Title: METHOD AND APPARATUS FOR SURGICAL ABLATION OF THE CORNEA

Abstract

Improved apparatus for surgically reprofiling the cornea to correct refractive error. A hand held assembly including a vacuum controlled fixation ring and adapter/sleeve assembly that is used as the initial set-up upon the cornea for supporting a micrometer adjusted surgical knife blade that can be manually or mechanically rotated or oscillated to correct the refractive error by ablation scraping or sculpting of the cornea. Video monitoring is provided. The apparatus also may be used in conjunction with other known refractive techniques to provide primary or secondary corneal reshaping, to finish or fine tune a known procedure, or to otherwise expand, smooth or enhance the anterior or stromal cornea.
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METHOD AND APPARATUS FOR SURGICAL ABLATION OF THE CORNEA

RELATED APPLICATIONS

This application is a continuation-in-part (CIP) of co-pending United States application S.N. 08/345,245 filed November 28, 1994 which is a continuation-in-part of United States Application 08/170,679, filed December 20, 1993, now United States Patent No. 5,368,604, which via mesne FWC applications was a CIP of United States Patent No. 5,063,942.

BACKGROUND OF THE INVENTION

This invention relates to a method and apparatus for adjusting the shape of components of the eye and more particularly to making fixed changes in the corneal curvature to correct refractive error.

Deviations from the normal shape of the corneal surface or the ordinary axial length of the eye produce errors of refraction in the visual process. The normal eye in a state of rest, without accommodation, focuses the image of distant objects exactly on the retina. Such an eye enjoys distinct vision for distant objects without effort. Any variation from this standard constitutes ametropia, a condition in which the eye at rest is unable to focus the image of a distant object on the retina.

Hyperopia is an error of refraction in which, with the eye at rest, parallel rays from distant objects are brought to focus behind the retina. Divergent rays from near objects are focused still further back. In one aspect of hyperopia, the corneal surface is too flat which decreases the angle of refraction of rays as they pass through the refractive surfaces of the cornea, causing a convergence or focus of the rays at a point behind the
retina. The retina is comprised partially of nerve fibers which are an expansion of the optic nerve. Waves of light falling on the retina are converted into nerve impulses and carried by the optic nerve to the brain to produce the sensation of light. To focus parallel rays on the retina, the hyperopic eye must either accommodate, i.e., increase the convexity of its lens, or a convex lens of sufficient strength to focus rays on the retina must be placed before the eye.

Myopia (Gr. to squint) is that refractive condition in which, with accommodation completely relaxed, parallel rays are brought to focus in front of the retina. One condition which commonly causes myopia is when the corneal curvature is too steep, thus the refraction of rays is greater as the rays pass through the refractive surfaces of the cornea, and the over-refracted rays converge or focus in front of the retina in the vitreous of the eye. When the rays reach the retina they become divergent, forming a blurred image. A concave lens is used to correct the focus of the eye for myopia.

The normal treatment of these classic forms of refractive error of the eye is with the use of eyeglasses or contact lenses, both of which have well-known disadvantages to the user. It has been estimated that 60 million pairs of eyeglasses and 3 million pairs of contact lens are sold annually.

Recent research has been directed to operative techniques to change the refractive condition of the eye. Such techniques are generally referred to as "keratorefractive techniques". Radial keratotomy (RK) is by far the most commonly used keratorefractive procedure to correct myopia. RK involves making equally spaced radial incisions in the peripheral cornea around
a 3.0 to 5.0 mm diameter central, uncut clear zone. These incisions weaken the paracentral and peripheral cornea, which under the influence of intraocular pressure, causes outward bowing of the peripheral cornea, and, in turn, a compensatory flattening of the central cornea. This central corneal flattening then leads to a reduction in myopia. Many factors have been identified that affect the outcome of the RK procedure which the predictability is significantly less than achieved with eyeglasses and contact lens. See Mechanical Methods in Refractive Corneal Surgery, Flowers, Jr. and McDonnell, Current Opinion in Ophthalmology, 1994, 5; IV:81-89. Refinements in RK, and alternatives thereto, continue to evolve.

