC	$\Delta r_2 / \Delta T^oC$	MEAN $\frac{\Delta r_2}{\Delta T^oC}$	MEAN CHANGE IN BACK RADIUS FROM 20 to 35^oC (mm)
*HEMA MA PVP PERMALENS UK	71	F4	+13.25	-0.48	15.00	-0.081		
*HEMA MA PVP PERMALENS UK	71	F4	+13.25	-0.87	15.00	-0.058	-0.055	-0.60
*HEMA MA PVP PERMALENS UK	71	E3	+14.50	-0.60	15.00	-0.040		
*HEMA MA PVP PERMALENS UK	71	E4	+15.00	-0.58	13.50	-0.043		

cont...

* - Denotes data taken from "The Influence of Temperature on the Base Curve of High Plus Soft Contact Lenses" (Table 3) Int Contact Lens Clinic (1981) January/February 1 43 p.49.

TABLE (VIII.1) cont.

TABLE (VIII.1) cont...

LENS MATERIAL	WATER CONTENT %	GIVEN BACK RADIUS (mm) r_2	GIVEN BACK VERTEX POWER (D) F'_v	CHANGE IN BACK RADIUS (mm) Δr_2	THROUGH ^{o}C	Δr_2 $/\Delta T^{o}C$	MEAN $\frac{\Delta r_2}{\Delta T^{o}C}$	MEAN CHANGE IN BACK RADIUS FROM 20 to 35^{o}C (mm)
PVP PMMA DURAGEL 66	60	8.70	+16.50	-0.32	8.5	-0.038		
PVP PMMA DURAGEL 66	60	8.40	+18.00	-0.32	8.5	-0.038		
PVP PMMA DURAGEL 66	60	8.10	+13.75	-0.43	8.5	-0.051		
PVP PMMA DURAGEL 66	60	8.60	+16.50	-0.36	8.5	-0.042		
PVP PMMA DURAGEL 66	60	8.20	+17.50	-0.12	8.5	-0.014	-0.034	-0.048
PVP PMMA DURAGEL 66	60	8.60	+16.00	-0.69	8.5	-0.081		
PVP PMMA DURAGEL 66	60	7.80	+16.75	-0.21	8.5	-0.025		
PVP PMMA DURAGEL 66	60	8.00	+14.50	-0.25	8.5	-0.029		
PVP PMMA DURAGEL 66	60	8.80	+18.50	-0.11	8.5	-0.013		
PVP PMMA DURAGEL 66	60	8.25	+17.25	-0.07	8.5	-0.008		

cont...

TABLE (VIII.1)

Change in back radius of high plus soft contact lenses with heating..

LENS MATERIAL AND DIMENSIONS								
LENS MATERIAL	WATER CONTENT %	GIVEN BACK RADIUS (mm) r_2	GIVEN BACK VERTEX POWER (D) F'_v	CHANGE IN BACK RADIUS (mm) Δr_2	THROUGH ^{o}C	$\Delta r_2 / \Delta T^{o}C$	MEAN $\frac{\Delta r_2}{\Delta T^{o}C}$	MEAN CHANGE IN BACK RADIUS FROM 20 to 35^{o}C (mm)
*HEMA	38	7.75	+13.00	-0.27	15.00	-0.018		
*HEMA	38	7.75	+13.00	-0.33	15.00	-0.022		
*HEMA	38	7.80	+14.00	-0.23	15.00	-0.015		
*HEMA	38	7.80	+16.00	-0.15	15.00	-0.010	-0.015	-0.20
*HEMA	38	8.10	+12.50	-0.24	15.00	-0.016		
*HEMA	38	8.70	+12.50	-0.23	15.00	-0.015		
*HEMA	38	8.70	+17.50	-0.14	15.00	-0.009		

cont....

* - Denotes data taken from "The Influence of Temperature on the Base Curve of High Plus Soft Contact Lenses" (Table 3) Int Contact Lens Clinic (1981) January/February 1 43 p.49.

keratometer scale setting.

(b) Results

Results are shown in Table (VIII.1). The change from 20°C to 35°C as a function of water content is shown in figure (VIII.2) and the least squares fit is given by the equation:-

$$(\Delta r_2)_{(20-35)} = 1.15 \times 10^{-2} WC - 0.23 \qquad \text{(VIII.2)}$$

when Δr_2 is the change in back radius from 20°C to 35°C and WC is the water content in per cent at 20°C. From this graph, it can be seen that the back radius of high plus soft lenses of 38% water content steepen by approximately 0.20 mm from room to eye temperature and that 55%, 60%, 71% and 78% water content high plus lenses steepen approximately 0.30, 0.50, 0.60 and 0.70 mm respectively from room to eye temperature. Table (VIII.2) shows the temperature coefficients of expansion of soft lens materials tested and their approximate steepening from room to eye temperature.

(3) The Change in Front Radius with Temperature

(a) Introduction

It would be expected from physical principles that the change in front radius would be proportional to the front radius and similarly the change in back radius would be proportional to the back radius.

Stated mathematically this is:-

$$\frac{\Delta r_1}{\Delta r_2} = m \frac{r_1}{r_2} \qquad \text{(VIII.3)}$$

when Δr_1 = change in front radius in millimetres on heating

Δr_2 = change in back radius in millimetres on heating

r_1 = front radius in millimetres at room temperature

r_2 = back radius in millimetres at room temperature

m is a constant.

Equation (VIII.3) can be expressed in a different way by saying that the front and back radius change in the same proportion and this can be expressed mathematically as:-

$$\frac{r_1}{r_2} = \frac{r_1'}{r_2'} \qquad \text{(VIII.4)}$$

when r_1' = front radius in millimetres at elevated eye temperature

r_2' = back radius in millimetres at elevated eye temperature

It is easier to use equation (VIII.4) because the components of $\frac{\Delta r_1}{\Delta r_2}$ are smaller than the components

TABLE (VIII.4)

Calculation of constant m on heating high plus soft lenses... (cont. of Table VIII.3)

Lens No	$\frac{r_1}{r_2}$	$\frac{r_1'}{r_2'}$	m
1	.80	.81	.99
2	.78	.78	1.00
3	.77	.78	.99
4	.78	.69	.99
5	.83	.84	.99
6	.77	.79	.97
7	.81	.81	1.00
8	.94	.94	1.00
9	.77	.77	1.00
10	.88	.89	.99
11	.82	.82	1.00
12	.88	.86	1.02
13	.82	.83	.99
14	.85	.85	1.00
15	.82	.85	.96
16	.89	.90	.99
17	.82	.83	.99
18	.79	.86	.92*
19	.85	.83	1.02
20	.81	.81	1.00
21	.84	.84	1.00

All data m = 0.99 SD 0.02

* - If No. 18 is omitted m = 0.99 SD 0.01

TABLE (VIII.3)

LENS NO	ROOM TEMPERATURE		ELEVATED TEMPERATURE	
	BACK RADIUS r_2 (mm)	FRONT RADIUS r_1 (mm)	BACK RADIUS r_2' (mm)	FRONT RADIUS r_1' (mm)
1	8.02	6.38	7.70	6.20
2	8.15	6.38	7.83	6.08
3	8.93	6.85	8.50	6.63
4	8.82	6.87	8.46	6.66
5	8.66	7.20	8.54	7.18
6	8.95	6.88	8.26	6.52
7	8.25	6.72	8.04	6.49
8	8.46	7.95	8.21	7.73
9	8.29	6.38	8.18	6.28
10	7.80	6.87	7.73	6.91
11	8.62	7.10	8.40	6.87
12	7.65	6.72	7.52	6.43
13	8.90	7.29	8.32	6.87
14	7.75	6.55	7.35	6.25
15	7.66	6.31	7.10	6.03
16	7.56	6.71	7.23	6.52
17	8.55	7.05	7.73	6.43
18	8.26	6.55	7.56	6.51
19	7.79	6.60	7.48	6.20
20	8.90	7.24	8.37	6.78
21	8.21	6.86	7.79	6.56

Measurement of back and front radii of high plus soft lenses of 60% water content at room temperature (approximately 20°C) and eye temperature (approximately 35°C) of $\frac{r_1}{r_2}$ or $\frac{r_1'}{r_2'}$ and errors of measurement will be magnified in the calculation of $\frac{\Delta r_1}{\Delta r_2}$ compared with errors of measurement used for calculation of $\frac{r_1}{r_2}$ or $\frac{r_1'}{r_2'}$

(b) Procedure

To confirm the proportional hypothesis, the following experiment was performed. Twenty-one high plus lenses of 60% water content were measured by the same method for measuring change in back radius of high plus soft contact lenses. The lenses were measured at room temperature of about 20°C and then elevated to a temperature of between 32°C and 36°C. Recording of the exact temperature is not important because the temperature coefficient $\Delta r_2 / \Delta T^{\circ}C$ has been found for different water content materials and is shown in equation (VIII.2).

The results from these measurements at room and elevated temperatures are shown in Table (VIII.3). The mean value for m was 0.99 with a SD of 0.01 when one value of m = 0.92 was omitted and the mean value for m when all data was used was 0.99 with a SD of 0.01 (see Table (VIII.4)).

It can be seen that:-

$$\text{Therefore } \frac{r_1}{r_2} = m.\frac{r_1'}{r_2'} \qquad \text{(VIII.5)}$$

when m = 1

(4) Discussion

This experiment shows that on heating hydrogel materials, the front and back radius change in the same proportion - that is:-

$$\frac{\Delta r_1}{r_1} = \frac{\Delta r_2}{r_2} \qquad \text{(VIII.6)}$$

It is probable that the linear dimensions in diameter (OD) and centre thickness (t_c) also change in the same proportion and that on heating an unstressed lens, the change in the extensive properties of radius, diameter and centre thickness change as:-

$$\frac{\Delta r_1}{r_1} = \frac{\Delta r_2}{r_2} = \frac{\Delta OD}{OD} = \frac{\Delta t_c}{t_c} \qquad \text{(VIII.7)}$$

(5) Conclusion

This means back vertex power for high plus lenses will show a higher plus back vertex power with elevated temperature and minus lenses will show a higher minus back vertex power with elevated temperatures in an unstressed soft lens.

CHAPTER IX

THE EFFECTS OF BENDING HIGH PLUS SOFT LENSES

The effects of bending high plus soft lenses

Many hypotheses have been put forward to explain the effect of flexure or bending of a soft lens on the eye. Wichterle's (early '60s) was one of the first. His approach was through the consideration of the interplay of internal stresses as the lens was deformed. Bennett (1976) arrived at a similar result by assuming a constant lens volume, an unchanging centre thickness and a spherical front surface if the back surface was spherical. Wichterle calculated the change in effective power, ΔF, whereas Bennett calculated the change in back vertex power $\Delta F'_v$. Wichterle's change in effective power ΔF is shown in equation (IX.1); Bennett's change in back vertex power $\Delta F'_v$ is shown in equation (IX.2). In these equations t is the centre thickness, r_2 is the original back radius and r_2' is the new back radius of the flexed or bent lens. The F term in equation (IX.1) is in the dimensions of dioptres. Bennett in a summary of Wichterle's paper states that Wichterle himself pointed out that this F term in his equation was so small that the entire second part of his equation could be ignored.

$$\Delta F = 270t \left[\frac{1}{(r_2')^2} - \frac{1}{(r_2)^2} \right] + 0.7tF \left[\frac{1}{(r_2')} - \frac{1}{(r_2)} \right] \qquad \text{(IX.1)}$$

$$\Delta F'_v = -300t \left[\frac{1}{(r_2')^2} - \frac{1}{(r_2)^2} \right] \qquad \text{(IX.2)}$$

The difference in sign between these two equations occurs because Wichterle considered the effective power change from a surface radius r_2 to a plane surface whereas Bennett considered the back vertex power change from a plane surface to a surface of radius r_2. These equations give power changes that do not differ by more than 10 per cent and the change in effective power will be similar to the change in back vertex power.

Kaplan (1966), Baron (1975) and Sarver (1976) suggested an equal change in front and back radius as the lens flexed. If the contact lens was considered to be spherical with concentric surfaces then $r_1 = r_2 + t_c$, where r_1 and r_2 are the radii of the front and back surfaces respectively and t_c is the central thickness. On flexure, the new front and back radii become r_1' and r_2' and the relationship $r_1' = r_2' + t_c$ holds. If the centre thickness remains constant, then this relationship can be expressed as -

$$r_2' = r_2 - r_1 + r_1' \qquad \text{(IX.3)}$$

Strachan (1973) proposed that the front and back radii changed by the same proportion and expressed this relationship by the equation -

$$r_2' = r_2 r_1'/r_1 \qquad \text{(IX.4)}$$

A similar hypothesis was presented by Holden et al (1976) based on the work of Wallace-Williams and Magabilen. Weissman and Zisman (1979) give Smith's analysis of the constant arc length hypothesis, which simplifies to Strachan's hypothesis in the case of plus lenses and nearly so in the case of minus lenses.

Holden (1976) also discussed the Wallace-Williams and Magabilen invarient normals hypothesis based on beam bending theory. This hypothesis calls for the normals to the surface to remain normal during bending and to remain of constant length. Smith, in the Weissman and Zisman paper (1979) gave the following equation for this hypothesis -

$$r_2' = \frac{y'^2 + \left((r_1'^2 - y'^2)^{\frac{1}{2}} - (r_1' - t_c)\right)^2 - t_y^2}{2t_y - 2\left((r_1'^2 - y'^2)^{\frac{1}{2}} - (r_1' - t_c)\right)} \qquad \text{(IX.5)}$$

where y' is the flexed hemichord length and t_y is the lens thickness at the hemichord length from the centre.

Smith, quoted in Weissman and Zisman (1979) proposed a constant change in saggital depth for each surface during flexure. This can be expressed as -

$$r_2' = \frac{r_1'^2 - r_1^2}{r_1^2 / r_2} + r_2 \qquad \text{(IX.6)}$$

Weissman and Zisman (1979) assumed a powered tear lens under a soft lens and calculated the new back radius r_2' from -

$$r_2' = \frac{(1 - n) + 0.3375}{\left[P_e - \dfrac{(n - 1)/r_1'}{1 - (t_c\,(n - 1)/nr_1')} - \dfrac{0.3375}{r_c} \right]} \qquad \text{(IX.7)}$$

where 1.3375 is taken as the index of refraction of tears and n is the index of refraction of the soft lens, r_c is the corneal radius and P_e is the power of the contact lens on the eye.

Bibby (1980) proposed a strain free boundary model and compared predicted and measured findings of lenses of back vertex power from -6.00D to +10.00D to assess lens bending effects in the back vertex power range of -20.00D to +20.00D. Bibby assumed the back of the soft lens conformed to the shape of the cornea, and that the centre thickness of the lens was constant. He assumed also that when the lens was on the eye the back surface of the lens was in a state of compression and that the front surface was in a state of elongation and in between these two surfaces there exists a surface which did not possess compression or elongation - a strain free neutral surface. Because this surface is strain free the distance between two points along this boundary will remain constant.

A discussion of power changes of a soft contact lens when placed on the eye centres around two points. First, is there a powered tear lens under the soft contact lens?

Second, what relationship describes the bending or flexing of a soft contact lens when placed on the eye? The experiments described below provide a basis for choosing among the various hypotheses already presented or for selecting a new one.

PROCEDURE

Fifteen high plus lenticulated soft lenses of given back radius between 7.50mm and 8.70mm and water contents ranging from 38-78% were studied.

Two kinds of lens radius measurements were required in this study. First it was necessary to measure the unflexed or unbent front and back radius of each lens. These radii represent lens geometry before the lens is placed on the eye. The second set of radius measurements were made on the lens in place on a PMMA dome that simulated the cornea. The unflexed lens radii were measured by means of a modified Haag-Streit keratometer and wet cell described previously by Chaston (1973). The light bulbs normally used in the Haag-Streit instrument were replaced by automobile bulbs. The mires were replaced by plates with a central circular aperture (about 2mm in diameter) large enough to image the line filament of the bulbs. The keratometer was calibrated for measurement of concave surfaces in saline by means of a series of concave PMMA buttons of known radius in air. See Chapter (VIII) for details. A +1.25D auxiliary lens was placed in front of the keratometer telescope so that the match of the mire images would be on the scale of the instrument. The keratometer reading for each button in saline was plotted against the known button radius in air. The linear plot was fitted with a least square line. From this relationship, any keratometer reading on a soft contact lens in the wet cell could be converted to the radius of the surface in air.

The radii of the surfaces of a lens on the simulated eye were measured in air. To calibrate the keratometer for these measurements, the keratometer reading for a series of PMMA domes, each of known radius, was plotted against the known dome radius. A least squares straight line was fitted to the data. This relationship allowed keratometer readings to be converted to radius of the surface.

When the back surface of the lens on the simulated eye was observed through the front surface of the lens, the radius in air as calculated from the keratometer was an 'apparent' radius and not the 'real' back surface radius. The 'real' back surface radius was calculated from the apparent radius by means of equivalent mirror theory (Bennett 1961).

Centre thickness of each lens was measured with the radiuscope by focussing on a PMMA dome steeper than the soft lens back radius and then on the front surface of the lens placed on the dome. These measurements gave 'real' thickness. Back vertex power in air, F'_V, was calculated from the front and back radius (as measured in the wet cell), centre thickness and the refractive index given by

TABLE (IX.1) cont.

Lens Number	Front radius (mm) In air	On 7.32 dome	On 7.77 dome	On 8.20 dome	Calculated back vertex power (D)** In air	On 7.32 dome	On 7.77 dome	On 8.20 dome
1	6.39	6.21	6.52	-	+11.66	+11.83	+11.82	-
2	6.23	6.08	6.30	-	+14.81	+14.15	+14.93	-
3	6.50	6.46	6.51	-	+11.67	+ 8.89	+11.62	-
4	6.61	6.31	6.65	-	+12.50	+10.84	+10.57	-
5	6.58	6.23	6.39	-	+11.97	+10.95	+12.39	-
6	6.57	6.16	6.45	-	+12.20	+11.73	+11.81	-
7	6.34	6.19	6.47	-	+11.75	+10.53	+10.89	-
8	6.40	6.21	6.38	-	+10.92	+10.36	+11.41	-
9	6.62	-	6.55	-	+14.40	-	+12.27	-
10	7.25	-	6.64	6.94	+12.29	-	+10.22	+10.86
11	6.95	-	6.71	6.74	+13.50	-	+ 9.89	+12.39
12	6.98	6.28	-	7.14	+13.35	+10.66	-	+ 8.53*
13	6.87	-	6.86	6.81	+13.33	-	+ 7.78*	+10.85
14	7.27	6.57	6.82	7.20	+11.01	+ 6.83	+ 7.60	+ 7.16*
15	6.67	6.39	6.48	6.98	+12.93	+ 8.66	+10.76	+ 8.98*

* - rejected values
** - using the dome radius as the new back radius

TABLE (IX.1) cont.

TABLE (IX.1)

Bending of high plus soft contact lenses...

Lens Number	Lens Specification	% Water Content	Refractive Index	Centre Thickness (mm)	Back radius (mm) In air	On 7.32 dome	On 7.77 dome	On 8.20 dome
1	7.75/+13.50	38	1.43	.39	7.56	7.34	7.80	-
2	7.80/+15.00	38	1.43	.60	7.65	6.99	7.70	-
3	7.80/+12.50	50	1.41	.50	7.76	7.34	7.79	-
4	7.80/+13.00	50	1.41	.60	8.01	7.27	7.75	-
5	7.80/+13.00	66	1.39	.55	8.00	7.32	7.75	-
6	7.80/+13.00	66	1.39	.57	8.02	7.30	7.79	-
7	7.80/+13.25	78	1.37	.55	7.71	7.25	7.73	-
8	7.50/+12.25	78	1.37	.50	7.69	7.29	7.77	-
9	8.40/+12.75	38	1.43	.63	8.20	-	7.81	-
10	8.70/+12.00	50	1.41	.62	8.97	-	7.74	8.21
11	8.30/+13.00	50	1.41	.58	8.73	-	7.82	8.28
12	8.70/+13.00	66	1.39	.66	8.86	7.38	-	8.19
13	8.40/+13.00	66	1.39	.47	8.76	-	7.90	8.17
14	8.70/+12.00	78	1.37	.45	9.08	7.32	7.84	8.25
15	8.40/+13.25	78	1.37	.52	8.45	7.26	7.85	8.26

the manufacturer.

The soft lenses were placed on simulated corneas that were PMMA domes of 7.32mm, 7.77mm and 8.20mm radius. The front and back radius of each lens was calculated from the keratometer readings.

RESULTS

Results are shown in Table (IX.1). The first eight lenses shown in this table, with measured unflexed back radius between 7.56mm and 8.02mm, would not 'bend' onto the 8.20mm dome without showing an air bubble between the back of the soft lens and the dome. These soft lenses also showed distorted mire images from the front surface of the soft lens as well as two distorted images close together from the back surface of the soft lens and the dome surface. Similarly, not all of the flatter (8.20mm to 9.08mm) soft lenses would 'bend' onto the 7.32mm dome without giving distorted and noncoaxial keratometer readings. The first eight soft lenses shown in Table (IX.1) gave clearer mire images than the other seven. All of the lenses showed only two sets of mire images from the soft lens on the dome. One image came from the front surface of the soft lens, the other from the contact lens back surface/dome interface.

