CHANGE IN CORNEAL CURVATURE INDUCED BY SURGERY

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CONTENTS

Chapter 1 Introduction: Refractive corneal surgery. (Ned. Tijdschr. Geneeskd. 130: 1313-1317; 1986) 1

Scope of the present study. 10

SECTION I:

CHANGES IN CORNEAL CURVATURE INDUCED BY SUTURES, INCISIONS AND INTRASTROMAL CONTACT LENSES

Chapter 2 Changes in corneal curvature induced by sutures and incisions. (Am. J. Ophthalmol. 98: 773-783; 1984) 15

Chapter 3 Radial corneal sutures for the correction of myopia. A laboratory experiment. (Doc. Ophthalmol., accepted for publication) 27

Chapter 4 Hydrogel keratophakia: a freehand pocket dissection in the monkey model. (Br. J. Ophthalmol. 70: 187-191; 1986) 33

Chapter 5 Hydrogel keratophakia: a microkeratome dissection in the monkey model. (Br. J. Ophthalmol. 70: 192-198; 1986) 38

SECTION II

PENETRATING KERATOPLASTY AND CORNEAL CURVATURE

Chapter 6 Configuration of corneal trephine opening in a laboratory setting. (submitted for publication) 47

Chapter 7 An experimental comparison of three methods for trephination of the cornea and the consequent variations in configurations of the trephine openings. (Graefe's Arch. Clin. Exp. Ophthalmol. accepted for publ.) 65

Chapter 8 Postoperative astigmatism after central vs eccentric penetrating keratoplasty.
(Am. J. Ophthalmol. 99: 317-320; 1985) 73

Chapter 9 Suture induced astigmatism after a circular wound in the Rhesus monkey. (Cornea 5: 25-28; 1986) 77

Chapter 10 Correction of postkeratoplasty astigmatism by razor blade and V-shaped knife wedge resection.
(Ophthalmic Surg. 14: 406-410; 1983) 81

Summary 87
Samenvatting 89
Acknowledgements 91
Curriculum vitae 92

REFRACTIVE CORNEAL SURGERY

Gabriel van Rij

(translated from: Ned Tijdschr Geneeskd 1986; 129: 1313-1317)

INTRODUCTION

By refraction of the eye we understand the relationship between the strength of the optic system and the length of the eye, measured at the optic axis. Approximately 20% of the Dutch population is affected by one or another refractive disorder; myopia, hypermetropia or astigmatism. The majority can be helped with glasses or contact lenses, though for many patients these optical devices prove to be an intolerable hindrance. Since long surgical techniques that would allow patients better vision without an optical device have been tried. Refractive surgery can be defined as an operation meant to change the strength of the optic system. The best known and generally accepted surgical method is the implantation of an artificial lens in the eye after lens extraction. [1] This method is well-known, has predictable results and a long term follow-up.

It is the aim of refractive corneal surgery to alter the known calculated strength of the cornea in such a way to achieve a desired change in refraction. With its diameter of only 12 mm and a thickness of 0.5 mm the cornea presents certain surgical limitations. A number of basic ideas about refractive surgery of the cornea have been known as early as the end of last century and the work in this field of our fellow countryman Lans is especially noteworthy. [2] The predictability of the results of this surgical intervention remained unreliable and it was only in the 1980's that this procedure gained recognition. Improved techniques leading to better reliability as well as an increase in public awareness has led to a greater demand for refractive surgery. Despite the fact that this operation is widely performed, there are ever again new developments. As patients are operated upon, who can otherwise, with the help of glasses, be brought to full vision, surgery must have been proved safe and reliable on the long term before it is performed on a large scale. The possible complications and effects of refractive surgery must always be weighed against the potential drawbacks of other generally accepted optical devices.

A brief outline of the most important clinical refractive surgery methods will be given. A more detailed description on radial keratotomy and epikeratophakia will follow, as these two methods are currently most in demand. Roughly there are two methods; lamellar refractive surgery of the cornea in which a lens is attached onto or in the cornea, and keratotomy in which cuts are made in the cornea to change the refraction. [3] The table shows a brief review of the most important methods; see figure for a clearer illustration of refractive surgery procedures.

LAMELLAR CORNEAL SURGERY

Keratomileusis

This technique was developed in 1940 by Dr. J.L. Barraquer in Bogota. With a motor driven microkeratome a lamellar section of cornea tissue is removed. This section is then quickly frozen, shaped to the correct strength on a cryolathe, thawed and then replaced and sutured in the patient's stromal bed. [4], [5] A number of keratocytes survive the freezing. This is a technically complex surgical procedure that requires the use of a wide range of surgical equipment and is therefore used in only a few centers in the world. Because of the complex and unpredictable distention of the tissue during freezing it is difficult to shape the lens so that after thawing it has the correct adjustment. This is one of the reasons why predictability of refraction is limited. At present new techniques are being developed in which the corneal section would no longer need to be frozen. [6] However, the clinical results are not well enough known yet. Adults, with a high degree of myopia who are unable to wear contact lenses or patients whose work requires a certain visual acuity without corrective devices, may be treated with keratomileusis.

Epikeratophakia

This technique, a much safer and less complicated method than the above procedure, was developed in the late 70's in New Orleans. [7]-[9] Human donor cornea tissue, of which the endothelial layer is of such poor quality that the donor cornea is not suitable for a penetrating corneal transplant, is ground in the laboratory with the Barraquer cryolathe into contact lenses and then freeze-dried. These contact lenses can be sent by mail and can be at a much later date attached to the cornea of the patient (figure). Only the edges of the grafted section attach to the circular groove in the patients cornea. If there are complications or the required change of refraction is not achieved, it is possible to remove the epikeratoplasty, after which the patient will return to his preoperative refraction.

The greatest problems with epikeratophakia are the epithelialization of the donor tissue, the unpredictability of refraction and the length of recovery time needed to restore sight to the original state, with glasses. As can be expected, all keratocytes are destroyed the process of freezing and as a result sometimes the patient's cornea epithelium will not grow over the dead tissue. In addition, because there are no living keratocytes in the donor tissue, this will remain cloudy for a long time. In aphakia patients a thick section of donor tissue is attached to the cornea which causes the recovery period to be much longer than in a myopia patient where only a thin section is attached. Because of this time factor a number of aphakic patients with an otherwise successful surgical intervention acquire a visual acuity that is slightly less than their previous acuity with an optical device.

One great advantage of the method is that it can already be used in children just over one year old. The predictability of the postoperative refraction is closely related to the preoperative condition. With hypermetropic and aphakic patients the refraction predictability is greater than that for myopic patients, but is still by far not as reliable as the intraocular lens. The technique is still liable to changes and results are improving, though results from a good study with a five year follow-up are not yet available. It is therefore understandable that this operation will only be used when an aphakic patient can no longer wear glasses or when there is a contraindication for secondary implantation of an intraocular lens. For patients with a myopia of more than 12 D who can not wear contact lenses the operation may be considered. These patients are able to see clearly with glasses but are handicapped by them. In this case both eyes must be operated on, otherwise anisometropia will develop. Because of a lack of donor tissue, this method will probably not be employed on a large scale in the near future.

Keratophakia

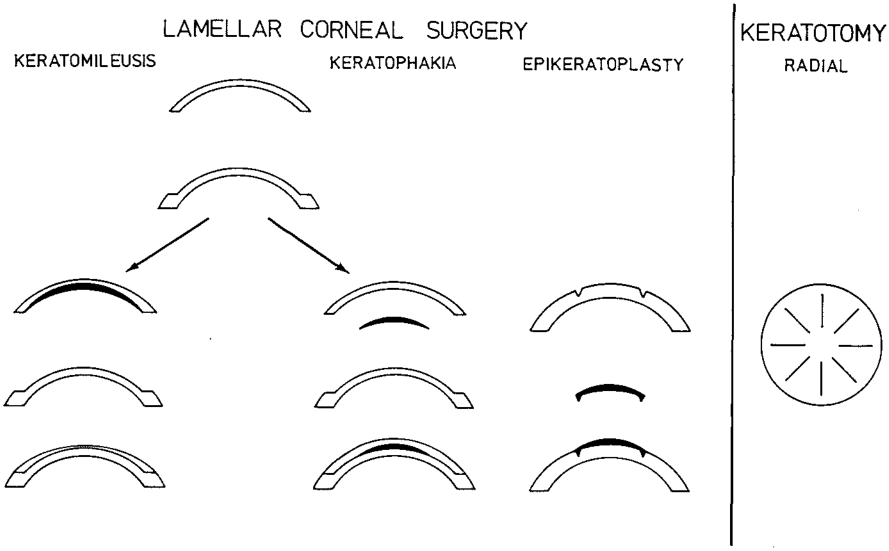
In keratophakia (lens in the cornea) a lens of human donor tissue [5] or of synthetic, soft [10], [11] or hard [12] contact lens material is planted in the stromal bed of the cornea (figure). Keratophakia with human donor tissue was first developed by Barraquer in Bogota. First, a piece of donor corneal tissue is, after freezing, shaped into a lens and kept in liquid nitrogen. A microkeratome is used to remove a lamellar section of the patient's cornea. The thawed donor lens is then placed on the patient's stromal bed and the lamellar section is sutured back into place over the donor lens. The curvature of the cornea is therefore altered, which in turn alters the refraction. As a piece of dead corneal tissue is used this will remain cloudy for a long period and visual recovery will, accordingly, be slow. The final dioptric power is fairly unpredictable and the method is therefore seldom used.

Synthetic contact lens material is readily available and can be easily and accurately

Table: Refractive corneal surgery.

surgical technique	*for the correction of*	*difficulty*	*freezing of corneal tissue*	*complications*	*number of patients (February 1986)*	*5 year follow-up*	*predictability*
lamellair							
keratomileusis	high myopia hypermetropia aphakia	+++	+	+++	> 2000	+	moderate
epikeratoplasty	high myopia hypermetropia aphakia keratoconus	+	+	+	1500	-	moderate/fair
keratophakia							
- lens of human donor	aphakia	+++	+	++	> 100	+	moderate/fair
- synthetic lens							
soft contact lens	myopia hypermetropia aphakia	++	-	++	a few	-	fair/good
hard contact lens	myopia hypermetropia aphakia	+	-	++	> 40	-	good
keratotomy							
- radial	low myopia < 6 D low astigmatism < 1.5 D	+	-	+	> 50.000	-	fair/good
- semi circular	high astigmatism	+	-	+	> 500	+	moderate/poor
keratectomy							
wedge resection	high astigmatism	+	-	+	> 500	+	fair

shaped into lenses. Soft contact lenses are implanted according to the above method. The refraction index of the soft contact lens is comparable to that of the cornea and its permeability allows adequate flow of water and glucose. In experiments with monkeys the predictability of the final optic power was good and the lens material was tolerated at least five years. Until now only a few lenses have been implanted in humans. Hard contact lenses are not water and glucose permeable and have therefore in the past led to trophic ulcers in the cornea. [13]



KERATOTOMY

Radial keratotomy

At the end of the last century our fellow countryman, Lans, tried to treat astigmatism by making non-perforating radial incisions in the cornea. [2] Even though the effects of such incisions in the cornea were known this surgical method was seldom employed, particularly because of the unpredictability of results owing to the insufficiency of the then available instruments. The goal of radial keratotomy is to correct slight myopia in adults. Patients who want to undergo radial keratotomy often give reasons of wanting normal visual acuity without a visual aid, [14] though of these patients only a few have occupational motives.

Technique. With the aid of a computer, into which information about the patient has been fed, the surgical technique is determined. After marking the optical zone 3-4 mm in diameter the corneal thickness is measured by means of ultrasound. With a calibrated diamond blade, four to sixteen radial incisions extending from the edge of the optical zone to the limbus, are subsequently made. The incisions must be made as deeply as possible without perforating the cornea. The deeper the incision and the smaller the optic zone the greater the effect. In patients with astigmatism additional small incisions can be made parallel to the limbus. It is wise to advise against operating on both eyes in the same session.

There are often great differences in **results.** Any number of factors; age, sex, intraocular pressure, curvature of the cornea, etc. can play a role. Of these factors the most important is the preoperative refraction. Literature shows that there is a possibility for reasonable prediction of refractive correction results in a myopia between 1 and 4 Diopters. Above 6 D the predictability becomes less accurate and fluctuations of diurnal visual acuity may exist for an extended period.

To further the study of radial keratotomy the American National Eye Institute subsidised in 1980 the PERK project, in which nine American eye centers cooperated in studying results of standardized techniques. The results after one year were not significantly different from other studies. [15], [16] The principal conclusions were that myopia can be treated with radial keratotomy and that limited predictability of intervention remains the most prominent problem.

Predictability decreased with a high preoperative myopia and with a small optical zone. After one year the PERK study showed that 48% of the patients were completely satisfied with their achieved visual acuity, 42% satisfied and 10% dissatisfied. [17] Accurate vision without correction and lack of fluctuation in visual acuity in daytime were the most important factors for satisfied patients. [17] A good investigation with a follow-up of five years has yet to be achieved. Deitz and Sanders published the first study with a follow-up of four years, [18] in which they found a progression of effect between one and four years after radial keratotomy. Most eyes became more hypermetropic. Results of other studies show that the desired visual acuity is often not achieved after the first year and that the cornea requires at least four years to heal completely. [19] In addition the cornea will always remain weaker where the incisions have been made.

Side effects and complications. The most frequent complications are over and under correction, fluctuating diurnal visual acuity, and problems with glare. [15], [16], [20] With a myopia of more than 6 D the degree of predictability decreases rapidly. Intrastromal epithelial cysts may lead to irregular astigmatism and loss of visual acuity. The loss of endothelial cells is slight and there seems to be no progression in the first year, [21] though there is little known about the long term effect. Changes in the cornea epithelium that resemble 'map-dot-fingerprint' cornea dystrophy, frequently occur without clinical consequences. [22]

Nearly all the serious complications that can appear in the field of eye surgery have been described in connection with radial keratotomy. [20], [23] However, these complications seldom occur and will occur even less frequently with the improvement of techniques. There is still too little known about safety and long term complications of radial keratotomy.

Semi-circular incisions and wedge resections

Many patients with serious cornea-astigmatism after a cornea transplantation or cataract surgery may be helped with contact lenses. If this is not possible the astigmatism can only be corrected by surgery (see table). [24], [25] The predictability of semi-circle incisions is very moderate while the wedge excision gives a greater predictability, though visual recovery time is much longer.

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SCOPE OF THE PRESENT STUDY

The cornea, aqueous, lens and vitreous body have a much higher refractive index than the air in front of the eye. This large difference in the refractive index, between the air in front of the eye and the cornea makes the cornea the most powerful lens of the optical system of the eye. The refractive power of the cornea depends on its curvature and its index of refraction. The refractive index of the cornea is 1.376. The radius of curvature of the anterior surface of the cornea can be determined by a keratometer and ranges from 7.0 to 8.5 mm. Small changes in the radius of curvature will result in relatively large changes in dioptric power. For instance: Changing the corneal radius from 8.0 mm to 7.5 mm will change the refractive power from 42 to 45 Diopters.

In most eyes, the central area of the cornea is nearly spherical. Sometimes, however, the corneal curvature is flatter in one direction (mostly from side to side) and steeper in the other direction. If the cornea has its direction of flatter curvature and steeper curvature at right angles to one another we call this regular astigmatism. In irregular astigmatism the surface of the cornea is irregular without symmetry. Although lenticular astigmatism, caused by a real or an artificial intraocular lens, exists, astigmatism is chiefly due to the curvature of the cornea.

A change in corneal curvature occurs frequently after cataract and corneal surgery. It is also the aim of refractive keratoplasty.

The first section of this thesis deals with the mechanisms by which sutures, incisions and intracorneal lenses produce a change in corneal curvature. Although corneal astigmatism is common after cataract surgery, the mechanisms by which incisions and sutures induce it need further elucidation. Common sense suggests that pulling by a suture on domed tissue would be expected to flatten it, but ocular surgeons know that a tight suture steepens the central cornea in the meridian of the suture. The mechanisms by which this occurs are discussed in chapter 2. The applicability of sutures and intracorneal lenses in refractive surgery are discussed in chapters 3-5.

In the second section corneal astigmatism after penetrating keratoplasty will be discussed.

Advances in instrumentation, suture materials, tissue preservation, HLA matching, surgical techniques and medication have improved the prognosis for a clear penetrating graft tremendously. Nowadays, however, a successful graft is not only considered to be a clear graft, but also a graft with low astigmatism. Clear grafts, with a visually debilitating astigmatism are often considered unsuccessful. The mechanisms that cause postoperative astigmatism are not completely understood.

Four of the main factors are: 1. preoperative state of the recipient cornea; 2. configuration of the trephine opening in the recipient cornea and the configuration of the donor cornea; 3. suture technique; 4. wound healing.

1. Preoperative state of the recipient cornea.
In 64% of 105 cases of penetrating keratoplasty it was shown that the postoperative astigmatism correlated well with the preoperative Placido axis [1]. It seems clear that a transplant in a cornea with a significant astigmatism, produced by e.g. a corneal scar, has an intrinsic astigmatism which is not dependent on the surgical technique we use. Thus, it seems necessary to consider the preoperative astigmatism when we look at the postoperative results.

2. Configuration of the trephine opening in the recipient cornea.
The precision of trephining of the recipient cornea is a very important factor. We measured the epithelial diameter, the endothelial diameter, and the angle between the epithelial surface and the cut of both human corneal buttons and pig's eyes (chapters 7 and 8). Slight decentration of the donor button in the host cornea does not seem to affect the postoperative astigmatism. Marked eccentricity, however, does (chapter 9).

3. Suture technique.
Many authors discussed the influence of suture adjustment during surgery on postoperative astigmatism. To resolve this problem we determined the influence of sutures on postoperative astigmatism before and after suture removal in a monkey experiment (chapter 10).

4. Wound healing.
A completely different approach is the selective removal of interrupted sutures in the early postoperative period [2]-[3]. By removing an interrupted suture in the early postoperative period, we can manipulate the wound healing and reduce the astigmatism. Our results with this technique are good. Other methods to influence wound healing are interesting but beyond our control at present.

If, in spite of our efforts, a high postoperative astigmatism is developed, which cannot be managed successfully with glasses or contact lenses, a surgical approach may be indicated (chapter 11).

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SECTION I

CHANGES IN CORNEAL CURVATURE INDUCED BY SUTURES, INCISIONS AND INTRASTROMAL CONTACT LENSES

CHANGES IN CORNEAL CURVATURE INDUCED BY SUTURES AND INCISIONS

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To clarify the mechanisms by which incisions and sutures produce corneal astigmatism, we made incisions and wedge resections closed by sutures in the corneoscleral limbus of human eye bank eyes, studying the changes in corneal curvature by shadowgraph photography of the corneal contour, by central keratometry, and by measurement of corneal diameter. The compression of tissue within the sutures or the closure of an excision of a wedge of tissue by sutures induced astigmatism in the meridian of surgery regardless of changes in the sagittal depth of the anterior chamber. Sutures and wedge resections closed by sutures in the anterior part of the cornea compressed or removed more tissue from the anterior part than the posterior part, producing a depression of the limbal cornea toward the anterior chamber and steepening the central cornea in the meridian of surgery. The corneal diameter decreased in that meridian. In the opposite meridian, the cornea flattened, the corneal diameter increased, and the sagittal depth decreased.

Corneal astigmatism occurs frequently after cataract and corneal surgery,[1-4] but the mechanisms by which incisions and sutures produce this astigmatism are not completely understood.[5-10]

We attempted to clarify the manner in which limbal corneal sutures and incisions change corneal curvature in human donor eyes.

MATERIAL AND METHODS

Methods of measurement—We used a shadowgraph technique to measure the sagittal depth and the profile of the cornea before and after incisions and suturing to document changes in corneal curvature. A fresh human donor eye was glued in a metal cup and held in a gimbal-like device that allowed rotation of the globe in all directions and alignment of the plane of the cornea horizontally (Fig. 1). To control the intraocular pressure, we inserted an 18-gauge needle through the metal cup and the posterior sclera into the vitreous and connected it by tubing to a bottle of normal saline solution placed 13.6 cm above the eye

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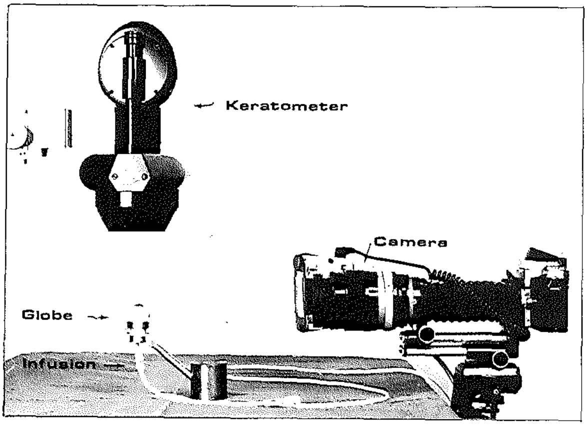

Fig. 1 (van Rij and Waring). Human donor eye is glued in a gimbal-like metal cup. The keratometer is mounted above the eye. The camera photographs the contour of cornea. Infusion tubing maintains the intraocular pressure.

to produce an intraocular pressure of 10 mm Hg.

During enucleation a few millimeters of the medial rectus muscle was left at the donor eye. This allowed determination of the 9 o'clock position. When the 9 o'clock position could not be determined it was marked arbitrarily.

Before the corneal incision was made, we measured the intraocular pressure with a Schiøtz tonometer. After the incision and suturing, the pressure was judged by palpation and kept around 10 mm Hg. We filled the anterior chambers of some eyes with sodium hyaluronate to seal the wound that had been closed with a loosely tied suture.

Black 7-0 silk sutures were placed superficially parallel to the corneoscleral limbus at the 12, 3, 6, and 9 o'clock positions into the sclera to serve as markers for measurement of the horizontal and vertical corneal diameter with a screw micrometer. To insure that the technique for measuring diameter was reproducible, we measured the same cornea ten times and calculated the mean and standard deviation.

