JOURNAL OF BIOMEDICAL OPTICS 2(1), 106–114 (JANUARY 1997)

NEW METHOD FOR RESHAPING THE CORNEA

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(Paper JBO-095 received May 28, 1996; revised manuscript received Oct. 9, 1996; accepted for publication Nov. 12, 1996.)

ABSTRACT

The optical theory behind a new technique for reshaping the cornea to correct refractive errors of the eye is presented. This technique is capable of excising both positive and negative meniscus (lenticular)-shaped tissues of predetermined optical power from the anterior cornea. The optical lens bending theory routinely used by optical designers to reduce the amount of spherical and comatic aberrations in a lens system is employed in this technique. This technique uses a microkeratome to remove a planoconvex, or planoconcave-shaped tissue from the cornea while the eye is in a deformed state. When the eye returns to its natural, undeformed state, a lenticular tissue of predetermined optical power has been removed, correcting for myopic or hyperopic refractive errors, respectively. An elementary introduction to the current surgical techniques used for the correction of refractive errors is presented. Meniscus cross sections of the excised tissues are shown to demonstrate the optical theory discussed.

Keywords cornea; refractive surgery; microkeratome; lamellar; lenticular.

1 INTRODUCTION

The aim of refractive eye surgery is to modify or eliminate existing refractive errors (myopia, hyperopia, astigmatism) to improve unaided visual acuity. Although many techniques have been proposed and tested over the past half century, radial keratotomy (RK), keratomileusis *in situ* (KMIS), photorefractive keratectomy (PRK), and laser assisted *in situ* keratomileusis (LASIK) are the most widely practiced.

RK was first introduced by Fyodorov and Durnev[1] in the former Soviet Union in the early 1970s. This procedure involves placing anterior, partially penetrating, radial incisions in the cornea. These incisions weaken the structure, flattening the uncut, central cornea. The first RK procedure was performed in the United States in 1978 and has subsequently undergone extensive clinical testing.[2]

Keratomileusis, as originally developed by Jose Barraquer in Bogota, Columbia, over 50 years ago, was a very complicated technique. It involved using a microkeratome to remove a central, anterior corneal cap, freezing it, placing it on a lathe and reshaping it, and then suturing the thawed tissue back onto the corneal surface.[3,4] A simpler procedure known as keratomileusis *in situ* (KMIS) was introduced by Luis Ruiz, a student of Barraquer.[5] In this technique, two lamellar (parallel-faced), concentric disks are removed from the central cornea, the second underlying excision being smaller in diameter than the first. By returning the first tissue to the surface of the eye in the absence of the second, optical correction is achieved.

With the advent of the argon fluoride excimer laser, a new technique known as photorefractive keratectomy (PRK) was introduced.[6,7] In this procedure, the outermost layer of the cornea, the epithelium, is first mechanically removed. The excimer laser is then used to ablate the underlying stromal tissue, reshaping the anterior curvature of the cornea and modifying its power. Problems associated with pain and regression have led to the development of a procedure known as laser-assisted *in situ* keratomileusis (LASIK).[8,9] With this technique, a microkeratome is first used to remove a central, lamellar disk from the cornea, preserving the epithelium and Bowman's membrane. The excimer laser then ablates the underlying stroma and the cap is replaced.

A new technique has been developed with the ability to mechanically excise both positive or negative meniscus lenses of predetermined optical power from the anterior cornea for the correction of myopia or hyperopia, respectively. The removal of these lenticular tissues occurs under a lamellar cap that maintains the cornea's epithelium and Bowman's membrane.

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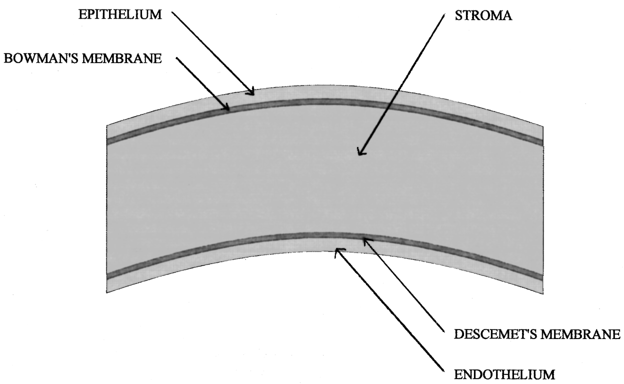

Fig. 1 The five principal layers of the central cornea.