Measured back radii of the lenses shown in Table (IX.1) are in close agreement with the radius of the dome. The differences between the dome radius and the measured back

FIGURE (IX.2)

The change in back vertex power of high plus soft lenses on bending with respect to the change in back radius

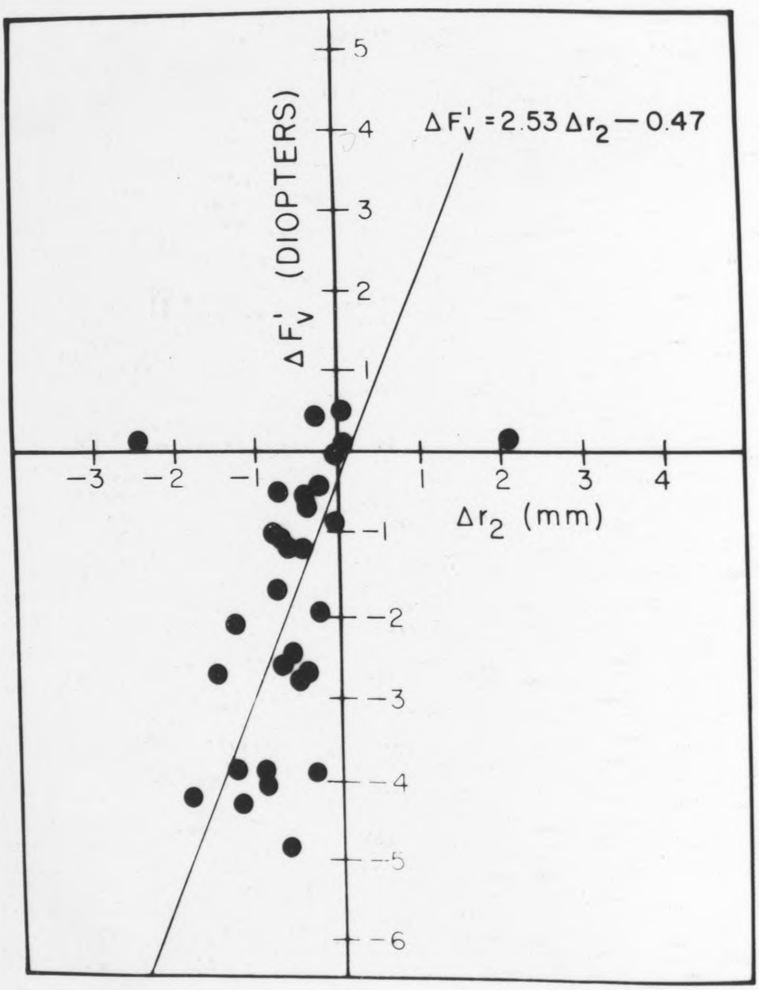


FIGURE (IX.2)

FIGURE (IX.1)

The difference between dome radius and measured back radius showing a normal distribution of spread of measurements

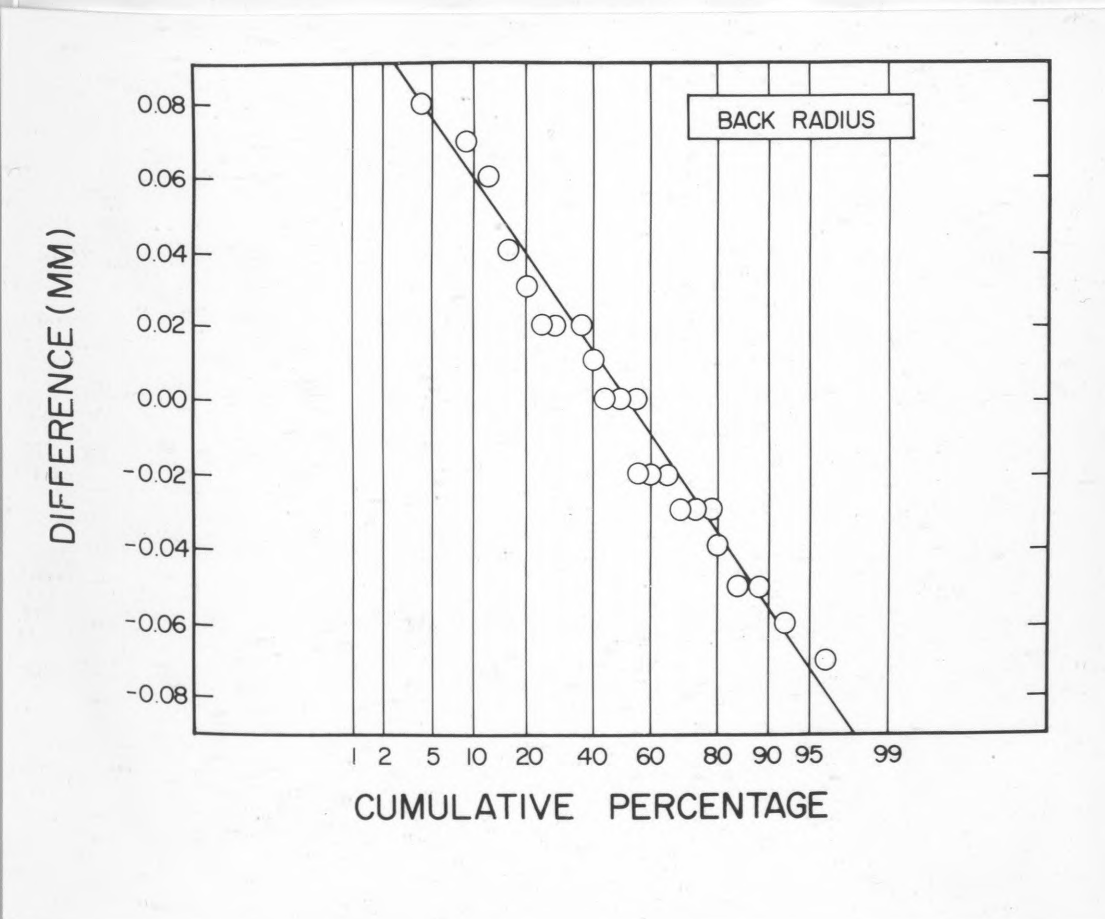


FIGURE (IX.1)

radius of the lens when plotted on normal probability graph paper gave a straight line as shown in Figure (IX.1). This linearity indicates a normal distribution of differences and leads to the conclusion that the differences were simply errors in measurement.

The conclusion is that the back of the high plus soft lenses studied here conform to the radius of the dome and that there is no powered tear lens between the dome and the back surface of the soft lenses as there would be in the case of a hard lens.

Table (IX.1) shows calculated back vertex power for soft lenses measured in air and when flexed on the dome. The new back radius for each flexed lens was taken to be that of the dome. The difference between the back vertex power in air and the back vertex power when flexed on the dome is $\Delta F'_v$.

Similarly, the difference between the back radius of the lens in air and the radius of the dome onto which the lens is placed is Δr_2. When $\Delta F'_v$ is plotted against Δr_2, as shown in Figure (IX.2), a linear relationship of the form -

$$\Delta F'_v = 2.53\Delta r_2 - 0.47 \qquad \text{(IX.8)}$$

is demonstrated. It is clear from the wide scatter of the points that the correlation is not high (r = 0.68).

The relationship cannot be exactly linear unless centre thickness and refractive index of all the lenses was the same. The term -0.47 can be ignored because if the back radius does not change ($\Delta r_2 = 0$), then the back vertex power cannot change. This term is simply a consequence of the errors in measurement and the approximate nature of equation (IX.8). This equation provides a rule of thumb for high plus soft lenses of refractive index between 1.36 and 1.43 and centre thickness between 0.40mm and 0.60mm.

DISCUSSION

Examining each hypothesis previously presented and knowing that there is no powered tear lens between the soft lens and the dome, how closely does each hypothesis fit the data?

The Bennett and Wichterle equations predict a loss of approximately 0.75D of plus power when a soft lens steepens by 1.00mm. Equation (IX.8) predicts a loss in plus power of 2.53D under the same condition.

The Kaplan, Baron and Sarver hypotheses of equal change in front and back radius upon flexure is not confirmed by the data. The front lens radius does not change as much as the back radius. Strachan, Wallace-Williams and Magabilen hypothesise that the back and front radius changes by the same proportion. This will lead to a gain in plus power of a soft lens upon steepening. The data shows that most lenses undergo a loss in plus power. Similarly, the invariant normals theory of Wallace-Williams and Magabilen and the constant sagittal height change theory of Smith do

TABLE (IX.2)

Comparison of Bibby's and Chaston-Fatt hypothesis of high plus soft lens bending...

F'_v (D)	r_2 (mm)	r_1 (mm)	r'_2 (mm)	r_1 (mm)	F'_{v_m} (D)	F'_v (D)
	9.0	7.35	7.67*	6.48	9.91	0.09
	8.8	7.22		6.47	"	"
	8.6	7.09		6.48	"	"
+10.00	8.4	6.96		6.48	"	"
	8.2	6.83		6.47	"	"
	8.0	6.69		6.46	"	"
	7.8	6.59		6.48	"	"
	9.0	6.70		–	–	–
	8.8	6.59		–	–	–
	8.6	6.49		5.98	+14.82	0.18
+15.00	8.4	6.38		5.97	"	"
	8.2	6.26		5.99	"	"
	8.0	6.15		5.93	"	"
	7.8	6.04		5.94	"	"
	9.0	6.16		–	–	–
	8.8	6.07		–	–	–
	8.6	5.98		–	–	–
+20.00	8.4	5.88		5.54	+19.90	0.10
	8.2	5.79		5.54	"	"
	8.0	5.69		5.54	"	"
	7.8	5.60		5.54	"	"

*7.67 is constant

TABLE (IX.2)

not fit the data.

The equation (IX.7) developed by Weissman and Zisman, assumes a powered tear lens between the soft lens back surface and the eye. This study did not show such tear lens.

Table (IX.2) shows data Bibby gave in his Figure 4 tabulated in the more familiar form of back and front radius of the unflexed soft lens r_2 and r_1, the back and front radius of this lens on the model r_2' and r_1' and the back vertex power of the unflexed lens F'_v, the back vertex power of the lens on the model F'_{vm}, and the change in back vertex power $\Delta F'_v$ found as the lens flexed, as computed by Bibby. For this table the lenses of back vertex power +10.00D, +15.00D and +20.00D were used and it was assumed that if they were 75% water content lenses their refractive index would be 1.364. A centre thickness of 0.50mm was assumed for all lenses.

It can be seen from Table (IX.2) that the changes in back vertex power for high plus lenses were very small and appeared to be constant for each vertex power no matter how much the degree of bending of the soft lens. This theory does not fit the experimental data.

The experimental results obtained are not explained by any hypothesis presented to date.

In seeking a new hypothesis that will describe this observed lens bending on the PMMA domes, examination of the previous hypotheses written in the simplified form suggested by Weissman and Zisman (1979) shows that the Baron-Kaplan-Sarver (1966-1975-1976) Strachan (1973) and Smith quoted in Weissman and Zisman (1979) hypotheses can be summarised in the following forms:-

(Baron, Kaplan, Sarver) -

$$\frac{\Delta r_1}{\Delta r_2} = 1 \qquad \text{(IX.9)}$$

(Strachan) -

$$\frac{\Delta r_1}{\Delta r_2} = \frac{r_1}{r_2} \qquad \text{(IX.10)}$$

(Smith) -

$$\frac{\Delta r_1}{\Delta r_2} = \left(\frac{r_1}{r_2}\right)^2 \qquad \text{(IX.11)}$$

A general expression for all of the above three equations can be written as -

$$\frac{\Delta r_1}{\Delta r_2} = \frac{1}{m}\left(\frac{r_1}{r_2}\right)^n \qquad \text{(IX.12)}$$

The value for m and n in the various hypotheses are then:-

Baron-Kaplan-Sarver: $m = 1, n = 0$

Strachan: $m = 1, n = 1$

and Smith: $m = 1, n = 2$.

Since none of the above hypotheses fit these data, values of m and n not appearing above but giving a good fit to the data in Table (IX.1) are m = 2 and n = 1. The relationship is then -

$$\frac{\Delta r_1}{\Delta r_2} = \frac{1}{m}\left(\frac{r_1}{r_2}\right) = \frac{1r_1}{2r_2} \qquad \text{(IX.13)}$$

which is the same as -

$$r_1' = \left(\frac{r_2'}{r_2}\right)^{\frac{1}{2}} r_1 \qquad \text{(IX.14)}$$

Equation (IX.13) can be derived from equation (IX.14) in the following manner -

$$\text{Let } r_1' = r_1 + \Delta r_1 \qquad \text{(IX.15)}$$

$$\text{and } r_2' = r_2 + \Delta r_2 \qquad \text{(IX.16)}$$

Therefore, equation (IX.14) can be rewritten -

$$r_1 + \Delta r_1 = \left(\frac{r_2 + \Delta r_2}{r_2}\right)^{\frac{1}{2}} r_1 \qquad \text{(IX.17)}$$

Rearranging this equation gives -

$$\frac{r_1 + \Delta r_1}{r_1} = \left(\frac{r_2 + \Delta r_2}{r_2}\right)^{\frac{1}{2}} \qquad \text{(IX.18)}$$

Squaring both sides gives -

$$\left(\frac{r_1 + \Delta r_1}{r_1}\right)^2 = \left(\frac{r_2 + \Delta r_2}{r_2}\right) \qquad \text{(IX.19)}$$

TABLE (IX.3) cont...

on 7.77mm dome

Lens Number	Δr_1	Δr_2	$(\Delta r_1/\Delta r_2)$	$(r_1/r_2)/(\Delta r_1/\Delta r_2)$ m
1	-0.13mm	-0.21mm	+0.62	1.35
2	-0.07	-0.12	+0.58	1.40
3	-0.01	-0.01	+1.00	.84
4	-0.04	+0.24	-0.17	5.14*
5	+0.19	+0.23	+0.83	1.00
6	+0.12	+0.25	+0.48	1.00
7	-0.13	-0.06	+2.17	0.39*
8	+0.02	-0.08	-0.25	3.28
9	+0.07	+0.43	+0.16	5.15*
10	+0.61	+1.20	+0.51	1.65
11	+0.24	+0.96	+0.25	3.43
12	-	-	-	-
13	-	+0.99	-	-
14	+0.45	+1.31	+0.34	2.53
15	+0.19	+0.68	+0.28	2.96

Mean m = 1.94
SD = 1.00

* - Entries omitted in calculation of average and standard deviation

TABLE (IX.3) cont.

TABLE (IX.3)

Value of constant $m = (r_1/r_2)/(\Delta r_1/\Delta r_2)$

on 7.32mm dome

Lens Number	Δr_1	Δr_2	$(\Delta r_1/\Delta r_2)$	$(r_1/r_2)/(\Delta r_1/\Delta r_2)$ m
1	+0.18mm	+0.24mm	+0.75	1.13
2	+0.15	+0.33	+0.45	1.93
3	+0.04	+0.44	+0.09	9.78*
4	+0.30	+0.69	+0.43	2.02
5	+0.35	+0.68	+0.52	1.64
6	+0.41	+0.70	+0.59	1.43
7	+0.15	+0.39	+0.38	2.25
8	+0.19	+0.37	+0.51	1.67
9	-	+0.88	-	-
10	-	+1.65	-	-
11	-	+1.41	-	-
12	+0.70	+1.54	+0.45	1.89
13	-	+1.44	-	-
14	+0.70	+1.76	+0.40	2.25
15	+0.28	+1.13	+0.25	3.52

Mean m = 1.97
SD = 0.65

* - Entries omitted of calculation of mean and standard deviation

TABLE (IX.3)

which is -

$$\frac{r_1^{\,2} + 2r_1\Delta r_1 + \Delta r_1^{\,2}}{r_1^{\,2}} = \frac{r_2 + \Delta r_2}{r_2} \qquad \text{(IX.20)}$$

ignoring $\Delta r_1^{\,2}$ because it is so small and dividing each side by its denominator gives -

$$1 + \frac{2\Delta r_1}{r_1} = 1 + \frac{\Delta r_2}{r_2} \qquad \text{(IX.21)}$$

which is -

$$\frac{2\Delta r_1}{r_1} = \frac{\Delta r_2}{r_2} \qquad \text{(IX.22)}$$

which rearranged is -

$$\frac{\Delta r_1}{\Delta r_2} = \frac{1}{2} \cdot \frac{r_1}{r_2} \qquad \text{(IX.13)}$$

It must be emphasised that equations (IX.13) and (IX.14) are exactly the same because by definition $\Delta r_1 = r_1' - r_1$ and $\Delta r_2 = r_2' - r_2$.

Equation (IX.13) can be arranged to read -

$$\frac{1}{m} = \left\{ \frac{\Delta r_1}{\Delta r_2} \right\} \bigg/ \left\{ \frac{r_1}{r_2} \right\} \qquad \text{(IX.23)}$$

Table (IX.3) tabulation is given of values of m for each lens placed on the PMMA domes. The average value for m on the 7.32mm dome is 1.97 with a standard deviation of 0.65. For the 7.77mm dome the average m is 1.94 with a standard deviation of 1.00. There are too few data points to draw any conclusion concerning the flexing of the lenses on the 8.20mm dome.

Two observations can be made from these statistics. First, an m value of 1 and an n of 1 in equation (IX.12) makes this equation a good predictor of radius change when a soft lens flexes onto the cornea. For the 7.32mm dome it can be said that with a confidence limit of 85 per cent that m is between 1.00 and 3.00.

This means that there is only a 15 per cent chance that Strachan's or Smith's relations, equations (IX.10) and (IX.11) respectively, describe lens flexing when a soft lens is placed onto the eye. There is a less than one per cent chance that the Baron-Kaplan-Sarver relationship equation (IX.9) is valid.

Second, the flatter dome, 7.77mm radius, yields the same average value of m but with a larger standard deviation. This larger uncertainty in m may stem from the smaller amount of flexing of lenses put on this dome and consequently larger experimental error in measuring the amount of radius change. Also, a smaller amount of flexing may lead to a less stable flexed lens shape and therefore a less certain change in lens radius.

Equation (IX.14) was used to calculate the new flexed front radius from the back and front radius in air and the dome radius for the new back radius. The differences between the expected new front radius and the measured

FIGURE (IX.3)

The difference between measured and calculated front radius on bending showing a normal distribution of spread of measurements

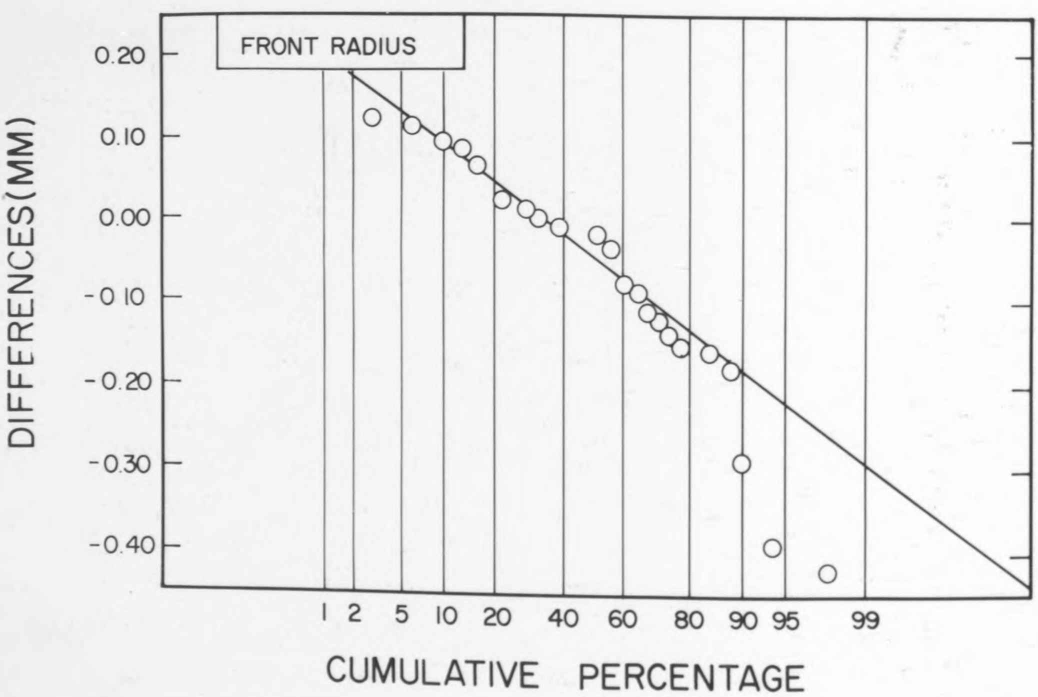


FIGURE (IX.3)

TABLE (IX.4)

Practical and theoretical values of front radius of high plus soft lenses on bending...

LENS NUMBER	FRONT RADIUS**					
	On 7.32 dome		On 7.77 dome		On 8.20 dome	
	Measured	Calculated	Measured	Calculated	Measured	Calculated
1	6.21	6,29	6.52	6.48	-	-
2	6.08	6.09	6.30	6.29	-	-
3	6.46	6.31	6.51	6.50	-	-
4	6.31	6.31	6.65	6.51	-	-
5	6.23	6.29	6.39	6.48	-	-
6	6.16	6.28	6.45	6.47	-	-
7	6.19	6.17	6.47	6.36	-	-
8	6.21	6.24	6.38	6.37	-	-
9	-	-	6.55	6.44	-	-
10	-	-	6.64	6.75	6.94	6.93
11	-	-	6.71	6.56	6.74	6.74
12	6.28	6.34	-	-	7.14	6.71*
13	-	-	6.86	6.47*	6.81	6.65
14	6.57	6.53	6.82	6.73	7.20	6.91*
15	6.39	6.21	6.48	6.40	6.98	6.57*

* rejected values

** using dome radius as new back radius r_2'

TABLE (IX.4)

new front radius were then calculated. These values were given in Table (IX.4). The differences between measured and calculated new front radius are plotted on normal probability graph paper in Figure (IX.3). A straight line can be drawn through the points with the exception of the last few. If the points that deviate widely from the linear probability plot are ignored, then equation (IX.8) changes from -

$$\Delta F'_v = 2.53\Delta r_2 - 0.47 \qquad \text{(IX.8)}$$

$$\Delta F'_v = 2.42\Delta r_2 - 0.27 \qquad \text{(IX.23)}$$

This is very similar to the equation given by the author in 1979 for high plus soft lenses on the aphakic eye. She found that:-

$$\Delta F'_v = 2.24\Delta r_2 + 0.06 \qquad \text{(IX.24)}$$

Thus on the dome at 23°C the change in power of high plus soft lenses is similar to the change in power on the eye at 34°C. Fatt and Chaston (1980) show that the nett result of the increase in refractive index, coupled with the decrease in centre thickness for high plus soft lenses of refractive index between 1.36 and 1.43 and centre thickness between 0.40mm and 0.60mm, on raising the temperature from 20° to 33°C, is a negligible change in back vertex power. Therefore, ignoring the last terms in equations (IX.23) and (IX.24) because they must arise from experimental error, these experimental results reported here in the form -

$$\Delta F'_v = 2.42 \Delta r_2 \qquad \text{(IX.25)}$$

is the same as the equation -

$$\Delta F'_v = 2.24 \Delta r_2 \qquad \text{(IX.26)}$$

based on clinical data from high plus soft contact lenses on aphakic eyes.