To measure the central corneal curvature, we mounted a keratometer vertically above the eye (Fig. 1). All measurements were repeated three times and the mean taken as the final value. In some instances, the eye was rotated and readings were taken 5 and 10 degrees from the center of the cornea.

To photograph the cornea and sclera, we placed the globe in front of a tripod-mounted 35-mm camera equipped with an autobellows, a telephoto or macro lens, and a flash secured to the end of the lens. The profiles of the cornea and anterior sclera were photographed and the resulting slide projected on white paper where the outline was traced like a shadowgram. Magnification was controlled by photographing a micrometer before photographing each globe.

Three or four stainless steel needles radially inserted into the globe served as reference points. One or two were inserted into the corneoscleral limbus and two into the equator 180 degrees apart. Shadows of these needles appeared on the projected photograph. Thus, when a sequence of slides of the same globe was projected on the same paper screen, the needles on each slide aligned with those traced from the previous slides. This placed each slide in the series in register so that the outline of the cornea could be traced, allowing direct comparison and measurement of changes in corneal contour after the surgical procedures.

All surgery was done in the periphery of the cornea at the previously marked 12 o'clock position to maintain the orientation of conventional human surgery. Monofilament 10-0 and 9-0 nylon suture material was used on a single curved side cutting needle. All experiments were repeated at least five times.

We studied changes in corneal contour as measured on the shadowgraph and power as measured by central keratometry after wedge and block resections, limbal incisions, and placement of sutures of varying tightness (Fig. 2). The Table lists the seven types of experiments and the number of eyes in each group.

Anterior suture with and without corneal incision—In 17 eyes we placed anterior radial sutures (Fig. 2) across the corneoscleral limbus to an approximate depth of two thirds of the corneal thickness with or without a corneal incision parallel to the corneoscleral limbus. Suture depth was estimated with a slit lamp. In 12 eyes with limbal incisions, the sutures were tightened and tied in a manner simulating that in human cataract surgery. In five eyes without incisions, we measured the suture length before and after tightening the suture. In these eyes the suture was tightened more and more by turning a stainless steel needle (diameter, 0.15 to 0.25 mm) in the suture loop to increase the tension until the suture was extremely tight. In one eye, we placed two sets of sutures, the first with short bites and the second with long bites.


anterior suture posterior suture


anterior wedge posterior wedge


block resection relaxing incision

Fig. 2 (van Rij and Waring). The six types of operations performed.

Anterior wedge resection and sutures—In five eyes we excised a crescentic wedge of corneal tissue between the 10:30 and 1:30 o'clock positions with a V-shaped knife[11] (Fig. 2). The width in the center of the wedge at the anterior surface was approximately 0.8 mm and the depth extended to Descemet's membrane. Six interrupted 10-0 nylon sutures at two thirds of the corneal depth closed the wound with the same moderate tension used in human surgery.

Full-thickness block resection and suture—In six eyes we excised a half-moon-shaped full-thickness strip of corneal tissue 0.8 mm wide from the 10:30 to 1:30 o'clock positions with a razor-blade knife. The sides were cut perpendicular to the cornea. Three full-thickness 10-0 nylon sutures were placed equidistant from each side of the wound and tied with moderate tension[12] (Fig. 2).

Corneal incision and posterior suture—In five eyes we made a full-thickness corneal incision parallel to the corneoscleral limbus, and then placed a single posterior radial suture (Fig. 2) through two thirds of the posterior corneal thickness. The first bite was placed in the incision from the stroma through the endothelium and the whole needle was then inserted into the anterior chamber and the second bite was made from the endothelium through the stroma extruding in the incision. The suture was tightened and the knot tied in the wound just under the corneal surface.

Posterior wedge resection and suture—In five eyes we made a full-thickness corneal incision parallel to the corneoscleral limbus, and then removed a wedge of corneal tissue with a central width of approximately 0.8 mm between the 10:30 and 1:30 o'clock positions at the posterior side of the cornea with a razor-blade knife and Vannas scissors (Fig. 2). Three interrupted 10-0 nylon sutures were placed into the posterior cornea (posterior suture) at a depth of two thirds of the corneal thickness and were tied in the wound to close the wedge resection.

Relaxing incisions—In five eyes we made a trephine mark 8 mm in diameter in the epithelium, and two relaxing (unsutured) incisions in the trephine mark from the 10:30 to 1:30 o'clock positions and from the 4:30 to 7:30 o'clock positions through 75% of the corneal thickness (Fig. 2).

RESULTS

The mean of ten repeated measurements of the same corneal diameter was 12 ± 0.03 mm (range, 11.96 to 12.06 mm), indicating that the method of measurement was precise. The Table summarizes the results of each experiment.

Anterior suture with and without corneal incisions—The tissue inside and around an anterior corneal suture in the vertical meridian moved posteriorly toward the center of the globe (Fig. 3), showing greater displacement on the central corneal side than on the peripheral scleral side of the suture. This posterior displacement decreased the sagittal depth of the cornea, so that the depth of the anterior chamber decreased slightly. Despite this, the center of the cornea steepened. In all anterior suture experiments, a suture at the 12 o'clock position steepened the vertical meridian and flattened the horizontal meridian (Table). The suture also decreased the vertical diameter of the cornea and increased its horizontal diameter. The maximal steepening and maximal astigmatism at the five measuring points along the vertical axis appeared 10 degrees from the center of the cornea adjacent to the suture (Fig. 4).

A longer suture bite placed at the same depth with approximately the same suture tension caused more steepening of the corneal apex in that meridian than a shorter suture did (Fig. 5).

TABLE

EFFECT OF LIMBAL SUTURES AND INCISIONS ON CENTRAL CORNEAL CURVATURE, CORNEAL DIAMETER, AND CORNEAL SAGITTAL DEPTH

Surgical Procedure*	No. of Eyes	Change in Central Corneal Curvature (mean diopters ± 1 S.D.)	
		Vertical Meridian	Horizontal Meridian
Anterior suture			
Normal tightness, with or without incision	12	+8.43 ± 3.16	−4.99 ± 2.63
Extreme tightness, without incision	5	+3.80 ± 2.83	−13.28 ± 3.58
Anterior wedge resection	5	+5.90 ± 1.64	−7.53 ± 1.10
Block resection	6	−2.17 ± 1.60	−8.78 ± 1.49
Posterior suture	5	−6.16 ± 1.42	−4.65 ± 3.77
Posterior wedge resection	5	−6.31 ± 3.71	−8.54 ± 3.09
Relaxing incisions	5	−5.35 ± 1.78	+4.24 ± 1.15

*All surgery was performed in the vertical meridian at the 12 o'clock position.

[†]Measured on the shadowgraph.

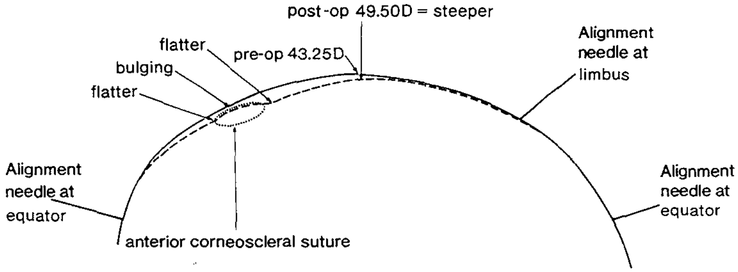

Fig. 3 (van Rij and Waring). Change in anterior corneal curvature induced by an anterior suture at the corneoscleral limbus. Three stainless steel alignment needles were inserted into the globe, two at the equator and one at the corneoscleral limbus, to serve as reference points. The tissue inside and around the suture moves toward the center of the globe, causing the central cornea to steepen. Sagittal depth decreases.

Increasing the tightness of the same suture by putting a needle in the tied suture loop and twisting it caused more steepening at the central cornea until a maximum was reached; thereafter, further tightening of the suture flattened the central cornea (Fig. 6). The sagittal depth decreased continuously as the suture was tightened.

In four eyes we measured the length of the suture before and after tightening and assumed that the reduced length reflected increased tissue compression. The mean suture length before tightening was 1.98 ± 0.11 mm. As the suture shortened, the central cornea in that meridian steepened until a maximum was reached when the suture length was decreased by 0.5 mm (Fig. 7).

Anterior wedge resection with suture—The tissue inside and around the sutures that close an anterior wedge resection moved posteriorly toward the center of the globe, decreasing the sagittal depth (Fig. 8). In the vertical meridian of the resection, the central cornea steepened and the corneal diameter decreased, whereas in the horizontal meridian the central cornea flattened and the diameter of the cornea increased. These changes were similar to those caused by an anterior suture, but were of greater magnitude (Table).

Full-thickness block resection with

TABLE *(Continued)*

Induced Astigmatism in Vertical Axis (mean diopters ± 1 S.D.)	Mean Change in Corneal Diameter (mean mm ± 1 S.D.) Vertical	Horizontal	Sagittal Depth (mean mm ± 1 S.D.)†
+13.13 ± 5.33	−0.10 ± 0.06	+0.08 ± 0.05	−0.10 ± 0.07
+17.08 ± 1.77	−0.29 ± 0.07	+0.15 ± 0.09	−0.29 ± 0.08
+13.43 ± 0.84	−0.35 ± 0.08	+0.30 ± 0.12	−0.26 ± 0.02
+6.60 ± 2.36	−0.33 ± 0.16	+0.24 ± 0.06	−0.45 ± 0.10
−1.51 ± 1.79	−0.01 ± 0.04	+0.05 ± 0.04	−0.12 ± 0.07
+2.82 ± 3.09	−0.32 ± 0.29	+0.18 ± 0.06	−0.32 ± 0.16
−9.59 ± 2.87	+0.13 ± 0.05	−0.06 ± 0.04	−0.01 ± 0.01

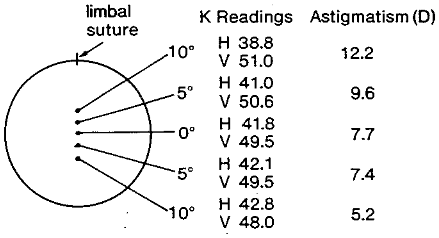

Fig. 4 (van Rij and Waring). An anterior suture at the 12 o'clock position of the corneoscleral limbus changes the corneal curvature (diopters) along the vertical meridian at 0, 5, and 10 degrees from the visual axis. Maximal steepening occurs 10 degrees above the center of the cornea.

suture—In the vertical meridian of the block resection, the diameter of the cornea decreased and the sagittal depth decreased, whereas the central corneal curvature flattened moderately in four eyes, did not change in one, and steepened minimally in one (Fig. 8). The horizontal meridian flattened and increased in diameter in all six eyes (Table).

Posterior suture—In the vertical meridian of the posterior suture, the central cornea flattened in all five eyes while the diameter of the cornea changed minimally. It decreased in three eyes and increased in two eyes. The horizontal meridian flattened in all eyes while the diameter increased in three and decreased in two eyes (Fig. 9; Table). The sagittal depth decreased in all five eyes.

Posterior wedge resection with suture—In the vertical meridian of the posterior wedge resection, the central cornea flattened and the corneal diameter decreased in all five eyes. The horizontal meridian also flattened but the corneal diameter increased (Table). The sagittal depth decreased (Fig. 9). The changes were similar to those caused by a posterior suture but of greater magnitude (Table).

Relaxing incisions—In the vertical meridian of the relaxing incisions, the central cornea flattened and the corneal diameter increased, whereas the horizontal meridian steepened with a decrease in corneal diameter (Fig. 10). The sagittal depth minimally decreased in three eyes and increased in two.

DISCUSSION

Although corneal astigmatism is common after cataract surgery, the mechanisms by which incisions and sutures induce it need further elucidation. There are four theories that attempt to explain the induced changes in corneal curvature (Fig. 11).

Theory 1: Pulling on domed tissue would be expected to flatten it (Fig. 11, B) but ocular surgeons know that a tight suture steepens the central cornea in the meridian of the suture. Pulling on one side of the tissue flattens it. Limbal sutures, however, do not pull the cornea taut but compress the tissue.

Theory 2: Some explain the steepening of the cornea induced by an anterior

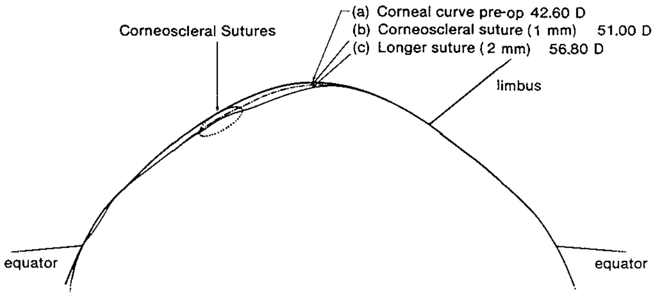

Fig. 5 (van Rij and Waring). Suture length influences astigmatism, with a longer suture causing more steepening of the central cornea.

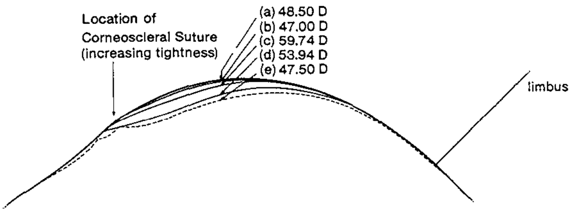

Fig. 6 (van Rij and Waring). Changes in central corneal curvature induced by increasing tightness of the same suture: a, preoperative keratometry reading of 48.50 diopters; b, incision at the corneoscleral limbus and loose suture flatten central cornea to 47.00 diopters; c, tightening of the suture steepens central cornea to 59.74 diopters; d and e, further tightening of the suture flattens central cornea to 53.94 diopters and then to 47.50 diopters. Sagittal depth decreases.

suture or anterior wedge resection in terms of the decreasing circumference of an imaginary circle of which the cornea is a segment[6,8] (Fig. 11, C). This circle theory assumes that removal of tissue decreases the circumference and the radius of the circle, increasing the curvature of the circle and its dioptric power. We do not think this theory adequately explains experimental or clinical observations.

If we assume that the cornea is a segment of a circle with a radius of 7.8 mm (43.26 diopters), the circumference of that imaginary circle would be $2\pi \times$ 7.8 mm or 49.009 mm. Removing 0.5 mm of tissue would make the circumference 48.509 mm. The new radius would be 7.72 mm (43.71 diopters). With this model the steepening would be 43.71 − 43.26 or 0.45 diopters. But our experiments demonstrated a steepening of more than 10 diopters when 0.5 mm of tissue was compressed by an anterior suture (Fig. 7) and a mean steepening of 5.81 diopters after an anterior wedge resection (Table). Moreover, the circle theory suggests that a posterior wedge resection, a block resection, and a posterior suture, all of which decrease the circumference of the imaginary circle, should steepen the cornea. But instead, the cornea flattened in all the eyes with posterior sutures and posterior wedge resections and in four of the six with block resections. Thus, some mechanism other than reduction of the circumference must account for the change of corneal curvature.

Theory 3: We think a major factor accounting for the change in corneal shape is compression or removal and suturing of tissue (Fig. 11, D). Our experiments on human eye bank eyes showed that tissue compression or removal and suturing induce astigmatism regardless of changes in the sagittal depth of the cornea. For example, if we remove a wedge from a long piece of wood and glue the two ends together, the surface from which the wedge was removed forms an acute angle

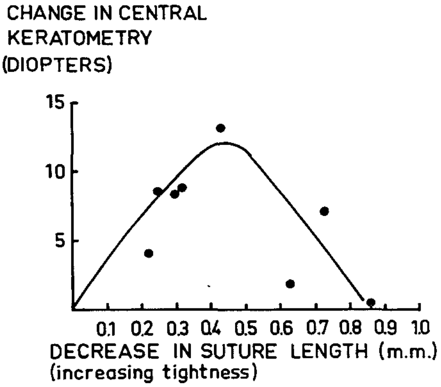

Fig. 7 (van Rij and Waring). As suture was tightened, its length decreased and the central cornea steepened. If length was reduced more than 0.5 mm, the central cornea flattened.

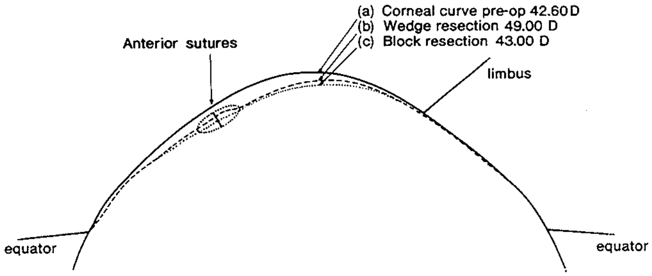

Fig. 8 (van Rij and Waring). Anterior wedge resection and full-thickness block resection closed with sutures decrease the sagittal depth of the central cornea, but only the wedge resection steepens the central cornea significantly.

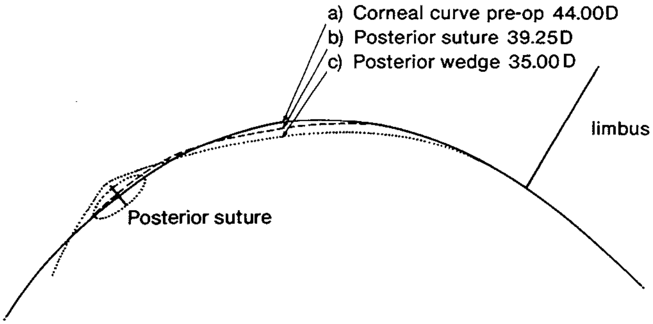

Fig. 9 (van Rij and Waring). Both a posterior suture and a sutured posterior wedge resection flatten the central corneal curvature. Sagittal depth decreases.

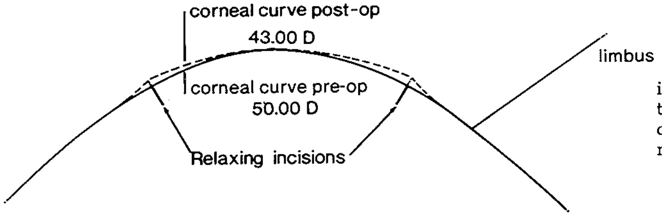

Fig. 10 (van Rij and Waring). Relaxing incisions flatten the central corneal curvature, changing the sagittal depth minimally.

(Fig. 12, a and b). Similarly, if we remove a wedge of tissue from the outside of the cornea and approximate the edges together with sutures, the corneal dome will be indented toward the center (Fig. 12, c and d), steepening the cornea at both sides of the wedge. This is what happens in the cornea after an anterior wedge resection or placement of an anterior suture. The wedge resection removes more tissue from the outside than from the inside of the cornea. An anterior suture compresses more tissue on the outside than on the inside of the cornea, effectively removing this compressed tissue. This moves the epithelial side of the cornea posteriorly towards the center of the globe and steepens the cornea at both sides of the compressed tissue (Fig. 11, D, and 12). The longer and tighter the suture, the greater the compression and the greater the deformation.

Conversely, a posterior suture and a posterior wedge resection move the tissue away from the center of the globe by compressing the tissue on the inside of the cornea. After a relaxing incision, the outer side of the cornea gapes open and the tissue moves away from the center of the globe, causing a flattening of the central curvature in that meridian.

Alterations in curvature occur independent of changes in sagittal depth (Table). The sagittal depth decreased in the first six experiments. In the vertical axis the center of the cornea steepened in all the anterior sutures and the anterior wedge resection experiments but flat-

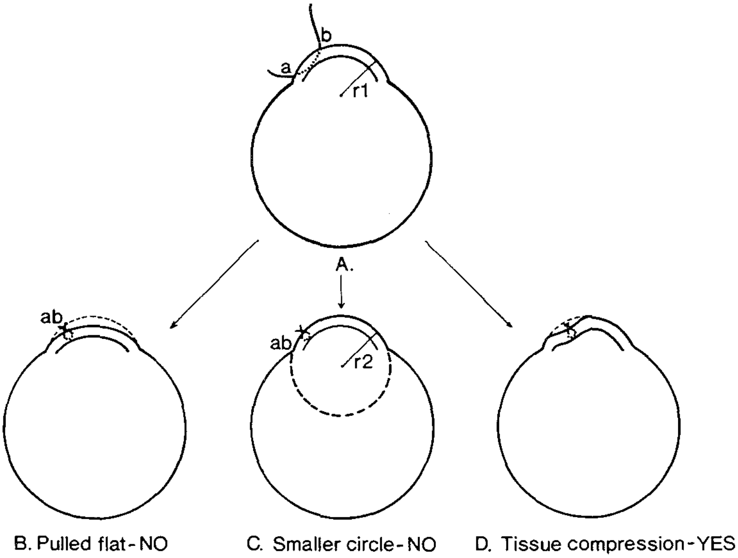

Fig. 11 (van Rij and Waring). Three theories used to explain the effect of a limbal corneal suture on central corneal curvature. A, Before suture (ab) is tied, the cornea has a radius of rl. B, The suture might pull the tissue taut, flattening the cornea centrally, but keratometric measurement demonstates that the cornea steepens centrally. C, The circle theory suggests that the circumference of the cornea is reduced, creating a smaller radius of curvature (r2) and a steeper cornea but the predicted amount of steepening is far less than the amount measured clinically or experimentally. D, The tissue compression theory suggests that the suture compresses the tissue focally depressing the cornea and steepening it centrally. This theory explains clinical and experimental observations.

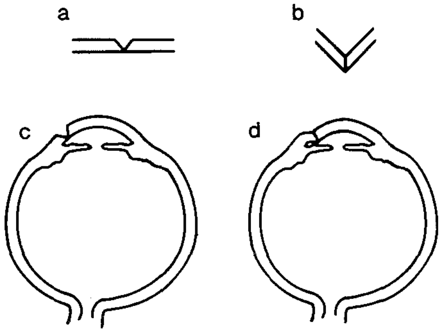

Fig. 12 (van Rij and Waring). Illustration of compression theory. A wedge is removed from a piece of wood (a) and from the corneoscleral limbus (c). When the two sides are approximated by glue (b) or sutures (d), the area around the wedge resection is depressed, while the area remote from the wedge is steepened.

