CORNEAL PARAMETER CHANGES AFTER CATARACT EXTRACTION

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ABSTRACT

National health services are receiving increased pressure to improve cost efficiency and quality of patient treatment outcome. Hence it is useful to re-evaluate corneal changes following cataract extraction, with a view to minimising astigmatism and corneal contour stabilisation time, such that patients can more rapidly obtain their best corrected vision and return to independent life.

In a prospective study of 140 patients undergoing routine extracapsular cataract extraction, the changes in refraction, in corneal curvature as determined by keratometry and keratoscopy, and in regional corneal thickness were closely monitored preoperatively and for 6 months postoperatively. Two groups were compared, one (C) receiving a corneal incision and nylon sutures, the other (L) receiving a limbal incision and silk sutures.

Both groups demonstrated a large 'with the rule' (steep meridian vertically) astigmatic shift immediately postoperatively. The (L) group showed faster stabilisation of refractive (8 to 10 weeks) and corneal astigmatism (8 weeks), and a moderate final mean 'against the rule' astigmatism value. The (C) group remained as 'with the rule' and stabilised later for refractive (12 weeks) and corneal astigmatism (16 weeks). Keratoscopy indicated similar central curvature changes but the pattern for the peripheral corneal shape changes had a large variability, which was also shown by the two control groups. Although greater corneal thickness change had been anticipated for the (C) group than the (L) group, no significant difference was found between the two groups even by their stabilisation time of about 10 weeks postoperatively. Only when comparing overall changes was (C) group found to show the greater amount.

Using the results, a flow chart guide was created for consideration by surgeons to help produce the most desirable optical outcome. A predictive second study of 45 patients demonstrated the valuable advantage of using this chart in conjunction with preoperative measurements, causing the majority of the patients to obtain minimal or appropriately balanced ocular astigmatism by 6 to 8 weeks and therefore a more satisfactory optical result.

KEY WORDS: cataract extraction, corneal astigmatism, corneal thickness, incision, keratoscopy.

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ABBREVIATIONS

ECCE	=	extracapsular cataract extraction
ICCE	=	intracapsular cataract extraction
IOL	=	intraocular lens
PEK	=	photoelectronic keratoscope
HSF	=	horizontal shape factor
VSF	=	vertical shape factor
VA	=	visual acuity
WTR	=	with the rule
ATR	=	against the rule
mm	=	millimetres
SD	=	standard deviation
SEM	=	standard error of the mean
ANOVA	=	analysis of variance
(C)	=	corneal incision group
(L)	=	limbal incision group
N	=	number in sample
D	=	dioptres of power
IOP	=	intraocular pressure
LED	=	light emitting diode
PMMA	=	polymethylmethacrylate
YAG	=	yttrium aluminium garnate (laser)

CHAPTER 1

INTRODUCTION

1.1 REASONS FOR THIS STUDY OF CORNEAL PARAMETERS

Cataract is probably the largest single correctable cause of blindness in the Western world. It is currently not preventable but can be corrected by the surgical procedure of crystalline lens extraction. The increasing frequency of surgery for cataract has been analysed by Jay and Devlin (1990). Many thousands of cataract extractions are performed in the United Kingdom each year, the yearly average at Moorfields Eye Hospital being about 5000. The College of Ophthalmologists Cataract Audit aims to assess this increasing surgery demand (Courtney 1992).

Complete lens extraction renders the patient aphakic, where an optical correction is necessary to help obtain sharply focused retinal images. This correction can be given by thick positive power spectacles, a contact lens, intraocular lens implantation or, rarely, an epikeratophakia procedure (Swinger and Troutman 1980, Kaufman and McDonald 1984, Lass et al 1987). The currently most popular method is by an intraocular lens (IOL) which is usually inserted into the eye at the time of surgery. Most IOL patients, termed pseudophakes, still require spectacles for residual correction due to inherent errors in IOL power calculation. At this time of financial stringency in the National Health Service, if the number of patient visits and the number of spectacle or contact lens changes needed during the postoperative management can be reduced, this will benefit both the patient and the Health Service. Modern methods of performance indicators and audit necessitate greater patient throughput per annum. At the same time, the patients visual outcome relating to astigmatism reduction, stabilisation factors etc. can be enhanced so improved quantity and quality of patient care, as also sought by the OCTET study (1986), can be achieved.

The aim of this study of the preoperative corneal parameters and cataract extraction methods was to determine which methods enabled patients to obtain more rapidly stabilised corneal contour and refraction, enabling them to reach their optical correction and best visual status in a shorter time. It is often an advantage to attain minimal astigmatism once the eye settles postoperatively, since this reduces the complexity and supply time of optical correction. Contact lens fitting can more easily be performed with stock lenses with less instability of lens movement. IOL patients can obtain improved unaided vision and rapid spectacle correction, without the disorientation of adapting to high degrees of astigmatic correction. Consideration of the corneal parameters at certain management stages can assist the surgeon in decisions regarding surgical method and suture removal, if necessary. These alter the astigmatism accordingly, minimising the amount or balancing with that of the fellow eye to avoid problems of aniseikonia (image imbalance between the eyes).

Changes in surgically produced corneal astigmatism have been extensively documented, especially with relation to suture technique, materials, size and type of section employed. Some studies (see Ch.3) suggest possible methods of minimising final corneal astigmatism. The rate of corneal stabilisation is an important factor when determining the time of initiating the final optical correction. A number of papers give details of methods of incision and wound closure, but few have followed the corneal changes sufficiently frequently to give a satisfactory guide as to when stabilisation occurs. The study described in this thesis involved corneal parameter measurements performed preoperatively and postoperatively every two weeks until 12 weeks, then at 16 and 24 weeks. Few previous studies have included peripheral corneal topography and regional corneal thickness measurements as does this study, yet these are particularly important both in indicating wound healing progress and in contact lens fitting; they can reveal continuation of corneal changes even when the cornea appears clear by general clinical assessment and the central corneal astigmatism (shown by keratometer or by refraction) appears to be stabilised.

THE RESEARCH AIMS WERE :

1) To quantify the changes in corneal curvature of the central region (2-3 mm diameter centred on the visual axis) and of the peripheral region (4-5 mm beyond the visual axis) after uncomplicated cataract extraction.

2) To relate these changes to the time interval postoperatively, thereby determining the period elapsed until stabilisation.

3) To measure the pattern of fluctuation of refractive astigmatism with time postoperatively.

4) To quantify the changes in central and peripheral corneal thickness following surgery.

The aim was to compare two groups of patients; one having corneal incision and nylon sutures (C), the other having limbal incision and virgin silk sutures (L), so that conclusions might be drawn between differences and similarities. Measurements were carried out over six postoperative months. All 140 patients underwent extra capsular cataract extraction (ECCE) and were monitored as regards refraction, corneal curvature and thickness (central and peripheral) at the following stages: pre-op., 1 day, 2,6,8,10,12,16,24 weeks postoperatively. Certain patient categories (eg.diabetes, previous anterior segment surgery) were excluded as they had other factors which could influence the results. A number of control eyes and a group of non-operated eyes were measured over 6 months for comparison.

Firstly this thesis describes basic corneal anatomy and physiology, astigmatism, and the refractive correction and corneal response of patients following cataract surgery. Further chapters provide information on the measurement instruments and techniques used in the study. Chapter 8 describes the results and the indications of relationships between the parameters and the surgical methods. After completion of this study, a further prospective trial was carried out, where the patients preoperative parameters were analysed to indicate which surgical method should give the best optical outcome. The surgeon took this into consideration when planning the surgical method, and these patients were monitored and described in Chapter 9. The significance of these is discussed in Chapter 10.

1.2 BASIC CORNEAL ANATOMY AND PHYSIOLOGY

1.2.1. Corneal Anatomy

The cornea (Fig.1.1.) consists largely of the stromal tissue (Fig.1.2.), covered externally by Bowmans membrane and the epithelium, and internally by Descemets membrane and the endothelium (Ruskell 1989). The mean human central corneal thickness is 0.523 mm SD 0.039,, but towards the periphery this becomes 0.660 mm,SD 0.076 (Martola & Baum 1968). The epithelium may be considered as the anterior continuation of the conjunctiva. It is 50-100 microns thick and consists of five or six layers of squamous epithelial cells. The superficial cells gradually fragment and are shed, being renewed from the basal cell layer about every 4 to 8 days.

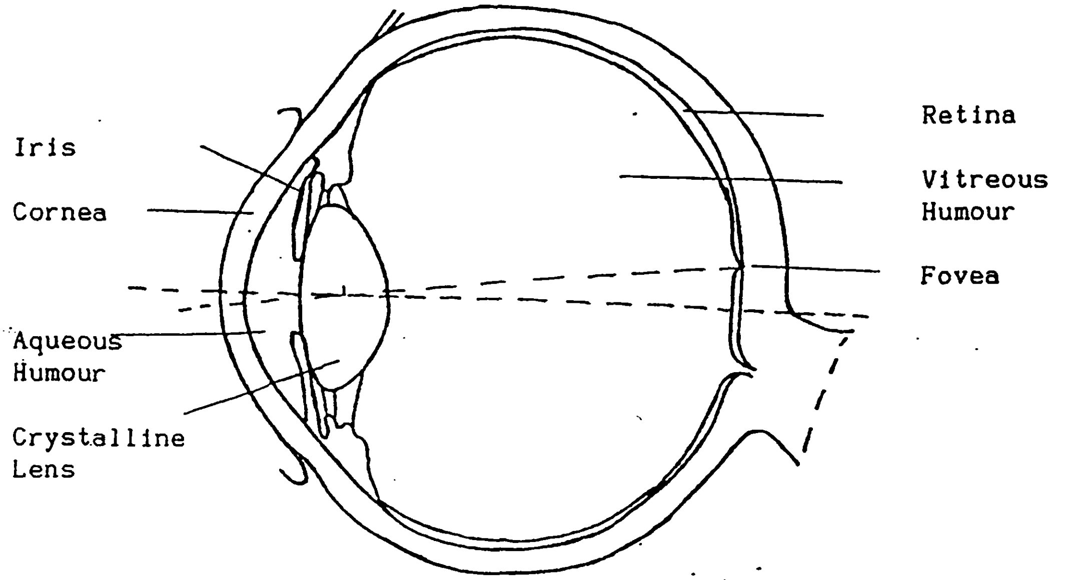


FIGURE 1.1 CROSS SECTION OF BASIC OPTICAL APPARATUS OF THE EYE

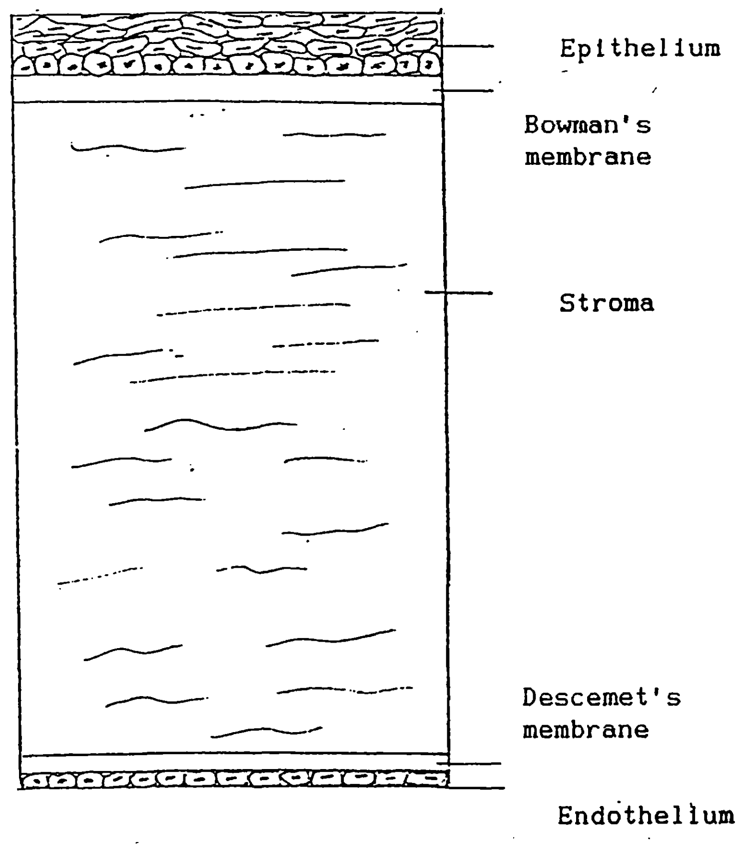


FIGURE 1.2 DIAGRAMMATIC MERIDIONAL SECTION OF THE HUMAN CORNEA

The stroma appears as a set of lamellae, superimposed on each other and running parallel to the surface. These fibrous layers consist of mucopolysaccharide and collagen fibrils. Bowmans layer is 8 to 14 microns thick, consisting of random but closely packed collagen fibrils merging with the stroma. Descemets layer is 5 to 13 microns thick. The endothelium is a layer of flattened cells, involved in the active pump of water to maintain the correct hydration of the stroma.

1.2.2. Corneal Transparency

Increased hydration affects corneal transparency in addition to increasing the thickness as described by Maurice (1962), and Benedek (1971). The corneal tissue power to exclude fluid relates to the metabolic energy available to resist the intrusion of fluid from the aqueous humour. In the normal eye, the active removal of fluid by the epithelium and endothelium just balances the influx from the limbus and tears. Interference by means of reduction of oxygen supply, trauma or provision of metabolic toxins leads to increased thickness with associated mistiness of the cornea.

1.3 CORNEAL ASTIGMATISM

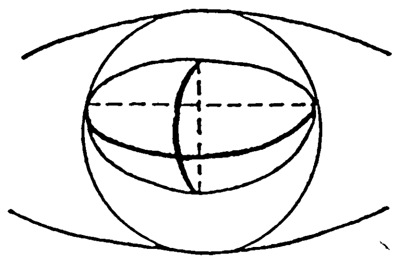
Corneal astigmatism is defined as that component of the astigmatism of the eye, beingthe difference in power between the two principal meridians of the corneal curvature, (at 90 degrees to each other). Refractive astigmatism is the power difference between the two principal meridians of the ocular refraction or total power determination of the eye. Astigmatism is due to the curvature and power of the cornea and other ocular structures. When the received spherical image is focused at two different planes by the astigmatic surface, a distorted image reaches the retina. The angle between these planes and the horizontal meridian is the angle of axis of the astigmatism. In this thesis, resultant astigmatism refers to the astigmatism which remains following treatment or surgery

1.3.1 Types and description of astigmatism

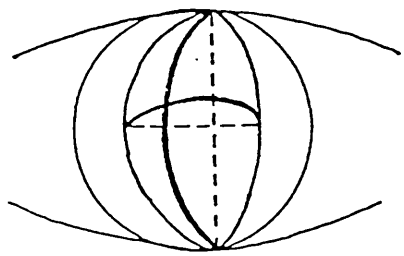
With the Rule astigmatism WTR, is when the more vertical meridian, ie. that positioned between 60 and 120 degrees, has a steeper curvature (shorter radius of curvature) than the horizontal meridian, see Fig. 1.3.1. Against the Rule astigmatism ATR, is where the horizontal meridian, ie. that positioned between 0 and 30 or between 150 and 180 degrees, is more steeply curved than is the vertical meridian, see Fig.1.3.2. Oblique astigmatism is when the astigmatic axis is at an angle of approximately 45 degrees to the horizontal meridian, Fig.1.3.3. Hirsch (1959) described the percentage of these types in people over the age of forty, indicating the change with age e.g. in 5th decade: 57% WTR, 21% ATR, 22% Spherical; in 7th decade: 32% WTR, 37% ATR, 31% Spherical.

Regular astigmatism.

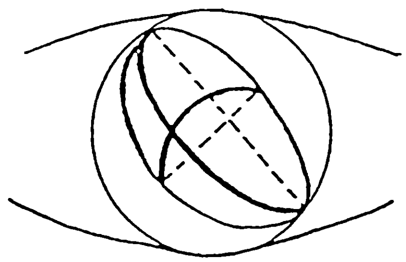
Parallel rays of light from a distant source, incident to the plane of the eye, will form a cone of focus within the eye. The



1) with the rule (WTR)



2) against the rule (ATR)



3) oblique

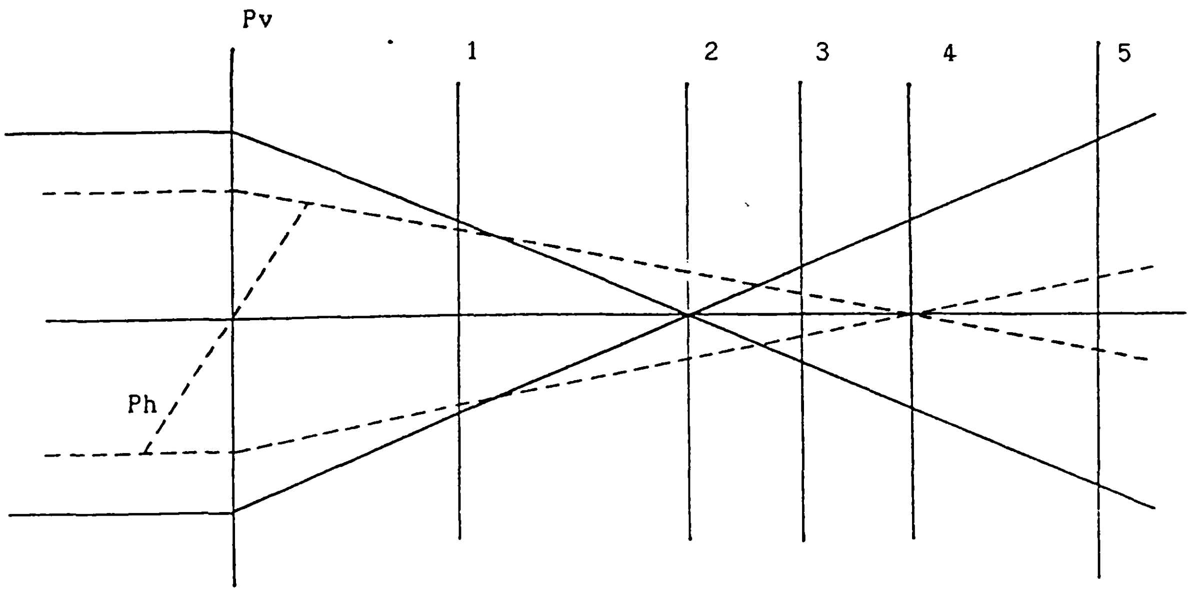
FIGURE 1.3 CORNEAL ASTIGMATISM

two images do not lie at the same plane of focus. The astigmatism types are shown in Fig.1.4 (Ruben and Woodward 1982). Astigmatism affects the retinal image by distortion, an example is shown in Fig.1.5. By using a spectacle lens which gives optical correction corresponding to each of the two principal meridians, a clear image can be obtained.

During contact lens fitting, corneal astigmatism affects not only the optical system, but also the lens fit and centration. A high degree of corneal astigmatism increases the risk of excess lens mobility and tolerance problems (Astin 1985). Soft (hydrophilic) contact lenses rely on the cornea for support and follow the corneal contours, so that even if lens mobility is acceptable, most of the visual distortion is revealed through the lens. Toric lenses, which are more steeply curved in one meridian than the other, may be fitted but often lead to problems with lens tolerance and visual image quality.

Irregular astigmatism.

This is when the refractive power of the ocular system cannot be resolved into two principal meridians. If the corneal surface is markedly irregular, eg. due to scarring after trauma or in conditions like keratoconus, the corneal shape is difficult to measure and spectacle correction is inadequate. The provision of an improved optical image by trapping tear fluid between the corneal surface and a rigid contact lens is complex (Astin 1987).



Pv = vertical eye plane

Ph = horizontal eye plane

The positions of the retina for the five astigmatism types are shown :-

1 = compound hyperopic

2 = simple hyperopic

3 = mixed

4 = simple myopic

5 = compound myopic

FIGURE 1.4 ASTIGMATISM FOCI

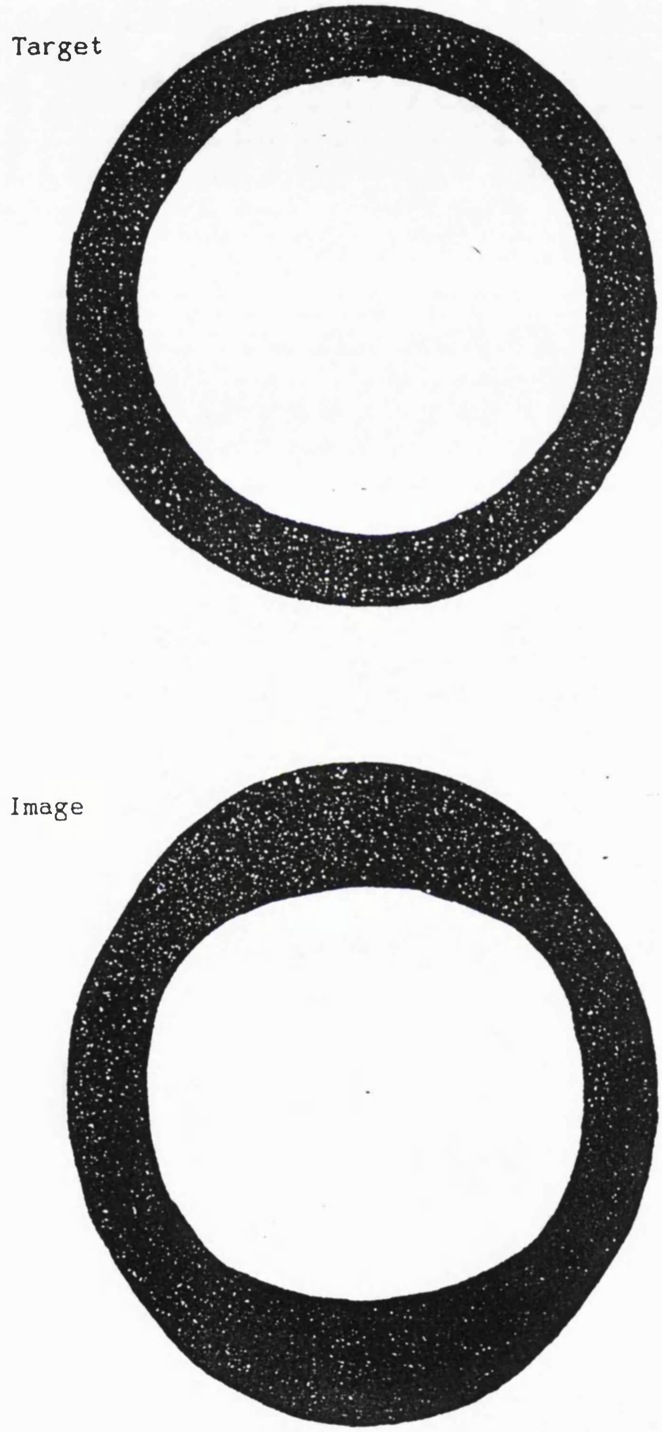


FIGURE 1.5 LETTER 'O' DISTORTED AS BY ASTIGMATISM

Few patients can tolerate a full correction of high degrees of astigmatism (e.g. 4.00D) straight away. Their spatial orientation is upset by meridional anisometropia, because they previously compensated for their uncorrected astigmatism, and confusion exists, eg. a corrected straight image is interpreted as sloping and circular images appear oval, until they have cortically adapted to their new spatial images. Most people have a small amount of physiological astigmatism between 0 to 1.0D at age forty, not requiring correction (Anstice 1971).

1.3.2 Changes in astigmatism

a) Due to lid influence

Wilson et al (1982), studying 36 eyes, confirmed that for corneas of more than 1.00D WTR astigmatism, lid retraction gave a decrease in astigmatism. He concluded that lid pressure on the globe is a factor influencing astigmatism. Vihlen and Wilson (1983), measuring 195 eyes, determined an elastic coefficient of lid tension but no correlation to WTR corneal toricity; both of these showed a statistically significant decrease with age. Pressure from thickened swollen lids after ocular surgery may encourage WTR astigmatism in corneas weakened by incisions.

b) Related to gender

Stenstrom (1948) showed that the distribution of total refracting power and corneal radius may be considered as samples taken at random from a normal distribution, and suggested that mean corneal power is greater in females than males. Hirsch

(1959) found high astigmatism more in men than women. Both Richards et al (1986) and Bishara et al (1988) concur that there is no significant difference between male and female groups, with regards to corneal astigmatism.

c) Anterior segment tissue defect

Pterygium and pseudo-pterygium can induce astigmatism as shown by Bedrossian (1960), and Hansen and Norn (1980). Gridley and Perlman (1986) studied variable astigmatism for different positions of gaze caused by a pseudopterygium. Patients with anterior segment defect were excluded from the current study.

d) Muscle tension

Kushner (1986) demonstrated that the tightening of the superior oblique muscle produced a long term incyclo-rotation, altering the axis of astigmatism. Past hypotheses proposed that the eye is squeezed by the lids and orbicularis muscle each time the eye is closed, causing steepest corneal curvature in the vertical meridian. Lopping and Weale (1965) obtained results which supported the hypothesis that horizontal corneal curvature is accentuated by the continual pull of the internal recti muscles which govern convergence. Elderly corneas showed negligible change on convergence as stromal cross linkages are often formed as the tissue ages so increasing its rigidity. No curvature change was found with accommodation without convergence. Patients with abnormal ocular muscle tensions, eg. those with strabismus, were excluded from the current study.

e) Age

The axis of corneal astigmatism broadly changes with age from WTR to ATR. Reading (1973) demonstrated that the horizontal curvature steepened with age. Hirsch (1959) reviewed a number of investigations and described this shift towards ATR. His study on 1,606 eyes over a 40 year span, found the mean astigmatic error changed from 0.25D WTR to 0.75D ATR. Lyle (1971) did repeated keratometry over a mean period of 24.1 years to show this shift. Anstice (1971) measured 621 subjects to reveal that total and corneal astigmatism have a high correlation, and WTR astigmatism decreases after the age of 40 years. Baldwin and Mills (1981) also supported this hypothesis. Kiely, Smith and Carney (1984) determined the corneal shape of 196 eyes by photokeratoscopy. Their results showed reduced WTR astigmatism with age, but no substantial variation in asphericity.

1.4 MODELS OF THE CORNEA

Various models for the corneal topography have been proposed e.g. Bibby (1976), Townsley (1970). Guillon, Lydon and Wilson (1986), proposed an ellipsoid corneal model based on a photokeratoscopic and keratometric study of 220 eyes representative of a normal population. This study showed a systematic difference between central keratometric and photokeratoscopic measurements that was statistically but not clinically significant; a significant number of corneas steepen at the periphery; the corneal shape varies greatly within a normal population; and the peripheral and central astigmatism are usually similar. The following data were given: a mean radius of curvature of 7.85 mm (SD +/-0.25) for the flattest meridian of the central cornea, and a mean difference between that of the flattest and steepest meridians of 0.15mm (SD +/-0.15); a mean shape factor (expressed in a different manner from that of Bibby) for the flattest meridian of the peripheral cornea of 0.85 (SD +/-0.15), and a mean difference between that of the flattest and steepest meridians of 0.00 (SD +/-0.15).

CHAPTER 2

MANAGEMENT OF APHAKIA

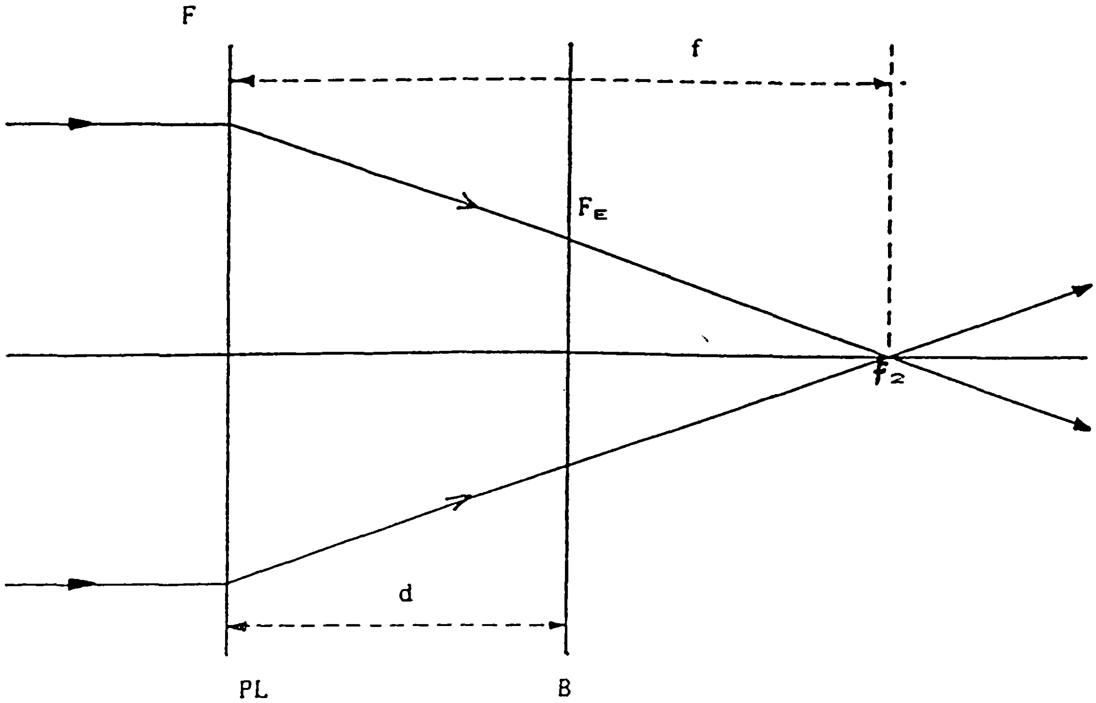
2.1 VISUAL OUTCOME IN APHAKIA

Aphakia is a condition where the crystalline lens is absent from the correct optical positioning within the eye, due to trauma, surgery or dislocation. After lens extraction accommodative ability is lost. The main categories of aphakia are age-related, paediatric and traumatic. Only patients with the age-related cataract extraction were considered in this study. The yellow filter effect of the sclerosed lens is lacking so they benefit from a ultra violet light filter in their optical correction. A rapid, successful outcome whether correction is by IOL or contact lens proves cost-effective for the patient, the clinician and the community (Woodward and Drummond 1984, Davies et al 1986) and improves the aphake's visual function (Bernth-Petersen (1981, 1982). The aphakic patients are loaned a set of high spherical power spectacles on their operation day. Those with IOLs are left temporarily uncorrected. After extracapsular cataract extraction, routine management often involves clinical checks at 2, 6 and 12 weeks and refraction for spectacle correction performed about 6 to 12 weeks after the operation. After small incision surgery, this can be done at 2 weeks.

2.1.1 Assessment of visual acuity and refraction

The target distance, illumination and contrast should be standardised and glare avoided. The most common clinical method for VA measurement consists of test letters viewed at six metres, subtending standard angles at the nodal point of the eye. Several factors affect this measurement including the eye's depth of focus (Tucker and Charman 1975) and whether the trial case lenses have dirty, misty or scratched surfaces. The traditional refraction method (Rabbetts 1973) using trial frame and lenses imitates the situation of spectacle wear. Automated instruments, e.g. Dioptron, (Kempster 1975), Autorefractor 6600, Ophthalmetron, and Humphrey subjective refractometer are bulky and expensive. Their accuracy relies on the subject having clear media, relaxed accommodation, steady eye fixation and no distortion of refracting surfaces. Hence they were not used for this study because preoperatively the patients media were not clear, also suitable funding was not available.

The distance between the plane of the lens and the principal plane of the eye is termed the back vertex distance BVD. This is important when relating refraction astigmatism to keratometry astigmatism. For example, for a spectacle prescription of +14.00D and +16.00D in the two principal meridians, hence refraction astigmatism of +2.00D, at the corneal plane these powers are effectively +16.83D and +19.80D, giving +2.97D of corneal astigmatism measured by keratometry. For a high positive power lens (more than +6.00D) the BVD markedly affects the image magnification and effective lens power (Fe) at the principal plane of the eye. Fig. 2.1 gives an example.



F = lens power

f = focal length of lens

f_2 = second focal point

PL = plane of lens

B = plane to measure effective power

d = distance (m) from lens to effective power plane

F_E = effective lens power = $\frac{F}{(1 - dF)}$

<u>FIGURE 2.1 CALCULATION OF EFFECTIVE LENS POWER</u>

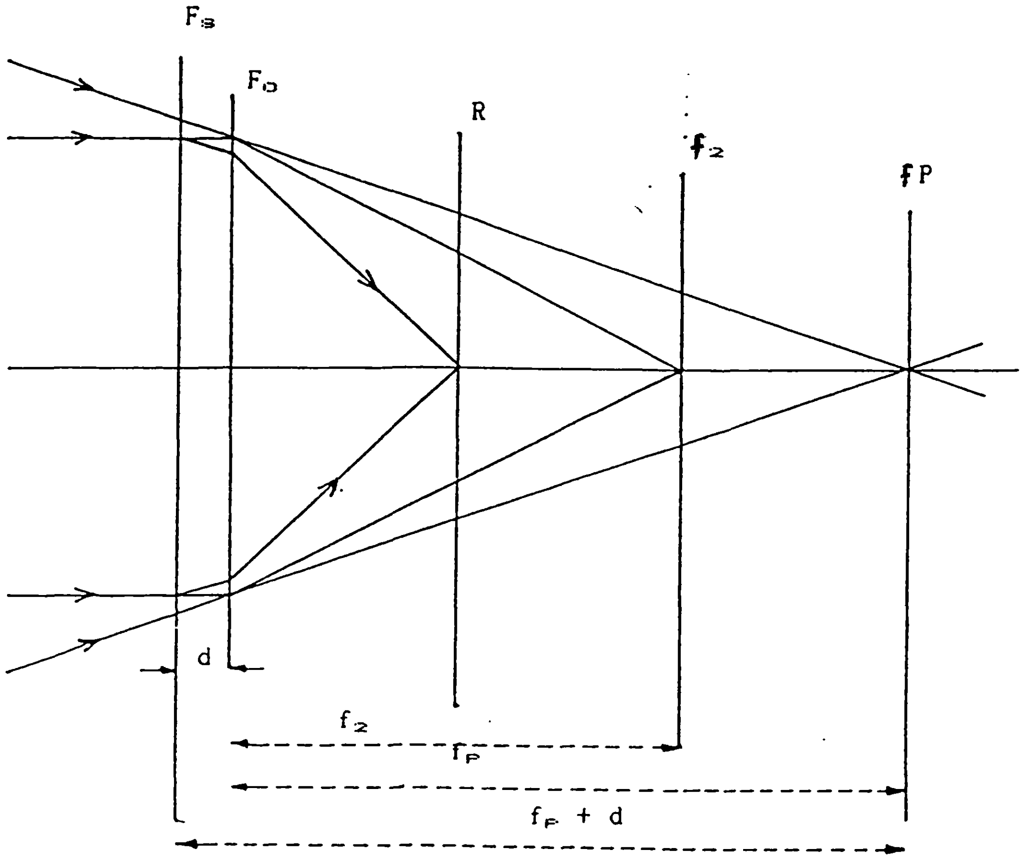
2.1.2 Visual problems in aphakia

Problems associated with external optical correction are: binocular - diplopia, suppression; - ghost images, variations in visual acuity and quality; spectacle - magnification, prism effects, restriction of field, distortion, aberration, lens weight; contact lens - magnification, prism effects, variation in visual acuity and quality due to lens movement and condition. Descriptions are given by Bennett (1966, 1968, 1972/3), Stone (1977), Ruben (1975), Ruben and Woodward (1982), Port (1989). Fig.2.2 indicates the focal planes in aphakia optical correction. The spectacle lens thickness, lens form, position and distance from the eye affect the effective power and aberration (Ruben and Woodward 1982).

2.1.3 Contact Lens and IOL

Many of the optical and physical problems of spectacle correction are much reduced by contact lens correction (Astin 1984,1986). Lens insertion and removal takes time and correct disinfection and regular aftercare are vital (Graham and Dart 1986, Stapleton et al 1989). Corneal astigmatism complicates the fitting, the optical correction, the stability and comfort of the lens so it is preferable to keep this to a minimum.

An IOL is a rigid plastic imitation lens held in position by haptic loops or 'legs'. Posterior chamber IOLs are also supported by the posterior capsule after extracapsular cataract extraction. Anterior chamber IOLs are positioned anterior to the



fP = far point of focus of the eye
f_2 = second focal length of the eye
R = position of retina
F_o = ocular refraction at anterior corneal surface
F_s = spectacle refraction
d = vertex distance between spectacle plane and anterior cornea
f_P = focal length of the eye

EXAMPLE :-
when fP = 70mm (approximately equivalent to 15.0 diotres)
F_o = +45.0 dioptres, d = 15mm
spectacle lens focal length = fP + d = 70 + 15 = 85mm
spectacle lens power = F_s = 1000/85 = +11.75 dioptres.

FIGURE 2.2 OPTICAL CORRECTION OF APHAKIA pupil with the legs resting on the scleral spur. Advantages of an IOL include: similar magnification to that with the original eye, as the lens is nearer to the optical entrance pupil of the eye; the patient need not maintain the appliance, and there are few distortions and visual problems. Generally there are lower costs to the health service (Davies et al 1986) and fewer visits needed than with contact lens aftercare. Preoperative corneal curvature measurements by keratometry are important in the calculation of the IOL power (Tutton 1985). Maltzman et al (1986) showed that the cornea and not the IOL was responsible for the postoperative astigmatism experienced by patients.

Usually the IOL remains in the correct place for satisfactory vision, and any residual astigmatism following surgery can be corrected by low power spectacle lenses. If serious problems occur with lens dislocation or corneal decompensation, the IOL can be removed. In some cases, refractive keratoplasty provides an alternative correction method (Waring 1985).

2.2 CORNEAL RESPONSE TO CATARACT SURGERY

The corneal tissues respond to the surgical trauma and to the new physiological balance in the eye. The future functioning of the ocular tissues will be influenced by the extent of this trauma and by any postoperative damage. Corneal rigidity is reduced in an eye that has undergone a penetrating incision. This depends on the size and type of incision and the strength of the scar tissue. Corneal sensitivity in the superior region is reduced after the severance of the superior region corneal nerves but may partially recover (Guillon and Morris 1982). This facilitates adaptation to contact lens wear, but corneal sensation and response to epithelial damage is reduced. Partial sensitivity is regained over two years, depending on the patients age. Often thin superficial vessels invade the superior peripheral region of the cornea following a corneal incision to reach the suture penetration sites. The vessels may increase if the corneal oxygen supply is diminished as in extended contact lens wear (Holden et al 1985).

Corneal thickness measurement was recommended by Dohlman and Hyndiuk (1972) to monitor corneal oedema after cataract extraction. Holden et al (1980) and Guillon and Morris (1981) showed that under reduced levels of oxygen, the cornea of the aphakic eye swells less than that of the fellow eye, although corneal oxygen uptake was shown to be unchanged. One theory is that there is a lower oxygen demand because oxygen is no longer required for the crystalline lens metabolism. Increases in corneal oedema and thickness following cataract extraction are often attributed to endothelial damage (Liesgang et al 1984, Buckley 1985). Less endothelial damage is usually caused by the use of small rather than wide apertures. Studies regarding endothelial cell damage following IOL implantation have been performed by Bourne and Kaufman (1976), Kaufman and Katz (1976), Katz et al (1977), Kirk et al (1977), Cheng et al (1977), Stark et al (1979), Sherrard (1983), Vannas et al (1985) and Jacob (1986).

CHAPTER 3

ASTIGMATISM AFTER CATARACT EXTRACTION SURGERY

3.1 REVIEW OF LITERATURE

The renewed attention to astigmatism following cataract extraction (described as resultant astigmatism) has been focused by the reduced incidence of serious postoperative complications, the revival of extracapsular cataract extraction (ECCE) and its comparison to phacoemulsification, improvements in surgical techniques and materials, and increased visual expectations of the patient. Improvements in IOL insertion and design have usually minimised astigmatism due to IOL tilt, especially when the IOL position is near to the nodal point of the eye (Kosaki et al 1991). Maltzman et al (1986) on studying 127 posterior IOL cases and 54 anterior IOL cases found that the cornea and not the IOL was most responsible for postoperative astigmatism.

The amount of postoperative astigmatism is influenced by a number of surgical factors: operating technique, incision size and position, suture material and technique, wound profile and healing. Changes in postoperative astigmatism can be made by adjustment of any of these, and by manipulation of the sutures and wound during the postoperative period (Jaffe 1976, Atkins and Roper-Hall 1985). A number of papers regarding these factors is given in Table 3.1.

Generally, there is agreement that small incisions such as those often used with phacoemulsification or aspiration techniques cause the least degree of astigmatism and the shortest stabilisation time (Arnott 1973, Hoffer 1984, Reading 1984, Bambery 1986). Several reports on the influence of the corneal incision site concur that a greater degree and variability of astigmatism are found following this method but they suggest stabilisation times ranging from 10 to 24 weeks. Several workers, eg. Jampel (1986), concluded that limbal incisions caused less corneal astigmatism than did corneal incisions. However, most of the studies followed the astigmatic changes at 6, 12 and 26 weeks.

Jaffe and Clayman (1975), and Meredith and Maumenee (1979), who monitored large numbers of patients, described the various influences of sutures, incisions and other factors on the degree of astigmatism but gave no definite conclusions regarding stabilisation time. Baranyovits (1990) performed regular serial refraction to determine the rate of stabilisation and found that after a limbal incision this occurred at three months if silk sutures were used but up to four to five months if the sutures were nylon. Swinger (1987) provided a useful review of studies on postoperative astigmatism and methods of its reduction.

Two other groups of surgeons placed more emphasis on astigmatism control, the first (Terry 1980, Troutman 1980) by judging corneal astigmatism during the operation using a surgical keratometer, the second (Roper-Hall and Atkins 1985) by selective suture removal at the clinical follow-up visits. These methods still needed experience and care to achieve moderately predictable results. Most of these authors monitored only central corneal astigmatism and at widely varying intervals so their contribution was limited. There was still the need for the investigation of peripheral corneal shape and thickness changes and for a closer study of postoperative astigmatism to more clearly determine the stabilisation time.

3.2 SURGICAL TECHNIQUES OF CATARACT EXTRACTION

The most common methods are described as follows:

3.2.1 Intracapsular Cataract Extraction (ICCE)

A limbal based incision is made into the anterior chamber, of size between 110°-160° of arc. The lens supporting zonule fibres are weakened by the application of 5% alphachymotrypsin. The cataractous lens is bodily removed with minimal pressure and slight traction with the forceps, or attached to a cryoprobe.

3.2.2 Extracapsular Cataract Extraction (ECCE)

Through the corneal or limbal incision, a capsulotomy needle or equivalent is inserted into the anterior chamber. This is used to cut a central disc of anterior lens capsule, which is then removed. The lens nucleus is expressed by pressure against the inferior limbus and behind the incision. The posterior lens capsule remains in situ. Irrigation and aspiration with buffered saline solution allows removal of the cortical lens matter.

3.2.3 Phacoemulsification

A small incision (approximately 3.0 mm) is made behind the superior limbus or in clear cornea, and extracapsular extraction carried out using a phaco-emulsifier. This uses ultrasonic energy to fragment the lens tissue, which is removed by simultaneous irrigation and aspiration. A manipulator is inserted via a second, smaller incision to guide the lens fragments towards the phacoemulsifier. A more detailed description is given by Snyder and Donnenfeld (1994).

3.2.4 Aspiration

Aspiration, or lensectomy, is a form of extracapsular extraction where two paracenteses, 1.5mm wide separated by 90-180° arc, are made in the cornea near the superior limbus. Fine cannulae, of 0.7 to 0.9 mm external diameter, are inserted so that after removal of the anterior capsule, one is used for aspiration of the soft lens material, the other for irrigation of the anterior chamber.

Advantages and disadvantages of the various techniques are given in Tables 3.2 and 3.3. Several complications can follow cataract extraction surgery, as it involves penetration of the globe and manipulation of tissues. In a few cases, stretching of the levator aponeurosis by the superior rectus stay suture or by the lid retractor can result in ptosis. After ECCE or phacoemulsification, the remaining posterior capsule can thicken, becoming opaque. The YAG laser can be used to create a hole in the capsule to restore vision in a non-invasive procedure. After ICCE the vitreous may protrude into the anterior chamber affecting fluid drainage, producing glaucoma, and pulling at weak retinal areas, producing retinal detachment. High prescription myopes often have peripheral retinal thinning which is vulnerable to tearing when a age-related cataractous lens is removed. Postoperative vitreous floaters are common (Buratto 1991).

3.3 SURGICALLY INDUCED ASTIGMATISM

Astigmatism may be induced during surgery by the incision method, surgical technique, tissue healing and sutures.

3.3.1 Incision

Size The larger the wound size the greater is the influence of the sutures and the greater are the variations in corneal astigmatism (Gills 1974, Reading 1984, Heslin and Guerriero 1984). Small incision techniques such as phacoemulsification show smaller variations in the induced changes in mean radii of corneal curvature. A wound of 4.0mm or less rarely tends to gape. There is a decreased tendency to overtighten sutures, if used.

Martin et al (1993), using keratoscopy, found significantly less wound related localised corneal flattening with small incisions compared to large incisions, but no significant difference in mean keratometric astigmatism. Several others (Steinert et al 1991, El-Maghraby et al 1993, Hayashi et al 1993) found significantly less astigmatism using small incisions such as 4.0mm compared to larger incisions as 6.5mm. LeMagne and Kallay (1993) found this even with a scleral pocket incision.

Site Incisions distant from the corneal optical zone tend to induce less astigmatism (Gills 1974, Bambery 1986). Jaffe and Clayman (1975) found WTR astigmatism to be associated with a mid limbal or a corneal incision, ATR astigmatism with a more scleral site. Placement of the incision further posteriorly decreases the iatrogenically induced astigmatism (Hardten and Lindstrom 1993). Storr-Paulsen (1991) also found significantly less surgically induced astigmatism after 1, 3, and 6 months postoperatively with a scleral incision compared to a corneoscleral incision. He concluded that the configuration of the incision appeared to be more important for the early surgically induced astigmatism than was the type of wound closure.

Some surgeons prefer the limbal site as this heals faster and does less damage to the corneal endothelium. Others prefer a corneal site (Fig.3.1) and recommend deep suturing and a peripheral corneal incision. These have less effect on limbal vessels, no haemorrhages, coaptation of wound edges is easier to control and correct, delayed reformation of the anterior chamber occurs more rarely and epithelial ingrowth is rare.

3.3.2 Surgical Technique

In ECCE, the surgical knife makes a superior region scleral or corneal section of about 60-130 degrees. Corneal oedema caused by

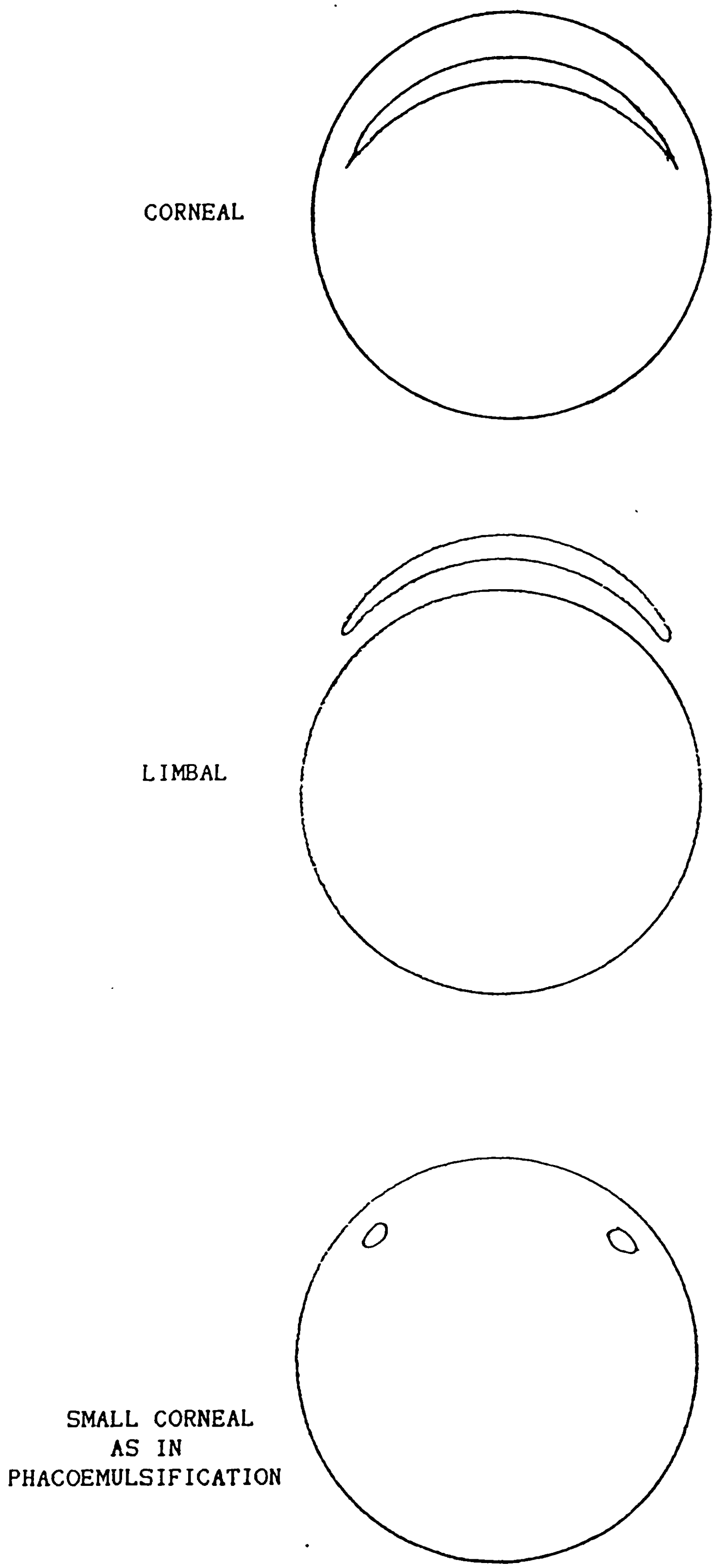


FIGURE 3.1 INCISION SITE

this trauma effectively increases the tightness of the sutures resulting in a large postoperative shift to WTR astigmatism. ATR astigmatism can result later due to the wound gaping or vertically stretching, thereby increasing the globe circumference and flattening the vertical curvature (Ernest 1994). The corneal incision technique and its advantages have been described by Steele (1977). Agapitos (1993) gave a good general review of surgical techniques. The corneal incision allows a better view during surgery of the anterior chamber and the lens extraction.

More recently, the scleral tunnel technique is gaining popularity. This method begins with a scleral groove, followed by a scleral tunnel and continues into the cornea before entering the anterior chamber. Studies on this method indicated a significant reduction in surgically induced astigmatism and stabilisation time (Storr-Paulsen 1991, Taylor, Solomon & Boyaner 1992, Hall et al 1993).

Example of a Corneoscleral (limbal) technique

This uses a limbal based conjunctival flap, diathermy to the limbal vessels and an incision just behind and parallel to the limbus, but with a 90-130° arc. The corneoscleral wall is opened to approximately 90% of tissue depth, with initial groove at right angles to the globe surface then a posteriorly slanted incision edge made. Five to seven separate nylon 10/0 monofilament sutures are inserted to 75% or greater depth and covered by a conjunctival flap secured by extra sutures. Although silk sutures are more rarely used nowadays, these begin to weaken by the fifteenth postoperative day.

Example of a Corneal technique

The incision is made free-hand, with a 90-130° arc, anteriorly to the limbal vessels, so diathermy is rarely needed. The direction of the initial incision groove through 90% of the corneal depth is vertical and the second stage of incision slopes posteriorly, or else a single posterior slanting incision is made . Closure is with five 10/0 monofilament nylon sutures placed at approximately 95% or more of the tissue depth, tensioning to give edge to edge closure and with the knots buried beneath the corneal surface. Mechanical stresses as the anterior chamber reforms tend to press the inner wound margin against the outer one to aid secure wound closure.

3.3.3 Tissue Healing

Troutman (1979) proposed that postoperative ATR astigmatism was due to a weak superficial corneal scar induced by too shallow a wound closure with sutures which loosen early, allowing scar tissue thinning and the superior and central corneal regions to flatten. A corneal incision gave less tissue trauma, hence a quiet white eye with lower risk of secondary raised intraocular pressure or uveitis. For aphakic patients Kersley (1985) recommended early soft contact lens fitting to give a bandage effect and rapid visual correction.