CORRECTION OF ASTIGMATISM

The flatter the soft lens is fitted with respect to the cornea, the more plus power it loses due to bending. Because the soft lens is usually fitted flatter than the cornea, some of the astigmatic element of the refraction will also be corrected by the flexing of a soft lens. With the rule astigmatism with its steeper vertical meridian will lose more plus power in the vertical than in the horizontal and therefore make the correcting soft lens act like a minus cylinder axis horizontal. Similarly, in the case of against the rule astigmatism the soft lens fitted flatter than the cornea will lose more plus power in the horizontal than in the vertical meridian. This makes the soft lens act like a plus cylinder with the axis horizontal. The amount of astigmatic correction will depend upon how flat the soft lens is fitted. If the amount of front surface cylinder induced by the flatness of the fitting exceeds the corneal cylinder, then the spectacle overcorrection will be in the opposite direction to the astigmatism of the cornea.

CHAPTER X

PHYSIOLOGY OF THE CORNEA

Physiology of the Cornea

(1) The Normal Cornea

The normal cornea untouched by contact lenses is avascular, sensitive to touch, pressure and heat, has its own mechanism to deal with infections and under normal conditions maintains its own thickness, shape and water content. An excised cornea, when placed in water, swells (Fatt 1977). Therefore the living cornea, bathed by tears and aqueous, must have some mechanism to prevent this swelling. Hodson and Miller (1976) have shown that the endothelial cell layer controls the thickness of the cornea. The endothelium acts as a semi-permeable barrier and has a balance of pressure:-

$$\triangle\pi_{eff} = (IP)_{3.5} \qquad (X.1)$$

where $\triangle\pi_{eff}$ is the osmotic pressure gradient across the endothelium and $(IP)_{3.5}$ is the imbibition pressure of the stroma at the normal hydration of 3.5 grams of water per gm of dry tissue.

The mechanism whereby the endothelial cells control thickness may be by the deposition of a thin layer of a bicarbonate ion solution on the posterior surface of the endothelium or simply by the depletion of the bicarbonate ion in the stroma and so reducing the concentration with respect of the aqueous humour agents that are osmotically active in the stroma or both mechanisms may be controlling corneal thickness (Maurice 1972). The combination of a bicarbonate layer on the endothelial surface and the depleted stroma yields an osmotic pressure gradient that is just equal to the imbibition pressure of the stroma in a cornea of the normal eye.

(2) Oedema

What happens when this balance becomes upset? If the epithelial surface is deprived of oxygen, it takes about 10 minutes to swell (Wilson et al 1973). From the diffusion law and the thickness of the normal cornea, it can be calculated that this is the time it takes a lactate ion produced in the hypoxic epithelial cells to travel to the corneal endothelium. Chaston and Fatt (1981) hypothesise that there is now an increase in lactate ion concentration in the stroma upsetting the balance of the endothelial semi-permeable barrier. This in turn changes the osmotic imbibition pressure relationship to:-

$$\triangle \pi_{eff} = (IP)_H + \triangle \pi_{Lac} \qquad (X.2)$$

where π_{Lac} is the osmotic pressure component of the extra lactate ion in the stroma and $(IP)_H$ is the new imbibition pressure. If the endothelial cells continue to deposit bicarbonate ion into the aqueous humour boundary of the endothelium at the same rate as before the epithelium becomes hypoxic, then the equality expressed by equation (X.2) can be maintained only if $(IP)_H$ is less than $(IP)_{3.5}$. This decrease in (IP) is necessary to compensate for the appearance of the additional lactate ion in the stroma (Klyce and Bernegger 1977). This hypothesis is strongly supported by calculations (Fatt et al 1974) that show that oxygen tension in the endothelium is only very slightly affected by changes in the oxygen supply to the anterior corneal surface. Returning to equation (X.2) and the known imbibition pressure-hydration-thickness relationships for the human stroma (Fatt and Hedbys 1970), calculations show that an increase in concentration of 1 milliosmole of lactate ion is sufficient to cause the imbibition pressure to fall by 20mm Hg and thereby lead to a 10 percent swelling of the stroma. The 1 milliosmole increase in concentration of dissolved lactate in the stroma represents only a 0.3% increase in total concentration of dissolved solids. The return to normal thickness of the cornea when hypoxic conditions at the anterior surface are removed can be explained by the removal of the excess lactate ion through leakage across the endothelium and by conversion to pyruvate by the epithelial cells as they return to their normal oxidative metabolic pathway (Krebs cycle). The endothelial cells may be carrying out some lactate conversion at all times because they are sufficiently oxygenated by the oxygen supplied from the aqueous humour. Because of continual leakage across the endothelium and conversion to pyruvate, there is need for continued production of lactate ion in the hypoxic epithelium if the cornea is to remain oedematous.

A recent report (Holden et al 1980) describing a well-controlled experiment confirms what has been noted at times in the clinic, namely that the cornea of the aphakic eye in a unilateral aphakic does not swell as much under a contact lens as does the cornea of the contralateral phakic eye under the same contact lens. There are two mechanisms that would make possible the different behaviour of the aphakic and phakic eye. One is that the epithelium of the cornea in the aphakic eye does not produce as much lactate under hypoxic conditions as does the cornea in the contralateral phakic eye. And the other is that reduced endothelial cell count in the aphakic eye (reported by Hoffer and Phillipi (1978) and Bourne et al (1980)) can account for the apparent low sensitivity of the aphakic eye cornea to hypoxia under a contact lens. The lenticular epithelium in the phakic eye is a consumer of oxygen supplied by the aqueous humour. When the lens is removed, this oxygen 'sink' is no longer present and a rise in aqueous humour oxygen tension would be expected provided that there has been no reduction in blood flow to the eye as a result of surgery. In the phakic eye, it has been shown that a very high increase in aqueous humour oxygen tension, far beyond that likely to take place after cataract surgery, is needed to deliver oxygen by anteriorly directed diffusion to the epithelium (Weissman et al 1981). Under any likely increase in aqueous humour oxygen tension in the phakic or aphakic eye, no oxygen will reach the epithelium under an ill-fitting contact lens unless some diffusion barrier in the cornea has been removed. This barrier can be the endothelium because of its high oxygen consumption rate and the partial removal can be indicated by reduced cell count (Hoffer et al 1978, Bourne et al 1980). Therefore a combination of a relatively small increase in aqueous humour oxygen tension following upon removal of the lens and its epithelium, together with reduced endothelial cell count, may explain why a contact lens that would be expected to cause corneal hypoxia and the attendant oedema very often does not do so on the aphakic eye.

Reduced endothelial cell count in the aphakic eye need not lead to an oedematous cornea in the absence of a contact lens even though the maintenance of normal corneal hydration resides in the endothelium. Maurice (1969) has shown that there is more metabolic work being done by the endothelium to counter water movement into the stroma than is needed to maintain the normal hydration. Maurice estimates that 5% of the metabolic work being done by the endothelium would be sufficient to pump out all of the water that would be drawn into the stroma by its imbibition pressure. Thus, the loss of 20% to 30% of the endothelial cells should not lead to corneal oedema in an eye that is not wearing a contact lens. In support of Maurice's contention that there is more work being done in the endothelium than is needed, is the observation that endothelial cell count decreases with age without any consequence to corneal hydration.

Finally, although Chaston and Fatt (1981) find no reports of the chemistry of the aqueous humour in an aphakic eye, one can expect that removal of the lens will cause that fluid to be richer in the metabolic substrates and poorer in the catabolic by-products. This change in chemistry may contribute to the cornea's insensitivity to hypoxia at the anterior surface of the aphakic eye.

(3) Neovascularisation

Another phenomenon observed in soft lens wear is neovascularisation. This is the new growth of limbal blood vessels into the cornea. This phenomenon has been observed in patients wearing corneal and scleral lenses and in 1973 Dixon & Bron proposed that the larger size of the soft lens which covers the corneal periphery was the stimulus to neovascularisation but Larke et al (1981) examined 76 soft lens wearers and recorded the presence or absence of neovascularisation; 37% had normal vascularisation while another 42% had only limbal congestion. This leaves only 21% with apparent neovascularisation. It would seem that the physical stimulus only of a soft lens on the eye is not the factor contributing to neovascularisation.

The smaller amount of vascularisation recorded by Larke et al compared with that recorded by Dixon and Bron is probably due to better lens design in the late 1970s compared with the late 60s/early 70s to yield at least an oxygen transmissibility of 5×10^{-9} (cm/sec)(mlO_2/ml x mm Hg) (if these were daily wear lenses) through the lens. From Larke's assessment of neovascularisation, it would seem that today some 75% of patients (who are probably daily wearers and have low myopic prescriptions) do not exhibit neovascularisation with soft lens wear. In agreement with general opinion (Maurice et al 1966) it is felt that neovascularisation cannot take place in the region of normal corneal thickness and it should be accepted that oedema is necessary to new vessel growth. Therefore it would seem that corneas without neovascularisation did not exhibit the corneal oedema required to start neovascularisation and the cornea's daily oxygen needs were probably being met by enough oxygen transmission through soft lens. If this is so, once corneal oxygen needs have been ascertained for the cornea of the aphakic eye and lenses designed to transmit enough oxygen to meet these needs, the cornea of the aphakic eye need not exhibit neovascularisation when a soft lens is being worn.

Critical experiments are still needed particularly if the needs of the aphakic eye are to be better understood. Although experiments on human eyes may not be possible, it is important to learn of the effect of cataract extraction on aqueous humour oxygen tension. The cat and rabbit eye may be suitable. The technology for making the measurement, in the form of needle-type polarographic oxygen sensors, is well-established (Fatt 1976). Measurement of oxygen tension at the closed anterior corneal surface, representing a tight contact lens, should be carried out on both eyes of unilateral aphakics with particular attention paid to the precision of the measurement at low oxygen tensions (below 20mm Hg). It has already been shown (Weissman et al 1981) that in the phakic eye very large increases in aqueous humour oxygen tension are not detected on the anterior corneal surface. If even very low values of oxygen tension are recorded on the closed anterior corneal surface of the aphakic eye, this will be good evidence for a reduction of the barrier to anteriorly directed oxygen diffusion in the cornea. If in such an eye there is also a reduction in endothelial cell count, then the evidence will point to the removal of endothelial cells and their oxygen consuming power as one reason why aphakic eyes may tolerate ill-fitting contact lenses.

(4) Oxygen Measurements

The next question is how much oxygen does the cornea need? Hill and Fatt (1963) used a polarographic oxygen sensor to monitor the depletion of oxygen in a small scleral lens chamber attached to a normal eye. Haberich (1966) used a direct volumetric estimation of oxygen in a gas-filled chamber attached to a contact lens on the eye. Both of these investigators showed that the experiment was slow and that it was technically difficult. Hill and Fatt (1963) replaced the scleral lens chamber with a thin membrane at the end of the polarographic oxygen sensor. This gave epithelial oxygen uptake only. The results from this experiment were obtained rapidly - because the oxygen sensor was placed on the living eye - but were not very accurate. These results gave only a comparison of oxygen tensions among eyes. Fatt and Bieber (1968) calculated the oxygen tension distribution in the cornea and Freeman (1972) measured the oxygen tension in the epithelium, endothelium and stroma of the excised rabbit eye.

Another method of finding how much oxygen a cornea needs is to provoke the cornea into swelling and to assess at what level the oxygen tension should be for acceptable levels of swelling and assess levels below which the cornea will swell excessively and will not be acceptable to the clinician.

The clinician monitoring 'good' PMMA contact lens fitting finds the cornea swells 4% and yet through years of experience learns that no long-term harm comes to the cornea.

Polse and Mandell (1971) found that by using a mixture of nitrogen and oxygen passed through a gas-tight goggle on a human eye, an unacceptable corneal thickening was observed if the gas incontact with the cornea fell below 11mm Hg. The 4% acceptable level was found to be equivalent to 15mm Hg of oxygen tension.

Fatt (1977a) showed various oxygen tensions under a contact lens as a function of the transmissibility of the lens and that for the open eye 5×10^{-9} (cm/sec)(mlO_2/ml x mm Hg) transmissiblity would give 15mm Hg oxygen tension. For the closed eye this transmissibility must be in the region of 10×10^{-9} (cm/sec)(mlO_2/ml x mm Hg) to fulfil the 15mm Hg oxygen tension requirements. Fatt (1978) measured the oxygen flux into the cornea by placing a polargraphic oxygen sensor onto a soft contact lens which had been fitted onto normal corneas. Mathematical assumptions made this method valid only for lenses of low water content and low oxygen transmissibilities (in the region of 2×10^{-9} (cm/sec)(mlO_2/ml x mm Hg). Rasson and Fatt (1981) overcame the previous mathematical assumptions and solved mathematically the complete model of the transient behaviour of the cornea/contact lens system. As a result, Rasson and Fatt (1981) gave graphical relationships between the decay of oxygen tension recorded by the sensor and the initial oxygen tension under the contact lens for a wide range of oxygen transmissibilities. Chaston and Fatt (1982) measured the oxygen flux into the corneas of 16 patients with unilateral aphakia by placing a soft contact lens of known oxygen transmissibility on the cornea and then measuring with the polarographic oxygen sensor, the oxygen tension decay of the soft contact lens. The Rasson and Fatt graphs enabled the oxygen flux and oxygen tension to be plotted as a function of the oxygen transmissibility of the lens for 16 unilateral aphakic patients. This procedure only takes one to two minutes and is not uncomfortable for the patient, needs no prior calibration and gives reproducible data.

(a) Procedure

The procedure used has been described in detail in two previous publications (Fatt (1978) and Rasson and Fatt (1981)). Briefly, it is as follows:

The current output of a polarographic oxygen sensor (Radiometer Model E5047/0, London Co, Sharon, Ohio) was determined first in air-bubbled

FIGURE (X.1)

Recorder chart units as a function of time

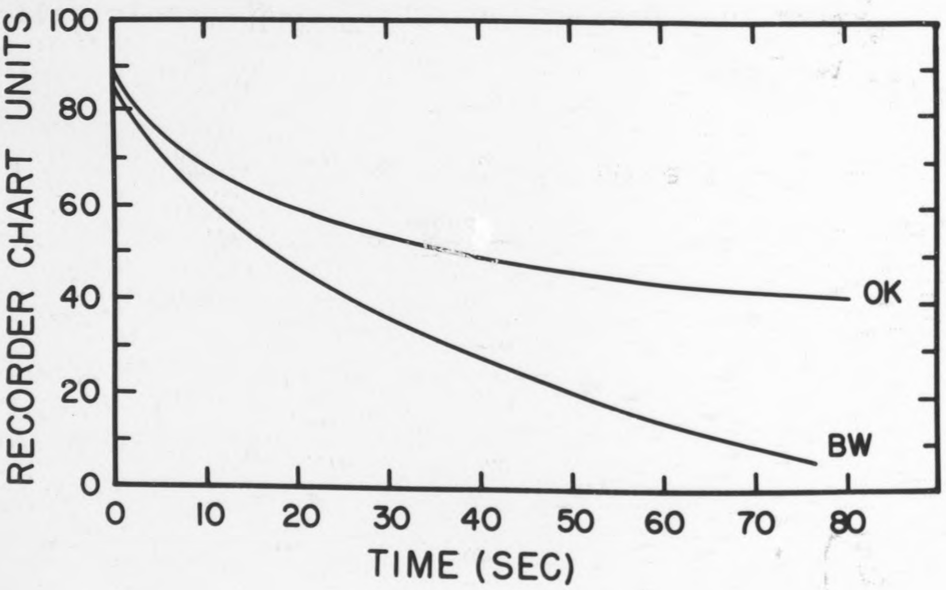


FIGURE (X.1)

saline at 35°C. This gave the current for approximately 155mm Hg. The sensor was then placed in a suspension of baker's yeast and glucose at 35°C to give the current at zero oxygen tension. The sensor current was amplified by a Schema Versatae polarographic amplifier (Scheme Versatae, Berkeley, CA94710) and recorded on a Smith Servoscribe potentiometric recorder. The 155mm Hg and zero points were set on the recorder paper to give maximum use of the span.

After calibration, the sensor was dipped into 70% ethyl alcohol to kill any adhering yeast cells and then washed and stored in isotonic saline at 35°C.

The unilateral aphakic subjects were fitted with soft contact lenses of low power (+1.00D to -3.00D) and known oxygen transmissibility (measured by the polarographic procedure of Fatt and St.Helen (1971)). After the soft contact lens was on the cornea for a few minutes, the senor was placed firmly on the front surface of the soft contact lens until the recorded oxygen tension was down to 10% to 40% of the initial reading. Two sample records, one for a lens of low oxygen transmiss-ibility, the other for a high value, are shown in Figure (X.1). After the record was obtained, the lens was removed from the eye, washed in saline, placed in the other eye and the procedure was

FIGURE (X.2)

Semilog arithmic plot of recorder

chart units with time

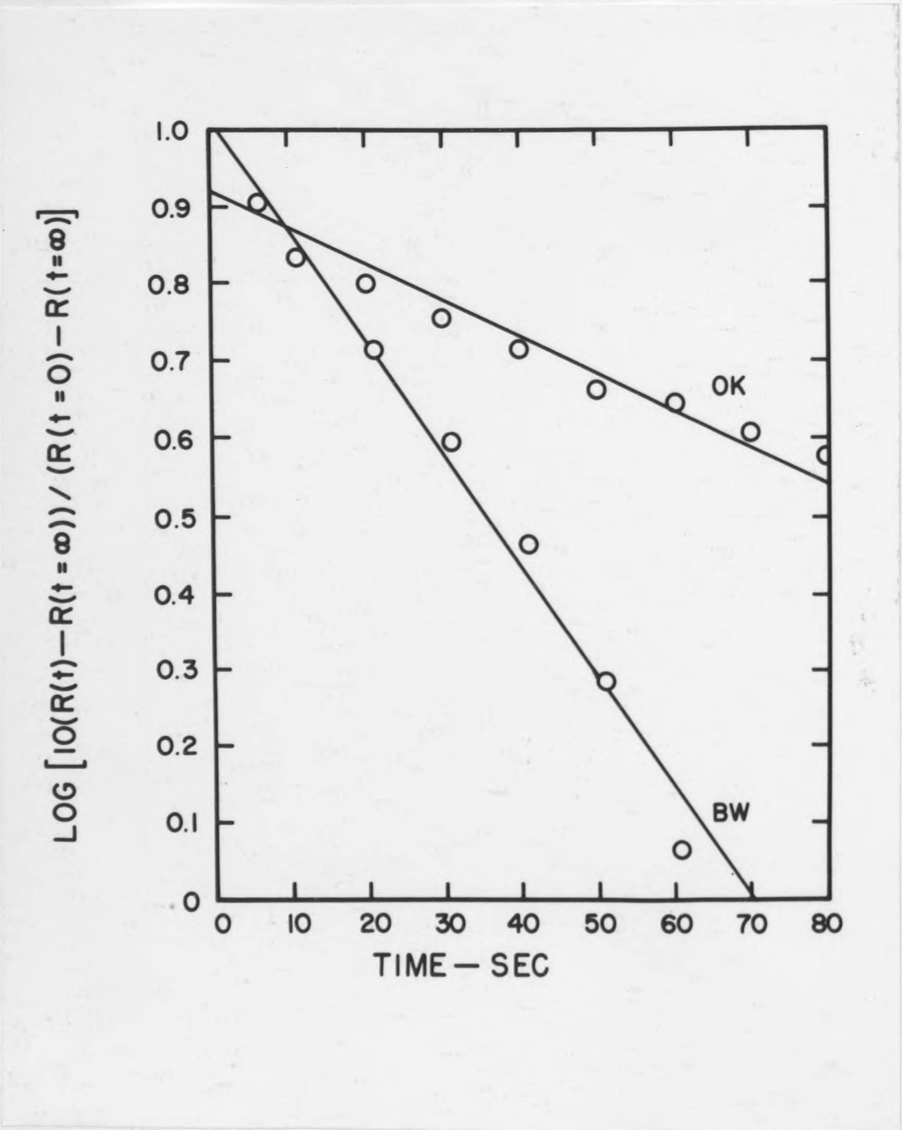


FIGURE (X.2)

TABLE (X.1) cont.

(1)	(2)	(3)	(4)	(5)	(6)	(7)
BW	APHAKIC (18)	DURAGEL 66	16.1×10^{-9}	1.44×10^{-2}	62	5.4
JC	PHAKIC	DURAGEL 66	16.1	2.10	50	6.1
PH	PHAKIC	DURAGEL 66	16.1	1.39	65	5.2
PH	APHAKIC (2)	DURAGEL 66	17.3	1.54	66	5.5
PJ	PHAKIC	DURAGEL 66	17.6	1.54	69	5.5
RK	PHAKIC	DURAGEL 66	17.6	2.57	45	7.0
RK	APHAKIC (10)	DURAGEL 66	17.6	1.60	65	5.7
FM	PHAKIC	DURAGEL 66	20.4	1.59	74	6.0
FM	APHAKIC (1)	DURAGEL 66	17.6	1.92	61	6.0
WS	PHAKIC	DURAGEL 66	21.6	2.32	65	7.0
WS	APHAKIC (4)	DURAGEL 66	17.6	1.21	72	5.3
WK	PHAKIC	DURAGEL 66	20.4	1.45	75	5.9
WK	APHAKIC (1)	DURAGEL 66	17.6	1.43	71	5.3
GS	PHAKIC	DURAGEL 66	20.4	2.03	69	6.3
GS	APHAKIC (2.5)	DURAGEL 66	20.4	1.38	75	5.9
PJ	PHAKIC	DURAGEL 66	21.6	2.39	62	7.2
JC	PHAKIC	DURAGEL 66	21.6	1.64	75	6.2
BAW	PHAKIC	SAUFLON 85	22.0	1.08	80	5.9

TABLE (X.1) cont.

TABLE (X.1) cont.

2

(1)	(2)	(3)	(4)	(5)	(6)	(7)
PJ	PHAKIC	B & L B3	5.0×10^{-9}	1.10×10^{-2}	35	2.1
PJ	APHAKIC (2)	B & L J3	5.3	1.21	30	2.4
JC(1)	PHAKIC	B & L J3	5.3	1.17	32	2.3
JC(2)	PHAKIC	B & L J3	5.3	1.10	40	2.1
PS	PHAKIC	SNOFLEX 50	5.9	0.48	67	1.9
PS	APHAKIC (0.5)	SNOFLEX 50	5.9	0.52	67	1.9
JP	PHAKIC	SNOFLEX 50	5.9	0.63	60	2.0
JP	APHAKIC (0.5)	SNOFLEX 50	5.9	0.53	67	1.9
BW	PHAKIC	SNOFLEX 50	5.9	0.51	67	1.9
BW	APHAKIC (0.5)	SNOFLEX 50	5.9	0.49	66	1.9
BAW	PHAKIC	B&L Plano T	5.9	0.85	55	2.1
JC	PHAKIC	SNOFLEX 50	5.9	0.53	66	1.9
CC	PHAKIC	DURAGEL 66	8.7	0.97	55	3.1
CC	APHAKIC (3)	DURAGEL 66	8.7	0.70	65	2.8
JC(1)	PHAKIC	DURAGEL 66	8.7	0.99	60	3.0
JC(2)	PHAKIC	DURAGEL 66	8.7	0.99	60	3.0
JC(1)	PHAKIC	DURAGEL 78	14.8	1.07	75	4.3
JC(2)	PHAKIC	DURAGEL 78	14.8	1.14	73	4.4
BW	PHAKIC	DURAGEL 66	16.1	1.56	64	5.3

TABLE (X.1) cont.