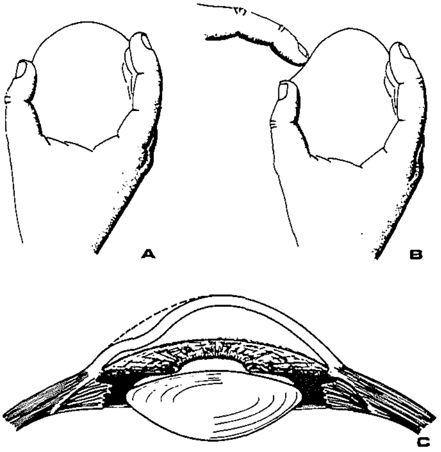

Fig. 13 (van Rij and Waring). Illustration of the compression theory. A. A card is arched between thumb and first two fingers. B, Forefinger depresses the area near the end of the arched card, causing a steepening of the central part of the card. C. Depression of peripheral cornea where sutures compress the tissue, steepening the central cornea.

tened in the block resections, posterior sutures, and posterior wedge resections.

Theory 4: These experiments supported the observations of Troutman[6] that a tight suture shortens the vertical diameter while it increases the horizontal diameter, a phenomenon referred to as ovaling. The horizontal flattening was increased despite a decrease in sagittal depth in most experiments (Table). The horizontal flattening was most marked when tissue was removed (wedges and block resection) or when the sutures were extremely tight.

Thus, tissue compression and tissue excision are the most important factors influencing the corneal curvature in the meridian of the surgery. They function independently of sagittal depth. The increase in diameter and decrease in sagittal depth are the most important factors influencing corneal curvature in the opposite meridian.

This can be illustrated by holding a card between the thumb and first two fingers and applying pressure to make the card arch over the palm (Fig. 13). When the forefinger of the other hand presses down near the arched card, this area moves toward the palm like limbal tissue near a suture and the arch of the central area of the card increases; resembling the steepening of the central cornea. The sagittal depth of the card changes minimally.

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Chapter 3

RADIAL CORNEAL SUTURES FOR THE CORRECTION OF MYOPIA

A LABORATORY EXPERIMENT

G. VAN RIJ, M.D.

SUMMARY

Radial interrupted nylon sutures were placed in the corneas of fourteen human donor eyes, in a laboratory setting, to produce a reversible surgical correction of myopia. Significant corneal flattening was achieved when a small optical zone (4-5 mm) was used but not with a larger optical zone. It may be possible that radial sutures have a permanent flattening effect when the sutures are left in place and keep their tensile strength.

INTRODUCTION

Recently there has been increased interest in radial keratotomy for the treatment for slight myopia. This is due to the enormously improved techniques and to the fact that the general public is better informed about the operation.

The principle of the action of non-perforating radial incisions was described by Dr. Lans [1] in the 19th century.

Sato introduced radial incisions for the treatment of myopia, [2] since then techniques have been considerably modified and improved. [3] The results of the operation vary greatly and many undesirable effects have been described such as: overcorrection or undercorrection, fluctuation of vision, progressive hypermetropia, reduced visual acuity and more serious complications. [4]-[7]

The operation is irreversible, which consideration led us to try and find a method that would be reversible and avoid some of the complications. In this study an attempt was made to flatten the center of the cornea of a human donor eye by placing radial sutures in the cornea.

METHODS

Fourteen fresh human donor eyes were used in the experiments. The eyes were stabilized by a gauze band sponge wrapped around the equator of the eye. The intraocular pressure was checked with a Schiøtz tonometer and kept between 10-15 mmHg. The plane of the cornea was horizontally aligned and keratometry was performed with a vertically mounted keratometer. All surgery was performed using an operating microscope.

Using a dull trephine, with a diameter ranging from four to seven mm, a superficial mark was made in the center of the cornea. Four radial, deep interrupted, 9-0 nylon sutures with a suture length between 1.5 and 2 mm were placed from the trephine mark toward the periphery in the four meridians (Figure 1). The sutures were tightened and tied in a manner simulating that used in human cataract surgery. The amount of tension of the suture was not measured directly, but was judged by visual inspection of the amount of tissue compressions and by moving the suture with a tying forceps. Those sutures that appeared inappropriately loose or tight were replaced until an approximate uniform tension was achieved. The intraocular pressure was then checked and keratometry was performed. Four additional sutures were placed between the first four and the examinations were repeated. Then, eight more interrupted 9-0 sutures were placed between the first set of sutures. At the end of the procedure all sutures were removed and keratometry repeated.

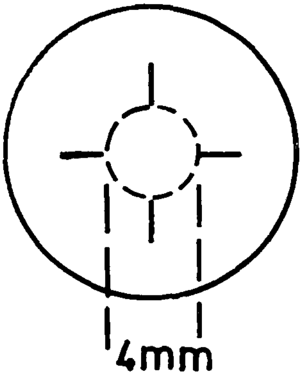

Figure 1. Four radial 9-0 nylon sutures from the central trephine mark towards the periphery of the cornea.

RESULTS

The table shows a summary of results of the experiments. With a large optical zone the central cornea tended to steepen. A small optical zone and eight sutures in place produced a significant amount of flattening of the cornea. With sixteen sutures the flattening was no longer within the range of the keratometer. These effects completely disappeared in all experiments after the sutures were removed.

Table. Keratometry Readings with 9-0 Nylon Radial Sutures

optical zone (mm)	change in keratometry readings in Diopters (spherical equivalent)			number of eyes
	4 sutures	8 sutures	16 sutures	
7	+ 2.50	+ 3.00	+ 0.5	1
6	+ 3.50	+ 2.75	+ 0.37	2
5	+ 2.50	- 2.75	- 2.33	5
4.5	- 6.50	-13.00	n.m.	2
4	- 9.7	-14.8	n.m.	4

COMMENT

Interrupted radial sutures were placed in human donor eyes to produce flattening of the cornea. The aim was to produce a reversible surgical treatment for myopia. Flattening of the cornea was only found when the optical zone was small (four to five mm), while with a larger optical zone some steepening of the cornea was produced. A radial corneal suture moves the tissue inside and around the suture posteriorly toward the center of the globe. [8] This posterior displacement creates a flattening directly adjacent to the suture and a steepening of the cornea further away. [8] By decreasing the diameter of the optical zone the steepening effect is lost and only the flattening effect; closer to the sutures, remains. By increasing the number of sutures more tissue is moved posteriorly toward the center of the globe, thus enhancing the flattening effect. The procedure of peripheral trephination and suturing has been performed in primates. [9], [10] In these experiments, when six and a half and seven mm trephine openings were made, only interrupted sutures were able to produce some flattening of the central cornea. [9], [10] A running suture produced some steepening.

Experiments in monkeys hold the most promise for providing information applicable to the human cornea, since monkey corneas have a Bowman's layer and are the most similar to the human cornea in structure. The diameter of the cornea of the Rhesus monkey, however, is smaller than the human cornea. A seven mm trephine mark in a Rhesus monkey cornea of 10.5 mm horizontal diameter would compare to an eight mm trephine mark in a 12 mm human cornea. It is probable that radial sutures produce a permanent flattening effect as long as the sutures keep their tensile strength. Unfortunately, the suture material that is commonly used becomes degradated in tissue. Therefore, new nonbiodegradable suture materials, such as metal sutures, etc., should be tested in animals in order to evaluate this approach.

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Hydrogel keratophakia: a freehand pocket dissection in the monkey model

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SUMMARY High water content hydrogels can be made with water and solute permeabilities comparable to those of the corneal stroma, thus making them feasible as intrastromal implants for refractive keratoplasty. The materials have been shown to be compatible with the cornea tissue, but for a lenticule of hydrogel to be effective in a refractive keratoplasty procedure it must alter the anterior curvature of the cornea. In this investigation hydrogel lenticules were implanted by a free-hand pocket dissection in eight *Macaca mulatta* (rhesus) and two *Macaca nemestrina* (pigtail) primate eyes. The results of pre- and postoperative keratometry and subjective retinoscopy as well as biomicroscopy were recorded. The alteration in refractive power was calculated in relation to the hydrogel lenticule parameters such as base curve, refractive index, etc. The corneal refractive change had a yield of +3±27% (±SD). The central keratometric change had a yield of +6±16%. The hydrogel plus power lenticule implanted in a free-hand intrastromal pocket created no significant steepening of the anterior cornea surface and therefore little change in refraction.

Refractive keratoplasty was introduced by Barraquer in 1949,[1] but recently interest in it has increased. The objective of the operation is to alter the anterior corneal curvature, providing a predictable, stable, and in some cases reversible change in refraction. Because of the large difference in the refractive indices of the precorneal tear film and air, small changes in the corneal radius will result in relatively large changes in its dioptric power. There are many types of refractive keratoplasty procedures, ranging from simple operations such as relaxing incisions and radial keratotomy to more complex, such as cryolathe keratophakia.

In 1966 Barraquer[2] placed alloplastic lenticules in the corneal stroma to achieve this goal. Successful implantation of different alloplastic lenses for therapeutic uses in corneal disease had been reported earlier.[3-6] Alloplastic implants of glass and Plexiglass were insufficiently permeable to water and nutrients to maintain normal corneal physiology. Celloidin implants caused foreign body reactions resulting in neovascularisation of the cornea.[2] Barraquer subsequently used human donor lenticules shaped on a cryolathe.[4] In recent years hydrogel polymers have evolved into materials that have permeabilities comparable to that of the corneal stroma, making them feasible as intrastromal implants for refractive keratoplasty. For example, McCarey and Andrews[7] used Permalens (Cooper Vision Laboratories, Inc.) as an aphakic intrastromal implant in keratophakia. The high water content hydrogels are well tolerated intralamellarly, eliciting no inflammation and minimal cicatricial response.[8-10] McDonald *et al.*[11] performed three hydrogel implantations within intrastromal pockets. The postoperative keratometry indicated that the corneal curvature changed by 4% of the predicted dioptric increase. A definition of the predicted dioptric change was not given nor was a descriptive technique of assuring keratometric centration over the implant. In a second report from the same laboratory Koenig *et al.*[12] performed seven pocket implantations of hydrogel lenses followed by trephine keratotomy 1 mm peripheral and concentric to the implant. They found that despite the +14·00 dioptre power of the implant (power is defined for an air/hydrogel interface) there was no significant alteration in the anterior curvature of the cornea.

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The McDonald and Koenig reports indicate that the presence of Bowman's membrane in the primate eye prevents the pocket implantation of a hydrogel lens from creating an alteration in the corneal anterior curvature. These findings support Barraquer's earlier observations.

Because of the impact this surgical procedure could have and the lack of refraction data in the previous studies, we considered the topic warranted a careful re-evaluation in the non-human primate eye with long-term (approximately one-year) follow-up to check for delayed or progressive reshaping of the anterior stroma to the implant.

Material and methods

Ten hydrogel intracorneal lenses (ICL) were implanted in the corneal stroma of six adult *Macaca mulatta* (rhesus) and one *Macaca nemestrina* (pigtail) monkeys. The monkeys were anaesthetised intramuscularly with ketamine hydrochloride, 10 mg/kg body weight.

ICL PARAMETERS

The parameters of the ICLs that were implanted are listed in Table 1. There were six eyes with Sauflon (American Medical Optics), an 80% water content hydrogel, three eyes with Permalens (Cooper Vision Laboratories), a 70% water content hydrogel, and one eye with Vistamarc (Vistakon), a 58% water content hydrogel. The implant centre thickness was determined with the laboratory specular microscope by multiplying the measured thickness and the ratio of the refractive index of the hydrogel relative to the saline in which the ICL was immersed. The powers of the ICLs in air ranged from +8·00 to +16·00 dioptres as provided by the manufacturer from measurements in the hydrate state. While the edge thickness is an important variable in describing the ICL configuration, it is not easily measured in the laboratory. In order to define this parameter a hydrogel contact lens design analysis was performed as part of the main data analysis programme referred to in the data analysis section.

SURGICAL PROCEDURE

A mid-depth 3 mm corneal incision was made 2 mm from and parallel to the superior limbus. When the stromal lamellae were sufficiently separated with a miniblade to form an intralamellar plane, a Martinez lamellar dissector was used to open a lamellar pocket large enough to centre the hydrogel intralamellar lens over the pupil. After completely forming the pocket, the incision entrance was enlarged with corneal scissors to allow the ICL to enter the pocket. The incision was closed with four to six interrupted 10–0 nylon sutures and the knots buried in the cornea peripheral to the ICL. Bacitracin-polymyxin ointment was applied topically.

PRE- AND POSTOPERATIVE EXAMINATIONS

The monkeys were anaesthesised intramuscularly with ketamine HCL (10 mg/kg). Cycloplegia was achieved with one drop of 1% cyclopentolate applied every five minutes for three doses one hour prior to retinoscopy. The examinations included biomicroscopy, pachymetry with a Haag-Streit I unit, central keratometry with a Bausch and Lomb keratometer, retinoscopy and corneal photography with a Zeiss photoslit lamp. The steepest and flattest keratometry readings were averaged to represent the central corneal curvature. The thicknesses of the anterior stroma, the hydrogel implant, the posterior stroma, and the combined components were recorded. The pachymetry data were used to determine the depth at which the implant lay. At each examination five pachymetry and keratometry measurements were taken and the mean computed as the representative value. Retinoscopy was performed by a single individual using trial lenses and was recorded as the spherical equivalent refraction.

DATA ANALYSIS

The measured refractive and keratometric changes

Table 1 *Intrastromal hydrogel lens parameters*

Monkey no.	*Hydrogel*	*Power in air (D)*	*Base curve (mm)*	*Diameter (mm)*	*Measured centre thickness (mm)*	*Calculated edge thickness (mm)*
Mil 10/OD	Permalens	15·00	7·4	6·0	0·24	0·04
Mil 10/OS	Permalens	15·00	7·4	6·0	0·24	0·03
NP80/OS	Permalens	14·50	7·4	6·0	0·29	0·09
P6/OD	Sauflon	10·00	6·4	6·4	0·24	0·07
P6/OS	Sauflon	10·50	6·2	6·4	0·23	0·10
RAM/OD	Sauflon	10·00	6·4	6·5	0·23	0·05
RAM/OS	Sauflon	8·00	6·4	6·5	0·22	0·08
MC82/OD	Sauflon	11·00	5·0	6·2	0·19	0·10
G1/OS	Sauflon	8·50	7·6	6·2	0·22	0·09
MC167/OD	Vistamarc	16·00	6·8	6·2	0·29	0·08

were compared with the expected or theoretical changes for the specific ICL and ocular parameters. An algorithm for the theoretical values was used to calculate the following variables: the corneal intralamellar bed radius, the new ICL diameter and anterior radius after altering the ICL base radius, and the postoperative corneal power including the effect of the refractive index of the ICL within the cornea. A complete discussion of the calculations is presented by Watsky *et al.*[13] The measured keratometric and refractive changes created by the ICL were compared with the theoretically predicted values and expressed as the keratometry yield and refractive yield. For example, a 75% yield means the measured postoperative value is 75% of the theoretical value.

Results

The preoperative corneal measurements are listed in Table 2. The 10 monkeys had a mean spherical equivalent refraction of −0·41±1·81 dioptres (±SD), central keratometry readings of 51·38±3·11 dioptres with a corresponding corneal radius of 6·56±0·38 mm, and a central corneal thickness of 0·47±0·04 mm.

Table 2 *Preoperative eye measurements*

Monkey no.	*Refraction (spherical equivalent, dioptres)*	*Central keratometry (average dioptres)*	*Anterior corneal radius (mm)*	*Central corneal thickness (mm)*
Mil 10/OD*	−3·75	47·54	7·10	0·50
Mil 10/OS*	−3·38	47·54	7·10	0·50
NP80/OS	−0·50	49·62	6·46	0·46
P6/OD	+0·87	52·80	6·39	0·41
P6/OS	+1·00	52·00	6·49	0·41
RAM/OD	−0·62	54·90	6·15	0·46
RAM/OS	+0·50	57·34	5·89	0·46
MC82/OD	+1·50	49·34	6·84	0·50
G1/OS	+0·75	51·06	6·61	0·45
M167/OD	−0·38	51·62	6·54	0·52

**Macaca nemestrina.*

After the postoperative follow-up period of 36 to 156 weeks biomicroscopy of the monkey eyes with ICLs showed: one eye with an intrastromal epithelial plaque, one with neovascularisation in the pocket, and three with debris in the pocket. The remaining six corneas were clear and quiet. Figure 1 illustrates the quiet appearance of the cornea 3·5 years after surgery. This animal continued to illustrate the biocompatibility of the hydrogel intracorneal implant even after 4·5 years.

The postoperative data are presented in Table 3. The average depth at which the implant was placed within the cornea was 74±10%, which was deeper than the desired 50%. The cornea refractive change had a yield of +3±27%. The central keratometric change had a yield of +6±16%. A perfect yield would have been +100%.

Discussion

The tissue tolerance of the hydrogel was excellent, as indicated by the 3·5 year follow-up of two eyes with Permalens intrastromal implants (Fig. 1). However, the hydrogel plus power lenticule implanted in a freehand intrastromal pocket created no significant steepening of the anterior corneal surface and therefore little change in refraction. The large standard deviations indicate poor predictability of this surgery. The main cause of the poor results is in the use of a pocket dissection in which the anterior collagen bundles and Bowman's layer are not severed; thus these structures resisted the anterior curvature change. Other variables included the animal model, manufacture of the ICL, and intrastromal bending of the ICL. The globe is an intact sphere consisting of collagen fibrils with limited short-term stretching characteristics. The ICL in the cornea increases total corneal thickness, and this

Table 3 *Results of placing high plus intrastromal hydrogel lenses in pocket incisions in the monkey cornea*

		Measured			*Theoretical*		*(Measured÷theoretical)×100*	
Monkey no.	*Follow-up (weeks)*	*Dissection depth (%)*	*Change in refraction (dioptres)*	*Change in keratometry (dioptres)*	*Change in refraction (dioptres)*	*Change in keratometry (dioptres)*	*Refractive yield (%)*	*Keratometry yield (%)*
MIL 10/OD	156	83	4·54	−0·43	11·48	10·64	40	−4
MIL 10/OS	156	86	5·59	−0·18	11·55	10·73	48	−2
NP80/OS	99	63	−3·30	4·71	11·07	10·57	−30	+4
P6/OD	55	66	−1·08	−0·53	7·12	7·55	−15	−7
P6/OS	55	75	−1·63	0·64	10·22	10·22	−17	6
RAM/OD	51	61	−0·91	0·82	6·85	7·35	−12	11
RAM/OS	51	72	1·16	−0·84	5·24	5·62	22	−15
MC82/OD	41	66	0·96	1·20	8·62	9·19	11	13
G1/OS	40	92	−1·17	0·52	5·98	6·12	−20	8
MC167/OD	36	79	0·40	0·80	12·63	10·83	3	1

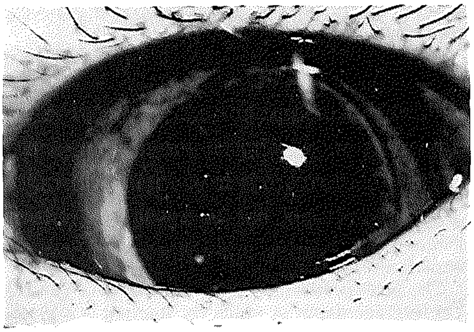

Fig. 1 *The quiet clear cornea illustrates the biocompatibility of the Permalens implant within the cornea. The photograph was taken 156 weeks postoperatively of animal no. MIL 10/OD.*

effect can be compared with the effect of oedema in the cornea. In both cases the lack of elasticity of the corneal collagen in Bowman's layer and the anterior stroma prevents the cornea from moving anteriorly (steepening) as it increases in thickness. One can think of the globe as being unable to increase its spherical size. The cornea increases its thickness only by expanding posteriorly (Fig. 2), a phenomenon that creates folds in Descemet's membrane and the posterior stroma as the thickness of the cornea increases and the arc distance from limbus to limbus decreases.

Problems in management of the monkeys makes evaluation of ICLs difficult. The postoperative medication was limited because it could be administered only to a sedated animal, and frequent anaesthesia may disrupt the health of the animal. The difficulty in identifying the optical axis of the anaesthetised animal made refraction and keratometry less accurate.

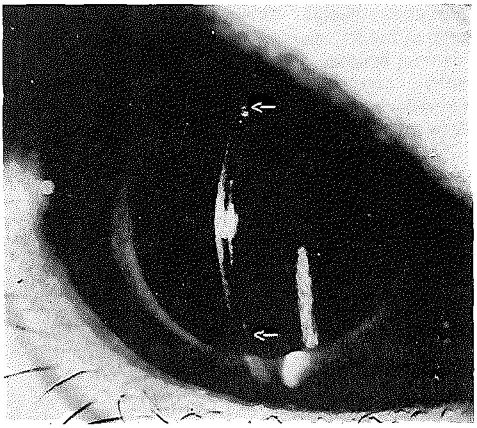

Fig. 2 *The hydrogel implant within the pocket dissection creates a posterior bulging of the stroma. The photograph was taken 6½ months postoperatively of animal no. MC-82 with a Sauflon material implant.*

An advantage of performing keratophakia with a hydrogel lenticule is the reproducibility in manufacturing the lenticule hydrogel. Unfortunately the small dimensions and high water content of the ICL make it difficult to lathe cut for the very steep monkey cornea. The average anterior corneal radius of the monkeys in this study was 6·56 mm (51·45 D). If the implant is located at 0·24 mm depth (about 50% thickness) in the cornea, the radii of the lamellar bed and the ICL base curve would be 6·39 mm. If the hydrogel being used contained approximately 70% water with a linear expansion factor of 1·6, then the manufacturer would have to cut the dehydrated hydrogel to a base radius of 3·94 mm. This small radius requires new technical skills for the manufacturer.