Several wound healing factors were described by Flaxel and Swan (1969), for example:

a) Thickness and rigidity of the sclera and cornea,

b) Raised intraocular pressure which may lead to wound gape and alteration of suture tension,

c) Steroids which slow wound healing,

d) General health and healing ability of patient,

Excessive eye rubbing causing sutures to loosen.

3.3.4 Sutures

Materials

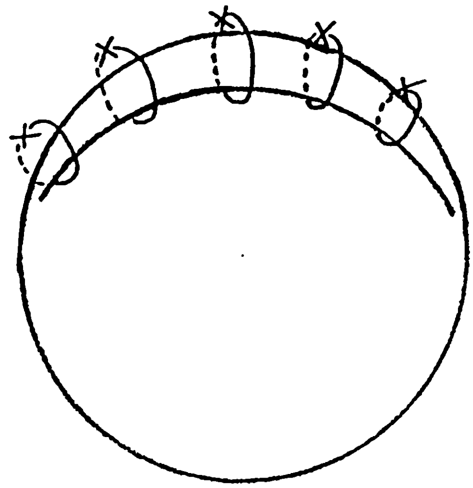
The major types are: non-absorbable material, eg. nylon, silk, and absorbable eg. catgut, collagen, some synthetics. The suture materials used by the co-operating surgeons at the time of this study were virgin silk and monofilament 10/0 nylon. With the latter, there was usually less tissue irritation, less postoperative hyperaemia and inflammation, and neater smooth scar formation due to prolonged firm apposition of the wound. Tissue reaction to nylon was minimised and scar formation delayed so that the nylon was usually left in the incision for several months. Nylon sutures could give significant suture induced astigmatism, especially if they were tight, but this could be reduced by selected interrupted suture removal, which was easier if the incision was corneal rather than subconjuctival.

Induced astigmatism with virgin silk sutures was less as interrupted sutures were used. Postoperative tissue oedema and weakening of individual sutures caused them to break, releasing tension on the incision and reducing the WTR astigmatism. The irritant sutures encouraged vessel activity and rapid scar formation; hence the astigmatism could not readily be influenced after the first two to three weeks since the sutures began to biodegrade. For corneal incisions, the suture had to remain firm for approximately eight weeks due to the slower wound healing of stromal tissue, therefore nylon sutures were used.

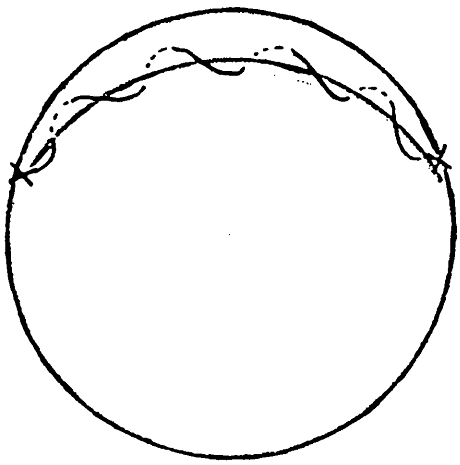
Gills (1974) confirmed that for all materials WTR astigmatism was present for ten to fourteen days postoperatively. Dekkers and Buijs (1989) found that silk sutures led to ATR while nylon led to WTR astigmatism. They explained that although silk is chemically non-absorbable, a special polymer is present in virgin silk which provokes a tissue reaction. The softening of tissue diminishes the tensile strength of the virgin silk suture and hence it behaves in a similar manner to an absorbable suture. They concluded that with respect to postoperative astigmatism, the suture material seemed more important than suture method.

Suture Techniques

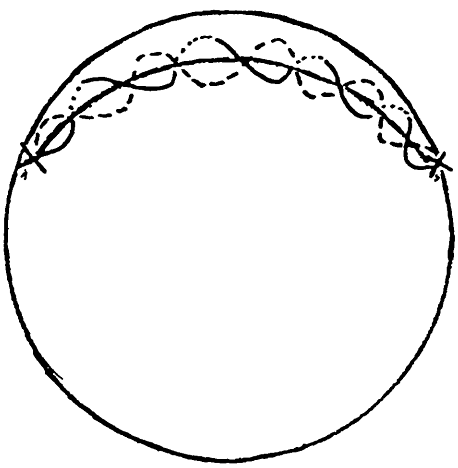
The loop must be 75% (or preferably more) of the corneal depth to control wound apposition. The closer the sutures are placed to each other, or sited in a crossed pattern as in the bootlace method, the more stable is the incision. Different suturing patterns have been described and compared by Roper Hall (1982), and Emery and McIntyre (1983) (Fig. 3.2). Extra sutures or knots closer to the horizontal meridian increase astigmatism. Nylon



INTERRUPTED



CONTINUOUS



BOOTLACE

FIGURE 3.2 SUTURE TECHNIQUES

sutures affect the wound for up to a year according to Gills (1974) and Meredith and Maumenee (1979). Continuous and mattress sutures tend to give a tighter wound closure with a steeper vertical curvature and more WTR astigmatism than do interrupted sutures.

3.4 PREOPERATIVE ASTIGMATISM

Preoperative corneal astigmatism may be due to: corneoscleral limbus shape, cicatricial modification, ectasia, and local modification of corneal thickness. Congenital astigmatism is usually associated with an oval limbal shape where the larger diameter corresponds to the flatter meridian. If the preoperative astigmatism is known, the surgeon can adjust the suturing method in order to reduce this. Floyd (1951) found that the sixth month postoperative astigmatism was often of the same type as that preoperatively. Brown and Sparrow (1988) tried to compensate for preoperative astigmatism by using additional sutures and agreed with Bambery (1986) that postoperative astigmatism can be controlled by selected suture removal.

Jampel et al (1986) recommended using computer analysis of postoperative astigmatism for each surgeon to determine the typical surgically induced astigmatism and to provide a basis for preoperative planning of surgical technique. They concluded that astigmatism changes continue towards a stable situation at four to six months postoperatively. Naeser (1990) attempted to express astigmatism and its direction in figures for mathematical analysis.

3.5 CURRENT METHODS TO REDUCE ASTIGMATISM

3.5.1 During surgery

Both the surgical keratometer and the keratoscope have been used to monitor astigmatism during surgery. Although there are a number of apparent advantages (Troutman, 1974, 1976, 1977, 1978, 1980, Terry 1980, Colvard et al 1981, Amoils 1986); other studies by Samples and Binder (1984) and Jacobi and Strobel (1985), found several errors remain with a surgical keratometer even with an experienced user. It was an asset in guarding against high degrees of astigmatism during the operation, but did not give as fine a control as its proponents suggested.

Troutman mentioned difficulties in using this keratometer effectively when using the interrupted suture technique. Roper-Hall (1982) emphasised that even if the desired corneal curvature is obtained with the aid of a surgical keratometer by the end of the operation, the final postoperative astigmatism is still not fully predictable. Conditions at the end of surgery are abnormal, healing processes are subject to many variables including intraocular pressure, patient health and treatment, which lead to changing corneal curvature and refraction. Tissue reaction to suture tension and material varies.

3.5.2 Postoperatively

Selected interrupted suture removal within the early weeks of healing has been recommended by several surgeons (Roper-Hall 1982,1985, Atkins and Roper-Hall 1985, Bambery 1986, Stanford et al 1993, Hayashi 1993). A tight suture would be noted on the meridian of steepest curvature (the axis of the positive power cylinder in refraction), so it could be removed under topical anaesthesia at the slit lamp to give a rapid reduction of corneal astigmatism. The refraction and keratometry was reassessed and the process repeated until optimal correction was obtained without wound gaping. Continuous sutures were gripped by microsurgical suture forceps and eased towards the tight steepest curvature meridian. For cases without IOL, Buxton (1975,1976) advised the surgeon to aim for postoperative WTR astigmatism to facilitate the fitting of aphakia contact lenses three to four weeks after surgery.

CHAPTER 4

KERATOMETRY

4.1 HISTORY

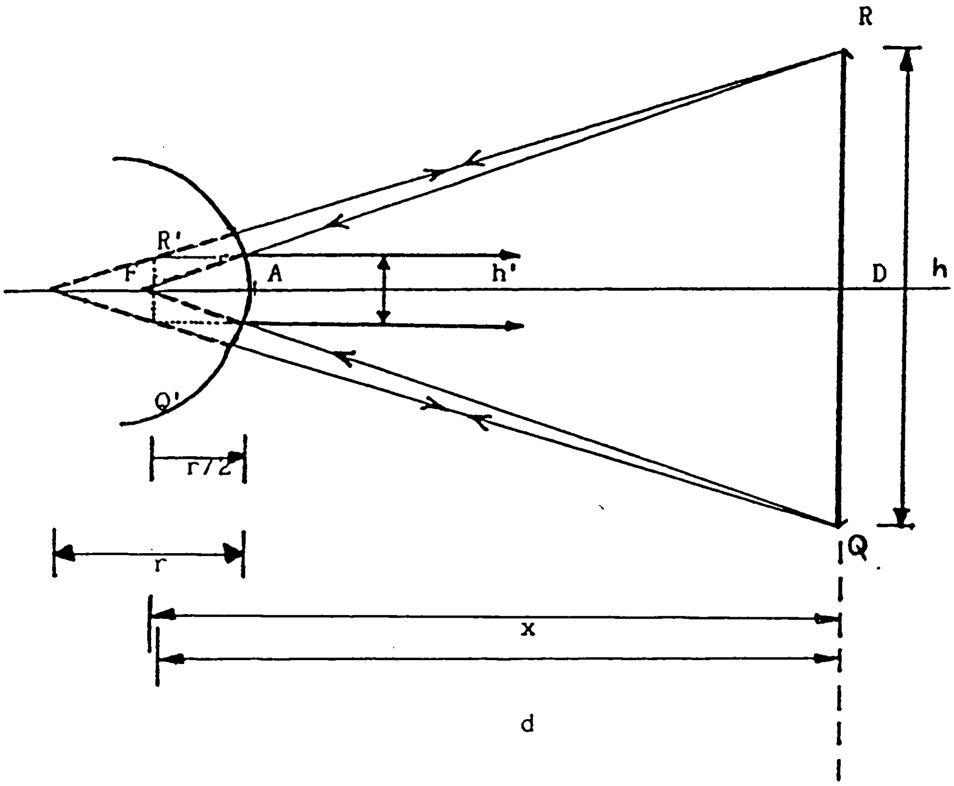
The main function of the keratometer is for the measurement of the radius of curvature of the central portion of the anterior surface of the cornea, usually referred to as the optic cap. Helmholtz (1909, cited in 1924) is usually credited with the invention of the keratometer, but Levene (1965, 1977) suggested that Scheiner attempted this in 1619, and that Hare and Ramsden in 1795 were the first to measure corneal radii. According to Helmholtz (1909 translated 1924), Kohlrausch in 1840 and Senff in 1846 performed corneal radius measurements on a living eye. Woodward (1980) noted that Valk in 1897, Tscherning in 1904, and Sorsby in 1961 used keratometry to measure the ocular refracting elements. As the cornea is aspheric, assumptions in central sphericity led to errors.

Woodward described Landolt's use in 1878 of a prism for doubling the keratometer image to assist measurement, and the use by Javal and Schiotz (1881) of a Wollaston prism with specially shaped 'mires' as test objects. The advantage of this method over Helmholtz's glass plates doubling method was that the operator could obtain a direct reading without further calculations. The work of Helmholtz and others in the development of the keratometer was discussed by Emsley (1952, 1960).

4.2 KERATOMETER DESIGN

Keratometric measurements are useful in contact lens fitting and aftercare; to aid calculations of the refracting power of optical elements and IOLs; to aid diagnosis of a corneal condition; to guide and monitor the progress of ocular surgery (Ruben 1975). Measurements are obtained indirectly from the angular size of the reflected image formed by the cornea of an object of known linear size (h) at a predetermined distance from the image plane (d). The derivation of the radius of curvature is shown in Fig. 4.1. If the eye was stationary, the image size could be measured directly using a graticule in the eyepiece, but the eye is continually moving with small saccadic movements, so a doubling principle must be incorporated. The two images can then be juxtaposed because even if moving slightly, they do so with the same speed and direction (Fig 4.2).

In practice, the object limits are represented by a pair of internally illuminated mires whose corneal images are seen magnified through a short focus telescope as described by Sheridan (1989). This incorporates the doubling device which produces the four images seen in the telescope field, the two central ones being brought into contact or superimposed. To obtain adjacent or superimposed images, either h' may be varied by altering the mire separation h, while the power and position of the doubling device are fixed; or the image size h' and the mire separation h may be fixed while the power of the doubling device, P, or its distance, a, from the image plane is varied.



The optical principle of the Keratometer is that r is directly proportional to the image size, h'.

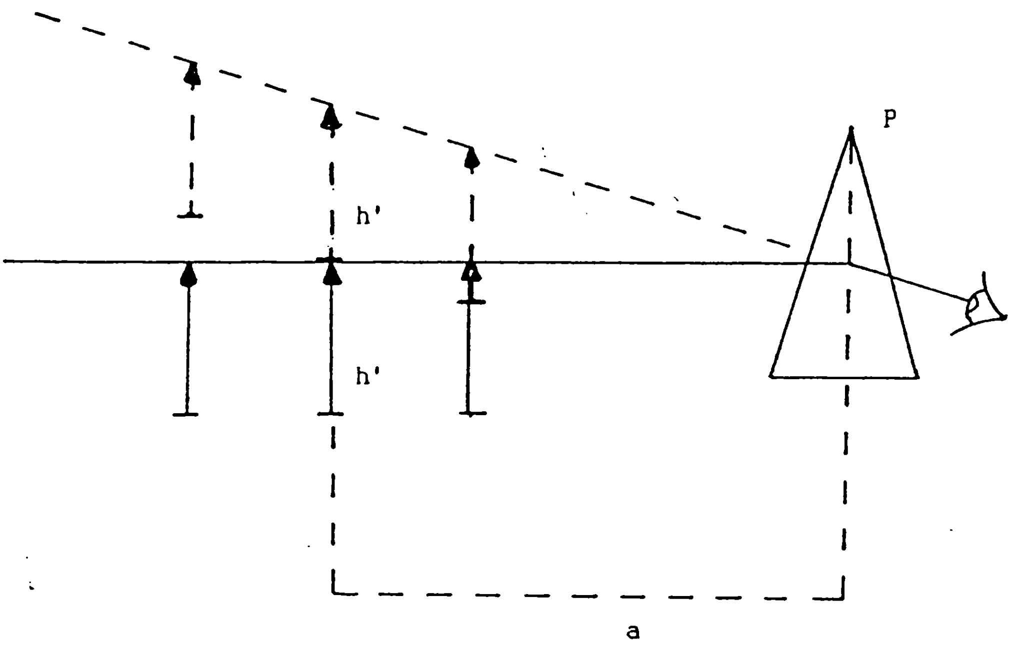
Q and R are the limits of an object of size h
Q' and R' are the limits of the image of size h' formed by the reflection at the anterior corneal surface
F = principal focus
RQ = object plane
d = distance between image plane R'Q' and object plane RQ
x = distance between F and RQ
A = pole of the cornea
C = centre of curvature of cornea surface

$\therefore$ $r = AC$ and $r/2 = AF$

$h'/h = (r/2)/x$ but d is approximately equal to x then

$h'/h = (r/2)/d$ $\therefore$ $r = 2dh'/h$

FIGURE 4.1 OPTICAL PRINCIPLE OF THE KERATOMETER



For a prism of power P dioptres fixed halfway in an observation aperture

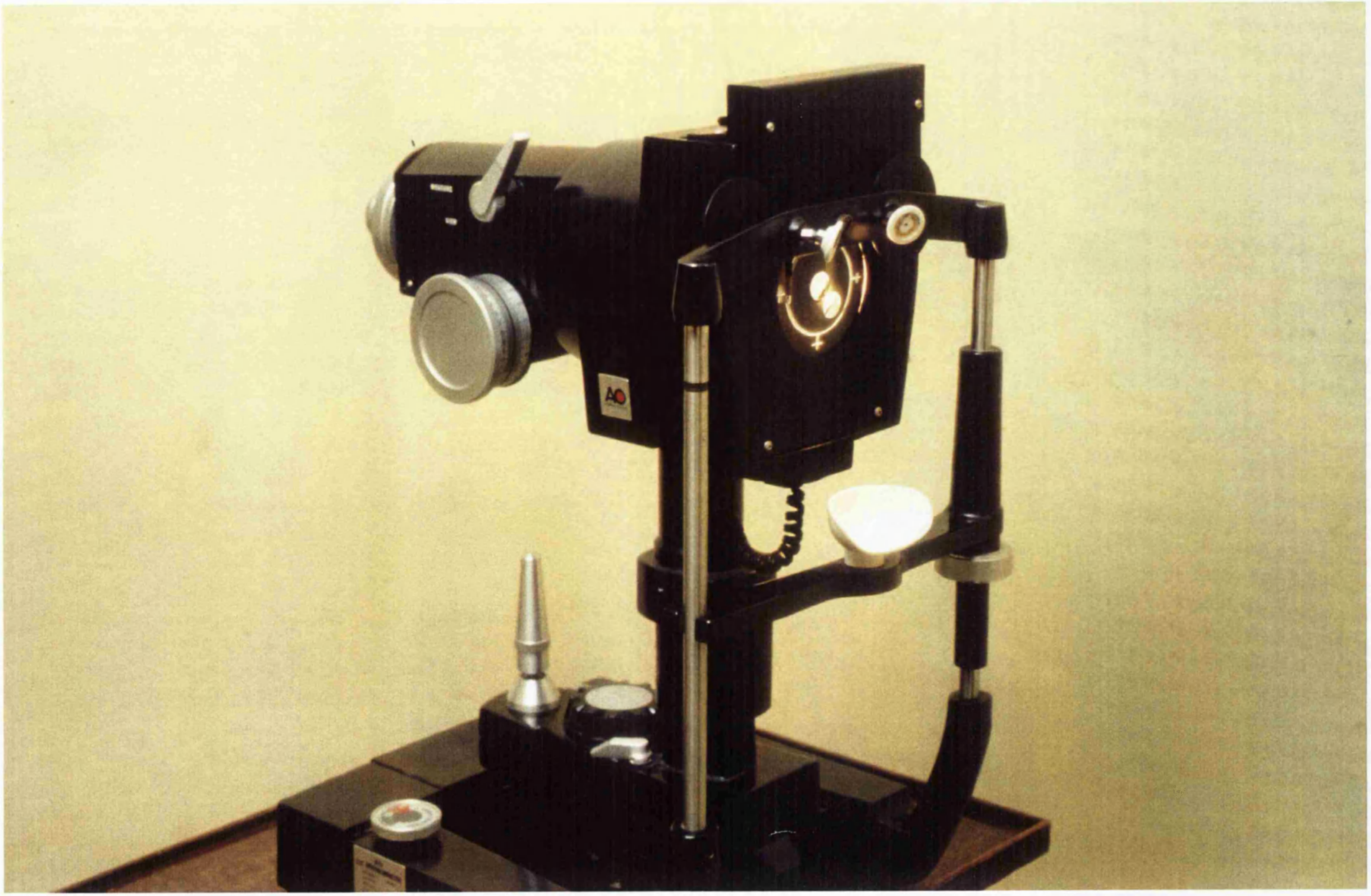
h' = image size - seen doubled
a = distance between plane of the prism and the position at which the doubled image are exactly adjacent to each other

h'/a = P/100 .. h' = aP/100 mm

FIGURE 4.2 IMAGE DOUBLING BY PRISM

These features distinguish between the 'fixed' and 'variable' doubling types of keratometers. In two position keratometry eg. Haag Streit, doubling usually occurs in only one meridian, ie. along the line joining the mires, hence the instrument would be rotated about its optical axis in order to align it with each of the principal meridians of the cornea in turn.

A one position keratometer is an instrument in which variable doubling of the mutually perpendicular image is produced by two doubling devices in the corresponding meridians, the distance a being varied as the prism travels along the instrument axis between the objective and the eyepiece. Such an instrument eg. American Optical (Fig 4.3) or Bausch and Lomb, must be rotated about its axis to align the mires with both principal meridians of the cornea (assumed to be perpendicular to each other) and the images in each can be brought into contact without further rotation. Fig. 4.4 shows the ring mire reflected by the cornea. These are the same type of ring mires as used in the Bausch and Lomb keratometer, and are useful for obtaining a measurement even if there is some distortion of the corneal contour. Distortion of the rectangular mires of the Haag Streit or Zeiss keratometers more greatly affects measurement. The variable doubling of the image is achieved in the Bausch and Lomb instrument by using four apertures placed between the two objectives of the viewing telescope (Fig. 4.5). Apertures C and D contain base in and base down prisms respectively, so C causes a doubled image horizontally and D vertically. The doubling is varied by



<u>FIGURE 4.3 AMERICAN OPTICAL KERATOMETER</u>

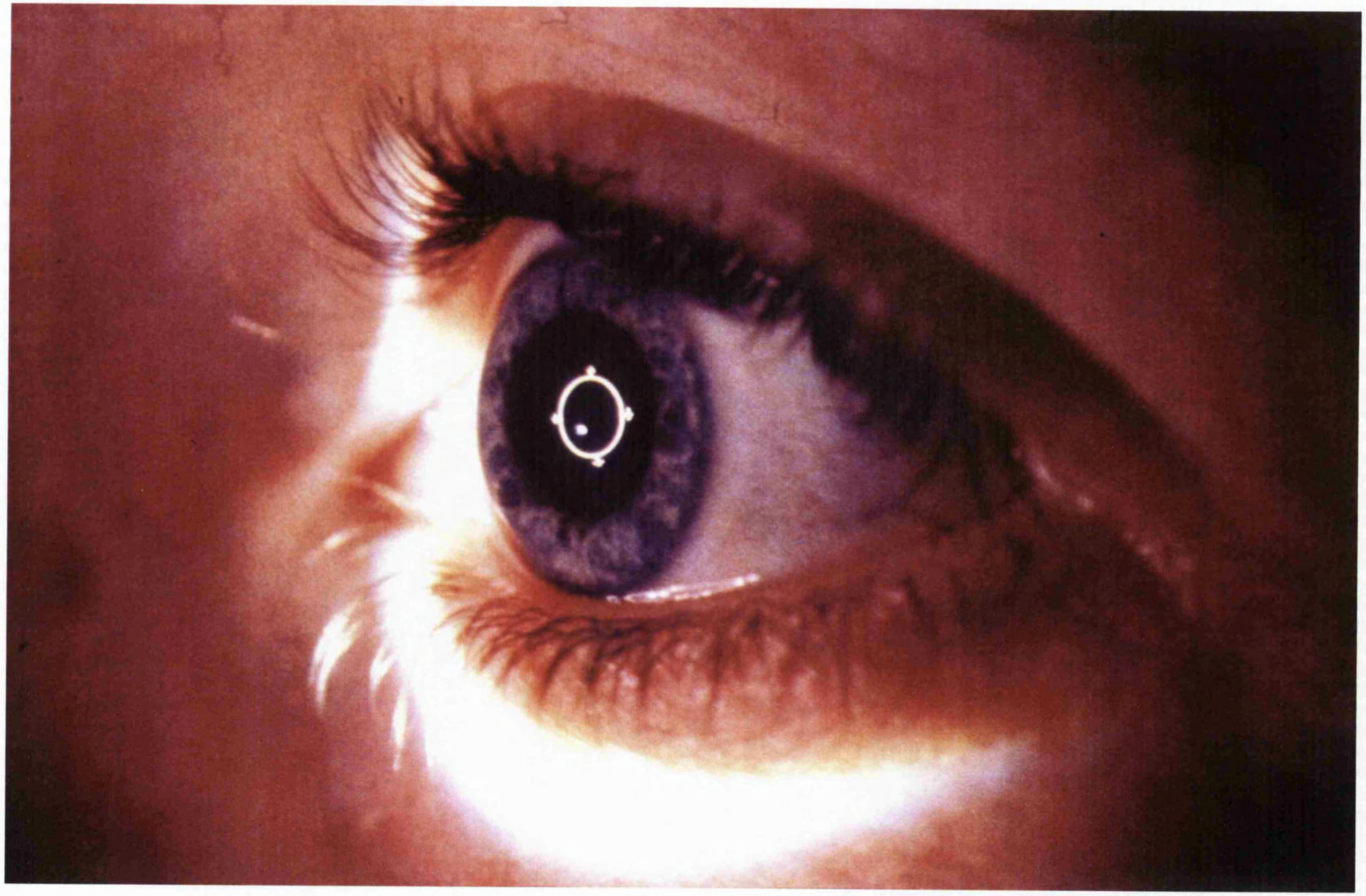


FIGURE 4.4 MIRE IMAGE REFLECTED BY THE CORNEA

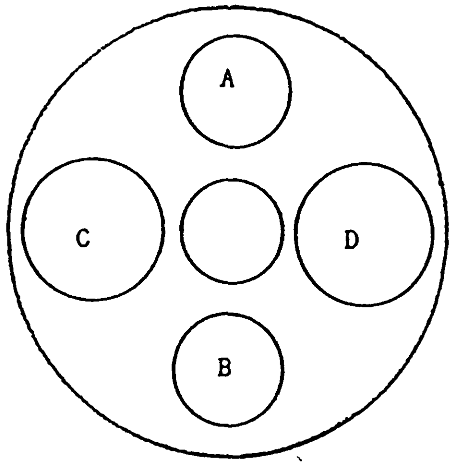


FIGURE 4.5 TELESCOPE APERTURES

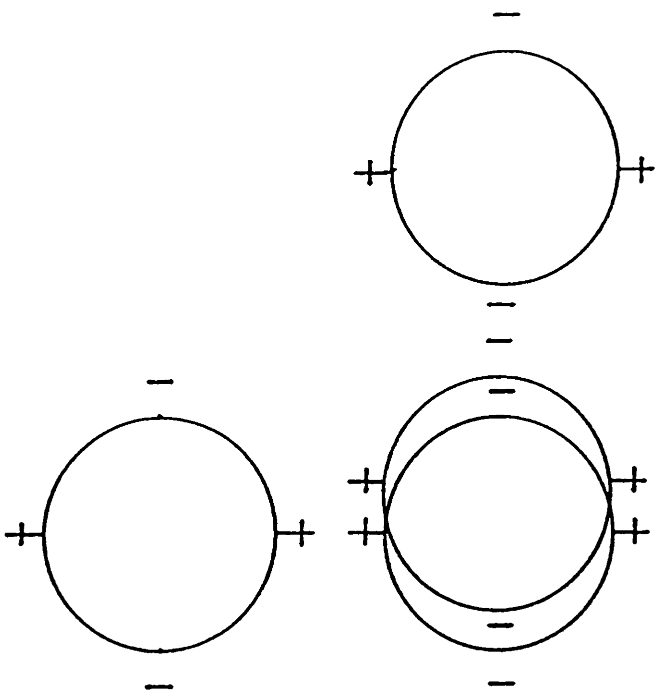


FIGURE 4.6 OBSERVER'S VIEW OF DOUBLED MIRE IMAGES

movements along the axis by the prisms. Apertures A and B follow the Scheiner principle, i.e. give two closely overlapping direct images (Fig 4.6) unless the telescope is sharply focused.

4.3 SOURCES OF ERROR IN KERATOMETRY

Several factors influencing the keratometer measurement accuracy are functions of the instrument theory and design. The relationships derived in Fig. 4.1 are based on paraxial optical theory, shown by Emsley (1960) to oversimplify the situation. Bennett (1966) adopted a trigonometrical ray-tracing procedure for several spherical surfaces of different radii and showed that as a convex mirror, the corneal focal length would be approximately 4.0 mm, yet the image forming rays from the mires are incident on the cornea at a distance of at least 1.0 mm from the vertex, i.e. over a zone of 2.0 mm diameter. Hence spherical aberration becomes significant and oblique astigmatism is involved since the incident pencils of light are far from being normal to the surface. Bennett estimated that calibration using the paraxial theory gives errors of about 4 to 5 percent in the results. Keratometer manufacturers have incorporated corrections for these.

The second of the equations derived using Fig. 4.1, namely ($r = 2dh'/h$), is an approximation in which d, the separation of object and image, is assumed to be the same as x, the distance of the object from the focal point. This assumption is used in most keratometer designs, the mires being mounted relatively close to the eye. The error is small because of the high reflecting power of the cornea. Emsley (1952) calculated that for a cornea of radius of curvature 8.0 mm, the error amounts to 0.02 mm with the Bausch and Lomb keratometer in which d is 72.0 mm, and that if d is increased to 150.0 mm the error reduces to 0.003 mm. It can be eliminated if the mires are made as targets of a collimating system as in the American Optical design.

Fig. 4.1 also shows that the light from the mires is reflected, not from the keratometric pole towards which the telescope is directed, but from two small areas either side. The instrument is calibrated on the assumption that these two areas are on a spherical surface and the resulting radius is attributed to the keratometric pole. The measurement becomes incorrect if these two areas where the mire images are reflected differ in curvature from that of the pole or from each other. The error is more serious if the two reflection areas are large or widely separated, or if the keratometric pole is markedly decentred within the optic cap (Mandell 1964). Table 4.1. gives the diameters of the corneal reflection areas for a single mire as determined by Lehmann (1967), who reported the width of the reflection zones of a Bausch and Lomb instrument to be 0.1 mm, with a separation of about 2.9 mm.

The main source of error controlled by the observer is focusing. If the mire images are inaccurately focused in the intended primary image plane, the radius measurement will be incorrect since the object to image separation is then incorrect. These out of focus images may not seem blurred if the observer accommodates. Collimated mires and a fully telecentric viewing system eliminate this source of error. The observers judgement of focus can be assisted by including a Scheiner disc in the viewing system as in the Bausch and Lomb type of keratometer, where the central mire image is seen as double if it is not accurately focused. By keeping errors to a minimum, repeatability of readings should be 0.02 mm. Calibration errors are very small, and show less influence on a longitudinal study noting changes in values, rather than attempting measurement of absolute values (Stone 1962, Bailey and Carney 1977). Sunderraj (1992) emphasised that although automated keratometers give a rapid reading, manual keratometry is preferred for accuracy when calculating intra-oculr power. The reliability of keratometry readings was discussed by Brungardt (1969,1973) and by Butcher and O'Brien (1991). Error is incurred since the measurements are made with respect to the visual axis rather than the corneal apical normal.

4.4 KERATOMETRY OF THE PERIPHERAL CORNEA

Mandell (1962, 1965) modified a Bausch and Lomb keratometer in order to reduce the mire separation from 64.0 mm to 26.0 mm and he made measurements of the corneal periphery by using the addition of a series of off-axis fixation points. The systems used by Bonnet and Cochet (1960), and that employed in the Guilbert Routit Topographic keratometer use only one mire for peripheral measurements which can be obtained from small corneal areas of diameter 0.50 mm. Their measurement of central radii is by the classic method of two mires over a wider corneal chord. The Zeiss keratometer can also give single mire keratometry and has a moveable fixation point and an extended radius scale needed for peripheral measurements.

Several instruments, including the Zeiss, Guilbert-Routit, Bausch and Lomb, and American Optical keratometers have topographical attachments whereby the subject's fixation is diverted to points away from the keratometer main axis so that the reflection zones fall on more peripheral portions of the cornea. With the Topogometer attachment for the Bausch and Lomb keratometer and with the Topographical attachment for the American Optical C.L.C. Ophthalmometer (keratometer), the device for varying the fixation is graduated in millimetres from the corneal centre. Full consideration of the position of the centre of rotation of the eye does not seem to have been made in the design. The calibration is based on the displacement of the fixation target and the distances from the keratometer objective to corneal vertex and from the corneal vertex to the centre of ocular rotation. Ludlam and Wittenberg (1966) emphasised the importance of taking into account this rotation centre. The American Optical Company design assumed that the corneal vertex distance from the centre of rotation was 11.3 mm, but there was no significant difference in normal practice where the corneal vertex distance may be 14.45 mm.

Keratometry theory also assumes a common axis for the centre of curvature of all parts of the cornea, whereas in practice the centres of curvature for the peripheral zones are offset from the central axis of symmetry. Mandell and St. Helen (1968) used small mire keratometry with peripheral fixation but found this very time consuming and the results insufficiently accurate and reliable. Douthwaite (1987) recommended an instrument adjustment using a method of Drysdale, in order to improve the keratometer for peripheral corneal measurement.

CHAPTER 5

KERATOSCOPY

5.1 METHODS OF ASSESSING CORNEAL TOPOGRAPHY

Antonio Placido in 1882 designed a disc of alternating black and white concentric circular rings with a small central hole through which the examiner observed the images formed by reflection from the corneal surface. Following major modification and further investigation of the keratoscope principle since its introduction by Gullstrand in 1896, sophisticated photokeratoscopes were invented for assessing corneal topography and for photographing images formed by the cornea. Gullstrand measured the corneal topography by analysing photographic data of the corneal ring images and calculating the radius of curvature of a given sector of the cornea from the target ring separation in the image reflected from that area. A valid corneal measuring device must be accurate, reproducible, easy to operatte, able tto produce results rapidly, harmless to the cornea, tolerable to subject and operator, and inexpensive.

Many of the methods of assessing corneal topography were reviewed by Clark in 1973, who criticised the majority as being invalid or unsuitable. He described the optical methods of autocollimation, interferometry, Moire fringe methods, and stereophotogrammetry. In describing profile and section methods he included direct profile photography, slitlamp photography, cast and template, and fluorescein methods. Attempts with television, sclerokeratometry, and ultrasonography were also mentioned.

Clark (1972) and Maguire (1988) recommended the use of the autocollimated photokeratoscope. Fowler and Dave (1994) reviewed the development of keratoscopy to the recently used computer-assisted videokeratography. Although the latter, eg. the EyeSys Corneal Topography System, provides an increased number of data points and contour description in the form of colour mapping, there remain problems in the consistent reproduction of measurements (McCarey et al 1992, Mandell 1992). Several keratoscope studies are summarised in Table 5.1(end of chapter).

5.2 PHOTOKERATOSCOPY

5.2.1 Introduction

The keratoscope provides information about whether the corneal region centred about the visual axis is spherical or toroidal, also about the directions of the principal meridians of a toroidal cornea and of the displacement direction of the corneal apex with respect to the visual axis. Information is given as to whether the peripheral corneal flattening is equal in all meridians and to the presence of any localised surface irregularities.

Factors affecting the accuracy of photokeratoscopes include: aberrations due to the camera lens, variation in magnification over the image plane, the grain size of high-speed film necessarily used which can make precise measurement difficult, and difficulty in accurately focusing the camera. As with most photography, methods of film developing and printing are rarely constant and possible film shrinkage can affect accuracy. Additional problems are caused by aberrations introduced by oblique reflections from peripheral portions of the cornea.

5.2.2 Advantages and disadvantages of photokeratoscopes:

These are listed as follows:

Advantages:-

Simultaneous acquisition of all the information,
provision of hard copy data that may be re-examined,
examination allowed of the apical cap within the usual 3.0 mm ring of the cornea,
the mid-peripheral cornea is examined so early astigmatic errors may be traced,
approximately 55% of the total corneal area can be examined compared to 8% using the clinical keratometer,
subtle topographic shifts induced by trauma, contact lens wear or progressive corneal dystrophies can be estimated,
complex contact lens fitting is assisted by the determination of peripheral corneal curvature,
sequential quantitative evaluations of astigmatism are improved.

Disadvantages:-

aberrations are introduced due to measurement being around the visual axis rather than the corneal apical normal,
some photography experience is required,

defocusing of the reflected images produces an inaccurate chord length measurement. This is large if the eye is too near the camera and small if the eye is too distant.

5.2.3 <u>Prerequisites for reliable photokeratography</u>:-

These include instrument stability and the accurate knowledge of the positions of the object and of the camera axis. The working distance of the system should be defined, the depth of focus should be minimal and maximum aperture photography be used. The view finder image should be magnified to assist accurate and consistent focusing of the camera and the alignment of the reflecting surface with the camera system must be assessed for each photokeratograph. The instrument must have freedom of movement in the lateral, vertical and anterior-posterior directions, and the subjects head movement must be controlled.

The resulting film images should be free from distortion, whether induced by the lens system or by dimensional instability of the film, so effects of processing can be assessed and controlled. The total system should have good accuracy and reproducibility and, regardless of the mathematical expression for the corneal shape, the units should be internally consistent.

When examining the keratoscopy photograph of the cornea the pattern can be interpreted in the same manner as for a contour map (Ruben 1975). If the reflected rings are circular and uniformly spaced, then the cornea is spherical, if elliptical then the cornea is toroidal in shape. If the spacing increases as the ring diameter increases, this indicates that the corneal curve flattens towards its periphery.

5.2.4 Autocollimation

Drysdale in 1900 showed that the radius of curvature of a convex spherical mirror could be determined by measuring the distance between the two positions where the mirror would reflect an incident converging beam of light back along a similar path. These are the two positions of autocollimation; the first is when the light is focused on the surface while the second position is when the light is focused towards the centre of curvature of the surface. The autocollimation method introduces an error due to the depth of focus, since the lens can be moved a short distance yet the focus seems the same. This error is given by w/2(NA), where w = the wavelength of light and NA is the numerical aperture of the system. The autocollimation instrument operates on the assumption that the surface is spherical beyond 1.0 mm, but except for the central optical cap the cornea is aspherical.

The autocollimating photokeratoscope can be used to measure corneal topography with greater accuracy than with the methods described by Clark (1973). Light from a set of target rings is directed onto a cornea at near normal incidence and the reflected real image from the cornea is projected onto a scale that indicates the radius of the reference sphere. The difference in position between any target point on the photograph and the corresponding point on a photograph taken with a spherical control reflector is used to calculate the departure of the corneal curvature from spherical.

This type of keratoscope allows qualitative or quantitative determination of the surface topography of the cornea by observation of a real image reflected from the cornea rather than of the first Purkinje image (virtual image) as used in a conventional keratoscope. Light from the target rings is directed onto the cornea at near normal incidence, enabling use of a wider corneal image area, whereas light from the flat or cylindrical target of the conventional keratoscope subtends an angle of about 150° at the eye, so the image area is limited. With this photokeratoscope many corneal meridians can be described in terms of asphericity, S, from a reference sphere as a function of the distance from the ophthalmometric axis. The reference sphere has a radius calculated to most readily fit the central 3.0 mm portion of the corneal diameter.

5.3 PHOTOELECTRONIC KERATOSCOPY PEK

5.3.1 PEK Instrument

This instrument was developed to improve the accuracy and reproducibility of topography measurement (Bibby 1976). Bibby and Townsley (1976) described this instrument and its value in obtaining information regarding the geometric axis displacement relative to the visual axis. Features of the PEK instrument include rapid use since the single lens reflex camera enables the clinician to obtain the correct camera position and focus swiftly; also rapid film development since the Polaroid camera within fifteen seconds develops the black and white negative keratograph. The cornea must correctly face the camera plane to avoid image distortions due to unusual oblique light incidence. Advantages are that keratograph measurements can be made at leisure, not requiring the patient to strain to maintain fixation for a long time, and a permanent record of the keratograph ring positions is obtained to compare with sequential measurements.

The observer, after instructing the patient to fixate on an internally illuminated target inside the PEK and to keep his head and chin steady on the supports, correctly positions and focuses the instrument using the joystick and focusing knob shown in Fig.5.1. He takes the photograph of the concentric target rings reflected by the patients cornea, after fifteen seconds the photograph negative is developed and removed (Fig.5.2).

The image plane of the photokeratoscope target, which is behind the cornea, should be flat, since a curved image plane gives a photograph with some points out of focus (Fig 5.3). The Wesley Jessen PEK has a target system of seven concentric rings arranged on an ellipsoidal surface such that their virtual image, as reflected by a cornea of 44.0D (7.63 mm radius of curvature), lies in a flat plane. The ring images increase in diameter from 3.0 mm to 9.0 mm in 1.0 mm steps. When monitoring changes in corneal topography it is important that successive photographs cover the same portion of the cornea.

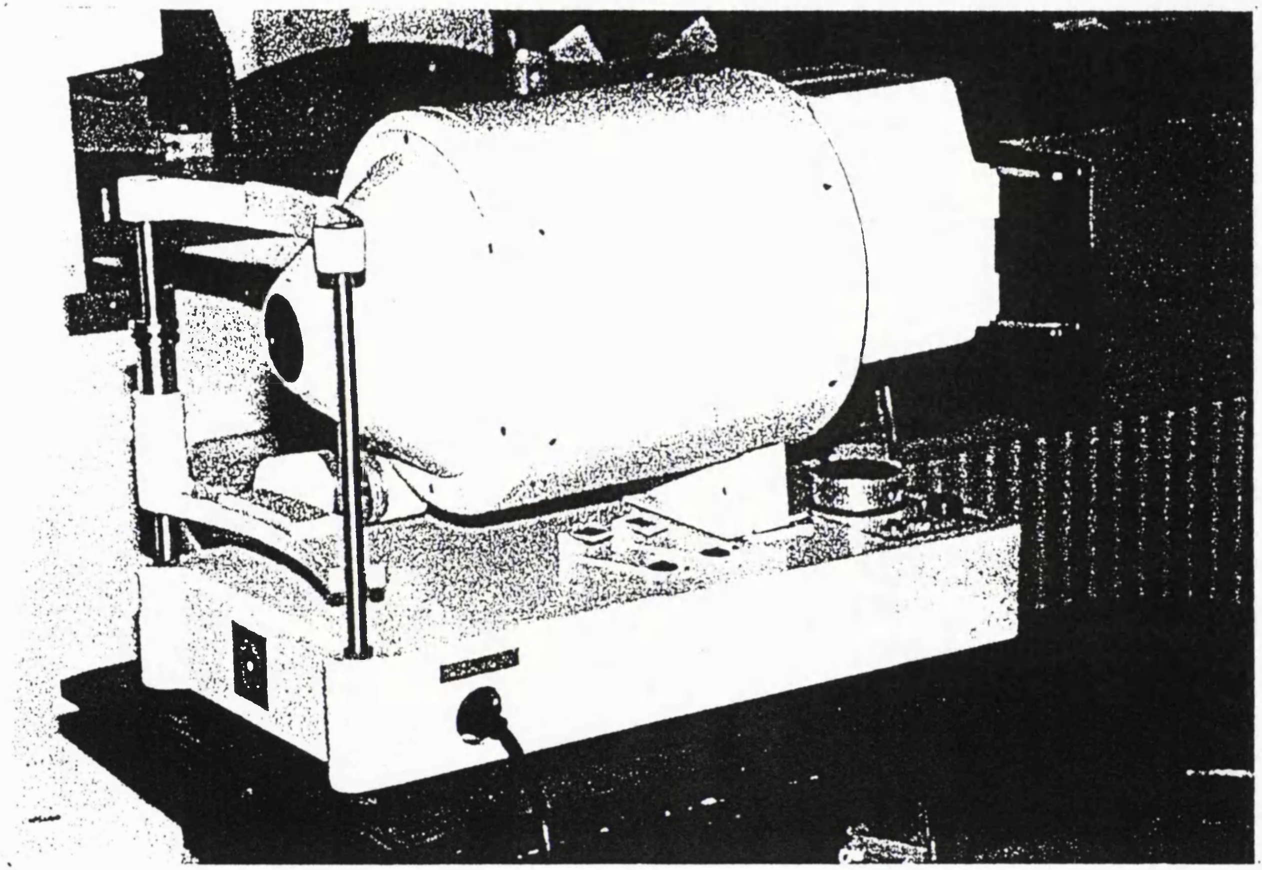


FIGURE 5.1 WESLEY JESSEN PHOTOELECTRONIC KERATOSCOPE PEK

Note: The rings are oval due to WTR astigmatism and the upper section of the rings are broken due to the eyelashes.

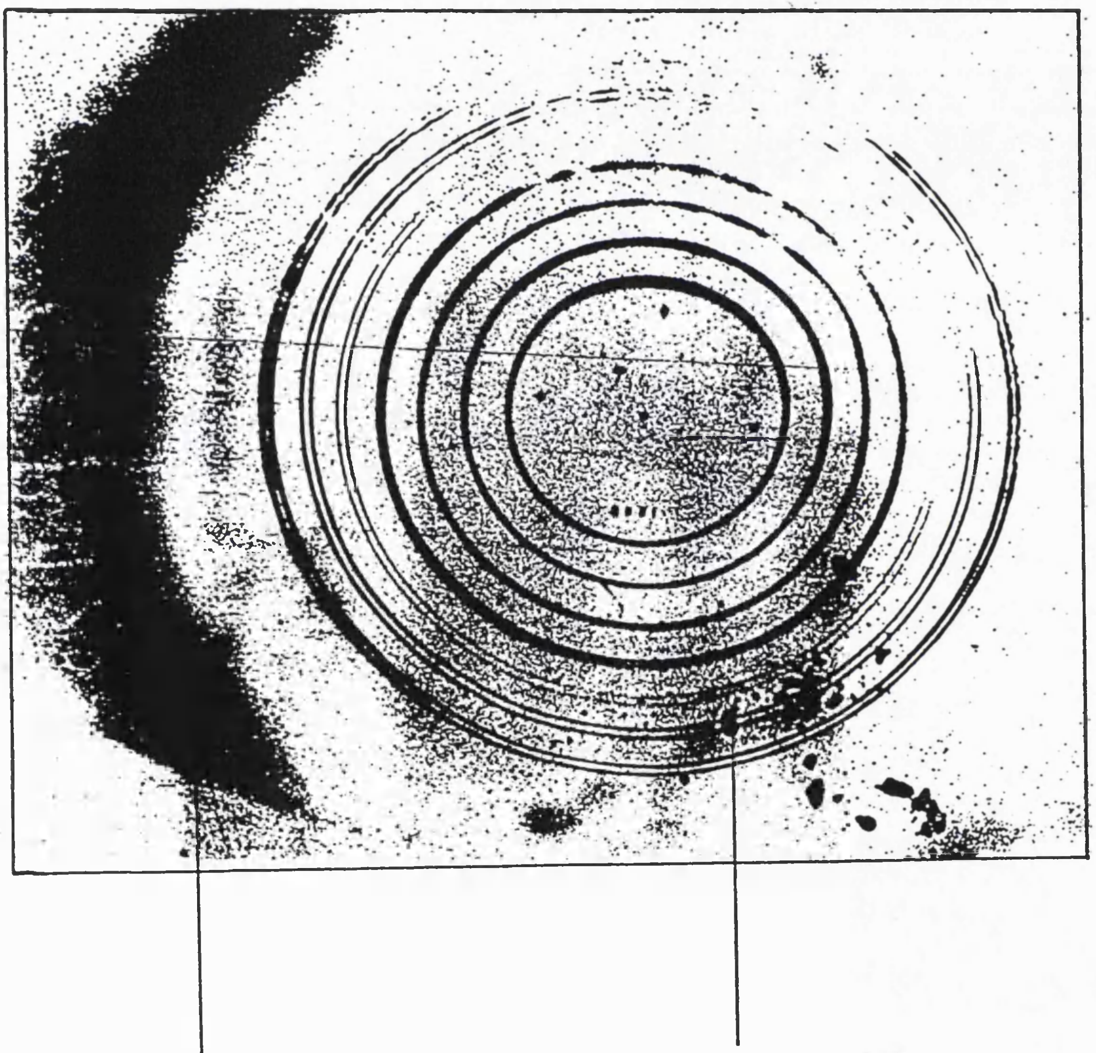


FIGURE 5.2 CORNEAL PHOTOGRAPH USING THE PEK

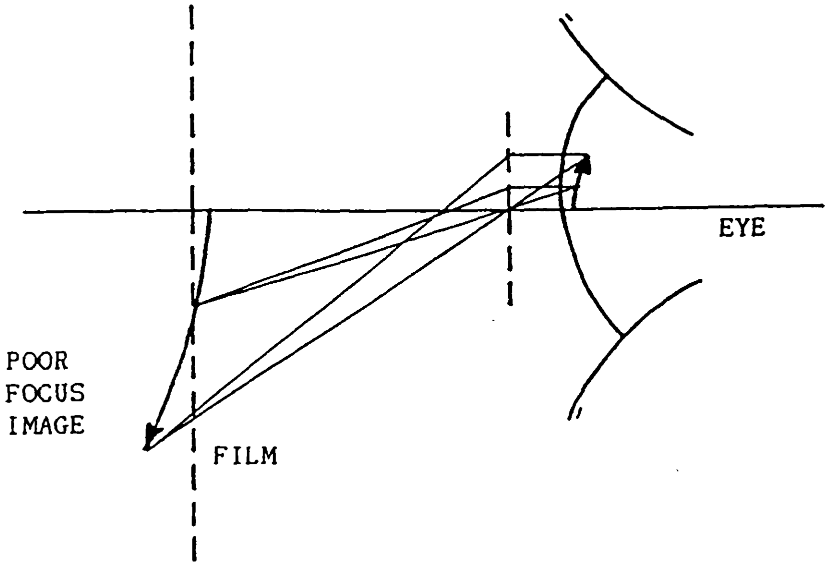


FIGURE 5.3 PROBLEMS WITH CURVED IMAGE PLANE

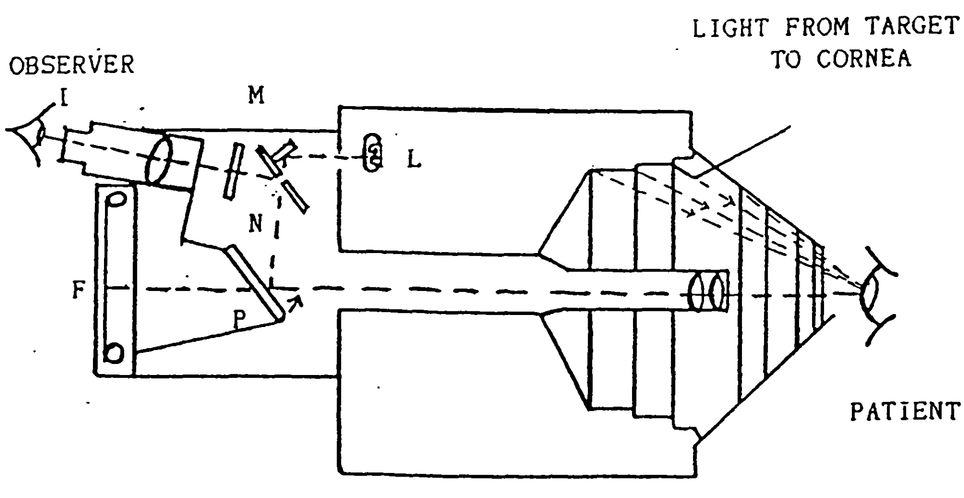


FIGURE 5.4 DIAGRAM OF THE WESLEY - JESSEN PEK

The PEK provides accurate, reproducible alignment of the patients visual axis with that of the instrument. For alignment ,the patient fixates a crosswire placed at the principal focus of the instrument. To assist reproducibility, light from lamp L (Fig.5.4), reflects off a mirror M, passes through a hole in mirror N to reflect at mirror P, directed to the patients cornea. If the incident light is normal to the corneal surface, the beam will be reflected back along the original path such that some rays will be reflected by N through eyepiece I to the observer. In the correct position, this allows the observer to see a dark spot, corresponding to the hole at N, surrounded by a light background. The shallow depth of field, approximately 0.01 mm, assists accurate alignment. When the photograph is taken, mirror P lifts and film F is exposed.

5.3.2 Corneal analysis of PEK photograph

There are three main measurement methods. The first uses a travelling microscope, improved by the use of a double ring target pattern so that the dark crosswires can be set on a relatively bright line at the centre of each photograph ring. the second variation is where the crosswires are set mutually perpendicular at 45 degrees to the ring centre line at the position measured. The third method uses projection of the photograph onto a screen to facilitate measurement. Ludlam et al (1966), using this, found measurement repeatability of 0.05 mm at the sixth ring image on steel calibration balls.

From a 50 times enlargement of the image the Wesley Jessen computer system analyses the photograph in the two principal meridians only, the flattest and that at 90 degrees to the flattest. Each meridian is analysed for the exact location of the reflection points corresponding to each of the seven target rings. This information is quickly and accurately computed in terms of sagittal depths and semi-chord lengths, up to a maximum of fourteen points per meridian. Values for central curvature and shape factor are given. An example analysis is shown in Fig.5.5. Mandell and York (1969) described a 'semi-automatic' system for photograph measurements, whilst Cochet and Amiard (1969) included photoresistors in their system.

Townsley (1970) studied the shape distribution of 350 human corneas and discussed the exact optical ray tracing principles of the corneal shape analysis, including the smooth fitting of a conoid section to the elliptical shape of the cornea. He claimed that inaccuracies by previous workers were due to the following:- flat plane target, blurred photographs, imprecise measurements, numerous assumptions and simplification of mathematical formulae, and a long time to calculate the loci of reflection points and to condense the information. Erikson (1981) described a modern algorithm for programming refractive astigmatism.