TABLE (X.1)

Corneal uptake in phakic and aphakic eyes...

SUBJECT (1)	EYE CONDITION (YEARS SINCE CATARACT SURGERY) (2)	CONTACT LENS (3)	OXYGEN TRANSMISSIBILITY Dk/L (cm/sec) (ml O_2/ml x mm Hg) (4)	SLOPE OF SEMILOG PLOT sec^{-1} (5)	OXYGEN TENSION UNDER LENS mm Hg (6)	OXYGEN FLUX $\mu l/cm^2$ x hr (7)
BAH	PHAKIC	HYDRON	2.0×10^{-9}	0.21×10^{-2}	10	1.0
HP	PHAKIC	DURAGEL 44	2.8	0.41	30	1.3
HP	APHAKIC (1)	DURAGEL 44	2.8	0.46	30	1.3
JC(1)	PHAKIC	DURAGEL 44	2.8	0.33	10	1.5
JC(2)	PHAKIC	DURAGEL 44	2.8	0.32	10	1.5
OK	PHAKIC	DURAGEL 44	2.8	0.47	50	1.1
OK	APHAKIC (4)	DURAGEL 44	2.8	0.46	50	1.1
KE	PHAKIC	DURAGEL 44	2.8	0.43	45	1.1
KE	APHAKIC (6)	DURAGEL 44	2.8	0.32	45	1.1
RT	PHAKIC	DURAGEL 44	2.8	0.38	45	1.1
RT	APHAKIC (0.5)	DURAGEL 44	2.8	0.41	45	1.1
JC	PHAKIC	SNOFLEX 50	4.9	0.70	57	1.7
SW	PHAKIC	B & L J3	5.3	1.28	27	2.4
SW	APHAKIC (0.5)	B & L B3	5.0	0.94	40	2.1
JF	PHAKIC	B & L J3	5.3	1.14	38	2.2
JF	APHAKIC (20)	B & L B3	5.0	1.07	37	2.1

TABLE (X.1)

repeated. In some cases another lens of the same or very nearly the same oxygen transmissibility was used in the contralateral eye. Two subjects had eyes that were both phakic; they were used to establish the reproducibility of the procedure. Columns 1 to 4 of Table (X.1) list the subjects, condition of the eye, soft contact lens type and soft contact lens transmissibility.

Each oxygen decay record was fitted by least squares to a straight line on a semilogarithmic graph. The vertical ordinate was the logarithm of $(10(R(t) - R(t = \infty)))/(R(t = 0) - R(t = \infty))$, where $R(t = 0)$ is the recorder reading at zero time, $R(t)$ is the reading at any time t, and $R(t = \infty)$ is the reading for the yeast-glucose suspension. The horizontal ordinate was time. Since the recorder readings, R, are linearly related to oxygen tension, P, detected by the sensor (Fatt (1976)) then -

$$\log(10(R(t) - R(t = \infty)))/(R(t = 0) - R(t = \infty)) = \log(10(P(t) - P(t = \infty)))/(P(t = 0) - P(t = \infty)) \tag{X.3}$$

Figure (X.2) shows the semilogarithmic plots for the records shown in Figure (X.1). The slopes of the semilogarithmic lines for all the eyes studied are given in column 5 of Table (X.1).

The slopes shown in column 5, Table (X.1), were used to enter Figures 5, 6 or 7 of Rasson and Fatt (1981) from which were read off the oxygen tension

FIGURE (X.4)

Oxygen flux into the cornea as a function of the oxygen transmissibility of the soft contact lens

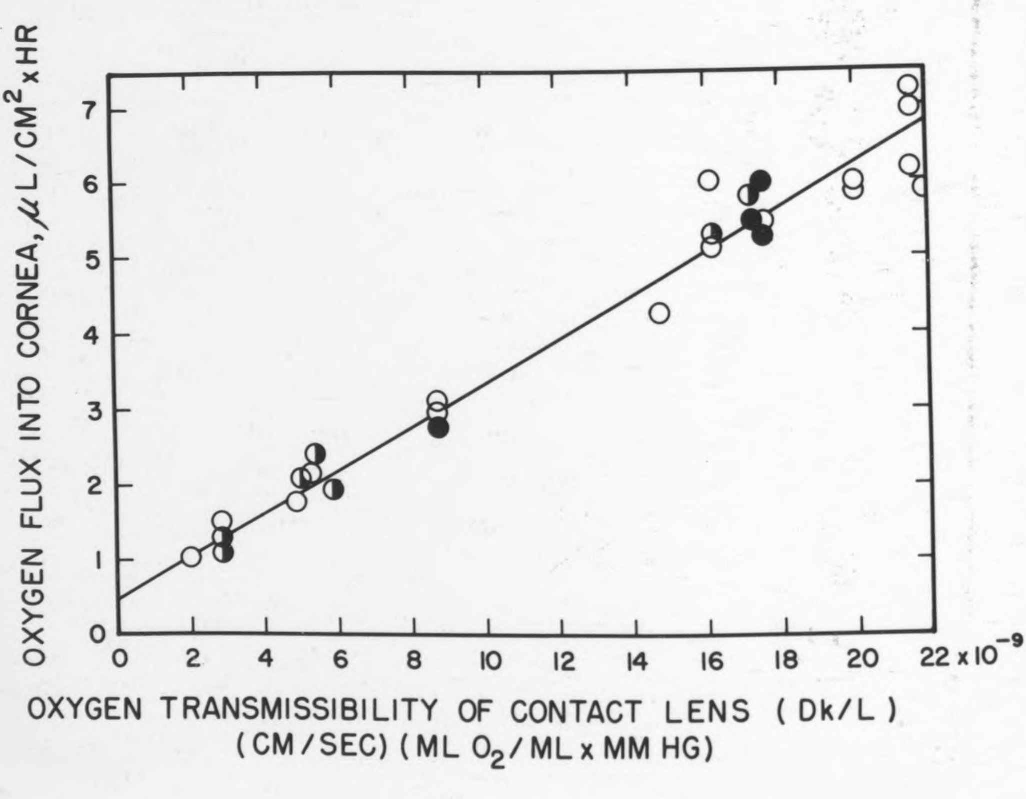


FIGURE (X.4)

FIGURE (X.3)

Semilog arithmic plot of the aphakic versus the phakic eye

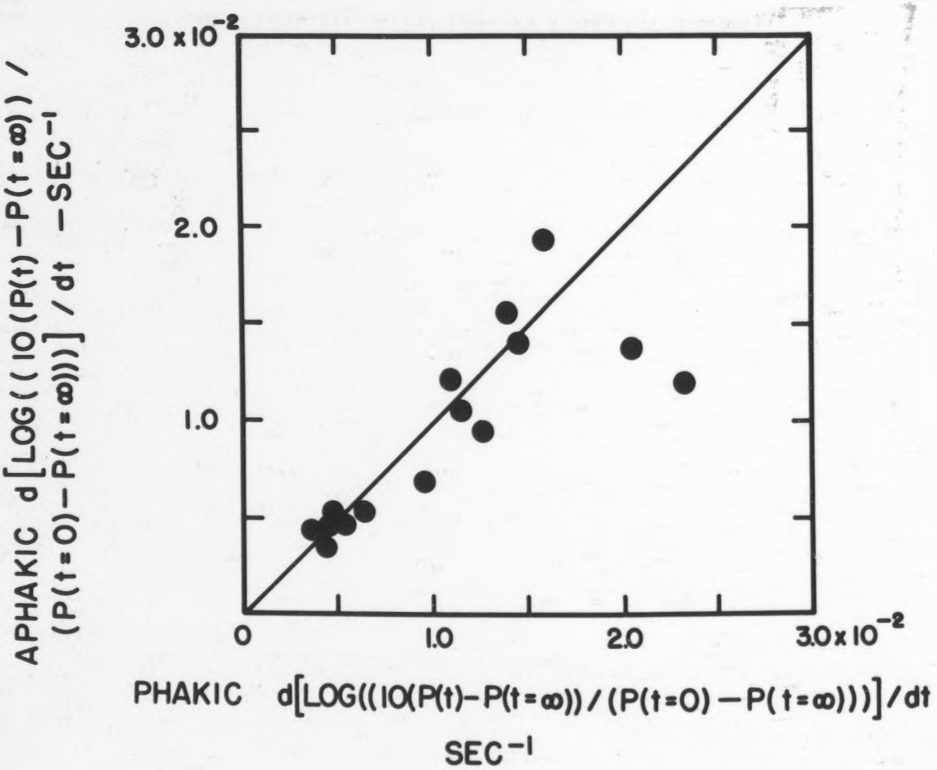


FIGURE (X.3)

under the lens (for the open eye before the sensor was applied) and the oxygen flux into the cornea. These quantities appear in columns 6 and 7 of Table (X.1). Note that the flux given in column 7 can be calculated from the data in columns 4 and 6 from the relationship -

$$j = (Dk/L)(155 - P_1) \qquad (X.4)$$

where Dk/L is the oxygen transmissibility from column 4 and P_1 is the oxygen tension under the lens as given in column 6. The graphs of Rasson and Fatt (1981) make this calculation, so both oxygen tension under the lens and oxygen flux are given directly on the graph.

(b) <u>Results</u>

Table (X.1) shows that for the repeat measurements on the normal eyes (indicated by JC(1) and JC(2)), the reproducibility is reasonably good.

Figure (X.3) shows a plot of the slope of the semilogarithmic line for the phakic eye versus that for the aphakic eye of the same subject.

Figure (X.4) shows the oxygen flux into the cornea as a function of the oxygen transmissibility of the soft contact lens. The open circles are the phakic eyes, the closed circles are for the aphakic eyes. The line in Figure (X.4) is a least squares fit to all of the data points.

FIGURE (X.6)

Oxygen flux into the cornea as a relationship of oxygen tension under the lens

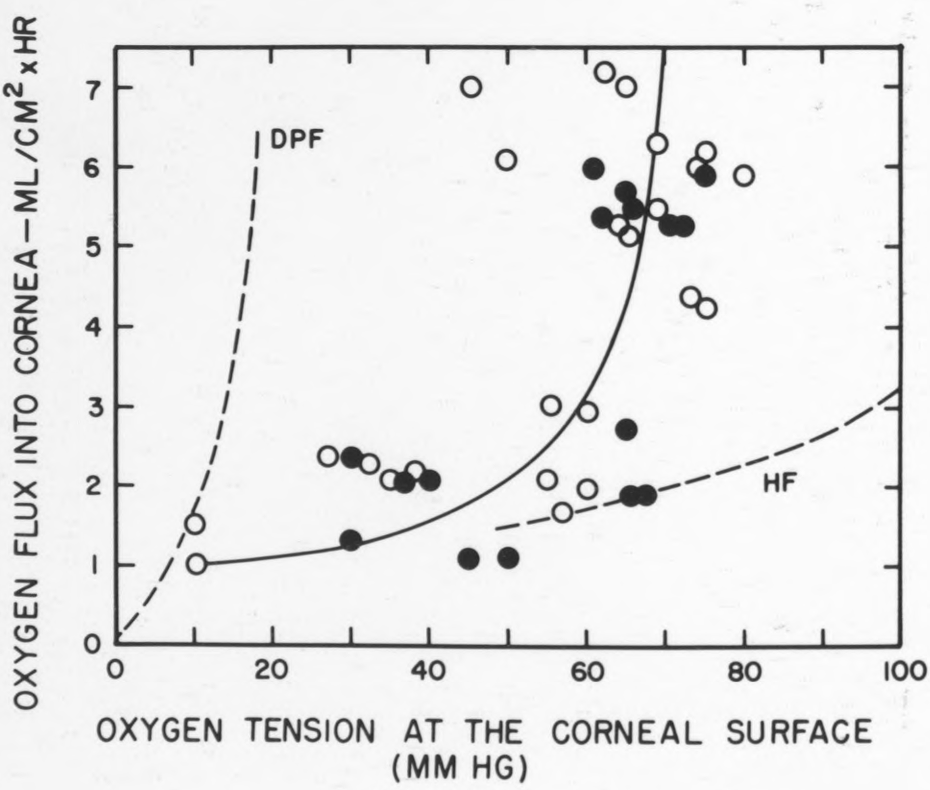


FIGURE (X.6)

FIGURE (X.5)

Oxygen tension under the lens as a function of the oxygen transmissibility of the lens

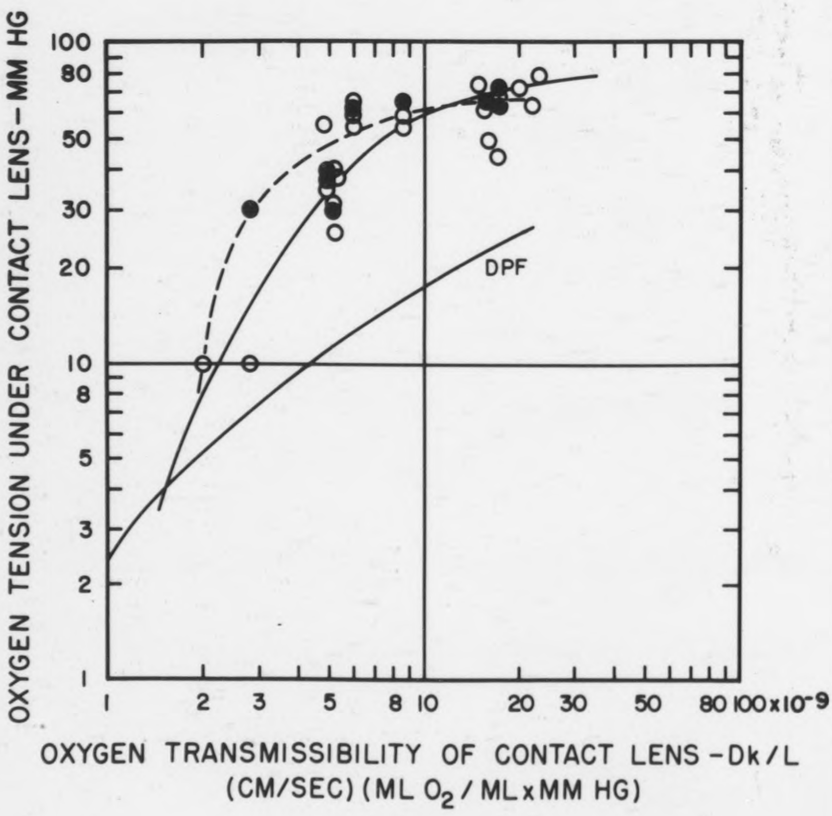


FIGURE (X.5)

Figure (X.5) shows the oxygen tension under the lens as a function of the oxygen transmissibility of the lens. Again, the open circles are for phakic eyes, closed circles for aphakic eyes. The solid line is the curve fitted to the data points by eye. The dashed curve was calculated from the line in Figure (X.4) by means of equation (X.4). The two curves are close but not the same because of the difference in statistical weight given to the points in the arithmetic plot of Figure (X.4) and the logarithmic plot of Figure (X.5).

Figure (X.6) shows the relationship of oxygen flux into the cornea to the oxygen tension under the soft contact lens. At first sight, there seems to be no simple means for drawing a single curve through all of the points. However, one need only recognise that the linear relation of oxygen flux into the cornea to the oxygen transmissibility of the soft contact lens offers a means for finding such a curve. The line in Figure (X.4) is described by the equation -

$$j = a + b(Dk/L) \qquad (X.5)$$

where a and b are constants that fit the line to the data points by the least squares method. When equation (X.5) is solved for Dk/L and this result substituted into equation (X.4), we have -

$$j = ((j - a)/b)(155 - P_1) \qquad (X.6)$$

Rearranging gives -

$$bj/(j - a) = 155 - P_1 \quad (X.7)$$

Equation (X.7) was used to construct the solid curve in Figure (X.6). This curve is a good fit to what appear to be scattered data points.

(c) Discussion

All of the oxygen readings taken on the soft contact lens surfaces of these unilateral aphakic subjects could be fitted to a semilogarithmic linear relationship with no more scatter than shown for the typical cases of Figure (X.2). Therefore the slope of the semilogarithmic line is the single parameter that describes the decay of oxygen tension in a contact lens on the eye when the atmospheric oxygen is blocked.

Figure (X.3) shows that of the 16 unilateral aphakic subjects studied, 14 points fell close to the equality line (one point near the line represents two subjects). This is good statistical evidence for believing that the aphakic eyes give a record that is no different from that for the phakic eye.

When the slopes of the semilogarithmic plots are converted into oxygen flux into the cornea, then Figure (X.4) shows that there is no difference in behaviour between phakic and aphakic eyes, when the oxygen flux into the cornea is greater than $1\mu l/cm^2 \times hr$. Figure (X.4) shows that the oxygen transmissibility of the contact lens controls oxygen flux into the cornea in the same way for phakic and aphakic eyes at fluxes above 1 $\mu l/cm^2$ x hr.

Figure (X.5) shows that oxygen transmissibility of the contact lens controls oxygen tension under the lens in the same way for phakic and aphakic eyes when the oxygen tension is in the range of about 30 to 80mm Hg.

Figure (X.5) also compares the relationship of oxygen tension under the lens to oxygen transmissibility uncovered in this study with that reported by Decker, Polse and Fatt (1978) (DPF). The procedure used by DPF is based on a calibration of oxygen tension at the corneal surface versus corneal swelling. Gas mixtures of different oxygen content are passed through a goggle on a human eye while the corneal thickness is monitored. The relationship between oxygen tension in the gas mixture and corneal swelling is used to infer the oxygen tension when a swollen cornea is observed under a contact lens. It is clear from Figure (X.5) that the two procedures predict different oxygen tensions under any given lens. In other words, this study predicts that lenses of low oxygen transmissibility, 2 to 4 x 10^{-9} (cm/sec)($ml O_2$/ml x mm Hg), will give oxygen tensions under the contact lens in the range 10 to 30mm Hg, whereas DPF would require transmissibilities in the range 5 to 30 x 10^{-9}. This means that, for the open eye at least, this study predicts that the Polse-Mandell (1970) region of minimum permissible oxygen tension, 10 to 20mm Hg, can be achieved with lenses of lower oxygen transmissibility than would be required by DPF.

The curve fitted to the data in Figure (X.6) suggests that oxygen flux into the anterior surface of the cornea rises slowly from 1 $\mu l/cm^2$ x hr at 10mm Hg oxygen tension at this surface to 2 $\mu l/cm^2$ x hr at 50mm Hg. There is then a rapid rise in flux to 6 to 7 $\mu l/cm^2$ x hr as the oxygen tension at the corneal surface rises above 50mm Hg. Hill and Fatt (1963) (HF) found a flux of 4 to 8 $\mu l/cm^2$ x hr with a best estimate of 4.8 $\mu l/cm^2$ x hr at 155mm Hg, 3.1 at 100mm Hg and 1.5 at 50mm Hg, whereas DPF reported from a goggle study that there is a rapidly rising flux in the range zero to 20mm Hg. The dashed curves in Figure (X.6) show the HF and DPF relationships of flux to oxygen tension under the lens. The data points of the present study fall between the curves fitted to the data of HF and DPF. The data collected by HF by direct measurement of oxygen flux into the cornea are in fair agreement with what is found here in the range of oxygen tensions of practical interest in contact lens fitting, namely 10 to 60mm Hg.

(d) Conclusions

The conclusion from this study is that when the oxygen flux is above 1 $\mu l/cm^2$ x hr and the oxygen tension is above 20mm Hg, then the relationship of oxygen flux to contact lens transmissibility is the same for both phakic and aphakic eyes. Similarly, in the same range, the relationship of oxygen flux to oxygen tension under the lens is the same for phakic and aphakic eyes. Furthermore, it has been found in this study that a lower oxygen transmissibility than previously suggested will give the minimum oxygen tension at the corneal surface specified by Polse and Mandell (1970).

If there are differences in the oxygen uptake rate of corneas in the phakic and aphakic eye, these differences must exist only at low oxygen fluxes (less than 1 $\mu l/cm^2$ x hr) and oxygen tensions below 20mm Hg. These differences, although they may be important in analysing the performance of soft contact lenses, will not be detected until more precise procedures are developed for measuring oxygen flux and oxygen tension under a soft contact lens.

CHAPTER XI

VISUAL ACUITY AND BEST FIT DIMENSIONS

Visual Acuity and
Best Fit Dimensions

(1) Introduction

The relationship between the fit of a high plus lens and the attainable visual acuity is well-known for hard polymethylmethacrylate (PMMA) contact lenses but these relationships are not yet fully understood for high plus soft lenses. When the high plus soft lens is worn on the eye, it is at a temperature of approximately 15°C higher than the temperature of the lens in the bottle. This temperature difference does not significantly affect the refractive index, water content or centre thickness except when the soft lens is a very high plus (+18.00D), high water content (80%) and thick lens (0.50mm). However, this temperature difference does affect the back radius of high plus soft lenses. In Chapter (VIII.1) the equation for the change in back radius ($\triangle r_2$) as a function of water content in percent (WC) when the change from room to eye temperature is approximately 15°C is given as:-

$$\triangle r_{2\,(20-35)} = 1.15 \times 10^{-2} WC - 0.23 \qquad (XI.1)$$

The radius steepens as the lens is placed and worn on the eye. Equation (XI.1) gives a steepening of 0.21mm for 38% water content lenses and a 0.63mm steepening for lenses of 75% water content. It would seem probable that the temperature changes in back radius would affect the fit of a high plus soft lens and therefore affect the visual acuity. How is this borne out clinically? Chaston

(1979) reported on an evaluation of high plus soft contact lenses from three manufacturers; Soflens N from Bausch and Lomb, Snoflex 38 from Smith & Nephew Optics Limited, and Sauflon 85 from Contact Lens Manufacturing Limited.

(2) <u>The Effect of the Back Radius of a Soft Lens on Visual Acuity</u>

A fuller and more comprehensive analysis is given here and is compared with the analysis given by Chaston in 1979 on the effect of the back radius of the soft lens fitted onto the eye and its effect on visual acuity.