In order to create a predictable steepening or flattening of the anterior corneal surface, the anterior corneal collagen layers must be disrupted. One way to do this is to remove the anterior corneal lamellae, place a conformer or wedge such as the ICL on the lamellar bed, and then replace the anterior cornea so that it conforms to the curvature of the ICL, thus altering the anterior corneal surface. This is the approach used by Barraquer[14] in keratophakia, and it may allow hydrogel keratophakia to be more effective and predictable.[15 16] Another approach is to use intracorneal implants of a high refractive index material.[17] This approach is attractive, since it can utilise the technically simple intralamellar pocket dissection. The implant itself can cause the refractive alteration without relying on subtle changes in anterior corneal curvature.

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Hydrogel keratophakia: a microkeratome dissection in the monkey model

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SUMMARY High water content intracorneal implants were fabricated from Vistamarc hydrogel (Vistakon, Inc.) at 58%, 68%, and 72% water content and a range of powers from +7·25 to +17·00 dioptres. The Barraquer microkeratome technique was used to implant the lens at 59·0±9% (± SD) depth in the corneas of 14 rhesus monkey eyes. The contralateral eye served as a control. Three eyes were lost to the study because of complications. The remaining 11 animals were followed up for 51±2 weeks with the refractive yield being 118±34% and the keratometric yield being 92±30%. The measured and theoretically expected refractive changes have a linear regression line correlation coefficient of 0·74, whereas the respective keratometric data had a correlation coefficient of 0·04. The measured refraction became stable within 2 to 3 dioptres after 20 postoperative weeks. The hydrogels were well tolerated within the corneal tissue. There was a minimum of interface problems except along the edge of the implant. Implants with abruptly cut edges versus a fine wedge tended to have more light scattering collagen at the implant margin.

Refractive keratoplasty with hydrogel implants has the potential to alter the anterior corneal curvature in the correction of either hypermetropia or myopia. The implants could be manufactured in limitless supply with well controlled parameters. Implanting high water content hydrogel lenses via a free-hand lamellar pocket dissection changes the refraction in rabbits[1] but not significantly in primate corneas.[2] Barraquer[3] proposed to use the microkeratome to produce a lamellar dissection that would cut the relatively non-elastic collagen bundles and Bowman's layer. The lamellar disc can be contoured over the intrastromal lens, thus altering the anterior corneal surface curvature. Binder *et al.*[4] found that hydrogel plus-power lenses implanted in a microkeratome incision could cause significant corneal topography steepening.

This paper reports the detailed results of hydrogel keratophakia by Barraquer's microkeratome technique in rhesus monkeys with lenses of three different water contents and various plus powers. The mean follow-up time of 12 months allowed evaluation of the predictability of the procedure as well as correlation of the keratometric and refractive changes relative to the parameters of the hydrogel lenticule.

Materials and methods

INTRACORNEAL LENS PARAMETERS

The parameters of the intracorneal lenses (ICL) that were implanted are listed in Table 1. A total of 14 eyes received Vistamarc (Vistacon) lenses with water contents of 58% (six eyes), 68% (three eyes) and 72% (five eyes). The power (7·25 to +17·00 D), base curve (6·50 to 7·2 mm), and diameter (4·5 to 5·8 mm) of these lenses as indicated by the manufacturer were used in determining the theoretical refractions and keratometer values.[2] The manufacturer measured the hydrated lens power with a lensometer after blotting the surface water from the lens. It is difficult to measure the power of the hydrated lens while it is submerged in saline. The hydrogel has a refractive index too similar to that of saline to give a reliable reflex with the lensometer. Furthermore, the base curve cannot be verified by the projection method, because of the small diameter of the lenses. The edge

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Table 1 *Preoperative data for 14 primate eyes undergoing intracorneal lens implantation*

Primate	*Corneal parameters*			*Intracorneal lens parameters*					
	Keratometry reading (D)	*Refraction* (spherical equivalent, D)*	*Thickness (mm)*	*ICL hydrogel, % water*	*Power (D)*	*Base curve (mm)*	*Thickness (mm)*	*Edge thickness† (mm)*	*Diameter (mm)*
Z27F	51·37	−0·25	0·47	Vistamarc 58%	16·25	7·25	0·29	0·11	5·8
886F	52·60	+0·50	0·51	Vistamarc 58%	17·00	6·65	0·22	0·11	4·5
Y178	52·26	+0·63	0·44	Vistamarc 58%	14·75	6·65	0·25	0·16	4·5
834F	52·52	0·00	0·45	Vistamarc 58%	15·00	6·65	0·24	0·14	4·5
Y188	52·64	+1·88	0·49	Vistamarc 58%	14·75	6·65	0·22	0·14	4·5
Y4	51·48	−1·25	0·46	Vistamarc 58%	13·50	6·65	0·25	0·16	4·5
Y79	49·89	+1·00	0·46	Vistamarc 68%	10·00	6·50	0·18	0·10	4·7
N254	51·18	−3·13	0·47	Vistamarc 68%	8·00	6·51	0·21	0·14	4·9
MC173	51·10	+0·50	0·47	Vistamarc 68%	10–25	6·50	0·19	0·11	4·7
MC155	49·66	+0·25	0·48	Vistamarc 72%	14·25	6·65	0·22	0·10	4·7
575F	51·93	+0·50	0·41	Visamarc 72%	12·25	6·50	0·20	0·10	4·8
3A	51·58	+1·00	0·46	Vistamarc 72%	13·50	6·50	0·20	0·10	4·9
Q522	49·19	+0·50	0·49	Vistamarc 72%	7·25	6·65	0·22	0·10	4·7
6019	52·45	+1·50	0·46	Vistamarc 72%	14·25	6·50	0·21	0·10	5·0

* Expressed as spectacle correction. † Calculated by an algorithm.

thickness was predicted by means of an algorithm described by Watsky *et al.*[5] The laboratory specular microscope was used to measure the thickness of the implants.

SURGICAL PROCEDURE

Fourteen hydrogel intracorneal lenses (ICLs) were implanted in the corneal stroma of 14 adult rhesus monkeys (*Macaca mulatta*) of both sexes (Table 1). The animals were anaesthetised with intramuscular ketamine HCl (10 mg/kg) with supplements of 5 mg/kg intravenously. After facial cleaning with providone-iodine solution the animal was placed in a supine position with the head in a sterotactic clamp and an adhesive plastic drape over the face. The plastic drape was cut open over the eye to be operated upon with the opening large enough to minimise interference with the movement of the microkeratome head. A 360° peritomy exposed the bare sclera so that the suction ring would adhere firmly. A lateral canthotomy with total mobilisation of the lateral canthal ligament was necessary to allow placement of the microkeratome on the globe. A needle-scratch reference mark was made at 12 o'clock in the corneal epithelium to allow accurate realignment of the corneal lamellar disc. The eye was proptosed by a retrobulbar injection of 2 ml of balanced salt solution to give access for the microkeratome.

The 10–9 paediatric suction ring of the Barraquer microkeratome (Steinway Instruments, San Diego) was placed on the bare sclera with the conjunctiva retracted. The desired 40 mmHg intraocular pressure was confirmed with the microkeratome applanation unit. The diameter of the lamellar disc to be removed was checked with the 8·5 mm calibrated sizing applanator. The thickness of the lamellar disc was theoretically set to be 0·35 mm with a baseplate no. 35 inserted in the microkeratome head along with a new blade for each eye. The microkeratome cut was made with a smooth sweeping movement. The suction was released immediately after the cut and never exceeded 90 seconds in duration. The lamellar disc of the cornea was replaced in its original position guided by the epithelial reference mark at the 12 o'clock position. The area was carefully irrigated, and three cardinal 10–0 nylon sutures were placed and tied at the nasal, 12, and 6 o'clock positions. The temporal suture was put in place and the intracorneal lens inserted from the temporal side after repeat irrigation of the lamellar bed. The ICL was carefully centred and the fourth cardinal suture tied. Sixteen interrupted 10–0 nylon sutures were used in preference to a running suture, so that selected sutures could be removed to reduce neovascularisation or irritation caused by a loose, disrupted suture. After all the sutures were tied, corneal curvature was measured with a Schmirmaul quantitative keratometer mounted on the operating microscope. High astigmatism was corrected by replacing or adjusting the tension of one or two tight sutures. All knots were buried on the peripheral side of the wound. The ICLs central location within the lamellar bed was secured by one 10–0 nylon suture through the anterior stroma and the margin of the ICL at the 12 o'clock position. In practice it was noted that the monkey could dislocate the unsecured ICL during the early postoperative period by rubbing its eye.

The lateral canthotomy was closed with one suture and the conjunctiva was repositioned on to the limbus. Atropine 1% solution and polymyxin B-bacitracin-neomycin ointment were instilled at the end of the procedure. 1 ml of saline was injected subcutaneously in the upper eyelid to cover the globe and protected it from rubbing during the immediate postoperative period. The monkeys were treated with intramuscular injections of the non-steroidal anti-inflammatory drug flurixin meglumine (Benamine), 1 mg/kg twice daily for three to five days.

PRE- AND POSTOPERATIVE EXAMINATIONS

Pre-examination anaesthesia and cycloplegia were performed as described by McCarey *et al.*[2] The examination included slit-lamp microscopy, central pachymetry with the Haag-Streit I unit, central keratometry, retinoscopy, and slit-lamp photography. All monkeys had at least one preoperative examination. Postoperative examinations were performed on the 3rd and 7th, 14th and 21st days after surgery, monthly for six months, and then bimonthly. During the immediate postoperative period the animals had a partial examination (that is, biomicroscopy and, if possible, estimated pachymetry and keratometry) on the 3rd and 7th postoperative day as well as removal of loose sutures. The suture through the ICL was removed on the 7th postoperative day. After three weeks all remaining sutures were removed. The retinoscopy data reported in this manuscript (except for Figs. 2 and 3) are the average value from the last three examinations and are expressed as the spectacle correction. The theoretical chance in refraction was calculated by means of an algorithm developed by Watsky *et al.*[5]

Table 2 *Postoperative pachymetry* of primate eyes with hydrogel intracorneal lenses*

Primate	*Anterior plus posterior (mm)*	*Anterior lamellae (mm)*	*Depth of ICL in cornea (%)†*
Y178	0·50	0·25	50
834F	0·52	0·24	46
Y188	0·57	0·36	63
Y4	0·55	0·42	76
Y79	0·53	0·31	58
N254	0·56	0·30	54
MC173	0·56	0·30	54
MC155	0·57	0·39	68
575F	0·53	0·31	58
3A	0·53	0·36	68
Q522	0·55	0·31	56

* Average of last three examinations.
† Anterior lamella thickness divided by anterior plus posterior lamella thickness.

Results

POPULATION STUDIED

The preoperative corneal measurements of the 14 corneas (Table 1) showed central keratometry readings averaged 51·40±1·12 D (±SD) or radius 6·57±0·15 mm, spherical equivalent refractions averaged 0·26±1·23 D, and central corneal thickness averaged 0·46±0·02 mm.

Three monkeys were omitted from the postoperative refractive results. Animal Z27 developed a corneal ulcer and the ICL was removed at week 12. One animal, 886F, died of aspiration pneumonia at week 18. Severe corneal vascularisation developed in response to fierce eye rubbing by animal 6019, and the ICL was removed at week 24. The results of the remaining 11 animals are presented with follow-ups ranging from 49 to 53 weeks.

PACHYMETRY

The preoperative full corneal thickness for the 11 eyes averaged 0·46±0·02 mm (±SD). After approximately one year of postoperative follow-up the same set of eyes minus the implant thicknesses averaged 0·54±0·02 mm. Pachymetry showed increasing thickness postoperatively in both operated and contralateral unoperated eyes. In five out of 10 animals the experimental cornea was signficantly (*t* test, $p<0.005$) thicker than the control cornea. No animals showed a significant decrease of total stromal thickness following implantation of a hydrogel lens. Since the implant separated the anterior and posterior lamellae, the postoperative values include two subjective pachymetry endpoint decisions. The thickness of the

Table 3 *Postoperative data for 11 primate eyes with hydrogel intracorneal implants*

Primate	*Week postoperative*	*Refractive change**				*Keratometry*		
		ICL power (D)	*Theoretical (D)*	*Measured† (D)*	*Yield (%)*	*Theoretical (D)*	*Measured* (D)*	*Yield (%)*
Y178	52	14·75	12·20	13·13±1·34	108±11	10·57	9·07±1·50	86±15
834F	51	12·50	12·31	12·49±1·67	101±14	10·76	6·94±3·16	64±29
Y188	52	10·50	11·94	10·63±0·42	89± 4	10·11	6·83±0·32	67± 4
Y4	48	13·50	10·94	9·18±0·55	86± 6	9·09	4·35±0·39	48± 4
Y79	52	10·00	7·79	7·85±1·71	100±22	7·76	6·85±0·45	92± 6
N254	52	8·00	6·40	8·32±0·44	125±14	6·22	8·19±0·97	131±15
MC173	53	10·25	7·88	9·93±1·02	127±13	7·57	9·41±1·66	124±22
MC155	53	14·25	5·91	9·06±0·95	153±16	5·78	6·58±0·35	114± 5
575F	49	11·25	9·39	11·37±0·63	121± 6	9·13	6·81±0·12	75± 1
3A	52	13·50	10·35	9·75±0·44	94± 4	9·96	7·83±0·45	79± 5
Q522	51	7·25	5·21	10·46±0·23	201± 3	5·30	7·23±0·63	136±10

* Expressed as spectacle correction. † Average of last three examinations.

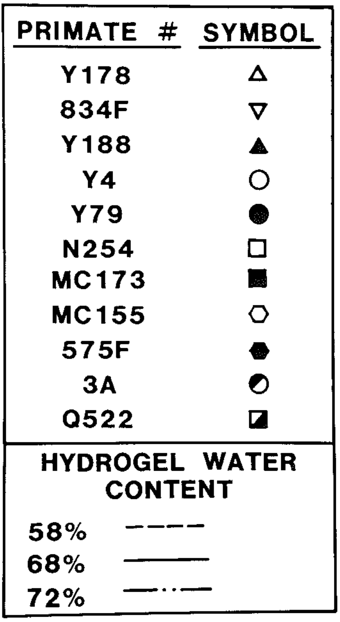
anterior lamellae excised with the no. 35 microkeratome base plate should be 0·35 mm, but it measured an average of 0·32±0·06 mm (mean±SD) (Table 2). The depth of the implant in the cornea averaged 59±9% (mean±SD) relative to its postoperative thickness (anterior+posterior lamellae).

CHANGES IN CORNEAL POWER AND REFRACTION

The postoperative data in Table 3 contain the theoretical and refractive changes as well as the measured change in refraction and keratometry (average of the last three examinations) for 11 animals. The average postoperative follow-up was 51±2 weeks with the refractive yield being 118±34% and the keratometric yield being 92±30%. The measured versus theoretical expected refractive changes had a linear regression line correlation coefficient of 0·74, whereas the respective keratometric data had a correlation coefficient of 0·04. The measured refractive changes of each animal was graphed for the 51 week follow-up (Figs. 1 and 2). The measured refraction became stable within 2 to 3 dioptres after 20 weeks. When data from the same animal group were graphed by the refractive yields (Fig. 3), a greater spread was shown. Although many animals had yields between 80 and 120% after 20 weeks, some of the higher water content lenses resulted in much higher yields (Fig. 4).

SLIT-LAMP MICROSCOPY

The hydrogel ICLs were tolerated well within the corneas of the animals. Most animals showed a slight grey lining at the implant margin. Hydrogel lenses with an abruptly cut edge instead of a rounded, tapered, or buffed edge tended to have more of this build-up. At the interface of the ICL and the stroma refractile particles could be detected in some animals. At the site of the microkeratome cut scarring to some extent was present in all animals. Epithelial downgrowth into the bed of the microkeratome cut did not occur in any of the animals. Animal Z27 was removed from the study at 12 weeks postoperatively because an ulcer developed at the margin of the implant. The implant was removed and subsequently the cornea became clear. After 24 weeks of observation the



PRIMATE #	SYMBOL
Y178	△
834F	▽
Y188	▲
Y4	○
Y79	●
N254	□
MC173	■
MC155	⬡
575F	⬢
3A	◐
Q522	◪

HYDROGEL WATER CONTENT	
58%	----
68%	——
72%	—··—

Fig. 1 *Key of symbols used in Figs. 2, 3, and 4.*

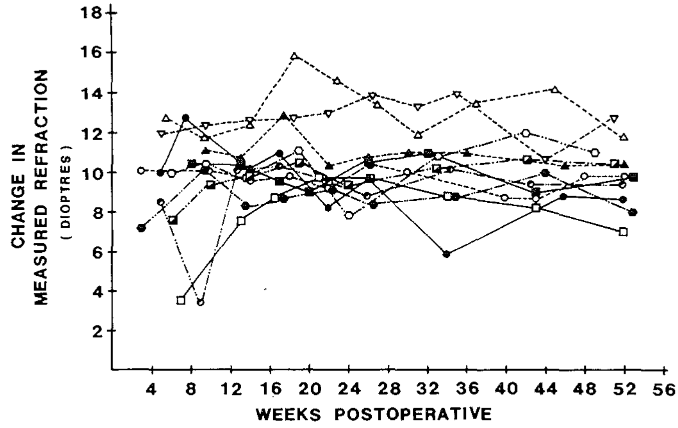


Fig. 2 *Long-term follow-up of the changes in the measured refractions relative to the preoperative refractions illustrates the stability refraction of the corneal/hydrogel implant complex. Symbols as in Fig. 1.*

implant was removed from the cornea of animal 6019. There was marked vascularisation and more than average scarring because this animal was rubbing his eye in an unusually fierce manner during the past surgical period.

Discussion

Since the monkey eye dimensions and facial structure are different from those in man, we had to adjust the Barraquer microkeratome technique. We found it necessary to use the paediatric microkeratome ring with a 360° conjunctival peritomy, a lateral canthotomy, and a retrobulbar injection of saline in order to gain exposure to the cornea and adequately to secure the microkeratome suction ring. Even then a smooth path of the microkeratome was sometimes impeded by orbital and nasal structures. After surgery the monkey's propensity to rub the irritated eye was only somewhat reduced by a saline injection to expand the

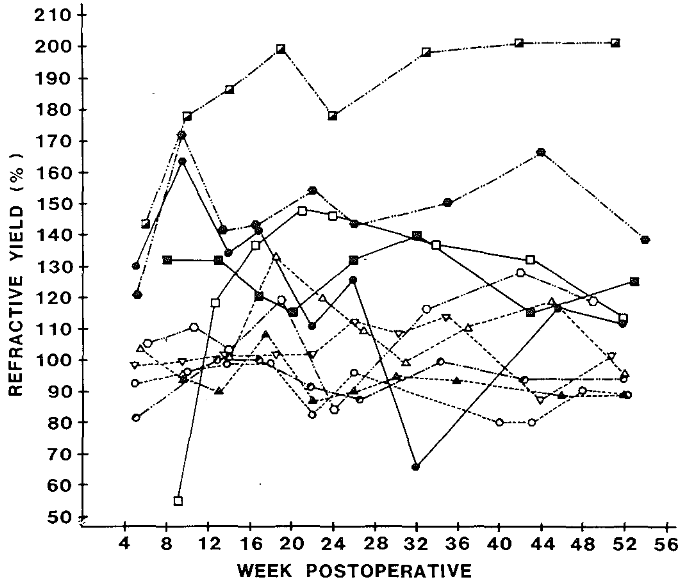


Fig. 3 *When the long-term data are graphed by the calculated refractive yield (measured refractive change divided by the theoretical change) the data appears to have an unacceptably excessive spread. Symbols as in Fig. 1.*

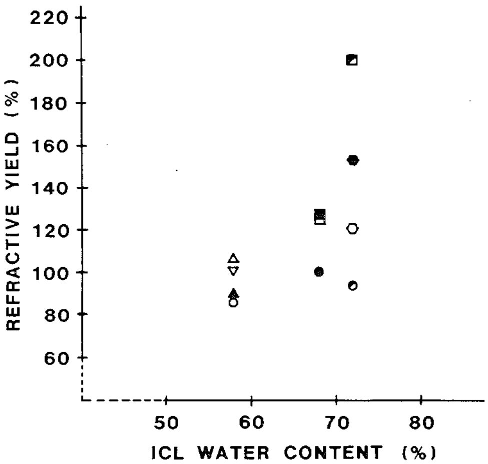


Fig. 4 *Summary of the refractive yields (measured refractive change divided by the theoretical change) relative to the water content of the hydrogel implant illustrates the increasing variability with increasing water contents which helps to explain the spread in Fig. 2. Symbols as in Fig. 1.*

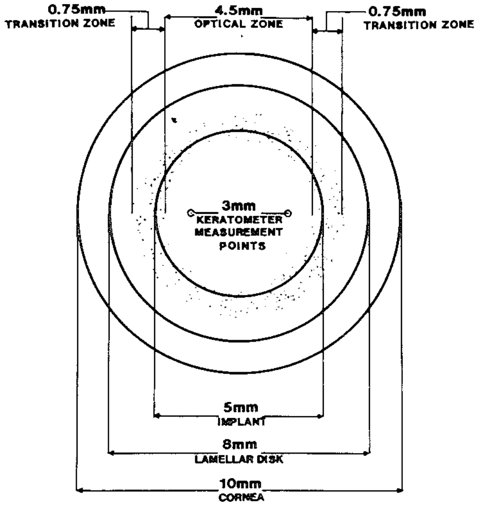


Fig. 5 *The corneal curvature measurement by Bausch and Lomb keratometer is taken at two points on a circle with a diameter of 2·8 to 3·1 mm. The estimated irregular transition zone at the edge of the ICL is represented as a dotted area. The keratometry readings should be centred over the ICL, which is very difficult to see, since even slight decentration will cause false readings in the transition zone.*

upper lid over the globe and frequent examinations to remove the irritating loose sutures.

The keratometry measurements are difficult on monkeys because of the optical principles of the instrument in combination with the animal model. The Bausch and Lomb keratometer with the addition of a +1·25 D auxiliary lens to extend the instrument's dioptric range measures the corneal curvature from points on a 2·8 to 3·1 mm circle (the range depending on the radius of curvature), (Fig. 5). The anaesthetised monkey cannot fixate on the central light of the keratometer, and therefore the exact surface location being measured is unknown. The ICLs have diameters of approximately 5 mm, with the optical zone being approximately 4·5 mm. If the keratometry is not precisely centred over the implant, which cannot be visualised through the keratometer, there will be a large variation of the readings. This is illustrated by the poor correlation between expected and measured keratometry values. Keratoscope photographs have the same problem of centration.