Two such alternative techniques are more particularly called keratophakia and keratomileusis. The initial approach to keratomileusis involved the regrinding of a corneal lamella into a meniscus lens to correct myopia or hyperopia. A corneal optical cryo-lathe was especially developed for this procedure and is also used in the keratophakia procedure, when a homograft ground into a meniscus lens is placed interlamellarly to correct aphakic hypermetropia. The homograft tissue (corneal lamella) was frozen with carbon dioxide and was cut by the lathe as a contact lens would be, i.e., to the optical power required to effect the desired optical correction of the cornea. In keratomileusis, the anterior corneal lamella is shaped by the lathe. Further evaluation and explanation of these procedures can be found in the American Academy Ophthalmology, Ophthalmic Procedures Assessment Committee report approved February 15, 1992, entitled: Keratophakia and Keratomileusis: Safety and Effectiveness.
Another form of correction called "myopic keratomileusis in situ" is widely reported. See *J Cataract Refract. Surg.*, Vol. 17, July 1991, pages 424-435, Arena-Archila, et al. *Myopic keratomileusis in situ: A preliminary report*. Instead of modifying the stromal side of the resected disc (corneal lamella), the correction is made in the stromal bed. It is thus seen that present procedures in keratorefractive techniques are best limited to situations where other more standard corrective practices are found ineffective. It is readily seen that the limiting factors in such surgical techniques is the gross complexity involved not only with multiple incisions in corneal tissue for affecting the procedures but also complex suturing patterns, resulting in gross restructuring of the eye. The eye is thus faced with a difficult job of adjusting to this trauma.

Over the past few years developments have been made in the use of lasers as a means to reshape the cornea in an attempt to get rid of refractive errors. In these processes, pulsed lasers remove tissue from the cornea by ablating or vaporizing portions of the corneal surface to cause it to flatten. The most common type is an Excimer laser. The fundamental effect of such a laser on tissue is a photochemical one, the breaking of molecular bonds with so much energy that the tissue fragments fly from the surface at supersonic speeds, leaving behind a discreet space. The process has been variously designated as ablative photodecomposition, photoablation or photorefractive keratectomy. Complete explanation of laser procedures can be found in *Refractive Keratotomy*, George O. Waring III, Mosby year Book, (1992) Chapter 19. The laser techniques are adaptable to be used in other corneal surgical techniques, including keratomileusis
in-situ.

One of the problems with keratomileusis procedures is obtaining a smooth curvature upon the exposed stromal bed. See In Situ Myopic Keratomileusis Results in 30 Eyes at 15 Months, Bas & Nano, Refractive & Corneal Surgery, Vol. 7, pages 223-231, May/June 1991. Using laser techniques can leave corrugated or rippled ablated surfaces, like a washboard. In addition the ablated surface becomes 'work hardened' and contains a pseudo membrane of burned tissue that must be cleaned and cleared up.

As in all refractive correcting techniques, the risk benefit ratio is always considered individually and is fully explained to prospective patients. See Corrective Measures for Myopia, Wilson and Keeney, Survey of Ophthalmology, Vol. 34, No. 4, Jan/Feb 1990, pages 294-304.
SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a new and improved keratorefractive technique involving a method and apparatus for changing the shape of the optical zone of the cornea to correct refractive errors of hyperopia (far-sightedness), myopia (near-sightedness), and astigmatism, the simplicity of which virtually eliminates the chance of error or further complications resulting from gross disturbances of the ocular system.

With this and other objects in view, the present invention contemplates a method and apparatus that can be variously described as ablating, scarifying, scraping, sculpting, or removing portions of the cornea for the purposes of correcting refractive error in human cornea. For the purposes of this invention, the apparatus and methods are applicable to correcting the cornea not only to the anterior surface but also to exposed stromal surfaces. The invention may be used in conjunction with keratomileusis and photorefractive (laser) keratectomy, as well as keratomileusis in-situ and other procedures where additional corneal reshaping or expanding, smoothing or enhancing an anterior or stromal corneal surface is advantageous. The invention is particularly useful in conjunction with anterior lamellar keratectomy.

Another object of the invention is to provide mechanical apparatus capable of easily being used by a surgeon for scraping the cornea in order to correct refractive errors of hyperopia, myopia, and astigmatism which includes means to provide consistency in depth of material removal and configuration of the surface.
Another object of this invention is to provide method and apparatus for scraping the cornea wherein the cornea is maintained in a more rigid posture during the procedure to eliminate flexure of the cornea and thus provide greater accuracy in determining predictable amounts of corneal material to be removed. This is accomplished by creating a vacuum not only as a means to establish the fixation of the apparatus upon the eye, but also in the operative space above the cornea during the process.