Mathematical models to describe the complex shape of the cornea have been sought (Mandell and St.Helen 1971, Bibby 1976, Brungardt 1981, Kiely, Smith and Carney 1984, Klyce 1984, Knoll

SYSTEM WJ 2000
CORNEAL ANALYSIS™
WESLEY-JESSEN (UK) LTD. (COMPUTER ANALYSIS)

PATIENT WILLIAMS DIANE DATE 26 9 85
PRACTITIONER 90099/MOORFIELDS EYE ACCOUNT # O/N:512774

INPUT DATA

	SPHERE	CYLINDER	AXIS	DIAM	TEAR LAYER THICKNESS	CYCON LIMIT	TRIAL LENS BCOR	BACK VERTEX POWER	DIAM
R	0.00	+0.00			0.015	0.50		+ 0.00	
L	0.00	+0.00	0		0.015	0.50		+ 0.00	

VERTEX DISTANCE	COLOUR	MATERIAL	MARKING
0.00	CL	P.M.M.A	

CONTACT LENSES

	BASE	INTER	PERIPH	THICK	DIAM	BACK VERT PWR	RESID ASTIG	V.I.D.
R	7.97	8.4	11.8	0.17	8.4	– 0.50	-0.64	0.0
L								

OTHER DATA

	RH	RV	LH	LV
BCOR	7.97	7.88	0.00	0.00

NOTES

SOFT 38: R 9.00/+ 0.25/13.5; L 0.00/ 0.00/13.5
IRREGULAR CORNEA - READINGS DIFFICULT

APEX RE 1. mm at 275 LE 0. mm at 0

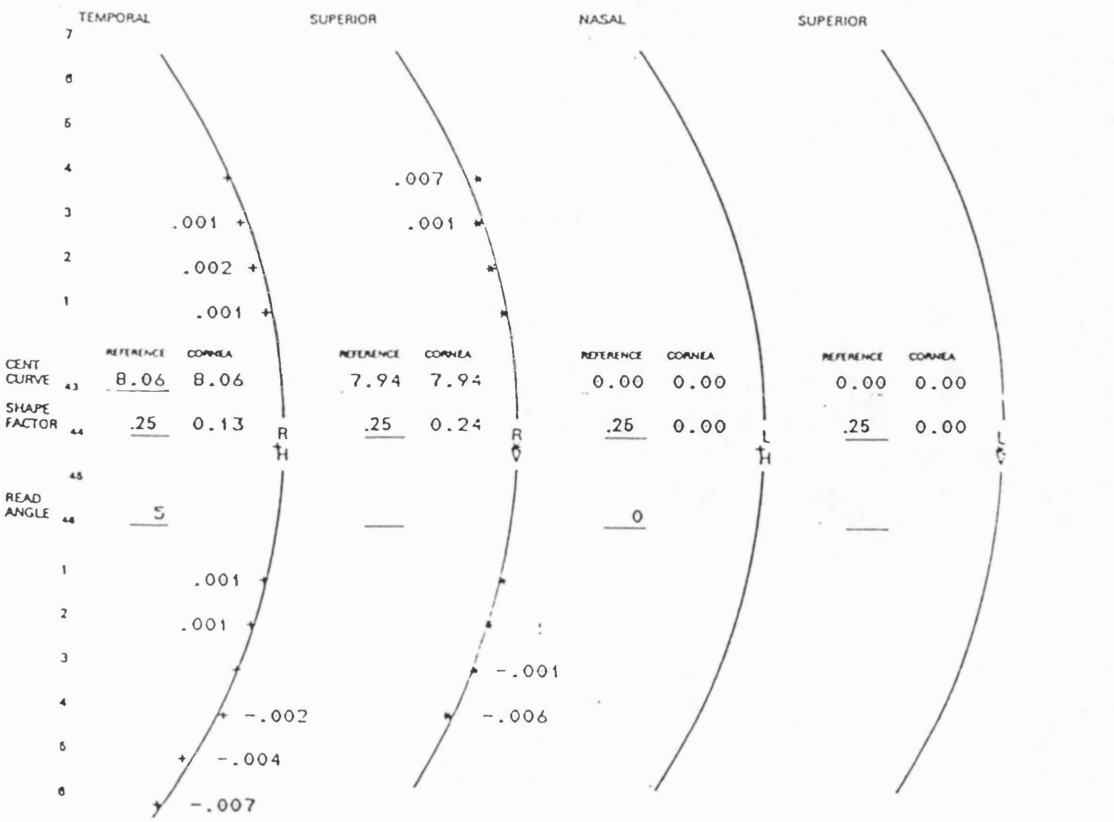


FIGURE 5.5 COMPUTER ANALYSIS OF PEK PHOTOGRAPH

1986). Most investigators described the normal corneal shape as forming part of a conic section, whether ellipsoidal, parabolic or hyperbolic. Conic sections have two parameters to define them - central curvature which defines the size of the section (Fig.5.6a) and shape factor which defines the shape and 'rate of peripheral flattening' (Fig.5.6b). Shape factor (SF) is given as the square of the eccentricity of the curve: $SF = -e^2$.

Kiely, Smith and Carney (1982) criticised the common model for corneal shape as being a rotationally symmetrical conocoid derived from the photokeratoscope data. Their results showed the cornea to be significantly asymmetric in both radius of curvature and asphericity. Townsley (1967) described the common model in the simple form of an ellipse with major and minor axis lengths a and b respectively. Thus eccentricity e is given by:

$$e^2 = 1 - b^2 / a^2$$

These expressions include some averaging of the corneal form so variations in corneal shape in a particular meridian may not be exactly specified.

Several advances have been made in both the keratoscope and the computer analysis systems. The Corneascope has been recommended as a technique involving automated image scanning of the photographs, hence providing a more accurate and reproducible analysis of the paracentral corneal contour (Doss et al 1981, Rowsey et al 1981,1989). The Nidek PKS 1000 photokeratoscope was preferred by some because it gave information on a larger surface

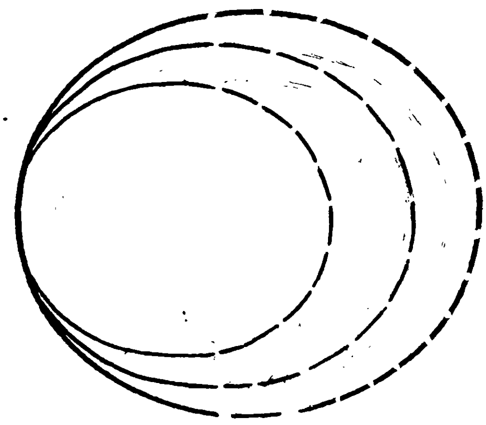


FIGURE 5.6a Constant shape factor (SF), various central curves, D.

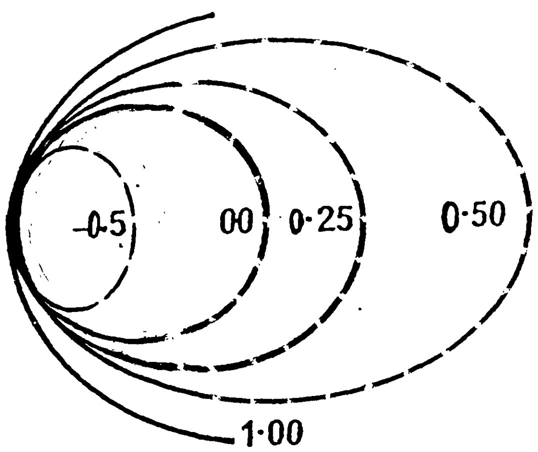


FIGURE 5.6b Constant central curve various shape factors

FIGURE 5.6 CENTRAL CURVATURE AND SHAPE FACTOR area than did the Corneascope (Klyce 1984, Maguire, Singer & Klyce 1987, Dingeldein & Klyce 1989). Wilson and Klyce (1991) discussed several corneal topographic analysis systems including the sixteen ring Eyesys Corneal Analysis System and the thirty two ring Corneal Modeling System. The latter uses a collimated videokeratoscope that provides a central fixation point as a reproducible reference for the computerised statistical analysis of the power points on the rings.

Hannush et al (1990) compared this system with the Corneascope and with a keratometer. The Corneascope gave the least reproducible results. The Corneal Modeling System was only 83% as reproducible as the keratometer for the central 3.0 mm zone but gave information about the remaining corneal topography in a more reproducible and visually useful manner. This suggests that the keratometer is still very suitable for central corneal measurements, but the modern videokeratoscopes with rapid data analysis are advantageous for the description of peripheral corneal changes.

CHAPTER 6

PACHOMETRY

6.1 PACHOMETRY DESCRIPTION AND HISTORY

6.1.1 Introduction

The pachometer is an instrument designed and calibrated to measure materials of refractive index 1.376. It is used for in vivo measurements of human corneal thickness, - a complex task since the cornea is a mobile, fairly transparent medium with transparent fluids bounding it anteriorly and posteriorly. Pachometry is a useful measure of the physiological stability of the cornea, since factors affecting the corneal metabolism, even in localised areas, alter the hydration and hence thickness of the cornea in those areas. Pachometry is becoming more widely used in monitoring eye conditions, eg. after surgery. The two main methods are optical and ultrasonic.

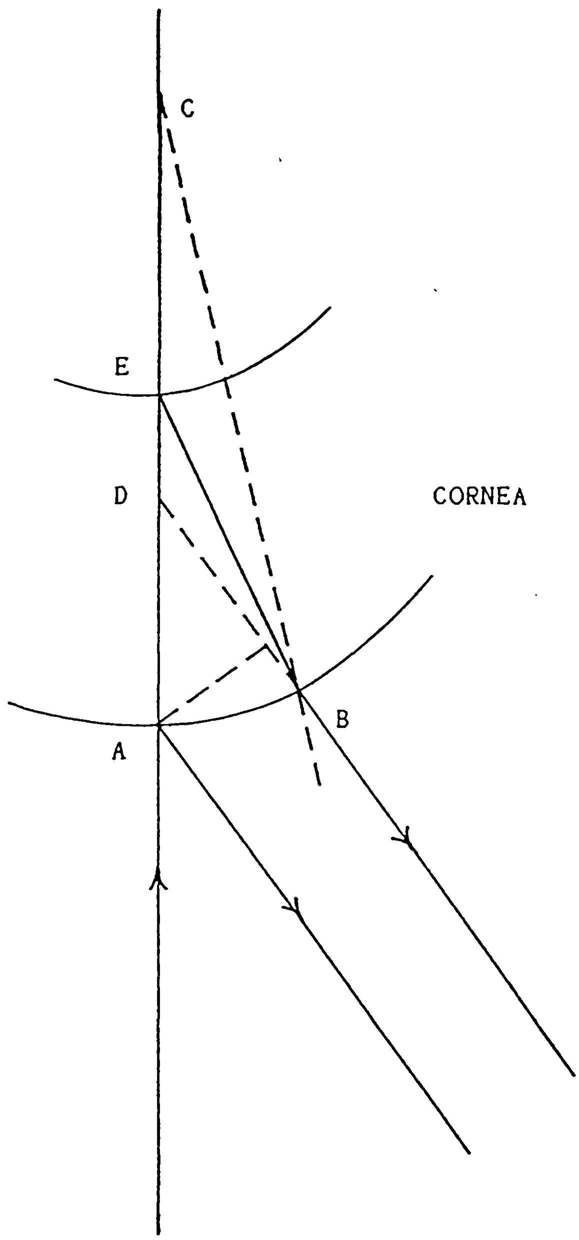
6.1.2 History

Early studies on corneal thickness tended to give rather high values eg. 0.90 mm, Thomson (1912), 0.80 mm, Salzmann (1912) cited by Von Bahr (1948). This was probably because those measurements were mostly on cadaver corneas which had undergone post-mortem swelling and decreased clarity. The first measurements on living eyes were attributed to Blix (1879) who found values of 0.48 to 0.58 mm. Values of 0.46 to 0.51 mm were found by Gullstrand in 1909 and a mean value of 0.53 mm found by Sobanski in 1934 (von Bahr 1948).

Various methods of pachometry based on optical principles have been described by Button (1986) and Woodward (1980). Blix used the method of successive focusing on the specular reflexes from the anterior and posterior corneal surfaces. The distance moved by the apparatus along the axis between the two microscopes is the apparent corneal thickness. If the refractive index and radius of curvature of the cornea are known, the real thickness may be calculated. Problems with this method included the possibility of corneal movements between measurements, also the large difference in brightness between the two reflected images.

Gullstrand (1909) made simultaneous observations of the specular reflexes and used a weak light source for the anterior corneal surface and a bright one for the posterior surface. Von Bahr (1948) used rotating parallel glass plates to superimpose the two reflections instead of using a travelling microscope. The successive focusing technique was later developed into a commercial instrument, claiming an accuracy of +/- 0.01 mm by Maurice and Giardini (1951).

Another method is to measure the apparent thickness of the optical section of the cornea, as seen by diffuse reflection of the stromal layers. Dependent upon the angle of incidence of the light and observation angle, the real thickness may be calculated in different ways from the measured apparent thickness (Juillerat and Koby 1928). The measurement is simplified if the surfaces are observed simultaneously. By applying this principle (Fig.6.1),



CB = corneal radius
AE = corneal thickness
AD = apparent thickness

FIGURE 6.1 JAEGER'S PACHOMETRY METHOD

Jaeger (1952) developed a commercial instrument for use with the Haag-Streit Slitlamp model 900 (Fig.6.2). Using this apparatus, Mishima and Hedbys (1968), and Lavergne and Kelecom (1962) found reliable results with a standard error of only +/- 0.003 mm. The two currently commercially available instruments use different principles. The Maurice-Giardini pachometer aligns the specular reflexes from the two corneal surfaces; and the Jaeger designed attachment measures the apparent thickness of the optical section. The Haag-Streit instrument used in this study is described in chapter 7.

6.2 FACTORS AFFECTING RELIABILITY OF MEASUREMENTS

6.2.1 Reliability factors (see Table 6.1)

Since 1723, corneal thickness measurements have been attempted by a number of researchers, with increasing attention on improving accuracy (Molinari 1982). Molinari noted that the clinician has difficulty achieving high accuracy because of standardisation problems including slit width and angle of incidence, accuracy of focusing during the measurements, fixation instability, the observers judgement and the need to determine the same point on the cornea for sequential measurements. Difficulties can arise if measuring abnormal eyes with irregular surfaces, poor transparency, disturbed epithelial or endothelial layers, photophobia, blepharospasm or nystagmus.

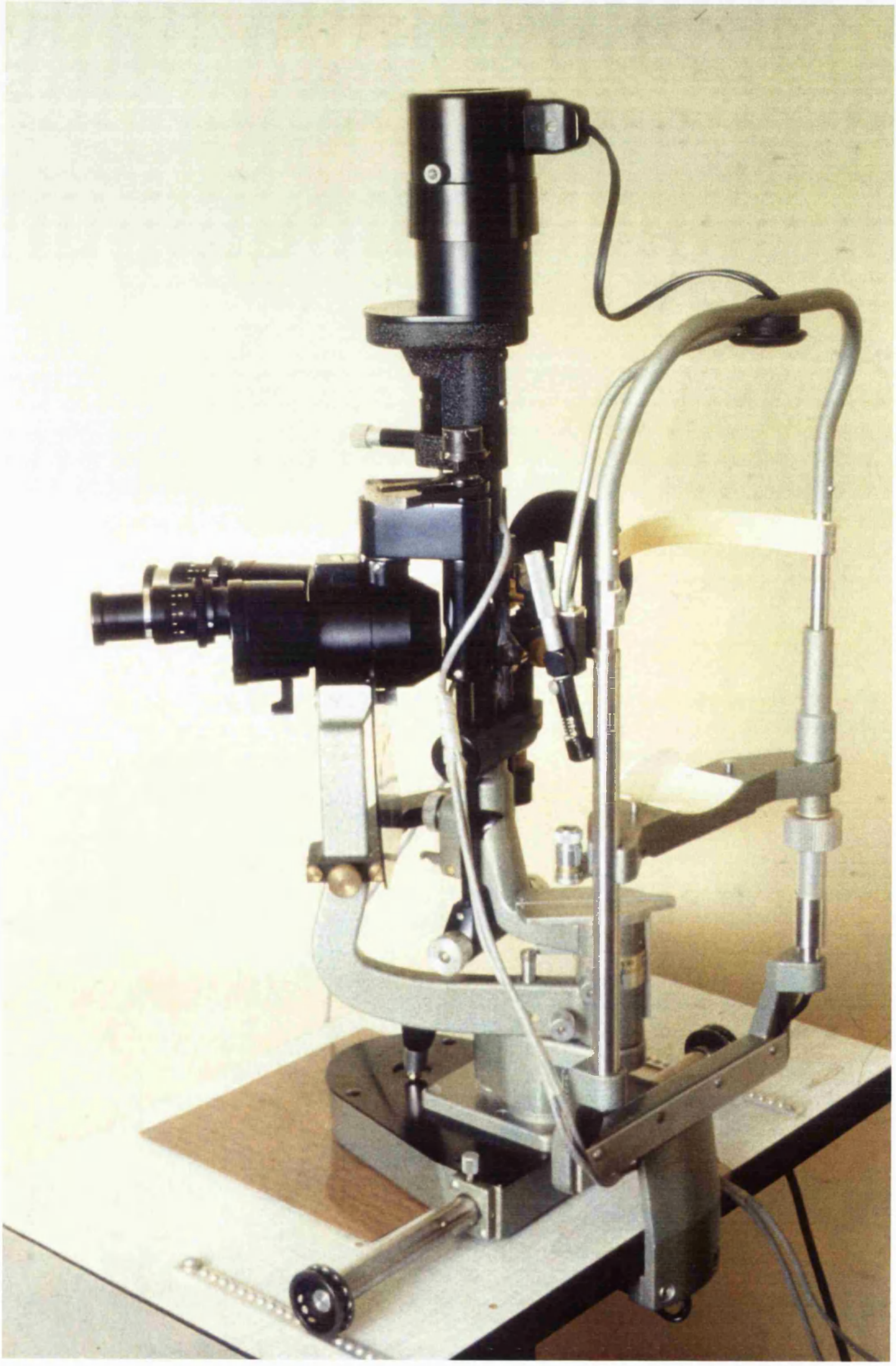


FIGURE 6.2 MICROSCOPE WITH HAAG STREIT PACHOMETER

Several problems were noted by Mishima (1968) as follows:

(a) Illumination

A bright slit beam and dim room illumination, as used in the current study, help the observer to judge the focusing of the slit beam, since the contrast is improved. Such little change in result has been found from changing the light wavelength, that single wavelength beams have been abandoned and the usual white slitlamp beam used. Slit width and the focusing of the microscope limit the accuracy of the optical section methods (Olsen et al 1980a,b). The Haag Streit microscope has relatively low magnification (10 times), and has fewer problems.

(b) Observer

Experience and dexterity with the pachometer enables swifter, more accurate measurements to be taken before the subject tires. Inter observer error may occur with differences in judging the optical section edge profile as shown by Patel (1981), Hirji and Larke (1978). The current study used the same experienced operator for all the pachometry.

(c) Tear layer

Sometimes fluorescein is put into the tear layer so that this layer is more easily distinguished, and the contrast improved when focusing on the epithelium (Crook 1979). Care is taken not to stimulate lacrimation, which would increase tear layer thickness and confuse the observer. Farrell and McCally (1976) indicated the problems associated with alignment setting of the optical section.

(d) Electronics

If the pachometer read-out system relies on electronics then these must be checked and ensured reliable. In the current study time was allowed for the electronics to stabilise before readings were taken.

(e) Regional fixation targets

These are steady, not glaring but easily visible without the need for focusing or good visual acuity. For all sequential measurements, they must have the same position as originally located. Their position from the centre is not so distant that the subjects eye is under strain to maintain fixation.

6.2.2 Ultrasonic versus Optical Pachometer

Salz et al (1983) from a study of 4 subjects claimed that the ultrasonic method gives more repeatable results and the following advantages: high reproducibility, negligible inter observer and inter ocular variations, simple operation and needs minimal patient co-operation. However, the ultrasonic measuring system has several disavantages. Measurements are only considered accurate to +/- 0.05 mm of tissue thickness, and since valid measurement of variations involves error if there is misalignment of the sound beam with the visual axis then this error could increase to +/- 0.10 mm (Coleman and Carlin 1967).

There is the need for physical contact between the probe and the cornea, requiring the cornea to be anaesthetized and the probe tip to be cleaned and sterilized immediately before use (Mandell, Polse and Bonanno 1988). Also the exact corneal area measured is difficult to localise and a wider range of measurements is obtained. This reflects the uncertainty of repositioning the ultrasound probe at the same point on the corneal surface for each reading (Patel and Stevenson 1994). The difference between results obtained by optical and ultrasonic methods increases with increasing corneal hydration (Nissel et al 1991). Ultrasonic methods tend to give thicker readings if set at higher velocity, depending on corneal temperature. Improvements to the accuracy of optical pachometry have been made by Donaldson (1966), Mishima and Hedbys (1968), Ehlers and Sperling (1977), Mandell, Polse and Bonanno (1988), and Stevenson (1989).

6.2.3 Angle Kappa

This is the angle between the subjects visual axis and the axis which is perpendicular to the cornea as according to Jaeger's principle. Usually in routine clinical pachometry, the patient fixates the incident light so the measurement is made along their visual axis. This limits pachometry to the central cornea only and also introduces measuring errors proportional to angle 'kappa' (Von Bahr 1948) and a difference between measuring right and left eyes, left eyes having higher readings. This difference has been shown to be statistically significant by

Kruse Hansen (1971) and by Woodward (1980) (As the sum angle kappa increased to 20 then the thickness error increased to +/- 0.02 mm). If consistent fixation is maintained, there should be no significant change in angle kappa.

Mishima and Hedbys (1968) designed the modification using two vertically mounted pinlights placed to one side of the incident beam such that their reflections were at an angle equal to the observation angle and were viewed through the eyepiece to allow measurements with the incident light falling perpendicular to the anterior corneal surface. No reduction in standard deviation of the measurements was demonstrated, possibly due to the patients' difficulty in maintaining accurate fixation on a small target near the source of the incident slit beam.

6.3 VARIATIONS IN NORMAL CORNEAL THICKNESS

These variations may relate to the normal range of thickness (Table 6.2) or to the region of the cornea. Other factors such as age, diurnal variation, menstrual related variation, contact lens wear, tears osmolarity, and intraocular pressure can also affect the corneal thickness.

6.3.1 Age and Gender

Weale (1971) mentioned that the mucopolysaccharides and collagen fibrils in Descemets membrane develop cross-linkages with ageing, decreasing elasticity and slowing down corneal swelling in the elderly eye. Although corneal thinning with age was suggested, no significant difference with regard to age or gender was found by Kruse Hansen (1971), Von Bahr (1948), Lowe (1969) or by Richards et al (1986). Martola and Baum (1968) found no significant difference between right and left eyes, nor a relation to gender, refractive error nor arcus senilis. Significant peripheral corneal thinning after fifty years of age was found by Alsbirk (1978).

6.3.2 Diurnal Variation

Kikkawa (1973) found that rabbit corneal thickness increased at night when lids were closed, was maximal on waking then decreased by the afternoon. The change was inconsistent but of mean value 0.014 mm. Other investigators include Mandell and Fatt (1965), Hirji and Larke (1978) and Friedman (1973).

Chan-Ling, Efron, and Holden (1985) on measuring cats, concluded that the 8.6% diurnal variation was due to corneal swelling after eye closure during sleep, but after two hours of activity corneal thickness returned to the base line value. Care was taken in the current study to perform pachometry at the same time of day for each patient and several hours after their waking.

6.3.3 Menstrual Related Variation

Kiely, Carney and Smith (1983) in a study of six women found corneal thickening at ovulation time, when oestrogen levels were raised, followed by corneal thinning. Feldman et al (1978) found similar results. No significant corneal thickness changes were found by El Hage and Beaulne (1973) nor by Hirji and Larke (1978). In some patients, menstrual cycle changes involve water retention in the tissues, which could explain the increasing corneal thickness. Certain general health problems eg. hypertension and diabetes can cause similar effects. To avoid these influences in the current study, patients with such conditions or pre menopause were excluded.

6.3.4 Osmotic Effect

Wilson and Fatt (1974) could not find a significant relationship between tears tonicity and corneal thickness. Chan and Mandell (1975) showed a relationship to the hypotonicity of eye bathing solutions. Chan (1987) found the corneal thickness change in cats was almost twice the value for the central than for the peripheral region. He proposed that this was due to a difference in the structure and/or hydration characteristics of the cornea at the limbus as shown by Maurice (1969), by Borcherding et al (1975) and by Hodson et al (1981).

6.3.5 Intraocular Pressure

Kruse Hansen (1971) showed that central corneal thickness can increase significantly with markedly raised intraocular pressure (IOP). This disturbs the endothelium and the corneal hydration balance, leading to stromal swelling, disruption of the lamellar pattern and decreased corneal transparency. Patients with markedly raised IOP were excluded from the current study.

6.3.6 Regional variation

Human corneal thickness is greater in the peripheral than in the central region and so the response to ocular surgery can differ. Fig.6.3 shows typical values found by Hirji and Larke (1978). Similar results were obtained by Martola and Baum (1968), Bailey and Carney (1972), Tomlinson (1972), El Hage and Beaulne (1975), and Kiely et al (1983).

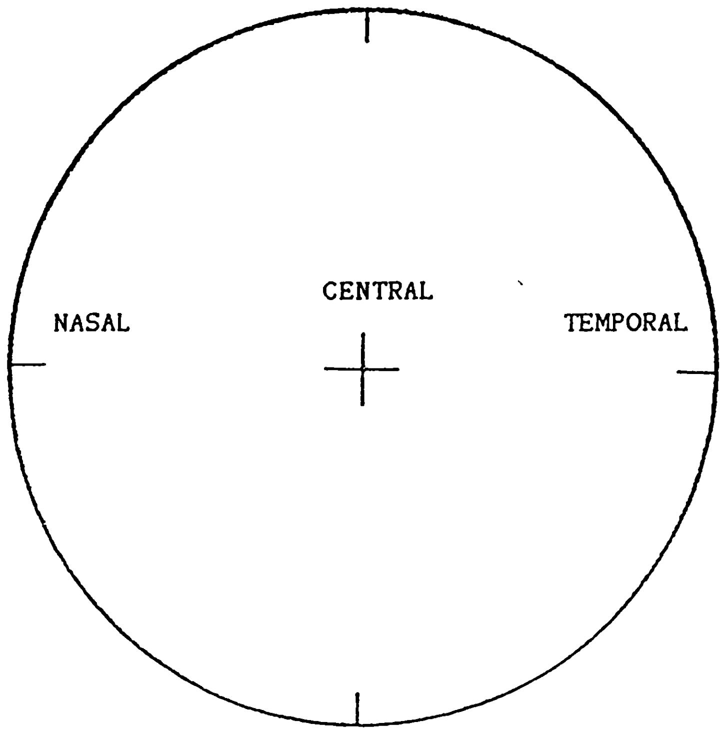
6.4 USE OF PACHOMETRY ON ABNORMAL EYES AND AFTER SURGERY

6.4.1 To judge treatment effect

Providing pre-treatment measurements are correctly taken, changes in corneal thickness can indicate corneal oedema (Stone 1975). Pachometry is a valuable indicator of the corneal response to treatment, whether surgery, topical medication (Jacob 1986) or contact lens wear (Guillon and Morris 1981, 1982). Cheng et al (1977) found greater and more widespread corneal oedema after IOL implantation following ICCE. Corneal oedema is more likely to occur if the endothelium is damaged, eg. by mechanical trauma during surgery or by intermittent contact between the IOL and the endothelium (Dohlman and Hyndiuk 1972, Cheng et al 1988).

Vannas et al (1985), comparing stabilised postoperative eyes to normal control eyes, found the former to have less corneal thickness increase under hypoxic stress but the same as the control eyes when under osmotic stress. This indicated that corneal surgery affects the corneal epithelium physiology in a manner proportional to the angular size of the incision.

SUPERIOR



INFERIOR

REGION	DEGREES	MEAN THICKNESS	SD
S	30	0.69	0.03
C	30	0.55	0.04
I	30	0.65	0.04
N	30	0.69	0.04
T	30	0.63	0.04

see Hirji and Larke (1978)

<u>FIGURE 6.3 REGIONAL CORNEAL THICKNESS</u>

Holden et al (1982) suggested that this decrease in corneal swelling of the aphakic eye results from a decrease in the overall metabolic activity of the epithelium. Pachometry is useful to monitor contact lens related corneal thickening, eg. Harris et al (1975), Hirji and Larke (1979), Holden et al (1980), Tomlinson et al (1981), Guillon (1982), Nilsson and Morris (1983), Snyder and Schoessler (1983), Holden et al (1985).

6.4.2 Diagnostic Aid

Pachometry is useful when monitoring corneal thickness changes due to ocular disturbances eg. those causing corneal decompensation. Pachmetry can assist diagnosis, as in cases of keratoconus and Terrians dystrophy. Preoperative pachometry is valuable to the surgeon as a guide to incision depth eg. in corneal transplant resection, and in refractive surgery such as radial keratotomy.

CHAPTER 7

EXPERIMENTAL PROCEDURE

7.1 PATIENT SAMPLE AND MEASUREMENT FREQUENCY

With the consultants' and patients' permission, consecutive patients undergoing routine cataract extraction (with or without IOL) were included in the study. The measurements, their frequency and the purpose of the study was explained to each patient who then completed a form of consent record, as shown on the next page. Patient exclusion criteria were as follows:

a) Previous anterior segment surgery, for example trabeculectomy or penetrating keratoplasty where the endothelium may have already been damaged so the cornea would be less likely to respond in a normal manner. This is also true for cases of traumatic cataract whose inclusion would have biased the grouping as an IOL would be unlikely if they had iris damage.

b) other ocular pathology, for example glaucoma. Sustained raised introcular pressure is known to have a deleterious effect on endothelium and hence on corneal thickness response and recovery. Corneal epithelial fragility is increased in diabetes (O'Leary & Millodot 1981) therefore the corneal response to surgery would be abnormal.

c) co-operation difficulty with the measurements required, for example Parkinsons disease or severe arthritis prohibiting a steady head position on the instrument head rest.

d) Difficulty with travelling to attend appointments, for example if a hospital ambulance or special escort was required.

e) Serious operative surgical complications. Although rare, should these occur the cornea would be likely to respond in an abnormal fashion.

During the study period approximately five thousand patients were admitted to Moorfields Eye Hospital for cataract extraction. As the study was carried out in the context of a routine service clinic and the author was often on duty in alternative clinics, the recruitment of patients occurred over a prolonged time. The first patient was measured in January 1984, the last of this sample in January 1988. this was unavoidable because the research programme was subordinate to service commitments. Furthermore, the protocol demanded measurements to be taken on ten separate occasions, which was a further constraint on the number of new patients who could be recriuted in a given period.

As Moorfields Eye Hospital is a postgraduate teaching hospital there is inevitably a large number of surgeons performing cataract surgery, unlike a district general hospital where the surgery is carried out by the same group of surgeons every year. At the time of this study two of the four surgeons were consultant ophthalmologists and two were lecturers at the Institute of Ophthalmology. By using more than one surgeon patients could be recruited more rapidly. In an area where surgical techniques were rapidly changing, this was an important factor, particularly in view of recruitment restraints already mentioned. Ideally, measurements on patients operated upon by a single surgeon would be less open to bias introduced by variations of surgical technique, nevertheless the other factors were thought to be more important. The results were aggregated as one of the requirements of the surgeons for their co-operation was that the outcomes of individual surgeons would not be described in the study.

One hundred and seventy patients were randomly selected, of which one hundred and forty were eligible and agreed to take part (see form of consent record). The surgical techniques were independently chosen by their surgeon. These were: using a corneal incision and nylon sutures (group C), and using a limbal incision and virgin silk sutures (group L). All the surgery was performed using operating biomicroscopy with ECCE technique and without detailed regard to preoperative astigmatism. Basic measurements of average corneal power and the axial length of the eye were noted to assist in the calculation of the power of the IOL when required. A reverse-sloping incision was used, with a similar range of incision size in the two groups (90 to 130 degrees). Corneal sections were sutured with five interrupted 10/0 monofilament nylon sutures, while limbal incisions were sutured with five interrupted 8/0 virgin silk sutures. An example of the type of intraocular lens used was: Coburn posterior chamber IOL model 72UV, control number I71228, power +20.00D, length 13.75mm.

A control group of thirteen non-operated fellow eyes in both groups was monitored at the same visits as the operated eyes; seven from patients undergoing corneal incision surgery, and six from those undergoing limbal incision surgery. A further control group of ten non-operated eyes of age matched volunteers from the hospital staff was also monitored.

Measurement Frequency

Where possible, assessment visits were combined with routine postoperative clinic visits to minimise patients' inconvenience. Measurements were carried out every 2 weeks to obtain a better appreciation of when the astigmatism changed. On the basis of previous work (see Chapter 3), it had been established that in the majority of cases, changes in astigmatism have stabilised by 3 to 6 months postoperatively, so the final measurement in this study was made at the 24 week stage. Measurements were taken at the following times: within 1 week preoperatively, within the first few days postoperatively, and postoperatively at 2, 4, 6, 8, 10, 12, 16, and 24 weeks. Hence, visits for measurements extra to the routine clinic visits of the first few days, 2, 6, 12 and 24 weeks, were only required on three to four occasions.

7.2 REFRACTION AND CORRECTED VISUAL ACUITY

A traditional method of refraction was carried out using a combination of objective assessment by Keeler hand-held spot retinoscopy and subjective refraction using small aperture trial lenses in front of the patients eyes. During the assessment visit (approximately 30 minutes) refraction was performed first so that the patient could more easily concentrate and give accurate subjective replies.

The first postoperative assessment was at one to three days after the operation when the patients lacrimation and photophobia had decreased. The internally illuminated Snellen test chart position and the refraction method were kept the same for each visit, as were room illumination and the back vertex distance of the trial lenses. Visual acuity was measured as a Snellen fraction with the best optical correction in the form of the trial lenses correctly positioned relative to the patient's visual axis. Glare sources were avoided.

7.3 KERATOMETRY PROCEDURE

Keratometry was performed using the circular illuminated mires of the American Optical keratometer (Model No. 11705) and the Bausch and Lomb keratometer (Model No. GH4389), ensuring the same instrument was used for all assessment visits, and taking the mean of three readings in each of the two principal meridia, recentering and refocusing for each reading.

For the preoperative assessments, precautions were taken to avoid unnecessary stimulation of accommodation in the operator. For example, keeping both eyes open but suppressing the unobserving eye, and carefully focusing the eyepiece on the graticule by turning it from the positive direction. The instrument was moved away from the patient then slowly moved forwards until the mire images became clear (Fig.7.1).

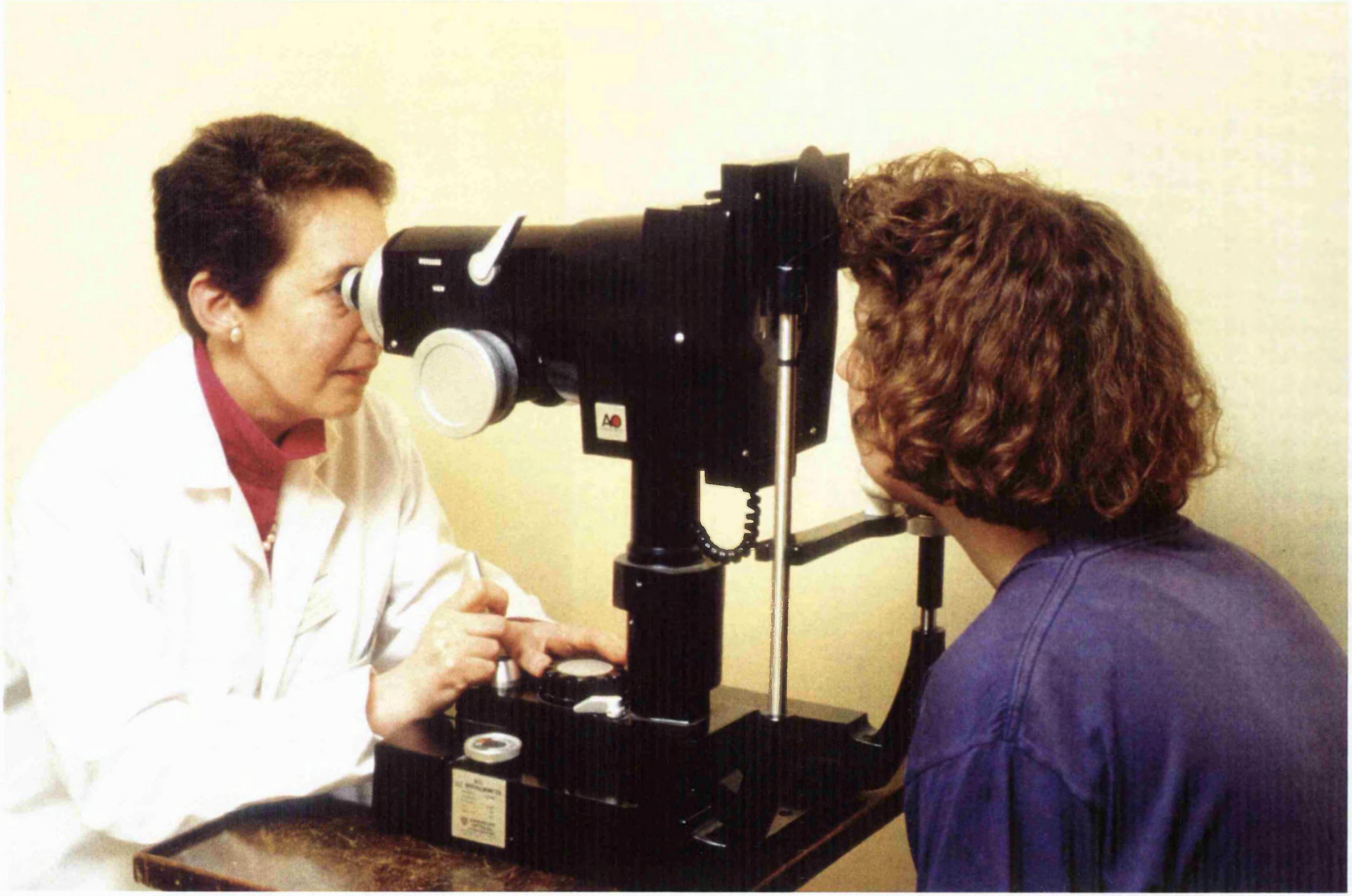


FIGURE 7.1 KERATOMETER IN POSITION

The patients fellow eye was covered and the patient fixated the central light target keeping their head position steady using the head and chin rests. Background illumination was kept low to improve the contrast of the mires and to avoid distracting the patient. The operator was experienced in taking measurements on eyes which had poor vision. Refraction, visual acuity and fixation are affected by a cataract, hence keratometry may be more reliable than refraction for measuring corneal astigmatism.

7.4 KERATOSCOPY PROCEDURE

The PEK was calibrated to establish the measurement precision and the reproducibility of results from a single operator. Precision assessment used the standard calibration spheres as for the keratometer and included comparison of shape factors as given by the PEK photograph analyses. The PEK photographs were all taken in the same illumination conditions using the Wesley-Jessen photokeratoscope (PEK Model No.1688) which has been previously described by Bibby (1976). The same experienced operator took the PEK photograph at each visit. The patient fixated on the central internally illuminated target inside the PEK, keeping his head steady on the head and chin supports and his eye wide open. Care was taken to obtain repeatable photographs, to avoid excessively bright or flickering lights, to avoid excess lid tension and to allow the patient to blink gently to give an even tear film for reflection of the illuminated target rings while the instrument was correctly positioned and focused (Fig. 7.2).

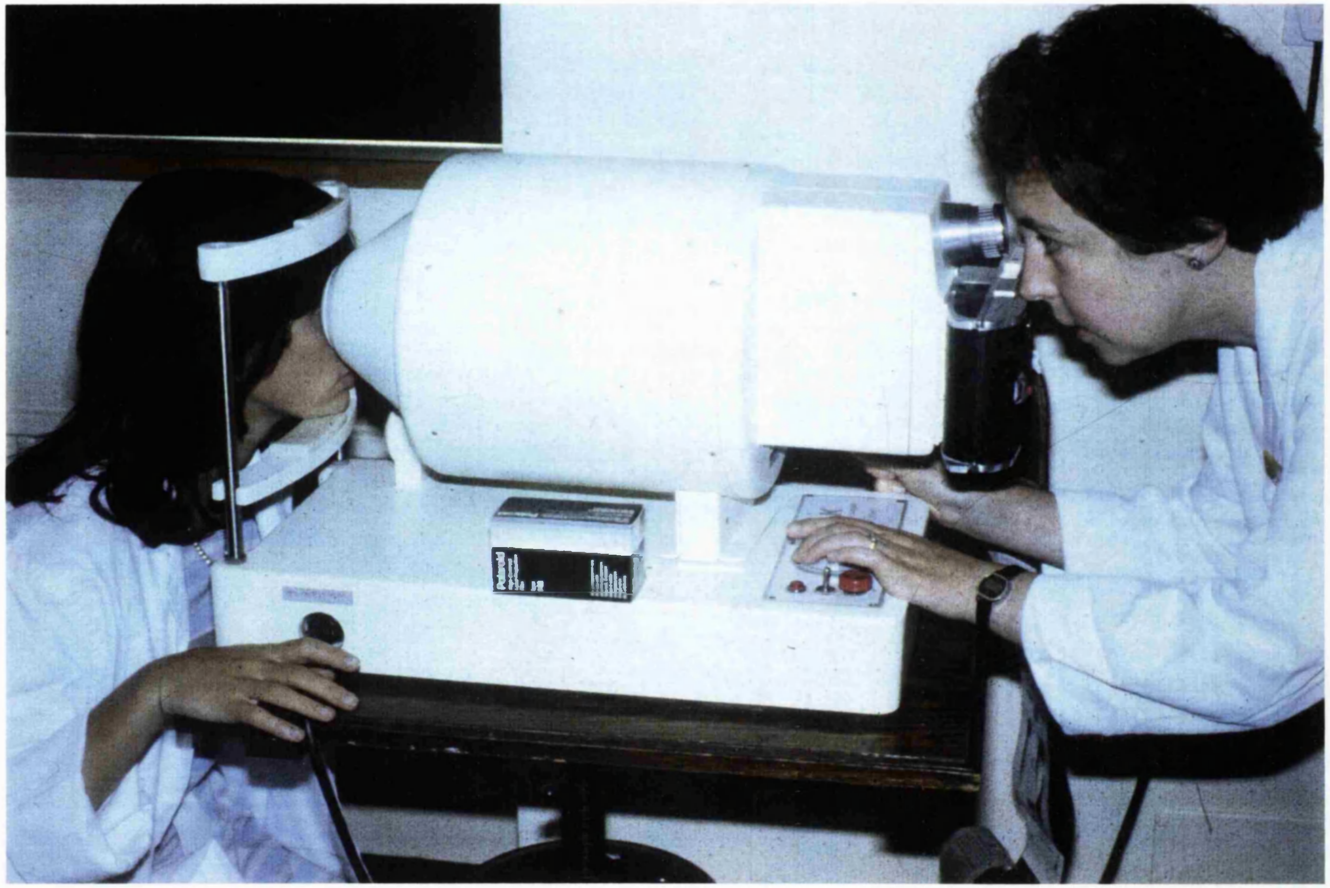


FIGURE 7.2 P.E.K. INSTRUMENT IN POSITION

Fifteen seconds after the photograph was taken, the polaroid negative was carefully removed, labelled and allowed to dry. If the photograph quality was poor because the patient moved, the procedure was repeated. The photograph was sent to Hamblin Contact Lenses Limited where, under 50 times magnification, measurements were made of the ring separations along the steepest and the flattest meridians. Computer analysis of these enabled the quantification of the central radii of curvature in the principal meridians, their orientation axes and the peripheral contours in terms of shape factor.

Photokeratoscopy was important to provide information regarding peripheral corneal shape, often ignored in previous studies on corneal surgery. Sanders, Gills and Martin (1993) emphasised advantages provided by the photokeratoscope. Cuaycong, Gay et al (1993) preferred keratoscopy to keratometry for data used in their intraocular lens calculations. They used the EyeSys Corneal Analysis system of computerised videokeratography. This was not available at the time of the study described in this thesis.

7.5. REGIONAL PACHOMETRY PROCEDURE

7.5.1 Description

A modified No. 1 Haag-Streit Depth Measuring Attachment, (pachometer) was used in conjunction with the 8900 model of Haag-Streit slit lamp, (model number M90018510) (Fig.7.3). This pachometer is a commercially available instrument based on the Juillerat and Koby principle developed by Jaeger (1952).

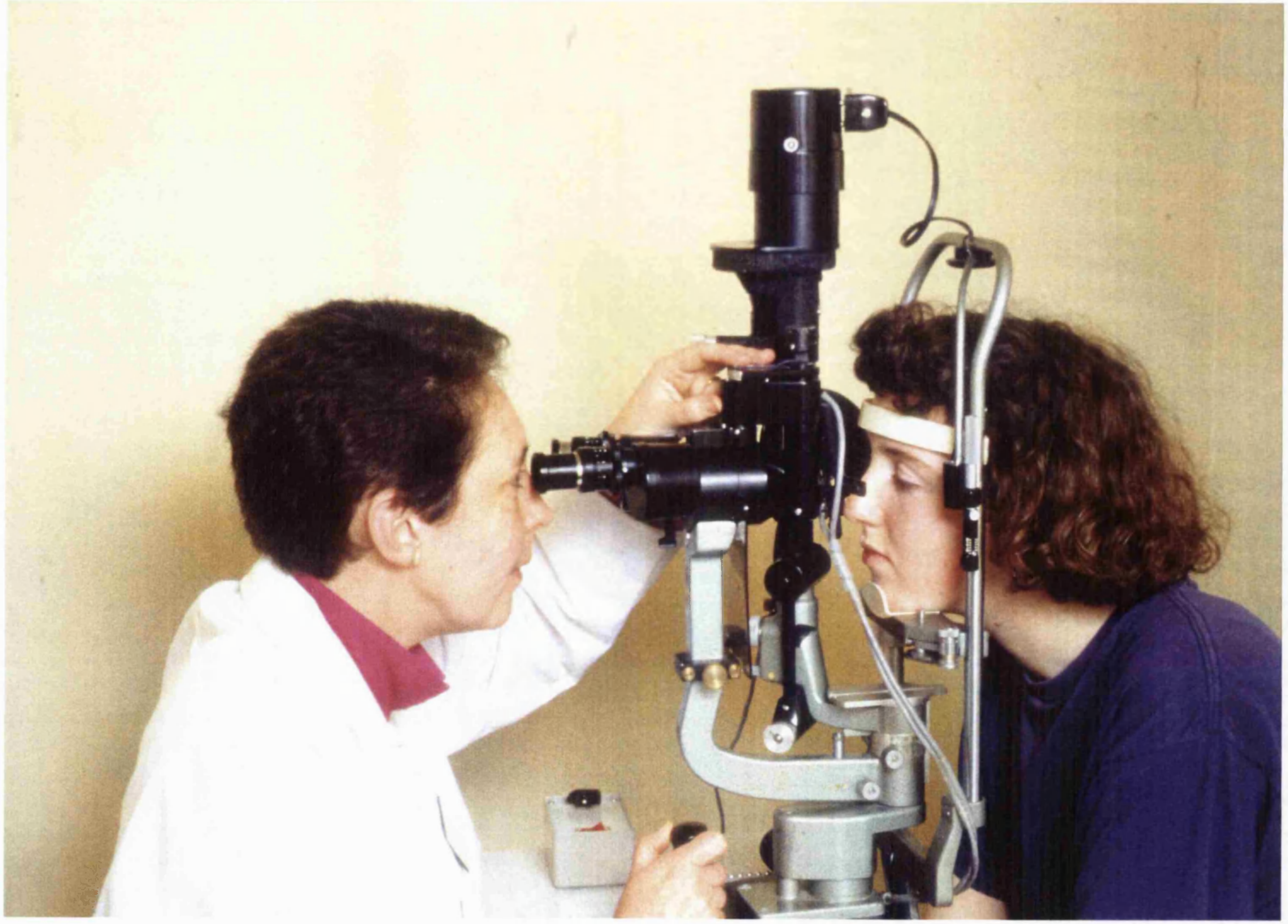


FIGURE 7.3 HAAG STREIT PACHOMETER AND SLITLAMP IN POSITION

The pachometer consists of an attachment incorporating two glass plates in front of the right hand microscope, the lower one is fixed but the upper is able to rotate about a vertical axis. The incident light enters a vertical aperture in a diaphragm extending from the attachment and securing an angle of 35° between the incident light beam and the axis of the right hand microscope. The right hand eyepiece is replaced by a special slit image eyepiece, dividing the visual field into upper and lower halves, which respectively allow passage of light through the upper and lower glass plates. Viewed through the microscope, the corneal optical section image appears displaced. When the displacement is such that the posterior edge of the upper section and the anterior edge of the lower section is aligned (Fig.7.4), then the angle of the plate rotation gives a measure of the corneal thickness and is read in millimetres directly from a calibrated scale connected to the rotatable glass plate.

In the Haag-Streit attachment this is already adjusted according to the assumed value for the corneal refractive index. Haag-Streit supply a correction for the variation in corneal curvature and non-linearity, but state that this correction is not significant except in cases of keratoconus, megalocornea etc.

In this study, the Haag-Streit pachometer was modified after the manner suggested by Donaldson (1966) and by Mandell and Polse (1969). A mounting was placed in front of the standard Haag-Streit instrument, which contained two green and four red

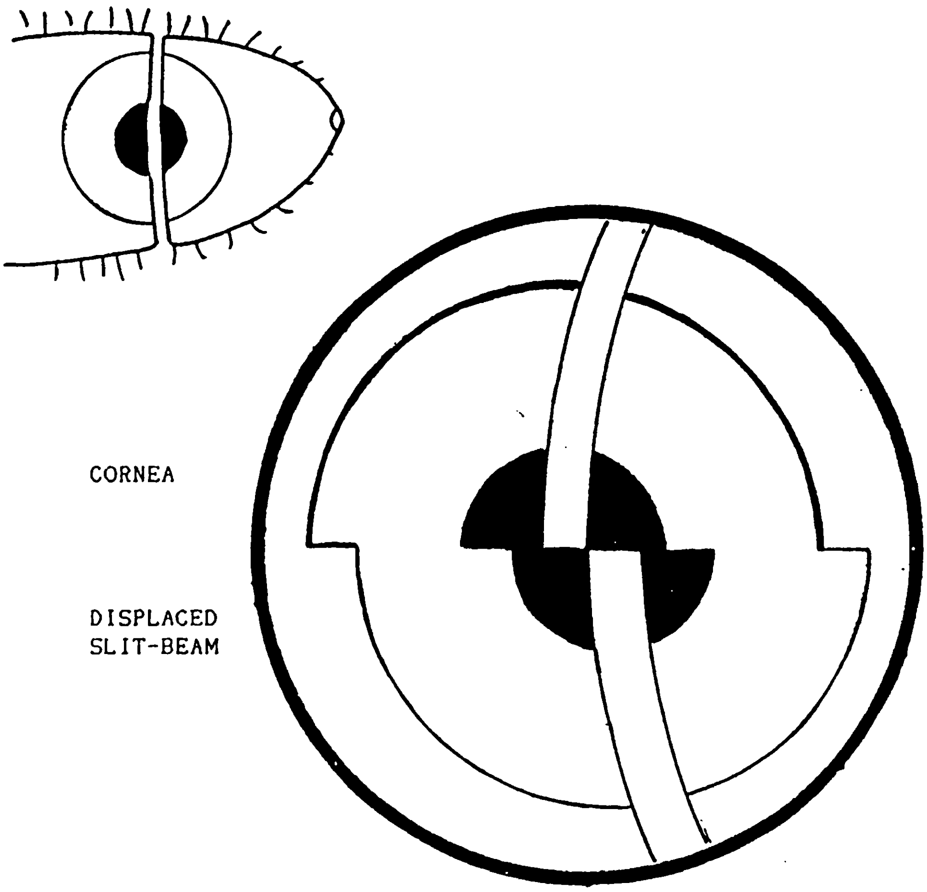


FIGURE 7.4 OBSERVER'S VIEW OF SPLIT IMAGE IN PACHOMETRY

light emitting diodes (LED) each controlled independently (Figs. 7.5 and 7.6). The two green LEDs were vertically displaced about 23.0 mm apart, equidistant from the axis of the right hand objective of the biomicroscope. The patients fixated half way between the two green lights, then the instrument was aligned such that the corneal reflected images of these 'Donaldson' lights as viewed through the microscope could be seen above and below the corneal section to be measured. This ensured that the microscope was perpendicular to the corneal surface at any measurement position. This is the reverse of the standard procedure where the patient fixates into the incident light beam through the vertical aperture diaphragm. The red 5.0 mm LEDs were arranged in a vertical cross formation, at 39.0 mm distance from the midpoint between the green LEDs. They had identical light intensity and were used as fixation targets for peripheral pachometry.