Hydrogel ICL implantation in lamellar pockets in primate eyes does not change the corneal surface curvature[2] as it does in rabbits.[1] A microkeratome dissection is necessary to allow the hydrogel implant to be placed between smooth surfaces in the corneal stroma at a level of even depth. Dissecting the anterior stromal lamella free from the cornea and placing it over the hydrogel lenticule results in the outer surface conforming to a predictable curvature. When a lenticule (positive or negative power) is introduced in the stroma to change the anterior corneal curvature, the arc length on the corneal surface will increase. The anterior stromal layers, including Bowman's layers of the primate eye, are not elastic as in the rabbit eye. These layers will not stretch to a larger arc length over an implanted wedge.

The relationship between the water content of the implanted lenticules and the yield of refractive change was examined (Fig. 4). The 58% water content lenticules have the best predictability (yields close to 100%). The 68% and 72% water content lenticules have less ideal yields. We think these differences are due to: (1) errors in the calculation of the expansion factor, and (2) variation of hydration of the materials by the manufacturer. Neither the hydration of each lot of lenses nor the refractive power was double checked in this study prior to implantation, for reasons explained above and in an earlier paper,[2] Another cause for differences in results between materials with various water contents might be a change in dimension, that is, hydration, of the hydrogel material within the corneal stroma due to mechanical compression or stromal swelling pressure. These factors have been considered in a separate study.[6] The conclusion of that study was that hydrogel materials up to a water content of 70% can be considered stable within the corneal stroma. Materials of higher water content undergo a hydration decrease by a few percent when exposed to physiological swelling pressures. This observation does not, however, explain the higher yields found in this study for the higher water content Vistamarc materials.

Pachymetric measurements have shown that the anterior lamellae are thinner than the intended 0·35 mm that would be expected with the microkeratome fitted with the no. 35 base plate (Table 2). This may be explained by the earlier observations that the hydration of the stroma anterior to the ICL decreases.[1]

In analysis of our pachymetric data we have considered mainly the difference between the stromal thickness of the experimental eye and the control eye at each measuring point. Both the experimental corneal thickness and the control values increased significantly in thickness over time. Subtracting the two values at each time point illustrated that half the experimental group was significantly greater than the control eye and the other half was statistically equal to the control. The increase in the control thickness over time can be ascribed to either age changes in the animal or measurement error, of which the latter is probably the most important factor. The retinoscopic reflex did not deteriorate during the follow-up period.

In conclusion, the implanted hydrogel materials were well tolerated in the primate corneal stroma; 11 out of 14 implants have been technically successful. The refractive change was stable after ICL implantation. The measured refractive change correlated well with the calculated refractive change in most animals, but the higher water content hydrogel implants gave less predictable results. Keratometry was an unreliable measure of the change in corneal power in this experimental primate study.

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SECTION II

PENETRATING KERATOPLASTY AND CORNEAL CURVATURE

Chapter 6

CONFIGURATION OF CORNEAL TREPHINE OPENING IN A LABORATORY SETTING

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SUMMARY

The factors that produce corneal astigmatism after penetrating keratoplasty [1]-[3] are not well defined; the most important are: the preoperative regularity, thickness and vascularization of the cornea, host wound and donor button configuration, suture configuration and tightness, and the rate and strength of wound healing. An exact circular full thickness trephine opening in the recipient cornea will facilitate uniform wound closure and will probably minimize postoperative astigmatism. Different methods of trephination produce different shaped corneal openings. Freehand trephination with a hand-held trephine is widely used, though motor trephines and razor blade trephines are also available.

In this study we used different trephination techniques on fresh human donor eyes and compared the variation in the shape of the trephine openings. Trephines that were held perpendicular to the corneal surface either by suction or by free standing showed less variation in shape than trephines applied at the end of a handle, which gave less control over the position of the trephine on the corneal surface.

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MATERIALS AND METHODS

Mounting and Measurement of Eyes

Sixty fresh human donor eyes, five in each experiment, were glued in a metal cup and held in a gimbal-like device that allowed rotation of the globe in all directions and alignment of the plane of the cornea horizontally (Fig. 1). [4] To control the intraocular pressure, we inserted a 10-gauge needle through the metal

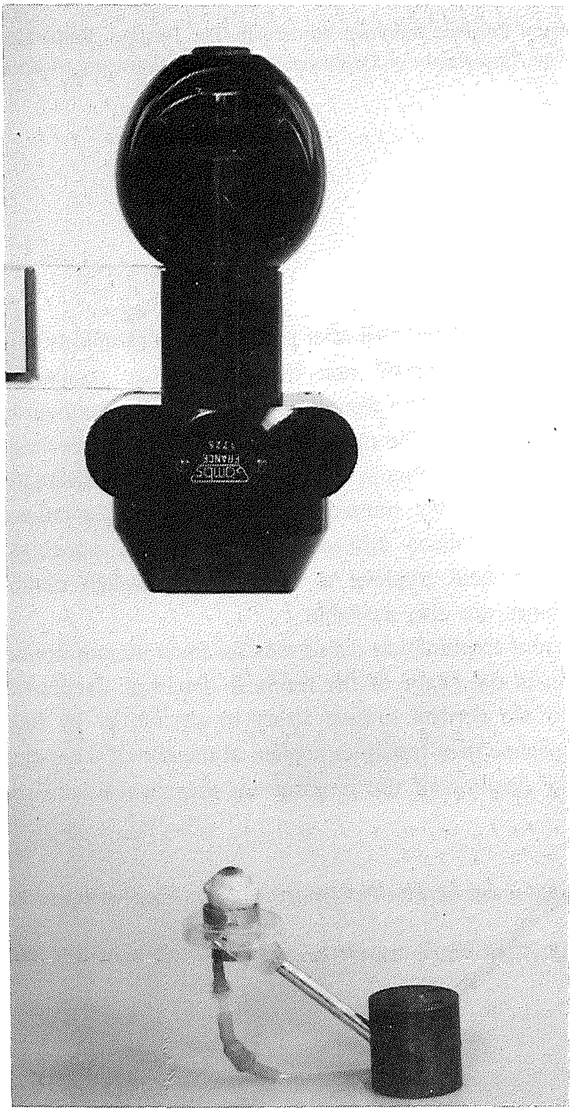

Fig. 1 Human donor eye is glued in a gimbal-like metal cup. The keratometer is mounted above the eye. Infusion tubing maintains the intraocular pressure.

cup and the posterior sclera into the vitreous and connected it by tubing to a bottle of normal saline solution placed above the eye at different heights, [4] measuring the intraocular pressure with a Schiøtz tonometer. The intraocular pressure was maintained at 10 to 15 mmHg in all experiments except numbers 1 (5 mmHg), 3 (40 mmHg), and 10 (20 mmHg).

The plane of the intact cornea was aligned horizontally and the central corneal astigmatism was measured with a vertically mounted keratometer, subtracting the flattest from the steepest measurement. Eyes with an irregular astigmatism or with an astigmatism of more than one diopter were excluded from the study. The five types of trephines are shown in Fig. 2 and the 12 different methods of trephination are listed in Table 1. All the trephines were new. The diameters of three new disposable trephine blades of each type and one new nondisposable motor trephine blade were measured at 30 intervals around their circumferences with a micrometer to confirm that they were circular. Each disposable blade was used only three times or less. The razor blade trephines were used only once.

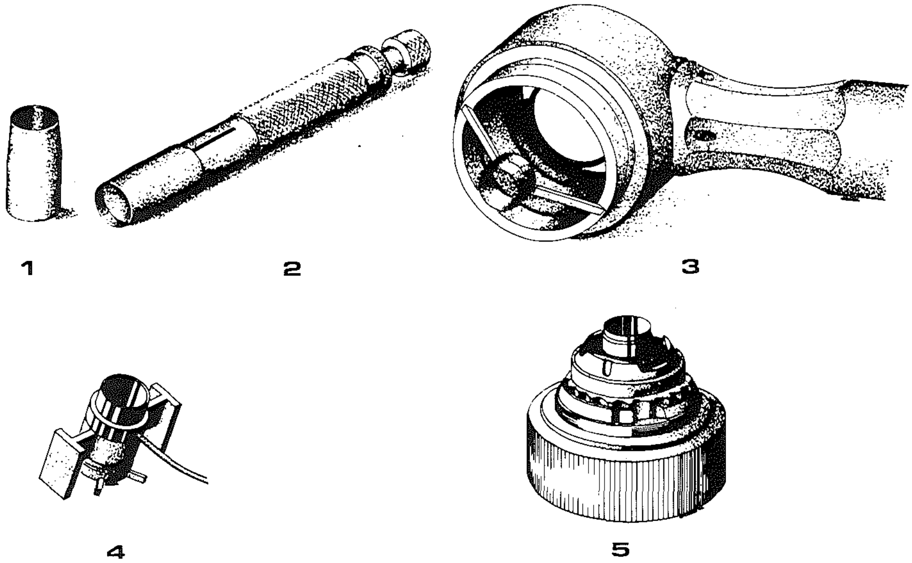

Fig. 2. Trephines used in the experiments. 1 and 2: disposable trephine blades, with and without obturator and handle a; 3: non disposable motor trephine b ; 4: disposable razor blade vacuum trephine c; 5: non disposable razor blade suction trephine (the outer portion is removed) d.

a Weck Company, Inc., North Carolina, USA
b Micro-Keratron System, Hans Geuder Ltd., Heidelberg, BRD
c Hessburg-Baron, Jedmed, St. Louis, USA
d Hanna trephine, Hydron, Paris, France

It was difficult to measure directly the diameters of the hole in the cornea created by the trephine because the edges of the hole collapsed irregularly. Therefore, we measured the diameters of the excised buttons, which reflected the true shape of the hole. [3] We placed the corneal button with the endothelial side up on top of a concave circular metal bar that had a radius of curvature of 7.8 mm and a diameter of 4 mm (Fig. 3). This bar rotated on a pedestal and was connected to a disc with vertical marks spaced every 30° around its circumference. The device was placed in front of a tripod-mounted 35-mm camera equipped with an autobellows, a macrolens, and a flash mounted on the end of the lens (Fig. 4). The camera photographed six profiles of the corneal button at 30° intervals around the circumference. [5] To determine reproducibility of the technique one corneal disc was photographed five times. The camera was defocused and refocused between each photograph. Magnification was controlled by photographing a micrometer before each button. The resulting slides were projected on a screen, and we measured the diameters of the button across both the endothelial and the epithelial surface in each of the six meridians. The angle between the cut edges and the epithelial surface was measured with a graduated arc protractor in steps of 5° at 12 locations 30° apart (Fig. 3). To compute the average epithelial and endothelial diameter, we averaged the six measurements for each button. To compute the ovality of the button, we subtracted

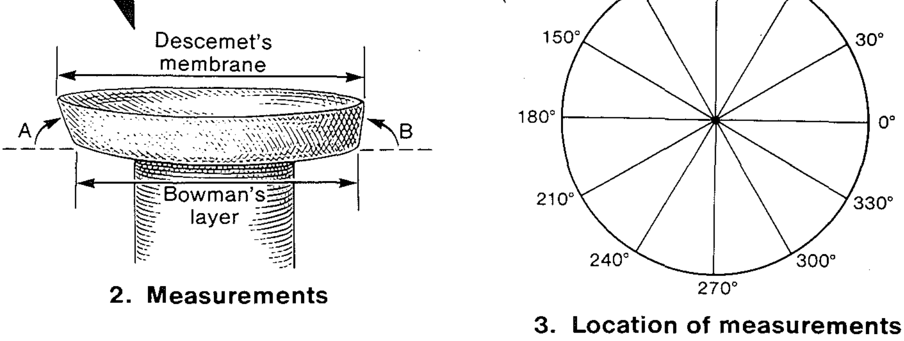

Fig. 3. 1. The corneal button is removed and 2. placed with endothelial side up on top of a concave circular bar. The bar rotated and the corneal profile is photographed at 30° intervals around the circumference (3).

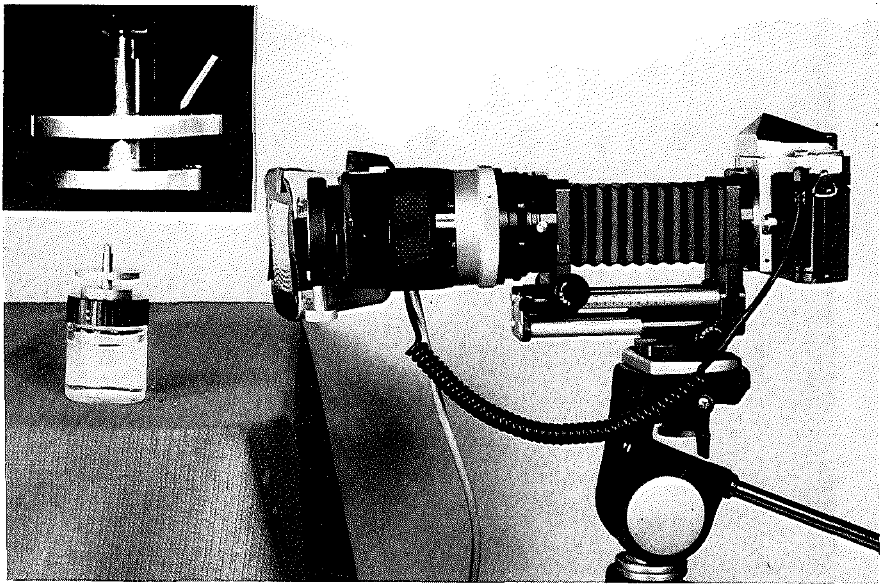

Fig. 4. Corneal button placed with endothelial side up on top of concave metal circular bar. This bar rotated on a pedestal and was connected to a disc with vertical marks (arrow) every 30°. The camera photographed the profiles of the corneal button at 30° intervals around the circumference.

the shortest diameter from the longest for the epithelial side and the endothelial side. To describe the configuration of the edge of the button, we computed the difference of the average diameter of the epithelial and endothelial sides and also subtracted the smallest from the longest angle formed by the edge (Table 1). We compared groups statistically by using the Student t-test.

Trephines and Experimental Conditions

The trephine was placed centrally on the cornea and was held vertically as determined by two protractors 90° apart. A partially penetrating incision was made. Trephination was stopped immediately on anterior chamber entry. The corneal button was then completely excised under the operating microscope with a razor blade knife. Extreme care was taken to follow the original trephination groove.

Disposable Trephine Blades with Handle and Variable Intraocular Pressure

In experiments one, two and three, we tested the influence of intraocular pressure on corneal trephine opening. In the first experiment the intraocular pressure

Table 1. Results of twelve different methods of trephination. There were five human donor eyes in each experiment. The intraocular pressure was between 10-15 mmHg unless otherwise specified.

method of trephination	diameter of trephine (mm)	average endothelial diameter (mm)	average ovality at endothelial side (mm)	average epithelial diameter (mm)	average ovality at epithelial side (mm)	endothelial diameter minus epithelial diameter (mm)	average maximum variation of angles (degrees)
exp. 1: disposable trephine blade with handle and obturator IOP 5 mm Hg	6.5	6.63	0.192 ∓ 0.200	6.76	0.156 ∓ 0.173	- 0.13	18.0 ∓ 16.0
exp. 2: disposable trephine blade with handle and obturator IOP 10-15 mmHg	6.5	6.77	0.274 ∓ 0.184	6.69	0.056 ∓ 0.034	+ 0.08	24.0 ∓ 15.5
exp. 3: disposable trephine blade with handle and obturator IOP 40 mmHg	6.5	6.80	0.242 ∓ 0.120	6.59	0.106 ∓ 0.040	+ 0.20	14.0 ∓ 6.5
exp. 4: disposable trephine blade with handle and obturator high astigmatic cornea (mean ast. 16.2 ∓ 3.6D)	6.5	6.81	0.142 ∓ 0.043	6.73	0.070 ∓ 0.031	+ 0.08	19.0 ∓ 12.9
exp. 5: disposable trephine blade with handle and obturator aphakia	6.5	6.92	0.252 ∓ 0.129	6.75	0.050 ∓ 0.026	+ 0.16	22.0 ∓ 16.8
exp. 6: disposable trephine blade with handle and obturator 60 gram	6.5	6.88	0.418 ∓ 0.220	6.74	0.044 ∓ 0.020	+ 0.14	24.0 ∓ 13.9
exp. 7: disposable trephine blade without handle	7.0	7.54	0.168 ∓ 0.054	7.19	0.070 ∓ 0.035	+ 0.35	12.0 ∓ 2.7
exp. 8: motor trephine blade turning	7.03	7.47	0.172 ∓ 0.078	7.13	0.076 ∓ 0.071	+ 0.34	12.0 ∓ 4.5
exp. 9: motor trephine blade still	7.03	7.51	0.200 ∓ 0.068	7.20	0.080 ∓ 0.034	+ 0.33	16.0 ∓ 6.5
exp. 10: motor trephine and suction ring IOP 11 -> 20 mmHg	7.03	7.56	0.316 ∓ 0.126	7.09	0.138 ∓ 0.140	+ 0.46	16.0 ∓ 4.2
exp. 11: disposable razor blade vacuum trephine	8.0	8.79	0.276 ∓ 0.120	8.35	0.072 ∓ 0.042	+ 0.44	10.0 ∓ 5.0
exp. 12: nondisposable razor blade suction trephine	7.12	7.61	0.096 ∓ 0.034	7.34	0.042 ∓ 0.032	+ 0.27	6.0 ∓ 4.2

was 5 mmHg. A 6.5 mm disposable trephine blade with holder and the obturator at the highest position so it did not act as a stop, was placed in the center of the cornea. The trephine, weighing 17.3 g, was held vertically and a partially penetrating incision was made by gently rotating the trephine between thumb and index finger, letting the weight of the trephine provide the force for penetrating the tissue. Care was taken not to push down on the trephine. In the second experiment the intraocular pressure was between 10 and 15 mmHg; in the third it was 40 mmHg.

High Astigmatism

To examine the influence of preexisting high astigmatism in the recipient cornea (experiment 4) on the shape of the trephine hole, we induced high corneal astigmatism (mean 16.2 D ∓ 3.5 D) in five donor eyes by an anterior radial 7-0 silk suture across the corneoscleral limbus. [4]

Aphakic Eye

To determine the effect of aphakia, we trephined five aphakic donor eyes that had undergone an intracapsular lens extraction in the past (experiment 5).

Weight of Trephine

To examine the influence of pressure on the trephine, we increased the weight of the trephine by wrapping lead wire around the handle until the total weight of the trephine was 60 g instead of the normal 17.3 g [6] (experiment 6).

Disposable Trephine Blade without Handle

To achieve the gentlest application of the trephine to the cornea with the least mechanical distortion of the cornea, we placed the free trephine blade without handle or obturator on the surface of the cornea. The blade weighed 1.4 gm. The trephine blade was gripped with thumb and index finger and gently rotated approximately 30°, applying minimal pressure on the cornea. After each rotation the trephine was released to allow it to return to a perpendicular position before beginning again (experiment 7).

Motor Trephine with Blade Turning

Under the operating microscope, the center of the cornea, as determined by the center of the pupil, was marked with a needle. The Geuder motorized trephine [7] allows direct visualization of the cornea through the microscope. The motor trephine was held in the right hand and was kept stable by putting the left index finger in the holder of the trephine blade. With the blade rotating at a velocity of 90 RPM, the trephine was slowly placed on the corneal surface and, using minimal pressure, the cut was made until the anterior chamber was entered (experiment 8).

Motor Trephine with Blade Still

The motor trephine was first placed on the cornea with minimal pressure and the motor was switched on by the foot pedal at a velocity of 90 RPM. The cut was made till the anterior chamber was entered (experiment 9).

Motor Trephine and Suction Ring

To examine the effect of a suction ring on the eye during trephination, we adjusted the intraocular pressure to between 10 and 15 mmHg. A Barraquer *) suction ring was placed on the sclera and suction was applied until the intraocular pressure measured 20 mmHg. Then the motor trephine with the blade turning was slowly moved toward the corneal surface and the cut was made (experiment 10).

Disposable Razor Blade Vacuum Trephine

The Hessburg-Barron vacuum trephine [8], [9] has a suction ring which supports the cornea 0.5 mm outside the trephine blade. It has a unidirectional blade rotation with descent of the blade. The center of the cornea can be visualized through the trephine and there is no obturator inside the trephine. The center of the cornea was marked with a needle. The trephine was centered, pushed gently against the cornea, and full syringe suction was applied holding the ring to the cornea. The instrument was held between the surgeon's left thumb and index finger, and the razor blade inside the suction ring rotated slowly without pressure on the eye with the index finger of the right hand until the anterior chamber was entered (experiment 11).

Nondisposable Razor Blade Suction Trephine

The Hanna suction trephine [10] fixates the globe by pneumatic suction, it has a unidirectional blade rotation with descent of the blade. The center of the cornea can be visualized through the small built-in obturator. The trephine weighs 59 g and has a height

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*) Barraquer suction fixation dovetailing, Steinway Instruments San Diego, U.S.A.

height of 3.5 cm. The blade movement mechanism consists of a rotation apparatus and a brake. The rotation apparatus allows circular movement and descent of the blade. [10] The depth of the incision can be regulated by settings on the outside of the blade movement mechanism. [10] A disposable blade is fixed in the movement mechanism of the trephine. The Hanna suction trephine, with the blade set at its maximal depth of 0.90 mm, was centered around the central corneal mark and syringe suction was applied, affixing the ring to the conjunctiva. With the trephine held vertical in the left hand, the right hand turned the knurled control knob which both rotated and descended the trephine blade until the anterior chamber was entered (experiment 12).