Specifically, the method objects of this invention involve the surgical reprofiling of the corneal portion of an eye of humans to change the corneal radius and thus correct refractive errors. The preliminary clinical evaluation steps are well known to the practicing surgeon of the art. That is, the refractive power of the patient’s eye is determined from the power of the cornea, the depth of the anterior chamber, the power of the lens, and the axial length of the globe. Of primary concern is the shape of the corneal surface and measurements are made to determine the radius of curvature. The steps typically include creating a keratograph of the cornea to determine the amount of refractive error. This data is analyzed, along with visual acuity and refraction data, to quantify refractive error.

A reprofiling tool is constructed to include a plurality of scraper blades of shape sufficient to change a corneal radius to that of a cornea that has a curvature resulting in 20/20 visual acuity. The reprofiling tool is then positioned within a holding sleeve that is contiguously positioned upon a vacuum fixation ring held on the eye such that the scraper blades will contact the cornea. A vacuum can also be used in the chamber above the
cornea wherein the scraping tool is positioned. The scraping tool is then rotated or oscillated either by hand or motorized with the axial movement of the scraping tool being changed and indexed until the corneal radius has been corrected to that of the simulated or ideal cornea.

The reprofiling tool also may be used in conjunction with other known refractive techniques to provide primary or secondary corneal reshaping, to finish or fine tune a known procedure, or to otherwise expand, smooth or enhance the anterior or stromal cornea.

The apparatus used to achieve the objects of this invention specifically include a cylindrical adapter/sleeve assembly having a resilient and transparent vacuum ring means on its bottom side for temporary attachment to a scleral portion of an eye surrounding the cornea that is to be reprofiled. A micrometer assembly, which holds the surgical knife in place is positioned upon the adapter/sleeve assembly. The shoulder of a micrometer nut assures proper translation alignment of the surgical knife. An optical viewer positioned along the axis of the device may include a camera and connected video monitor. This capability can provide continual real-time viewing of the ablation process. Illumination of the cornea for the optical viewer is possible with the use of a fiberoptic bundle. The assembly can also be connected to a handle. Alternatively, an optical lens and surgical microscope or other viewing means can be used in place of the camera. In addition to the video monitor and an illumination source, a vacuum console provides instrumentation and control of vacuum to the adapter/sleeve assembly and to the space above the cornea as needed.
Although the anatomic zones of the cornea include a geometric center, apex, the pupillary axis, line of sight, the visual axis and optical axis, which axis to position the apparatus is subject to some conflicting definition. Whichever it may be for the purposes of this invention, it will be called the "visual axis". Further discussion can be found in Refractive Keratotomy, supra in Chapter 16.
BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic illustration of a horizontal section of the eye.

FIG. 2 is a schematic illustration of a hyperopic eye showing adjustment of the cornea to shorten the radius of curvature.

FIG. 3 is a schematic illustration of a myopic eye system showing adjustment of the cornea to increase its radius and thus flatten the corneal slope.

FIG. 4 is a detailed schematic illustration of a horizontal section of the frontal portion of an eye showing the various layers of the cornea.

FIG. 5 is an exploded view showing the system components of the apparatus of this invention.

FIG. 6 is an exploded view of the various components of the basic apparatus for performing the ablation process of this invention.

FIG. 7 is a partial sectional view of the micrometer assembly of the invention.

FIG. 8 is a partial sectional view of the lower portion of the assembly as placed upon the eye.

FIG. 9 is an elevational view of the knife assembly.

FIG. 10 is an end view of the knife assembly taken along the line 10-10 of FIG. 9.

FIG. 11 is a partial sectional view of the optical viewer used with the apparatus of this invention.

FIG. 12 is a partial sectional view of a motorized form of apparatus.

FIG. 13 is a schematic of a keratomileusis procedure.
DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Before explaining the present invention in detail, it is to be understood that the invention is not limited in its application to the details of the construction and arrangement of parts illustrated in the accompanying drawings. The invention is capable of other embodiments and of being practiced or carried out in a variety of ways. It is to be understood that the phraseology and terminology employed herein is for the purpose of description and not of limitation.

Referring first to FIG. 1 of the drawings, a horizontal section of the eye shows the globe of the eye resembling a sphere with an anterior bulged spherical portion 12 representing the cornea. Thus the eye is actually comprised of two somewhat modified spheres placed one in front of the other. The anterior of these two segments is the smaller more curved cornea.