Mandell and Polse (1969) used a similar arrangement and plotted graphs of corneal thickness against the distance of the peripheral measurement position from the thinnest corneal point. These were acceptable for peripheral targets with reflections measuring 7.0 to 8.0 mm apart on the cornea, but were anomalous for targets requiring ocular excursions of 28°, due to invalid assumptions regarding the centre of rotation of the eye. Hence, off-centre measurements are not at exactly the same distance from the visual axis for different patients, but the instrument

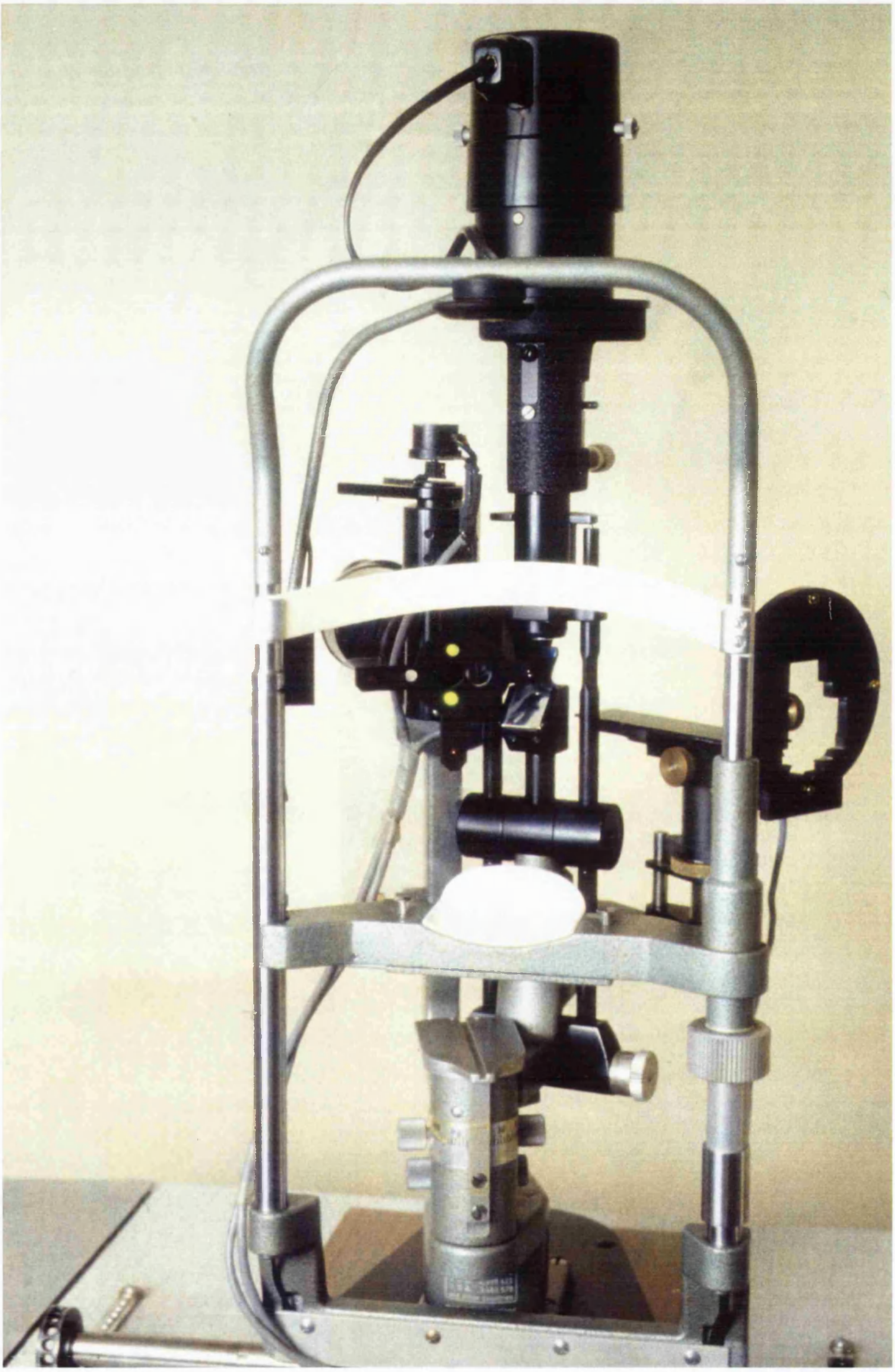


FIGURE 7.5 PATIENT'S VIEW OF L.E.D. TARGETS

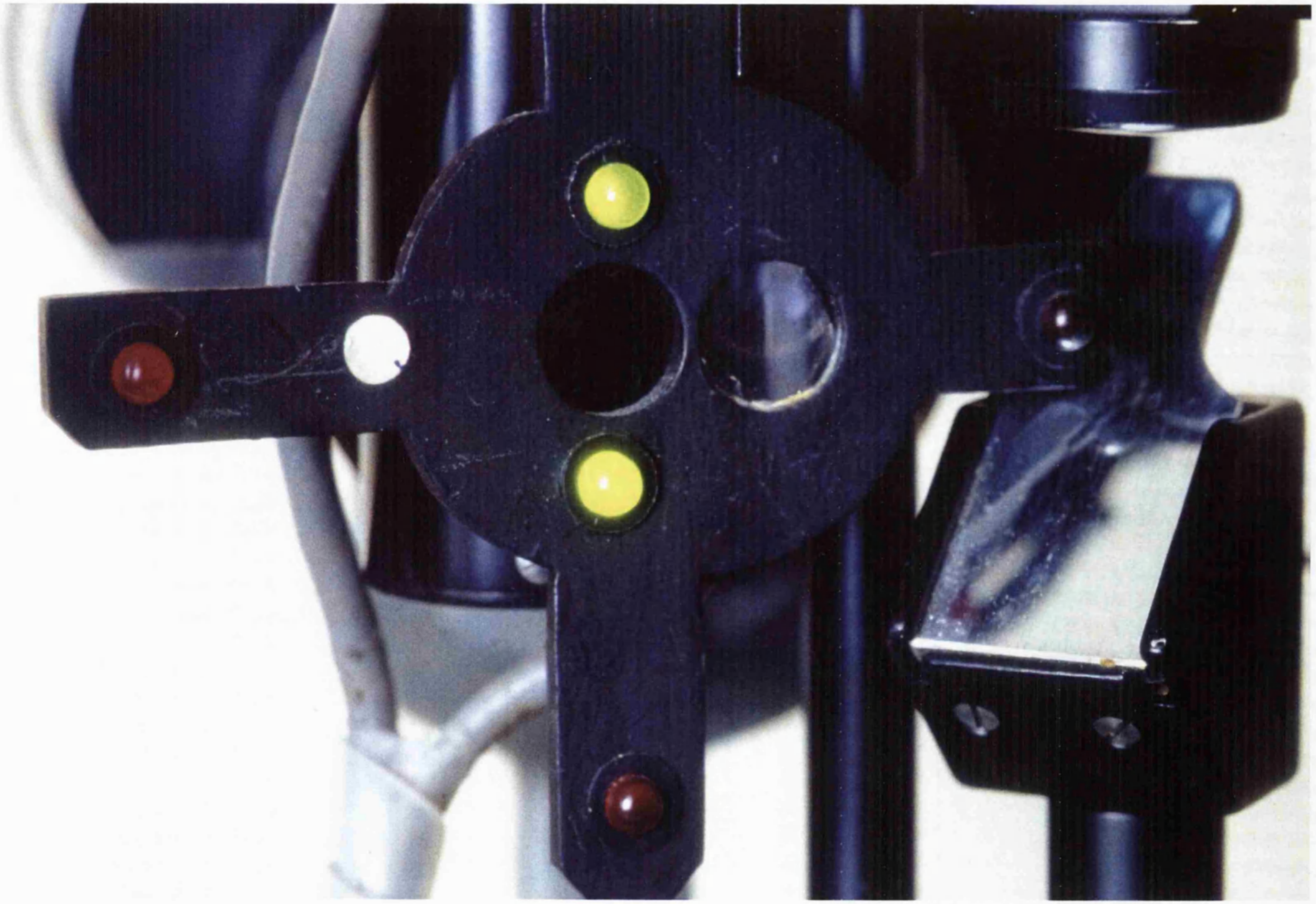


FIGURE 7.6 CLOSE UP VIEW OF L.E.D. TARGETS

measures corneal thickness at the same positions at each visit on a given patient.

The recording system was modified by coupling the measurement shaft of the basic instrument to a digital readout meter in an electronic recording system by a potentiometer (Fig.7.7). Since the modified version had the viewing system perpendicular to the corneal surface instead of to the illumination system and because of the position of the LED support plate, a 35° separation was used between the viewing and illumination axes, recalibration of the instrument was necessary. As the rotating plates were not modified, the right hand 10 times magnification eye piece was set at +2.00 D as with the standard instrument. The standardised slit width was 0.70 mm, being the narrowest setting which still gave a bright enough image to judge the alignment of the measurement points.

7.5.2 Calibration

The calibration method was the same as that used by Woodward (1980), and by Mandell and Polse (1969) in that measurements were taken of rigid contact lenses of known thickness and a correction made for the different refractive indices of the lens material (PMMA) and the cornea. Four afocal rigid contact lenses with radius of curvature 7.81 mm were supported vertically in a large plastic disc clamped to the headrest of the bimicroscope. The 7.81 mm radius was chosen since it was close to 7.80 mm, the mean

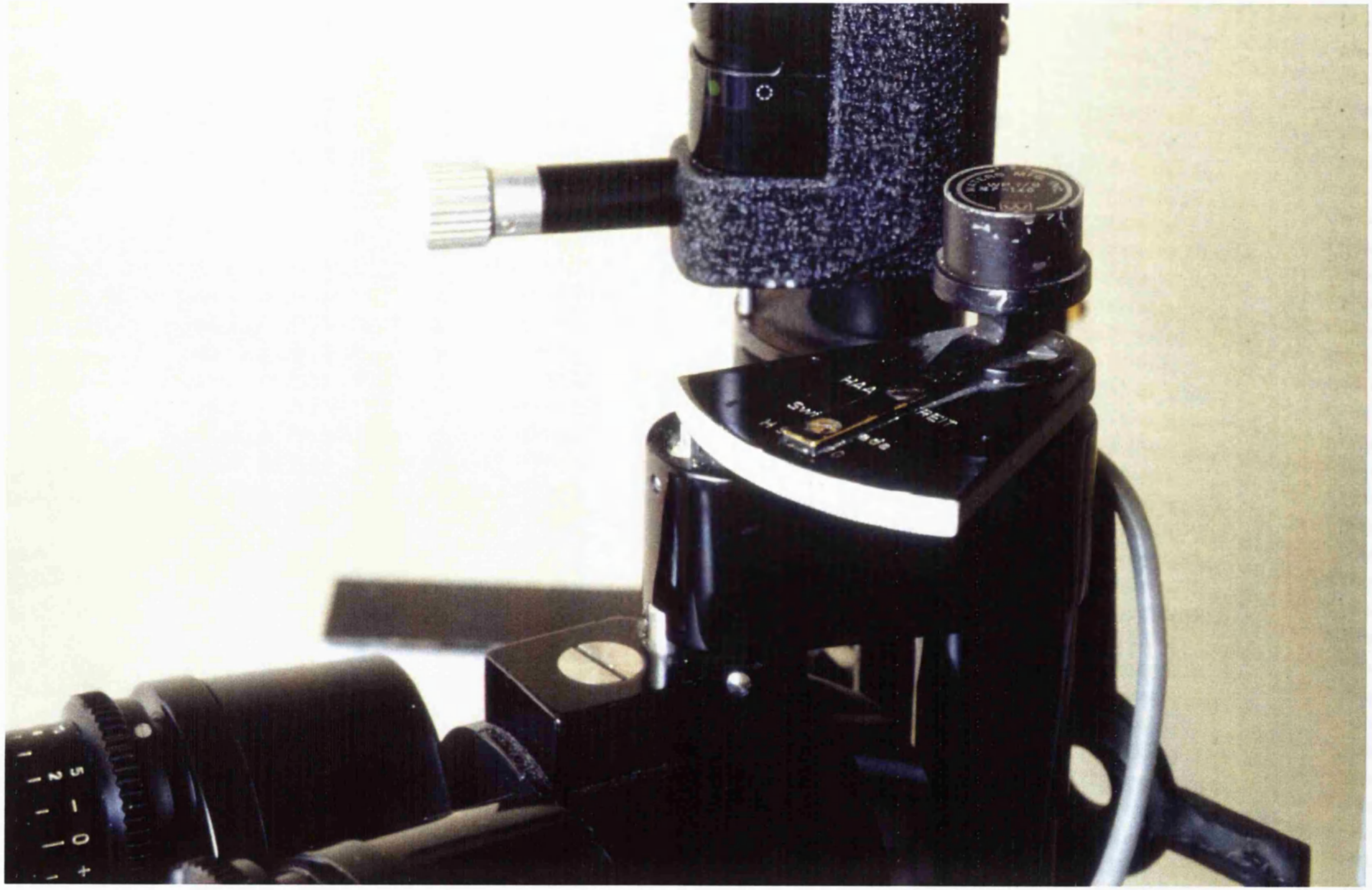


FIGURE 7.7 POTENTIOMETER ATTACHMENT ON PACHOMETER

value of a normal central cornea. The lens thicknesses had been checked mechanically with a micrometer.

Apparent thickness measurements were taken with the viewing systems perpendicular to each lens. Using the calculated calibration factor, a table was prepared converting the thickness values of the PMMA contact lenses to 'equivalent corneal thickness'. Using linear regression, a straight line graph was prepared from these data, so that direct conversion could be made from the pachometer digital readout to the true corneal thickness value.

7.5.3 Regional Pachometry

The fellow eye was occluded. Pachometry was carried out in a dimly lit room to improve image contrast. A modified Haag-Streit system with digital readout was used and the mean determined of five readings taken at each corneal position, ie. superior, central, inferior, nasal, temporal. The peripheral targets were 39.0 mm from the centre of the target system so the peripheral corneal positions were approximately 3.5 mm from corneal centre.

To ensure that the observation axis was perpendicular to the cornea, the split of the viewed optical secion was at each time positioned half way between the reflection of the 'Donaldson' green lights, as previously described. The patient fixated halfway between the green LEDs for the central measurement, then at each of the peripheral red LEDs in turn. With the use of the potentiometer attachment on the pachometer and of a digital voltmeter, pachometer readings accurate to 0.01 mm could be determined using the calibration graph. The LEDs were easily visible, even for patients with poor uncorrected visual acuity.

Pachometry is an important method of monitoring postoperative corneal oedema. Its use preoperatively may help to identify those patients at risk of delayed recovery from corneal oedema and who may be susceptible to the development of chronic peripheral bullous corneal oedema at a later date (Tuft et al 1992).

CHAPTER 8 PART I

CORNEAL TOPOGRAPHY RESULTS

8.1 CALIBRATION RESULTS

8.1.1 Calibration of keratometer

Originally calibrated using three steel spheres of various radii of curvature, the calibration was checked after each service. The mean of twenty readings was obtained and compared to the physical radii values found using a mechanical gauge, as shown in Table 8.1. The tables are given in the appendix. These indicate that the instrument read slightly flatter by 0.04 mm. The readings were repeatable to +/- 0.01 mm. The 20 measurements on a single human cornea gave a mean radius of curvature of 7.76 mm, SD = +/- 0.02 horizontally and 7.67 mm, SD = +/- 0.02 vertically, indicating that the repeatability of the readings on a human eye was +/- 0.02 mm.

8.1.2 Calibration of PEK

The physical measurement of shape factor was zero as the test curve was spherical. The test curves for the PEK were on the three calibration spheres, of radii 7.00, 7.50 and 8.00 mm. The readings are given in Table 8.2a and indicate that the instrument reads slightly flatter by 0.01 mm on radius of curvature. When the readings on the calibration steel spheres were compared to their physical measurements, this revealed an accuracy of +/- 0.02 mm in the central radius of curvature and +/-0.02 in shape factor value. To test repeatability, the standard black calibration spherical curve model provided with the instrument was measured, and measurements were also performed on demonstration subjects. These are given in Table 8.2b. The results showed that the PEK tended to read slightly flatter, by 0.01 mm in radius of curvature, by 0.03 in horizontal shape factor and by 0.02 in vertical shape factor. The repeatability on the black calibration eye was +/-0.02 in radii and shape factor. On human eyes this was found to be for a right eye +/- 0.02 mm in the radius measurement and +/- 0.06 in the shape factor, and for a left eye +/- 0.04 mm in the radius and +/- 0.06 in shape factor. The readings were more variable on human eyes because of variation introduced by the instability of the subjects fixation. At the time when this study was carried out the PEK was the best available instrument for measuring central and peripheral corneal shape.

8.2 DESCRIPTION OF PATIENT GROUPS AND DATA ANALYSIS

8.2.1 Patient groups

Of the 140 eligible patients, 105 completed the measurement period and their preoperative and postoperative corneal parameter measurements were analysed according to the surgical method group. All of the corneal group (C) of 54 patients had nylon sutures whilst all of the limbal group of 51 patients except 3 had silk sutures. The age distribution of the patient sample is shown in Table 8.3a.

The mean age of the 63 males was 59.5 years, SD = +/- 12.6, and that of the 42 females was 63.3 years, SD = +/-11.0. There was no significant difference between the corneal parameters or ages of the two gender groups so they were considered as a combined sample.

The measurements on this patient group continued from 1984 to 1989. As the study was on a part time basis and measurement times were restricted, patient recruitment was very lengthy and was spread over this time to fit in with clinic commitments and patient availability. Analysis of these patient group results was carried out at group number N = 50 and later at N = 105. At some of the time stages several patients were unable to attend due to problems with general health or commitment. The attendance numbers are given in Table 8.3a.

Of the 35 patients who failed to complete the study, 20 decided after their operation to withdraw from the patient sample because they no longer wished to attend as frequently as requested. They tended to be either younger patients, who could not leave their work often enough to keep the required appointments, or elderly ones who found difficulty travelling to the hospital. The remaining 15 patients, as shown in table 8.3b gradually failed for the following reasons: 1 had a red eye and chalazion, 2 had clinically significant early corneal oedema, 2 had poor vision due to a thickened lens capsule, 1 suffered binocular control problems and 9 had a poor attendance record. All 15 patients had IOL implantation, 10 had corneal incision, 5 had limbal incision, 10 were male, 5 were female. Their mean age was 61.0

years, SD = +/- 11.4; this was not significantly different from that of the study group.

The Control group of thirteen patients whose unoperated eyes were also measured had a mean age of 59.2 years, SD = +/- 14.2. Originally this group was considered as two groups, the first of 7 patients whose operated eye had a corneal incision, the second of 6 patients whose operated eye had a limbal incision. On assessing the data by 't' tests and by regression no significant difference in the group means and standard deviations was found for any of the control eye parameters measured so these control patients were reconsidered as a single group of 13. The 'Non operated' control group of 10 staff members, 5 male, 5 female, were of mean age 53.0 years, SD = +/- 6.4, and had a good attendance record for all six fortnightly assessment visits.

8.2.2 Data Analysis

The following statistical techniques were applied : student 't' test, linear regression, linear correlation, multiple regression, and analysis of variance (ANOVA) (Walpole 1982). It was understood that if too many tests were done on the data, an apparent significance may be indicated at $p<0.05$ level which was not strictly due to the relationship of the variables but due to random probability.

The student 't' test was used to test the distribution of the sample and to give an estimate of the variance of the data about the mean value, dependent on sample size. The larger the sample size, the closer the distribution approached that of a standard normal population. The test was useful for comparison of the (C) and (L) groups preoperative mean values to show whether they were from similar populations.

Linear regression was carried out to determine whether the results demonstrated a simple linear relationship between the dependent variable (eg.astigmatism) and the known values of one or more independent variables (eg.time). The results were tested to show how close were the measured parameter points on the graph to the linear regression line. This indicated how good was the regression line in predicting future results.

Linear correlation was sometimes used to test the strength of relationships between variables, according to their correlation coefficient. A high positive correlation signified that the data points on the graph comparing two variables tended to follow the pattern of a straight line of positive slope. The greater the correlation value, the closer do the data points approach the linear regression line.

Multiple regression was used when estimating the value of one dependent variable, on the basis of a set of measurements taken on several independent variables. The prediction equation would be obtained by using a least squares procedure on the data collected from the parameter measurements, and attempts made to determine the coefficients in the descriptive polynomial equation. This assisted in the estimation of the components of the regression equation and helped in the evaluation of the effect of a variable on the outcome whilst taking into account the effect of other variables and their interaction.

ANOVA was used to test for the equality of several means simultaneously, by measuring different sources of variation, eg. time and operation type. Two main criteria apply: that the variance at each data point should be homogeneous and be of a relatively normal distribution. The 'F' value provided information on the comparison of the two components, to give an independent estimate of the experimental error, by considering the larger number of data sets. Multiway ANOVA gave information on the type of changes within a sample group related to time. By this comparison, an estimate of the experimental error could be ascertained and taken into account in the search for a relationship.

The criterion for the stabilisation time of the parameters measured was that this was the stage after which the mean result and its SEM showed no significant deviation from that of the preceding stage. This was usually indicated by the slope beginning to 'plateau' on the graph of corneal parameter changes from original value, related to time. The codes used in the graphs in the Figures included the following: Plus astigmatism values = WTR, minus astigmatism values = ATR. Time at -2.0 weeks = preoperatively 1 to 7 days, vertical dotted line = day of surgery. Postop = 1 to 2 days after the surgery. Error bars = standard error of the mean SEM. This was felt to be more appropriate than standard deviation SD, which would typically be large and misleading. SEM indicated the most likely range within which the true mean would lie if a very large population had been studied. When analysing the data of changes from original value (except for shape factor where large changes were already apparent) these were multiplied by 1000 to facilitate the analyses and the graphs presentation.

Statistical analyses of the refraction and corneal topography results are shown in tables 8.4 to 8.9.

8.3 OCULAR ASTIGMATISM SHOWN BY REFRACTION

For the Control group, on studying the raw data and analysing by ANOVA, as shown in appendix table 8.4, each patient showed little significant change at p=0.05 level. Most of the control patients were aged over 55 years and 27% had ATR astigmatism, common in that age range. The Control group changes graph in Fig. 8.1.a shows only a slight variation over the study period.

For the Non operated group, there was no significant difference in the original astigmatism value (at $p<0.05$ level) between the Non operated group and the operated groups. This indicated that they were from a similar population sample. A fairly steady mean value of 0.12 D WTR for the Non operated group was maintained over the 16 weeks of their study, and changes were minimal. This had been expected since these subjects had no treatment, but the results provided an indication of the natural variation in refraction to which that of the operated patients could be compared. ANOVA showed that the changes over time were not significantly different ($F = 0.37$, $df = 45,4$, $p>0.05$), as agreed by correlation.

The Fig. 8.1.a illustrates ocular astigmatism changes of the patient groups according to operation method. It is worthwhile studying the actual values of ocular astigmatism in addition to postoperative changes. Although the latter are important, the patient judges the success of his operation by the actual ocular astigmatism disturbing the vision. The surgeon is also concerned with the final actual ocular astigmatic state of the patient. There was no significant difference between the (C) and (L) groups preoperatively, so they were considered as being from the same population.

After the initial shift towards WTR astigmatism within the first postoperative day, changes occurred as the incision wound healed. Thus a significant time effect ($p<0.01$) was demonstrated. The (C) group stabilised at 12 to 16 weeks at a mean value of 1.00D WTR, The (L) group astigmatism underwent a rapid change in the first few weeks, stabilising at week 6 at a mean astigmatism value of 1.00D ATR. In order to compare astigmatism changes in the two operation groups (C) and (L), ANOVA was performed but showed no significant difference at the $p = 0.05$ level. However, there was found a marked difference in the variances at $p = 0.01$ level at stages Postop, 10, 16, and 24 weeks, with (C) having the greatest variance. No significant relationship at $p = 0.05$ level was found between preoperative and postoperative

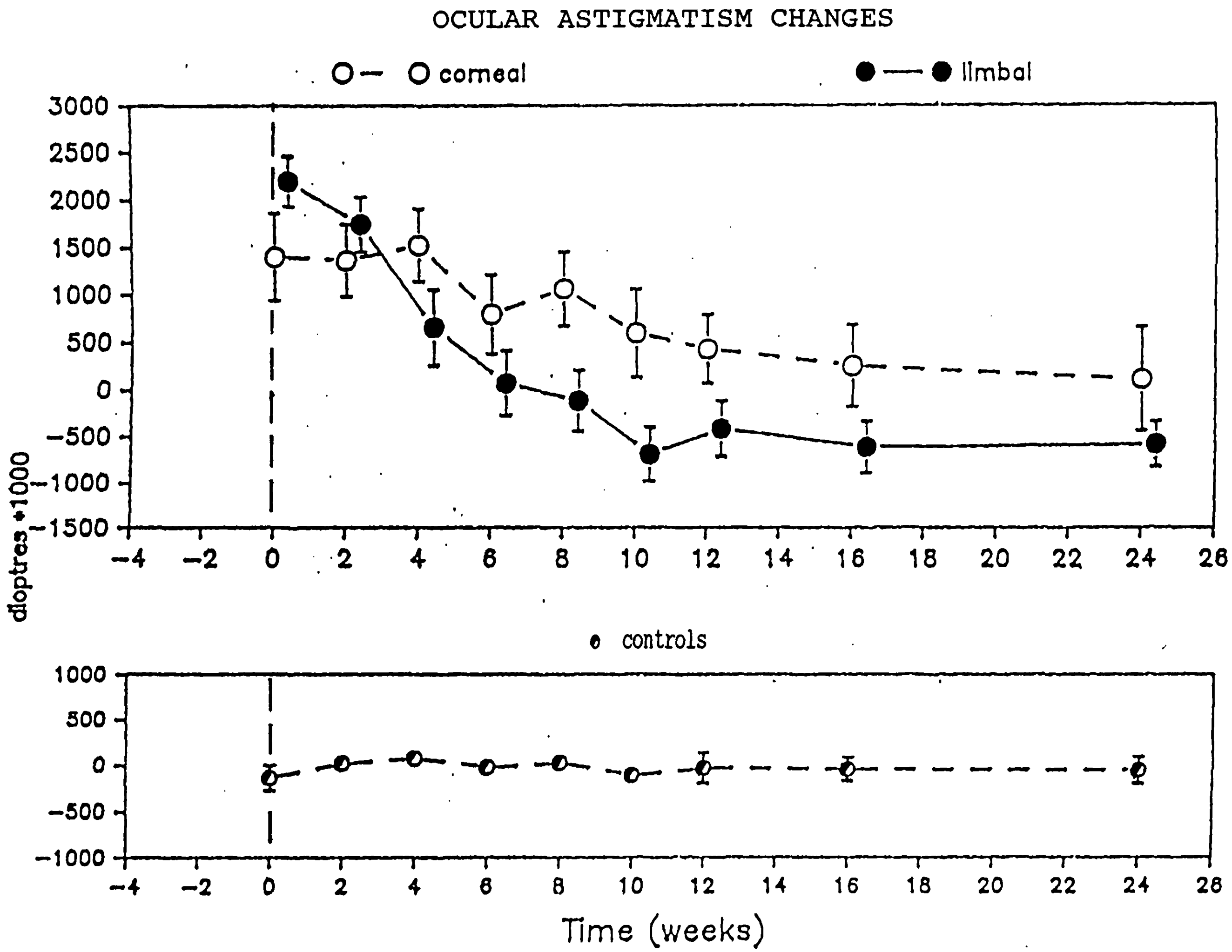


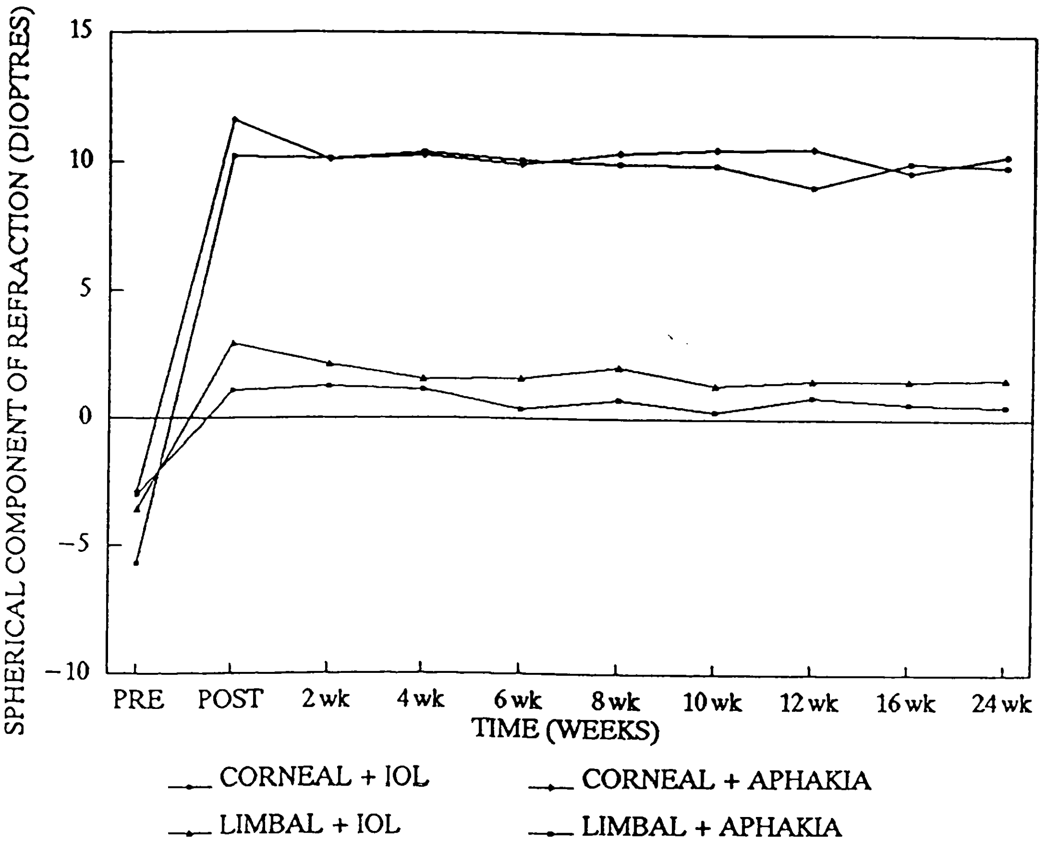
FIGURE 8.1.a. OCULAR ASTIGMATISM CHANGES RELATED TO TIME.

values using regression. This probably indicated that the effects of the sutures and incision on the postoperative astigmatism masked the influence of the preoperative corneal shape. However, no definite conclusion could be drawn regarding ocular astigmatism because the opaque lens media inhibited accurate assessment of preoperative ocular astigmatism.

A short survey was performed on the spherical component of the refraction, i.e. that spherical power value when the ocular astigmatism was corrected by negative cylinder power. The results are shown in Fig. 8.1.b. During the first few postoperative weeks, the result indicated a hypermetropic shift but was rather variable because the eyes were recovering from the surgery and possibly still influenced by medication. By 2-4 weeks the spherical component tended to stabilise with a variation of about 0.5D, which can easily occur with subjective refraction of elderly patients. This was true whether the corneal or limbal method was used, and whether or not an IOL was implanted. For the aphakes, the mean result at 2 weeks postoperatively was +10.0D, which was the power of the temporary spectacles supplied. For the IOL groups, the mean stabilised results were +0.50D (C) and +1.50D (L).

8.4 CORNEAL ASTIGMATISM SHOWN BY KERATOMETRY

The Control group mean changes did not show a significant time effect. There was no significant difference between the Control and Non operated and operated groups values preoperatively. ANOVA showed no significant time effect for changes ($F=0.65$, $df=74,8$, $p>0.05$). As expected, the Non operated group changes over the



	PRE	POST	2 wk	4 wk	6 wk	8 wk	10 wk	12 wk	16 wk	24 wk
CA+	1.85	16.32	14.76	16.37	15.05	15.80	15.45	15.40	14.89	15.26
CA	-2.86	11.60	10.08	10.25	9.93	10.39	10.56	10.58	9.68	10.32
CA-	-7.57	6.88	5.39	4.13	4.81	4.99	5.68	5.75	4.47	5.38
LA+	0.76	14.62	14.95	15.15	14.50	14.36	13.85	13.79	14.47	14.95
LA	-5.71	10.21	10.13	10.36	10.08	9.97	9.93	9.12	10.04	9.93
LA-	-12.18	5.81	5.31	5.57	5.66	5.57	6.00	4.44	5.62	4.91
LI+	0.08	4.84	4.03	2.44	3.17	3.10	2.96	2.71	2.65	2.84
LI	-3.58	2.92	2.08	1.50	1.54	2.00	1.33	1.50	1.53	1.60
LI-	-7.25	1.01	0.14	0.56	-0.09	0.90	-0.31	0.29	0.40	0.35
CI+	0.13	3.45	3.56	3.38	2.71	2.87	2.56	2.59	2.65	2.67
CI	-2.98	1.13	1.24	1.15	0.41	0.83	0.30	0.92	0.66	0.60
CI-	-6.09	-1.19	-1.07	-1.08	-1.88	-1.22	-1.95	-0.76	-1.33	-1.47

CA = MEAN OF CORNEAL + APHAKIA.
CA+ = UPPER VALUE OF ERROR BAR.
CA- = LOWER VALUE OF ERROR BAR.
SIMILARLY
LA = LIMBAL LI = LIMBAL + IOL, AND CI = CORNEAL + IOL

FIGURE 8.1.b
SPHERICAL COMPONENT OF REFRACTION RELATED TO TIME

time period also showed no significant time effect at $p<0.05$ level, tested by ANOVA ($F=0.56, df=45,4$, $p>0.05$).

The patient groups changes related to time are shown in Fig. 8.2.1. There was no significant difference at the $p = 0.05$ level between the two groups (C) and (L) preoperatively, so it was valid to compare them as two samples from a similar population. Although both groups showed a large shift towards WTR astigmatism at the Postop stage, followed by a shift towards ATR, by the 6 weeks stage there was a significant difference ($p<0.05$) between the actual mean values of the two groups. (C) group astigmatism gradually reduced and stabilised by 16 weeks at 0.20 mm WTR and (L) group stabilised by 8 weeks at 0.15 mm ATR astigmatism. As shown in appendix table 8.5, on analysis of (C) group data, multiple regression showed that these changes had no significant relation to preoperative value, except at week 16 ($F=6.35$, $df=31,1$, $p=0.01$). This indicated that by considering preoperative corneal astigmatism alone one could not predict the postoperative corneal astigmatism at most of the time stages. This is probably because the preoperative corneal topography had less influence than did the sutures and incision characteristics. Using 't' tests on the (C) group, the changes showed a significant increase on preoperative values ($p=0.01$), towards WTR astigmatism.

On analysis of (L) group data by multiple regression, a significant relationship was indicated between the preoperative value and the changes at 8 and 12 weeks ($p<0.001$) and at 16

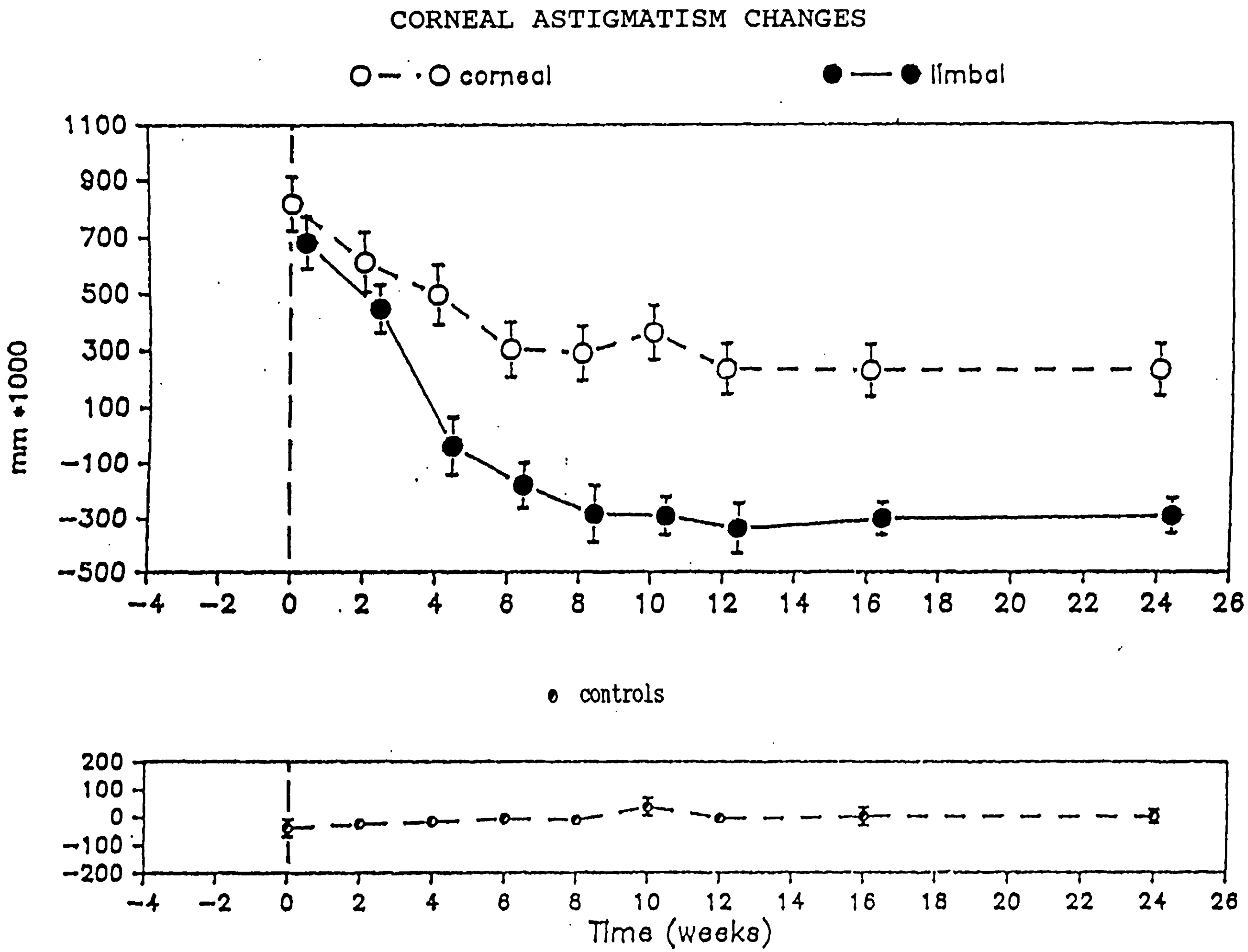
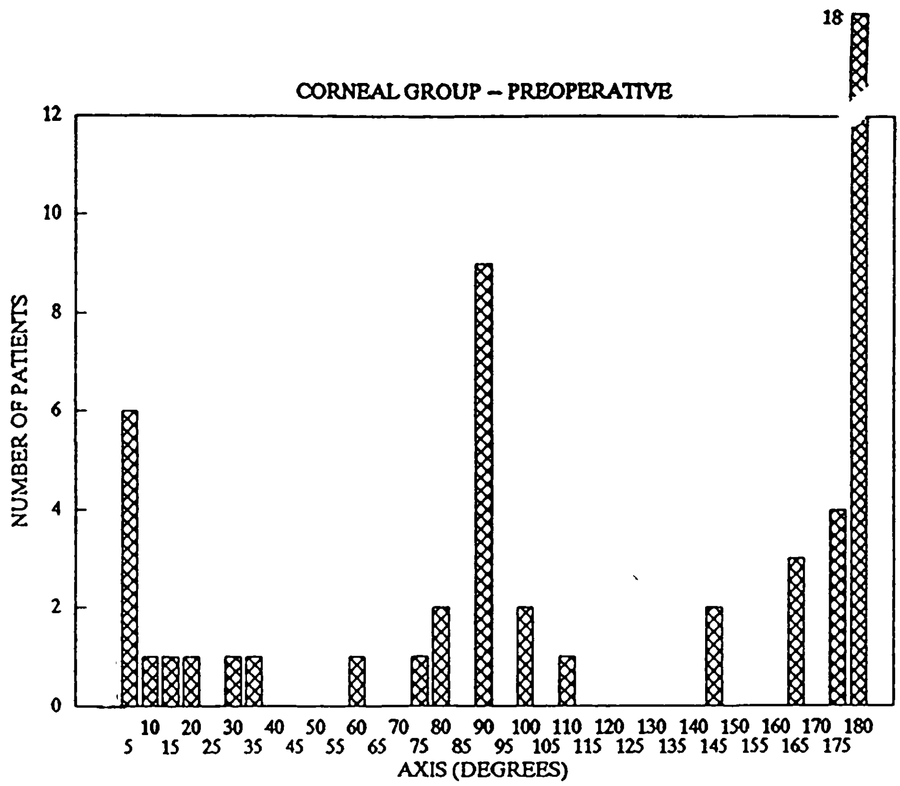


FIGURE 8.2.1. CORNEAL ASTIGMATISM CHANGES RELATED TO TIME.

weeks (p=0.04). When multiple regression was used to compare the postoperative changes between (C) and (L) groups, no significant difference was found at Postop and 2 week stages but a significant difference was found between the two groups at 4 weeks (F=0.26, df=41,29, p=0.001), which remained (at p<0.001) over the following weeks.

To check whether this result was influenced by data omission due to patient attendance failure, the data were re-analysed by multiple regression, considering only those 12 (C) and 6 (L) patients who attended every visit. No significant difference at the p = 0.05 level was found between groups (C) and (L). However no firm conclusion can be drawn from this because the patient numbers were small. When comparing postoperative changes of these two samples at the 8 week stage according to operation type, linear regression showed no significant relation at the p = 0.05 level, although both group mean actual values were significantly different from their preoperative mean values (p<0.01).

In order to investigate how the corneal astigmatism axes varied following the surgery the number of patients for each axis group at each of the ten measurement stages were noted. These are shown by the histograms in Figs. 8.2.2 a-j. Preoperatively, the distribution was very similar between groups (C) and (L), with the majority of patients having with-the-rule (WTR) astigmatism, ie. negative cylinder at axis 180 or near, and 8 to 9 patients having against-the-rule (ATR) astigmatism, ie. negative cylinder at axis 90 or near.



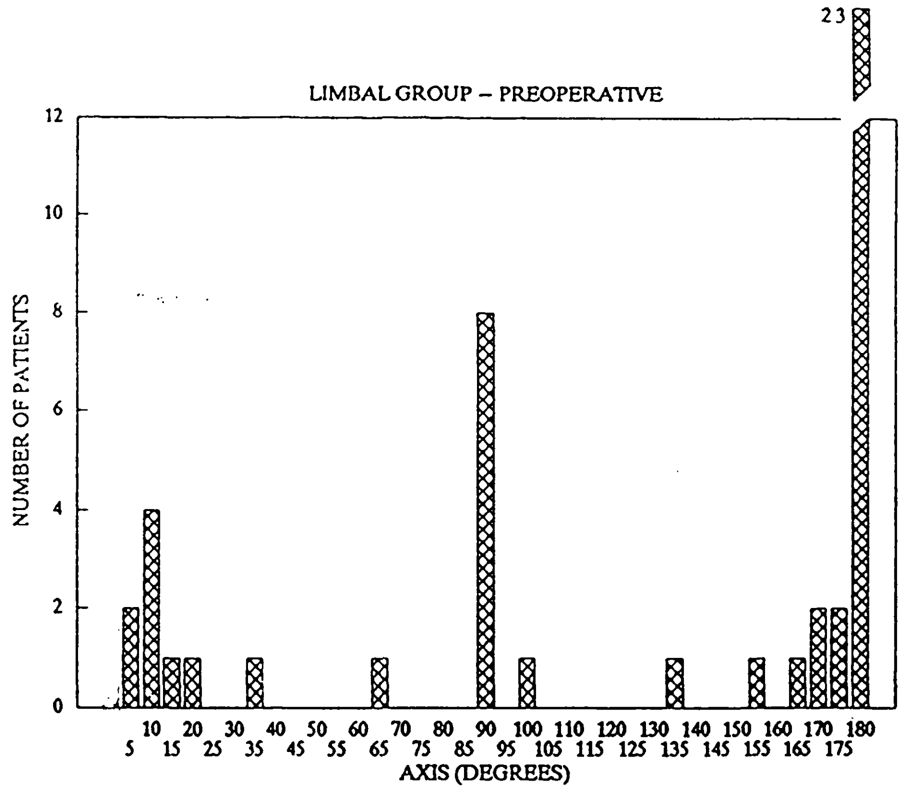
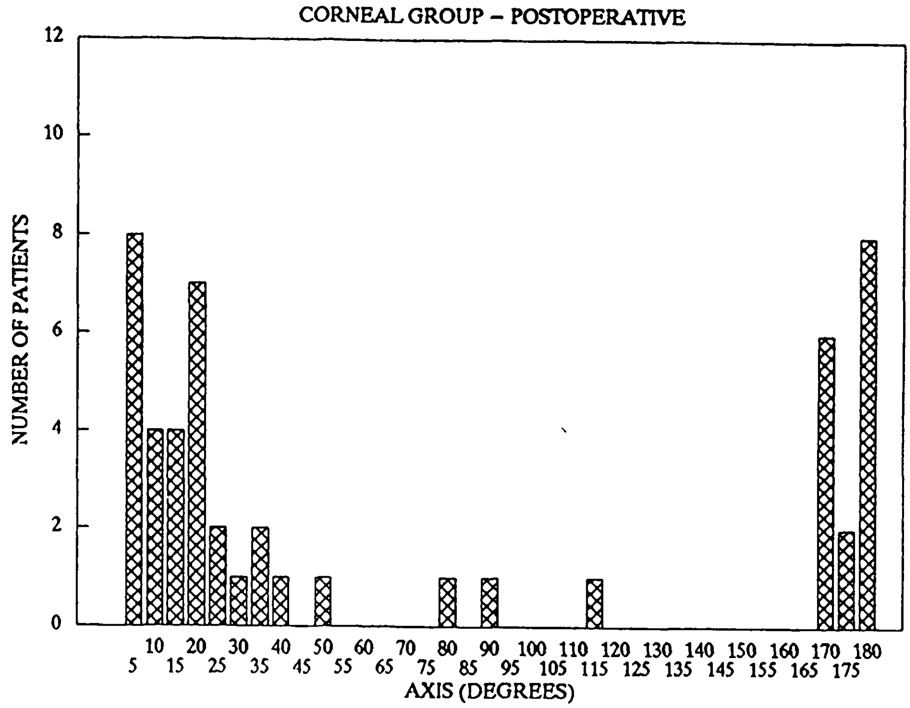


Figure 8.2.2.a.

Distribution of astigmatism axis - preoperative.



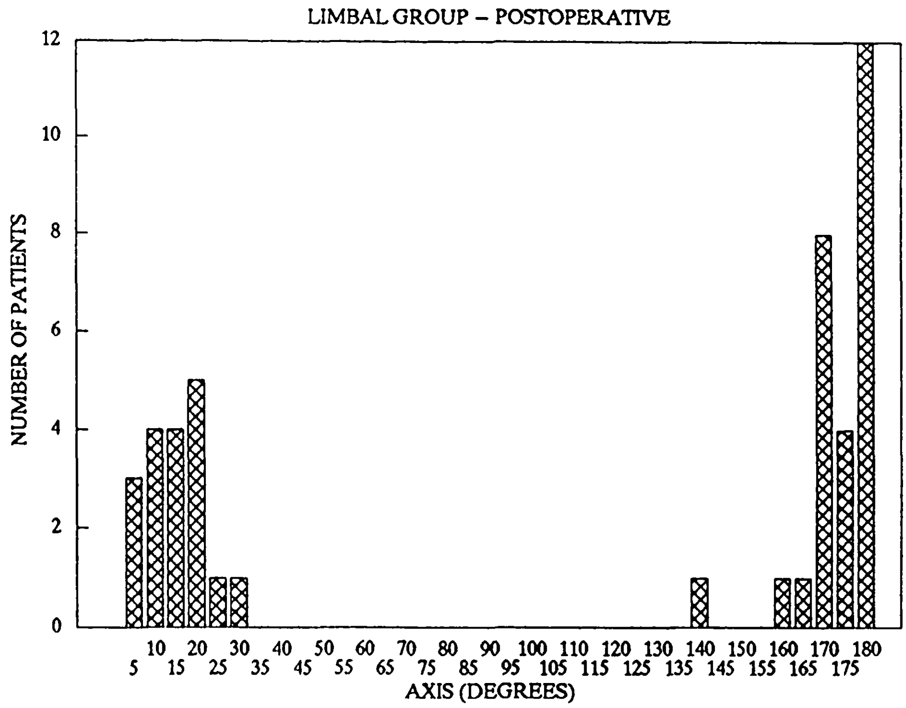
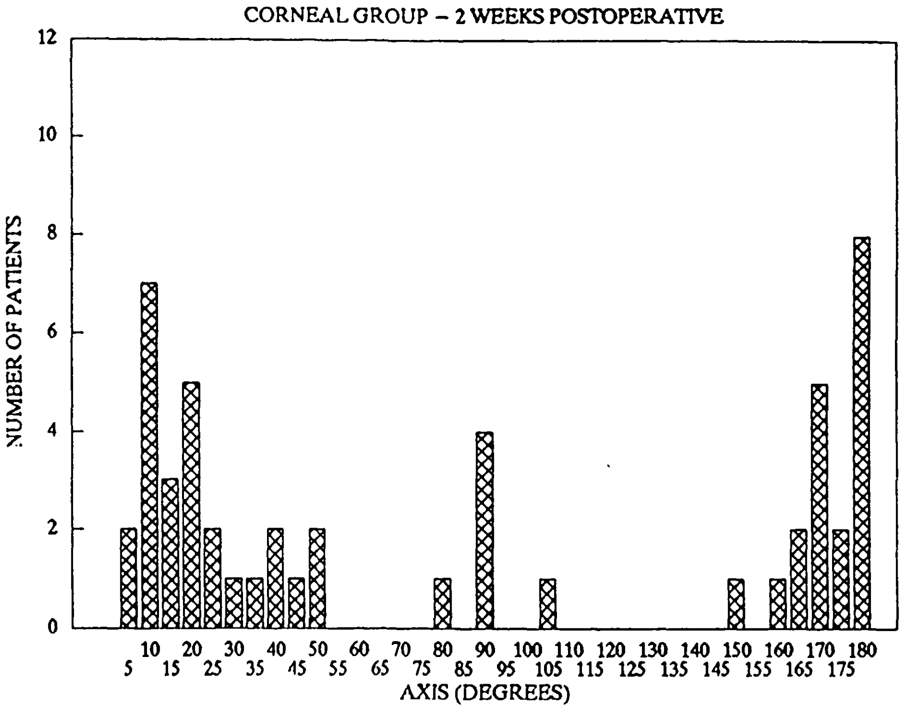


Figure 8.2.2.b.

Distribution of astigmatism axis - postoperative.