RESULTS

Standardization

All trephine blades had a constant diameter (standard deviation <= 0.01 mm). The trephine diameters were as stated except for the motor trephine blade that was 0.03 mm larger and the disposable razor blade for the Hanna trephine which was 0.12 mm larger than the stated 7.0 mm. Repeated photography of the same button produced a mean diameter of 6.72 ∓ 0.0089 mm. This shows that the method is precise.

General Results

The average results of all twelve experiments are summarized in Table 1. The specific results of the second experiment, using the disposable trephine with handle - the most commonly used clinical technique- are shown in Table 2.

In all experiments the average diameter of the buttons was larger than the diameter of the trephines. The mean variation in diameter (ovality) at the epithelial side was smaller than at the endothelial side in all experiments. This was statistically highly significant ($p < 0.001$).

Results of Specific Experiments

Effect of Intraocular Pressure: Increasing the intraocular pressure from 5 mmHg to 10-15 and to 40 mmHg in experiments 1 to 3 decreased the mean epithelial

Table 2. Measurement of five corneal buttons obtained with a disposable trephine with obturator and handle*) handle*)

endothelial side							epithelial side
button	mean diameter at endothelial side (mm)	range (mm)	ovality (maximal diameter variation, mm)	mean diameter at epithelial side (mm)	range (mm)	ovality (maximal diameter variation, mm)	maximal angle variation (°)
1	6.63	6.70-6.59	0.11	6.60	6.61-6.57	0.04	5
2	6.95	7.21-6.77	0.53	6.76	6.81-6.72	0.09	40
3	6.68	6.72-6.64	0.08	6.69	6.72-6.67	0.05	20
4	7.05	7.27-6.95	0.32	6.68	6.68-6.67	0.01	15
5	6.54	6.70-6.37	0.33	6.72	6.77-6.68	0.09	40
mean of five buttons	6.77		0.274 ∓ 0.184	6.69		0.056 ∓ 0.034	24.0 ∓ 15.5

*) The intraocular pressure was between 10-15 mmHg. The trephine diameter was 6.5 mm (experiment 2).

diameter while the endothelial diameter increased. Thus, the endothelial diameter was larger than the epithelial diameter in all experiments except number one, with the low intraocular pressure of 5 mmHg, where the epithelial diameter was greater than the endothelial diameter. The ovality at the epithelial side was the largest with the low intraocular pressure.

Effect of Preexisting Astigmatism: Trephination of high astigmatic corneas in experiment 4 resulted in an opening comparable to one after trephination of a spherical cornea.

Effect of Aphakia: Trephination of aphakic eyes in experiment 5 produced a larger diameter button, particularly on the endothelial side, as compared to the phakic eyes trephined under the same circumstances in experiment 2.

Effect of Trephine Pressure: The 60 gram trephine in experiment 6 cut a larger endothelial and epithelial diameter than the standard 17.3 gram trephine. The average ovality on the endothelial side increased with a 60 gram trephine. The free-standing, lightweight blade in experiment 7 produced a larger difference between endothelial and epithelial diameters than a trephine with the holder and obturator at the same intraocular pressure. The difference was statistically significant ($p < 0.005$).

Effect of the Motor Trephine: The Geuder motor trephine used in experiment 8 to 10 also produced buttons with a much larger diameter at the endothelial side than at the epithelial side. The results were slightly better when the trephine was rotating when placed on the cornea.

Effect of Suction Rings: Stabilization of the globe and elevation of intraocular pressure with the Barraquer suction fixation ring in experiment 10 did not improve the results. The ovality of the buttons actually increased and the difference between the motor trephine with and without the Barraquer suction fixation ring was statistically significant at the endothelial side ($p < 0.05$).

Effect of Suction Trephines: The Hessberg-Baron disposable razor blade vacuum trephine in experiment 11 consistently produced buttons with a greater difference in diameter between the endothelial (larger) and epithelial sides. The Hanna nondisposable razor blade suction trephine in experiment 12 cut buttons with the smallest ovality at the endothelial and epithelial side. The difference in ovality between the two razor blade trephines was statistically significant at the endothelial side ($p < 0.001$).

Effect of Perpendicularity: The three trephines that were held perpendicular to the corneal surface either by suction (experiments 11 and 12) or by free standing (experiment 7) showed less variation in shape than trephines applied at the end of a handle, either by hand (experiments 2 and 6) or motorized (experiments 8 and 9). The differences in variation of angle was statistically significant ($p < 0.001$, and $p < 0.05$).

Effect of Motor Trephine: The motor trephine (experiments 8 and 9) showed more variation in size at the epithelial side and less variation in size at the endothelial

Table 3. In eight experiments the average ovality at the endothelial side and at the epithelial side and the maximum variation of angles was ranged from 1-8. The smallest ovality got the highest number and the largest ovality the lowest. The intraocular pressure was between 10-15 mmHg unless indicated.

	ovality at endothelial side	ovality at epithelial side	maximal variation of angles	total
nondisposable razor blade suction trephine (exp. 12)	8	8	8	24
disposable trephine blade without handle (exp. 7)	7	5	5.5	17.5
motor trephine blade turning (exp. 8)	6	3	5.5	17.5
disposable razor blade vacuum trephine (exp. 11)	2	4	7	13
disposable trephine blade with handle (exp. 2)	3	6	1.5	10.5
motor trephine with blade still (exp. 9)	4	2	4	10
disposable trephine 60 gram (exp. 6)	1	7	1.5	9.5
disposable trephine IOP 5 mmHg (exp. 1)	5	1	3	9

side than trephines applied at the end of a handle (experiments 2 and 6). These differences were statistically not significant.

Comparing different trephination techniques that are clinically used, on phakic donor eyes with an intraocular pressure between 5 and 15 mmHg, we could range the average ovalities and variation of angles from 1-8 and summarize them (Table 3).

DISCUSSION

We measured the shape of the trephine openings in the corneas of human donor eyes by measuring the shape of the removed button. We measured epithelial and endothelial diameter and the angle between the epithelial surface and the cut of the excised button, which reflects the true shape of the hole. [3] In all experiments the average diameter of the buttons was larger than the diameter of the trephines. This can be explained by ballooning of cornea tissue inside the trephine [3] (Fig. 5).

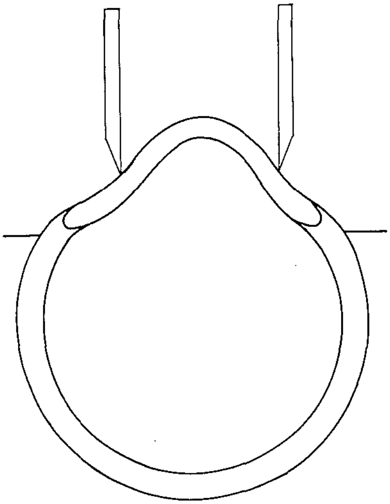

Fig. 5. A trephine on the cornea causes the cornea to balloon up into the trephine resulting in a larger button than the intended diameter.

The endothelial diameter was larger than the epithelial diameter in all experiments, except experiment one, with the low intraocular pressure of 5 mmHg. The larger endothelial diameter is due to lamellar deflection of the trephine knife in the lamellar corneal tissue. [11] The corneal dome consists of a regular arrangement of layers with a varying resistance to cutting. If a blade is applied to the lamellae at right angles it encounters a symmetrical lateral resistance and can advance in the direction intended. [11] As the trephine blade is applied obliquely to the lamellae, the lateral resistance becomes asymmetrical and the incision deviates. [11] To prevent lamellar deflection during trephination, the majority of trephine blades are ground only on the outside of the blade. The thicker the blade and the larger the angle of grinding the less lamellar deflection. A thinner blade, like the motor trephine blade, which allows a better visualization of the cornea through the microscope, results in more lamellar deflection, creating a larger endothelial diameter, as was found (experiment 8-10). Razor blades are thin and ground on both sides. Hence a larger endothelial diameter can be expected especially if the trephine has no obturator (experiment 11).

The mean variation in diameter (ovality) at the epithelial side was smaller than at the endothelial side in all experiments. This is not surprising. The cornea inside a centrally placed trephine is spherical [12] and a round trephine will cut a more or less round button when it starts cutting, while the endothelial side is reached at the end of the cutting.

The three trephines that were held perpendicular to the corneal surface either by suction (experiments 11 and 12) or by free standing (experiment 7) showed less variation in shape and size than trephines applied at the end of a handle (experiments 2 and 6) (Table 2). In experiments 2 and 6 the trephine was placed centrally on the cornea and was held vertically as determined by two protractors 90° degrees apart. However in clinical practice the eye and the trephine with handle are frequently tilted forward in order to see the incision process under the operating microscope. This turning gives even less control over the position of the trephine on the corneal surface and might cause an uneven distribution of trephine weight on the cornea. Significant poorer quality trephine cornea openings might be expected.

Some surgeons lower the intraocular pressure before surgery with orbital compression or drugs. In our laboratory experiments the mean epithelial diameter increased and the mean endothelial diameter decreased with a lower intraocular pressure. At an intraocular pressure of 5 mmHg the epithelial diameter was even greater than the endothelial diameter. This was not found in any of the other experiments. The larger epithelial diameter can be explained by ballooning of more cornea tissue inside the trephine at a lower intraocular pressure. The cornea balloons up into the trephine and the greater the amount of corneal tissue inside the trephine, the larger the diameter of the resulting buttons. [3], [5], [6] This substancially moving of the corneal tissue into the trephine might explain the larger ovality at the epithelial side at this low intraocular pressure. As the intraocular pressure increases the eye tends to remain more its own shape and there is less corneal tissue moving inside the trephine, resulting in a smaller button at the epithelial side. At a low intraocular pressure the trephine collapses the globe and the trephine takes a completely new angle with the cornea lamellae resulting in a much smaller diameter at the endothelial side. [11], [13]

The larger buttons obtained with the 60 gram trephine as compared with the button cut with a 17.28 gram trephine, under the same circumstances, must result from more ballooning of corneal tissue inside the trephine. A trephine weighing 60 gram or more is quite common in clinical practice because already a slight pressure on a trephine during trephination will easily result in a pressure of 60 gram or much more, as can easily be discovered trephining donor eyes on a scale.

An obturator at the highest position touches the corneal tissue inside the trephine and presses it down when the cut is made. This results in less tissue inside the trephine and thus a smaller diameter at the endothelial side. A free standing trephine blade without obturator (experiment 7) will not press down the tissue inside it when the cut is made and will result in a larger diameter at the endothelial side, increasing the difference between endothelial and epithelial diameter. The variability of the angle was low. Most likely because a free standing blade is always perpendicular to the corneal surface.

It is known that central corneal astigmatism that is induced with 1 or 2 silk sutures at the limbus disappears completely if a trephine of 15 gram or more is placed on the center of the cornea, [12] and so it is not surprising that the measurements of the buttons trephined from highly astigmatic corneas and from spherical donor eyes were comparable (Fig. 2). The larger buttons obtained from aphakic eyes (experiment 5) were a surprise. Probably intracapsular lens extraction makes the eye less stable and more susceptible to deformation and the movements of tissue inside the trephine. Our findings explain why many surgeons empirically use a more oversized graft in aphakic patients.

Centering a rotating trephine moving towards the corneal surface is more difficult than placing the motor trephine on the cornea and then switch the motor on. The results however were slightly better.

Stabilization of the globe with a Barraquer suction ring increased the intraocular pressure. The epithelial diameter decreased and the endothelial diameter increased with the higher introacular pressure (as was found in experiment 3, Table 2). The increase of the average ovality, at the epithelial and the endothelial side, was a surprise. We hoped to improve the results with a suction ring. As the results worsened so much, we discourage the use of a fixation suction ring in penetrating keratoplasty.

Both razor blade trephines are suctioned onto the eye and so, just as the free standing blade, always perpendicular to the corneal surface. This explains the lower variability of the angle.

These experiments show that different trephine systems and a variation in trephine technique make a considerable difference in the size and shape of the recipient opening. We calculated the ovality and the variation of the angles of the trephine openings because the variation in size and shape of the trephine opening in the recipient cornea is probably more important than the exact diameter of the trephine opening to reduce astigmatism. [2], [14] Measuring the angles, as is rarely done in this kind of experiments, might be important because a large variability of the angle may produce an irregular wound an cause high astigmatism even with a fairly round trephine opening.

The two key factors in achieving round corneal buttons during trephination are 1) good centration of the trephine on the cornea [5] and 2) holding the trephine perpendicular to the corneal surface.

Good centration is facilitated by a hollow trephine which makes it possible to see the center of the cornea through the trephine under the operating microscope. The three trephines that were perpendicular to the corneal surface either by suction (experiment 11 and 12) or by free standing (experiment 7) showed less variation in shape and size than trephines applied at the end of a handle (experiments 2 and 6). Thus, when compared with the other techniques, trephines with handle, as is commonly used in clinical practice, may have considerable disadvantage.

The Hanna nondisposable razor blade suction trephine (experiment 12) showed the smallest variation in size and shape. Next was the free standing blade (experiment 7). The Hanna nondisposable razor blade trephine has the disadvantage of its high price and is more complicated to use while the free standing disposable trephine blade is cheap and simple to use.

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Chapter 7

AN EXPERIMENTAL COMPARISON OF THREE METHODS FOR TREPHINATION OF THE CORNEA AND CONSEQUENT VARIATIONS IN THE CONFIGURATIONS OF THE TREPHINE OPENINGS

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ABSTRACT

We used the pig eye as an experimental model. The corneas of 51 whole eyes were trephined in a laboratory setting, using three different techniques to compare the variations in the trephine openings. Since it is difficult to assess the diameter of the hole created by trephination, we measured both the epithelial and endothelial diameters, as well as the angle between the epithelial surface and the cut of the excised corneal button, since these dimensions reflect the true shape of the hole. Trephination with either a freestanding trephine blade without a handle or with a motor-driven instrument gave the same results. However, our findings showed that the results obtained using a trephine in a holder - as is commonly used in clinical practice - were statistically significantly inferior.

INTRODUCTION

Corneal astigmatism after penetrating keratoplasty is a common clinical problem (Jensen and Maumenee 1974; Troutman 1979; Perlman 1981). The factors that produce this astigmatism are not well defined, although four of the main factors may be: preoperational condition of the cornea, wound configuration, suture technique, and subsequent wound healing.

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A small degree of variation in the shape and size of the circular trephine opening in the operated cornea can be important. Various methods for trephination result in different corneal openings. Free-hand trephination with a hand-held trephine is widely used clinically, even though motor trephines are also available. Our present study was therefore undertaken to compare the range of variation of trephine openings in the pig eye as an animal model, using different trephination techniques.

MATERIALS AND METHODS

Fifty-one fresh pig eyes (17 in each experiment) were used and were taken from five-month-old pigs. The corneas of these eyes are very soft, making it almost impossible to measure the correct epithelial and endothelial diameters and angles of the corneal button edges after trephination. Therefore, the eyes were submerged in a 2% formaldehyde solution for 2 h. The result was a greater firmness, more comparable to human corneal stroma, and better sectility. To stabilize the eye and to maintain the intraocular pressure between 10-15 mmHg, a gauze band sponge was wrapped around the equator of the eye and tightened with a pair of forceps. The intraocular pressure was then checked with a Schiotz tonometer. The plane of the cornea was horizontally aligned and the corneal astigmatism present was measured with a vertically mounted keratometer. All trephinations were performed under an operating microscope. A micrometer was used to measure the diameters of three new 7.0 mm disposable trephine blades and one 7.0 mm motor trephine blade at 30° intervals. New 7.0 mm disposable trephine blades, with and without obturator and handle, were used in the experiments. Each disposable blade was used four times, but only one new nondisposable motor trephine (The Micro-Keraton System, Hans Geuder Ltd., Heidelberg) blade was employed (Fig. 1). Three types of experiments were performed (Table 1).

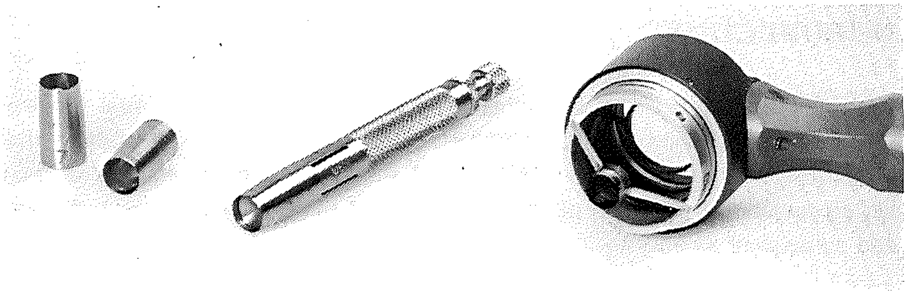

Fig. 1. Disposable trephine blades (left), disposable trephine blade with handle and obturator (middle), and nondisposable trephine (right)

Trephine with handle

With the trephine in its holder and the obturator in the highest position, a superficial mark was made on the corneal epithelium to check the position of the trephine on the cornea. Then with the eye tilted forward at a 45 angle, a partially penetrating incision was made in the cornea by gently rotating the trephine between the thumb and index finger. The procedure was terminated upon entering the anterior chamber. The corneal button thus created was then completely excised with a razorblade knife, taking care to follow the original groove of the trephine's incisions.

Freestanding trephine blade

The plane of the cornea was first horizontally aligned. Next, under the microscope, a freestanding, single blade without handle or obturator was placed in the center of the cornea. The trephine blade was gripped with thumb and index finger and was gently rotated approximately 30°, during which time the blade was pressed with minimal pressure into the cornea. After each rotation, the trephine was released to allow it to return to a perpendicular position before beginning again.

Motor trephine

Under the operating microscope, the center of the cornea was marked with a needle. Through the microscope the trephine allows direct visualization of the cornea during subsequent trephination. The trephine's rotating was increased to 90 rpm, and the instrument was gently moved toward the corneal surface. The motor trephine was held in the right hand and was kept stable by putting the left index finger in the holder of the trephine blade, taking care to keep the holder as steady as possible during trephination. Using minimal pressure, the corneal cut was made, and the corneal button was then excised completely with a razorblade knife.

Since it is difficult to measure the exact diameter of the hole created by trephination, we measured the diameters of the excised corneal buttons, since these correspond to the true shape of the hole created (Perlman 1981). The corneal button was then placed with its endothelial side up on top of a concave circular metal disk (van Rij et al. 1985). The disk's radius of curvature was 7.8 mm and its diameter was 4 mm (Fig. 2). The disk can be rotated on a pedestal and has vertical marks at 30° intervals around the circumference. This device was placed in front of a tripod-mounted 35 mm camera equipped with an autobellows, a macrolens and a flash mounted on the end of the lens. Using this setup, the camera photographed profiles of the corneal button at 30° intervals while the disk rotated in front of the camera. Six photographs were taken of each button. Magnification was defined by photographing a micrometer to mark the dimensions of each tissue button. The finished slides were projected on a screen and the diameters of the buttons were measured across their endothelial and epithelial surfaces. In addition, the angles between the cut and the epithelial surfaces

Table 1. Results of trephine experiments on the 5-month-old pig cornea.

Group	Average endothelial diameter (mm)	Average epithelial diameter (mm)	Average asphericity at endothelial side (mm)	Average asphericity at epithelial side (mm)	Maximum variation of angles (degrees)
Trephine with handle (N = 17)	6.68 ∓ 0.24	6.94 ∓ 0.14	0.32 ∓ 0.13	0.22 ∓ 0.12	19.2 ∓ 8.33
Freestanding trephine blade (N = 17)	6.83 ∓ 0.16	7.06 ∓ 0.12	0.22 ∓ 0.10	0.16 ∓ 0.08	11.8 ∓ 6.34
Motor-driven trephine (N = 17)	7.08 ∓ 0.12	7.08 ∓ 0.10	0.17 ∓ 0.08	0.14 ∓ 0.08	11.6 ∓ 4.50

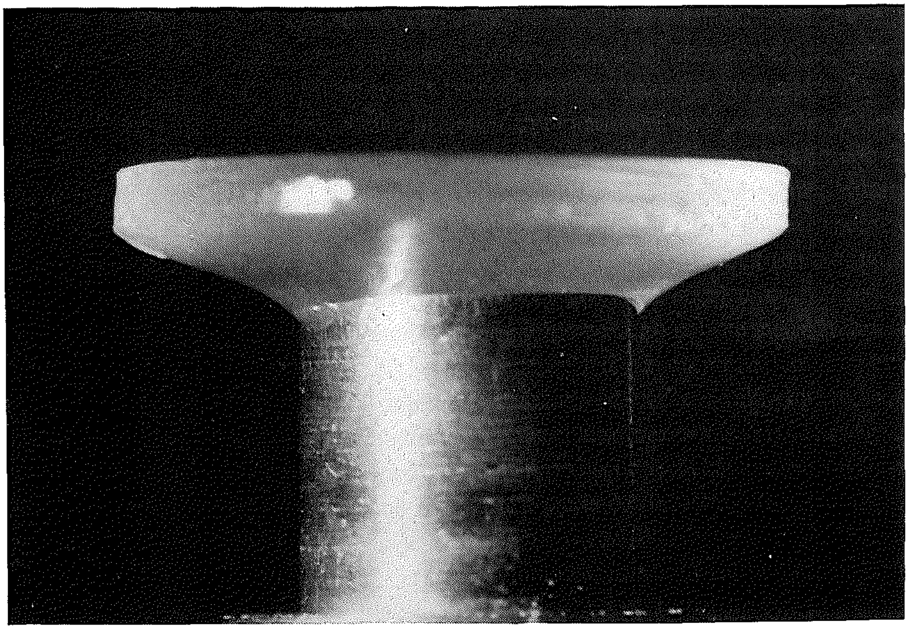

Fig. 2. Profile of corneal button (endothelial side up) on top of a concave metal disk

on both the left and the right side were measured with a graduated arc protractor, thus giving a good 360° profile of each button. The average endothelial and epithelial diameter were calculated, as were the ranges of these diameters for each button. The differences between the largest and the smallest diameters were taken to represent the asphericity of each button. The average left and right angles and the maximum variation of these angles on the left and right side were then calculated for each button.