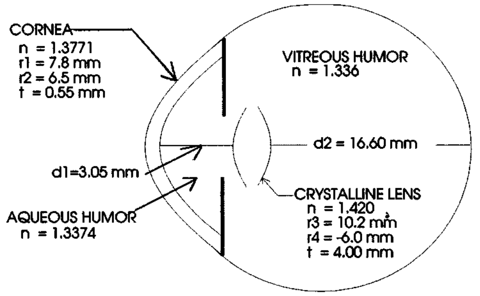

Fig. 2 The Gullstrand–LeGrand schematic eye.

2 THE CORNEA

Because of its critical role in refractive surgery, a brief introduction to the structure and optical characteristics of the human cornea is presented. The cornea, which is generally 560 μm thick in the center and nearly 800 to 900 μm thick at the periphery, consists of five principal layers (Figure 1). These are the epithelium, Bowman's membrane, stroma, Descemet's membrane, and endothelium.[10] The epithelium has two main functions, first to provide a smooth interface for the refraction of light, and second to act as the first line of defense against infection. The entire epithelium is 50 to 70 μm thick, and can completely regenerate every 3 to 5 days. Bowman's membrane serves to anchor the epithelium to the stroma. Once destroyed, this layer cannot regenerate. The stroma makes up 90% of the corneal thickness, and is composed of lamellar layers of collagen-oriented orthogonally to one another. This orthogonal relationship plays a crucial role in maintaining the transparency of the cornea. Under the stroma is Descemet's membrane, which provides function similar to that of Bowman's membrane, anchoring the endothelium to the posterior stroma. The most posterior layer is the endothelium. The endothelium has the dual function of transporting nutrients from the aqueous humor to the cornea, as well as pumping fluid out of the stroma in order to maintain proper corneal hydration and clarity.

Optically, the eye may be represented by the Gullstrand–LeGrand schematic eye (Figure 2).[11] In this model, four refractive surfaces are used to approximate the optical properties of the eye. The total power of the eye is 60 diopters (D), where a diopter is the inverse of the focal length in meters. The greatest part of the optical power of the eye, 48D, occurs at the air/tear film interface at the front of the cornea, with the remainder provided by the crystalline lens. The crystalline lens has the ability to change its shape and increase its optical power in order to image near objects. This process is known as accommodation. Typically, in the fourth to fifth decade of life, the eye slowly loses its ability to flex this lens, causing the individual to develop a need to wear glasses for near vision, a condition known as presbyopia.

When the cornea has more power than required, and/or the axial length of the eye is too long, distant objects will be imaged in front of the retina, and the individual is said to be myopic or nearsighted. Conversely, if the cornea does not have enough power, and/or the axial length of the eye is too short, images of near objects will be focused behind the retina. The eyes in this situation are said to be farsighted or hyperopic. When no visual disorder occurs, the eye is said to be emmetropic.

All three of the conditions mentioned above (myopia, hyperopia, presbyopia) represent refractive errors of the eye, and will result in a decrease in the quality of the image formed at the retina. Astigmatism is also a refractive error, and can occur at the cornea, crystalline lens, or both. Astigmatism occurs when the different meridians of an optical element have different radii. Since each meridian has its own radius, and hence its own power, each will form an image at a different location. An analogy that is often used to describe this aberration is that an optical element with no astigmatism would have a spherical surface resembling a cereal bowl, whereas the surface of an optical element with astigmatism may be better represented by a soup spoon.

Since most of the optical power of the eye is produced by the air/tear film interface at the front of the cornea, a small change in the anterior radius of the cornea can result in large changes in refractive power. It is for this reason that many of the refractive surgical techniques attempt to modify this surface to correct refractive errors.

3 CURRENT SURGICAL TECHNIQUES

In order to fully appreciate the significance of removing lenticular-shaped tissues from the cornea to correct refractive errors, it is first necessary to understand how existing surgical techniques achieve optical correction of those refractive errors. Although other corrective techniques exist, the four surgical procedures mentioned earlier (RK, KMIS, PRK, and LASIK) are currently the most frequently used. The reviews of these techniques presented

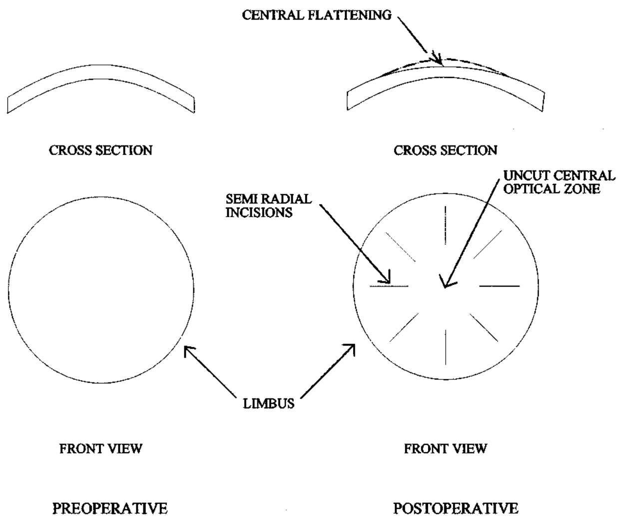

Fig. 3 Radial keratotomy correction of myopia.