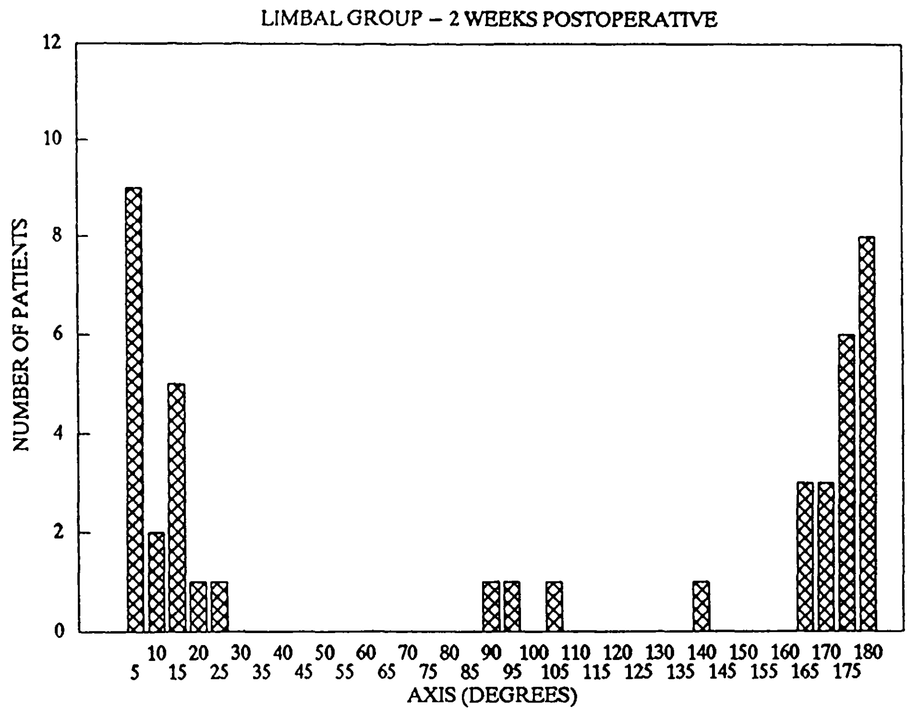
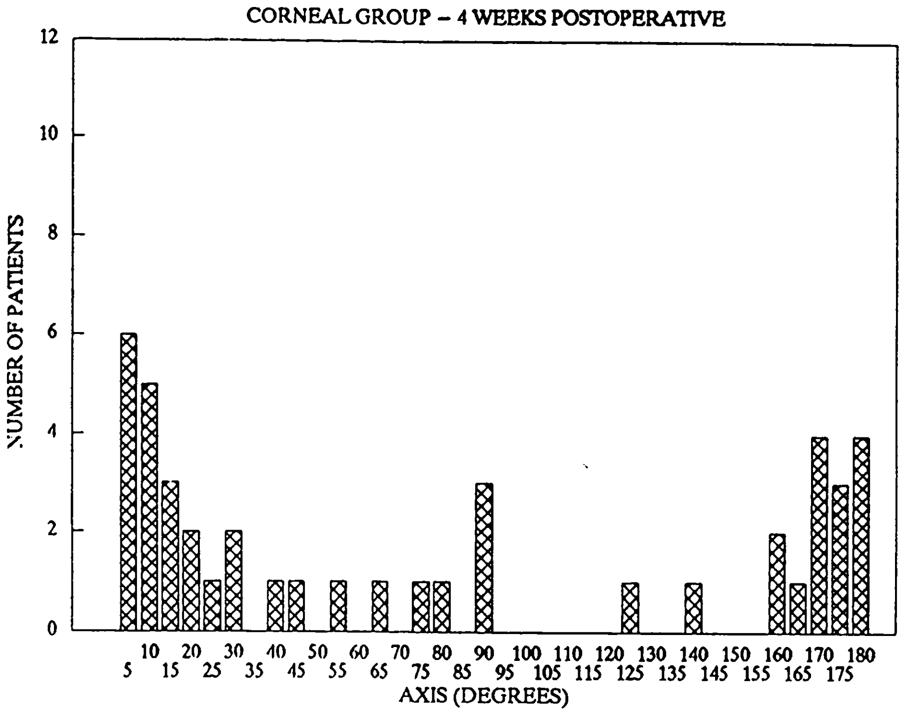


Figure 8.2.2.c.

Distribution of astigmatism axis - 2 weeks postoperative.



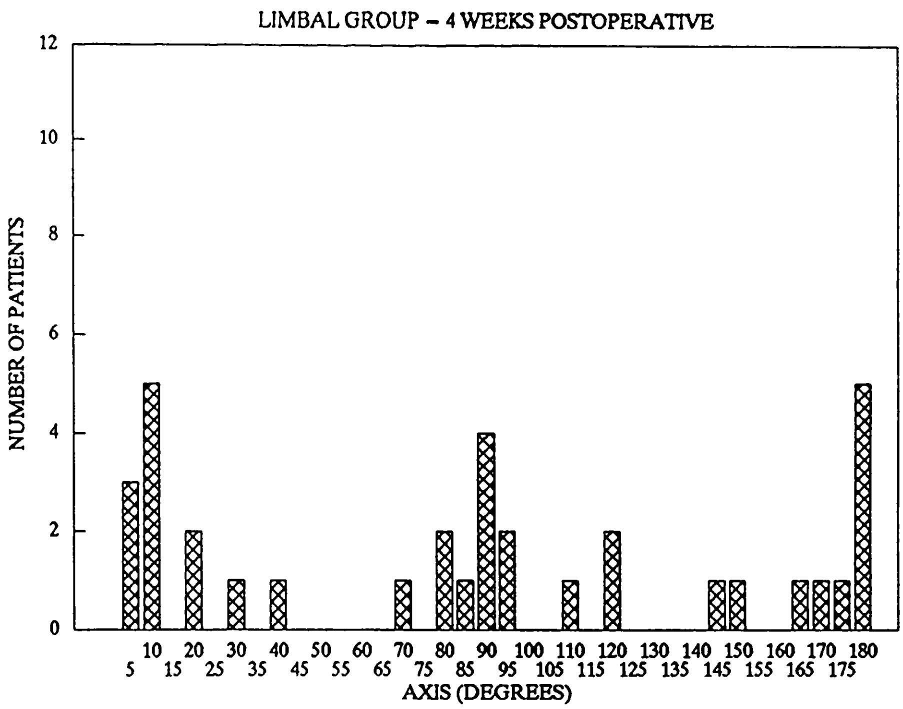
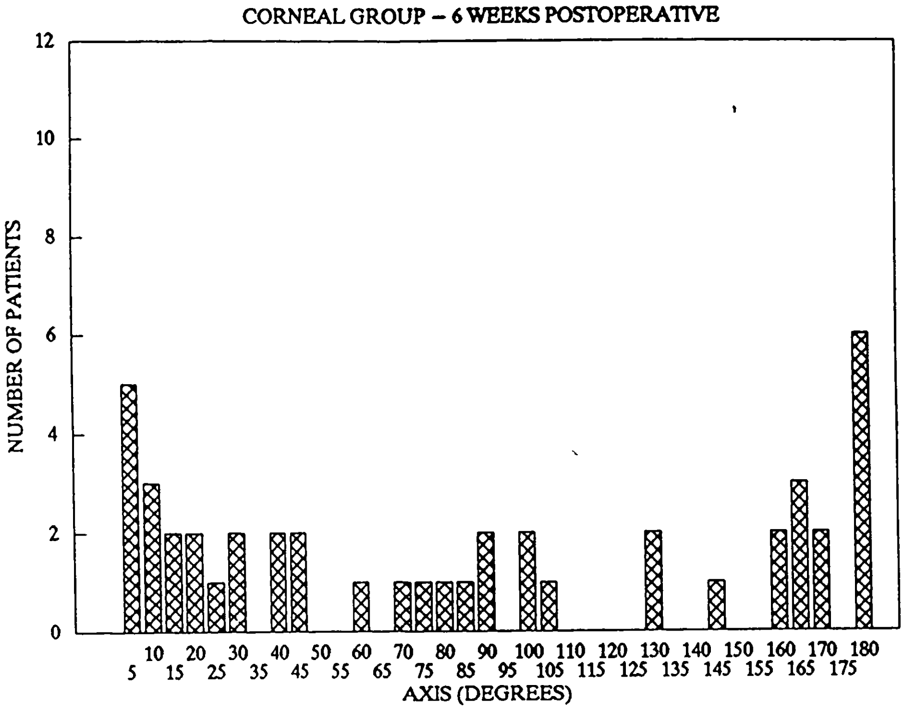


Figure 8.2.2.d.

Distribution of astigmatism axis - 4 weeks postoperative.



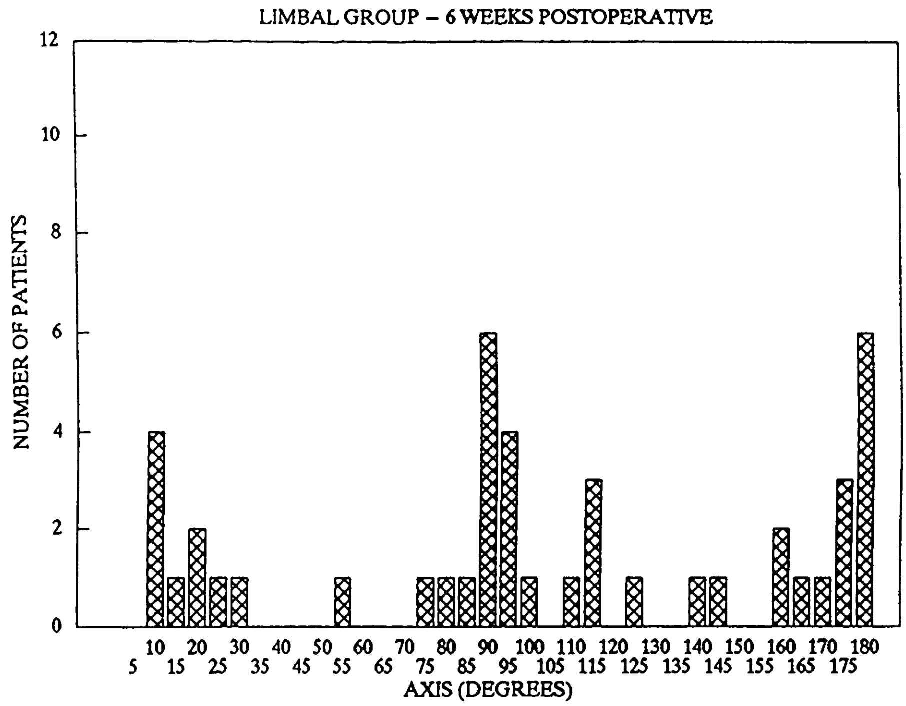
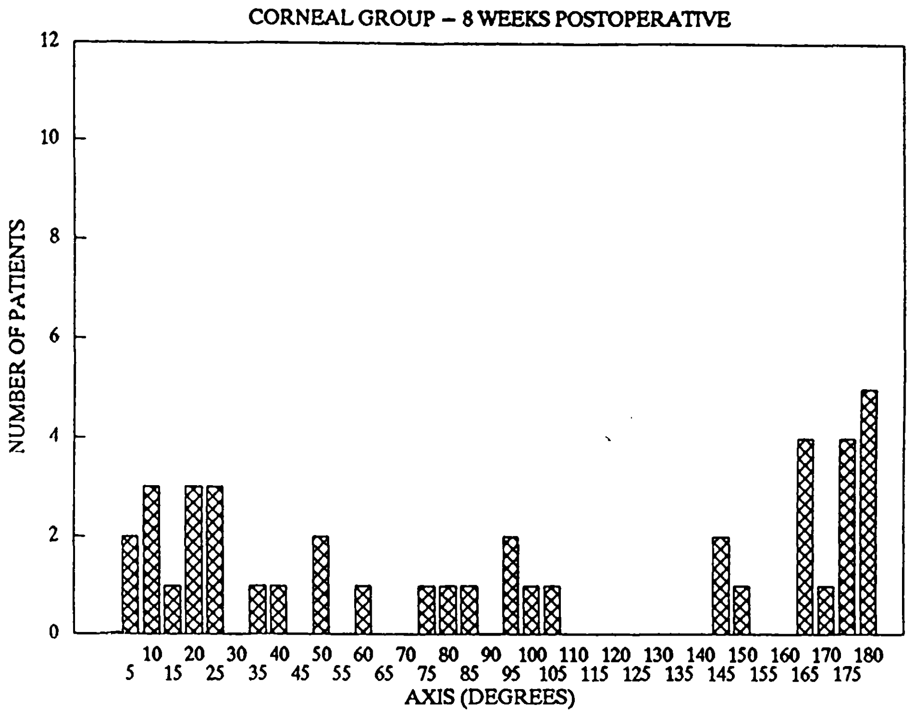


Figure 8.2.2.e.

Distribution of astigmatism axis - 6 weeks postoperative.



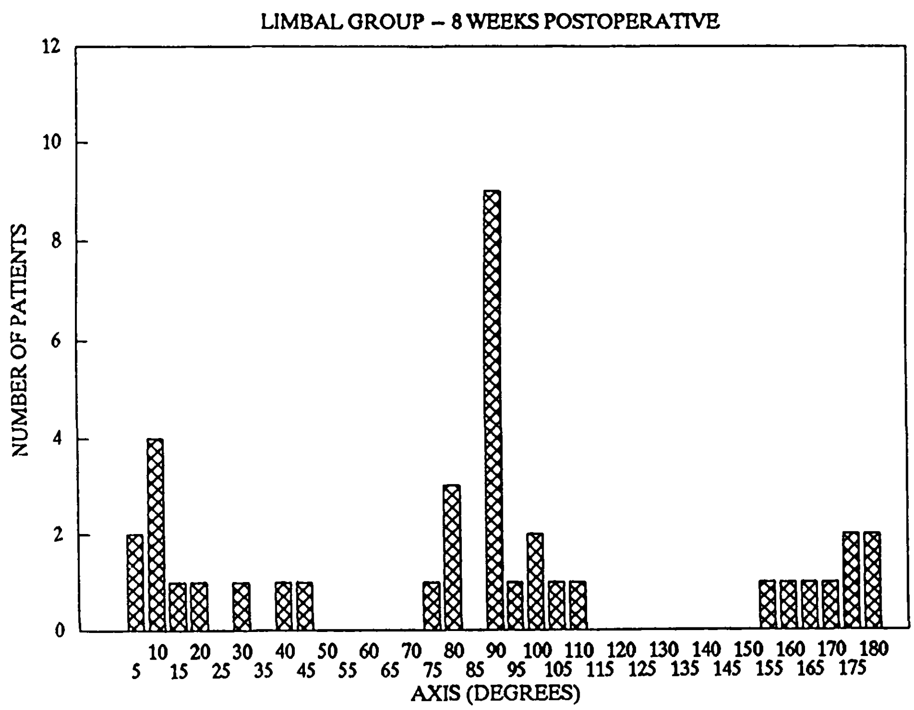
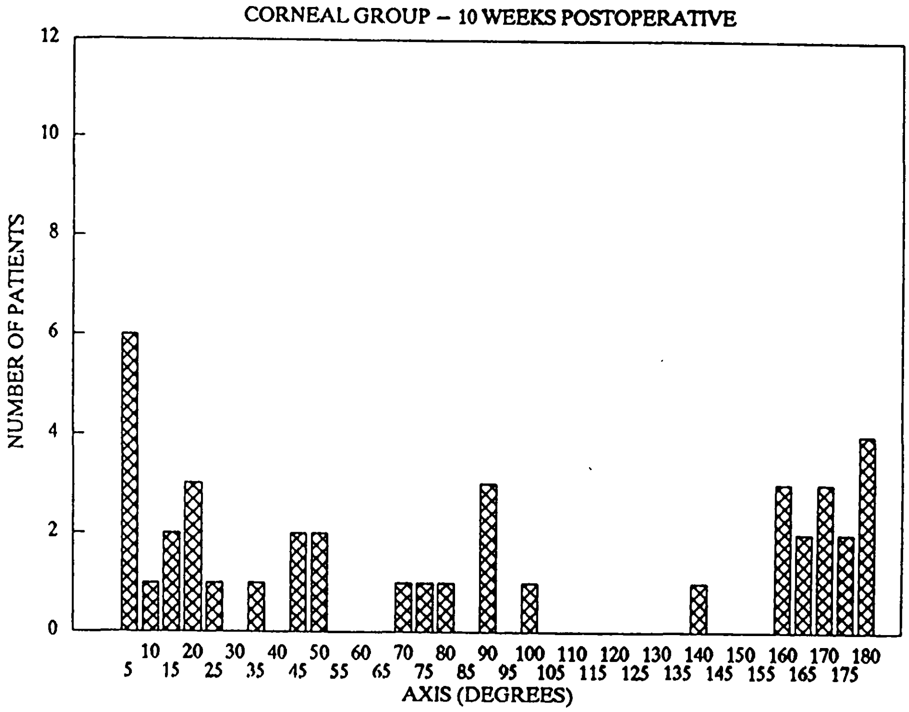


Figure 8.2.2.f.

Distribution of astigmatism axis - 8 weeks postoperative.



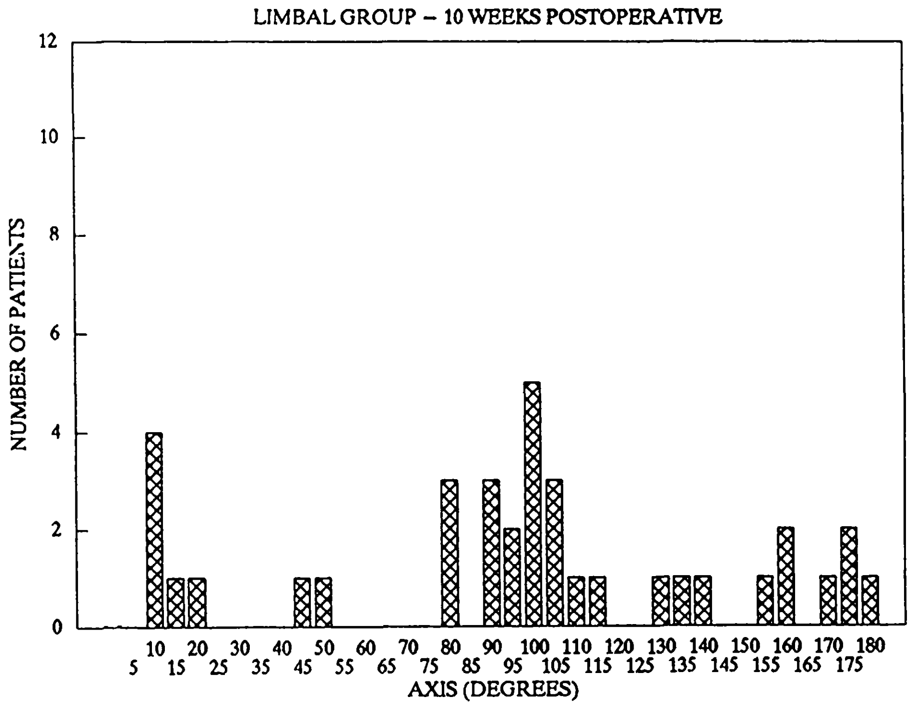
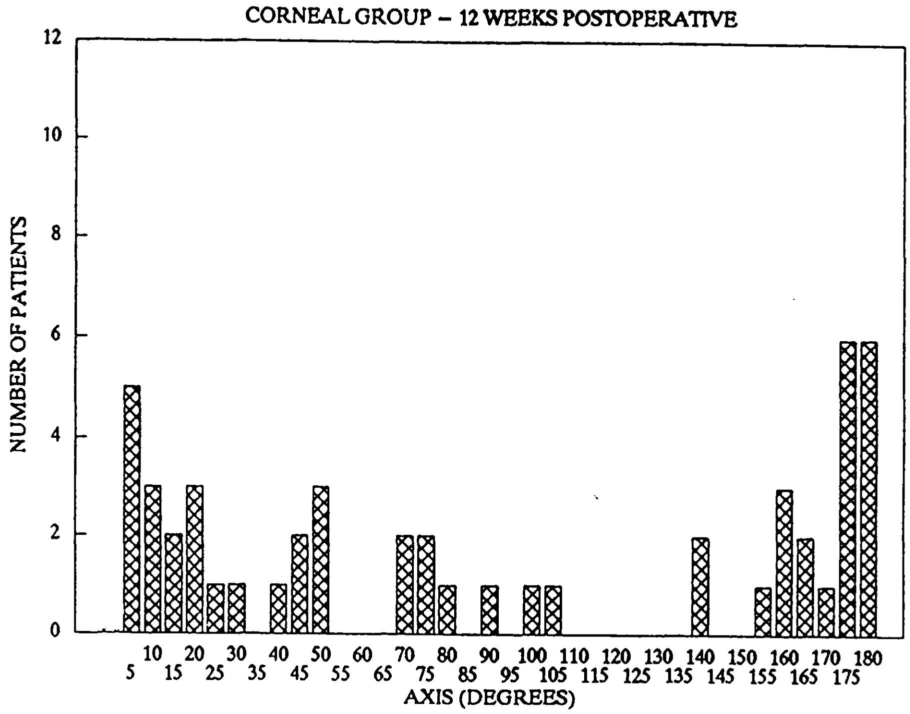


Figure 8.2.2.g.

Distribution of astigmatism axis - 10 weeks postoperative.



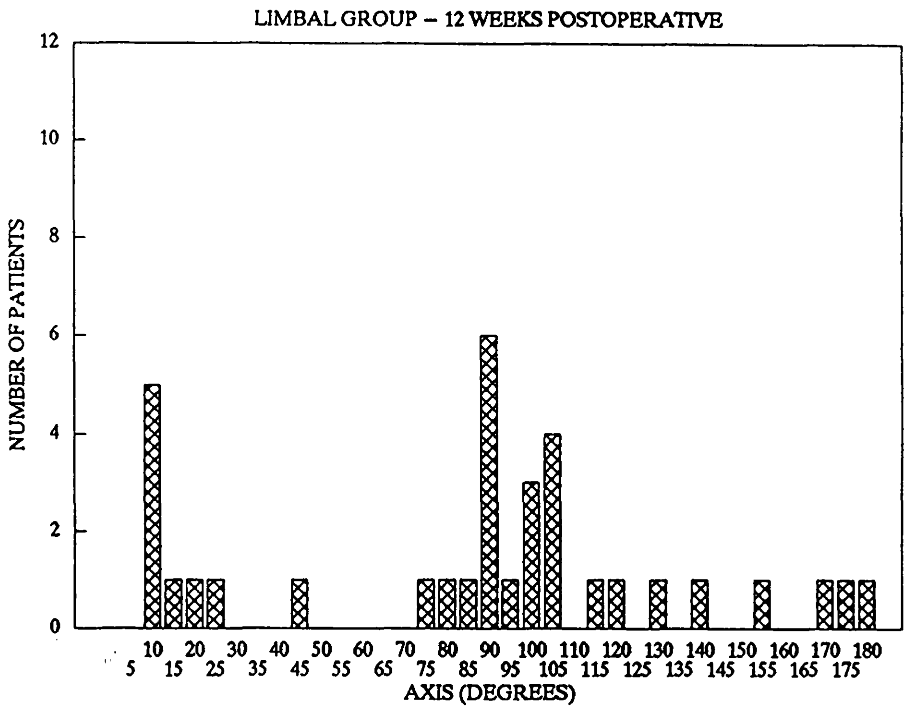
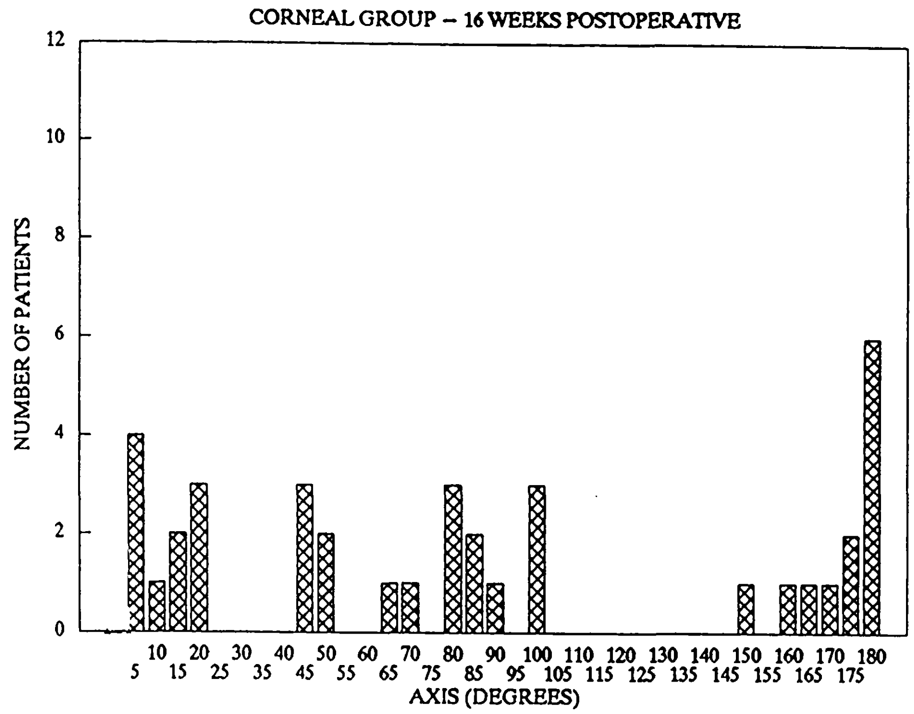


Figure 8.2.2.h.

Distribution of astigmatism axis - 12 weeks postoperative.



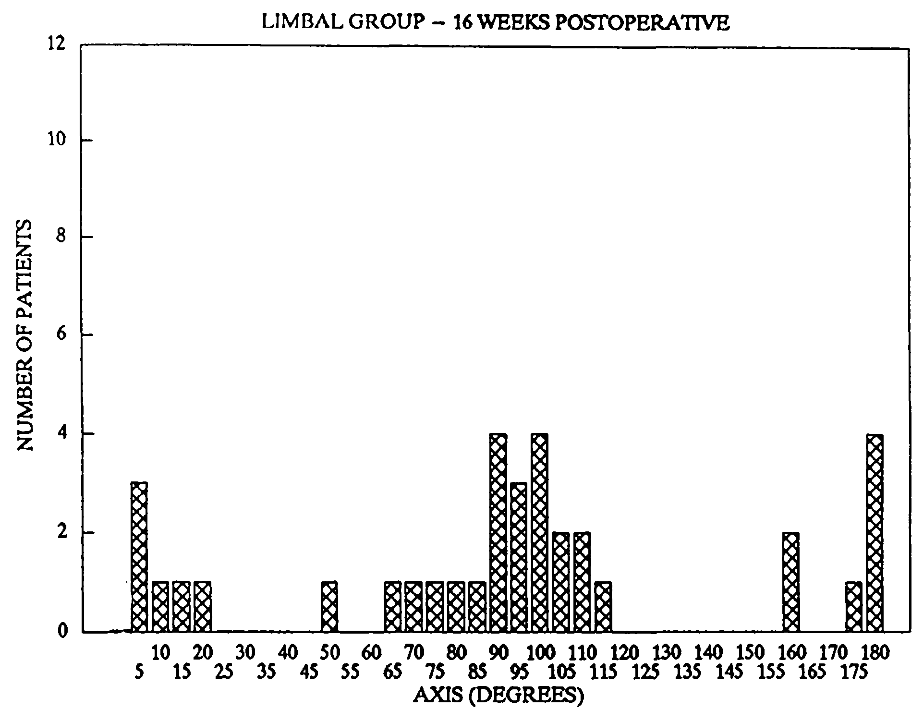
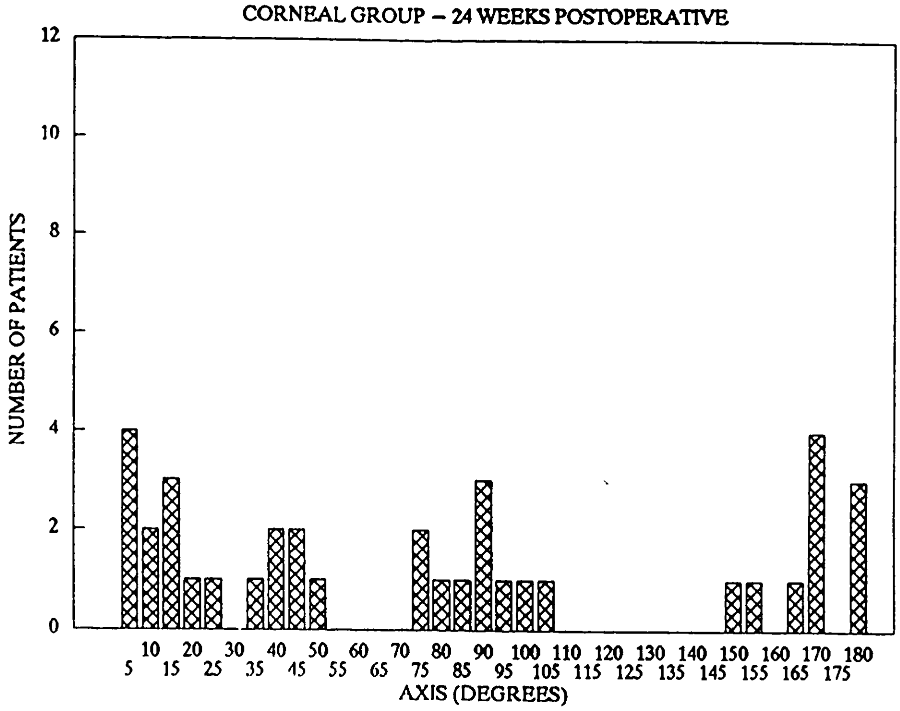


Figure 8.2.2.i.

Distribution of astigmatism axis - 16 weeks postoperative.



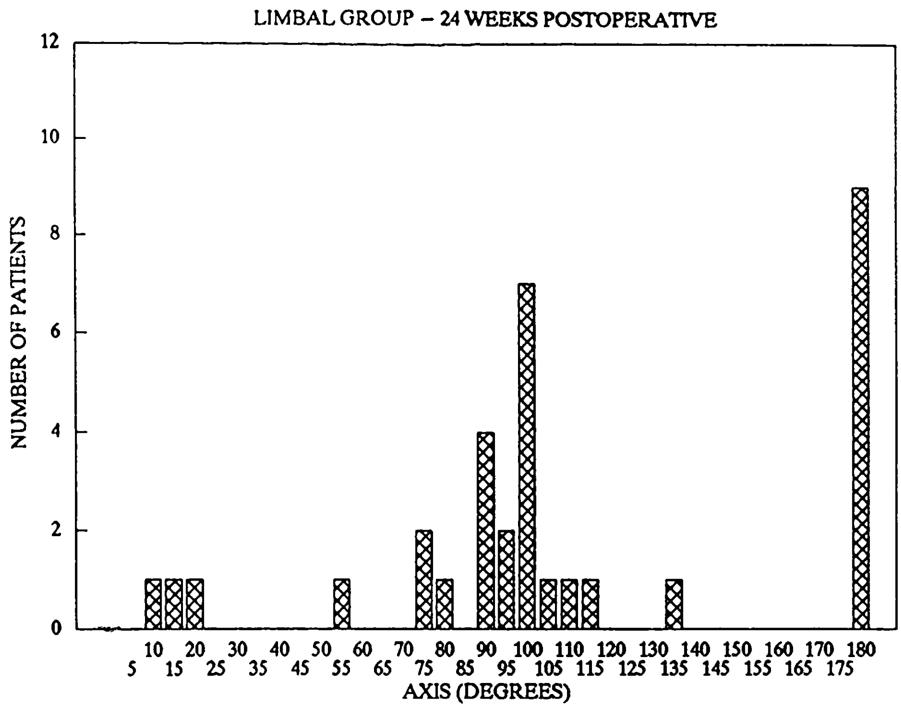


Figure 8.2.2.j.

Distribution of astigmatism axis - 24 weeks postoperative.

At the Postop stage the groups were similar but almost all of the patients showed WTR axes, although the distribution was more widely spread about the horizontal (180) axis. This pattern was still evident at the 2 and 4 weeks stages, plus a few patients of each group having oblique and ATR axes. By the 6 weeks stage, the distributions were becoming increasingly dissimilar. The (C) group still had a majority of WTR axis cases with a scatter of oblique and ATR axis cases but about half of the (L) group demonstrated ATR axes. This dissimilarity was very pronounced at the 8 week stage when the majority of the (L) group showed ATR axes. The same pattern continued over the following weeks. At the 24 weeks stage, for the (L) group, most cases with oblique axes had changed to ATR orientation and a few to WTR.

8.5 CORNEAL ASTIGMATISM SHOWN BY PEK

The corneal astigmatism changes of the Control group are shown in Fig. 8.3. There was no significant difference between the Control group and the patient groups preoperatively. For the Control group no significant time effect on changes was demonstrated at the $p < 0.05$ level. The data were useful to compare changes shown by eyes with and without an operation. The Control data also showed that although the patients had suffered the disturbance of an operation they were reliable in co-operating with the measurement procedures. For the Non operated group there was no significant time effect at $p < 0.05$ and no significant difference between the original value and any

CORNEAL ASTIGMATISM (P.E.K.) CHANGES

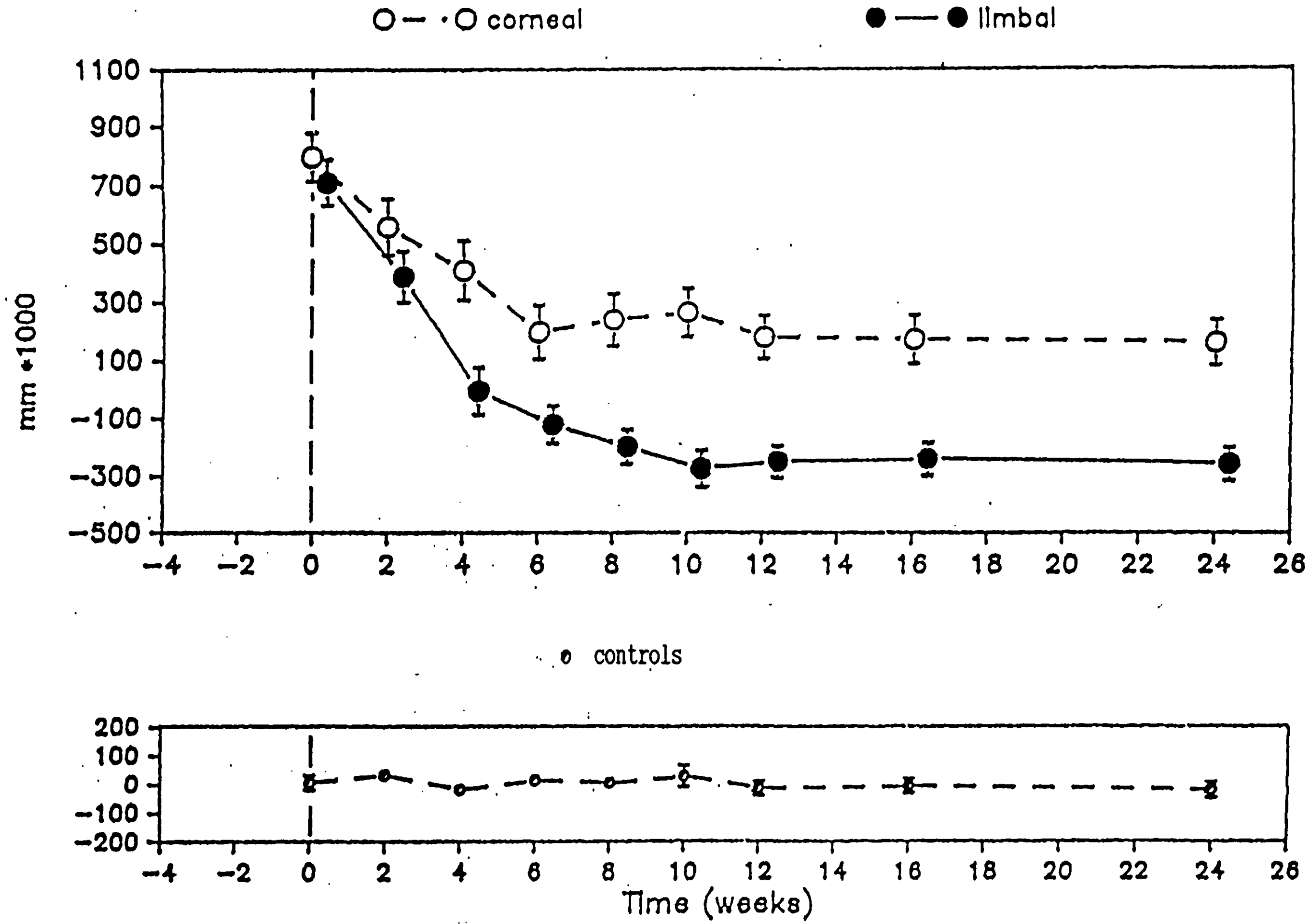


FIGURE 8.3. CORNEAL ASTIGMATISM (P.E.K.) CHANGES RELATED TO TIME.

subsequent values, according to multiple regression and to ANOVA ($F = 0.36$, $df=45,4$, $p>0.05$).

Patient groups mean postoperative changes related to time are shown in Fig. 8.3. Preoperatively, there was only a low value of astigmatism in each of the (C) and (L) groups. No significant difference at $p<0.05$ was demonstrated by 't' tests between the groups either in their mean values or in their standard deviations, so the two groups could be considered as being drawn from the same population. In a similar manner to that shown by corneal astigmatism measured by keratometry, both groups showed a rapid WTR shift following surgery. This shift quickly regressed in the following weeks, the (L) group changing more rapidly than did the (C) group. At 8 weeks there was a significant difference ($p<0.05$) between the mean values of the two groups, (C) group remaining at WTR astigmatism and (L) group becoming ATR astigmatism. As shown by 't' tests, the (C) group postoperative actual mean values remained significantly different from the preoperative values (at $p<0.05$).

The time effect on (C) group changes was significant ($p<0.05$) until the 16 and 24 week stages, hence it was concluded that this group stabilised at 16 weeks. The (L) group mean actual values showed no significant difference at $p<0.05$ between the preoperative stage and 2, 4 and 6 week stages. During these stages the corneal astigmatism changed from WTR to ATR. This would correspond to the period when the wound stretched and the vertical corneal curvature flattened. The mean values for 8 weeks and later showed a significant difference at $p<0.05$ from preoperative mean value.

For the (C) group changes, and for the (L) group changes, linear regression showed no significant relation at $p<0.05$ between postoperative changes and preoperative values. These findings are comparable to those found for corneal astigmatism measured by keratometry. When comparing the mean actual values of the two groups (C) and (L), multiple regression showed no significant difference at $p=0.05$ level at any time stage. Although the mean values indicate differing trends in postoperative response according to the groups, the standard errors of the means were large, therefore the significance of the difference between the means was reduced. At the 10 week stage the group mean values appear to be the most disparate. However, on comparing the postoperative changes according to operation type, these do differ significantly ($p<0.05$).

The mean actual values of corneal astigmatism shown by PEK, when analysed by linear regression corresponded very significantly to those given by keratometry ($p=0.01$). Hence central corneal curvature can be monitored successfully by either instrument, and they both measure over the central corneal diameter of 3.0 mm.

8.6 HORIZONTAL SHAPE FACTOR

The Control group changes are shown in Fig. 8.4. In the Control group, the standard errors of the means were large, but this is typical for a random selection of human eyes. As noted in table 8.7, ANOVA showed no significant time effect for mean changes ($F=0.85$, $df=8,70$, $p=0.56$). Studying the 95% confidence interval of +/- 0.15, with the pooled SD of +/-0.19, the overall mean change was found to be -0.02. In clinical use of the PEK, a shape factor change needs to be greater than 0.05 to be regarded as significant. Hence generally the Control group showed no significant change with time at $p<0.05$ level.

Considering the original data from the thirteen Control eyes and comparing the mean values with those of their fellow operated eyes, for all time stages, linear regression indicated no significant difference at $p<0.05$ level between the means of the Control and operated eyes. On original values, by 't' tests (C) group showed $t=-0.18$, $p=0.86$ and the (L) group showed $t=1.82$, $p=0.11$. One would have expected the operated eyes to have demonstrated several changes, but due to the wide variation in shape factor measurements, no significant difference at $p<0.05$ was proved between changes exhibited by the fellow operated eyes and those typical changes shown by the Control eyes. This questions the value of using the PEK to measure peripheral corneal shape when monitoring postoperative corneal topography changes.

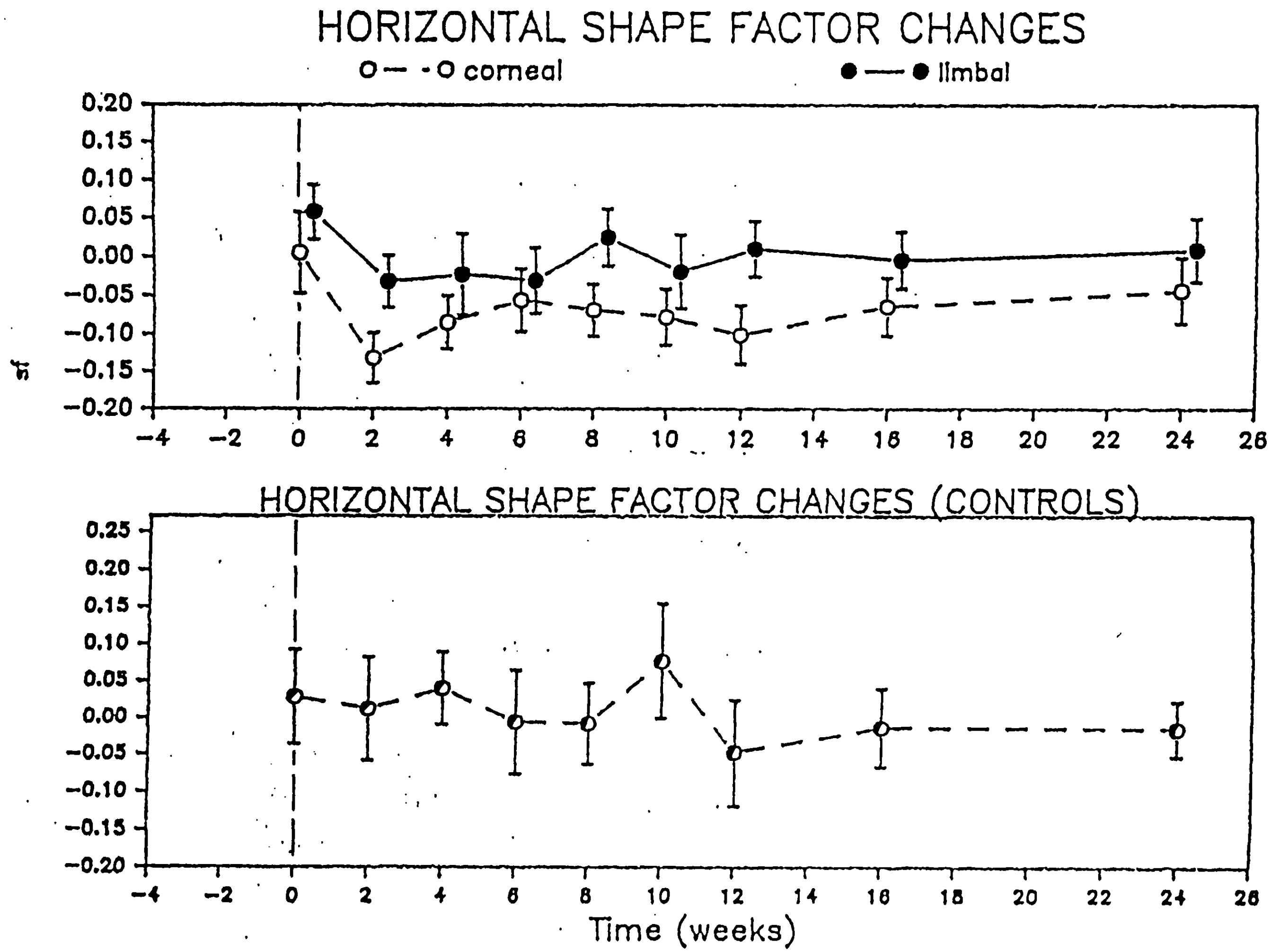


FIGURE 8.4 HORIZONTAL SHAPE FACTOR CHANGES RELATED TO TIME

In the Non operated group no significant changes with time were found (F= 0.64, df=45,4, p>0.05). Close correlation was noted between the values of the postoperative changes at each visit (p=0.01) . This group gave more stable values, possibly because they had good vision, health and co-operation so maintained better fixation during the measurements. As shown by the wide variability of the patient group data, yet good reliability on the non operated group, obtaining accurate measurements on elderly or infirm patients can be difficult.

Patient group mean postoperative changes are shown in Fig 8.4. 't' tests on the mean preoperative values showed no significant difference between the two groups (C) and (L) (t=1.13, p=0.26), so they could be regarded as being taken from the same population. The (C) group HSF results were considered first. 't' tests showed that all the mean values were significantly different from zero, at p<0.05, so the mean corneal contour remained at a positive value rather than becoming spherical. 't' tests on postoperative changes indicated a significant time effect at the following stages: 2 weeks (p<0.01), 4 weeks (p=0.02), 10 weeks (p=0.04), 12 weeks (p=0.01).

This result suggested some influence of the operation in reducing the preoperative positive shape factor value but no definite pattern was revealed. According to ANOVA and when tested by linear regression, the changes showed no significant relation at p<0.05 to time nor to preoperative values. This was probably

affected by the wide variation in patient measurements. Only the correlation between the changes and preoperative values was significant (p=0.05). The 95% confidence interval was +/-0.20 (range +0.13 to -0.27). The overall mean change was -0.07, pooled SD =+/-0.26, SEM =+/-0.05, F=1.01. However, multiple regression on changes showed significant time effects at p<0.05 at 6 weeks and at p<0.001 at 8, 12, 16 weeks. Some data were missed when patients failed visits so the results were re-analysed considering the data from those twelve (C) patients who attended every visit. Again, ANOVA on the mean postoperative changes in this small subgroup was only significant at the following stages: 2 weeks (mean = -0.19, p<0.001),
4 weeks (mean = -0.17, p=0.02), 12 weeks (mean = -0.18, p=0.04).

These all showed a shift towards negative shape factor, due to the influence of the wound healing. Correlation of the changes showed a significant relation to the values at the Postop stage (P=0.01), and at 2 and 4 weeks stages (p<0.05). Linear regression on postoperative changes showed a significant relation to preoperative values, at 12 weeks (p<0.01) and at 24 weeks (p<0.01). These results indicate that the variability in the data in the early postoperative weeks was often too great to allow a significant relationship to be revealed. By the 12 weeks stage the results were more stable and relationships were found.

The (L) group HSF results were next considered. Analyses of the data by ANOVA and linear regression were performed. Actual mean values were significantly different from zero, ie. spherical curve, but only showed a significant time effect ($p<0.05$) at the Postop and 2 weeks stages. ANOVA and linear regression showed no significant time effect at $p<0.05$ level for postoperative changes, but multiple regression indicated a significant time effect after the first four weeks of corneal disturbance. The overall mean change was 0.001, pooled SD=+/-0.23, which indicated that the changes were minimal but that the data had a high variability. This difficulty in demonstrating a time effect on changes was disappointing. The 95% confidence interval was found to be +/- 0.18 (range +0.18 to -0.18).

Multiple regression on postoperative changes showed a significant relation to preoperative value at 6 weeks ($p=0.01$), 8 weeks ($p<0.01$), 12 weeks ($p<0.01$) and 16 weeks ($p<0.01$). This indicated that the disturbance of corneal topography due to the operation was recovering by 6 weeks. When combining data from both (C) and (L) groups to improve the pool size, one way ANOVA showed no significant time effect ($p=0.56$) for postoperative changes.

At the Postop stage, there was no significant difference between the (C) and (L) mean actual values ($t=-0.27$, $p=0.79$). However, when analysing the overall changes, one way ANOVA showed a significant relation, according to group type ($F=12.84$, df=649,1, $p<0.01$). Greater changes occurred in the (C) group generally.

This was expected since the corneal incision was usually made closer to the horizontal meridian than was the limbal incision. The (C) group had an overall mean change of -0.07, SD=+/-0.26. The (L) group had an overall mean change of <0.01, SD =+/-0.23. Linear regression on overall change showed no significant time effects but did show a significant relation to group type (t=3.58, p <0.01). On analysing the changes data from the twelve (C) and six (L) patients attending every visit, no significant group or time effects at p<0.05 level were found. Their small number hindered the demonstration of possible significance.

8.7 VERTICAL SHAPE FACTOR

The Control group changes are shown in Fig.8.5. Two sample 't' tests preoperatively comparing Control eyes to their fellow operated eyes showed no significant difference . ANOVA on changes from the original value showed no significant time effect (F=0.78, df=8,70, p=0.63). ANOVA on the overall changes showed no significant time effect nor significant difference from zero, i.e. spherical shape, (F=0.58, df=9,82, p=0.81). The overall mean change was 0.06, pooled SD =+/- 0.28, and SEM =+/-0.03. This indicated that the variability of the data was significant.

The 95% confidence interval was +/- 0.22. As the Control eyes had no treatment only minimal changes were expected. Comparing overall changes, no significant difference at p<0.05 level was found between HSF and VSF.

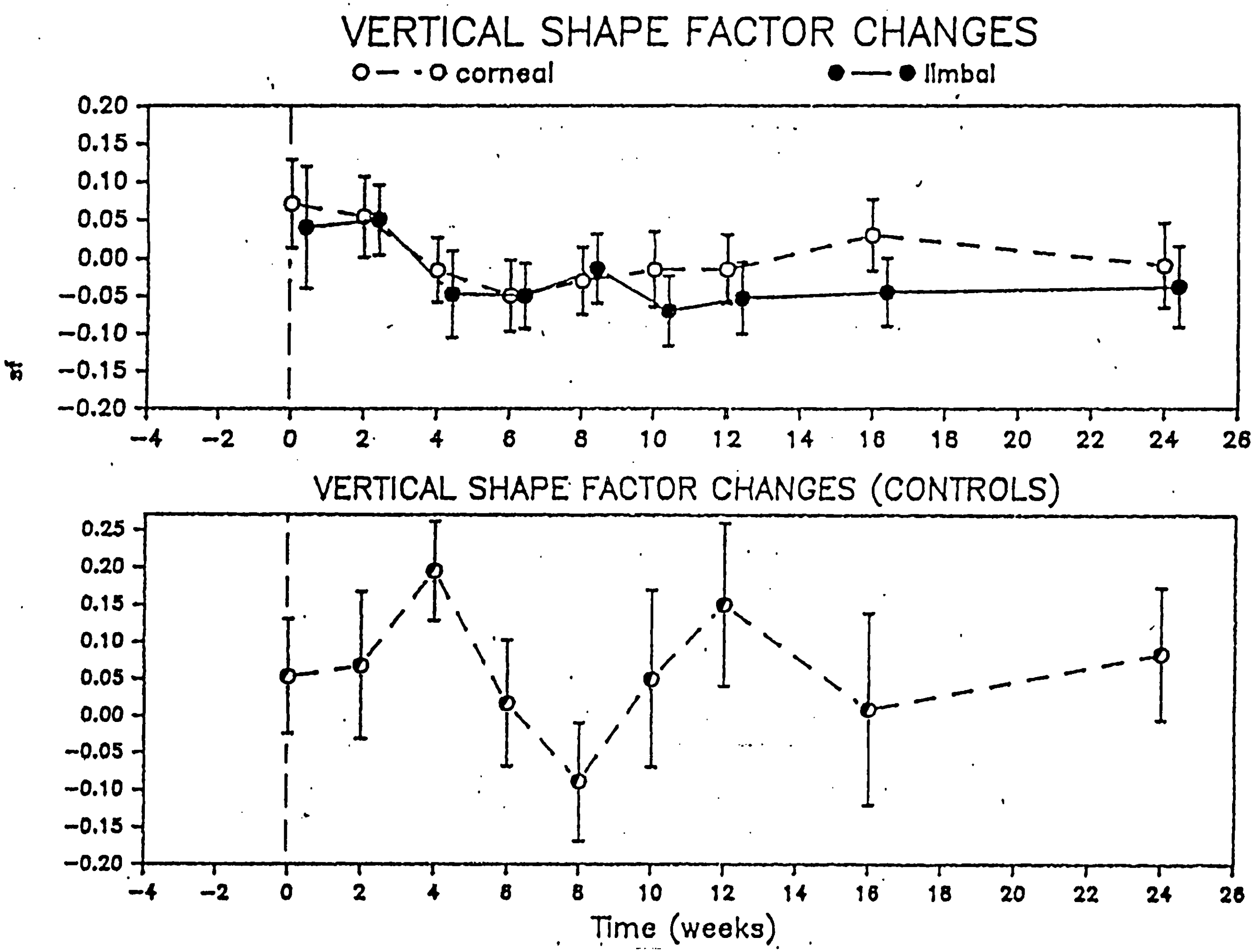


FIGURE 8.5 VERTICAL SHAPE FACTOR CHANGES RELATED TO TIME

Generally there seemed more variability in VSF possibly due to the greater difficulty in obtaining a clear PEK photograph of the superior corneal region due to interference by lids and lashes.

For the Non operated group, there was no clear pattern of changes although the original shape factor value reduced slightly. The variability was less than that shown by the Control group, probably because the subjects had better vision and target fixation. One way ANOVA showed no significant time effect ($F=0.67$, $df=45,4$, $p>0.05$) in this non-treated group.