RESULTS

The mean astigmatism of the pig eyes measured with the keratometer was 1.5 ∓ 0.9 diopters in all three groups. The diameter of each of the disposable trephine blades was 7.00 mm (standard deviation < 0.01 mm), while the nondisposable motor trephine blade was 0.03 mm larger than the stated 7.00 mm (standard deviation < 0.01 mm).

Table 1 summarizes the results of the experiments performed. The trephine with handle cut the smallest corneal buttons, while the motor-driven trephine cut the largest buttons. In the motor trephine experiments, the mean endothelial and epithelial diameters were the same (Table 1), while the epithelial diameters were larger than the endothelial diameters in the other experiments.

The average asphericity of the diameter was lower at the epithelial side than at the endothelial side in all experiments. The largest mean endothelial and epithelial asphericities were found when trephinations were done with the trephine on the handle. At the endothelial side, this finding was statistically significant when compared to findings using the freestanding trephine blade ($P < 0.02$) and the motor-driven trephine ($P < 0.001$; Student's t-test). At the epithelial side, the difference between the trephine with handle and the motor trephine was statistically significant ($P < 0.05$; Student's t-test), but the difference between the trephine with handle and the freestanding trephine blade was not significant ($P < 0.10$; Student's t-test). There was also no statistically significant difference between the motor trephine and the freestanding trephine blade at the endothelial and epithelial sides with respect to these parameters ($P > 0.10$; Student's t-test).

The maximum variation of the angles present was largest with the trephine on the handle and was statistically significant when compared to the other experiments ($P < 0.01$; Student's t-test). There were no differences in the maximum variation of angles between the motor trephine and the single trephine blade (Table 1).

DISCUSSION

Freehand trephination using a corneal trephine on a handle with obturator resulted in the smallest button diameters. Corneal tissue balloons into the trephine opening as the circular incision is made (Perlman 1981; van Rij and Waring 1983). An obturator touches the corneal tissue inside the trephine and presses it down, resulting in less tissue inside the trephine and thus a smaller diameter of the buttons removed (Olson 1979). In the motor-driven trephine experiments, the mean endothelial diameter was larger than in the other experiments. This is because the blade of the motor-driven instrument is thinner and allows for better visualization of the cornea during the procedure (especially when a microscope is used). This results in more lamellar deflection (Eisner 1980), creating a larger endothelial diameter.

To prevent lamellar deflection during trephination, trephine blades are ground only on the outside of the blade. The thicker the blade and the larger the angle of grinding, the less lamellar deflection occurs (Eisner 1980). Probably more important than the mean size of the trephine opening is the variation in size and shape of the trephine opening in the recipient cornea (Troutman 1979; Heidemann et al. 1985), since these latter variables can be correlated to reductions in corneal astigmatism. Our experiments showed that only the motor-driven trephine and the single trephine blades gave the same results with regard to the average asphericity in endothelial and epithelial diameters and the maximum variation of the angles present. Use of the trephine in the holder resulted in significantly inferior trephine corneal openings. This may be caused by the position in which the trephine must be held in order to see the incision process. This method gives less control over the position of the trephine on the corneal surface and causes an uneven distribution of trephine weight on the cornea.

There were no significant statistical differences between the motor-driven trephine and the single trephine blade with regard to the average asphericity in the endothelial and epithelial diameters or in the maximum variation of the angle present. However, the motor-driven trephine produced straighter edges than the single blade, possibly because it is easier to keep the motor-driven instrument completely still during trephination at 90 rpm. The two key factors in achieving round corneal buttons during trephination are 1) keeping the trephine blade centered on the cornea and 2) holding the trephine in a perpendicular position towards the cornea. To do this procedure successfully it is necessary to be able to view it through the hollow trephine with the operating microscope. This is only possible with the single trephine blade and the motor-driven trephine. Thus, when compared with the other two methods, the trephine with the holder, as is commonly used in clinical practice, may have a considerable disadvantage.

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Postoperative Astigmatism After Central vs Eccentric Penetrating Keratoplasties

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Six patients with markedly eccentric penetrating keratoplasties had severe corneal astigmatism (mean, 10.38 ± 2.91 diopters). In four of these patients the flat meridian was lying in the direction of graft displacement. Laboratory experiments disclosed no statistically significant difference in diameter between the major and minor axes of the corneal buttons in the centrally and eccentrically trephined eyes and we could not elucidate the mechanism of the severe astigmatism. However, in the eccentrically trephined eyes the longer axis consistently lay in the direction of decentration whereas in the centrally trephined eyes the long axis was oriented randomly.

CORNEAL ASTIGMATISM occurs frequently after keratoplasty, but the mechanisms that cause postoperative astigmatism are not completely understood.[1-6] In operations done to improve vision, most corneal surgeons try to place the donor button in the center of the host cornea.[7-11] Although slight decentration does not seem to affect the postoperative astigmatism, marked eccentricity does.[11] We report six cases of markedly eccentric penetrating keratoplasties with severe postoperative astigmatism. In four cases the flat axis lay in the direction of decentration. We also performed laboratory experiments on human donor eyes in an attempt to correlate the axis and amount of astigmatism with an oval configuration of the eccentric trephine opening.

Subjects and Methods

Subjects—Among the approximately 1,455 penetrating keratoplasties performed by four surgeons from 1975 to 1982, we identified six patients with eccentric grafts who were followed up for 16 months to nine years postoperatively and had no other complications. In all cases, the widest portion of the host corneal rim was at least twice the width of the narrowest portion as measured with the slit-beam ruler.[12] The position of the graft in the host was recorded by slit-lamp photography and by drawings in the patient record. Keratometry readings were taken in the area of the visual axis and were stable in all patients. All sutures were removed.

As a control group we selected for every patient with an eccentric graft, four to six consecutive patients with central grafts done for the same corneal disease by the same surgeon at approximately the same time. This group consisted of 34 eyes.

Laboratory methods—We designed an experiment to test the hypothesis that an eccentric trephine incision creates an oval opening that contributes to the severe astigmatism.

Ten fresh human donor eyes were glued in a metal cup held in a gimbal-like device that allowed rotation of the globe in all directions so that the plane of the cornea could be aligned horizontally. To control the intraocular pressure, a 10-gauge needle was inserted through the metal cup and sclera into the vitreous and was connected to a bottle of normal saline solution placed 13.6 cm above the eye to produce an intraocular pressure of 10 mm Hg, as measured by a Schiøtz tonometer.

In the first set of five eyes, a 10-0 nylon radial suture was placed in the periphery of the cornea at approximately one half of the corneal thickness to serve as a marker. A 6.5-mm disposable trephine, weighing 17.5 g, with the obturator at the highest position was placed on the cornea so that the widest portion of the cornea outside the trephine was more

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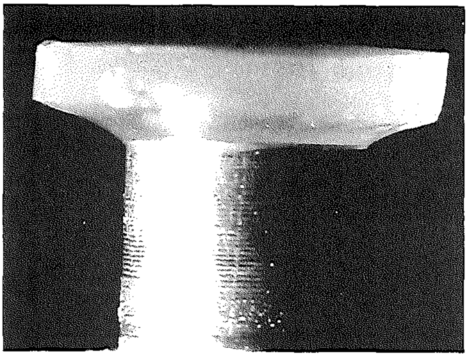

Figure (van Rij and associates). Profile of corneal button, endothelial side up, on top of a concave metal disk. Diameter of button was computed by averaging the endothelial and epithelial diameters.

than twice but less than three times the width of the narrowest position adjacent to the marking suture. The trephine was held vertically and gently rotated into the tissue so that it cut the 10-0 nylon suture and entered the anterior chamber. The corneal button was then completely excised with a razorblade knife. Extreme care was taken to follow the original trephination groove.

In the second set of five eyes, a central trephine incision was made in the manner described. It was difficult to measure the diameters of the hole created by trephination because the edges of the hole collapsed irregularly. Therefore we measured the diameters of the excised buttons, which reflected the true shape of the hole.[6] The corneal button was placed endothelial side up on top of a concave circular metal disk with a radius of curvature of 7.8 mm and a diameter of 4 mm. This disk rotated on a pedestal and had vertical marks spaced every 90 degrees around its circumference. The device was placed in front of a tripod-mounted 35-mm camera equipped with an autobellows, a macrolens, and a flash mounted on the end of the lens. The camera photographed a profile of the corneal button (Figure) in the major axis marked by the 10-0 nylon suture and in the minor axis 90 degrees away. Magnification was controlled by photographing a micrometer before each button. The resulting slides were projected on a screen and the diameters of the button measured across both the endothelial and the epithelial surfaces. These two measurements were averaged to obtain the diameter of the button in one axis. The difference between the diameters in the major and minor axes measured the ovality of the trephine hole.

Results

Subjects—In the six eccentric grafts, the average keratometric astigmatism in the visual axis was 10.38 ± 2.91 diopters, with the flat meridian lying within 23 degrees of the direction of graft displacement toward the corneoscleral limbus in four of the six cases (Table 1). The average astigmatism among the 34 central grafts in the control group was 4.66 ± 2.15 diopters (Table 2). This difference was statistically significant ($P<.001$, randomization test).

Laboratory findings—The mean difference in the diameter of the corneal button between the major and the minor axes in the eccentrically trephined eyes was 0.11 ± 0.07 mm (range, 0.05 to 0.21 mm), with the long axis lying in the direction of the eccentric displacement. The mean difference in the

TABLE 1

POSTOPERATIVE ASTIGMATISM IN SIX PATIENTS WITH ECCENTRIC PENETRATING KERATOPLASTIES

PATIENT NO.	DIAGNOSIS	KERATOMETRIC ASTIGMATISM (DIOPTERS)	FLATTER AXIS (DEGREES)	DIRECTION OF GRAFT DISPLACEMENT (DEGREES)	LENGTH OF FOLLOW-UP (MOS)
1	Fuchs' endothelial dystrophy	8.00	65	295	16
2	Keratoconus	11.75	112	135	18
3	Aphakic corneal edema	9.25	116	110	28
4	Herpes simplex	11.25	40	35	29
5	Aphakic corneal edema	15.00	90	90	36
6	Herpes simplex	7.00	38	350	108
Mean		10.38 ± 2.91			

TABLE 2
POSTOPERATIVE ASTIGMATISM IN CONTROL GROUPS OF CONSECUTIVE PATIENTS WITH CENTRAL GRAFTS*

GROUP. NO.	NO. OF PATIENTS	DIAGNOSIS	MEAN KERATOMETRIC ASTIGMATISM (DIOPTERS)
1	6	Fuch's endothelial dystrophy	2.75 ± 1.72
2	6	Keratoconus	3.51 ± 1.79
3	6	Aphakic corneal edema	5.35 ± 1.77
4	4	Herpes simplex	6.10 ± 2.03
5	6	Aphakic corneal edema	7.08 ± 1.77
6	6	Herpes simplex	3.67 ± 2.94

*All patients were treated by the same surgeons.

diameter of the corneal button between the major and minor axes in the centrally trephined eyes was 0.13 ± 0.10 mm (range, 0.05 to 0.23 mm), with the long axis lying in different directions.

The mean difference between diameters of the major and minor axes in these two groups was not statistically significant. However, in the eccentrically trephined eyes the longer axis consistently lay in the direction of decentration, whereas in the centrally trephined eyes the long axis was oriented randomly.

Discussion

The observations in our six cases of eccentric keratoplasty confirmed those of others[11] that a markedly eccentric keratoplasty is associated with severe astigmatism. In our cases, the average astigmatism was approximately 10 diopters, with the flat axis lying in the direction of graft decentration in four of the six cases. Thus, surgeons should take extra precautions in centering the host trephine incision.

In attempting to explain why eccentric grafts produce severe astigmatism with an orientation of the flat axis in the direction of the graft decentration, we formulated a hypothesis. Based on the premise that corneal tissue balloons into the trephine opening as the circular incision is made,[6,13] we suggested that eccentric trephination causes different amounts of tissue to balloon into the trephine in different axes during trephination. Thus, an oval host wound results, with the long axis in the direction of displacement because the trephine touches and depresses the cornea, along this axis first, including more tissue in this direction than in the direction 90 degrees away. Because more tissue is excised in this direction, an oval incision results, with the long axis in the direction of displacement. When the round donor button is sutured into this oval recipient opening, it becomes asymmetrically shaped, resulting in astigmatism.

To test this theory, we designed a series of experiments on eye bank eyes that compared the shape of eccentric and central trephine openings by measuring the dimensions of the button that was removed. We found that both the eccentric and the central openings were slightly oval, with an average of 0.1 mm difference between the major and minor axes. Therefore, the theory that the eccentricity produces enough increased ovality to account for the increased astigmatism is seemingly untrue and the mechanism by which it is produced is not clear.

However, the experiments demonstrated consistency in the direction of ovality, with the eccentric cuts having the long axis in the direction of decentration, whereas the central cuts had the long axis oriented at random. This supports our theory that the ovality has something to do with the axis of the resulting astigmatism.

There are two possible mechanisms: (1) If we assume that the recipient cornea is rigid and has a slightly oval trephine opening, the placement of a round spherical donor button into this hole will result in compression of the donor across the shorter axis which will steepen the cornea in this direction and a stretching of the donor in the longer axis which will cause a flattening in this direction. (2) If the round spherical donor button is assumed to be rigid, and the oval host opening is assumed to conform to it, no astigmatism will result in the donor button, but the diameters of the whole cornea will change as the host opening is made to conform to the round donor, the diameter decreasing in the area of the longer host axis and lengthening in the direction of the shorter host axis.

In reality, neither the recipient hole nor the donor button is rigid, and both will deform during keratoplasty.

Thus, we could not elucidate the mechanisms of this astigmatism. Factors such as wound healing, variations in corneal thickness between the periphery and the center, and possible differences in ease of displacement of the tissue between limbal and central cornea are some factors to be considered.

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Chapter 9

Suture-Induced Astigmatism After a Circular Wound in the Rhesus Monkey

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Penetrating homolateral autokeratoplasties were performed in five adult rhesus monkeys to determine the influence of the length of sutures on the postoperative astigmatism both before and after suture removal. Our purpose was to minimize the effect of wound irregularities on corneal astigmatism by replacing the homolateral button without rotating it. The mean postoperative astigmatism with sutures in place was 10.55 D; suture removal reduced this to 2.37 D. Our results suggest that it is unlikely that sutures induce permanent astigmatism.

After penetrating keratoplasty, corneal astigmatism is a common problem that perplexes and frustrates both the clinician and the patient (1,2). The factors that produce corneal astigmatism after penetrating keratoplasty are not well defined, but the four main ones are the preoperative state of the cornea, wound configuration, suture configuration, and wound healing.

Experiments in monkeys hold the most promise for translating information to the human cornea, since monkey corneas have a Bowman's layer and a structure most similar to the human cornea. We designed an experiment in rhesus monkeys to try to determine the effect of sutures on astigmatism after penetrating keratoplasty. We did not set out to mimic human corneal surgery, but rather tried to dissect the effect of sutures from wound configuration by using an autograft model.

We report our results on the effect of suture length on corneal astigmatism.

MATERIALS AND METHODS

The experiments were performed on five adult rhesus monkeys, four ranging from 7 to 9 years of age and one ranging from 28 to 30 years. The animals were anesthetized with intramuscular ketamine hydrochloride, 10 mg per kg body weight for all examinations. If needed, this was supplemented with ketamine 5 mg per kg intramuscularly or varying doses of diazepam intravenously. For surgery, the ketamine was supplemented with pentabarbital intravenously. Before surgery, a slit-lamp examination was performed and central keratometry readings were taken in triplicate using a keratometer, of which the range was extended by attaching a 1.25 D or 2.00 D spherical lens over the central aperture of the keratometer wires and converting the readings on a nomogram (3). The surgery was performed in an operating room under the same strict regulations that govern human surgery.

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All surgery was performed using an operating microscope. The animal was placed in a supine position with the head held in a clamp. The eyes were prepared and draped in sterile fashion. A child-size Barraquer lid speculum was placed.

After a central superficial circular incision into the corneal epithelium was made with a 6.5 mm disposable corneal trephine, 16 equally-spaced identifying marks were made approximately 0.75 mm outside the trephine mark to ensure equal spacing of the sutures. The marks were placed using a marker that consisted of a 10 mm Fliering ring with 16 equally-spaced engraved lines. This ring was placed on the cornea just around the superficial trephine mark and the identifying points were made with a 27 G hypodermic needle central to the engraved lines in the ring. The corneal trephine was placed in the circular mark previously made and was advanced through approximately 60% of the stroma. The incision was deepened to Descemet's membrane with a diamond knife in an attempt to obtain a uniform 360° wound. Four preplaced 10-0 nylon sutures at 3, 6, 9, and 12 o'clock were placed to insure accurate alignment. A diamond knife was used to enter the anterior chamber and to excise the central corneal disk. An iridectomy was performed. The buttons were lifted slightly out of the wound and sutured back in place with interrupted 10-0 nylon sutures on a bicurved needle (curvature 105°–85°, length 6.17 mm, radius 0.86/3.10 mm, wire 0.15 mm). One drop of 1% atropine was applied directly after the four cardinal sutures were tied. The anterior chamber was reconstituted using balanced salt solution, and the knots of each suture were rotated into the peripheral stroma. The amount of tension of the suture was not measured directly but was judged by visual inspection of the amount of tissue compression and by moving the suture with a tying forceps. Those sutures that appeared inappropriately loose or tight at the end of the procedure were replaced until an approximately uniform tension was achieved at 360°. At the conclusion of surgery, one drop of 1% atropine and 1% prednisolone acetate were applied topically three times at 5 min intervals, followed by topical hydrocortisone-bacitracin-polymixin ointment. No topical therapy was applied after the day of surgery.

Experimental Eyes

The experimental eye of each animal was selected from a random-number table, and the other eye served as a control. Eight 10-0 sutures with large bites (⅜ circle needle, suture length 1.5 mm) were placed in the vertical axis, while eight small bites (bicurved needle, suture length 1.0 mm) were placed in the horizontal axis at 80% corneal depth. All of the sutures were tied with uniform tension and with minimal compression of the wound.

Control Eyes

Interrupted sutures were made of equal length and tightness in the control eyes and placed at approximately 80% depth. All animals were examined daily in their cage. Benamine (7.5 mg), which is a nonsteroidal antiinflammatory drug, was given intramuscularly twice a day for 3 days postoperatively. Slit-lamp examinations and central keratometry readings, taken in triplicate, were performed 2 days postoperatively and at 1- to 2-week intervals for 11 weeks after surgery. All sutures were removed 11 weeks after surgery. After suture removal, the examinations were performed at 4-week intervals for 5 months. The mean of the last three measurements was taken as the final value.

Only eyes with a clear cornea devoid of vessels and scar tissue outside the wound were included in the analysis of the results.

RESULTS

Eyes Excluded from Analysis

There was no case of a flat anterior chamber postoperatively. Three experimental and one control eye exhibited iris incarceration in the wound the day after surgery. One of these was related to a loose suture. Two days after surgery, the iris was separated from the wound with use of Healon and a Barraquer sweep following a puncture incision at the limbus. One eye had severe hemorrhage which resulted in secondary glaucoma. This eye was excluded from analysis. Other complications are summarized in Table 1. Vessels from the limbus had reached clear grafts at 6 to 10 weeks postoperatively in both eyes of the monkey whose age was 28

TABLE 1. *Complications associated with autokeratoplasty in rhesus monkeys*

	7–9 years old (8 eyes)	28–30 years old (2 eyes)
Postoperative loose suture	1	0
Iris incarcerated in the wound	3	1
Secondary glaucoma after removing the iris from the wound	1[a]	0
Vessel ingrowth and superficial scar tissue	0	2[a]

[a] Eyes excluded from analysis.

TABLE 2. *Corneal astigmatism before and after suture removal in rhesus monkeys*

			Before suture removal		After suture removal	
Monkey/eye	Age (years)	Average keratometric power before surgery (diopters)	Keratometric astigmatism (diopters)	Average keratometric power (diopters)	Keratometric astigmatism (diopters)	Average keratometric power (diopters)
Control eyes						
1/OD	9	51.13	1.03 × 90°	49.49	2.65 × 66°	50.28
2/OS	9	51.16	2.30 × 77°	49.61	0.32 × 95°	51.40
3/OS	7	55.59	0.84 × 100°	53.39	0.78 × 100°	56.09
4/OD	7	51.00	2.40 × 110°	46.18	0.27 × 80°	48.36
Mean		52.22 ± 2.25	1.64 ± 0.82	49.67 ± 2.95	1.01 ± 1.12	51.53 ± 3.29
Experimental eyes						
5/OD	9	51.13	8.77 × 65°	46.80	4.32 × 105°	49.43
6/OD	7	55.35	5.85 × 90°	51.44	0.49 × 175°	54.69
7/OS	7	50.99	17.04 × 75°	48.42	2.29 × 70°	49.47
Mean		52.49 ± 2.48	10.55 ± 5.80	48.89 ± 5.05	2.37 ± 1.92	51.20 ± 3.03

to 30 years. This was followed by superficial scar formation. Although the sutures did not loosen, the vessels grew along the sutures and created superficial scars, but the central portions of these grafts remained clear. At 10 weeks postoperatively, no reliable keratometry readings could be taken in these eyes.

Eyes Included in Analysis

Seven of the 10 eyes could be analyzed (Table 2). A significant difference ($p < 0.03$, Mann-Whitney *U* test) in astigmatism was observed before suture removal between the control group (mean 1.64 ± 0.82 D) and the experimental group (mean 10.55 ± 5.80 D). After suture removal, there was no statistically significant difference between the control (mean 1.01 ± 1.12) and the experimental groups (mean 2.37 ± 1.92). A striking reduction in astigmatism in the experimental group occurred immediately after suture removal. During the following 5 months, there was no significant change in astigmatism. The mean central keratometry readings in both groups increased after suture removal.

COMMENT

Our purpose in these experiments was to minimize the effect of wound irregularities on corneal astigmatism by replacing the homolateral button without rotating it. While this successfully isolated the effect of the sutures, it does not simulate the clinical situation in human keratoplasty, where the configuration of both the donor button and the host wound probably create most of the permanent postoperative astigmatism.