(a) <u>Procedure</u>

Soflens N and Snoflex 38 were made of the same material - polyhydroxyethylmethacrylate (PHEMA) and had a water content of 38%. Soflens N was a spuncast lens - the original technique has been described by Wichterle and Lim (1960) and has been refined by Bausch and Lomb. The Soflens N lenses were designed with a constant front radius (6.45mm) and overall diameter (13.60mm), the back apical radius and thickness varied with power. The manufacturer supplied a stock of lenses with a range of powers from +10.00D to +18.50D. The soft lens used in fitting was chosen by the power needed to correct the ametropia irrespective of the corneal radius.

Snoflex 38 was a lathe-cut lens. A trial set was supplied to assess the fit of this soft lens. This lens was fitted approximately 1.0mm flatter than the mean corneal radius and 1½mm to 2mm larger than the corneal diameter. The back vertex power of the lens to be ordered was found by adding the over refraction sphere to the power of the +13.00D trial lens.

Sauflon 85 was a high water content (75%) lathe-cut lens made from a copolymer of polymethyl-methacrylate and polyvinyl pyrollidone (PMMA and PVP). The manufacturer supplied a stock of lenses of back radii from 7.8 to 8.2mm and overall diameter 13.5mm to 14.5mm with back vertex powers ranging from +9.00D to +20.00D. The initial soft lens used in fitting was approximately 0.3mm flatter than the mean corneal radius and 1½mm to 2mm larger than the corneal diameter. Soflens N and Snoflex 38 were daily wear lenses while Sauflon 85 was an extended wear lens.

Patients fitted with Soflens N and Snoflex 38 were chosen at random from referrals to the Contact Lens Department at Moorfields Eye Hospital. Patients fitted with Sauflon 85 were selected because they were unable to tolerate and/or handle other soft daily wear lenses. Visual acuity was taken at 6m with a Snellen chart. Refraction was carried out with trial spectacle lenses and frame and the corneal and front soft lens radius was measured with a Bausch and Lomb keratometer. Back vertex power, back apical radius and centre thickness of Snoflex 38 and Soflens was checked using respectively, the Nikon projection focimeter with a modified 4mm aperture stop and the Haag-Streit keratometer and saline cell (Chaston 1973) and the Haag-Streit pachometer. Parameters of Sauflon lenses were not checked because the back apical radius could not be verified with the Haag-Streit keratometer. All lenses were lenticular in form.

The numbers of patients and eyes fitted with Soflens N, Snoflex 38 and Sauflon 85 were: 48 patients and 57 eyes for Soflens N; 22 patients and 25 eyes for Snoflex 38; and 44 patients, 57 eyes for Sauflon 85. In the analysis, the measurements were used only from one eye of each patient and the measurements from eyes with abnormally low acuity ($< 6/60$) were excluded. The measurements for analysis were from 40 eyes fitted with Soflens, 17 eyes fitted with Snoflex 38 and 30 eyes fitted with Sauflon 85. It can be seen that 40/48, 17/22 and 30/44 results were used for respectively Soflens N, Snoflex 38 and Sauflon 85. The patients fitted with the Soflens N and Snoflex 38 lenses included a large number of children with unilateral aphakia with the aphakic

TABLE (XI.1)

Spearman rank-correlation test used for testing the hypothesis that H_o: $M=M_o$

H_o: $M=M_o$	r_s	n	Significance Level
Soflens : Snoflex	0.97	7	1%
Soflens : Sauflon	0.93	7	1%
Snoflex : Sauflon	0.86	7	5%

Comparison of spectacle visual acuities of aphakic patients

TABLE (XI.1)

eye of $< 6/60$ visual acuity. The patients fitted with the Sauflon 85 lenses were much older than the adults in the other 2 soft lens series (they were often patients who could not handle daily wear lenses) and many had poor visual acuity due to retinal pathology.

(b) Results

The spherical soft contact lens did not correct corneal astigmatism and supplementary spectacles were usually needed to obtain the maximum visual acuity with soft lenses. In this report, visual acuity achieved with a soft lens means the visual acuity obtained with the soft contact lens and the supplementary overrefraction spectacle lens. The values of spectacle visual acuities did not show a normal frequency distribution and the standard deviations for each group of spectacle visual acuities were not similar, so the Spearman rank-correlation test was used to compare spectacle visual acuities and testing the hypothesis H_o: $M=M_o$. The 7 ranks used were the Snellen chart lines 6/4, 6/5, 6/6, 6/7.5, 6/9, 6/12 and 6/18 and less. Table (X1.1) shows in each case H_o: $M=M_o$ and that all the correlation coefficients r_s were significant between 1% and 5% level giving a high correlation between all three groups of spectacle visual acuities.

FIGURE (XI.3)

Difference between spectacle and contact lens visual acuities expressed as lines lost on the Snellen chart for patients fitted with Soflens N, Snoflex 38 and Sauflon 85 lenses

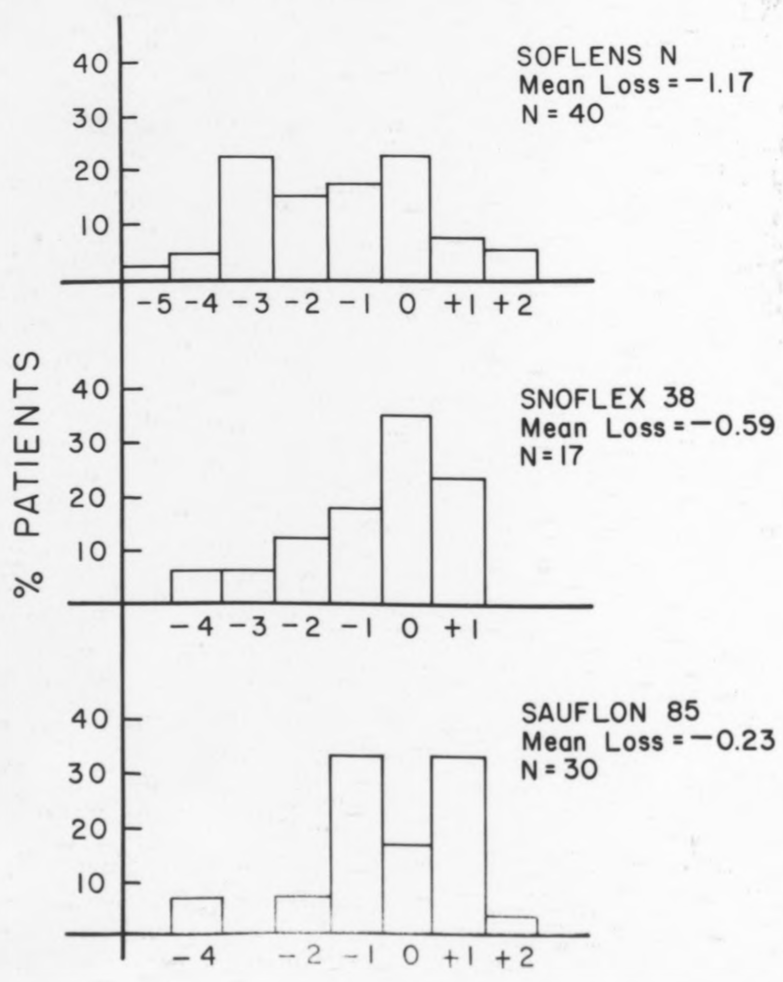
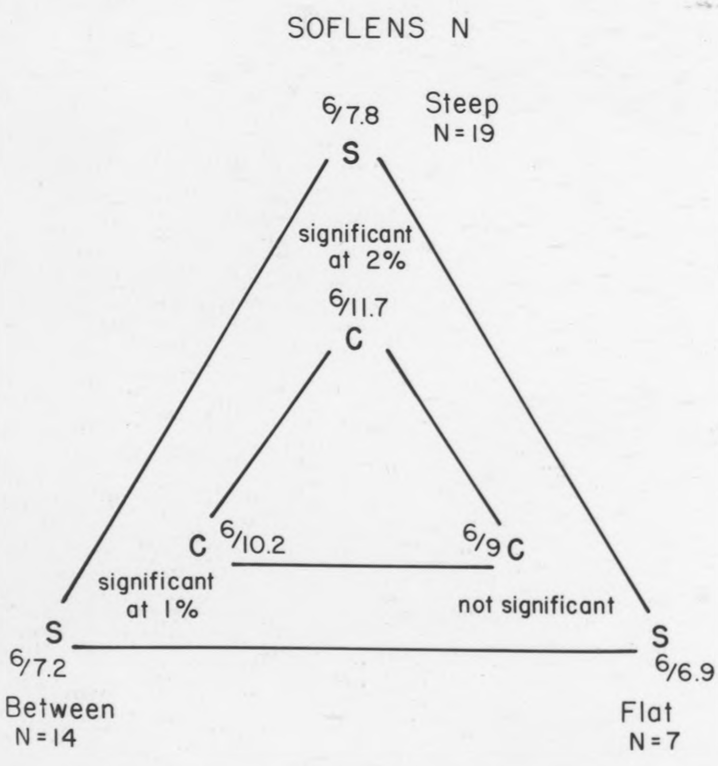


FIGURE (XI.3)

FIGURE (XI.2)

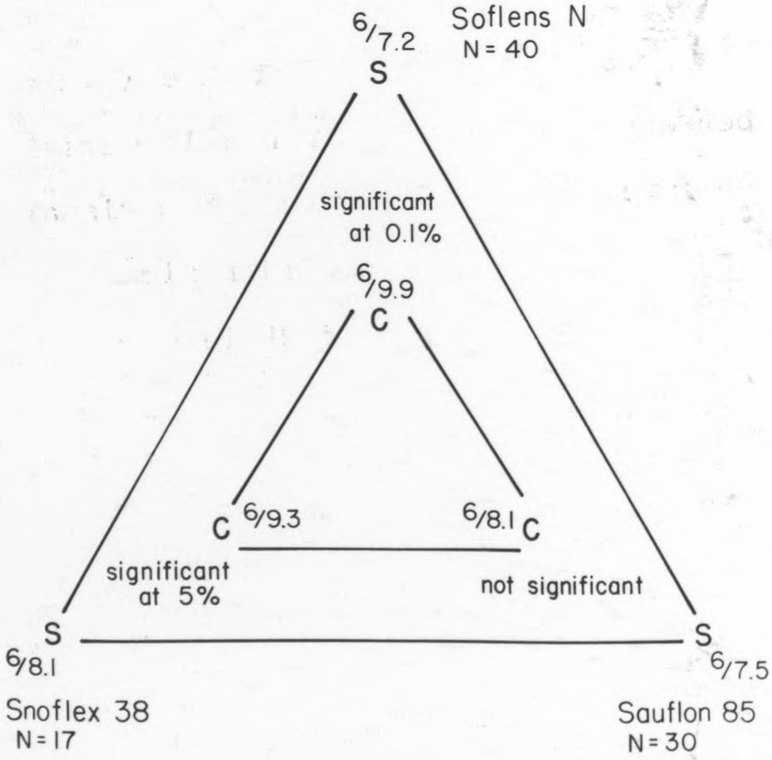
Comparison of spectacle and contact lens visual acuities of patients fitted with different back radii of Soflens N lenses



Mean Snellen Visual Acuity between Spectacles (S) and Contact Lens (C) of Soflens N lenses.

FIGURE (XI.1)

Comparison of spectacle and contact lens visual acuities of patients fitted with Soflens N, Snoflex 38 and Sauflon 85 lenses



Mean Snellen Visual Acuity between Spectacles (S) and Contact Lens (C) of Soflens N, Snoflex 38, and Sauflon 85 lenses.

The paired t test was used to compare the visual acuities between spectacles (S) and soft contact lenses (C). For statistical purposes the visual acuities on the Shellen chart were transposed to Snell-Sterling Visual Efficiency (E) from the equation:-

$$E = 0.8363^{\left(\frac{1}{VA} - 1\right)} \quad \text{(Snell \& Sterling 1925)}$$

It was found that there was no significant difference in visual acuities between spectacles (S) and soft contact lenses (C) for Sauflon 85 but a significant difference at the 5% level for Snoflex 38 and significant difference at the 0.1% level for Soflens (see Figure (XI.1)). The Soflens group was then divided into lenses fitted steeper, between, and flatter than both corneal radii and spectacle and soft contact lens visual acuities again were compared. A significant difference was found at the 1% and 2% levels when Soflens was fitted steeper or between the corneal radii but those lenses fitted flatter than both radii did not show a significant difference between the visual acuities (see Figure (XI.2)).

The difference between spectacle and contact lens visual acuities for all three lens designs also can be shown as lines lost or gained on the Snellen chart (see Figure (XI.3)). Soflens N with a significant difference at 0.1% level for all forms of soft lens fitting was equivalent to a mean loss

FIGURE (XI.4)

The difference between spectacle and contact lens visual acuities of patients fitted with different back radii of Soflens N

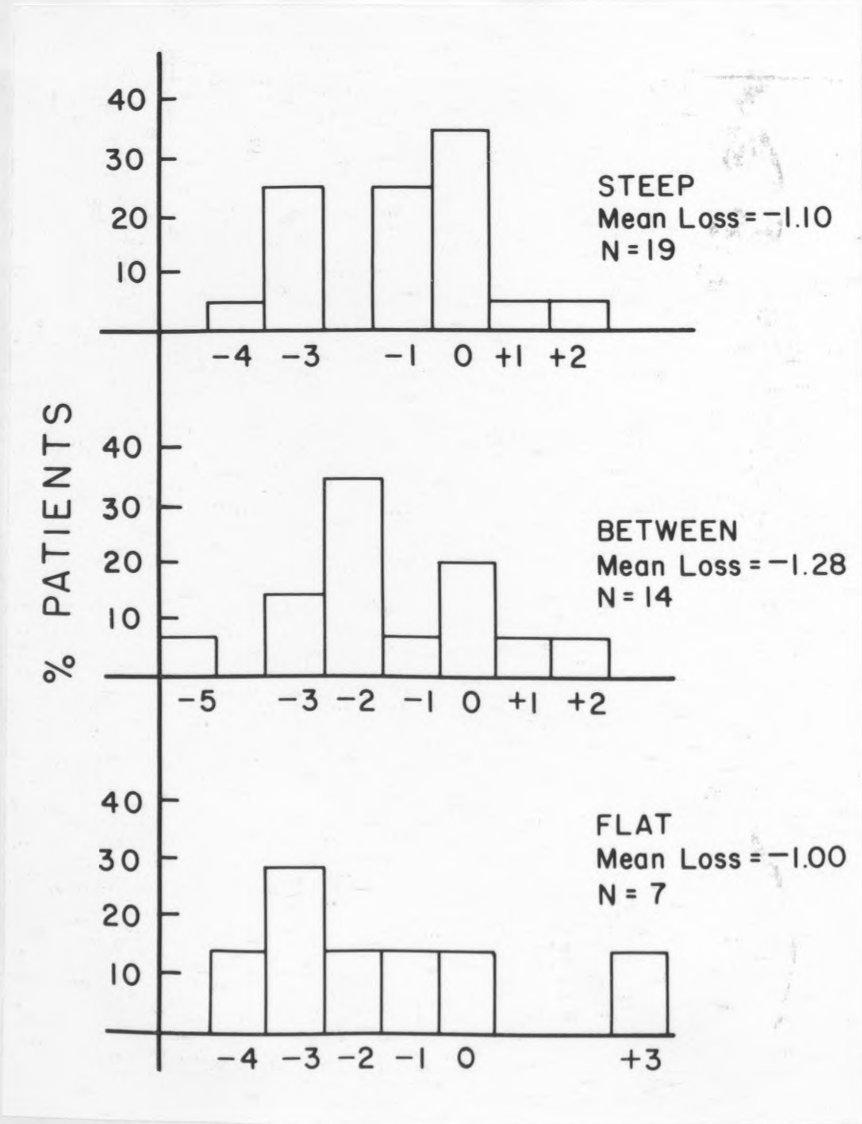


FIGURE (XI.4)

of visual acuity of 1.17 lines on the Snellen chart, compared with spectacles, whereas the significant difference at the 5% level for Snoflex 38 was equivalent to a mean loss of 0.59 Snellen lines. While the loss of 0.23 Snellen lines between the contact lens and spectacle visual acuity was not considered significant for Sauflon 85.

Figure (XI.4) shows that when Soflens N was fitted steeper than both corneal radii, the contact lens mean visual acuity was 1.10 Snellen lines lower than with spectacles. Soflens N fitted between or flatter than both corneal meridians also show a reduction in visual acuity with the contact lens - those lenses fitted between the corneal radii showed a mean drop of 1.28 Snellen lines while those fitted flatter showed a mean drop of one line. Thus a mean loss of visual acuity of one line for Soflens N lenses fitted flatter than both corneal radii was not considered significant when using the paired t test.

(3) Discussion

Those Soflens N series of lenses fitted steeper than both corneal meridians had a mean measured radius at room temperature of 0.33mm steeper than the steeper meridian and 0.66mm steeper than the flatter meridian. If the effect of temperature on back radius is now taken into account,

TABLE (XI.3)

The fitting of the back radius of high plus soft contact lenses at eye temperature with respect to the corneal radius...

	SOFLENS N STEEPER (mm)	SOFLENS N BETWEEN (mm)	SOFLENS N FLATTER (mm)	SNOFLEX FLATTER (mm)	SAUFLON 85 FLATTER (mm)	SAUFLON 85 BETWEEN (mm)
N	19	14	7	17	20	8
$\bar{x}_{(S)}$ eye temp	+0.54	-0.04	-0.27	-0.99	+0.05	+0.32
$\bar{x}_{(F)}$ eye temp	+0.87	+0.46	+0.04	-0.72	+0.38	+0.83

To show the mean $\bar{x}$ and standard deviation SD of the back radius of the contact lens in Table (XI.2) measured at eye temperature

TABLE (XI.2)

The fitting of the back radius of high plus soft contact lenses with respect to the corneal radii...

	SOFLENS N STEEPER (mm)	SOFLENS N BETWEEN (mm)	SOFLENS N FLATTER (mm)	SNOFLEX FLATTER (mm)	SAUFLON 85* FLATTER (mm)	SAUFLON 85 BETWEEN (mm)
N	19	14	7	17	20	8
$\bar{x}_{(S)}$	+0.33	-0.24	-0.48	-1.20	-0.58	-0.31
$SD_{(S)}$	0.23	0.12	0.20	0.37	0.26	0.25
$\bar{x}_{(F)}$	+0.66	+0.25	-0.17	-0.93	-0.25	+0.21
$SD_{(F)}$	0.27	0.23	0.16	0.39	0.17	0.17

* 2 Sauflon 85 omitted because they were steeper fitting than both corneal meridian.

To show the mean $\bar{x}$ and standard deviation SD of the back radius of the contact lens measured at room temperature with respect to the flatter (F) or steeper (S) corneal meridian (Sauflon 85 back radii could not be measured with the Haag-Streit keratometer in this evaluation and the back radius at room temperature was taken to be the labelled radius). + denotes a steeper back radius with respect to the corneal radius, and - denotes a flatter back radius with respect to the cornea.

because when the Soflens N is placed on an eye at approximately 35^{o}C, the mean back radius of the soft lens will steepen by 0.21mm giving a mean back radius of 0.33mm + 0.21mm or 0.54mm steeper than the steeper corneal meridian and similarly the soft lens will be 0.66mm+0.21mm or 0.87mm steeper than the flatter meridian. This type of fit on average gave a reduction of visual acuity between spectacles and soft lens of 1.50 Snellen lines and this is significant at the 2% level. This data is summarised in Tables (XI.2) and (XI.3).

Similarly, using the same reasoning, those lenses fitted between the corneal meridians showed on average a measurement of back radius of 0.24mm flatter than the cornea in the steeper meridian and 0.25mm steeper than the cornea in the flatter meridian. Using 0.21mm for the steepening of the back radius of a 38% water content lens from room to eye temperature gives a lens fitted -0.24mm + 0.21mm = 0.04mm flatter than the corneal radius on average in the steeper meridian and +0.25mm + 0.21mm = 0.46mm steeper than the corneal radius in the flatter meridian. This type of fitting on average showed a mean drop of 1.28 Snellen lines in soft contact lens visual acuity compared with spectacles. This gave a significant difference at the 1% level in the comparison of spectacle and soft lens visual acuity.

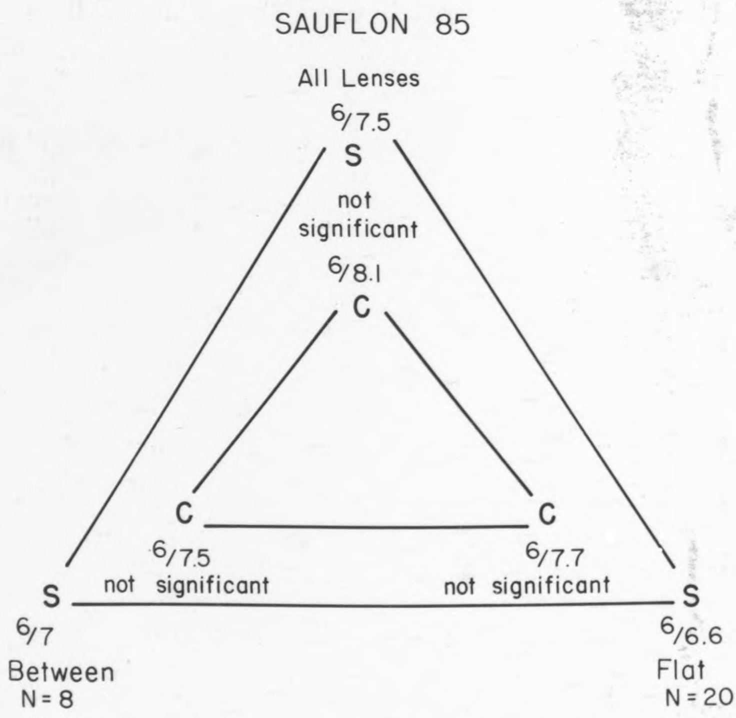
Soflens N fitted flatter than both meridians gave measurements on average 0.48mm flatter in the steeper meridian and 0.17mm flatter in the flatter meridian so allowing for 0.21mm steepening in each meridian because the lens is placed on the eye and this will mean that the steeper meridian was on average fitted 0.27mm flatter than the corneal radius and the flatter meridian was fitted on average 0.04mm steeper than the corneal radius. This flat fitting gave a loss of visual acuity of 1 Snellen line between soft contact lens visual acuity and spectacle visual acuity but statistically this gave no significant difference between soft contact lens and spectacle visual acuities. This result should be treated with caution because this group only had 7 entries.