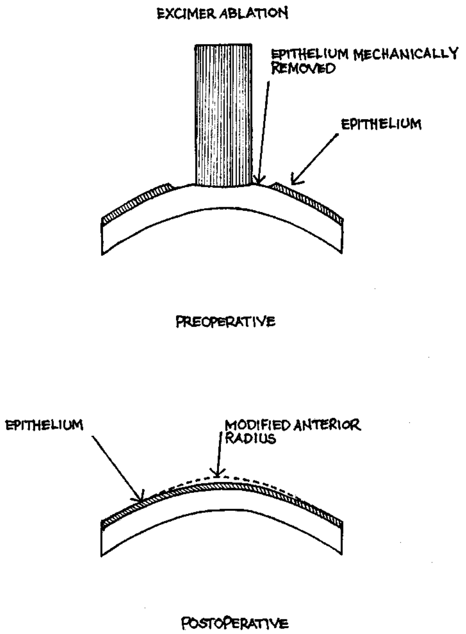

Fig. 4 Photorefractive keratectomy correction of myopia.

here are intended for the nonophthalmologist, and in some cases may oversimplify a rather complex technique or mechanism of correction. The reader is referred to the cited publications for a more detailed analysis of the subjects covered.

3.1 RADIAL KERATOTOMY

Radial keratotomy is a technique that introduces semiradial incisions through the anterior surface of the cornea, penetrating to 90% of its thickness.[2,6,12] It is commonly believed that the radial incisions weaken the cornea, allowing the intraocular pressure of the eye to deform the peripheral cornea, flattening the central cornea (Figure 3). Other theories suggest that the extra tissue generated during scar formation produces the overall flattening. In either situation, the flattening of the uncut, central cornea reduces its optical power and corrects for nearsightedness (myopia).[2,13] Straight or arc-shaped incisions of similar depth may be placed in one or both hemimeridians to correct for astigmatism.[14] No safe method for treating farsightedness (hyperopia) with radial keratotomy currently exists.[15]

The amount of optical correction achieved with radial keratotomy is a function of the number of incisions and incision length and depth. No optical relationships exist that describe the number or length of cuts that will correct for a known optical refractive error. Instead, refractive surgeons use a nomogram to determine the parameters mentioned above. A nomogram is simply an empirically derived table that identifies the number of incisions to be made and the optical zone from which they should originate in an attempt to achieve a desired optical correction in diopters. These nomograms, being empirically derived, rely upon postoperative statistics to determine future surgical parameters. Numerous factors, including age, sex, the aggressiveness of the healing response, the direction in which the incisions are created, and the amount of initial refractive error being corrected influence the final correction achieved.[16–18]

3.2 PHOTOREFRACTIVE KERATECTOMY

In PRK, an excimer laser emitting a 193-nm wavelength is used to ablate corneal stromal tissue, reshaping the anterior surface of the cornea (Figure 4).[19,20] Unlike radial keratotomy, the excimer laser corrects for refractive error (myopia, hyperopia, and astigmatism) in an optically correct fashion. Through controlled ablation of the corneal tissue, the anterior radius of the cornea may be modified to obtain a known spherical optical correction in diopters.[7,21–25] It should be noted that in order to ablate the stromal tissue, the epithelium must first be mechanically removed due to its different ablation rate compared with the stroma.[26,27] This often induces moderate to severe pain postoperatively, which persists until the epithelium can regenerate over the open wound, although postoperative regimens are beginning to reduce the amount of pain associated with this technique. Complete epithelial regeneration may take as long as 3 to 4 days. In addition, Bowman's membrane is ablated during this procedure. Its destruction initiates an active healing response that can lead to a loss of correction (myopic regression) from the initial refractive correction.[28–30] Because of the loss of best-corrected visual acuity (BCSVA), corneal scarring, and the limited predictability seen with deep surface ablation using the PRK technique, interest in the LASIK procedure has increased substantially.[31,32]

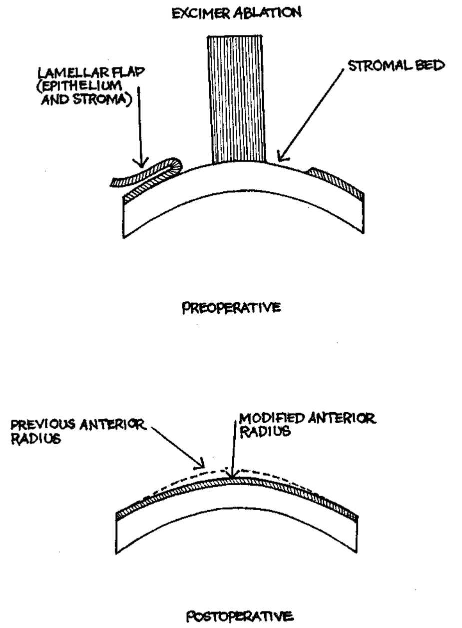

Fig. 5 Laser *in situ* keratomileusis correction of myopia.