Trephination from the epithelial side on intact globes produces a larger average button than punching from the endothelial surface of corneas that are stored in MK media (4,5). A donor button punched from the endothelial side might have almost the same diameter as a button trephined from the epithelial side on an intact globe with a 0.25 mm smaller trephine (5). So using a 0.25 mm "oversized" punched button might be similar to a same size donor recipient technique as used "in the old days," when the majority of donor eyes were trephined from the epithelial side on intact globes. Our autograft model is similar to that same size donor recipient technique. A 6.5 mm corneal transplant in a 10.5 mm horizontal diameter rhesus monkey cornea would compare to a 7.5 mm transplant in a 12 mm human cornea. No corticosteroids or other topical therapy was applied after the day of surgery, and the sutures were removed at 11 weeks. In human keratoplasty the wound healing is delayed severely by corticosteroid therapy, and the sutures must be left in place much longer.

Our findings suggest that sutures do not create the final astigmatism after penetrating keratoplasty in the rhesus monkey. Sutures can be tightened or loosened to achieve a spherical cornea at the end of the surgical procedure, but our results demonstrate that it is unlikely that this will minimize the astigmatism after suture removal. This opinion is shared by others (2,6). We performed homolateral autokeratoplasties and sutured the button exactly back in its place using 16 sutures of which some had longer bites. This displaced the wound towards the iris, shallowing the anterior chamber (7), and may explain the high frequency of iris incarcerations in the wound, especially in the experimental eyes with the longer sutures. Oversized donor buttons may overcome this problem, but could add wound configuration problems to the experimental model.

The problems with corneal wound healing (Table 1) in the older monkey came as a surprise. We found a similar tendency in another group of monkeys aged 28 to 30 years used for a different set of experiments that involved penetrating keratoplasty. This would indicate that old rhesus monkeys are not useful for corneal surgery experiments.

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Correction of Postkeratoplasty Astigmatism by Razor Blade and V-Shaped Knife Wedge Resection

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SUMMARY

Improvement in microsurgical techniques and tissue storage has resulted in a higher rate of clear grafts after penetrating keratoplasty. The postoperative astigmatism however still remains a major problem. If a high corneal astigmatism cannot be managed successfully with glasses or contact lenses, a surgical approach may be indicated. We developed a V-shaped knife which makes a crescentic wedge resection easier to perform. Before the introduction of the V-shaped knife we obtained an average reduction in corneal astigmatism of 6.6 diopters. With the V-shaped knife the reduction was 8.0 diopters.

We think that the V-shaped knife makes a wedge resection easier and safer.

INTRODUCTION

Due to improvements in microsurgical technology the chance for a successful long-time clear graft has improved markedly. Both the use of a surgical keratometer[1] and modifying operative techniques have reduced the postoperative corneal astigmatism, but they did not solve the whole problem of postoperative astigmatism.[2-4] A clear graft with high astigmatism is often interpreted by the patient as a bad result. Many surgeons have attempted to reduce corneal astigmatism. Historical surveys in the work of Barner,[5] Krachmer,[6] and Szuniewicz[7] indicate that methods of treatment aim at steepening the flat meridian or flattening the steep meridian of the cornea. If a high residual corneal astigmatism cannot be managed successfully with glasses or contact lenses, a surgical approach may be indicated.

Corneal wedge resections[6,8] and relaxing incisions[6,9] can be effective. The wedge resection is a difficult procedure when performed with a razor blade or a diamond knife. In particular, the second incision is difficult since the cornea is more flaccid as the result of the first incision. Unintended perforation during the procedure renders the eye soft and hinders completion of the wedge resection. The surgery has not been quantitated and the results are sometimes unpredictable.

In 1979 we developed a V-shaped knife which makes a crescentic wedge resection easier to perform. We report here our experience with wedge resections before and after the introduction of this V-shaped knife.

MATERIALS AND METHODS

Seventeen consecutive patients with a clear graft and high astigmatism who could not be managed successfully with glasses or contact lenses were included in this series from November 1974 until January 1982. During the operation we identified the steep and the flat corneal meridian with a contact keratoscope,[10] an 18-mm diameter cylindrical device that is placed on the globe to project concentric rings over the graft and host cornea, including the limbal area. A wedge resection at the flattest end of the flat meridian was performed.

From November 1974 through December 1977, the late A.H.J. van Loenen Martinet did 14 wedge resections most of the time assisted by one of us (GvR) with a 30° razor blade knife. He used the technique described by Troutman.[8] The wedge resection encompassed the graft scar. The first

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author performed three wedge resections with the V-shaped knife in 1979. The V-shaped knife (Figure 1) consists of a V-formed razor blade band that cuts along its entire anterior edge and that is ground obliquely on the posterior edge for a better view of the cornea through the operation microscope. At 0.6 mm from the tip the space between the blades is 0.8 mm.

Under general or retrobulbar anesthesia and using a surgical microscope, concentric wedges of tissue, one within the other and decreasing in length with each new incision, were excised at one end of the flat meridian of the cornea. The wedges were cut in the transplant scar (Figures 2A-D). The first wedge was cut about 0.1 mm deep and three clock hours in length. The second wedge, starting a little bit inside the first wedge, was cut in the opposite direction and less than three clock hours in length. The third wedge was made in the same direction as the first incision but slightly less in length than the second wedge. In doing so we created a wedge broadening and deepening from the outer edges on to the middle, reaching its maximum dimensions in width and depth in the axis of the flat meridian. In patients who had astigmatism of 8 diopters or more we continued cutting until in the end we perforated the cornea in the center of the wedge and removed a strip of Descemet's membrane and endothelium.

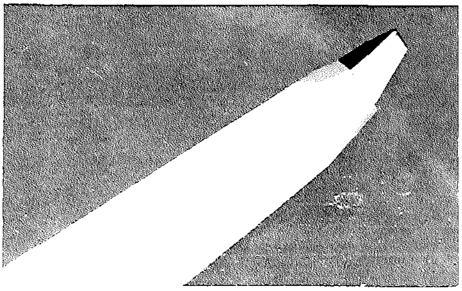

FIGURE 1: The tip of the V-shaped knife.

One 8-0 silk suture closed the wedge in the center, followed by six or seven deeply placed interrupted 10-0 nylon sutures with the knots buried. The 8-0 silk was removed. We tried to approximate the sides of the wedge and not to pull the sutures firmly. The contact keratoscope[10] was used to be sure that the preoperative flat meridian changed in the steep meridian at the end of the procedure. The surgeon administered a subconjunctival injection of

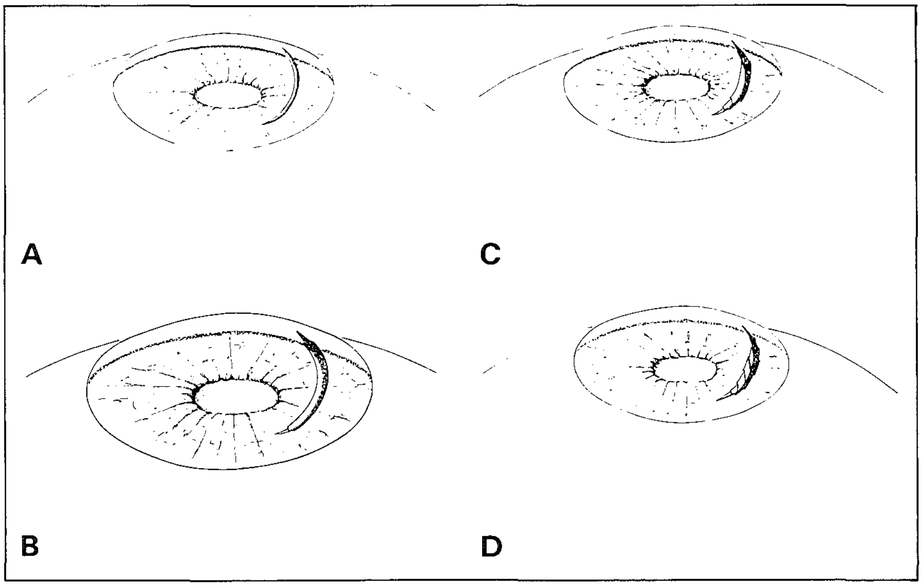

FIGURE 2: (A) The wedge is cut clockwise along 90° of the transplant scar; (B) the second wedge is cut counterclockwise starting a little bit inside the first wedge and less than 90° in length; (C) the third wedge is cut clockwise and slightly less in length than the second wedge; (D) etc.

TABLE 1

POSTOPERATIVE FOLLOW-UP OF A WEDGE RESECTION FOR HIGH ASTIGMATISM POSTKERATOPLASTY (CASE 16)

Time (months postop.)	Corneal astigmatism in diopters	Steepest meridian	Suture removal
Preoperative	13 x	23°	
1 week	12 x	95°	
2 mo	12 x	90°	
3 mo	12 x	90°	1 x
4 mo	8 x	90°	3 x
6 mo	4.5 x	105°	1 x
8 mo			1 x
10 mo	3 x	65°	1 x
13 mo	3 x	65°	
16 mo	2.5 x	60°	
19 mo	2 x	50°	

gentamycin and corticosteroids at the end of the operation.

The patients were discharged with a regimen of topically applied antibiotics and corticosteroids. In most cases the sutures were removed one by one, starting between three and 12 months postoperatively. Keratometer readings were taken on every visit, and the suture removal depended on the amount and the changing of the astigmatism. When the astigmatism after the wedge resection was high with the steep axis 90° to the preoperative steep axis, we removed the first sutures in the steep axis at approximately three months.

The typical follow up and suture removal in a 56-year-old patient (Case 16) is shown in Table 1. This patient underwent a perforating graft in 1961 and a wedge resection in 1980.

RESULTS

The underlying corneal disease, the preoperative and postoperative corneal astigmatism, remarks and the follow-up of all 17 consecutive patients are shown in Table 2. In three of the 14 cases operated with a razor blade knife, the anterior chamber was entered and the incision could not be completed. The wound was closed with interrupted 10-0 nylon sutures. Table 3, summarizes the results of the two groups. The average reduction in corneal astigmatism was 6.6 diopters in the 14 wedge resections performed with the razor blade knife and 8.0 diopters in the three wedge resections performed with the V-shaped knife.

COMMENTS

High postkeratoplasty astigmatism occurs frequently in patients undergoing keratoplasty for keratoconus. This astigmatism is not easy to prevent.[11] Seven of our 17 patients underwent keratoplasty for keratoconus. In all patients glasses and various types of contact lenses were extensively tried and were not successful.

From 1974 until 1977 the wedge resection of Troutman[8] was used. Because the procedure is sometimes difficult and the results are not always predictable, attempts were made to simplify the procedure. Jensen[12] also tried to quantitate the excision and introduced a double knife, which gives a parallel incision but not a crescentic wedge resection. The knife is difficult to construct and did not become widely available for clinical use. Soll[13] constructed a special wedge resection knife with two disposable razor blades set on an angle of 40 degrees to each other. The knife is cumbersome, and the view of the cornea through the operation microscope is insufficient.

We tried to simplify the procedure and to develop a knife which, at the same time, could be used to cut also a strip of Descemet's membrane. This resulted in a V-shaped knife of which we used the third prototype for the last three years. The knife cuts excellently on donor eyes but, unfortunately, in treating patients the procedure is not always as easy. For instance, in a patient operated in 1981 the anterior part of the keratoplasty wound was too weak and opened during the third cut. Adhesions between the Descemets were much stronger and the Descemet stayed intact. With a knife and Vannas scissors the superficial wedge was completed. Afterwards we perforated Descemet's membrane in the center of the wedge with the V-shaped knife. But even in this case the procedure was felt to be easier than it would have been, when using a simple knife. Contrary to the razor blade knife, the anterior chamber was never entered

TABLE 2

SEVENTEEN CONSECUTIVE WEDGE RESECTIONS FOR HIGH ASTIGMATISM POSTKERATOPLASTY

Patient	Diagnosis	Corneal astigmatism in diopters preop.	postop.	Remarks	Follow-up (months)
		RAZOR BLADE			
1	Herpes simplex	6	1		33
2	Keratoconus	17	3		19
3	Keratoconus	10	6		13
4	Keratoconus	11	6	perforation,* sutured	44
5	Herpes simplex	11	1.5		67
6	Keratoconus	10	5		34
7	Ruptured bacterial ulcer	18	13	perforation,* sutured	3
8	Fuchs' endothelial dystrophy	7.5	1		55
9	Luetic interstitial keratitis	10	6		5
10	Herpes simplex	20	9		8
11	Terrien's marginal degeneration	20	6		48
12	Keratoconus	14	2.5		43
13	Trauma	7	7.5		42
14	Herpes simplex	5	6	perforation,* sutured	9
		V-SHAPED KNIFE			
15	Keratoconus	8	1.5		24
16	Keratoconus	13	2		19
17	Scrofulous keratitis	10	3		21

**incision not completed*

TABLE 3

RESULTS: RAZOR BLADE — V-SHAPED KNIFE

	Corneal Astigmatism in Diopters Razor Blade	V-Shaped Knife
Preoperative	11.9 (5-20)	10.3 (8-13)
Postoperative	5.3 (1-13)	2.3 (1.5-3)
Change	6.6 (−1-14)	8.0 (6.5-11)
	n = 14	n = 3
Follow-up	30 months	21 months

abusively with the V-shaped knife. The results were slightly better with the V-shaped knife, but still not quantifiable.

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SUMMARY

The first section deals with the mechanisms by which sutures, incisions and intracorneal contact lenses produce a change in corneal curvature. To clarify the mechanisms by which incisions and sutures produce astigmatism, we made incisions and placed sutures in the corneoscleral limbus of human eye bank eyes (chapter 2). The changes in corneal curvature were studied by central keratometry and by shadowgraph photography of the corneal contour. A radial corneal suture induces astigmatism by tissue compression. A radial anterior suture comprises more tissue on the outside than on the inside of the cornea. This moves the epithelial side of the cornea posteriorly towards the center of the globe. This posterior displacement decreased the sagittal depth of the cornea, so that the depth of the anterior chamber decreased slightly. The center of the cornea steepened in the meridian of the suture. This can be illustrated by holding a card between the thumb and first two fingers and applying pressure to make the card arch over the palm. When the forefinger of the other hand presses down near the arched card, this area moves toward the palm like limbal tissue near a suture and the arch of the central area of the card increases; resembling the steepening of the central cornea. With this theory we can understand the mechanism by which sutures produce corneal astigmatism after cataract surgery. Incisions in the anterior layers of the cornea weaken the mechanical stability. The intraocular pressure then causes the wound to gape and outward bulging of the cornea. The central corneal curvature flattens. Corneal incisions are clinically used with radial keratotomy, an operation for the correction of myopia. It is one of the techniques of refractive corneal surgery. Refractive corneal surgery (chapter 3) constitutes of surgical techniques to change the corneal power so that the patient can see better without contact lenses or glasses. All these techniques are irreversible which led us to try and find a method that would be reversible. We found it to be possible to flatten the central corneal curvature of human eye bank eyes by radial interrupted nylon sutures (chapter 4).

In chapter 5 and 6 we discuss the feasibility of implantation of hydrogels into the cornea for refractive keratoplasty. High water content hydrogels can be made with water and solute permeability comparable to those of corneal stroma and the lenses are well tolerated into the cornea. However, the hydrogels have a refractive index comparable to the corneal stroma and so a hydrogel must alter the anterior curvature of the cornea to change the refraction of the eye. The hydrogel plus power lenticule implanted in a free-hand intrastromal pocket created no significant steepening of the anterior corneal surface and therefore little change in refraction (chapter 5). Bowman's layer and the anterior stroma prevented the cornea from steepening. In order to create a predictable steepening of the anterior corneal surface, the anterior

corneal collagen layers must be disrupted with a microkeratome (chapter 6).

In the second section corneal astigmatism after penetrating keratoplasty is discussed. The cutting precision of the recipient cornea is a very important factor in corneal astigmatism after penetrating keratoplasty. We measured the diameter of the hole in the cornea of human eye bank eyes (chapter 7) and pig eyes (chapter 8). Different methods of trephination produced differences in size and shape of the corneal openings. Trephines that were held perpendicular to the corneal surface showed less variation in shape and may have considerable advantage in clinical practice. Keeping the trephine blade centered on the cornea is also important. Patients with eccentric penetrating keratoplasties had severe corneal astigmatism (chapter 9). Factors such as wound healing and variation in corneal thickness between the periphery and the center of the cornea are factors to be considered. Many surgeons wondered if suture adjustment during surgery could influence the final astigmatism after penetrating keratoplasty. We examined this in the rhesus monkey (chapter 10). Our findings suggest that it is unlikely that suture adjustment during surgery could influence the final astigmatism after penetrating keratoplasty. If patients with a high corneal astigmatism cannot be managed successfully with contact lenses or glasses, a surgical approach may be indicated. High postkeratoplasty astigmatism can be managed successfully with a wedge resection (chapter 11). A V-shaped knife makes a wedge resection easier.

SAMENVATTING

Het eerste gedeelte van dit proefschrift gaat over het veranderen van de kromming van het hoornvlies door middel van hechtingen, incisies en contactlenzen in het hoornvlies. Hiertoe werden in hoofdstuk 2 menselijke donor ogen geopereerd. De verandering van de vorm van het hoornvlies werd door middel van een keratometer en door het maken van schaduwfoto's van het profiel van het hoornvlies nagegaan. Een radiaire hechting in het hoornvlies comprimeert het weefsel en induceert zodoende astigmatisme. Een perifere radiaire hechting in de voorzijde van het hoornvlies comprimeert het weefsel meer aan de voorzijde dan aan de achterzijde van het hoornvlies en leidt zodoende tot een verplaatsing van het hoornvliesweefsel naar het centrum van het oog. De voorste oogkamer wordt daardoor ondieper. Het centrum van het hoornvlies wordt hierdoor krommer in de meridiaan van de hechting. Dit kan gemakkelijk worden nagebootst door een visitekaartje tussen duim en wijsvinger iets krom te buigen. Met de wijsvinger van de andere hand drukken we van opzij tegen het kaartje en we zien dat het kaartje naar binnen toe buigt en dat de boog van het kaartje spitser wordt. Met deze theorie kan het astigmatisme dat klinisch gevonden wordt na een cataract operatie goed verklaard worden. Incisies in de voorste lagen van het hoornvlies verzwakken het hoornvlies daar ter plaatse. Door de intraoculaire druk gaan de wondranden wijken en wordt het weefsel vanaf het centrum van het oog naar buiten toe verplaatst. Hierdoor wordt het centrum van het hoornvlies vlakker. Corneale incisies worden klinisch toegepast bij de radiale keratotomie. Dit is een van de vormen van refractie chirurgie. Onder refractie chirurgie (hoofdstuk 3) verstaan we operaties die bedoeld zijn om de sterkte van het optische stelsel te veranderen en zodoende patienten beter te laten zien zonder bril of contactlenzen. De verschillende methoden van refractie chirurgie worden in hoofdstuk 3 besproken. Al deze technieken zijn niet reversibel. Daarom gingen wij op zoek naar een methode die reversibel moest zijn.

Het blijkt mogelijk om bij donor ogen door middel van hechtingen de centrale kromming van het hoornvlies te verminderen (hoofdstuk 4). Het voordeel van deze methode is dat de hechtingen postoperatief eventueel verwijderd kunnen worden waarna de preoperatieve kromming weer terugkomt.

In hoofdstuk 5 en 6 wordt nader ingegaan op het veranderen van de refractie door het implanteren van zachte contactlenzen in het hoornvlies. De doorgankelijkheid van zachte contactlenzen voor water en glucose is ongeveer gelijk aan die van cornea stroma en de lenzen worden goed in het stroma verdragen. Aangezien de brekingsindex van zachte contactlenzen ongeveer gelijk is aan die van het hoornvlies, moet de kromming van het hoornvlies door de contactlens veranderd worden om een refractie verandering te bewerkstelligen. De kromming van het hoornvlies veranderde weinig en was bovendien slecht voorspelbaar na implantatie van een positieve zachte contactlens in een met de hand geprepareerde pocket (hoofdstuk 5). De membraan van Bowman en de voorste lagen van het hoornvlies konden de verandering van de kromming tegenhouden. Om een meer voorspelbare vormverandering van de hoornvlieskromming te veroorzaken moesten de voorste lagen eerst doorgesneden worden met een microkeratoom (hoofdstuk 6).

In het tweede gedeelte wordt op het astigmatisme na hoornvlies transplantaties ingegaan. Een van de belangrijkste factoren voor het postoperatieve astigmatisme is de trepanatie opening bij de patient. De trepanatie openingen van menselijke donor ogen (hoofdstuk 7) en varkensogen (hoofdstuk 8) werden opgemeten. Verschillende trepanatie methoden leidden tot duidelijke verschillen in vorm en grootte van de trepanatie opening. Trepanen die loodrecht op het hoornvlies oppervlak stonden gaven de beste resultaten en zouden klinisch tot betere resultaten kunnen leiden.

Het is ook belangrijk om de trepaan goed op het hoornvlies te centreren. Eccentrische transplantaties leidden tot een hoog postoperatief hoornvlies astigmatisme (hoofdstuk 9). De wondgenezing en de verschillen in cornea dikte tussen de periferie en het centrum van het hoornvlies spelen hierbij mogelijk een rol.

Vele chirurgen hebben zich afgevraagd of het postoperatieve astigmatisme beinvloed zou kunnen worden door het veranderen van hechtingen gedurende de operatie. In hoofdstuk 10 werd dit bij rhesusapen onderzocht. Het is niet waarschijnlijk dat het veranderen van hechtingen tijdens de operatie het astigmatisme op de lange duur kan beinvloeden. Wanneer patienten met een hoog cornea astigmatisme niet bevredigend met contactlenzen of een bril kunnen worden geholpen, kan het astigmatisme alleen langs operatieve weg gecorrigeerd worden. In hoofdstuk 11 blijkt door middel van een wig excisie het astigmatisme goed behandeld te kunnen worden. Een V-vormig mes maakt de ingreep gemakkelijker.

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