The Patients group postoperative changes are shown in Fig. 8.5. 't' tests on preoperative actual mean values showed no significant difference at $p<0.05$ level between the (C) and (L) groups so they could be regarded as being from the same population. The SEMs were smaller than those of the Control group, probably due to the larger patient numbers.

The (C) group VSF results were considered first. Although the graph in Fig. 8.5 indicates an operation induced positive shape factor shift, analyses by one way ANOVA and linear regression showed no significant time effect at $p<0.05$ for postoperative changes. This was probably due to the high variability of the measurements disguising any trends which resulted from the influence of the operation.

Correlation showed a significant relation at $p<0.05$ level between mean preoperative value and mean postoperative actual values at each stage. The overall mean change was <0.001, pooled SD= +/-0.32, and the 95% confidence interval was +/-0.25.

This emphasised the large degree of variability. When re-analysing the changes data for the 12 (C) patients who attended every visit, correlation and multiple regression showed no significant time effects at the $p<0.05$ level. Only multiple regression on changes at 24 weeks showed a significant relation to preoperative value ($F=6.76$, $df=12,1$, $p=0.03$). Correlation of changes showed no significant relation to preoperative values, but some relation at the $p<0.05$ level between the Postop stage and all stages except 2 and 10 weeks.

The VSF results from the (L) group were next considered. A rather variable response to the operation was demonstrated, similar to that of the (C) group. Analyses by one way ANOVA and multiple regression on postoperative changes showed no significant time effect at $p<0.05$. However, linear regression on changes did show a significant time effect for the following stages: 6 weeks ($p=0.04$), 8 weeks ($p<0.01$), 12 weeks ($p=0.01$), and 16 weeks ($p<0.01$).

The overall mean change was -0.03 which indicated only a small shift, reducing the positive shape factor. The pooled SD was +/- 0.31, the SEM was +/-0.06, and the 95 % confidence interval was +/- 0.24 (range +0.22 to -0.27). These indicated a wide variability of results so made it difficult to draw definite conclusions regarding the shape factor changes.

Re-analysing the data for the six (L) patients who attended every visit, correlation and multiple regression again showed no significant time effect at the $p<0.05$ level. The corneal shape attempted to return to a similar contour as that found preoperatively although the values were still very variable.

When comparing the actual mean values of the (C) and (L) groups and comparing their overall changes, ANOVA showed no significant difference at $p=0.05$ level. This was also true for the 18 patients who attended every visit.

When comparing HSF to VSF, one way ANOVA on the actual mean values showed a significant difference between the two types of shape factor ($F=11.95$, $df=649,1$, $p<0.01$) but no significant time effect $p>0.05$. As expected, VSF underwent a greater change than did HSF, since the incisions cut through the vertical corneal meridian.

ANOVA and linear regression on changes indicated a significant difference between HSF and VSF for the (C) group ($t=3.46$, $p<0.01$) but not for the (L) group. This implied that a corneal incision had a greater influence on VSF than had a limbal incision. This was expected because the corneal incision more directly affected the vertical corneal meridian.

The operation appeared to cause a temporary shift towards a positive shape factor. This was a typical effect of the tightness of the sutures on the oedematous tissue near the incision. As the wound settled and the oedema subsided, the VSF tended to revert towards the original topography value. Comparison of the mean operated eye value with the mean control eye values using linear regression for each stage showed no significant difference at $p<0.05$ level. This implied that the large variability of the data made it more difficult to demonstrate the postoperative corneal changes using this method.

CHAPTER 8 PART II

CORNEAL THICKNESS RESULTS

8.8 CORNEAL THICKNESS

8.8.1 Calibration of pachometer

In calibrating the pachometer, the means of ten thickness readings of the four PMMA calibration contact lenses were obtained as shown in Table 8.9. As the pachometer is designed to measure corneal material whose refractive index is 1.376, when used on other material (PMMA) having the significantly different refractive index of 1.490, a correction factor must be applied. This provides the equivalent corneal thickness values. The derivation of this correction factor is given.

r = radius of anterior surface

t = true thickness

X = apparent thickness of optical section

t' = paraxial image of true thickness

X is proportional to the paraxial image t' .

Hence $1/t' - 1.376/t = -0.376/r$

Therefore $t = (1.376 \times t' \times r)/(0.376 \times t' + r)$

Therefore for a PMMA lens of refractive index = 1.49,

$t = 1.49\, t' \times r)/(0.49\, t' + r)$

Thus the ratio of corneal thickness to contact lens thickness when the apparent thickness is equal to t' is:-

$t\ cornea/t\ lens = 1.376\,(0.49\, t' + r)/1.49\,(0.376\, t' + r)$

In the calibration exercise, the mean value of r was 7.81 mm and the apparent thickness, t' , taken to be 0.45 mm as being central in the range.

Thus the ratio of t cornea/ t lens is equal to:

1.376 (0.49x0.45 + 7.81)/ 1.49 (0.376x0.45 + 7.81) = 0.9294

Hence 0.929 is the value of the calibration factor required to convert the physical thickness value for each lens into equivalent corneal thickness value.

(Calibration factors previously found: 0.93 by Woodward 1980, 0.925 by Mandell and Polse 1968).

The equivalent corneal thicknesses of the lenses in mm were:

lens S = 0.435, lens T = 0.528, lens U = 0.621, lens V = 0.711.

These corneal thickness values were used in a linear regression to plot a graph of corneal thickness value against the pachometer readout numbers. This calibration graph was used to convert the readout numbers during pachometry on the patients. The repeatability of the readings is given in Table 8.9.

8.8.2 <u>Control and Non-operated groups corneal thickness</u>

Statistical analyses of the data from the five corneal regions are given in Table 8.10. ANOVA showed no significant difference between the (C) and (L) Controls overall means for any of the corneal regions ($F=2.53$, $df= 63,1$, $p<0.05$), so these Control eyes could be considered as a single group of thirteen from the same population. When comparing data according to corneal position, only the central corneal position had a preoperative actual value significantly different from those of the other positions

(F=9.17, df=4,60, p=0.01). This was to be expected because in normal human corneas the central cornea is thinner than in the periphery.

One way ANOVA on changes from the original value showed no significant time effect at p<0.05 level. One way ANOVA, combining all positions ,indicated no significant`overall changes from zero (F=0.55, df=4,40, p=0.70). Only negligible changes were anticipated since these were non treated eyes. However, when using one way ANOVA to test overall changes related to corneal position, there was some significance for the following regions, superior, t= 2.93, p=0.004, central, t = 3.56, p<0.001, temporal t=2.29, p=0.03. Unstable fixation may have caused apparent changes in these regions. Overall mean change was 0.01mm, the pooled SD +/-0.04, and the 95% confidence interval was +/-0.05.

For the Non-operated group actual values and changes ANOVA showed no significant time effect at p<0.05 level, for any of the regions. This was expected since the subjects were co-operative and had no treatment. Their results act as a baseline to emphasise the degree of change in the operated patients. For the superior and central corneal regions correlation indicated no significant relation between the stages. For the inferior, nasal and temporal regions the majority of stages correlated well with each other at the p<0.05 level. This suggested slightly more variation in the values for the superior and central regions.

Statistical analyses of the controls and patient groups data are indicated in Tables 8.10 to 8.15.

8.9 PATIENT GROUPS CORNEAL THICKNESS

8.9.1 Superior region

Both 't' tests and one way ANOVA showed no significant difference (F= -0.42, df=76,5, p=0.67) between the preoperative means of the two groups, (C) mean 0.63mm, SEM +/-0.01, and (L) mean 0.64mm, SEM +/-0.01, so they could be considered as being from the same population. The corneal thickness changes related to time are shown in Fig.8.6.

For the (C) group, multiple regression on actual values showed a significant time effect, p<0.01. Linear regression showed a significant relation (p<0.05) between postoperative values and preoperative value for all stages, eg. 8 weeks, F=8.07,df=30,1,p=0.01, except for the Postop stage, which was when the cornea was most disturbed by the surgery. Multiple regression on postoperative changes showed a significant time effect (F=100.42, df=372,1, p<0.01) at all stages, and showed a significant relation of the changes to the preoperative value at the following stages: 8 weeks p=0.01, 12 weeks p=0.04, 16 weeks p=0.02. This suggests that those corneas which were originally thick demonstrate the greater thickness changes. This was probably also true for the other time stages but not shown as significant due to the variability of the data.

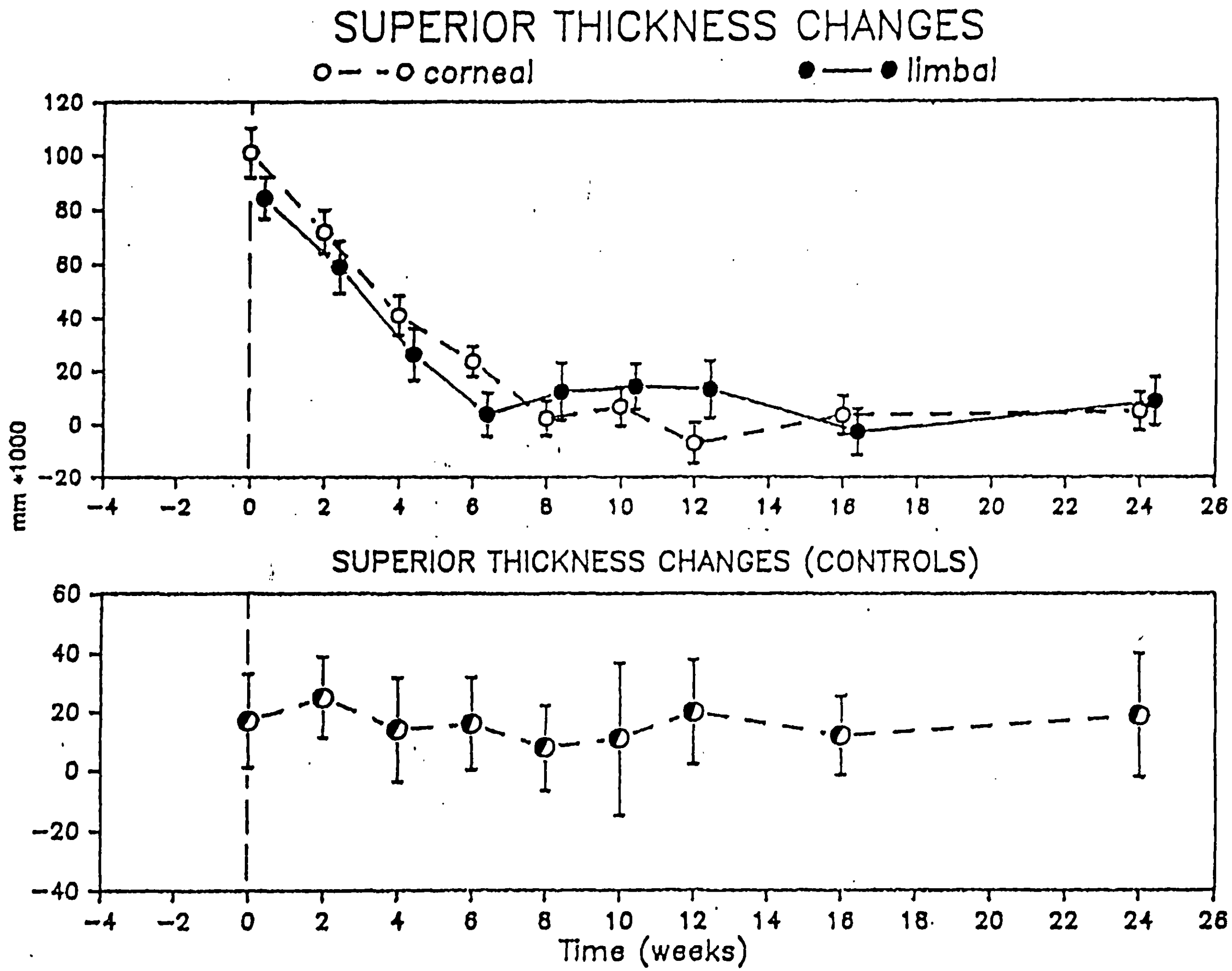


FIGURE 8.6 SUPERIOR CORNEAL THICKNESS CHANGES RELATED TO TIME

For the (L) group, linear regression on actual values showed a significant time effect ($p<0.01$) and a significant relationship of postoperative actual values to preoperative value at the $p<0.05$ level. Thickness changes stabilised at 6 weeks compared to about 8 weeks for the (C) group, both settling at a level with minimal change from their preoperative values. Linear and multiple regression on changes showed a significant time effect eg. Postop stage, $F=40.2$, $df=339,1$, $p<0.001$, and showed a significant relation ($p<0.05$) between changes and the preoperative values. When comparing the mean changes of the (C) and (L) groups at the Postop stage, two sample 't' tests showed no significant difference ($t=1.38$, $p=0.17$), and only a weak significant difference was shown by linear regression ($F=2.35, df=93,3$, $p=0.10$) and by ANOVA ($F=2.35$, $df=711,2$, $p=0.10$).

The results indicate that both operation methods cause similar immediate postoperative corneal oedema, although overall the (C) group response is greater. This similarity was surprising because a greater amount of superior corneal oedema had been expected following a corneal incision since this directly traumatises the corneal tissues and permanently damages the endothelium. Examining overall changes, linear regression and one way ANOVA showed dissimilarity between the two groups but no significant difference at $p<0.05$ level ($F=2.4, df=711,2$, $p=0.10$), but there was a significant difference between the axis intercept of the two regression slopes ($t=-3.19$, $df=713,1$, $p<0.05$). Multiple regression reiterated this but also emphasised the very significant time effect shown by the two groups when combined (F=132.0, df=713,1, p<0.001).

8.9.2 Central region

Corneal thickness changes related to time are shown in Fig. 8.7. Two sample 't' tests showed no significant difference between the preoperative mean values, (C) = 0.51 mm, SEM +/-0.01, and (L) =0.52 mm, SEM +/- 0.01. Postoperative changes stabilised for the (C) group by 10 weeks and for the (L) group by 4 weeks. Considering (C) and (L) groups together and all changes combined, multiple regression and ANOVA revealed a very significant time effect, F =63.9, df=714,1, p<0.001.

For the (C) group, actual values at each time stage showed a significant relation at p<0.05 to preoperative value, eg. 8 weeks, F=22.3, df=30,1, p<0.001, with the exception of the Postop stage when the data were very variable. Linear regression and ANOVA on postoperative changes showed a significant time effect (F=54.4, df=373,1, p<0.001). Multiple regression indicated stabilisation of the changes at a level showing insignificant change from preoperative value.

For the (L) group, there was a significant relation between actual values and preoperative values at each stage, eg. 8 weeks F=7.3, df=23,1, p=0.01, except for the Postop stage, where the corneal response to the trauma was greatest and the data rather variable.

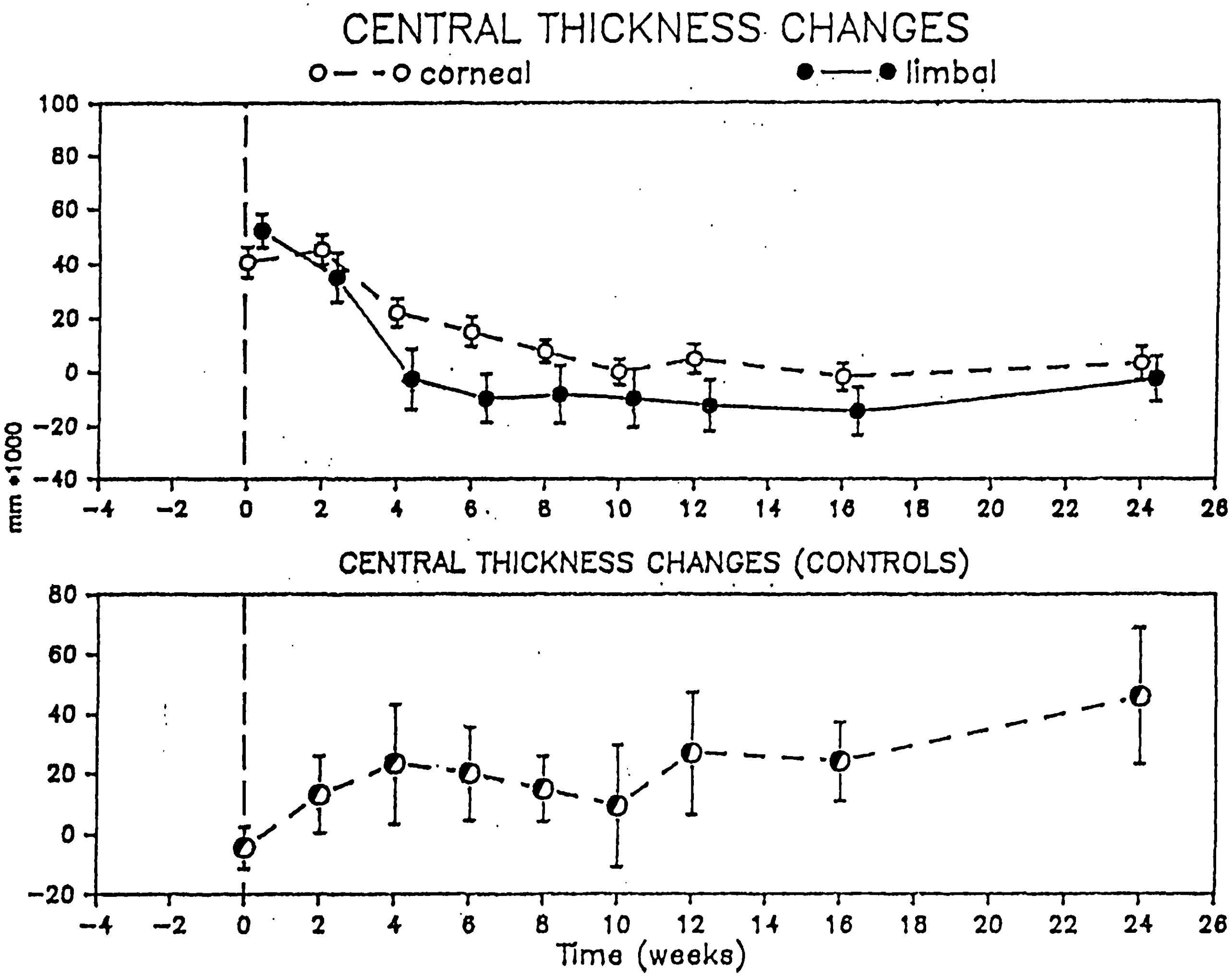


FIGURE 8.7 CENTRAL CORNEAL THICKNESS CHANGES RELATED TO TIME

Linear regression showed a significant time effect for the overall changes ($p=0.01$), with which multiple regression at each stage agreed (eg. Postop stage, $F=22.65$, $df=339,1$, $p<0.001$). Multiple regression showed a significant relation between changes and preoperative values at the $p<0.05$ level, eg. 8 weeks, $F=3.32$, $df=22,1$, $p=0.013$. This indicated that those patients who had a greater degree of preoperative corneal thickness showed larger thickness increases following surgery.

Comparing the changes of groups (C) and (L) at the Postop stage, two sample 't' test showed no significant difference ($t=-1.37$, $p=0.17$). These results indicate that both operation methods cause a similar immediate disturbance of the cornea although a greater amount had been expected for the (C) group because the corneal incision was closer to the central cornea than was the limbal incision. Multiple regression of overall changes did show a significant difference between the two groups ($F=5.15$, $df=2,712$, $p=0.01$), the (C) group thickness being slower to recover. The linear regression graphs of changes related to time had slopes which were not equal to zero, but the axis intercepts of the slopes differed according to group. The overall group mean changes, (C)=0.017 mm (L)=0.005 mm, differed significantly ($t=-3.19$, $p<0.01$).

8.9.3 <u>Inferior region</u>

The corneal thickness changes related to time are shown in Fig. 8.8.

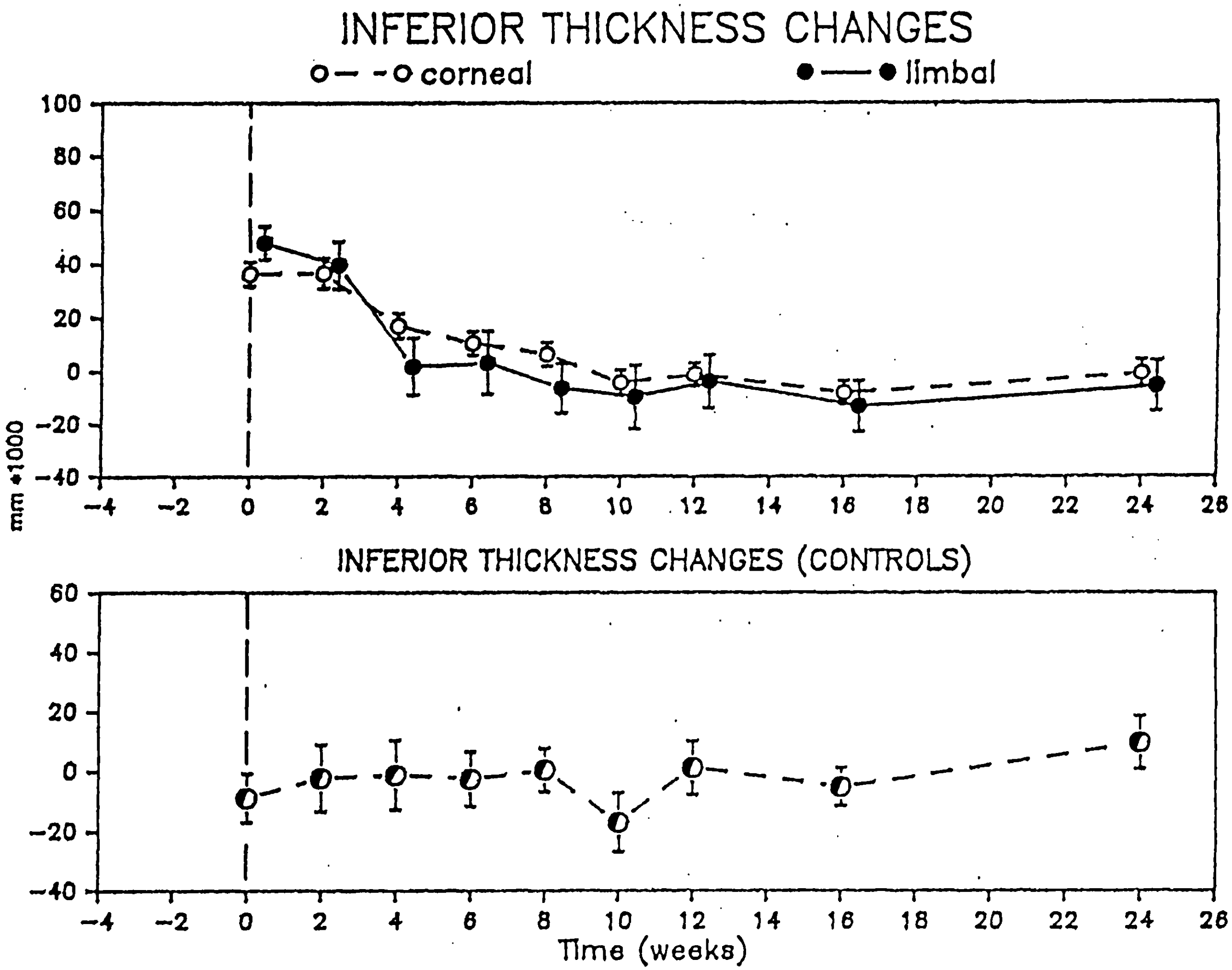


FIGURE 8.8 INFERIOR CORNEAL THICKNESS CHANGES RELATED TO TIME

Two sample 't' tests showed no significant difference (t=0.34, p=0.73) between the preoperative mean values of the two groups, the (C) and (L) means were both 0.59 mm, SEM +/- 0.01, so they were considered as being from the same population. The thickness changes stabilised for the (C) group at 8 weeks, but at 4 weeks for the (L) group. When actual values for (C) and (L) groups were combined, ANOVA showed à very significant time effect, F= 64.66, df=714,1, $p<0.001$.

For the (C) group, one way ANOVA on actual values indicated greater significant time effects for the Postop and 2 weeks stages. The results suggested that by 4 weeks the oedema response began to settle then stabilised by about 8 weeks. Linear regression showed a significant relation at the $p<0.05$ level between the actual values and the preoperative value, eg. at 8 weeks F=13.04, df=30,1, p=0.001. Considering the overall changes, ANOVA and multiple regression showed a very significant time effect, F=63.90,df=373,1, $p<0.001$. The overall changes had a significant relation to the preoperative value eg. 8 weeks, F=4.91, df=35,1, p=0.001. This indicated that thicker corneas underwent greater thickness increases.

For the (L) group, one way ANOVA on actual values showed significant time effects at the $p<0.01$ level for the Postop and 2 week stages, (Postop, F=22.64,df=339,1,p=0.001) then the significance decreased with time. This indicated that the postoperative corneal oedema, which was the sign of stromal disturbance in the first two weeks, mostly recovered by 4 weeks to a level similar to the preoperative value. Linear regression showed a significant relation at p<0.05 level between actual values at each time stage and the preoperative value, eg. for the 8 week stage, F=17.09, df=23,1, p<0.001. Thus thicker corneas preoperatively remained the thicker ones later. On analysis of changes ANOVA showed a significant time effect, eg. Postop stage F=22.54, df=339,1, p<0.001, but no relation to preoperative values until 4 weeks when the thickness returned to near original values. This reinforced the conclusion that the response settled at 4 weeks for the (L) group but 8 weeks for the (C) group.

On comparison of the groups (C) and (L) mean overall actual values, ANOVA showed no significant difference, F=0.69, df=712,2, p=0.50. The slopes of the regressions were similar but they had different intercepts of the axes. On analysis of changes, ANOVA and multiple regression showed no significant difference between the groups at p<0.05 level. This was expected because the inferior region was furthest from the incision so would be least influenced by the incision position. Both groups exhibited a general corneal oedema response to the cataract surgery.

8.9.4 Nasal region

The nasal corneal thickness changes related to time are shown in Fig. 8.9. Two sample 't' tests on the preoperative mean values showed no significant difference (t=-0.35, df=66,5, p=0.73) between the two groups, (C)= 0.59 mm, SEM=+/-0.01, (L) =0.60 mm,

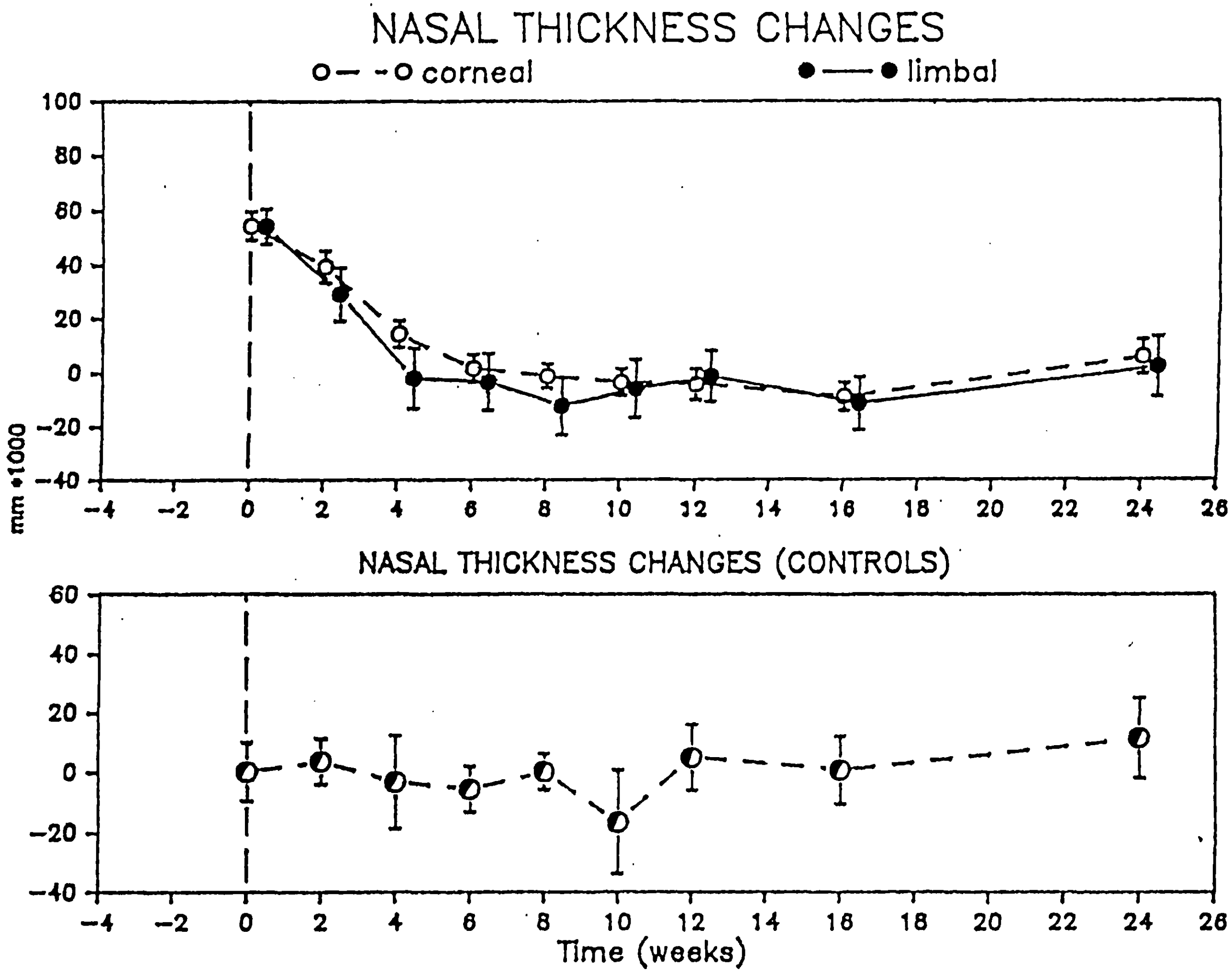


FIGURE 8.9 NASAL CORNEAL THICKNESS CHANGES RELATED TO TIME

SEM= +/-0.01, so they could be considered as being from the same population. The thickness changes stabilised for the (C) group at 6 weeks and for the (L) group at 4 weeks. For the groups combined there was a significant time effect, F=53.72, df=714,1, p<0.01.

For the (C) group, one way ANOVA on actual values showed a very significant time effect at the Postop and the 2 weeks stages, eg.Postop F=58.26, df=372,1, p<0.001. The significance was much less by 4 weeks which suggested that the oedema response began to stabilise. The changes became negligibly different from zero by 6 weeks. Linear regression showed that the actual values and changes were significantly related to preoperative value at the p<0.05 level, and this was also shown when (C) and (L) data were combined. eg. 8 week , F=25.36, df=30,1, p<0.001. This indicated that the thickness responses were regular and related to preoperative thickness. Linear regression on changes showed a significant time effect, p<0.01.

For the (L) group, ANOVA on actual values only showed a significant time effect for the Postop and 2 weeks stages, eg.Postop F=14.56, df=340,1, p<0.001. The changes were not significantly different from zero by the 4 week stage, which indicated that the corneal oedema recovered to within original range by 4 weeks. Actual values were significantly related to preoperative value, eg. 8 weeks, F=9.56, df=23,1, p=0.005. Linear regression on changes showed a significant time effect, F=14.56, df=340,1, p=0.002.

Multiple regression at p<0.001 level showed a significant relation between changes and preoperative values. This verified the hypothesis that thicker corneas demonstrated a greater amount of swelling response than did thinner corneas.

When comparing the overall changes for groups (C) and (L) at each time stage, no significant difference was found (F=1.07, df=712,2, p=0.34). A greater change had been expected for the (C) group whose incision approaches the nasal region more closely than does that of the (L) group, but these results indicate a similar oedema response for both groups, particularly at the Postop stage, t =0.02, df=89,9, p=0.98.

8.9.5 <u>Temporal region</u>

The corneal thickness changes related to time are shown in Fig. 8.10. Two sample 't' tests showed no significant difference (t=-1.01, p=0.31) between the preoperative mean values of the two groups, (C) = 0.58 mm, SEM= +/-0.01, (L) = 0.60 mm, SEM=+/- 0.01, so they were considered as being from the same population. The changes stabilised for the (C) group at 6 weeks, and for the (L) group at 4 weeks. For the two groups combined, there was a significant time effect for postoperative changes, (F=15.92, df=707,8, p<0.001).

For the (C) group, ANOVA showed a significant time effect for the actual values at the Postop and 2 weeks stages, F=60.15,

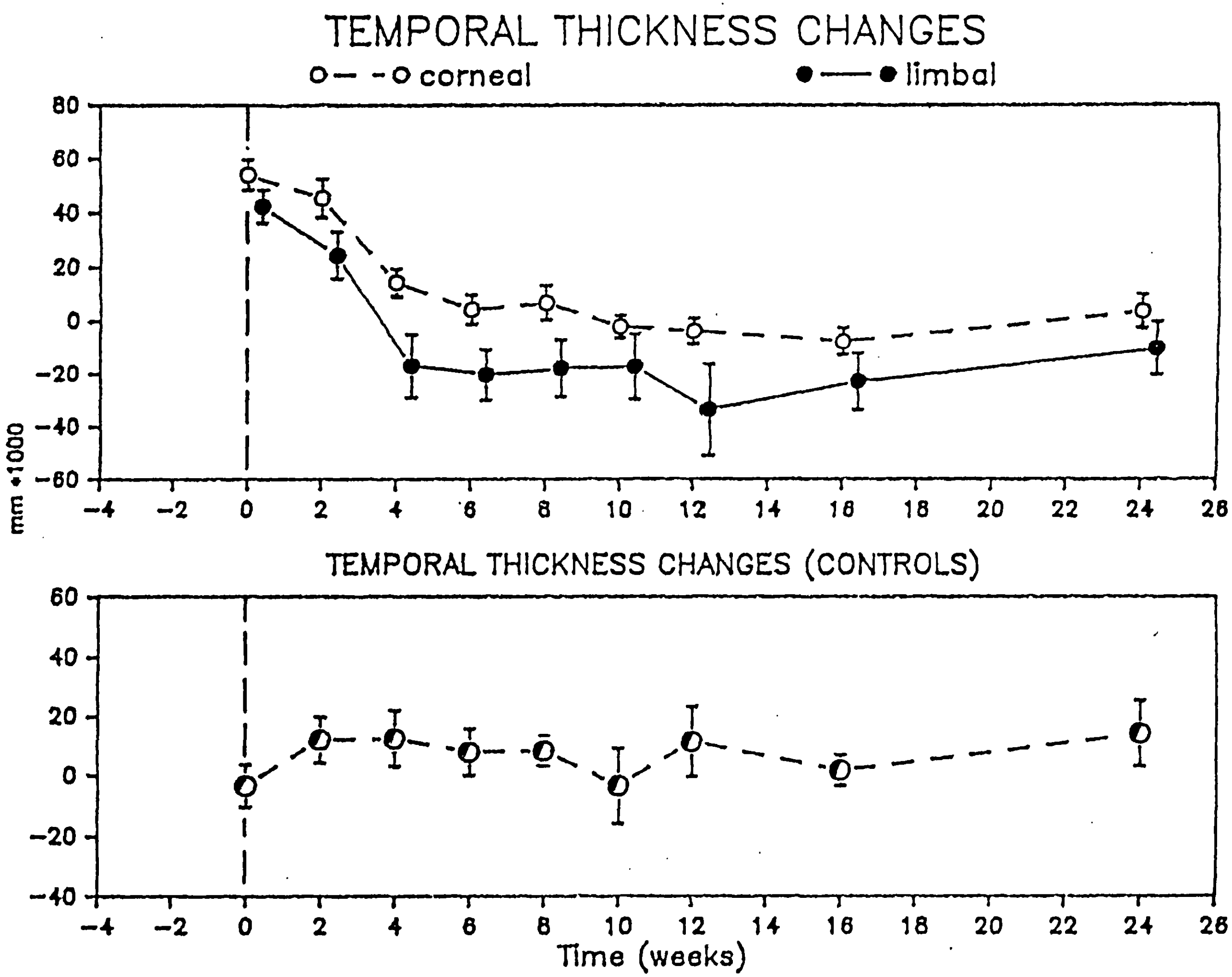


FIGURE 8.10 TEMPORAL CORNEAL THICKNESS CHANGES RELATED TO TIME

df=373,1, p=<0.001. By 4 weeks, the oedema response was much reduced and was stabilised by 6 weeks. Linear regression showed that actual values at each stage were significantly related at p<0.05 level to preoperative value eg. at 8 weeks F=6.47, df=30,1, p=0.017. Hence the oedema response was regular and related to preoperative thickness. Multiple regression on overall changes showed that for (C) and (L) groups combined, there was a significant time effect (p=0.01). Multiple regression showed a significant relation (p<0.05) between (C) group changes and preoperative values only after 6 weeks, eg. 8 weeks, F=25.05, df=29,1, p<0.001, and 16 weeks, F=4.81, df=29,1, p=0.04.

For the (L) group, after 4 weeks the mean actual values remained steady. ANOVA on actual values showed a significant time effect, F=15.55, df=339,1, p<0.001. ANOVA on changes only showed a significant time effect (p<0.05) for the Postop and 2 weeks stages, and indicated that by 4 weeks the thickness changes stabilised. Linear regression at each time stage showed a significant relation at p<0.05 level between the actual values and the preoperative values, eg. 8 weeks F=9.33,df=23,1, p=0.006. This relation was not shown at the 10 weeks stage since the variability of the results was greater. Multiple regression on overall changes indicated a significant relation at p<0.01 level to preoperative values, which was also true for the changes at 6, 8, and 12 weeks stages. This indicates that the thickness changes were more predictable at these times.

When comparing the changes of the two groups (C) and (L) at the Postop stage, 't' tests showed no significant difference between groups (t=1.37, df=93,1, p=0.17). This indicated that a similar immediate postoperative oedema response to the surgery was apparent in both groups. The overall group mean changes, (C) = 0.02mm, SEM=+/-0.003, (L) = -0.01mm, SEM =+/-0.003, differed significantly (t=-4.88, p<0.001). ANOVA also showed this group difference, F=11.94,df=712,2, p<0.001 and showed that (C) group thickness change was slower to decrease. As shown in Fig. 8.10, the (L) group changes were more negative and variable than those of the (C) group. This was puzzling as the (C) group returned to values similar to the original values, although a corneal incision had been expected to influence the temporal corneal region to a greater extent than had a limbal incision.

CHAPTER 8 PART III. PARAMETER RELATIONSHIPS

8.10 PARAMETER RELATIONSHIPS

8.10.1 Parameter comparison

Analysis by multiple regression was used to investigate the postoperative changes at stages 6 weeks and 16 weeks for HSF, VSF and corneal astigmatism by PEK to find whether these were related to preoperative corneal astigmatism (keratometry) values and so might be predictable to some extent. No significant relationship at $p<0.05$ level was found (see Table 8.16). There was also no significant relationship found to the preoperative actual values of HSF and of VSF. Postoperatively, although there was no significant time effect demonstrated by either HSF or VSF because of the variable results, (C) group did show a significant difference between HSF and VSF changes, F=11.95, df=715,1, $p<0.01$. (L) group did not do so. This indicated that a corneal incision disturbed VSF to a greater extent than did a limbal incision. Corneal astigmatism by PEK showed a significant relation at $p<0.01$ level to corneal astigmatism by keratometry, so either instrument could be used to measure central corneal curvature. No significant relationship was found between preoperative corneal thickness in whatever region, and HSF, VSF, and corneal astigmatism whether by PEK or keratometry.

No significant difference was found between males and females as regards the time effect on the parameters measured, nor on their relation to preoperative measurements.

8.10.2 Relation to the presence of IOL

As the presence of an IOL was a possible factor in the corneal response to the surgery, the results were re-analysed with regard to whether an IOL was implanted (Table 8.17). Coincidently the IOL and non-IOL group sizes were very similar; mean age with IOL (N=54) was 65.4 years, SD=+/-8.7, and the mean age without IOL (N=51) was 56.5 years SD=+/-13.4. There was no significant difference between the mean ages, although the surgeons were more reluctant to implant an IOL in the younger patients because at that time little was known regarding the corneal tolerance to several decades of IOL presence.

An imbalance was noted between the proportions of IOL/non IOL and operation type; (C) and IOL N=35, (C) and non IOL N= 19, (L) and IOL N=19, (L) and non IOL N=32. This tended to reflect the clinical opinions of the surgeons in the study. More recently improvements in IOL design and surgery techniques have led to fewer cases of IOL induced endothelial damage so IOLs can be implanted into a wider variety of patients. If the original proposal had been to study the influence of an IOL then more balanced numbers would have been sought.

On examining the response of the corneal astigmatism (by keratometry) , multiple regression showed no significant relation at $p<0.05$ level to whether or not an IOL was present. The exception was at 16 weeks when $p=0.04$ but only 8 eyes with IOLs were measured at this stage so this one result may be spurious.

Multiple regression showed that the relation between postoperative changes and preoperative values was not dependent on the presence of an IOL. The two exceptions to this were for patients with an IOL, at 8 weeks (p=0.03, N=7) and at 12 weeks (p=0.03, N=7). At these stages there was an apparently significant relation between changes and preoperative values, but as the numbers were small no definite conclusion was drawn. At these two stages, data was compared between patients with and without IOLs. 't' tests showed no significant difference between these groups (8 weeks, t=0.66, p=0.51, 12 weeks, t=0.44, p=0.66). Multiple regression on corneal astigmatism (PEK) changes found no significant relation at p<0.05 level to the presence of an IOL.

For HSF, no significant time effect at p<0.05 was found either for actual values or postoperative changes, whether or not an IOL was present. On analysis of the VSF data by multiple regression, no significant relation at p<0.05 level was demonstrated between the time effect and the presence of an IOL. No influence was apparent by the IOL on the relation of postoperative changes to preoperative values.

Next, the influence of an IOL on the corneal thickness response was considered. No significant influence on the time effect or the amount of postoperative thickness change was revealed. Table 8.18 lists the postoperative changes related to their preoperative thickness. Table 8.19 lists the significance of the relation of changes to the preoperative thickness and the presence of an IOL. There are a few occasions when the IOL appears to influence this. For example, the (L) group superior thickness changes are significantly related (at $p<0.01$) to preoperative value in those patients without an IOL, except for the 6 week stage when postoperative oedema is still somewhat variable. This suggests that their postoperative response is more predictable than that of IOL patients and that patients with an IOL take longer to stabilise at a corneal thickness similar to the original value. This feature is also demonstrated by the (L) group inferior region changes and to a relatively lesser extent by the other regions.

Generally, (L) group changes appear to stabilise nearer to the preoperative value at a quicker rate than do those of the (C) group. The latter present a more variable response such that the changes at many stages show no significant relation to preoperative value nor to the presence of an IOL. This is understandable for the superior region is near the incision site, yet even the inferior region changes also show variability and no significant relation to preoperative values. No previous reports of the relation between postoperative thickness stabilisation and the presence of an IOL have been found.

CHAPTER 9

CORNEAL PARAMETERS PREDICTIVE STUDY

9.1.1 FLOW CHART DESIGN

Information from the main study was used to produce a simplified chart shown in Table 9.1, which aimed to assist surgeons in planning the refractive management of their patients. The choices given in the chart are described as follows:

Choice 1. Type of correction intended?

If a contact lens is intended as the postoperative form of optical correction, most aphakia patients would be satisfactorily fitted by a rigid gas permeable lens (Astin 1984). On patients with ATR corneal astigmatism a rigid lens is more liable to decentre. On those with WTR astigmatism, the upper lid can more easily hold the lens on the steeper curve of the superior cornea to maintain good centration and stability. A soft flexible contact lens will wrap round the cornea and usually centre well with either type of astigmatism provided the degree is not extreme.

Choice 2. Has fellow eye astigmatism >1.00D and good vision?

If the fellow eye has significant astigmatism (>1.00), then the amount and axis should be considered. The operative method and suture tension can be adjusted in order to produce similar balancing astigmatism to that in the fellow eye to avoid problems of anisometropia.

If the fellow eye has poor vision, good binocular vision is prohibited and the significance of anisometropia is reduced. The poor vision may be due to a developing cataract, so the astigmatism of this eye can be adjusted when the cataract is removed. If the fellow eye has minimal astigmatism, the surgery for the operated eye can be adjusted to encourage the cornea to stabilise with matching minimal astigmatism.

<u>Choice 3. Is fast stabilisation of refraction more important than astigmatism control?</u>

Some patients require a fast stabilisation of refraction so they may rapidly obtain their optimal visual correction. This may be because they need the correction in order to return to work or they rely greatly on the operated eye for independent life. The study indicated that the astigmatism stabilised at about 6 weeks after limbal incision and after 12 to 16 weeks following a corneal incision. Hence the limbal method can be recommended for these patients.

<u>Choice 4. Does operated eye have >1.00 D of preoperative astigmatism?</u>

Significant preoperative astigmatism can be reduced by the choice of surgery method. The study showed that a limbal incision led to a ATR astigmatism shift, so for a patient with preoperative WTR astigmatism, this shift would reduce the astigmatism to a more spherical contour. The study indicated that those patients having a corneal incision had on average, WTR astigmatism, so this would be preferred for a patient with preoperative ATR astigmatism to reduce the amount.

Choice 5. Type of preoperative astigmatism?

Even if the degree of astigmatism is not large, the surgeon may wish to aim towards reducing astigmatism as described in choice 4. The patient would be pleased with their minimal astigmatism which allows good unaided vision in IOL patients and cheaper, faster supply of spectacle or contact lens correction.

The importance of reducing anisometropia, postoperative astigmatism and recovery time was emphasised. A predictive study was carried out where this chart had been used in the consideration of the most appropriate surgery method for each patient. The results of this predictive study are given.

9.1.2 PATIENT GROUPS AND EXPERIMENTAL PROCEDURE

Forty five patients listed for cataract extraction were randomly selected from a similar population and with the same exclusion criteria as those patients in the original study. Nine patients were lost from this predictive study because of inadequate attendance. Five of the nine had general health problems which made travelling to appointments difficult, whilst the four younger ones had good unaided vision and limited commitment. None failed to complete because of ocular inflammation. Of these nine patients, five had a corneal incision, four had a limbal incision; six were female, three were male; the mean age was 68.7 years (SD = +/-16.0). For the thirty six remaining patients there was a good overall attendance record; only nine failed visits from a total of one hundred and eighty (ie. 5%).

Mean age (C) Corneal group (N=17) : 69.6 years (SD =+/-8.7)
(L) Limbal group (N=19) : 63.7 years (SD =+/-13.2)

The age and gender distributions were similar to those in the original study but there was an increased proportion of women.

Mean age Males (N=15) : 63.3 years (SD =+/-14.2)
Females (N=21) : 68.8 years (SD =+/-8.9)

All patients had posterior chamber IOL implants.

The patients were measured preoperatively by refraction, keratometry and regional pachometry in the same manner and with the same precautions as in the original study. Keratoscopy using the PEK was not performed because the PEK shape factor results of the original study were rather variable. They provided insufficient information regarding the peripheral corneal shape changes to be of adequate help in the predictive study. The central corneal curvatures were as satisfactorily and more rapidly measured by keratometry than by PEK.

Two experienced surgeons and one observer were involved. The surgical methods were the same as in the original study but the surgeons chose to use 10/0 nylon sutures in all cases. During the years of the original study surgical techniques changed such that virgin silk sutures became rarely used. Therefore the relevance of the protocol chart changed. Recommendations for corneal incision method with nylon sutures were still valid, but one could no longer recommend a limbal incision to cause a ATR shift in astigmatism because this wound would behave differently when controlled by nylon sutures. The preoperative corneal measurements and the protocol chart in Table 9.1 were used in order to help the surgeons to decide whether the astigmatism should be minimised or adjusted to balance with that of the fellow eye.

This predictive study was compromised on a few occasions when the chart indicated a ATR shift, by using a limbal incision with silk sutures, but the surgeons chose to use nylon sutures. By this time silk sutures were rarely used. However, the second study was carried out to compare the corneal parameter changes of limbal versus corneal incision with both groups receiving nylon sutures.

The surgical method was noted and the measurements were repeated at the patients clinic visits at 2, 6, 12, and 24 weeks postoperatively. The data gathered on the astigmatism and corneal thickness were analysed statistically by 't' tests, by ANOVA and by correlation, as listed in Table 9.1. Table 9.2 gives the mean refraction astigmatism results according to the three subgroups. These were as follows: PS = Push to spherical, which aimed to reduce existing astigmatism to a minimum (N = 16), FS = Fast stabilise, where there was minimal existing astigmatism so either operation method could be used, but that which gave a more rapid stabilisation time was preferred (N = 12), and MA = Match astigmatism, where the aim was for stabilised astigmatism to more closely match that of the fellow eye (N=8).

As mentioned in Chapter 8, although ocular astigmatism was measured by refraction, because the patients poor vision affected subjective responses the objective measurement of corneal astigmatism by keratometry was felt to be more reliable. Hence preoperative astigmatism in Table 9.2 is corneal astigmatism given in dioptres.

9.2 RESULTS

When the surgeons felt it appropriate to use the flowchart, the results were as follows:

9.2.1 Astigmatism measured by refraction and keratometry

Most of the thirty six patients were pleased with their good unaided vision and minimal astigmatism, or with a refractive correction which balanced with that for the fellow eye. In cases 8, 10, 11, 12, 25 and 31, for reasons not given, the surgeon chose a different method from that recommended.

In case 8 the fellow eye was blind and had only 1.00D ATR astigmatism, so the faster stabilisation of refraction more common following a limbal incision was recommended. Although a (C) method was performed, hence spectacles were only prescribed after the twelve weeks stage, the degree of astigmatism was acceptable.

The three patients in cases 10, 11 and 12 were dissatisfied with their final astigmatic result. A high degree of postoperative astigmatism was found in cases 10 (4.25D WTR) and 12 (4.00D ATR) but the fellow eye had reasonable vision and a low degree of astigmatism. Although this large amount of astigmatism was emphasised on their clinic notes, no suture adjustments were carried out. This problem also occurred in cases 15 (3.50D WTR) and 27 (1.50D ATR) who had the recommended operation method but incorrect suture tensions. The large degree of anisometropia led to adaptation problems with binocular control and image distortion. A small suture adjustment was attempted after the 12 week follow-up visit.

In case 11 the patient had a postoperative result of good unaided vision and a small degree of stabilised astigmatism (1.00D WTR). However, he complained of binocular fusion difficulty with the fellow eye, which had good visual acuity with a long standing high astigmatic correction of 4.25D ATR. He had low tolerance of this 5.25D of anisometropia and preferred to wear his old prescription spectacles to which he was well adapted rather than concentrate with the operated eye.

In cases 25 and 31, although the corneal incision method performed was different from the limbal method which had been recommended, the optical outcome was satisfactory. The astigmatism in case 25 remained at 1.00D ATR which was adequately similar to the 2.00D ATR of the fellow eye. By the six weeks stage, the 0.50D WTR astigmatism in case 31 was low as desired.

Of those nine patients who had to be excluded due to poor attendance, three cases had a higher degree of astigmatism than had been anticipated. In case 2, the patient was pleased to return to work by the six weeks stage and had 1.00D ATR astigmatism in the fellow eye so the 2.25D ATR astigmatism in the operated eye proved acceptable. In case 4, the fellow eye had very poor vision so there was no disturbance due to anisometropia. The fellow eye in case 5 had 2.50D WTR astigmatism so the 3.50D WTR of the operated eye, although at an oblique axis, gave a reasonable balance.

There was no significant difference at the $p<0.50$ level between the (C) group and the (L) group preoperative values, so they could be considered as being from the same population. Astigmatism actual values and postoperative changes still showed a relatively large variation. As shown in graphs in Figs 9.1 and 9.2, at each stage the mean change from preoperative value was less for the (L) group than for the (C) group, but this was not statistically significant. As predicted, the (L) group rapidly stabilised to minimal astigmatism levels by the six weeks stage.

<u>Ocular astigmatism by refraction</u>

ANOVA on actual values and on changes (Table 9.1) showed no significant difference at $p=0.05$ level between the means of groups (C) and (L) at each stage. By 6 weeks, the (L) group returned to a similar astigmatism amount as that found preoperatively, whereas even by 24 weeks the (C) group showed a mean change of 1.07D WTR. Ocular astigmatism showed no significant difference between groups (C) and (L) probably because the variability affected the statistics. Both groups (C) and (L) stabilised at small values of astigmatism which was the main desired outcome. Considering the 2 weeks stage mean changes, the (L) group in this second study had 1.00 D WTR compared to 1.75 D ATR for the (L) group in the original study, where there had been a greater shift towards ATR astigmatism.