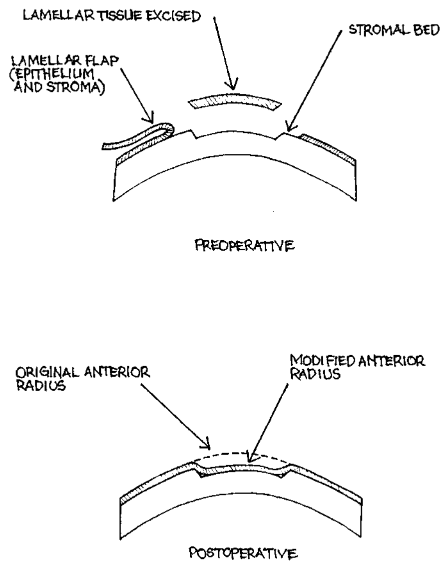

Fig. 6 Keratomileusis *in situ* correction of myopia.

3.3 LASER-ASSISTED *IN SITU* KERATOMILEUSIS

The pain induced by the mechanical removal of the epithelium, along with the ablation of Bowman's membrane during PRK, has led to the development of a new procedure known as laser-assisted *in situ* keratomileusis (LASIK) (Figure 5).[8,9]

In this technique, a superficial (160-μm thick) lamellar, circular disk containing the epithelium, Bowman's membrane, and some anterior stroma is resected, leaving only a small hinge where the tissue remains attached. This disk is then flapped to the side to ensure that the tissue is not lost during the procedure, and that it can be easily replaced in its presurgical position. A laser tissue ablation is performed on the exposed stroma, modifying the anterior radius (the so-called flap and zap technique). By replacing the flap, LASIK avoids damage to the Bowman's layer or the epithelium, minimizes postoperative pain, and increases the speed of visual rehabilitation. Like PRK, LASIK has the potential to correct for myopia, hyperopia, and astigmatism, depending upon the shape of the ablated tissue. Problems associated with the LASIK procedure can include decentration of the corneal cap, loss of the cap postoperatively, interface opacity caused by epithelial cell ingrowth between the cap and the stroma, entrapment of foreign bodies (cellulose, cotton, dust) between the cap and stroma, induced astigmatism, and photophobia.[33]

3.4 KERATOMILEUSIS *IN SITU*

Keratomileusis *in situ* (Figure 6) consists of removing two concentric, lamellar disks from the anterior cornea, the second underlying resection being smaller in diameter than the first.[34–37] The devices that remove these lamellar tissues are known as microkeratomes. The first disk contains the epithelium, Bowman's membrane, and some anterior stroma, and is left attached to the stroma by a hinge as discussed earlier. The second disk contains only stromal tissue.

Optical correction under the KMIS technique is achieved by placing the first disk back onto the surface of the eye where the second disk had been. The first disk falls into the space created by the removal of the second, and hence a flattening of the central cornea occurs. The amount of optical correction that is achieved is controlled by both the diameter and the thickness of the second disk.[2,6,25,38] As in radial keratotomy, there are no optical relationships that may be used to determine these parameters; instead, an empirically derived nomogram specifies the diameter and thickness of the resections needed for an attempted correction of refractive error. Disadvantages of the procedure include the creation of irregular astigmatism, loss of BCSVA, prolonged recovery of visual acuity, and large percentages of enhancements for undercorrection.[3,5]

The surgical techniques discussed above are limited by the range of refractive error correction any one technique can achieve. Surgeons in general will use RK to correct for myopic refractive errors from 1.5 to 6 diopters and PRK from 2 to 6 diopters, while KMIS is used for myopic refractive errors above 6 diopters.[39] The effective range of the LASIK procedure is still being outlined.