This type of analysis carried out for the 17 Snoflex 38 lenses can be made only for lenses fitted flatter than both meridians because all 17 lenses came in this group. Table (XI.2) gives the mean values of the lens back radius at room temperature of 1.20mm flatter and 0.93mm flatter when fitted to the steeper and flatter corneal meridians respectively. So even with a steepening of 0.21mm these lenses fitted flatter on the eye by 0.99mm and 0.72mm. Although these lenses were obviously not too tight by virtue of their flat fitting, this fitting gave a loss of 1.2 Snellen lines of visual acuity when the soft contact lens acuity was compared with spectacles and this was significant at the 5% level.

A similar analysis can be made of the Sauflon 85 lenses. Twenty lenses were fitted flatter than both corneal

FIGURE (XI.5)

Comparison of spectacle and contact lens visual acuities of patients fitted with different back radii of Sauflon 85



Mean Snellen Visual Acuity between Spectacles (S) and Contact Lens (C) of Sauflon 85 lenses.

FIGURE (XI.5)

meridians and 8 lenses were fitted between the corneal meridians. (The two lenses fitted steeper than both corneal meridians were omitted from the analysis). It has been shown in Figure (XI.1) that all 30 Sauflon 85 lenses grouped together did not give a significant difference in visual acuity from spectacle visual acuity. When the lenses were grouped into lenses fitted flatter than both meridians (N = 20) or when lenses were grouped into those fitting between the corneal meridians (N = 8), there was not a significant difference in contact lens visual acuity compared with spectacle lens visual acuity in either group. Again these results should be treated with caution. In the group of lenses fitted between the corneal meridians there were 8 entries and the standard deviations of the visual acuities were not similar (spectacle lens visual acuity 95.23% Snell-Sterling with a SD of 11.22% and contact lens visual acuity 95.66% Snell-Sterling with a SD of 6.08%. The equivalent Snellen visual acuities are shown in Figure (XI.5)).

It may well be that for a 75% water content lens the relationship between the back radius and the corneal radius is not crucial but on the other hand it could be that information gleaned from such a small number of lenses with different standard deviations for the visual acuities do not give so much information as the larger group of Sauflon lenses which were fitted flatter than both corneal meridians (N = 20). 38% water content lenses fitted steeper or between the corneal meridians (Soflens N series) gave a drop in visual acuity when high plus soft contact lenses were worn when compared with spectacle lens visual acuity. Those lenses which were fitted much flatter (Snoflex 38 series) also showed a drop in visual acuity when high plus contact lenses were worn. It is interesting to see that those Sauflon 85 lenses fitted flatter than both meridians gave a mean fitting in the steeper meridian of 0.58mm flatter than the corneal meridian. The steepening in back radius ($\triangle r_2$) of a 75% water content lens from room to eye temperature is 0.63mm. This means on average that the fit of these high plus lenses was -0.58mm + 0.63mm or + 0.05mm steeper than the cornea in the steeper meridian and -0.25mm + 0.63mm or + 0.38mm steeper than the cornea in the flatter meridian.

Table (XI.2) expresses the means and standard deviations of soft lens measurement at room temperature with respect to the steeper and flatter corneal meridians.

Table (XI.3) gives the means of the back radius at 35°C with respect to the steeper and flatter corneal meridians.

(4) Conclusion

The hypothesis that needs to be tested states that the fit of a high plus soft lens to give the best visual acuity is probably the lens that is fitted flatter than the corneal radius by the amount of steepening induced by the change from room to eye temperature. That is, 38% water content lenses should be fitted 0.21mm flatter than the flatter corneal meridian; 60% water content lenses should be fitted 0.46mm flatter than the flatter corneal meridian; and 75% water content lenses should be fitted 0.63mm flatter than the flatter corneal meridian. This allows for alignment in the flatter meridian on reaching the eye temperature and allows, in the steeper corneal meridian, a slightly flat fit - the flatness of the fit depending on the corneal toricity.

CHAPTER XII

DESIGN CRITERIA FOR A HIGH PLUS SOFT CONTACT LENS THAT FULFILS THE OXYGEN NEEDS OF THE CORNEA IN THE APHAKIC EYE

Design Criteria for a High Plus Soft Contact Lens that Fulfils the Oxygen needs of the Cornea in the Aphakic Eye

(1) Introduction

The soft lens should have the lowest possible water content because low water content materials have maximum mechanical strength and are easier to manufacture and reproduce to prescription. Hydrophilic soft lens materials now available tend to become mechanically weaker as the water content is increased. The centre of high plus lenses and carriers should be of minimum thickness. The carrier should however be thick enough to support the lens mechanically and not fold on the edges when the lens is on the eye. A high powered soft lens that is excessively thick in the centre or at the edge does not allow the lids to close completely on blinking so that surface deterioration and deposits appear on the front optic zone. In extended wear, the closure of the lids while asleep may cause corneal deformation due to mechanical pressure and result in fluctuating vision on awakening while the cornea adjusts to its open eye shape. For a given soft lens material, production of a lens with minimum thickness, small front optic zone and thin carrier depends upon the skill of the manufacturer. Low water content materials have a higher refractive index and therefore for a given back vertex power, a lens of such material can be made thinner than a lens made from a high water content material.

(2) Oxygen Needs of the Cornea

One important requirement for contact lens wear is the oxygen needs of the cornea. How much oxygen does the cornea need? Many studies, the most recent of which by Polse (1979), have shown that lid movement over a soft contact lens pumps very little oxygen-bearing tear fluid under the lens; almost all of the oxygen reaching the cornea must come by diffusion through the lens.

A method of finding how much oxygen a cornea needs is to provoke the cornea into swelling and to assess at what level the oxygen tension should be for acceptable levels of swelling and assess levels below which the cornea will swell and will not be acceptable to the clinician. A clinician monitoring a 'good' PMMA contact lens fitting finds the cornea swells 4% and yet through years of experience learns that no long-term harm comes to the cornea.

Polse and Mandell (1971) found that, by using a mixture of nitrogen and oxygen passed through a gas tight goggle on the human eye, an unacceptable corneal thickening was observed if the gas in contact with the cornea fell below 11mm Hg. The 4% acceptable level was found to be equivalent to 15mm Hg oxygen tension.

Fatt (1977a) showed various oxygen tensions under a contact lens as a function of the transmissibility of the lens and that for the open eye 5×10^{-9} (cm/sec)(mlO_2/ml x mm Hg) transmissibility would give 15mm Hg oxygen tension requirements. Fatt (1978) measured the oxygen flux into the cornea by placing a polarographic sensor onto a soft contact lens which had been fitted onto normal corneas. Mathematical assumptions made this method valid for lenses of lower water content and low oxygen transmissibilities (in the region of 2×10^{-9} (cm/sec)(mlO_2/ml x mm Hg)). Rasson and Fatt (1981) overcame the previous mathematical assumptions and solved mathematically the complete model of the transient behaviour of the cornea/contact lens system. As a result, Rasson and Fatt gave graphical relationships between the decay of oxygen tension recorded by the sensor and the initial oxygen tension under the contact lens for a wide range of oxygen transmissibilities. This has been discussed in Chapter X. Chaston and Fatt (1982) measured the oxygen flux into the corneas of patients with unilateral aphakia by placing a soft contact lens of known oxygen transmissibility on the cornea and then measuring with the polarographic oxygen sensor the oxygen tension decay of the soft contact lens. The Rasson and Fatt graphs enabled the oxygen flux and oxygen tension to be plotted as a function of oxygen transmissibility of the lens for unilateral aphakic patients. This study indicated that a Dk/L of 6×10^{-9} to 12×10^{-9} will give oxygen tension at the cornea of the closed eye in the range 10mm to 20mm Hg.

(3) <u>Back Vertex Power</u>

The other parameter that affects the choice of water content is the back vertex power. This requirement is set by the refractive condition of the eye and the amount of bending and flexing that the soft lens undergoes as it conforms to the shape of the cornea. The back central and peripheral radii and their back diameters are set for the best fit for stability of the lens on the eye, while the front optic diameter is set by the size of the pupil.

(4) Lens Design

The aim of lens design is to combine the lens parameters needed clinically such as back vertex power, back radii and back diameters, with adjustable parameters such as central thickness, peripheral thickness, refractive index and water content, so that the clinical criteria for 'best fit' and maximum visual acuity are combined with minimum interference to the oxygen requirements of the cornea. The resulting lens should be mechanically strong, not easily damaged and easily maintained.

The description that follows shows how the graphs giving choice of water content for different back vertex powers have been calculated.

(a) Manufacturing Constraints of Thickness *

The first step was to ask the manufacturer what minimum thickness and minimum diameters could be cut with the lens material in the dry state. Focus Contact Lens Laboratory will give a 0.16mm carrier junction thickness in the dry state for a lenticular plus lens. The swelling factor of the material will determine the carrier junction thickness when the lens is hydrated. The front optic diameter could be

* see Appendices 1 & 2

cut as small as 4.25mm in the dry state. Again the hydrated front optic diameter will depend upon the swelling factor of the material (Bryant 1980).

(b) Front Optic Diameter

The second step was to choose the front optic diameter that is needed clinically. In all probability soft lenses of over +8.00D will be for the aphakic population who tend to be elderly and have small pupils. The size of the pupils of patients with aphakia are usually in the region of 1mm to 4mm (assuming that the iridectomy is small) therefore we do not need much more than 5mm to 6mm front optic diameters for plus lenses over +8.00D. Other naturally hypermetroptic patients tend to have smaller pupils than the myopic and emmetropic population. Therefore, it can be assumed that in most cases all our hypermetropic patients need small front optic diameters in the region of 5mm to 6mm.

The third step is to choose materials in a range of water contents and knowing their refractive indices and swelling factors, feed this information into a manufacturer's computer, in this case Radio Shack 2 from Focus Contact Lens Laboratories. This data enables front and back radii and centre and edge thicknesses of a large range of back vertex powers to be calculated.

(c) Refractive Index

As the contact lens is to be worn upon the eye at the eye temperature of approximately 35°C, we need to know the refractive index of the lens material at this temperature. Fatt and Chaston (1980) gave the relationship of refractive index at 35°C as a function of water content to be:-

$$n_{35^{\circ}C} = 1.51932 - 1.96 \times 10^{-3}WC \quad \text{(XII.1)}$$

where WC is the water content in percent.

(d) Swell Factor

To design 'best form' lenses, assumptions have to be made about linear swell factors if manufacturers will not release them. If the dry density of each material is known and the volumes are taken to be additive, then the volume of hydrated polymer can be calculated.

$$\text{Density} = \frac{\text{Mass}}{\text{Volume}} \quad \text{(XII.2)}$$

Similarly -

$$\text{Volume} = \frac{\text{Mass}}{\text{Density}} \quad \text{(XII.3)}$$

Taking the density of water to be $1g/cm^3$ and the density of dry polymer to be $1.19g/cm^3$ (that of PMMA), a series of tables can be generated to show linear swell factor as a function of water content.

For example, for a 40% water content hydrogel for every 100 gms of material 40g will be water and 60g will be polymer. From equation (XII.3) the volume of water will be 40ml and the volume of polymer will be 60/1.19 = 50.42ml.

The volume of water + volume of polymer = total volume

$$(40 + 50.42)\text{ml} = 90.42\text{ml}$$

Original volume was = 50.42ml

Therefore, the volumetric swell factor = 90.42/50.42

= 1.79

Therefore, the linear swell factor = $\sqrt[3]{1.79}$

= 1.21

Working through similar calculations, we can show linear swell factor as a function of water content and if the reciprocal of the linear swell factor ($\frac{1}{SF}$) is taken the relationship to water content can be given as:-

$$\frac{1}{SF} = 1.092 - 0.0065WC \qquad \text{(XII.4)}$$

where WC is in percent in the range of 30 to 80% water.

Fatt and Chaston (1982a) show that for a series of measured dry densities of hydrogel polymers, the density values do not differ greatly from 1.19g/cm^3 and that for this series of soft lens materials, the least squares fit line for the reciprocal of the

TABLE (XII.2)

Linear swell factor calculated from water content assuming the dry density of hydrogels to be that of PMMA and volumes to be additive...

1	2	3
WATER CONTENT %	RECIPROCAL OF LINEAR SWELL FACTOR $(\frac{1}{LSF})$	LINEAR SWELL FACTOR (LSF)
40	0.832	1.20
45	0.800	1.25
50	0.767	1.30
55	0.735	1.36
60	0.702	1.42
65	0.670	1.49
70	0.637	1.57
75	0.605	1.65
80	0.572	1.75
85	0.540	1.85

TABLE (XII.1)

Linear swell factor calculated from measured water content from various manufactured soft lens materials...

1	2	3	4
MANUFACTURER'S MATERIAL	WATER CONTENT %	DRY DENSITY CALCULATED FROM TRUE WATER CONTENT	LINEAR SWELL FACTOR CALCULATED FROM TRUE WATER CONTENT
GELFLEX	36	1.27 g/cm^3	1.20
HYDRON HEMA	38	1.29	1.21
HYDROCURVE II 45	45	1.30	1.27
HYDROCURVE II 55	54	1.38	1.39
SAUFLON 70	67	1.19	1.51
SAUFLON 85	80	1.19	1.79

TABLE (XII.1)

linear swell factor as a function of the water content can be given by the equation:-

$$\frac{1}{SF} = 1.029 - 0.00548WC \qquad \text{(XII.5)}$$

Table (XII.1) shows linear swell factor calculated from the water content from various manufactured materials and Table (XII.2) shows the linear swell factor calculated from assuming the dry density of hydrogel to be that of PMMA.

(e) <u>Calculation of Centre and Saggital Height Carrier Junction Thickness</u>

The computer was programmed with the following formulae (Mandell 1974) for front radius r_1 and edge thickness t_e:-

$$r_1 = (r_2)(n - 1)((r_2)(F'_v) - (1 - n))^{-1} + t_c - (t_c/n) \qquad \text{(XII.6)}$$

$$t_e = r_c + (r_2 - r_1) - 0.5(\sqrt{4r_2^{\,2}-d^2}-\sqrt{4r_1^{\,2}-d^2}) \qquad \text{(XII.7)}$$

Centre thicknesses were calculated for a range of back vertex powers for plus lenses of water contents from 40% to 85%. The back radius was taken to be 8.60mm (differing values of back radius r_2 make very little difference to the choice of water content) and the front optic diameter was taken to be 4.25mm in the dehydrated state. The front optic diameter of the hydrated lens is a function of the

TABLE (XII.3)

Water Content %	Linear Swell Factor	Front Optic Diameter Wet (mm)
40	1.20	5.10
45	1.25	5.33
50	1.30	5.53
55	1.36	5.78
60	1.42	6.04
65	1.49	6.33
70	1.57	6.67
75	1.65	7.01
80	1.75	7.44
85	1.85	7.86

To show front optic diameter in the hydrated soft lens when the dry front optic diameter is 4.25mm.

TABLE (XII.3)

swelling factor and the hydrated front optic diameters are shown in Table (XII.3). The front optic diameters range from 5.10mm to 7.86mm, more than adequate for 1mm to 4mm pupils. The first plus lens series had a carrier junction thickness of 0.16mm in the dehydrated state. This was the minimum carrier junction thickness that this manufacturer was prepared to make. But more recent technology at this Laboratory has produced lenses of 0.10mm as a minimum carrier junction thickness. So a second set of calculations was made with a minimum carrier junction thickness of 0.10mm.

(f) Average Thickness Calculated Along the Radius

Knowledge of centre and edge thickness of a lens enables calculation of the average thickness of a lens (Fatt 1979). It has been shown that the amount of corneal swelling under a soft contact lens depends upon the oxygen transmissibility of the lens. The oxygen transmissibility (Dk/L) is defined as the oxygen permeability (Dk) divided by the lens thickness (L). The amount of oxygen moving through a lens depends upon the average thickness and the flow of oxygen is always along the normal to the surface. Therefore, the average thickness for oxygen transmissibility should be calculated from the thickness along the radius of curvature. But the manufacturer has calculated the centre and the edge thickness from sagittal heights. The average sagittal height thickness is not the same as the average thickness calculated along the radius of curvature. An approximation to the average radial thickness of a high powered lens can be obtained from sagittal measurements by an empirical equation using weighted centre and carrier junction thicknesses. An equation for the average thickness $\bar{L}$ that is within 5% to 10% of the average radial thickness is:-

$$\bar{L} = {}^{2}/_{3}t_{c} + {}^{1}/_{3}t_{j} \quad \text{(Parkin 1982)} \qquad \text{(XII.8)}$$

where t_c is the centre thickness and t_j is the carrier junction thickness. Finally, the last step is to calculate from dividing permeability (Dk) of the soft lens materials on the eye at 35°C by the transmissibility requirements for daily or extended wear and find the average thickness of the lens to fulfil these transmissibility requirements. Permeability (Dk) at 35°C is given by:-

$$Dk = 2 \times 10^{-11} \text{ exp. } 0.0411WC \qquad \text{(XII.9)}$$

where WC is water content in percent. (Fatt and Chaston 1982).

For daily wear lenses, transmissibility requirements are given by 5×10^{-9} (cm/sec)(ml0_2/ml x mm Hg) and in experiments performed on unilateral aphakic patients, extended wear transmissibility requirements are in the region of 10×10^{-9} (cm/sec)(ml0_2/ml x mm Hg). Just to be on the safe side, extended wear conditions needing 15×10^{-9} (cm/sec)(ml0_2/ml x mm Hg)

FIGURE (XII.3)

Water content as a function of back vertex power to fulfil oxygen requirements of $15\text{x}10^{-9}$ (cm/sec)(MlO$_2$ml x mm Hg)

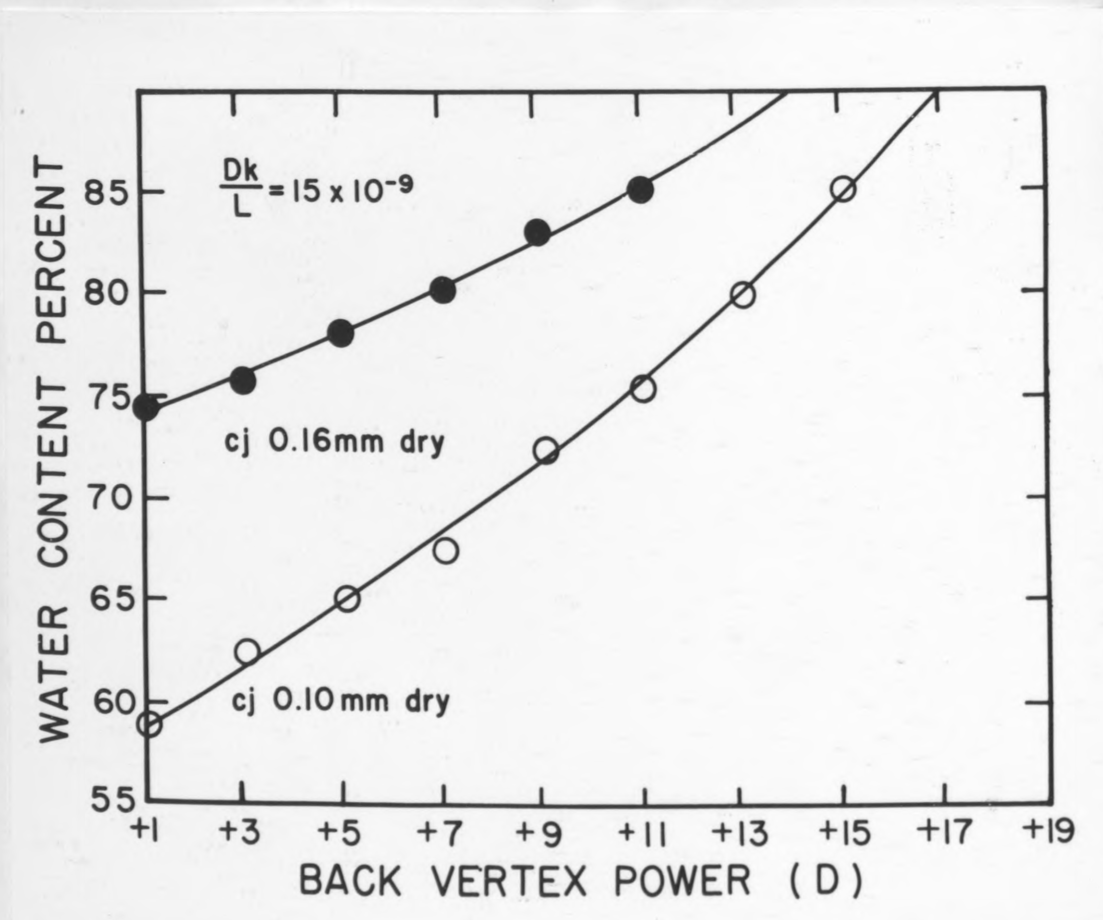


FIGURE (XII.3)

FIGURE (XII.2)

Water content as a function of back vertex power to fulfil oxygen requirements of 10×10^{-9} (cm/sec)(MlO_2ml x mm Hg)

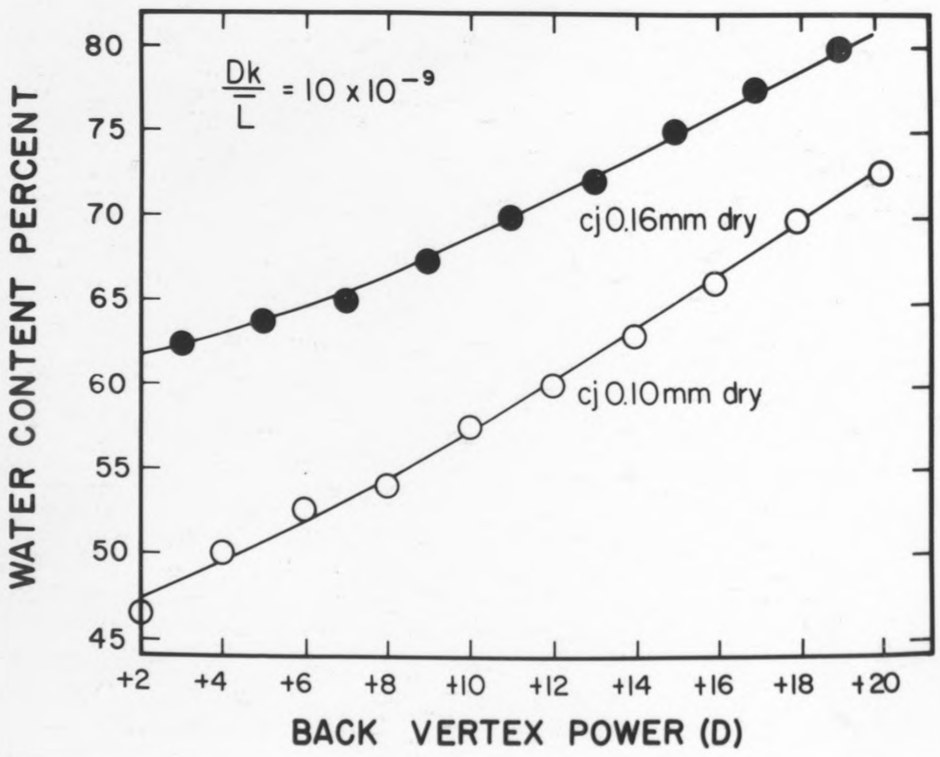


FIGURE (XII.2)