This emphasised the difference caused by consideration of astigmatism and the use of nylon sutures. ANOVA on the combined group of (C) and (L) showed a significant time effect for actual values ($F = 2.45$, $df = 167,4$, $p<0.05$), as agreed by correlation, but this was not proved significant for the postoperative changes ($F = 1.26$, $df = 132,3$, $p>0.05$) due to the variability in the results. ANOVA showed no significant time effect on changes because the variability was large, (C)$F=0.26$, $df=3,61$, $p>0.05$, (L) $F=1.6$, $df = 3,67$, $p>0.05$, although correlation appeared significant at the 5% level .

't' tests on the preoperative values of the two study batches, i.e. the original study (N=105) and the predictive study (N=36), showed no significant difference between the (C) groups ($t=1.30$) nor the (L) groups ($t=0.50$), so they could be considered as being from the same population. By 6 weeks, the two (L) groups became very dissimilar as the first group progressed to ATR astigmatism.

At 24 weeks, the (C) groups were similar (t=0.25) but the (L) groups were significantly different (t=1.97, p<0.05). This indicates a more controlled postoperative astigmatism outcome for the second study (L) batch.

<u>Corneal astigmatism by keratometry</u>

The relationships with time as shown by mean actual values and by changes are shown in Figs.9.1 and 9.2. ANOVA showed no significant difference between the group actual mean values nor between group changes, but did show a significant time effect (actual values: F=4.48, df=4, 166, p<0.01, changes: F=5.14, df=3, 131, p<0.01), agreed by correlation. When retested for each group separately, (C) had a significant time effect (F=3.46, df=3, 64, p<0.05) but (L) did not (F=1.80, df=3, 63, p>0.05). This suggests that the (L) method induced only slight changes.

Ocular astigmatism stabilised by the 12 week stage and for the (C) group was always greater than the original value. Corneal astigmatism by keratometry was a more accurate method of astigmatism assessment and here it indicated a closer similarity between the groups, which obtained a low stabilised astigmatism value. By 6 weeks the (L) group changes were small and almost stabilised at minimal change from preoperative value, but the (C) group took 12 to 24 weeks to stabilise at this level.

On comparison to the original batch (N=105), this predictive study batch (N=36) showed only small final astigmatism values,

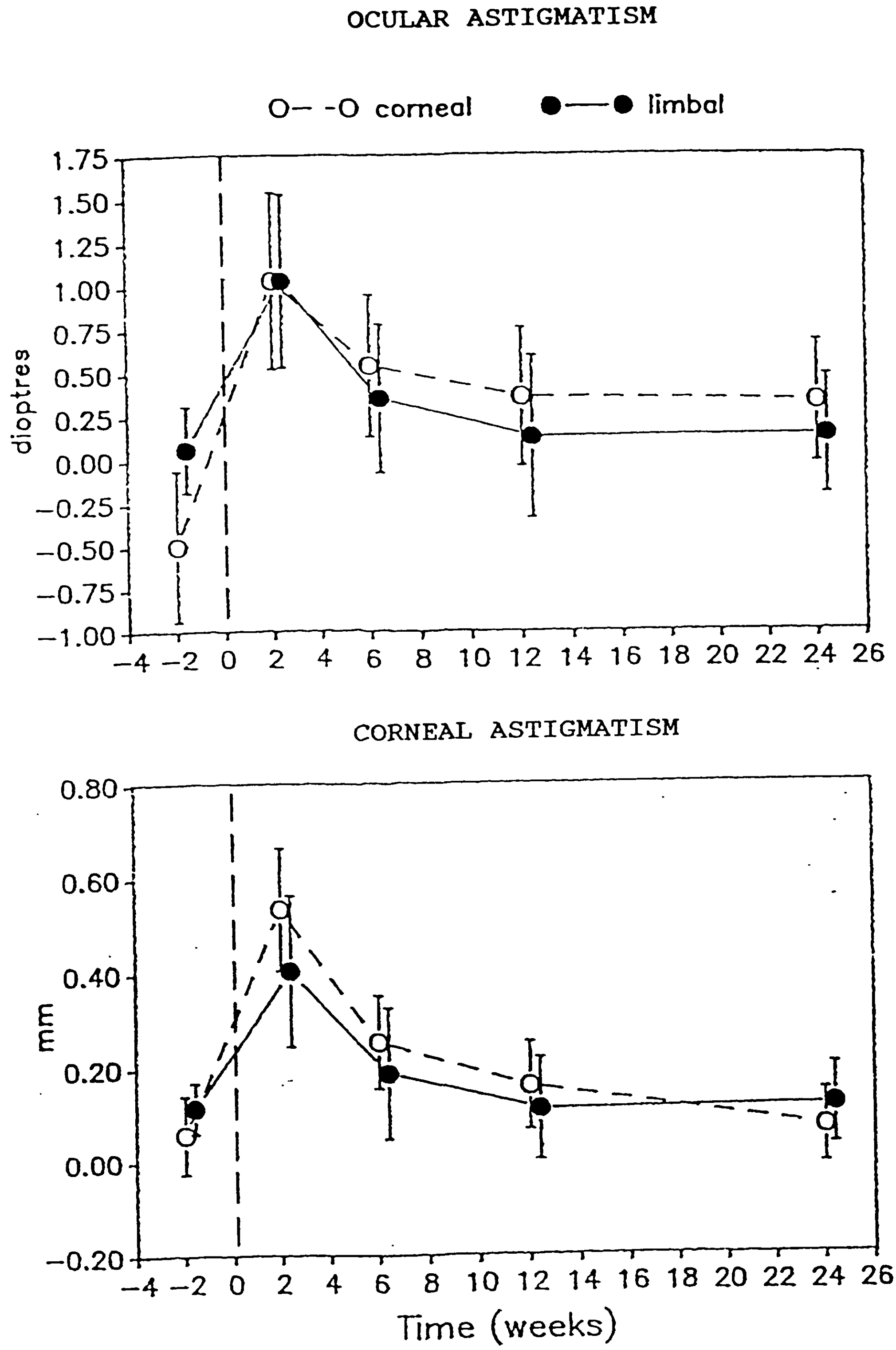


FIGURE 9.1. OCULAR ASTIGMATISM AND CORNEAL ASTIGMATISM RELATED TO TIME

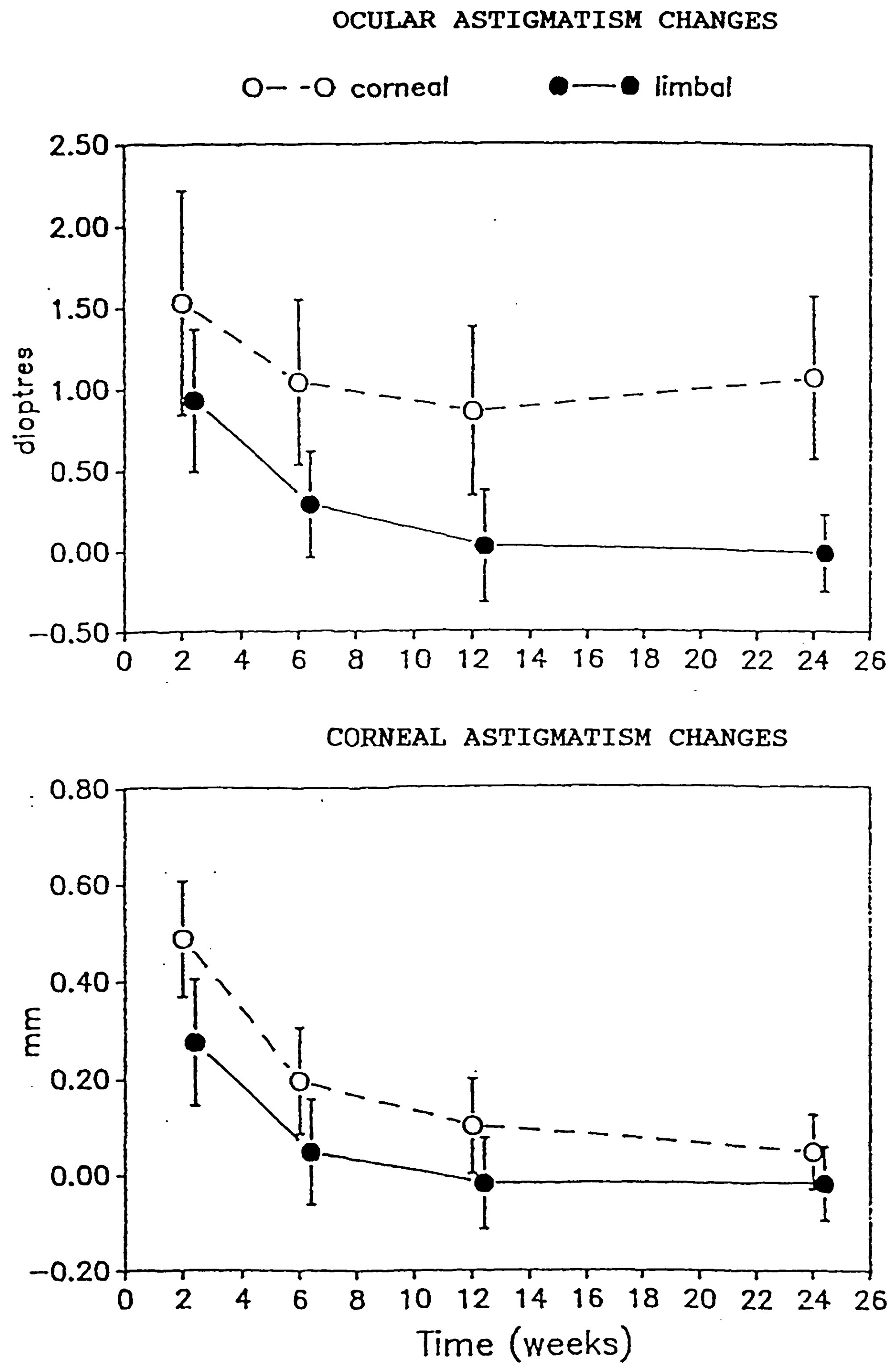


FIGURE 9.2. OCULAR ASTIGMATISM AND CORNEAL ASTIGMATISM CHANGES RELATED TO TIME

and no large shift towards ATR astigmatism for the (L) group. On comparing the preoperative mean values, there was no significant difference at p=0.05 level between the two (C) groups (t=0.38) nor between the two (L) groups (t=0.55) so there were from similar populations. However, at the 24 week stage, the two (C) group means were not significantly different at p=0.05 level but the two (L) groups differed significantly (t=2.64, p<0.01). This difference was noted from 6 weeks when the first (L) group had their ATR shift in astigmatism.

For most of the predictive study patients, the astigmatism had been successfully controlled such that it stabilised at a minimal level or was balanced with that of their fellow eye. The original study ocular astigmatism results indicated that, on average, a (C) incision led to a +0.50D (WTR) astigmatism shift and a (L) incision led to a -1.00D (ATR) astigmatism shift.

The predicted postoperative astigmatism was estimated according to the surgical method carried out. The difference between the predicted amount and the actual corneal astigmatism at 24 weeks (as measured by the dioptric equivalent by keratometry) was recorded. The overall mean difference was +0.25D, SD=+/-1.73. The mean difference for patients undergoing (C) method was -0.43, SD=+/-1.46, and for (L) method was +0.86D, SD=+/- 1.77. In addition to high variability, these results indicated that for the predictive group there was a tendency to over estimate the WTR shift for the (C) group and also the ATR shift for the (L) group, as the response was different to that of the (L) group of the original study. For the poor attenders (N=9) the mean difference between the predicted astigmatism and that at 24 weeks was +0.20D, SD=+/-2.21. This was not significant.

The 'push to spherical' subgroup. This group of 16 patients, where the aim was to push the corneal curvature towards a spherical value, were reconsidered separately. Cases 10, 12, and 31 were omitted because the recommended surgery method was not carried out by the surgeon, and also case 15 because this was an unusual instance of distortion due to over tight sutures. This subgroup of 13 showed no significant difference at p=0.05 level in preoperative mean astigmatism values (by either refraction or keratometry) from those of the original group of 105, so they were from a similar population. Comparing astigmatism at the 24 weeks stage, the two (C) groups showed no significant difference from each other but the two (L) groups did so (ocular astigmatism by refraction, t=2.98, p<0.01; corneal astigmatism by keratometry, t=3.75, p<0.01). At 24 weeks, neither the mean ocular astigmatism value (mean =0.62 D, SD=+/-1.28) nor the mean corneal astigmatism value (mean =0.20 mm, SD=+/-0.28) were significantly different from zero (spherical).

For the subgroup of 16, the mean difference between the predicted astigmatism and that at 24 weeks (equivalent dioptric power of the keratometry astigmatism) was +0.33D, SD=+/-1.74, which became +0.19D, SD=+/-1.09 when the six cases of high degree astigmatism due to suture tension or high degree of preoperative astigmatism were omitted. The results of this subgroup indicated that the attempts to minimise existing astigmatism towards a spherical end result to improve unaided vision had been generally successful.

9.2.2 Corneal thickness

The mean actual thickness values and postoperative changes are shown in Figs 9.3 to 9.8. For each of the five corneal regions, ANOVA showed no significant difference between optype groups. For the superior corneal region combined group actual values, ANOVA showed a significant time effect (F=20.57, df=166,4, p<0.01), as agreed by correlation. ANOVA showed a significant time effect for postoperative changes (F = 28.65, df=3,131, p<0.01), which was also found for each group separately, (C) F=14.61, df=3,60, p<0.01 and (L) F=14.19, df=3,67, p<0.01.

For the central corneal region combined group actual values, ANOVA showed a significant time effect (F= 8.25, df=4,166, p<0.01), as agreed by correlation. ANOVA on the combined groups corneal changes showed a significant time effect (F = 15.86, df =3,131, p<0.01), which was also true for the two groups separately, (C) F=5.88, df =3,60, p<0.01 and (L) F=10.24, df= 3,67, p<0.01. Correlation confirmed this significant corneal response to the surgery.

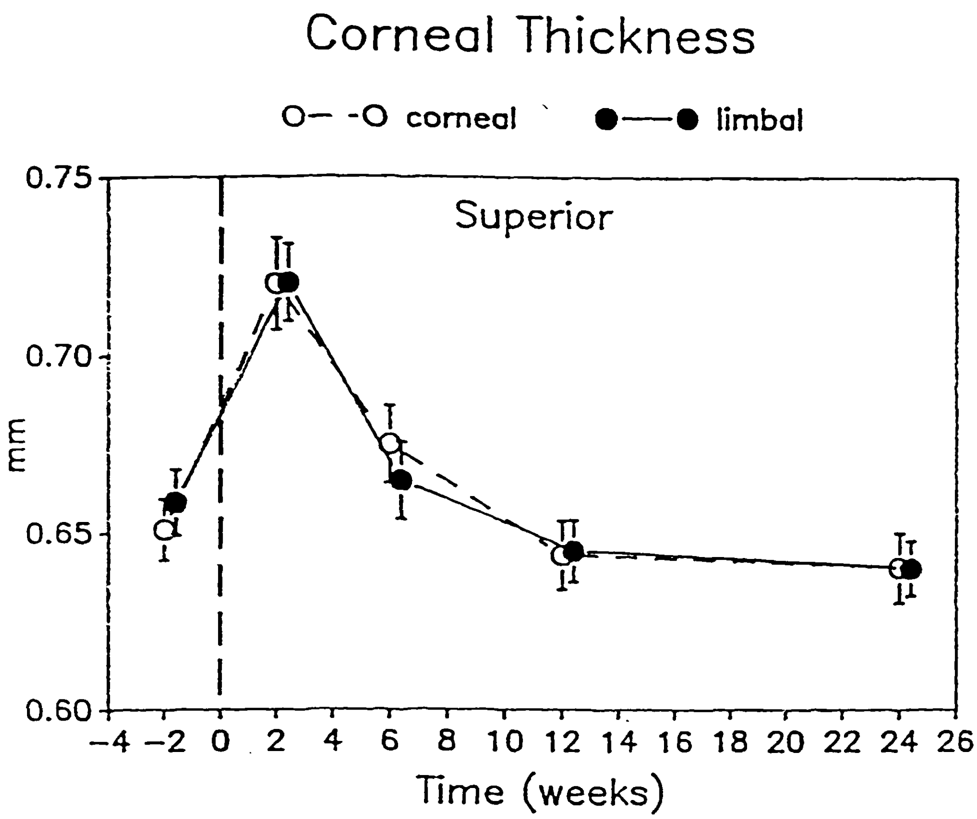


FIGURE 9.3 SUPERIOR CORNEAL THICKNESS RELATED TO TIME

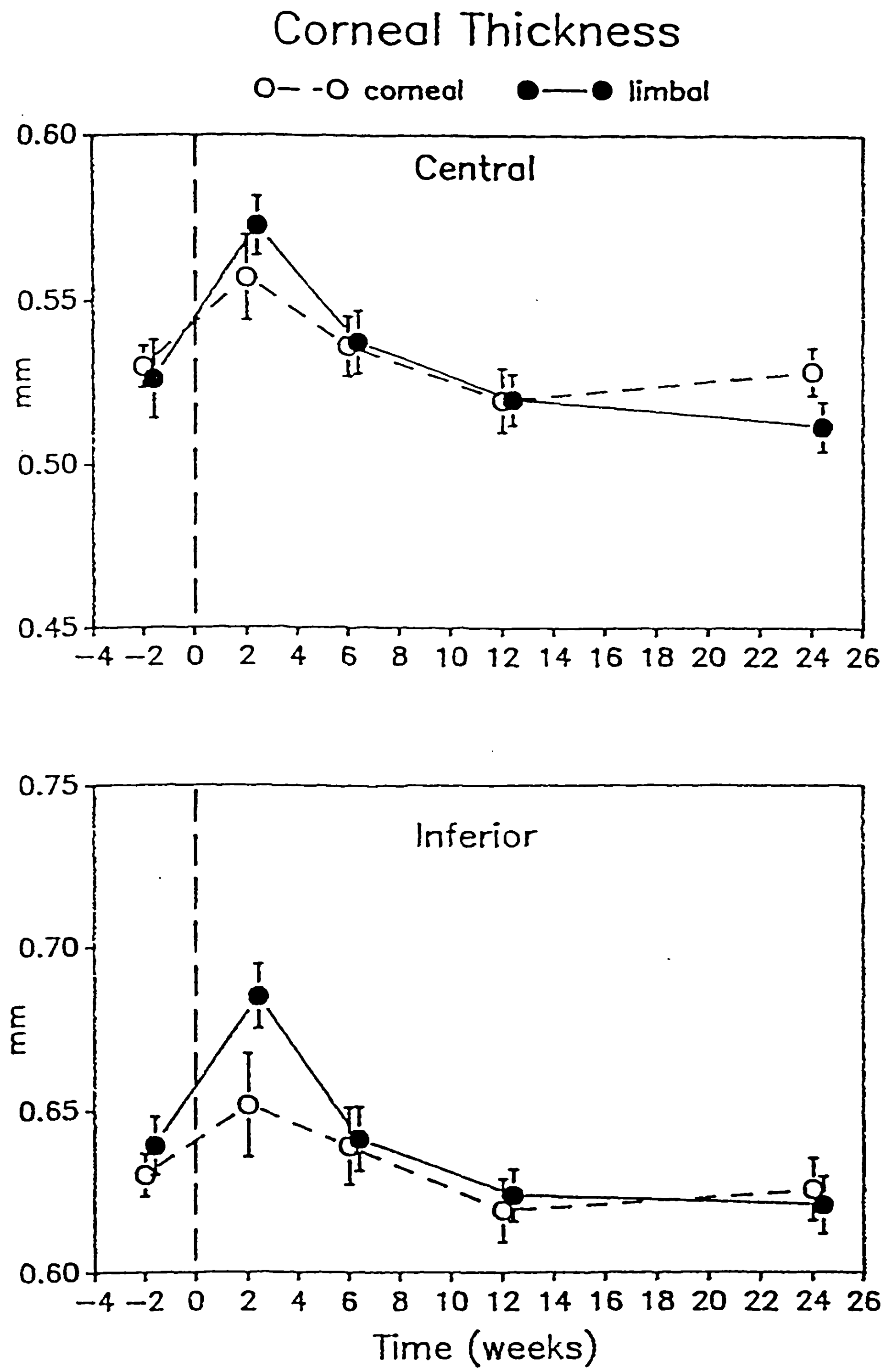


FIGURE 9.4. CENTRAL AND INFERIOR CORNEAL THICKNESS RELATED TO TIME

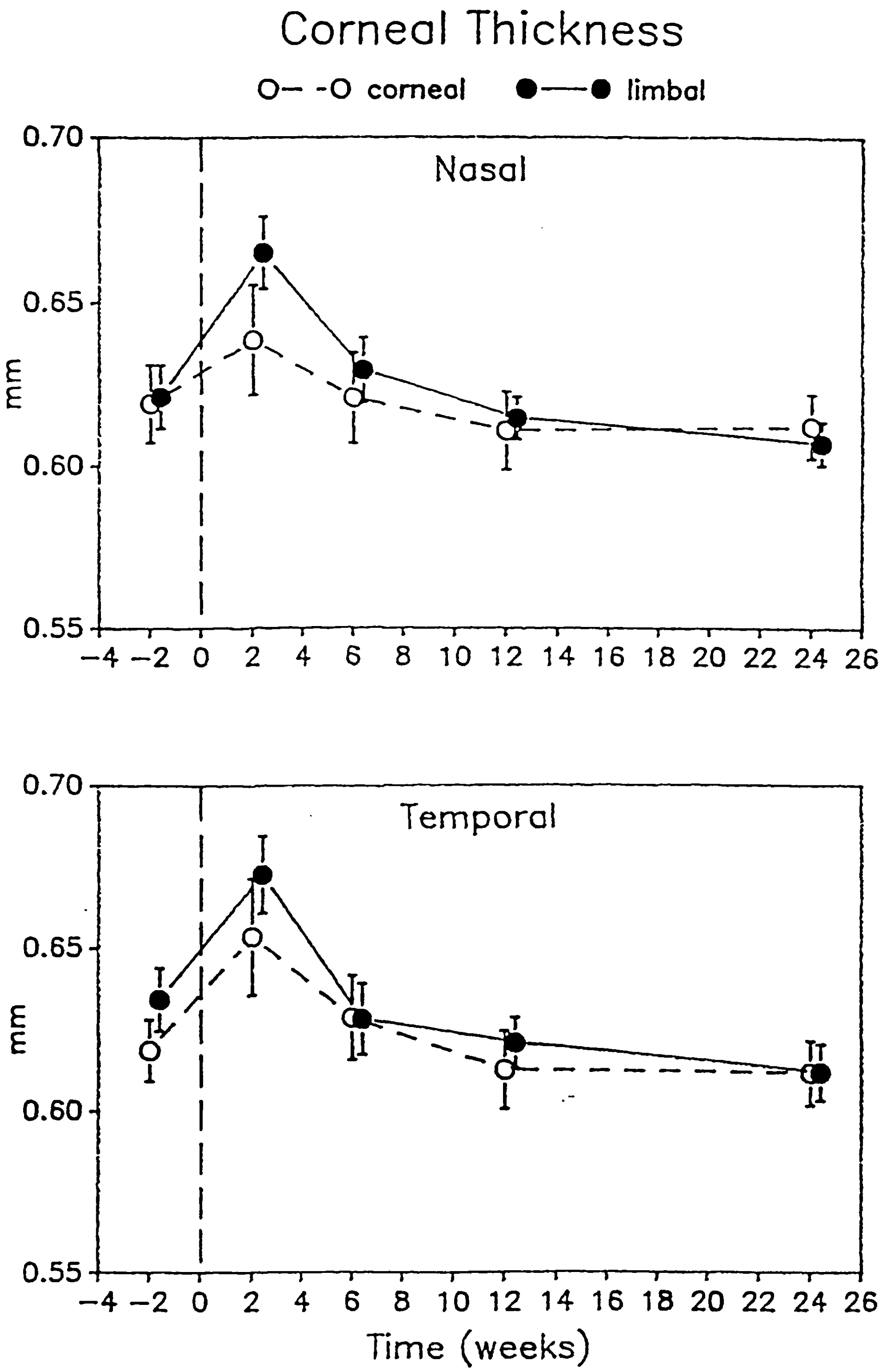


FIGURE 9.5. NASAL AND TEMPORAL CORNEAL THICKNESS RELATED TO TIME

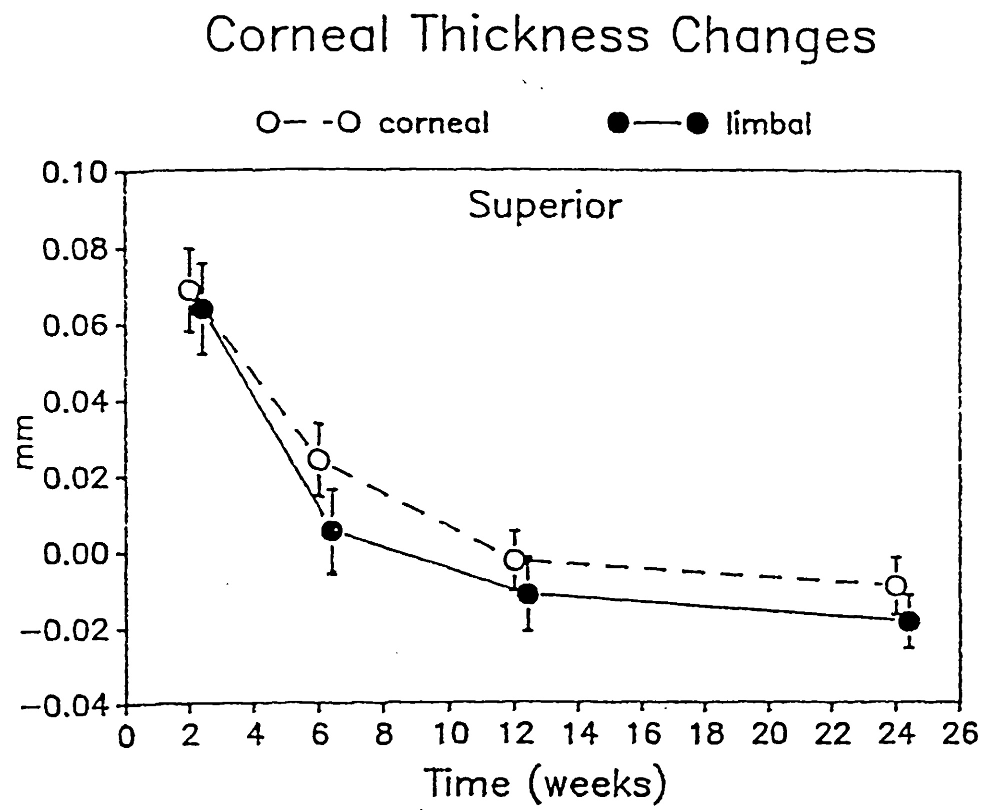


FIGURE 9.6 SUPERIOR CORNEAL THICKNESS CHANGES RELATED TO TIME

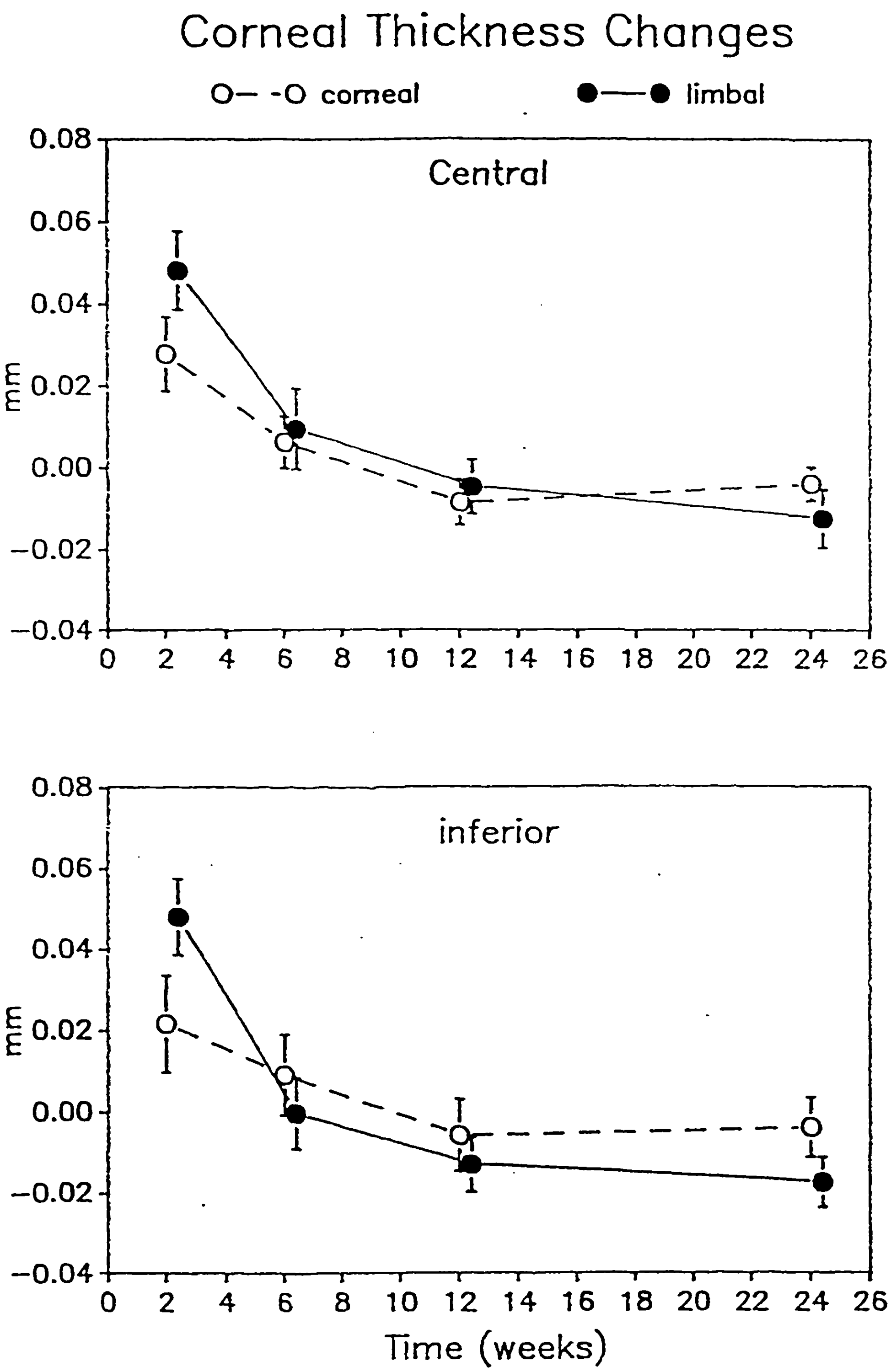


FIGURE 9.7. CENTRAL AND INFERIOR CORNEAL THICKNESS CHANGES RELATED TO TIME

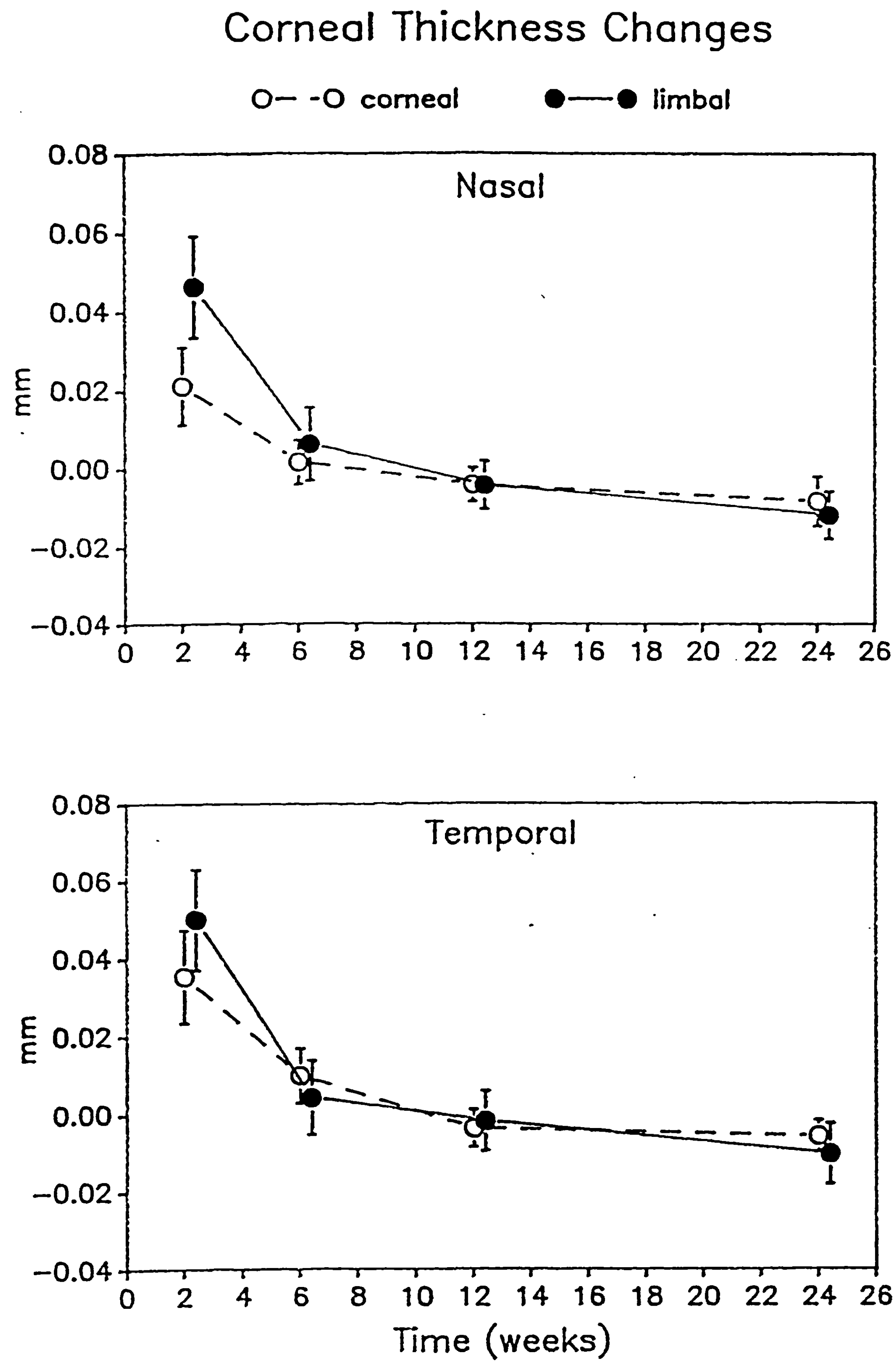


FIGURE 9.8 NASAL AND TEMPORAL CORNEAL THICKNESS CHANGES RELATED TO TIME

ANOVA showed a significant time effect on the inferior region combined group actual values (F=7.01, df=4,166, p<0.01), and also on the combined group mean changes (F=11.7, df=3,131, p<0.01). When mean changes in (C) and (L) groups were analysed separately by ANOVA, the (C) group showed no significant time effect (F=1.64, df =3,60, p>0.05). There was a thickness increase due to the operation but the large SD values inhibited demonstration of the significance.

The (L) group mean changes did show a significant time effect (F=14.45, df =3,67, p<0.01). This suggested that the thickness response to the operation rapidly recovered with less variability in the results obtained. Correlation for the (L) group agreed with this, as the graph plateau showed no significant time effect.

For the nasal corneal region results, ANOVA showed a significant time effect for combined group actual values (F=4.82, df=4,166, p<0.01) and also for changes (F=11.74, df=3,131, p<0.01). ANOVA showed a greater significant time effect for the (L) group (F=8.41, df = 3,67, p<0.01) than for (C) group (F=3.42, df =3,60, p<0.05). The (C) group underwent a thickness increase due to the operation but the variability in results affected their significance. Correlation for actual values was significant p<0.05, but for changes there was no significance after the 6 weeks stage.

For the temporal corneal region, ANOVA on the combined group showed a significant time effect on actual values ($F=6.52$, df $=4,166$, $p<0.01$) and on changes ($F=13.12$, df $= 3,131$, $p<0.01$). ANOVA on group changes showed a greater significant time effect for (L) group ($F = 7.52$, df $=3,67$, $p<0.01$) than for (C) group ($F= 5.58$, df $=3,60$, $p<0.01$). This was partly because the (C) group results were more variable. Correlation for actual values and for changes showed no significance after the 6 weeks stage. On comparison of the two batches, for each of the corneal regions in turn, no significant differencein the thickness was found between the (C) groups nor between the (L) groups. This was true for each of the time stages.

9.3 DISCUSSION

The measurements at the preoperative stage informed the surgeon of the patients astigmatism and helped him decide whether this should be minimised or adjusted to balance with that of the fellow eye, whose astigmatism was also measured. The best corrected visual acuity was checked. Corneal thickness was recorded to assist in monitoring postoperative changes. The 2 weeks stage information recorded the best corrected visual acuity, and indicated whether tight sutures were causing a large degree of astigmatism and whether the corneal oedema response was within normal range. The 6 week stage measurements allowed a preliminary prescription of spectacle correction or suture adjustment to be carried out where necessary.

Pachometry ascertained whether the cornea remained oedematous or was returning to normal thickness. The 12 week stage measurement allowed the determination of the main spectacle prescription if this had not already been done. A few patients were able to have further suture removal to minimise astigmatism where necessary. The 24 week stage measurements confirmed the stabilisation of the corneal parameters and patients satisfaction with the results.

Corneal astigmatism by keratometry showed a closer similarity between the two groups (C) and (L) than that demonstrated in the first study. The astigmatism induced by the operation was also less; eg. mean changes at 2 weeks, first study: (C) =0.60 mm, (L) =0.45 mm, second study: (C) =0.49 mm, (L) =0.28mm. Both groups stabilised at a small astigmatism value as was usually desired. The (L) group did not present the large shift to ATR astigmatism exhibited by the first study group and less postoperative changes were demonstrated. Examination of the records revealed that in most cases any residual astigmatism was acceptable to the patient because it balanced with their fellow eye. Many patients were pleased that their optical outcome provided minimal astigmatism and good unaided visual acuity. Had it been possible to eliminate further variables in the surgical technique, more information could have been obtained. However, during the procedure, there are so many variables affecting the surgeons choice of technique that this type of study can never insist on rigorous adherence to a protocol to the possible detriment to the patient.

On considering the corneal thickness changes, for the superior region, both groups (C) and (L) showed a similar postoperative response and by 12 weeks they stabilised to a value not significantly different from preoperative value. This indicated that both methods disturb the cornea similarly even though greater disturbance would usually be expected after a corneal incision. For the other corneal regions both groups responded similarly, although (L) group showed greater change at 2 weeks than did (C) group. These results indicated that immediately following the operation (L) method disturbed the thickness of all the cornea to a greater extent than did the (C) method, but by 6 weeks recovered to a similar thickness to the (C) group.

Apparently, each of the regions stabilised at a mean thickness less than the preoperative value but this was not significant statistically. Superior and temporal regions suffered greater thickness changes than did the other regions in the first study, but only the superior region showed the greatest changes in the second study.

This predictive study showed that consideration of preoperative measurements was helpful in obtaining the preferred stabilised optical correction, usually aiming for minimal astigmatism. It further demonstrated the advantage of obtaining refraction and corneal parameter measurements including corneal thickness at each of the clinical appointments, so that the clinician had up to date information to assess postoperative recovery and to promptly decide at what date spectacles should be prescribed or sutures removed. The patients were pleased that the regular refractions revealed good potential visual acuity. Those who were anxious about their poor vision postoperatively were reassured that their operation had been successful.

A greater proportion of the patients than in the first study obtained a more rapid and reduced astigmatism optical outcome. The stabilised optical corrections were balanced where necessary with those of the fellow eyes, except for one case where the operated eye achieved a good, rapidly stabilised, minimal astigmatism refraction but the patient had previously adapted to an astigmatic spectacle correction for both eyes and was reluctant to adapt to any refractive changes.

The preoperative record of pachometry, especially whether the cornea was unusually thick or thin, was useful. Postoperative monitoring also gave a quantifiable indication of corneal recovery, particularly important if the IOP was raised. An important feature was that in the first study the limbal incisions were closed with silk sutures, whereas 10/0 nylon sutures were chosen by the surgeons in the second study. Silk sutures were weaker, led to a more hyperaemic conjunctival reaction and lost strength in the first 4 to 8 weeks so allowing some wound gaping and ATR astigmatism shift. Although nylon was elastic, hence making knots more difficult to tie, once in situ with the knots carefully buried to avoid irritation, it was a good choice of inert suture material and allowed suture adjustment for astigmatism control at several weeks postoperatively.

From this predictive study on 45 patients it has been demonstrated that the use of the flowchart guide in Table 9.1 and the associated preoperative measurements was helpful to the surgeons in determining the optimum procedure to be adopted, to the advantage of the patients. The two surgeons involved continued to consider the flowchart recommendations and preoperative measurements when dealing with current patients.

CHAPTER 10

DISCUSSION

10.1 INTRODUCTION

In the past, cataract extraction technique was chosen with less consideration of the astigmatic outcome. Some surgeons chose a corneal incision to avoid the hyperaemic tissue reaction following a limbal incision whilst others preferred a limbal incision to avoid the endothelial damage often following a corneal procedure. Corneal parameters were presumed to stabilise at twelve to sixteen weeks postoperatively, whatever method, and determination of optical correction was only begun after that time. Recent improvements in surgical equipment, operating microscopes and techniques allow more attention to be paid to obtaining the best refractive surgical outcome after cataract extraction, including minimising astigmatism.

The stabilised postoperative corneal astigmatism has a bearing on the final visual outcome, whether corrected by spectacle lens, contact lens or intraocular lens. The amount and type of postoperative corneal astigmatism and peripheral curvature affects the quality of vision, for example, the degree of spherical aberration, relative magnification and prismatic effect, the binocular balance and in the case of contact lenses, the stability of the lens fit. The supply of optical correction is easier and more rapid when astigmatism is kept to a minimum.

Therefore it is important to investigate corneal parameter changes following surgery in order to improve the optical management and the efficiency of the service given to these patients. In more recent years, surgeons have become increasingly interested in the refractive outcome, both to minimize astigmatism and to obtain improved unaided vision with IOLs (Hall, et al 1993). Some of the popular methods are selective suture removal and small incision surgery techniques.

Few previous studies have measured peripheral corneal thickness changes. Those described in this thesis reveal interesting results. The Corneal incision method had been expected to lead to greater corneal oedema and thickness increase, resulting from the direct corneal trauma. However, the Limbal method resulted in similar degrees of corneal oedema, possibly due to tissue inflammation, but this oedema recovered more rapidly.

In the first of these two studies, the two groups of cataract extraction patients, (C) with corneal incision and nylon sutures, and (L) with limbal incision and silk sutures, were compared regarding their postoperative changes in corneal curvature and thickness. Information gained indicated that the (L) group patients showed faster stabilisation of their ocular parameters, so they could achieve best corrected visual acuity and return to work and independent life more quickly. This information was incorporated in the design of the final predictive study, described in Chapter 9, where the surgeon took into consideration the preoperative measurements when attempting to optimise the refractive outcome for each patient.

10.2 CONSIDERATIONS IN PERFORMING MEASUREMENTS

10.2.1 Problems in monitoring

Cataract surgery involved many variables: surgeon, surgical method, suture technique and tension, medication, patients health and ocular parameters, so it was not possible to keep almost all the influences constant, and study only one factor.

The study results therefore give an overview of the trends of cataract extraction surgery over a certain time period at one hospital. The close monitoring at every two weeks for the first study and four to six weeks for the second study meant that these were very time consuming but gave a better description of the progress of the corneal changes than did the majority of previous reports by other authors. Some problems in the regular monitoring arose because both studies were carried out on a part time basis avoiding interference of the clinics so that patient sampling was over a long time period.

Preoperative refraction was difficult because the patients visual acuity and the retinoscopy reflex were poor due to their cataractous lens opacities. The changes in astigmatism from preoperative values were more accurately monitored by corneal astigmatism (keratometry) than by ocular astigmatism (refraction) Simple bright light targets for ease of fixation, an experienced observer, and extra time and patience allowed for the measurements were advantageous. The thorough preoperative refraction sometimes revealed visual acuity improvement by a new spectacle prescription, so it was possible to avoid the surgery.

Several difficulties arose when dealing with the frequent visits of the large group of patients eg. failed appointments led to gaps in the data which complicated the statistical analysis. Some patients failed to attend because they were keen to return to work quickly, others were elderly with mobility and general health problems. Few were lost to the study due to ocular complications. The sample at 24 weeks was reduced because some patients had to be excluded since by that stage they had undergone suture removal or contact lens fitting which influenced the corneal astigmatism.

10.2.2 <u>Value of parameter measurements</u>

Keratometry proved to be clear, objective, rapid, simple to use and more accurate than refraction as a measure of corneal astigmatism. Observation of any distortion of keratometry mires provided a guide for monitoring postoperative corneal astigmatism including that due to suture tension. Several surgeons found this useful when deciding on selective suture removal. Keratoscopy had been expected to provide valuable information on peripheral corneal contour changes. The PEK instrument seemed to give reasonably repeatable results during calibration on younger, very co-operative patients. However, the shape factor results on these elderly patients showed such variability that this questions the value of its use on patients with poor visual acuity and therefore poor fixation. Hence the PEK was not included in the final prospective trial. There was a very significant relationship ($p<0.01$) between the PEK and keratometry readings regarding central curvature.

No significant relationship was found between peripheral shape factors and central corneal astigmatism.

Regional pachometry results gave useful information. A very thin cornea could be suspected of a tendency to additional distortion due to suture tension, or a very thick cornea could indicate a naturally occurring low endothelial cell count and hence a susceptibility to corneal oedema. The results revealed that superior and central regions best indicated the corneal thickness response to the surgery. As the central corneal region is important for vision, it was important that any changes in this region should also be closely monitored.

10.3 RESPONSE OF THE CONTROL GROUPS

Although the fellow eyes of patients were used for the Control group, in case there was some unknown relationship between the eyes, a separate control group of Non-operated patients was enlisted. A larger standard error of the mean (SEM) was shown by the Control group than by the Non-operated group, who had better health and unaided vision. Both groups showed insignificant changes in corneal astigmatism and corneal shape during their 16 to 24 weeks monitoring period. They were useful to help the judgement of the results of the operated patients when determining stabilisation times.

The variation of the Control group results was greater than originally anticipated, particularly vertical shape factor at the 8 weeks stage. It was unlikely that the fellow eye had responded sympathetically to operated eye changes otherwise greater changes would have been noted in the early postoperative period. A more probable explanation is that there were fewer patients attending at that appointment (only 7 of 13), so giving an unrepresentative data set. The wide variation in shape factor values shown by Control and Non-operated patients was disappointing, but this evidence assisted the interpretation of the similar irregular pattern demonstrated by the operated group.

On consideration of corneal thickness changes, both Control and Non-operated groups showed no significant time effect. The Control group showed by 't' test of the overall means a significant change ($P < 0.01$) from the preoperative values of the superior and central regions; also the mean central thickness was 0.48mm. This was thinner than normal due to very low values measured on some of the control eyes. A large variation in the measurements is understandable in an elderly, reduced vision, possibly inaccurately fixating patient group, but these apparent thickness changes were puzzling.

10.4 RESPONSE OF THE PATIENTS

10.4.1 Corneal topography

The results confirmed those found in the literature (see Chapter 3) that limbal incisions with silk sutures produce an ATR shift in stabilised astigmatism whereas corneal incisions with nylon sutures produce a small WTR shift. A major factor is the use of silk sutures which biodegrade and weaken within a few weeks and allow wound stretching, leading to ATR astigmatism as described by Reading (1984) and by Dekkers and Buijs (1989).

For the (L) group, a good indication of the final astigmatism was gained at week eight and following this only small changes were detected. Therefore an optical correction could be prescribed at the eight week stage. This is slightly sooner than the twelve to thirteen weeks quoted by Baraynovits (1990). He proposed that the refraction astigmatism stabilised at four to five months following the use of corneal incision and nylon sutures, with which this study agreed.

The results also concur with those of Jaffe and Clayman (1975) and Gills (1974) who described the greater incidence of WTR astigmatism following a corneal incision, especially if closed with deep firm sutures. A number of previous studies eg. Bambery (1986), suggested that a corneal incision causes a higher degree of astigmatism as it affects the cornea more directly than does a limbal incision. This study did not find a significant difference between the two groups regarding the degree of astigmatism but did so on comparison of postoperative changes and variance at each stage. Bambery advised suture division several weeks postoperatively to relieve high degrees of astigmatism where necessary. This is advantageous and is more easily achieved and controlled with nylon sutures. Silk sutures degrade after only a few weeks so they cannot then be adjusted. Suture removal is also more facile from an easily accessible corneal incision rather than a subconjunctival incision.

The results agree with Floyd (1951) who indicated that rapid astigmatism changes occurred within the first four weeks postoperatively then slow down in the following three months. The data demonstrate the wide variability of the values, which had been shown by Beasley (1967) and which can continue for at least 6 months postoperatively, as suggested by Gills (1974). Few studies have tried to relate the preoperative and postoperative astigmatism to reveal trends. Floyd found that by six months the astigmatism had settled to a level similar to that shown preoperatively but the vertical meridian had slightly steepened.

The current study generally agreed with this but found no predictable significant relationship between preoperative and postoperative values. This was probably because the influence of the sutures and wound healing was greater than that of the original corneal topography. However, there is support for the idea suggested by Jampel et al (1986) that each surgeon should determine the typical astigmatism changes he causes by his personal suture method, then he can plan his surgical technique according to the preoperative astigmatism values.

The (L) group showed a larger astigmatism change from the immediate postoperative stage to the stabilisation stage (twice that of the (C) group) which some patients might have found disturbing, but the shorter time to best corrected stabilised vision was more important.

For the (C) group, the optical correction could be prescribed at the twelfth to sixteenth week stabilised astigmatism stage. Both groups stabilised at similar degrees of astigmatism even if at different axes, so those patients intended for IOL and spectacles could have either operation. If the proposed management included rigid contact lens fitting, then WTR astigmatism and a positive shape factor gave the advantage of easier fitting and more stable lens centration during the future years of lens wear.

In the predictive study with the second batch of patients, the astigmatism outcome was more favourable, and the limbal group underwent less astigmatic change. On comparing the corneal groups astigmatism in the two batches, the statistics showed no significant difference at each stage. For the two limbal groups there was no significant difference in preoperative astigmatism, so the groups were comparable. At the 24 week stage, there was a significant difference in ocular astigmatism ($t=1.97, p<0.05$) and in corneal astigmatism ($t=2.64, p<0.01$). This was further emphasised by the 'push to spherical' subgroup of the second study: ocular astigmatism ($t=2.98, p<0.01$) and corneal astigmatism ($t=3.75, p<0.01$). This indicates a marked difference between the outcome of the limbal method of the first study, where the use of silk sutures often resulted in ATR astigmatism, and that of the second study, where the use of nylon sutures resulted in WTR astigmatism.

It was anticipated that the corneal shape factor changes would reveal the different influences of the two surgical techniques on the peripheral corneal contour, particularly vertical shape factor after a corneal incision, but the variability confused the determination of the pattern of changes. There was no significant difference found between the groups, nor between preoperative and postoperative values. Neither was a significant relationship found between preoperative keratometry and postoperative changes in PEK astigmatism, HSF, VSF or corneal thickness.

Limited information has previously been given regarding the peripheral corneal topography of an elderly population such as in these studies. The Non-operated group had mean shape factor values (HSF +0.26 SEM +/- 0.05, VSF +0.25, SEM +/- 0.03) which were similar to the usually accepted SF value of +0.25 described by Bibby (1976). A higher positive SF value indicates a more rapidly flattening ellipse. The Control group had significantly lower mean values (HSF +0.15, SEM +/-0.04, VSF +0.15 , SEM +/- 0.06). The patient group also had low mean values preoperatively as follows: HSF = (C) +0.18, SEM +/-0.02, (L) +0.15, SEM +/-0.03; VSF =(C) +0.21, SEM +/-0.03, (L) +0.19, SEM +/-0.03. These values were notably lower than the Wesley Jessen PEK shape factor of 0.25 (SD 0.35) given by Townsley (1970) and Bibby (1976).

However, they tend to agree with those of Guillon, Lydon and Wilson (1986), who describe the true shape factor as equal to 1 - Wesley Jessen 'shape factor', and give a mean value of 0.83 (SD 0.13) for flat meridians (more commonly horizontal) and 0.81 (SD 0.16) for steep meridians.