4 A NEW TECHNIQUE

The removal of only lamellar tissues by the microkeratomes used in LASIK and KMIS procedures limits their ability to correct for refractive errors because the removal of a tissue of uniform thickness from the surface of the eye will not result in any

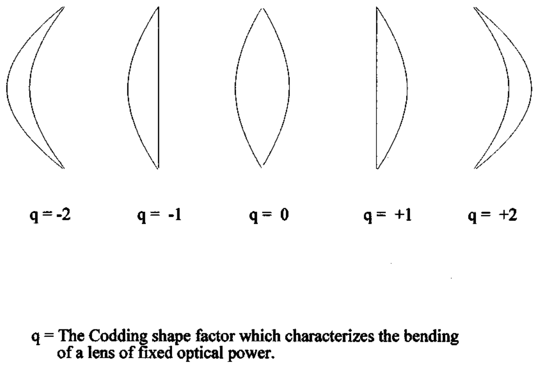

Fig. 7 Optical theory of lens bending. q is the Codding shape factor that characterizes the bending of a lens of fixed optical power.

predictable change in its optical power. Refractive error correction as discussed under the KMIS procedure is essentially achieved by reducing the volume of the central cornea, resulting in an overall flattening of that surface. A new microkeratome, the UniversalKeratome™, is capable of mechanically removing either a positive or negative meniscus (lenticular), as well as a lamellar-shaped tissue from the cornea. The mechanical resection of meniscus-shaped lenses modifies the optical power of the cornea to correct refractive errors.

4.1 OPTICAL THEORY

This new technique uses the theory of optical lens bending to mechanically correct refractive errors of the eye. The thin lens equation, which describes the power of an optical element in air, is given by:

$$1/f=(n_L-1)(1/r_1-1/r_2), \tag{1}$$

where f is the focal length, n_L is the refractive index of the lens, and r_1 and r_2 are the first and second radii of the lens, respectively. From Eq. (1) it may be shown that different combinations of radii will produce the same focal length and hence the same optical power. Figure 7 demonstrates the "bending" effect that occurs in a lens as the radii are varied but the focal length and refractive index are kept constant.

We categorize this "bending" by a parameter known as the Coddington shape factor, "q."[40] This shape factor is given by:

$$q=r_2+r_1/r_2-r_1. \tag{2}$$

As an example, a thin lens of a focal length of 200 mm (5 diopters) and a refractive index of 1.5 may result from an equiconvex lens (q=0) of r_1=200 mm, r_2=−200 mm; a planoconvex lens (q=1) of r_1=100 mm; or a positive meniscus lens (q=2) of r_1=66.7 mm, r_2=200 mm.

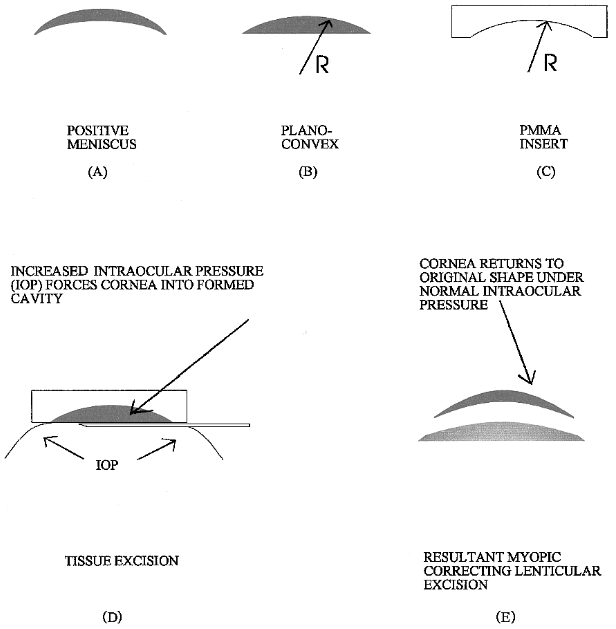

Fig. 8 Myopic refractive correction by excision of a positive meniscus lens.

4.2 CORRECTION FOR MYOPIA

In myopia, either the power of the cornea is too strong, and/or the axial length of the eye is too long, resulting in an image being formed in front of the retina. The refractive solution to this is to decrease the anterior curvature of the cornea (increase the radius), decreasing its optical power. The procedure by which this is accomplished is shown in Figure 8.

For myopic correction, the desired shape of tissue to be removed from the cornea is a positive meniscus lens [Figure 8(A)]. Figure 8(B) shows an equivalent powered planoconvex lens with a shape factor q=1. As may be seen, the power of this lens is uniquely determined by the radius of curvature of its spherical surface (under the thin lens assumption) and its refractive index. For a known refractive error, i.e., 3 D, it is possible to determine the radius of a planoconvex lens that will produce this power. This radius is then turned on a lathe into a polymethylmacrylate (PMMA) button shown in Figure 8(C). After the PMMA button is inserted into the microkeratome, it is centered on the eye and a vacuum is applied to the eye via a suction ring. This vacuum raises the intraocular pressure (IOP) of the eye, forcing the cornea into the cavity created in the button. A reciprocating blade then traverses along the bottom of the insert, removing the desired tissue [Figure 8(D)]. Finally, once the vacuum is released and the cornea returns to its natural shape, the removal of a lenticular tissue has been achieved [Figure 8(E)]. In Figure 8(E) the anterior radius of the cornea has been increased, thus decreasing its optical power and correcting the myopia.