The globe of the eye consists of three concentric coverings enclosing the various transparent media through which the light must pass before reaching the sensitive retina. The outermost covering is a fibrous protective portion, the posterior five-sixths of which is white and opaque and called the sclera 13, and sometimes referred to as the white of the eye where visible to the front. The anterior one-sixth of this outer layer is the transparent cornea 12.

A middle covering is mainly vascular and nutritive in function and is comprised of the choroid 14, ciliary body 15 and iris 17. The choroid generally functions to maintain the retina. The ciliary muscle is involved in suspending the lens and accommodation of the lens. The iris is the most anterior portion of the middle covering of the eye and is arranged in a frontal
plane. It is a thin circular disc corresponding to the diaphragm of a camera, and is perforated near its center by a circular aperture called the pupil 19. The size of the pupil varies to regulate the amount of light which reaches the retina. It contracts also to accommodation, which serves to sharpen the focus by diminishing spherical aberration. The iris divides the space between the cornea 12 and the lens 21 into an anterior chamber 22 and posterior chamber 23. The innermost portion of covering is the retina 18, consisting of nerve elements which form the true receptive portion for visual impressions.

The retina is a part of the brain arising as an outgrowth from the fore-brain, with the optic nerve 24 serving as a fibre tract connecting the retina part of the brain with the fore-brain. A layer of rods and cones, lying just beneath a pigmented epithelium on the anterior wall of the retina, serve as visual cells or photoreceptors which transform physical energy (light) into nerve impulses.

The vitreous 26 is a transparent gelatinous mass which fills the posterior four-fifths of the globe. At its sides it supports the ciliary body 16 and the retina 18. A frontal saucer-shaped depression houses the lens 21.

The lens 21 of the eye is a transparent bi-convex body of crystalline appearance placed between the iris 17 and vitreous 26. Its axial diameter varies markedly with accommodation. A ciliary zonule 27, consisting of transparent fibers passing between the ciliary body 16 and lens 21 serves to hold the lens in position and enable the ciliary muscle to act on it.

Referring again to the cornea 12, this outermost fibrous transparent coating resembles a watch glass. Its curvature is
somewhat greater than the rest of the globe and is ideally spherical in nature. However, often it is more curved in one meridian than another, giving rise to astigmatism. A central third of the cornea is called the optical zone with a slight flattening taking place outwardly thereof as the cornea thickens towards it periphery. Most of the refraction of the eye takes place on the surface of the cornea.

Referring next to FIG. 2 of the drawings, the globe of an eye is shown having a cornea 12 with a normal curvature represented by the solid line 39. If parallel rays of light 41 pass through the corneal surface 39 of FIG. 2, they are refracted by the corneal surfaces to converge eventually near the retina 18 of the eye. The diagram of FIG. 2 discounts, for the purposes of this discussion, the refractive effect of the lens or other portions of the eye. The eye depicted in FIG. 2 is hyperopic and thus the rays of light 41 are refracted to converge at point 42 behind the retina. If a peripheral band of pressure is applied inwardly at the chord 43 of the cornea, the walls of the cornea are caused to steepen. This is because the volume of fluids within the anterior chamber 22 remains constant, thus the anterior portion of the cornea, including the optical zone (inner third of the cornea) steepens in slope to form a curvature (shown in exaggeration) following the dotted line 44. The rays of light 41 are then refracted from the steeper surface 44 at a greater angle to direct the refracted rays into focus at a shorter distance, such as directly on the retina 18.

FIG. 3 shows a similar eye system to that of FIG. 2 except that the so-called normal corneal curvature of FIG. 3 causes the light rays 41 to refract into focus at a point 46 in the vitreous
which is short of the retinal surface 18. This is typical of a myopic eye. If chord 43 of the cornea is expanded uniformly outwardly as shown by the arrows, the walls of the cornea are flattened. Light rays 41 refracted by the now-flattened corneal surface will be refracted at a smaller angle and thus converge at a more distant point such as directly on the retina 18.

Referring now to FIG. 4, a more detailed drawing of the anterior portion of the globe shows the various layers of the cornea comprising an epithelium 31. The cornea itself is 550μm thick centrally, 700μm peripherally, 12mm diameter horizontally, and 11mm diameter vertically. (Compare a credit card about 800μm thick and a dime 13mm in diameter.)