Jaffe and Clayman (1975) explained that wound compression such as that caused by thin nylon sutures steepens the vertical meridian and slightly flattens the horizontal meridian to give WTR astigmatism. The flattening was shown in this study by the horizontal shape factor of the (C) group undergoing a negative change from preoperative value. Troutman (1979) suggested that the weak wound tissue of the limbal incision allows flattening of the superior cornea. The study also demonstrated this when the vertical shape factor of the (L) group showed negative changes after eight weeks.

10.4.2 <u>Corneal thickness</u>

Few other workers have reported changes in peripheral corneal thickness changes in a group of elderly patients. Alsbirk (1978) found significant thinning in corneas over age fifty. This agreed with Weale (1971) who suggested that the increased number of stromal lamellae cross links due to ageing can delay corneal swelling.

The current study also found corneal thinning. As shown in Table 6.2, previously reported central thickness values were mostly about 0.51 to 0.52 mm. The Non-operated groups mean value of 0.53 mm was similar to this, but the Control group had a mean value of 0.49 mm. This could not be used to support the suggestion of thinning in elderly subjects since there was not a significant difference between the ages of the sample groups. The Control group consisted only of thirteen members of which a few corneas were markedly thinner than expected and so affected the mean value. The preoperative mean central corneal thickness for the patients was for (C) 0.51 mm, SEM +/-0.01, for (L) 0.52 mm, SEM +/-0.01, which agrees with the normally accepted value. The regional mean corneal thickness results were thinner than those found by Hirji and Larke (1978) in younger patients.

As the corneal incision method directly disturbed the superior corneal region and the sutures were left in place for up to twelve months, it had been expected that the (C) group superior corneal regions would demonstrate greater thickness changes and be slower to stabilise than those of the (L) group. However, both groups behaved in a similar manner, so it was concluded that the (L) group also suffered similar transient corneal oedema in the superior region. Flaxel et al (1969) described the trauma suffered by the wound, the conjunctival flap and the severed episcleral vessels. These tissue disturbances probably explain this greater than anticipated oedematous response. The hyperaemia and tissue inflammation encourages new vessel activity, after which the increased supply of oxygen and nutrients, via the new vessels, assists the oedema to decrease. Apart from the superior region, which was close to the incision, the other regions stabilised at approximately six to eight weeks, although (L) showed more variability than (C). Only when all thickness change data was collated and regressed was there revealed a significant difference between the group means of the operation methods, (L) group showing less overall thickness changes than did (C) group.

It was interesting to note that for both groups the mean values indicated a decrease of 1 to 2% in the superior corneal thickness by the final stage. A hypothesis to explain this is that postoperative visual acuity was so good that target fixation was much improved and therefore a less peripheral area was measured. Changes in the temporal region appeared to be greater than in the nasal region. Possible explanations include:- i) obstruction of view by the patients nose encouraged the surgeon to extend the incision slightly more temporally, so there was a greater postoperative oedema response, ii) due to the visual axis not aligning exactly with the geometric corneal axis, nasal region measurements were nearer to the limbus than were temporal ones; if this was the case, tighter fibril linkage nearer the limbus may have inhibited corneal swelling in the periphery.

An early hypothesis that preoperatively thin corneas would respond more easily to suture tension and show greater astigmatism change was not proved; nor was the theory that greater peripheral thickness changes caused increased peripheral shape changes. As expected, thicker corneas showed greater thickness increase due to the operation than did thin corneas.

This emphasises the point that when pachometry is used as a quantitative indicator of corneal recovery from inflammation or trauma, the change in corneal thickness is more important than the actual value.

No significant difference was found in the results between males and females. This agreed with the investigation of Richards and Brodstein (1986). There was a greater proportion of males in the under age sixty group. This probably reflects the surgeons tendency for males to have their operation at an earlier stage of cataract development, because they were more likely to request good vision for driving and a job.

As regards age, one would expect healing processes and parameter stabilisation to be faster in younger eyes. In the context of this study, there were no young adults, so this comparison could not be made. When observing the tendencies of changes according to whether the patients were under or over age sixty, no significant trends were found.

Cheng et al (1977) noted greater and more widespread corneal oedema after IOL implantation. However, in the present study no significant relationship was found between most of the parameters and the presence of an IOL implant. This was probably because the well designed IOLs were carefully inserted into the lens capsule in the posterior chamber by experienced surgeons who avoided endothelial disturbance or IOL tilting. The IOL patients had a greater mean age because the younger patients were encouraged to have their aphakia correction by contact lenses. This was because they could handle contact lenses more easily than older patients could, also they would need a correction for several future decades, and little is yet known of IOL tolerance in patients using them for longer than twenty five years.

The (C) group corneal thickness was still rather variable by 16 to 24 weeks, so no significant trend was exhibited. The (L) group corneal thickness stabilised by about 6 weeks at a value closely related to preoperative value. Table 8.20 shows that the relationship between postoperative thickness and preoperative value was more significant in the non-IOL patients than in the IOL patients. This was probably because the oedema response was more variable in the IOL patients. This was particularly true for the superior, inferior and temporal regions. A likely reason for this is that insertion of an IOL is liable to require more manipulation of superior and temporal incision margins and flexing of the inferior region when the IOL enters. This can damage the endothelium and cause oedema to a greater extent than does cataract extraction alone.

10.5 RECOMMENDATIONS FOR CLINICAL MANAGEMENT AND RESEARCH

10.5.1 Clinical management

Refraction and keratometry of both eyes should be performed in the clinic when listing the patient for cataract extraction. This screens out those patients who get reasonable visual acuity from a thorough refraction, so have a less urgent need for cataract extraction. Patients with low degree astigmatism may be considered for day case surgery. This allows a more efficient use of time by the surgeon and support staff and it reduces operation waiting list time. Those with high degree astigmatism which requires reduction can be booked for a surgery session designed to allow more time for suture calculation and adjustment. Serial pachometry (peripheral and/or central corneal region) can be used to give a relatively rapid quantitative assessment of postoperative corneal recovery, rather than rely on the variable qualitative assessments.

Routine performance of refraction and keratometry at postoperative clinic visits give the clinician useful information, e.g. highlight those patients with significant astigmatism so that suture adjustments to reduce the astigmatism can be made early and the appropriate clinic time allowed. The clinician may also decide to prescribe temporary spectacles at two to four weeks postoperatively to promote the patients rapid return to work then give a prescription of the stabilised refraction at a clinic visit between six and sixteen weeks postoperatively.

The patient would have been warned of the probability of this procedure and of suture adjustments, when reading the preoperative explanation leaflet, which they will have discussed with their family and friends. They will be more prepared for this proposal and should appreciate the efforts to improve the efficiency of the service provided. When the operation date is booked, the postoperative clinic visit dates should also be booked. Advanced knowledge of these will help the patient to arrange transport assistance from friends, and will assist the clinic organiser in future clinic management.

10.5.2 Suggestions for further research

1) A study of how the consideration of preoperative corneal parameters can be useful as part of clinical audit.

2) Corneal topography and pachometry changes could be monitored following different surgery techniques, eg. limbal incision method compared with a scleral tunnel method.

3) Little is still known regarding the effects of surgery on the parameters of the fellow (contralateral) eye. This could be a fruitful area of research as the results of this first study indicate there may be some effect.

4) It has been shown that rigid gas permeable contact lens wear can cause reduction of corneal astigmatism in eyes which have had penetrating keratoplasty (Woodward and Moodaley et al 1990), so this may also be true after cataract surgery. Various methods of astigmatism control after suture removal could be developed.

5) The measurement of suture tension in situ and the design of an instrument to measure this easily and reliably may be of benefit.

6) The feasibility of adjustable interrupted sutures in cataract surgery and in clinical follow-up could be investigated.

7) Following the peripheral corneal topography results of this study, further work is recommended on the topography and related factors of the ageing cornea, using a more reliable keratoscope than the PEK.

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TABLE 3.1 STUDIES ON ASTIGMATISM FOLLOWING CATARACT EXTRACTION

Measurement: Refraction = R Keratometry = K

Name & Type	Sample & Date	Main topic	Conclusions
Amoils (K)	(--) 1986	surgical keratometer	reduce induced astig during surgery
Arnott (R)	(--) 1973	phakoemulsifier stabilise time	Small incision=0.50D astig & short time
Axt & McCaffery	(80) 1993	reduction of astigmatism	Lateral incision reduces ATR astig
Bambery (K)	(41) 1986	astig at set postop times	WTR astig, interrupt sutures slow change
Beasley (K)	(84) 1967	corneal incision postop astig	increases variable often ATR astig
Binkhorst (R+K)	(--) 1980	IOL & astig differences	refraction astig similar to keratom
Blaydes (R+K)	(107) 1984	Terry surgical keratometer	3 mnth astig similar with & without it
Brown & Sparrow(R)	(100) 1988	postop astig control	selected removal of extra sutures
Buxton (K)	(--) 1976	surgery methods sutures, incision	good wound strength so CL fit at 4 wks
Colvard et al(K)	(225) 1981	Terry surgical keratometer	at 6 wks astig<3.0D 46% with, 29% without
Cravy (K)	(50) 1980	surgical keratom tight sutures	suture removal aids astig control

<u>**Table 3.1 Continued**</u>

Name & Type	Sample & Date	Main topic	Conclusions
Dowling (R)	(200) 1981	synthetic versus nylon sutures	nylon =less astig & less complications
El-Maghraby (K)	(--) 1993	incision size & astigmatism	3.5 size had less astig than 6.5mm.
Emery & McIntyre(K)	(--) 1983	surgery effects astig amount	wound gape & shallow sutures flatten curve
Floyd (K)	(47) 1951	incisions affect astig changes	1 month =6.6D,2 mnth =1.4D, 3 mnth =1.1D
Funder, et al (K)	(--) 1974	Graefe section continual suture	astig stabilisation at 9 months
Gaisiner (K)	(100) 1980	surg microscope postop & 3 mnth	less astig with microscope
Gills et al (K)	(1500) 1974	Limbal section suture type	6mnth stable time astig reduced
Girard et al (K)	(36) 1984	lensectomy scleral adjust	mean induced astig =ATR 0.33 D by 1 yr
Gould (K)	(650) 1974	incision size & position	high postop astig if wide corneal incision
Heslin &(R) Guerriero	(350) 1984	postop astig ECCE vs Phako	Phako =less astig & short stabilise time
Hilding (R)	(555) 1962	ICCE no of sutures	increased no = less astig, and ATR
Hoffer (K)	(87) 1984	Phacoemulsifier Terry keratom	Postop astig = 4.0D, 1 month = 1.30D

Table 3.1 Continued

.Name & Type	Sample & Date	Main topic	Conclusions
Hyde (K)	(--) 1980	wound compressed alters astig	tight suture = WTR keratoscope helps
Hyde (K)	(--) 1984	surgical astig ruler	elliptical reflex estimates astig
Huber (R)	(40) 1981	nylon sutures corneal incision	planned astig aids dist & near VA
Iliff et al (R)	(300) 1968	incision sites compared	% 8wks postop<1.00D limbal 71,corneal34
Jacobi et al (K)	(720) 1985	Terry keratom ECCE & post IOL	astig less with surg keratometer
Jaffe Clayman(K)	(1557) 1975	sutures, method incisions	astig change due to combined factors
Jampel et al (K)	(203) 1986	ECCE & IOL limbal incision	2.2D WTR Postop, later to 0.35D ATR
Luntz &(K) Livingston	(40) 1977	corneal section nylon suture	80% astig=0.75-1.0D post suture removal
Maltzman et al(R&K)	(54) 1986	preop and postop 6 wks	Refraction astig from cornea not IOL
Martin et al (K)	(196) 1993	incision size 0,3,6 months	no significant difference found
Meredith et al (R)	(1000) 1979	techniques and sutures ICCE	97% VA=6/12, 6 wks sutures alter astig
Moore (R)	(174) 1977	corneal incision long suture	most astig at 8 days 6 wks same as preop .

Table 3.1 Continued

.Name & Type	Sample & Date	Main topic	Conclusions
Paton (R)	(--) 1979	suturing techniques	astig control by suture site, adjust.
Reading (K)	(37) 1984	incision size ICCE	small incision =4wk stable, less astig
RoperHall & Atkins(K)	(--) 1985	surgical keratom suture adjust	postop astig control by suture adjust
Samples, et al (K)	(90) 1984	Terry surgical keratometer	measurement errors if inexperienced
Singh & Kumar(R&K)	(100) 1976	positioning of sutures	postop astig =1.2D 45% ATR; 37% WTR
Stainer et al (K)	(52) 1982	corneal incision nylon sutures	postop shift to ATR variable for 10 wks
Steinert et al (K)	(--) 1991	incision size astigmatism	small size had less astigmatism
Swinger (R&K)	(--) 1987	cause & correct of postop astig	reviewed 208 papers on surgical astig
Taylor et al (K)	(260) 1992	stability astig ECCE vs phako	scleral incision more stable than corneal
Terry (K)	(--) 1980	surg keratom tight sutures	best =Terry keratom wound close method
Thrasher et al (R)	(103) 1984	incision placement	anterior site gives greater astig

Table 3.1 Continued

Name & Type	Sample & Date	Main topic	Conclusions
Thygesen et al (K)	(--) 1979	corneal versus limbal incision	corneal=more change . settles at 4 mnths
Torchia et al (R)	(154) 1983	limbal nylon surg keratom	79 % <1.50D astig at 2 mnth postop
Troutman (K)	(--) 1984	Troutman surg keratometer	methods alter postop astig
Van Rij (K)	(43) 1984	suture, incision placement	anterior sutures steepen cornea
Welsh (K)	(--) 1980	surgical astig reduction	incisions & sutures minimise changes
Wishart (K)	(57) 1986	astig change & suture removal	wound gape & press determine astig

TABLE 3.2

CLINICAL IMPLICATIONS OF VARIOUS CATARACT EXTRACTION METHODS

Techniques = ICCE, ECCE, Phacoemulsification (PHACO)

1) **ICCE**: simple, quick method, suitable for all types of cataract, but IOL designs are limited as there is no support from a posterior capsule. A large incision size is needed involving several sutures, therefore there is an increased risk of surgically induced astigmatism. Significant inflammatory reaction to the large wound causes corneal oedema and up to 3 months for stabilisation of wound healing and corneal shape changes.

2) **ECCE**: moderately simple, quick method, suitable for nearly all types of cataract, although it involves careful manipulation of the lens capsule. A wide variety of IOLs available, usually inserted into the empty capsule. A moderate to large incision size is needed with several sutures, hence increasing the risk of surgically induced astigmatism. Significant inflammation at the large wound leads to 1 to 3 months needed for stabilisation of the corneal oedema and shape changes.

3) **PHACO**: more complex, slower method requiring special lens phacoemulsification and aspiration equipment. Choice of IOLs limited by the small wound aperture. Small incision requires minimal suturing, so less corneal oedema and astigmatism changes are incurred. Minimal inflammatory reaction, so rapid recovery time and less follow-up checks required.

TABLE 3.3 POSTOPERATIVE COMPLICATIONS WITH VARIOUS METHODS

1) ICCE Vitreous prolapse into anterior chamber may compromise cornea; risk of bullous keratopathy, retinal detachment, and cystoid macular oedema; corneal stress if large IOL pushed through small incision; larger wounds give greater risk of infection, fluid leak and tissue disturbance.

2) ECCE As above, but capsule supports vitreous and may thicken and reduce vision; lens debris may disturb eye.

3) PHACOEMULSIFICATION Rare but possible: endothelial damage by chemicals in prolonged irrigation, especially in older patient, aspirator can damage the iris, ultrasound may damage endothelium.

4) ASPIRATION. Increased fluid pressure in anterior chamber; risk of iris damage by aspiration probe.

TABLE 4.1 DIAMETER OF CORNEAL REFLECTION AREAS FOR A SINGLE MIRE

(as determined by Lehmann (1967)

Keratometer	Diameter of area (mm) in which each mire is reflected if corneal radius of curvature is:		
	7.00 mm	9.00 mm	10.00 mm
Bausch and Lomb	0.10	0.10	0.10
Zeiss	0.20	--	0.40
Gambs	0.20	--	0.40
Guilbert Routit(topog)	0.50	--	0.80
American Optical	0.10	0.10	0.10
Haag Streit	0.40	--	0.30

TABLE 5.1 KERATOSCOPY INVESTIGATIONS

Name & Date	Features Investigated
Placido 1882	Qualitatively assessed corneal surface regularity used flat disc, black & white concentric circles
Gullstrand 1909, 1924	First quantitative method. Estimated to 0.5% in radius of curvature, SD=+/-0.07 for 8.0 mm radius
Knoll 1961	Claimed accuracy of +/- 0.2mm, elliptical ring positions
Stone 1962	Hemisphere target, claimed accuracy of +/-0.25mm on ball
Levene 1965	Keratoscope developments
Ludlam 1966 Wittenberg	Accurate reproducible alignment of axes and target positions, plane virtual image of sphere
Ludlam 1966	Ellipse target best, radius ball SD=+/-0.036mm
Townsley 1967	Development of the photoelectronic keratoscope (PEK)
Ludlam et al 1967	Co-axial radius of curvature range +/- 0.036mm on steel balls, +/- 0.06 mm for the cornea
Mandell & StHelen1968	Telecentric stop, ray of each point on virtual image is parallel to camera axis, SD= +/-0.08mm
Cochet & Amiard 1969	Telecentric stop, accuracy claim of +/-0.012 mm, also used metal rod targets, accuracy +/-0.08 mm

Table 5.1 Continued

Name & Date	Features investigated
Mandell & York 1969	Cylindrical target of 10 rings, good calibration Improved keratograph measurement
Wesley 1969	Described results fitting ellipses, SD=+/-0.04mm
Holden 1970	Radius ball SD+/-0.01-0.07mm cornea SD=+/-0.023mm
Prechtel 1970	Description of PEK and keratogram measurement
El Hage 1971	Sagittal depth peripheral curve error to 0.02mm
El Hage 1972	Differential equation determines topography
Donaldson 1972	Hemispherical target to aim for flat image plane
Pulvermacher & Rott 1972	Accuracy +/-0.015mm peripheral corneal shape, cross reflection helps note corneal position
Clark 1973, 1974	Literature review, keratograph analysis methods
Fry 1975	Ray-tracing & formulae related to keratoscope
Ruben 1975	Description of corneal topography measurement
Schultz 1978	Keratoscopy shows peripheral astigmatism decrease
Rowsey 1981	Quantitative analysis of keratoscope photographs
Rowsey & Isaac 1983	Corneal topography analysis using Corneascope

Table 5.1 Continued

Name & Date		Features investigated
Klyce	1984	Curvature change, hemi-meridians at 2 degree gap
Cohen	1984	Photogrammetric method of shape description as indices, keratogram rings related to circular
Guillon et al	1986	Systematic difference between keratometry and photokeratoscopy measurements, periphery similar
Maguire	1987	Developed contour map of corneal surface power
Roddy & Goss	1988	Comparison of repeatability of Corneascope with Comparator keratoscope
Ghormley	1988	Review of corneal modelling methods
Zabel	1989	New, reduced cost, easily portable keratoscope
Bogan	1990	Survey of normal topography with videokeratoscope
Camp	1990	Optical effect model of irregular corneal shape
Hannush et al	1990	Comparison of reproducibility of keratometry, photokeratoscope and video-imaging system
Heath et al	1991	Reliability of videokeratoscope measurements
Tsilimbaris	1991	Comparison of keratometry and the Corneal Analysis System (Eyesys)
Wilson & Klyce	1991	Comparison of keratometry, keratoscopy & computer assisted topographic analysis systems

Table 5.1 Continued

Name & Date	Features investigated
Koch 1992 et al	Comparison of reproducibility and accuracy of the keratometer and the Corneal Analysis System
McCarey 1992 et al	Reliability and repeatability with EyeSys corneal topography system.
Riss, Dupuy, Hostyn 1992	Reliability and reproducibility of results with the keratogram analyser
Stevenson 92	1992 review of corneal topography modelling
Waring 1992	Description of use of videokeratography
Antalis 1993	Comparison of TMS-1 and Corneal Analysis System
De Cunha & Woodward 1993	New method to determine a contour map of irregular corneal shape
Fowler 1994	Review of corneal topography measurement

TABLE 6.1 PACHOMETRY RELIABILITY FACTORS

Name	Date	Subjs	Factors Considered	Comments
Donaldson	1966	268	Split ocular & fixation lights	Increased accuracy, decreased distortions
Mishima & Hedbys	1968	-	Altering incident light angle	Topographic attachment, fixation targets
Ehlers & Kruse Hanson	1971	-	Optical section, Angle Kappa	Haag-Streit instrument best, SD =+/- 0.008 mm
Fatt & Harris	1973	-	Refractive index	Minimal significant thickness decrease
Stone	1975		Diurnal, position	Purkinje images assist
Binder	1977	-	Electronic optical	Rapid & reliable
Ehlers & Sperling	1977	-	Angle Kappa error	Adjustment eliminates RE:LE angle errors
Hirji & Larke	1978	19	Experience in use, topographical	Experience improves SD from+/-0.032 to 0.006mm
Patel	1981	-	Methods curvature refractive index	Section width etc are error sources
Molinari & Bonds	1983	12	Touch vs overlap methods	Similar result but stat significantly different
Snyder	1984	3	Repeatability, on PMMA lenses	Experienced operator: 1% variation, SD<1%
Edmund & la Cour	1986	29	Diurnal variation, instruments	Statistical variance component model shown

TABLE 6.2 NORMAL CORNEAL THICKNESS BY OPTICAL METHODS

Author	Year	Subjects	Central thickness(mm)
Von Bahr	1948	224	0.565 +/- 0.035
Maurice & Giardini	1951	44	0.507 +/- 0.028
Lavergne & Kelecom	1962	198	0.510 +/- 0.040
Donaldson	1966	268	0.522 +/- 0.041
Martola & Baum	1968	209	0.523 +/- 0.039
Mishima & Hedbys	1968	40	0.518 +/- 0.020
Lowe	1969	157	0.517 +/- 0.034
Kruse Hansen	1971	76(RE)	0.520 +/- 0.018
Kruse Hansen	1971	74(LE)	0.524 +/- 0.020
Carney	1975	....	0.463 +/- 0.028

TABLE 7.1 FORM OF CONSENT RECORD

CONSULTANT NAME : HOSPITAL NO :

PATIENTS NAME : Date of Birth :

ADDRESS:

CORNEAL PARAMETER CHANGES AFTER CATARACT EXTRACTION

CLINICAL TRIAL : EXPLANATION FOR THE PATIENT

This study is of patients having a routine cataract extraction operation. The measurements are performed on the eye before the operation and the surgeon takes them into account along with many other factors to help decide which surgical technique is most suitable for each patient. The measurements are repeated at regular intervals after the operation. The measurements do not involve touching your eye but may require you to spend more time at the hospital on your routine visits. There may be future benefit for other patients undergoing cataract extraction from the results of the study. If you choose not to take part in this trial please be assured that you will continue to receive the best appropriate treatment and care. Your participation in this trial is greatly appreciated.

I agree to participate in the clinical trial organised by Miss C.Astin. The nature of this trial has been fully explained and has been understood by me.

Patients signature.........................Date.............

TABLE 8.1 KERATOMETER CALIBRATION READINGS

Radii of curvature of 3 calibration spheres, 20 readings taken

Test sphere number	(1)	(2)	(3)
Physical measurement of radii(mm)	7.00	7.50	8.00
Mean radii by keratometry	7.05	7.54	8.04
Standard deviation SD +/-	0.01	0.01	0.01

(N=60) Overall mean error = 0.04 SD =+/-0.01

Repeatability on human eye, 20 measurements, mean radii:

Horizontal: 7.76 mm, SD=+/-0.02, vertical: 7.67mm, SD=+/-0.02

TABLE 8.2a PEK CALIBRATION READINGS

Radii of curvature of 3 calibration spheres, 10 readings taken

Test sphere number	(1)	(2)	(3)
Physical measurement of radii(mm)	7.00	7.50	8.00
Mean radii by PEK (mm)	7.00	7.51	8.01
Standard deviation SD +/-	0.03	0.02	0.03

(N=30) Overall mean error = 0.02 SD =+/-0.02

TABLE 8.2b PEK REPEATABILITY READINGS

Ten readings taken of black PEK calibration sphere

Physical measurement radius = 8.00mm, shape factor = 0.00

Mean horizontal radius value = 8.01mm, SD =+/-0.01,

Mean vertical radius value = 8.01mm, SD =+/-0.02,

Mean horizontal shape factor = 0.03, SD =+/-0.01,

Mean vertical shape factor = 0.02, SD =+/-0.02,

TABLE 8.2b (continued)

Ten readings of human cornea, right eye

Mean horizontal radius value = 7.58mm, SD =+/-0.02,

Mean vertical radius value = 7.57mm, SD =+/-0.01,

Mean horizontal shape factor = 0.29, SD =+/-0.06,

Mean vertical shape factor = 0.41, SD =+/-0.07,

Ten readings for human cornea, left eye

Mean horizontal radius value = 7.60mm, SD =+/-0.04,

Mean vertical radius value = 7.60mm, SD =+/-0.04,

Mean horizontal shape factor = 0.28, SD =+/-0.05,

Mean vertical shape factor = 0.24, SD =+/-0.06,

TABLE 8.3a PATIENT AGE DISTRIBUTION AND ATTENDANCE

Age	group (C)		group (L)	
	36 Male	18 Female	27 Male	24 Female
20-29	1	0	0	1
30-39	3	1	2	0
40-49	1	1	3	2
50-59	10	1	8	5
60-69	15	6	10	11
70-79	4	9	3	5
80-89	2	0	1	0

Mean Ages:

Males =59.5 years, SD=+/-12.6, Females =63.3 years SD=+/-11.0

Groups: (C) =61.8 years, SD=+/-12.7, (L) =60.2 years SD=+/-11.4

Patient attendance:

TIME	preop	Postop	2wk	4wk	6wk	8wk	10wk	12wk	16wk	24wk
(C)	54	50	50	43	46	44	41	44	42	33
(L)	51	46	43	31	44	38	36	35	39	34

TABLE 8.3b PATIENTS WHO FAILED TO COMPLETE THE STUDY

All patients had IOLs implanted.

No	Age	Sex	Op	Last appnt	Last refraction	V.A.	Reason to fail
1.	44	M	C	10 weeks	-1.0/-1.0 ax155	6/6	poor attendance
2.	74	M	L	4 weeks	+2.50/-0.75 ax10	6/5	poor attendance
3.	66	F	C	2 weeks	+1.75/-1.0 ax30	6/12	corneal oedema
4.	81	M	C	3 weeks	+1.25/-1.25 ax85	6/24	low VA, thick capsule
5.	63	M	L	12 weeks	+3.00/-4.00 ax72	6/6	2w red eye, chalazion
6.	58	M	C	12 weeks	+1.00/-2.0 ax30	6/9	poor attendance
7.	67	F	C	1 week	not known	6/9	poor attendance
8.	56	M	C	16 weeks	+2.50/-1.25 ax90	6/5	poor attendance
9.	66	F	L	3 weeks	+6.50/-2.0 ax110	6/9	poor attendance
10.	59	F	C	14 weeks	+2.00/-5.0 ax15	6/9	diplopia problems
11.	44	M	L	2 weeks	+4.00/-2.50 ax5	6/18	corneal oedema
12.	47	M	C	10 weeks	+10.00DS	6/9	poor attendance
13.	56	F	C	4 weeks	+3.00/-3.00 ax95	6/9	poor attendance
14.	77	M	L	2 weeks	poor response	6/36	low VA, thick capsule
15.	52	M	C	2 weeks	+3.00Ds	6/12	poor attendance

Table abbreviations:

Ch = change, Con = Controls, Nor = Non-operated, Pat = patients,
Pre = preoperative, C = corneal group, L = limbal group
Postop = Postop stage, AC = attended every stage corneal,

AL = attended every stage limbal, A = ANOVA, TT = T test,
K = keratometry astigmatism, PEK = PEK astigmatism,
HSF = horizontal shape factor, VSF = vertical shape factor

Th = thickness, Optype = operation type,
LR = linear regression, MR = multiple regression,

Cor = correlation, SIG = statistically significant,
NS = not statistically significant at p=0.05 level.

TABLE 8.4 OCULAR ASTIGMATISM

Group	Factor	Stats	Significance
Con	Time	A	NS
ConPre	PatPre	TT	NS
NorPre	PatPre	TT	NS
Nor	Time	A	NS
Pat	Time	A	SIG p<0.01
PatCh	Time	A	SIG p<0.01
PatPre	Optype	TT	NS
PatCh	Optype	A	NS (Post,10,16,24wk, p=0.01)
Pat	PatPre	A	NS
Pat	PatPre	LR	NS

TABLE 8.5 CORNEAL ASTIGMATISM

Group	Factor	Stats	Significance
Con	Time	A	NS
ConCh	Time	A	NS
ConPre	PatPre	TT	NS
Nor	Time	A	NS
NorPre	PatPre	TT	NS
Pat	Time	A	SIG p<0.01
Pat	Optype	TT	NS (6wk,8wk p=0.05)
CPatCh	Time	A	SIG p=0.01
CPat	Zero	TT	SIG p=0.01, 12wk p=0.02
CPatCh	PatPre	MR	NS (16wk p=0.01)
LPat	Time	A	SIG p<0.05
LPat	Zero	TT	SIG p<0.01 (4wk NS, 6wk p=0.03)
LPatCh	PatPre	MR	NS (8, 12wk p<0.01,16wk p=0.04)
PatCh	Optype	MR	SIG p<0.01 (NS Post, 2wk)
APatCh	Optype	MR	NS
APatCh	Optype	LR	NS
ACPat	PatPre	LR	SIG p<0.01
ALPat	PatPre	LR	SIG p<0.01

TABLE 8.6 CORNEAL ASTIGMATISM (PEK)

Group	Factor	Stats	Significance
Con	Time	A	NS
ConPre	PatPre	TT	NS
NorPre	PatPre	TT	NS
Nor	Time	A	NS
Nor	NorPre	A	NS
Nor	NorPre	MR	NS
Pat	Time	A	SIG p=0.01
PatCh	Time	A	SIG p=0.01 (12wk etc p=0.05)
PatPre	Optype	TT	NS
Pat	Optype	A	NS
Pat	Optype	MR	NS
PatCh	Optype	TT	SIG p<0.05
CPat	Time	A	SIG p<0.05 (16,24wk NS)
CPatCh	PatPre	MR	NS
LPat	Time	A	SIG p<0.05 (8wk NS)
LPat	PatPre	A	NS (8wk etc SIG p<0.05)
LPatCh	PatPre	MR	NS
Pat	Keratom	LR	SIG p<0.01

TABLE 8.7 HORIZONTAL SHAPE FACTOR

Group	Factor	Stats	Significance
Con	Time	A	NS
ConCh	Time	A	NS
Con	Zero	TT	SIG p<0.05 (2, 10wk NS)
Con	Pat	LR	NS
Nor	Time	A	NS
NorCh	Time	A	NS
NorCh	NorPre	Cor	SIG p=0.01
Pat	Time	A	NS
PatCh	Optype	A	NS (Postop p<0.01)
PatPre	Optype	TT	NS
CPat	Zero	TT	SIG p<0.01
CPat	Time	MR	NS (A NS, Cor NS)
CPatCh	Time	A	NS (Cor NS, TT 2,12wk p=0.01)
CPatCh	Time	MR	NS (6wk p<0.05,8wk etc p<0.01)
CPat	PatPre	MR	NS (A NS, Cor NS)
CPatCh	PatPre	A	NS (8,12,16wk p<0.01)
CPatCh	PatPre	MR	NS (Cor p=0.05)
ACPat	Time	A	NS
ACPatCh	Time	A	NS (2,4,12wk p<0.05)
ACPatCh	Postop	Cor	SIG p=0.01 (2,4wk p<0.05)
ACPatCh	PatPre	MR	NS (24 wk p=0.03)
ACPatCh	PatPre	A	NS (12,24wk p<0.01)
ACPatCh	PatPre	LR	NS (Cor NS))

TABLE 8.7 (continued)

Group	Factor	Stats	Significance
LPat	Zero	TT	SIG $p<0.01$
LPat	Time	A	NS (Postop,2wk $p<0.05$)
LPatCh	Time	LR	NS (A NS)
LPatCh	Time	MR	SIG $p<0.01$ (2;4wk NS)
LPat	PatPre	Cor	SIG $p=0.05$
LPatCh	PatPre	MR	SIG $p<0.01$ (2,4wk NS)
ALPat	Time	A	NS
ALPatCh	Time	A	NS
ALPatCh	PatPre	A	NS
Pat	Optype	A	NS
PatCh	Optype	A	SIG $p<0.01$
PatCh	Optype	LR	SIG $p<0.01$
AC+ALPat	Optype	TT	NS
Pat	SFtype	A	SIG $p<0.01$
CPatCh	SFtype	LR	SIG $p=0.01$
LPatCh	SFtype	LR	NS
LPatCh	SFtype	A	NS

TABLE 8.8 VERTICAL SHAPE FACTOR

Group	Factor	Stats	Significance
Con	Optype	TT	NS
Con	Pat	TT	NS
Con	Time	A	NS
ConCh	Time	A	NS
ConCh	Zero	A	NS
Nor	Time	A	NS
NorCh	Time	A	NS
Pat	Optype	TT	NS
CPat	Time	A	NS (MR NS)
CPatCh	Time	A	NS (MR NS)
CPat	PatPre	Cor	SIG p=0.05
ACPatCh	Time	MR	NS (24wk p=0.03) (Cor NS)
ACPatCh	PatPre	Cor	NS
ACPatCh	Postop	Cor	SIG p<0.05 (2,10wk NS)
LPat	Time	A	NS (MR NS)
LPatCh	Time	A	NS (MR NS)
LPatCh	Time	LR	NS (6wk p=0.04,8,12,16wk p<0.01)
ALPat	Time	MR	NS (Cor NS)
Pat	Optype	A	NS
PatCh	Optype	A	NS
AC+ALPat	Optype	A	NS

TABLE 8.9 PACHOMETER CALIBRATION READINGS

Lens thickness (mm) measured by micrometer gauge:
lens S =0.468, lens T =0.568, lens U =0.668, lens V =0.765

Equivalent corneal thickness of each lens in mm:
lens S =0.435, lens T =0.528, lens U =0.621, lens V =0.711

Repeatability: ten thickness readings of human cornea

Region	Mean(mm)	SD +/-
superior	0.613	0.006
central	0.500	0.009
inferior	0.603	0.008
nasal	0.619	0.007
temporal	0.584	0.005

TABLE 8.10 CORNEAL THICKNESS (CONTROLS AND NON OPERATED)

For all corneal regions:

Group	Factor	Stats	Significance
Con	Optype	A	NS
Con	Time	A	NS
ConCh	Time	A	NS
ConCh	Zero	A	NS
Con	Region	A	NS (central p=0.01)
ConCh	Region	A	NS (sup, cent, p<0.01, tem p=0.03)
Nor	Time	A	NS
NorCh	NorPre	Cor	SIG (sup, cent NS)

TABLE 8.11 SUPERIOR REGION CORNEAL THICKNESS

Group	Factor	Stats	Significance
Pat	Optype	A	NS
CPat	Time	MR	SIG p<0.01
CPat	PatPre	LR	Sig p<0.05 (Postop NS)
CPatCh	Time	MR	SIG p<0.05 (Postop NS)
CPatCh	PatPre	MR	NS (8,12,16wk p<0.05)
LPat	Time	MR	SIG p<0.05
LPat	PatPre	MR	SIG p<0.05
LPatCh	Time	LR	SIG p<0.05
LPatCh	Time	MR	SIG p<0.01
LPatCh	PatPre	MR	SIG p<0.05
PatCh	Optype	LR	NS
PatCh	Optype	A	NS

TABLE 8.12 CENTRAL REGION CORNEAL THICKNESS

Group	Factor	Stats	Significance
PatPre	Optype	TT	NS
PatCh	Time	A	SIG p<0.01
CPat	PatPre	A	SIG p<0.01
CPatCh	Time	LR	SIG p<0.01
CPatCh	Time	A	SIG p<0.01
CPatCh	Zero	MR	SIG p<0.05 (8wk etc NS)
CPatCh	Time	MR	SIG p<0.01
LPat	PatPre	A	SIG p=0.01
LPatCh	PatPre	MR	SIG p<0.05
LPatCh	Time	LR	SIG p=0.01
LPatCh	Time	MR	SIG p<0.01
PatCh	Optype	MR	SIG p=0.01

TABLE 8.13 INFERIOR REGION CORNEAL THICKNESS

Group	Factor	Stats	Significance
PatPre	Optype	TT	NS
Pat	Time	A	SIG p<0.01
CPat	Time	A	NS (Postop,2wk, p<0.05)
CPat	PatPre	LR	SIG p<0.01
CPatCh	Time	A	SIG p<0.01
CPatCh	Time	MR	SIG p<0.01
CPatCh	PatPre	A	NS (8wk p<0.01)
LPat	Time	A	NS (Postop,2wk,p<0.01)
LPat	PatPre	LR	SIG p<0.01
LPatCh	Time	A	SIG p<0.01
LPatCh	PatPre	A	NS (4wk etc p<0.01)
Pat	Optype	A	NS overall
PatCh	Optype	MR	NS overall

TABLE 8.14 NASAL REGION CORNEAL THICKNESS

Group	Factor	Stats	Significance
PatPre	Optype	TT	NS
Pat	PatPre	LR	SIG p<0.01
PatCh	Time	MR	SIG p<0.01
CPat	Time	A	NS (Postop, 2wk, p<0.01)
CPat	PatPre	LR	NS
CPatCh	PatPre	LR	SIG p<0.01
LPat	Time	A	NS (Postop, 2wk p<0.01)
LPat	PatPre	A	SIG p<0.01
LPatCh	Time	LR	SIG p<0.01
LPatCh	PatPre	LR	SIG p<0.01
LPatCh	PatPre	MR	SIG p<0.01
PatCh	Optype	MR	NS

TABLE 8.15 TEMPORAL REGION CORNEAL THICKNESS

Group	Factor	Stats	Significance
PatPre	Optype	TT	NS
PatCh	Time	MR	SIG p=0.01
CPat	Time	A	NS (Postop, 2wk p<0.01)
CPat	PatPre	LR	SIG p=0.02
CPatCh	Time	MR	SIG p=0.01
CPatCh	PatPre	MR	NS (6wk etc p<0.05,)
LPat	Time	A	SIG p<0.01
LPatCh	Time	A	NS (Postop, 2wk p<0.05)
LPat	PatPre	LR	SIG p<0.01
LPatCh	PatPre	MR	SIG p<0.01 overall
PatCh	Optype	A	SIG p<0.01 (Postop p=0.17)
PatCh	Optype	MR	SIG p<0.01 overall

TABLE 8.16 PARAMETER COMPARISONS

Group	Factor	Stats	Significance
HSFPre	KPre	MR	NS
VSFPre	KPre	MR	NS
PEKPre	KPre	A	SIG p<0.01
HSFCh	KPre	MR	NS
VSFCh	KPre	MR	NS
PEKCh	KPre	MR	NS
CHSFCh	VSFCh	A	SIG p<0.01
LHSFCh	VSFCh	A	NS
HSF	ThPre	A	NS
VSF	ThPre	A	NS
PEK	ThPre	A	NS
KCh	ThPre	A	NS
ThPre	Optype	A	NS
ThCh	Optype	A	NS (cent p<0.05, temp p<0.01)
LThCh	ThPre	MR	NS (sup, int, nonIOL, p <0.01)
LThCh	KCh	A	NS (cent 16wk p=0.01)

TABLE 8.17 PARAMETERS RELATED TO IOL

Group	Factor	Stats	Significance
K	IOL	MR	NS (16wk p=0.04)
KCh	IOL	MR	NS (8, 12wk p=0.03)
KCh8wk	IOL	TT	NS (A = NS)
KCH12wk	IOL	TT	NS (A = NS)
PEKCh	IOL	MR	NS
HSF	IOL	MR	NS
HSFCh	IOL	MR	NS
VSF	IOL	MR	NS
VSFCh	IOL	MR	NS
ThCh	IOL	MR	NS

TABLE 8.18 CORNEAL THICKNESS CHANGES RELATED TO PREOP VALUE

Multiple regression p values

IOL and non-IOL combined   ns = not significant

Time stage	Superior	Central	Inferior	Nasal	Temporal	N
(C) 6 weeks	ns	ns	ns	ns	ns	31
(C) 8 weeks	0.013	0.016	0.001	ns	<0.001	31
(C) 12 weeks	0.038	ns	ns	0.006	ns	31
(C) 16 weeks	0.019	ns	ns	ns	0.036	31
(L) 6 weeks	ns	<0.001	0.009	<0.001	0.004	31
(L) 8 weeks	<0.001	<0.001	0.007	<0.001	0.001	24
(L) 12 weeks	0.001	0.001	0.001	0.001	0.001	24
(L) 16 weeks	<0.001	<0.001	<0.001	<0.001	<0.001	31

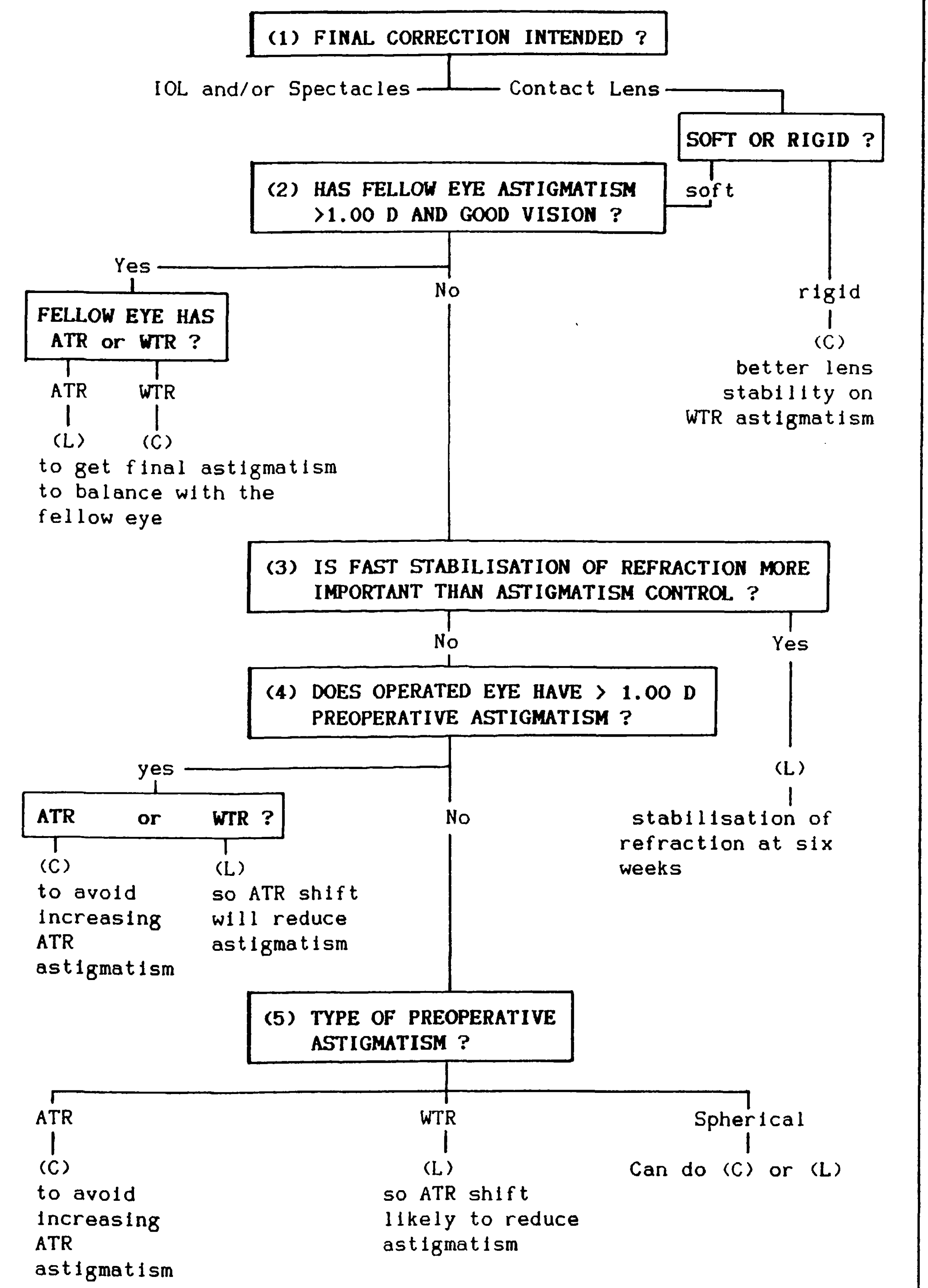
TABLE 8.19 CORNEAL THICKNESS CHANGES RELATED TO PREOP AND IOL

Multiple regression p values

ns = not significant   N = sample   **Bold = non-IOL**

Time stage	Superior	Central	Inferior	Nasal	Temporal	N
(C) 6 weeks	**ns**	**ns**	**ns**	**ns**	**ns**	**7**
	ns	0.017	ns	ns	ns	24
(C) 8 weeks	**ns**	**ns**	**0.014**	**ns**	**0.002**	**11**
	0.019	0.017	ns	ns	0.013	20
(C)12 weeks	**ns**	**ns**	**ns**	**0.014**	**ns**	**11**
	0.048	ns	ns	ns	0.034	20
(C)16 weeks	**ns**	**ns**	**ns**	**ns**	**ns**	**7**
	0.042	ns	ns	ns	ns	24
(C)24 weeks	**ns**	**ns**	**ns**	**ns**	**ns**	**2**
	ns	ns	ns	ns	0.048	21
(L) 6 weeks	**ns**	**0.006**	**0.035**	**0.009**	**0.020**	**23**
	ns	0.007	ns	0.001	0.026	8
(L) 8 weeks	**0.002**	**0.001**	**0.015**	**0.004**	**0.004**	**18**
	ns	ns	ns	0.013	0.047	6
(L)12 weeks	**0.001**	**0.013**	**0.002**	**0.007**	**0.008**	**18**
	ns	0.005	ns	0.006	0.039	6
(L)16 weeks	**<0.001**	**0.006**	**<0.001**	**<0.001**	**<0.001**	**23**
	0.037	0.016	ns	0.001	0.046	8
(L)24 weeks	**0.005**	**0.002**	**<0.001**	**<0.001**	**0.002**	**15**
	0.038	0.006	ns	0.003	ns	6

TABLE 9.1 GUIDE FOR CHOICE OF CATARACT EXTRACTION METHOD TO ADJUST ASTIGMATISM



ATR = positive cylinder at axis 180, (C) = Corneal incision
WTR = positive cylinder at axis 90, (L) = Limbal incision

TABLE 9.2 ANALYSIS OF PARAMETERS

Table abbreviations as in Chapter 8.

Batch = 1st or 2nd study

Ocular astigmatism (refraction)

Group	Factor	Stats	Significance
PatPre	Optype	TT	NS
Pat	Optype	A	NS
PatCh	Optype	A	NS
Pat	Time	A	SIG (F=2.45,df=167,4,p<0.05)
PatCh	Time	A	NS
CPat	Time	A	SIG (12wk etc NS)
CPatCh	Time	Cor	SIG (p<0.05)
CPatCh	Time	A	NS
CPatCh	PatPre	A	NS
CPatPre	Batch	TT	NS
CPat24w	Batch	TT	NS
LPat	Time	A	SIG (p<0.05, 6wk etc NS)
LPat	Time	Cor	SIG (p<0.05)
LPatCh	Time	A	NS
LPatCh	PatPre	A	NS
LPatPre	Batch	TT	NS
LPat24w	Batch	TT	SIG (t=1.97,p<0.05)

TABLE 9.2 (continued)

Corneal astigmatism (keratometry)

Group	Factor	Stats	Significance
PatPre	Optype	TT	NS
Pat	Optype	A	NS
PatCh	Optype	A	NS
Pat	Time	A	SIG (F=4.48, df=4, 166, p<0.01)
Pat	Time	Cor	SIG (p<0.05)
PatCh	Time	A	SIG (F=5.14, df=3, 131, p<0.01)
PatCh	Time	Cor	SIG (p<0.05)
CPatCh	Time	A	SIG (F=3.46, df=3, 64, p<0.05)
CPatCh	Zero	A	SIG (12w etc NS)
CPatPre	Batch	TT	NS
CPat24w	Batch	TT	NS
LPatCh	Time	A	NS overall
LPatCh	Zero	A	SIG (6wk onward NS)
LPatPre	Batch	TT	NS
LPat24w	Batch	TT	SIG (t=2.64)

Push to sphere subgroup

Ocular astigmatism (refraction)

PatPre	Batch	TT	NS
LPat24w	Batch	TT	SIG (t=2.98, p<0.01) (C = NS)
Pat24w	Zero	TT	NS

Corneal astigmatism (keratometry)

KPatPre	Batch	TT	NS
KLPat24w	Batch	TT	SIG (t=3.75, p<0.01) (C = NS)
KPat24w	Zero	TT	NS

TABLE 9.2 (continued)

Corneal thickness

Group	Factor	Stats	Significance
PatPre	Optype	TT	NS
Pat	Optype	A	NS overall
PatCh	Optype	A	NS overall

Superior region

Pat	Time	A	SIG (F=20.57, df=166, 4, p<0.01)
Pat	Time	Cor	SIG p<0.05 (2wk NS)
PatCh	Time	A	SIG (F=28.65, df=3, 131, p<0.01)
CPatCh	Time	A	SIG (F=14.61, df=3, 60, p<0.01)
LPatCh	Time	A	SIG (F=14.19, df=3, 67, p<0.01)

Central region

Pat	Optype	A	NS
PatCh	Optype	A	NS
Pat	Time	A	SIG (F=8.25, df=4, 166, p<0.01)
Pat	Time	Cor	SIG (p<0.05)
PatCh	Time	A	SIG (F=15.86, df=3, 131, p<0.01)
PatCh	Time	Cor	SIG (p<0.05)
CPatCh	Time	A	SIG (F=5.88, df=3, 60, p<0.01)
LPatCh	Time	A	SIG (F=10.24, df=3, 67, p<0.01)

TABLE 9.2 (continued)

Inferior region

Pat	Optype	A	NS
PatCh	Optype	A	NS
Pat	Time	A	SIG (F=7.01, df=4, 166, p<0.01)
PatCh	Time	A	SIG (F=11.7, df=3, 131, p<0.01)
CPatCh	Time	A	NS
LPatCh	Time	A	SIG (F=14.45, df=3, 131, p<0.01)
LPatCh	Time	Cor	NS

Nasal region

Pat	Optype	A	NS
PatCh	Optype	A	NS
Pat	Time	A	SIG (F=4.82, df=4, 166, p<0.01)
Pat	Time	Cor	SIG p<0.05
PatCh	Time	A	SIG (F=11.74, df=3, 131, p<0.01)
PatCh	Time	Cor	NS
CPatCh	Time	A	SIG (F=3.42, df=3, 60, p<0.05)
LPatCh	Time	A	SIG (F=8.41, df=3, 67, p<0.01)

Temporal region

Pat	Optype	A	NS
PatCh	Optype	A	NS
Pat	Time	A	SIG (F=6.52, df=4, 166, p<0.01)
PatCh	Time	A	SIG (F=13.12, df=3, 131, p<0.01)
Pat	Time	Cor	NS (PatCh NS)
CPatCh	Time	A	SIG (F=5.58, df=3, 60, p<0.01)
LPatCh	Time	A	SIG (F=7.52, df=3, 67, p<0.01

TABLE 9.3 SUBGROUPS OCULAR ASTIGMATISM (REFRACTION)

Subgroup Name	Time Stabilised	N	Mean (D)	SD+/-
Fast to Stabilise	Preop	12	-0.10	0.61
	6 wks	6	-0.05	0.45
	12 wks	6	+0.46	1.45
C group		1	+2.00	...
L group		11	-0.04	1.09
Push to Spherical	Preop	16	+0.36	1.81
	6 wks	7	+0.38	0.92
	12 wks	5	-0.50	0.58
	24 wks	4	+0.84	1.04
C group		8	-0.35	0.63
L group		8	+1.22	1.32
Match Astig	Preop	8	+0.88	2.13
	6 wks	4	+0.69	0.80
	24 wks	4	+0.82	2.11
C group		8	+0.75	1.48

Predicted group poor attenders, N = 9 :

Preoperative mean = +0.33D, SD =+/-0.74 N = 5C,4L

Stabilised at approx 12 wks, at mean = +0.45D SD =+/-2.10