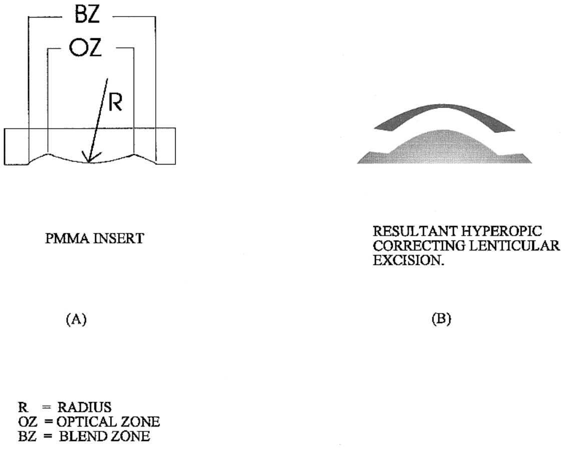

Fig. 9 Optical insert used to correct hyperopic refractive error and its resultant effect on the cornea. R, radius; OZ, optical zone; BZ, blend zone.

Although it is not shown for clarity, the meniscus tissue removed for myopic correction discussed above, and for hyperopic correction (to follow), is excised from the stromal bed after a lamellar flap has been resected as discussed earlier.

4.3 CORRECTION FOR HYPEROPIA

In hyperopia, either the power of the cornea is too weak, and/or the axial length of the eye is too short, resulting in an image being formed behind the retina. The refractive solution for this is to increase the anterior curvature of the cornea (reduce the radius), increasing its optical power. This is accomplished by inverting the optical insert radius which was used to correct myopia. Figures 9(A) and 9(B) show the optical insert used to correct hyperopia and its resultant effect on the cornea. The hyperopic insert shown in Figure 9(A) has a corrective diameter, or optical zone (OZ), and a blend zone (BZ). The blend zone is used to ensure a smooth transition on the surface of the cornea. As may be seen in Figure 9(B), more tissue is removed from the periphery and less from the center, resulting in a steepening of the cornea, increasing its power.

4.4 LAMELLAR (PARALLEL-FACED) TISSUE EXCISION

Figures 10(A) and 10(B) demonstrate the optical insert that is used to remove parallel-faced (lamellar) tissue and its resultant effect on the corneal surface. Excision of lamellar tissue alone will not provide any change in the optical power of the eye because it does not alter the anterior radius of the cornea. Its usefulness resides mainly in providing a lamellar flap under which a corrective cut or laser ablation can be performed.

4.5 OPTICAL VERIFICATION

The lens bending theory is a convenient tool for the optical design industry. By bending the lens while maintaining the same optical power, optical designers are able to significantly reduce the amount of spherical or comatic aberration in a lens system.[41,42] In a production environment, the designers can simply calculate which radius ratios (q) will retain the same optical power using Eq. (1). Whether a fixed biological tissue of predetermined optical power may be physically bent while still maintaining that power, as assumed in Secs. 4.2 and 4.3, must still be demonstrated. Keratomileusis, the predecessor to keratomileusis *in situ*, demonstrated this to be a feasible assumption.[43]

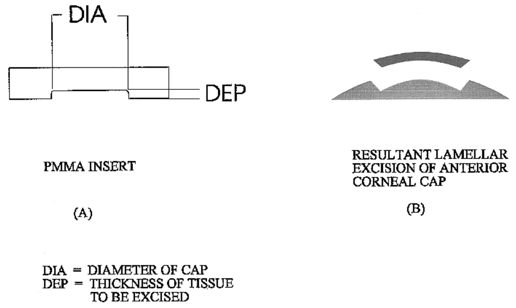

Fig. 10 Optical insert used for lamellar tissue resection and its resultant failure to modify the optical power of the cornea. DIA, diameter of cap; DEP, thickness of tissue to be excised.

The mathematical relationships which suggest that the lens bending theory may be used with biological tissues may be geometrically derived and are shown below. For demonstration purposes, the equations presented are for the correction of myopia. Derivations for the hyperopic correction are similar.