The epithelium is a five-to seven-layer (30 to 50μm) which has three major functions:

1. Act as a mechanical barrier to foreign material and microorganisms,
2. Create a smooth, transparent optical surface for the tear film to adhere, and
3. Maintenance of a barrier to the diffusion of water solutes, and drugs.

Epithelial cells on the surface thereof function to maintain transparency of the cornea. These epithelial cells are rich in glycogen, enzymes and acetylcholine and their activity regulates the corneal corpuscles and controls the transport of water and electrolytes through the lamellae of the stroma 32 of the cornea.

An anterior limiting lamina 33, referred to as Bowman’s membrane, is positioned between the epithelium 31 and the substantia propria or stroma 32 of the cornea. The stroma is comprised of lamella having bands of fibrils parallel to each
other and crossing the whole of the cornea. While most of the fibrous bands are parallel to the surface, some are oblique, especially anteriorly. The fibrous bands within alternate lamella are at a near right angle to bands in the adjacent lamella. A posterior limiting lamina 34 is referred to as Descemet's membrane. It is a strong membrane sharply defined from the stroma and resistant to pathological processes of the cornea.

The endothelium 36 is the most posterior layer of the cornea and consists of a single layer of cells. The limbus 37 is the transition zone between the conjunctiva 38 and sclera 13 on the one hand and the cornea 12 on the other.

Referring now to FIGS. 5-11, the assembly of the basic parts of the apparatus are shown in exploded and assembled views. These parts include an adapter 50 having a resilient vacuum ring 52 extending from its bottom side for contact with the eye of the patient being treated. A vacuum hose 54 comprised of two hoses 54A and 54B provides communication between the inside of the resilient ring 52 and a controllable vacuum pump source and console means 56 to retain the assembled parts upon the eye for the surgical procedures herein described. Vacuum tube 54A connects with the adapter 50 and is in communication with the vacuum ring 52 by way of a plurality of conduits 58 in the adapter communicating with a plurality of conduits 60 in the resilient ring 52. Vacuum conduit 54B is in communication with the interior space 62 at the bottom of the adapter. The upper portion of the adapter 50 includes a plurality of micrometer-like threads 64, while the exterior of the adapter includes a plurality of vertical alignment indicia generally designated by
the numeral 66. A positioning nut or sleeve is generally designated by the numeral 70 and comprises a reduced diameter lower tip 72. This tip is inwardly beveled so as to make surface contact with the cornea during the procedure as explained hereinafter. Micrometer threads 74 are adapted to engage with the threads 64 of the adapter 50. The upper portion of the sleeve 70 terminates with a larger diameter knurled hand wheel 76 below which is a cylindrical micrometer indicia skirt 78 which are used for alignment with the indicia 66 of the adapter 50.

The interior of the sleeve 70 includes openings to receive the surgical micrometer assembly, generally designated by the numeral 80, having lower body 82 and an upper body 84, the assemblage of which is best shown in FIG. 7. In alternative embodiments, the lower body 82 and sleeve 70 are covalently joined at their interface or are made as a single piece. The lower body 82 may be retained within a horizontal support arm 100 by threads 88 or by any fastening means and held by a retention bolt 102. Above the support arm 100 and formed as a part of the lower body 82 is flange 86 which includes a plurality of indicia comprised of a series of spaced, vertical lines around the circumference. The remaining part of the lower body 82 above the flange 86 includes a threaded portion 90, in the middle of which is an O-ring groove 92 and O-ring 94. The upper body 84 includes internal micrometer threads 96 which engage with threads 90. Exteriory, is a skirt 98 and a hand wheel 99. The skirt 98 includes micrometer indicia which are used during the surgical procedure to accurately adjust the surgical knife vertically relative to the cornea the desired amount. An opening 83 is found in the lower portion of the lower body 82 to permit vacuum to enter the interior, which will be
above the cornea during the surgical procedure. Alternatively, the opening 83 can be placed in sleeve 70.

The surgical knife of this invention is generally designated by the numeral 110 and is comprised of a vertical body 112 having an opening 114 therethrough. At the lower end of the surgical knife are plurality of transverse surgical blades 116 and 118. At the upper end is a sleeve 120 and a handle nut 122. The opening 114 is adapted to receive the optical viewer generally designated by the numeral 130. The diameter of the body 112 is adapted to slideably fit within the interior 87 of the micrometer assembly lower body 82.