FIGURE (XII.1)

Water content and function of back vertex power to fulfil oxygen transmissibility requirements of $5x10^{-9}$ (cm/sec)(M10_2ml x mm Hg)

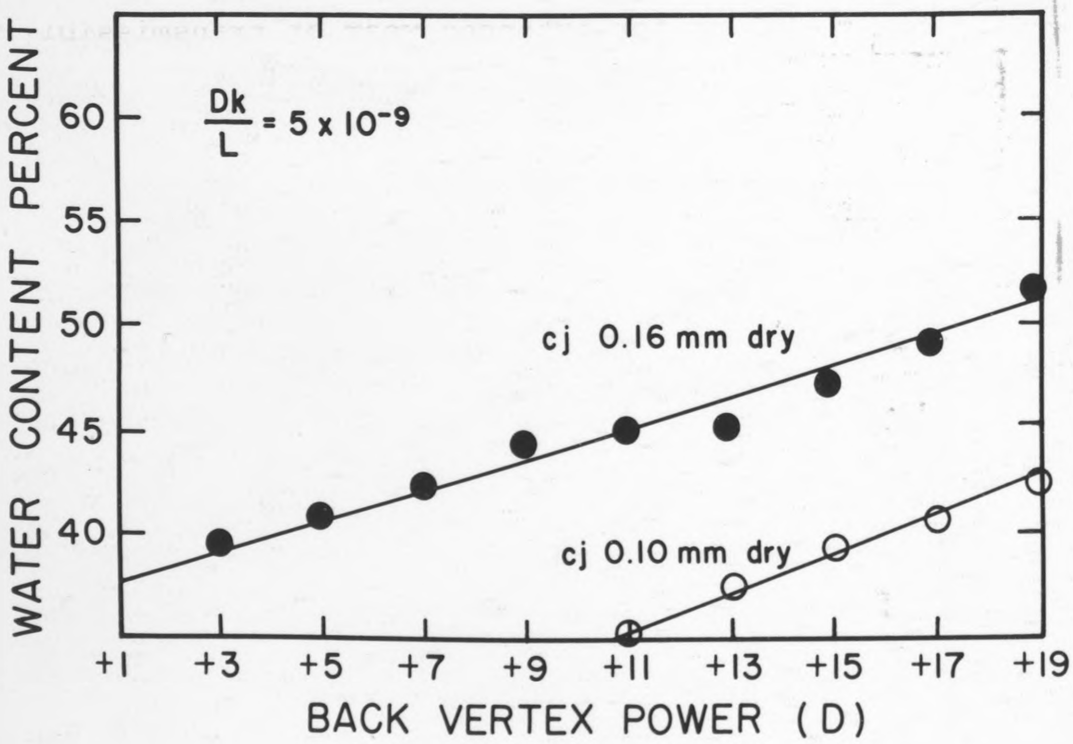


FIGURE (XII.1)

have also been calculated.

Dividing permeability of each water content material at 35°C by transmissibility requirements, the average thickness of a lens that is required for daily or extended wear can be found. If the manufacturer's average thickness for any given water content lens is less than the average thickness calculated from permeability of the lens material at 35°C, divided by the transmissibility requirements of $Dk/\bar{L}$ of 5, 10 or 15 x 10^{-9} (cm/sec)(mlO_2/ml x mm Hg) then this water content lens can be used for daily wear of transmissibility requirements of 5 x 10^{-9} or for extended wear of transmissibility requirements of 10 or 15 x 10^{-9}.

(g) <u>Preparation of Calculational Graphs</u>

The results of these calculations are shown on the Figures (XII.1), (XII.2) and (XII.3). Figure (XII.1) gives $Dk/\bar{L}$ as 5 x 10^{-9} and Figures (XII.2) and (XII.3) give $Dk/\bar{L}$ as 10 x 10^{-9} and 15 x 10^{-9} respectively. It can be seen that if oxygen transmissibility requirements needed are much higher than 15 x 10^{-9} (cm/sec)(mlO_2/ml x mm Hg) it is impossible to design extended wear lenses for the aphakic eye with these manufacturing criteria.

CHAPTER XIII

THE USE OF PMMA DIAGNOSTIC LENSES AND THE TRANSPOSITION TO SOFT LENS PARAMETERS

The Use of PMMA Diagnostic Lenses and the Transposition to Soft Lens Parameters

(1) Introduction

High plus soft lenses are fitted by the traditional method used for fitting PMMA lenses, namely by use of a fitting set. The soft lens is selected for back radius and diameter and then the back vertex power is found by adding the over refraction to the back vertex power of the fitting set lens. Several difficulties arise when using this procedure. Unlike PMMA lenses, the parameters of soft lenses are not so easy to check nor are the tolerances of some of the required optical dimensions so fine. Sometimes errors in the soft lens fitting set - especially in back vertex power - are compounded by the manufacturer's errors in the lens ordered for the patient. This means that the patient's soft lens, when placed on the eye, may give a poor fit, poor visual acuity, corneal oedema or a combination of these. How can this problem be overcome? Is there an alternative to the use of the soft lens fitting set?

A method of fitting high plus soft lenses that use a PMMA fitting set will be described. The dimensions of the diagnostic PMMA lens are modified to give the soft lens prescription by using the now known effects of bending and temperature on high plus soft lenses.

This method is based upon the hypothesis that the manufacturer's description of a soft contact lens on the bottle delivered to the practitioner gives the dimensions of the lens at room temperature (20°C) and in an unstressed condition. On taking the lens from its bottle and putting it on the eye, the lens is raised in temperature to about 35°C and is bent or draped onto the cornea thereby taking on a new set of dimensions. It is the dimensions while on the eye that must give a proper fit of the lens to the eye and provide the necessary refractive correction.

Apart from geometrical and optical considerations, the soft contact lens on the eye must not lower oxygen flux to the anterior corneal surface below some minimum that gives a clinically acceptable corneal oedema. Since the oxygen flux to the anterior surface of the cornea is governed by the oxygen transmissibility of the contact lens, a minimum oxygen transmissibility is required. This transmissibility is further dependent upon whether the lens is to be worn daily or for extended periods of time.

The task then is to describe, from the diagnostic lens in the PMMA fitting set, a best form soft lens in its bottle that when placed on the eye will give an optimum fit. Chapter (XII) describes how the requirements of oxygen transmissibility, manufacturing techniques, back radius and back vertex power regulate the minimum water content of the high plus soft lens suitable for extended wear in aphakia. Chapter (VII) concludes that unless the lens has a water content in the region of 80% and back vertex power in the region of +18.00D and centre thickness in the region of 0.50mm, the changes from room to eye temperature are so small that for practical purposes these effects can be ignored. Chapter (VIII) gives the change in back radius ($\triangle r_2$) of different water content hydrogels from room to eye temperature. Chapter (IX) gives the change in radius of high plus lenses on 'bending' onto the eye from the 'in air' position. Clinical data from Chapter (XI) gives a good criterion of back radius on the soft lens for best fit for visual acuity purposes to be fitted aligned to the corneal meridian on a spherical cornea or to be fitted on the flatter meridian on a toroidal cornea. This information allows calculation from PMMA diagnostic lens parameters on the eye to be transposed to the soft lens in the bottle.

(2) <u>To Find the Back Vertex Power of the Soft Lens on the Eye</u>

Taking an example of the corneal radius to be 7.80mm and placing a 7.80mm PMMA high plus diagnostic lens on the eye will enable the practitioner to over refract and find back vertex power of the PMMA lens needed to correct the ametropia. Let the sum of the back vertex power of the contact lens and the over refraction be +15.00D. This +15.00D will represent the back vertex power of the soft lens on the eye at a temperature of approximately $35^{\circ}C$ because a high plus soft lens conforms to the shape of the cornea and so the back radius of the soft lens on the eye will be 7.80mm. From Figures (XII.1), (XII.2) and (XII.3) in Chapter (XII), the water content needed for oxygen transmissibilities of 5×10^{-9} and 15×10^{-9} (cm/sec)(mlO_2/ml x mm Hg) can be found. If the conservative assumption is made that oxygen transmissibility of 10×10^{-9} (cm/sec)(mlO_2/ml x mm Hg) is needed for extended wear in aphakia, the water content for a +15.00D soft lens will be 65%.

(3) <u>To Find the Maximum Centre Thickness</u>

The next stage is to find the maximum centre thickness allowed to meet this oxygen transmissibility requirement. If the minimum carrier junction thickness in the dry state is 0.10mm and the swelling factor (SF) is given by:-

$$\frac{1}{SF} = 1.092 - 0.0065WC \qquad \text{(XIII.1)}$$

the hydrated carrier junction thickness (t_j) will be:-

$$t_j = 0.10 \times \left\{ \frac{1}{1.092 - 0.0065 \times 65} \right\}$$

$$= 0.15\text{mm}$$

Using the criterion of 10×10^{-9} (cm/sec)(mlO_2/ml x mm Hg) for oxygen transmissibility requirements and substituting values for permeability of a 65% water content material in the equation below will give the average thickness $\overline{L}$ as:-

$$\overline{L} = \frac{2 \times 10^{-11} \exp 0.0411 \times 65}{10 \times 10^{-9}} \text{ cms}$$

$$= 0.29\text{mm}$$

Substituting 0.15mm for the hydrated carrier junction thickness (t_j) and 0.29mm for the average thickness $\bar{L}$, the centre thickness t_c now can be found from equation

$$\bar{L} = {}^2/_3 t_c + {}^1/_3 t_j \qquad \text{(XIII.2)}$$

solving for t_c gives -

$$0.29 - {}^1/_3(0.15) = {}^2/_3 t_c$$

$$\text{Therefore} \quad t_c = \frac{3}{2}\,(0.29 - {}^1/_3(0.15))$$

$$= 0.36\text{mm}$$

From Chapter (VII), the refractive index as a function of water content at 35°C is given by:-

$$n_{35} = 1.51932 - 1.98 \times 10^{-3}\,WC \qquad \text{(XIII.4)}$$

where n_{35} = refractive index at eye temperature and WC is the water content in percent. For a water content of 65%

$$n_{35} = 1.392$$

(4) <u>To Find the Front and Back Radius of the Soft Lens on the Eye</u>

From the above information, the front radius of the lens on the eye can be found from the vertex power formula:-

$$F'_v = \frac{F_1 F_2 - \frac{t}{n} F_1 F_2}{1 - \frac{t}{n} F_1} \qquad \text{(XIII.5)}$$

$$(r)_1\text{eye} = (r_2)\text{eye}(n-1)((r_2)(F'_v)-(1-n))^{-1}+t_c-(t_c\div n) \quad \text{(XIII.6)}$$

$$= (0.0078)(1.392-1)((0.0078)(15)-(1-1.392))^{-1} +0.00036-(0.00036\div 1.392)$$

$$= 6.11\text{mm}$$

From the bending formula and the change in back radius from room to eye temperature, the details of the soft lens in the bottle can be found. The change in back radius (Δr_2) from the lens on the eye to the lens in the bottle is given in Chapter (VI) as:-

$$\Delta r_2 = 1.15 \times 10^{-2}\text{WC} - 0.23 \qquad \text{(XIII.7)}$$

where WC is water content in percent. If this equation is substituted into the bending formula of high plus lenses shown in Chapter (IX), the change in the front radius Δr_1 can be found:-

$$\Delta r_1 = \frac{1}{2}\ \Delta r_2\left\{\frac{r_1}{r_2}\right\} \qquad \text{(XIII.8)}$$

this formula becomes

$$\Delta r_1 = \frac{1}{2}\left\{1.15 \times 10^{-2}\text{x}65-0.23\right\}\left\{\frac{6.11}{7.86}\right\}$$

Equation (XIII.7) gives $\Delta r_2 = 0.52$mm

Equation (XIII.8) gives $\Delta r_1 = 0.20$mm

Both r_2 and r_1 flatten on cooling from the eye temperature to the room or bottle temperature. Therefore, the back radius of the lens in the bottle = 7.80mm + 0.52mm = 8.32mm. The front radius of the lens in the bottle

FIGURE (XIII.3)

Change in back vertex power of high plus soft lenses as a function of a change in back radius when the corneal radius is 8.40 mm

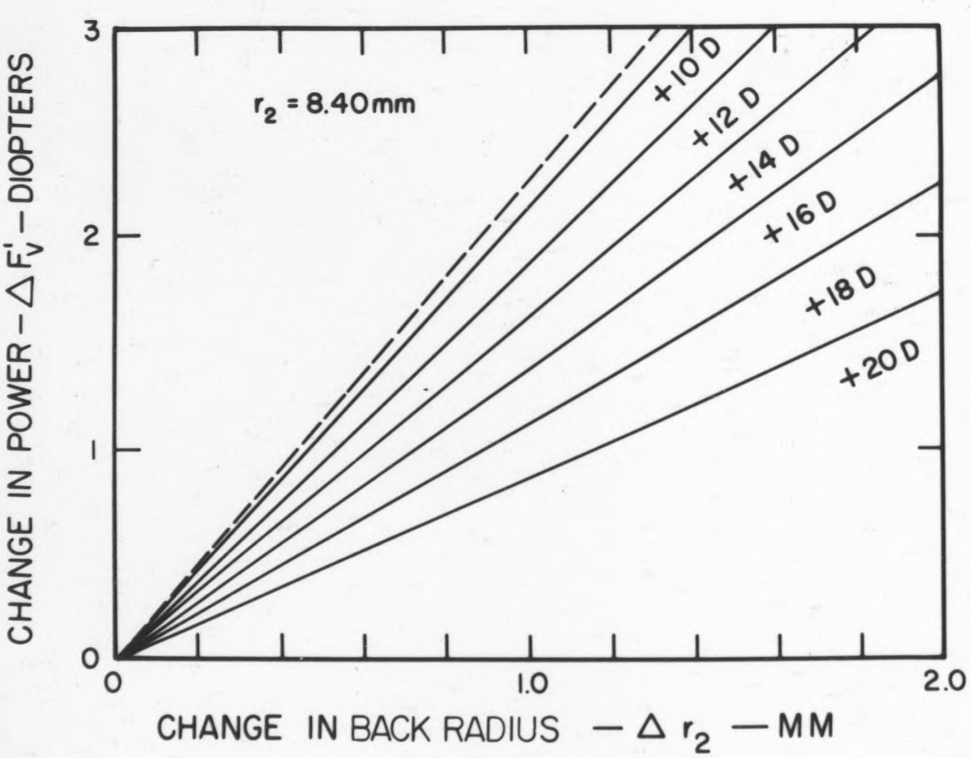


FIGURE (XIII.3)

FIGURE (XIII.2)

Change in back vertex power of high plus soft lenses
as a function of a change in back radius
when the corneal radius is 8.10 mm

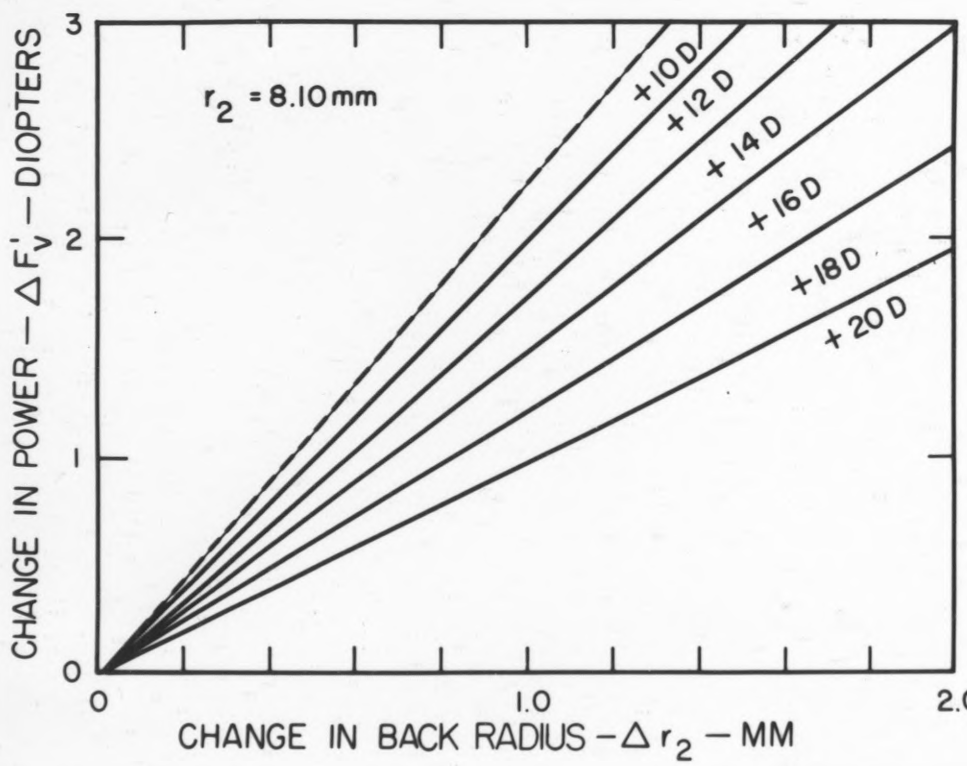


FIGURE (XIII.2)

FIGURE (XIII.1)

Change in back vertex power of high plus soft lenses as a function of change in back radius when the corneal radius is 7.80 mm

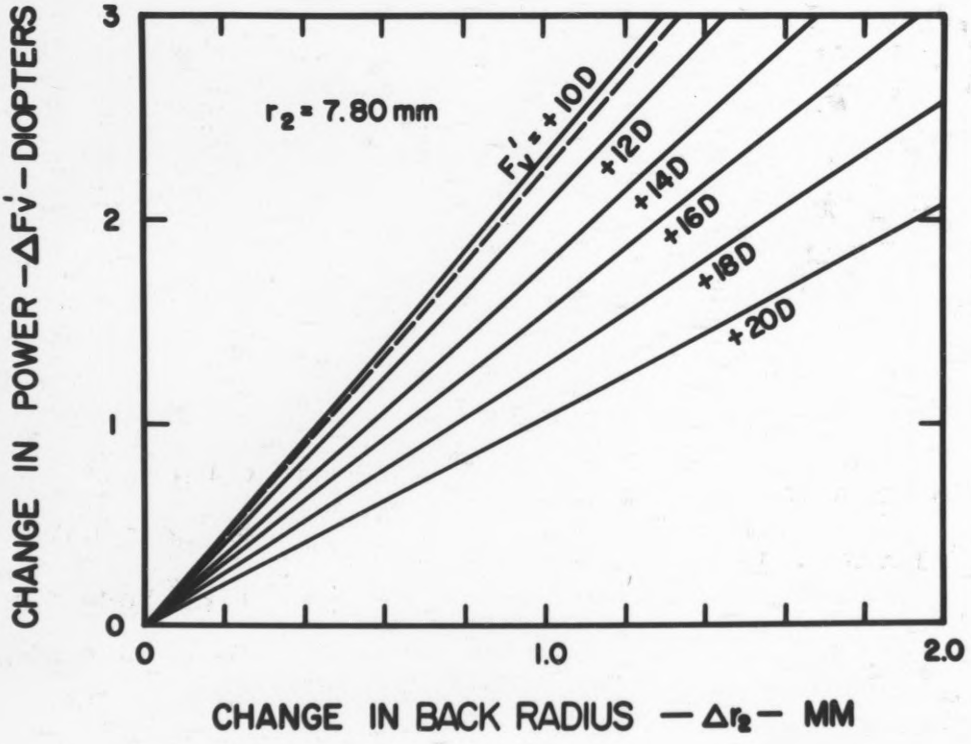


FIGURE (XIII.1)

$= 6.11mm + 0.20mm = 6.31mm.$

(5) To Find the Back Vertex Power of the Lens to be Ordered from the Manufacturer

It can be assumed that changes in refractive index and centre thickness are so small from eye to room temperature and that their effect on back vertex power change is negligible and therefore can be ignored. The parameters of the soft lens at room temperature - i.e., the parameters in the bottle have now been calculated and these are:-

$$r_2 = 7.80 + 0.52 = 8.32mm$$

$$r_1 = 6.11 + 0.20 = 6.31mm$$

$$t_c = 0.36mm$$

$$n = 1.392$$

Substituting the above figures into the formula for back vertex power F'_v

$$F'_v = ((r_1 \times (n - 1)^{-1} - (t_c \div n))^{-1} + ((1-n) \div r_2) \quad \text{(XIII.9)}$$

$$= ((0.00631 \times (1.392-1)^{-1} - (0.00036 \div 1.392))^{-1} + ((-1.392) \div 0.00832)$$

$$= +16.07D$$

So from the keratometry and diagnostic PMMA lens, calculations of the soft lens needed to be ordered from the manufacturers can be made. From the above type of calculation Figures (XIII.1), (XIII.2) and (XIII.3) were produced when r_2 is taken to be the keratometry reading/

FIGURE (XIII.4)

Change in back vertex power divided by the change in back radius as a function of back vertex power

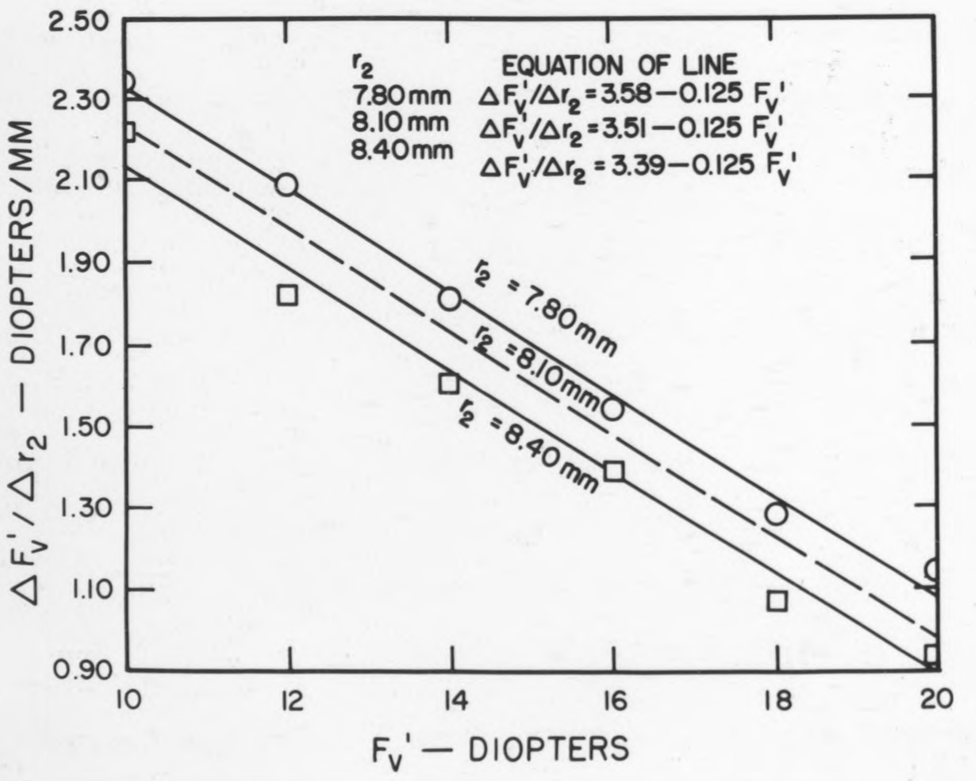


FIGURE (XIII.4)

PMMA diagnostic lens radius/back radius of the soft lens on the eye. The change in base curve Δr_2 is found from equation (XII.7). The change in back vertex power $\Delta F'_v$ is found from the diagnostic lens. he soft lens needed on the eye and its water content required to fulfil oxygen transmissibility requirements is found from Figures (XII.1), (XII.2) and (XII.3) in Chapter XII and then from equations (XIII.1) to (XIII.19) in this Chapter.