Equation (3) determines the radius (R_I) that must to be cut into the acrylic insert in order to achieve a predetermined optical power (P), where (n_1) is the refractive index of air and (n_2) is the refractive index of the cornea (n_2=1.376):

$$R_I=(n_2-n_1)/P. \tag{3}$$

Equation (4) calculates the maximum central thickness (t) of the tissue to be excised as a function of insert radius (R_I), and the diameter of the corrective cut (diameter cut into the insert) (D_I).

$$t=R_I-(R_I^2-D_I^2/4)^{1/2}. \tag{4}$$

Equation (5) determines the resultant diameter of the cornea (D_C) as a function of the radius ground into the insert (R_I), the initial radius of the cornea (R_O), and the diameter ground into the insert (D_I).

$$D_C=2R_O \sin[(R_I/R_O)\sin^{-1}(D_I/2R_I)]. \tag{5}$$

Finally, Eq. (6) determines the new corneal radius (R_N) after the tissue has been excised;

$$R_N=[(y^2+(1/4)D_C^2)/2y]. \tag{6}$$

As an example, Eqs. (3) through (6) will be used to determine the reduction in power at the corneal surface for an attempted 1-D corrective cut with an optical zone of 5.0 mm. Equation (3) yields an insert radius R_I of 376 mm. Equation (4) yields a central tissue thickness of 8.311 μm. Equation (5) indicates that the actual optical zone achieved will be 4.92 mm. Using the original corneal radius R_O to be 8 mm (47.0 D), the new corneal radius R_N can be calculated from Eq. (6) to be 8.159 (46.08 D), or a lenticular removal of 0.92 D.

Similarly, it may be shown that a 10-D corrective cut at 5.5 mm will have an insert radius of 37.6 mm, a central tissue thickness of 100.70 μm, a 5.4-mm optical zone, and a resultant power reduction of 9.7 D. It may be analytically shown that the preoperative anterior corneal radius R_O does not significantly affect the insert radius R_I required to correct for a known refractive error.[4,34,43] Therefore the optical inserts only need to be specified in terms of optical power and not as a function of preoperative corneal radius.

5 MATERIALS AND METHODS

The new technique was initially demonstrated on human cadaver eyes from two different eye banks up to 7 days postmortem.[33] The time of death to enucleation varied from 68 to 111 h. Prior to the experiment, the eyes were irrigated with Neosporin ophthalmic solution (Burroughs Wellcome, Research Triangle Park, North Carolina) and then totally immersed in a 15% dextran solution for 10 to 15 min before use. (Upon death, the human cornea will hydrate to as much as twice its original thickness. The immersion in 15% dextran solution dehydrates the cornea to its normal thickness of approximately 560 μm). The globes were inflated with balanced salt solution (BSS, Alcon Laboratories, Fort Worth, Texas) injected through the optic nerve to obtain a firm intraocular pressure. Ultrasonic pachymetry (Humphry Instruments, San Leandro, California) was performed to determine the preoperative corneal thickness, and verify that the cornea had been sufficiently dehydrated.

The testing consisted of first resecting a 9-mm diameter, 160 μm-thick lamellar flap, followed by a second concentric, myopic or hyperopic resection. The myopic and hyperopic resections consisted of one 30-D myopic tissue resection at 5.5 mm diameter; and one −30-D hyperopic tissue resection at 5.5 mm diameter. Following the resection, the excised tissues were placed in Optisol solution (Chiron, Inc., Irvine, California) and transported to the laboratory for processing.

5.1 TISSUE ANALYSIS

The excised tissues were prepared for light microscopy using previously published techniques.[44–46] The tissues were removed from the Optisol solution and placed in half-strength Karnovsky's fixative for 10 min, after which the myopic and hyperopic resections were bisected in the 12:00 to 6:00 meridian and again placed in the fixative for an additional 8 h.

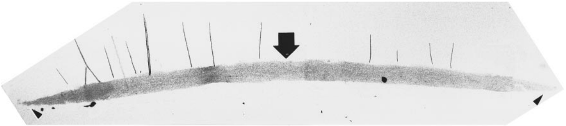

Fig. 11 Myopic resection showing broadening of resection toward the middle of the cut at the central cornea (arrow). The resection tapers at both ends (arrowheads) to form a smooth transition between the cut and the corneal surface (human donor cornea, ×26, toluidine blue).

Following fixation, 1 μm-thick sections of the excised stromal tissue were taken through the 12:00 to 6:00 meridian and then stained with toluidine blue to verify their meniscus shapes.[47] Photographs of the lenticular stromal resections were obtained at 26× magnification using an Olympus 35 AD, 35 mm camera (Tokyo, Japan) on Kodak Tri-X-Pan film (Eastman Kodak, Rochester, New York).

6 RESULTS

Figures 11 and 12 contain the cross-sectional views of the 30-D myopic and −30-D hyperopic tissue resections, respectively. These ''power'' tissue excisions were performed under a lamellar flap as would be done in a clinical setting in order to retain the epithelium and Bowman's membrane.

In Figure 11, a 30-D positive meniscus tissue has been resected from the stromal bed of a donor globe for the correction of myopia. As may be seen, this lenticular tissue is thicker in the center and decreases to zero thickness at the periphery, with the net result being an increase in the anterior radius of the cornea, or a decrease in its optical power. The tapering of the tissue from a finite central thickness (t) to zero thickness in the periphery provides a smooth stromal interface for the lamellar flap to be returned to.

Figure 12 identifies a −30-D, negative meniscus lens that was excised to correct hyperopia. As may be seen, the tissue is thinner in the center and

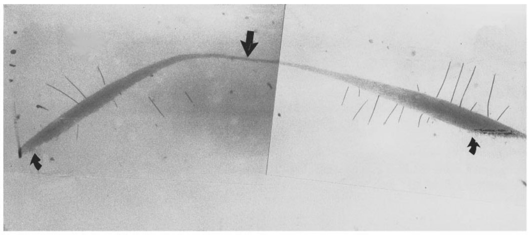

Fig. 12 Hyperopic resection. The resection tapers toward the center of the cut (arrow) and is wide at the lateral edges (small curved arrows). The transition between the resection and the cornea is again marked by a smooth tapering at these edges (human donor cornea, ×26, toluidine blue).

thicker in the periphery, with the net result being a decrease in the anterior radius of the cornea, or an increase in its optical power. As with the myopic case, a smooth interface for the lamellar tissue to be returned to is desired. For this reason, a blend diameter was incorporated into the hyperopic lens design. This blend diameter creates a smooth transition from the corrective optical zone to the outside of the transition zone. (The initial blend zone in this study was ground too small in the optical insert and is not readily identifiable in the figure.)

7 DISCUSSION

The intent of this paper has been to introduce the optical theory behind a new technique employed by the UniversalKeratome™ for reshaping the cornea to correct for refractive errors of the eye, and to provide the reader with background information on existing refractive techniques for comparison. The results are intended to be qualitative rather than quantitative in nature. In this investigation, we wanted to verify the removal of a positive and negative meniscus-shaped lens for the correction of myopia and hyperopia, respectively. Figures 11 and 12 are the first photographs taken that demonstrate that a mechanical technique is capable of excising tissues of these specific geometric shapes. The optical corrections attempted in those figures were extreme in order to emphasize the meniscus shapes (90% of the nearsighted population has refractive errors less than −6 D).

In Sec. 4.5 it was shown that for a theoretical 1-D excision at a 5.5-mm optical zone, only 0.92 D would be obtained, resulting in an undercorrection of 0.08 D. Similarly for an attempted 10-D correction at 5.5 mm, a residual undercorrection of 0.3 D would remain. In both cases, the eye would be left with a slight amount of residual myopic error. This is considerably more desirable than overcorrecting a patient from a preoperative condition of myopia to a postoperative condition of hyperopia. The magnitude of the error, up to 0.3 D for a 10-D attempted correction, is less than the typical residual error of 0.5 to 1.0 D of myopia, which is considered quite acceptable in this type of surgery. Further clinical evaluations are being performed which will document the safety and efficacy of this new technique, and will be presented in the appropriate ophthalmic journals.

With the ability to excise nonlamellar-shaped tissues from the cornea, refractive surgeons now have a mechanical, optically correct technique for correcting refractive errors of the eye. The lenticular tissues that are mechanically excised from the cornea are identical in shape and power to those ablated under the PRK or LASIK techniques. In the future, the refractive surgeon may have the option of correcting over the entire range of refractive errors with either a mechanical resection using a microkeratome, or through tissue ablation using an excimer laser.

This new microkeratome is indeed ''universal'' in its ability to correct for both myopia and hyperopia, while still being able to produce lamellar tissue excisions required for both the LASIK and KMIS procedures. As identified earlier, the tissue removed from the cornea is completely dependent upon the shape that is lathed into the optical insert. With this in mind, it may be noted that the potential exists for simultaneous correction of nearsightedness and presbyopia (need for reading glasses) through creation of a multifocal optical insert. Similarly, the potential also exists for correction of regular astigmatism through turning of a toric shape, or providing an aspherical correction through turning of an aspheric optical insert. Future directions may also incorporate the use of corneal topography units in turning nonsymmetrical shapes for the correction of corneal irregularities. The complexity of excising multifocal, regular astigmatic, and irregular astigmatic tissues from the corneal surface and achieving desirable optical results increases dramatically from the spherical considerations presented in this paper.

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