(6) <u>Graphical Method to Find the Back Vertex Power to be Ordered from the Manufacturer</u>

The dashed line in Figures (XIII.1) and (XIII.3) and the heavy line in Figure (XIII.2) represent the actual change in back vertex power $\Delta F'_v$ with change in back radius Δr_2 found in clinical practice (Chaston 1979).

Figures (XIII.1), (XIII.2) and (XIII.3) can be consolidated into Figure (XIII.4).

The slopes from Figures (XIII.1), (XIII.2) and (XIII.3) ($\Delta F'_v / \Delta r_2$) are a function of Δr_2, the change in back radius and the least squares fit for the 7.80mm and 8.40mm corneal radius are given as:-

$$(7.80)\Delta F'_v/\Delta r_2 = 3.58 - 0.125F'_v$$

$$(8.40)\Delta F'_v/\Delta r_2 = 3.39 - 0.125F'_v$$

and by interpolation the 8.10mm corneal radius is given as:

$$(8.1)\Delta F'_v/\Delta r_2 = 3.51 - 0.125F'_v$$

(7) Conclusions

In conclusion it can be seen that a high plus PMMA diagnostic lens set with an over refraction, along with Figures (XIII.1), (XIII.2) and (XIII.3) in Chapter (XII), Figure (XIII.4) in this Chapter will give the information required, as to minimum water content , change in back vertex power from the lens on the eye to the lens in the bottle and the change in back radius as the lens back radius flattens from the eye temperature on cooling to the lens in the bottle.

The method of using a PMMA diagnostic lens and an over refraction to find the back vertex power of the soft lens needed and use of graphs presented here to find the lens needed from the manufacturer will remove some of the inaccuracies inherent in using the usual method of a high plus soft lens fitting set. This is a step towards helping the practitioner remove one source of back vertex power errors.

CHAPTER XIV

CONCLUSIONS

Conclusions

For successful extended wear of a contact lens there are six areas needing investigation. These are outlined fully in Chapter (V). The first area is the change in properties, other than dimensions as the soft lens is changed from room to eye temperature. These are the intensive properties of refractive index, water content and oxygen permeability. These properties are usually determined in the research and production laboratory at room temperature but may not be the same when the material is fabricated into a lens and worn on the eye.

The second area is the extensive or dimensional changes in the lens brought about by the contribution of increase in temperature from the storage vial (20^{o}C) to the eye (35^{o}C) and the bending of the lens onto the cornea.

The third area is the minimum amount of oxygen needed for adequate corneal metabolism during extended wear of contact lenses. The fourth area needing investigation is the clinical criteria of the fit of the high plus soft lens that gives maximum visual acuity. The fifth and sixth areas needing investigation are the dehydration of the lens and its spoilation in wear.

(2) Changes in Intensive and Extensive Properties

Room temperature - at which the physical properties and dimensions of the soft lens were checked - were easy to measure with a thermometer; these temperatures ranged in the United Kingdom from about 18° to $24^{\circ}C$. Temperature of the eye's anterior surface vary from patient to patient but was found to be in the region of $33^{\circ}C$ to $36^{\circ}C$. So in round numbers it is convenient to take the difference between room and eye temperature to be about $14^{\circ}C$ to $15^{\circ}C$. How does this temperature difference affect the change in physical properties and dimensions of the soft lens on the eye? From the measurement of refractive index of a number of hydrogel materials at $21^{\circ}C$ and then at $35^{\circ}C$, the following relationships were found:-

$$n_{21} = 1.52003 - 1.98 \times 10^{-3} WC_{21} \qquad \text{(XIV.1)}$$

$$n_{35} = 1.51932 - 1.96 \times 10^{-3} WC_{35} \qquad \text{(XIV.2)}$$

$$WC_{35} = 0.98647 WC_{21} - 1.41648 \qquad \text{(XIV.3)}$$

where n is the refractive index, WC the water content in percent, 21 and 35 represent these temperatures in degrees C.

The small loss of water from hydrogels on heating from room to eye temperature gives a reduction of the central thickness of the lens. Calculations show that this reduction in thickness and change in refractive index will give a small change in back vertex power of soft contact lenses. Using equations (XIV.1), (XIV.2) and (XIV.3) and assuming relevant details of front and back radii and central thickness of the soft lens at room temperature, differences of back vertex power can be found. For example, for a soft lens of +18.00D, 80% water content lens and central thickness of 0.50mm, calculations show the higher refractive index at 35°C adds 0.35D to the back vertex power, but that the reduction in centre thickness reduces the back vertex power by 0.01D so that the nett change gives an additional +0.34D to the back vertex power of this lens. Because the contact lens practitioner is still unable to verify the soft lens to 0.25D, the change in back vertex power due solely to temperature differences of the eye and its surroundings is not yet observable by the clinician. The conclusion is that for clinical purposes the change in back vertex power due to the change in refractive index and centre thickness can be ignored.

Measurement of the unstressed back radius (r_2) of soft lenses of water contents ranging from 38% to 78% showed the change in back radius Δr_2 from room to eye temperature was given by the equation:-

$$\Delta r_{2\,(20-35)} = 1.15 \times 10^{-2} WC - 0.23 \qquad \text{(XIV.4)}$$

where (20-35) denotes the change in temperature from 20°C to 35°C and WC is the water content in percent.

Further measurement of the unstressed front and back radius of high plus lenses showed the change in back radius Δr_2 is proportional to the back radius r_2 and that the change in front radius Δr_1 is proportional to the front radius r_1:-

$$\frac{\Delta r_2}{r_1} = \frac{\Delta r_1}{r_1} \qquad \text{(XIV.5)}$$

or

$$\frac{\Delta r_1}{\Delta r_2} = \frac{r_1}{r_2} \qquad \text{(XIV.6)}$$

Therefore, from equations (XIV.5) and (XIV.6) it would be concluded that an unstressed lens raised in temperature would gain in plus power. This is in fact Strachan's theory of lens bending. But clinical experience has shown that this is not so for high plus lenses, so further research was needed to establish the change in back vertex power of the soft lens on the eye as observed in the clinic.

From the measurement of the high plus soft contact lens as it bends on models of the cornea - the hemispherical plastics domes were of radius 7.32mm, 7.77mm and 8.20mm - it was found that the back radius of the soft lens conforms to the shape of the dome and that the relationship between the change in back radius Δr_2 and the change in front radius Δr_1 is given by:-

$$\frac{\Delta r_1}{\Delta r_2} = \frac{1}{2}\,\frac{r_1}{r_2} \qquad \text{(XIV.7)}$$

This was not the same as the change in radius by heating the unstressed lens (see equations (XIV.5) and (XIV.6)). It has been shown by clinical experience (Chaston 1979) that the approximate change in back vertex power of a high plus lens follows the least squares fit line of:-

$$\Delta F'_v = 2.24\,\Delta r_2 + 0.06 \qquad \text{(XIV.8)}$$

where $\Delta F'_V$ was the change in back vertex power and Δr_2 was the change in back radius when the high plus soft lens was placed on the eye from the 'in air' position. This equation can only be an approximation because it does not include the terms for centre thickness and refractive index.

If the data on the change in back radius Δr_2 from the corneal model of the PMMA domes was used to calculate the approximate change in back vertex power, the least squares fit lines was given by the following equation:-

$$\Delta F'_V = 2.42 \ \Delta r_2 - 0.27 \qquad \text{(XIV.9)}$$

where $\Delta F'_V$ was the change in back vertex power and Δr_2 was the change in back radius as the soft lens bends or flexes on the dome from its 'in air' position. Again this equation is an approximation because it does not include the terms for refractive index and centre thickness. Equations (XIV.8) and (XIV.9) are similar.

It can be concluded that the combination of heating and bending leads to the clinically observed loss of this power of high plus lenses, but it is the bending of the soft lens which is the controlling mechanism.

(3) Oxygen Transmissibility Requirements

The next question to be answered was how much oxygen does the cornea need for contact lens extended wear? From experience with polymethylmethacrylate corneal lenses a good clinical fit may still allow a 4% corneal swelling in daily wear and yet have no long-term repercussions for the cornea. This 4% swelling in terms of oxygen transmissibility (Dk/L) is equivalent to 5×10^{-9} (cm/sec)($ml0_2$ml x mm Hg) or 15mm Hg oxygen tension. From the experiment described in Chapter (X) on measuring corneal oxygen uptake from the cornea in 16 unilateral aphakic patients, it was found there was no statistical difference in corneal oxygen uptake between the corneas of the phakic or the aphakic eyes. This experiment was designed with the hypothesis in mind that there would be such a difference. Because of the assumed hypothesis, the experiment was planned using as many patient variables as possible, such as age, sex, race, type of cataract and length of time of aphakia - with the idea that all corneas in the phakic eyes would exhibit more oxygen need than the corneas in the aphakic eyes. Results showed that in all 32 eyes of these 16 patients, a scatter of oxygen transmissibility needs for extended wear of between $6\text{-}12 \times 10^{-9}$ (cm/sec)($ml0_2$/ml x mm Hg).

Further studies should be undertaken, isolating the patient variables to establish a general conclusion for corneas of aphakic and phakic eyes that contact lens oxygen transmissibility requirements for extended wear be between 6×10^{-9} and 12×10^{-9} (cm/sec)($ml0_2$/ml x mm Hg).

(4) <u>Visual Acuity with Soft Lenses</u>

The maximum visual acuity with soft lenses was found to be achieved by a flat fitting lens. Lenses fitted with back radius steeper than the cornea - such as the early high plus Bausch & Lomb lenses - did not give such a high visual acuity as Snoflex 38% lathe-cut soft lenses - both 38% water content lenses. On average, the spuncast Bausch & Lomb lenses were fitted with a back radius steeper than corneal radii but the lathe-cut Snoflex 38 was fitted 1.10mm flatter than the flatter corneal radius. The standard of visual acuity with both these 38% water content lenses was not as high as the corresponding spectacle lens visual acuity. So it would seem that neither of these fittings is correct to achieve the maximum visual acuity with soft lenses. Lack of movement with steep fitting lenses gives a distorted front surface to the soft lens and so lowers the standard of acuity and excessively flat lenses move too rapidly on blinking and eye movements to allow the optic of the soft lens to be positioned correctly in front of the pupil. Olsen & Sarver (1976) give the maximum visual acuity for 38% water content spuncast lenses as fitted 0.3mm to 0.4mm flatter than the flatter corneal radius.

Sauflon 85 - a 75% water content lens, on the other hand, gave maximum visual acuity when it was fitted - on average - with a back radius between the corneal radius readings. Morris (1982) fitted children with aphakia with lenses of this material and as a rule fitted these lenses steeper than the corneal radius.

What is the correct back radius of a soft lens with respect to the corneal radius? Olsen & Sarver (1976) show that maximum visual acuity has been achieved with a 38% water content lens by fitting it 0.3mm to 0.4mm flatter than the flatter corneal meridian but the higher water content lens of 75% water can be fitted between the corneal radii or even steeper than both corneal radii and still give a good visual acuity. It may well be that the stiffer lower water content materials show a maximum visual acuity when the lids are able to move the lens without the lens distorting and allowing tear fluid to circulate easily underneath the lens. The softer high water content materials such as Sauflon 85 may be able to move without distortion on the eye of a blink or eye movement because the material is softer and more pliable than lower water content lenses and still give good visual acuity.

It is known that the back radius of a soft lens steepens by the least squares fit equation of:-

$$\Delta r_{2(20-35)} = 1.15 \times 10^{-2} WC - 0.25 \qquad \text{(XIV.10)}$$

where $\Delta r_{2(20-35)}$ is the back radius change from $20^{\circ}C$ to $35^{\circ}C$ and WC is the water content in percent.

It could be concluded that to fit a soft lens flatter than the flatter corneal meridian by at least the amount of steepening that these lenses will show when worn on the eye at its higher temperature of about $35^{\circ}C$. It may well be that Olsen and Sarver, in fitting Bausch & Lomb soft lenses 0.3mm to 0.4mm flatter than the flatter corneal meridian, were allowing for 0.20mm steepening of the lens because of the heating phenomenon and 0.1mm to 0.2mm flatter on top of this to allow for adequate circulation of tears and so adequate corneal metabolism with the absence of swelling of the cornea.

For maximum visual acuity and the absence of corneal swelling, it probably helps to fit lenses flatter than the flatter corneal radii by the amount of steepening found by heating the soft material from 20°C to 35°C.

The above hypothesis should be tested clinically to ascertain if soft lenses fitted this much flatter than the cornea do stop swelling or whether the clinician needs to add 0.1mm to 0.2mm to the fitting data to allow adequate tear circulation.

The practitioner should also ascertain if a bicurve or tricurve soft lens is needed to provide adequate peripheral tear circulation. The numerical values of the flatter peripheral curves in a bicurve or tricurve design will probably be found empirically by the clinician - just as an adequate peripheral fit and axial edge lift were arrived at with PMMA fitting techniques.

(5) Lens Dehydration and Spoilation

The fifth and sixth areas that need investigation are the dehydration of the lens and its spoilation in wear. These areas have not been covered in this thesis and remain two very important subjects to be researched thoroughly before extended contact lens wear can be assessed as successful. Dehydration of drying of the lens means less water in the lens; consequently, less central thickness and a higher refractive index. This means optically that as a lens dries out on the eye, it gains plus power. The gain of plus power will depend upon the amount of water lost from the lens which in turn will depend upon the humidity and wind velocity conditions in which the soft lens is worn.

Spoilation - or disintegration - is the degradation of the soft lens material with time and exposure to the atmosphere and lacrimal secretions. Ideally, the soft lens material should be tough and not split or break easily, should not discolour and methods found to remove all debris such as mucus and calcium deposits with 'patient-proof' methods of disinfecting the lens, so that should chemicals be used to disinfect and clean the lens, these chemicals will not build up in the lens and leak out onto the cornea when the soft lens is worn.

(6) <u>Use of PMMA Diagnostic Fitting Set</u>

Lastly, this thesis suggests a simple way to fit high plus soft lenses to minimise fitting and refraction errors. Practitioners use high plus soft lens fitting sets in a similar manner to PMMA fitting sets. The uncertainty of the soft lens fitting set parameters, coupled with the uncertainty of the over-refraction can lead to inaccurate ordering of the patient's own soft lens.

APPENDICES

Centre thickness of an hydrated soft lens if carrier junction thickness dry is 0.10mm FCOD dry 4.2

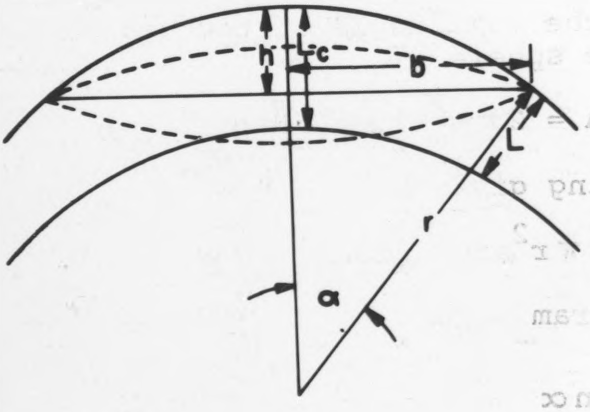
Back Vertex Power (D)	Centre thickness mm x 10^2									
	Water content %									
	40	45	50	55	60	65	70	75	80	85
+1	13	13	14	15	15	16	17	18	19	20
+2	13	14	15	16	16	17	17	17	17	18
+3	14	15	16	17	17	19	20	21	23	24
+4	15	16	17	18	19	20	21	23	25	27
+5	16	17	18	19	20	21	23	25	27	29
+6	16	18	19	20	21	22	24	26	30	33
+7	17	19	20	21	22	24	26	29	31	34
+8	18	19	20	21	23	26	28	31	34	38
+9	19	21	22	24	25	27	30	32	36	39
+10	20	21	22	24	26	28	30	34	38	43
+11	21	23	24	26	27	30	33	36	40	44
+12	21	22	24	26	28	31	35	38	42	47
+13	22	24	26	28	30	33	36	40	45	50
+14	23	25	26	28	31	34	38	42	47	52
+15	24	26	28	30	33	36	40	44	50	56
+16	24	27	28	30	33	37	41	45	51	57
+17	26	28	30	33	35	39	43	48	54	61
+18	26	28	30	32	36	40	44	48	55	63
+19	27	30	32	35	38	42	47	52	59	67
+20	27	30	32	35	38	42	47	53	60	69

Centre thickness of an hydrated soft lens if carrier junction thickness is 0.16mm dry FCOD dry 4.2

Back Vertex Power (D)	Centre thickness mm x 10^2									
	Water content %									
	40	45	50	55	60	65	70	75	80	85
+1	20	21	22	23	24	25	26	28	30	31
+2	20	21	23	24	25	26	27	29	32	33
+3	21	22	24	25	26	28	29	31	34	35
+4	22	23	25	26	27	29	31	33	36	38
+5	23	24	26	27	29	30	32	35	38	40
+6	23	25	27	28	30	32	34	37	40	43
+7	24	26	28	29	31	33	35	39	42	45
+8	25	27	29	30	32	34	37	41	45	48
+9	26	28	30	32	33	36	39	42	47	50
+10	27	29	31	33	34	37	40	44	49	53
+11	28	30	32	34	36	39	42	46	51	56
+12	28	30	33	35	37	41	44	48	54	58
+13	29	31	34	36	39	42	45	50	56	61
+14	30	32	35	37	41	44	47	52	59	64
+15	31	33	36	38	42	45	49	54	61	67
+16	32	34	37	39	43	47	50	56	63	70
+17	33	35	38	41	44	48	52	58	65	72
+18	33	36	38	42	46	49	54	60	68	75
+19	34	37	40	43	47	51	56	62	70	78
+20	35	38	41	44	48	52	58	64	72	80

APPENDIX 3

Figure 1



APPENDIX 3
Figure 1

Mean Radial Thickness of a Lens

Mean areal radial thickness is:-

$$\bar{L} = \frac{\int_0^A L\,dA}{A}$$

when $\bar{L}$ = average radial thickness
L = radial thickness
A = area of spherical cap

The area of a spherical cap is $2\pi rh$ when r is the radius of the sphere and h is the axial height of the cap. (see Figure facing page 162).

$$A = 2\pi rh$$
$$= 2\pi r(r - r\cos\alpha)$$

where α is the semi angle of the cap subtended at the centre of the sphere

$$\text{i.e. } A = 2\pi r^2 - 2\pi r^2\cos\alpha$$

Differentiating gives

$$dA = 2\pi r^2 \sin\alpha\ d\alpha \qquad (1)$$

From the diagram

$$\frac{b}{r} = \sin\alpha$$

Therefore $db = r\cos\alpha\ d\alpha$

whence $d\alpha = \frac{1}{r\cos\alpha}\ db \qquad (2)$

substitute into (1)

$$dA = 2\pi r^2 \sin\alpha \ \frac{1}{r\cos\alpha}\ db$$
$$= 2\pi r\tan\alpha\ db \qquad (3)$$

It can be shown that the value of L at a radius b from the axis on the anterior surface is given by the approximate expression:-

$$L = \left[\left[b^2 + \left\{ (r^2 - b^2)^{\frac{1}{2}} + r_2 - r_1 + L_c \right\}^2 \right]^{\frac{1}{2}} - r_2 \right]$$

where L_c is the axial (centre) thickness.

Substituting this and (3) into the mean thickness equation gives:-

$$\bar{L} = \frac{\int_0^A L dA}{A}$$

$$= \frac{1}{A} \int_0^{b_{tc}} \left[\left[b^2 + \left\{ (r^2-b^2)^{\frac{1}{2}} + r_2 - r_1 + L_c \right\}^2 \right]^{\frac{1}{2}} - r_2 \right] .$$

$$2\pi r \tan\alpha . db$$

where b_{tc} is the limiting value of b in the case considered

$$= \frac{1}{2\pi r^2 (1-\cos\alpha_{max})} \int_0^{b_{tc}} \left[\ldots \quad \ldots \right] 2\pi r \tan\alpha \ .db$$

$$= \frac{1}{r(1-\cos\alpha_{max})} \int_0^{b_{tc}} \left[\ldots \quad \ldots \right] \tan\alpha . db$$

$$= \frac{1}{r-(r^2-b_{tc}{}^2)^{\frac{1}{2}}} \int_0^{b_{tc}} \left[\ldots \quad \ldots \right] \frac{b}{(r^2-b^2)^{\frac{1}{2}}} .db \qquad (4)$$

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