The optical viewer 130 comprises a rod lens 132 which is potted into the optical housing 134. The upper end of the rod lens 132 is retained within a lens mount 136 which retains lens 138 as shown. A C-mount adapter 140 is adapted to accept at its upper end the video camera 142 which in turn is connected to the TV monitor 145 through an electrical cable 144 which loops above the top of the camera and is contained within a cable groove 151 located in the back of handle 150. The optical assembly is inserted concentrically in the surgical knife assembly opening 114. The bottom end of the viewer system is designed to be located just above the orthogonal knives and relays the corneal image to the other end of the viewer which then focuses the image upon the camera 142. The handle support bracket 150 and its connected support arm 100 provide means to retain in axial alignment the micrometer assembly 80, optical viewer 130 and the fixation ring and adapter sleeve assembly and provide means for the surgeon to handle and control the device. There is a groove in the bottom of the handle 150 to accommodate a fiber optic
illumination cable 162 the output end of which is positioned contiguous to the fixation ring/adapter sleeve assembly.

In place of optical viewer 130, alternate viewing means may be used in connection with the present invention. For example, the surgeon may simply look through the knife opening or bore 114 without the aid of viewing equipment if the view is satisfactory. A magnifying lens or stem, such as an acrylic magnifying lens, may also be inserted into the bore 114 and a surgical microscope used to look through the bore 114.

The console 56 connects to the adapter/sleeve assembly and provides vacuum supply by way of conduits 54A and 54B to the vacuum ring 52 and the adapter 50 respectively. Two independent vacuum pumps and dedicated vacuum regulators comprise the working system of the console. The vacuum for each conduit is adjustable using regulators. Actual vacuum is read on analog gauges for each vacuum source and is documented with an optical chart recorder connected to vacuum pressure transducers that are contained within the console.

The vacuum ring 52 is preferably made of silicone rubber that is designed to be placed over the eye contacting the sclera, and held there by vacuum ranging from 10-20 inches Hg (depending upon variations of corneal topography). The purpose of the vacuum ring is to provide a means by which the corneal contouring system is positioned over the operative sight. The vacuum ring is snapped onto the base of the adapter 50. The adapter 50 is typically made of polycarbonate and is preferably transparent and provides a mounting for the micrometer assembly and for alignment of the assembled device with the cornea. The nut or sleeve 70 is designed to be lowered onto the surface of the cornea in order
to assist in holding it in place, i.e., prevent "corneal creep", during the procedure. Vacuum line 54B attaches to the adapter 50 which receives the sleeve 70 to assist stabilizing the cornea during the surgical procedure. The adapter 50 also serves the function of allowing the transmission of light from source 164 onto the operative sight which is required when using the optical viewer system 130.

The micrometer assembly 80 consists of two parts: the micrometer body 82 (through the bore 87 of which the surgical knife passes) and the micrometer nut 84 (which is threaded onto the micrometer body). The micrometer assembly 80 is retained to the support bracket 100 by threads 88. The bracket 100 connects with the tubular handle 150 and is locked in place there by a thumb screw. Rotating the micrometer nut adjusts the height of the top surface of the micrometer upon which the surgical knife 110 rests. The markings upon the micrometer nut and body represent 10μm and provide a visual indication to the surgeon of the depth of movement. For example, a movement of one mark to an adjacent mark on the micrometer nut raises or lowers the micrometer 10μm.

The surgical knife assembly 110 has two stainless steel sharpened blades permanently staked at 90° angles at the end of the surgical knife shaft. The proximal end of the shaft is hexagonally shaped turning knob 122 which can be knurled for ease and gripping during a manual hand-turning operation. The turning knob is used to rotate the surgical knife blade. The knife blade assembly 110 fits into the bore of the micrometer assembly 80 and rests flatly on top of the micrometer nut 84. Thus, as the micrometer nut is rotated, the surgical nut assembly raises or
lowers accordingly.

It should be understood that the present invention also encompasses the use of the optical viewer 130 and its associated components and alternative embodiments in connection with the apparatus disclosed and described in U.S. Patent No. 5,368,604, the subject matter and disclosure of which is incorporated herein by reference. Reference being made to FIGS. 5-9 of said patent, by modifying the scraping tool therein described to have a bore extending axially therethrough analogous to bore 114 herein, the referenced apparatus is easily made compatible for use with the present invention. The same is equally applicable to the apparatus disclosed and described in U.S. Patent Nos. 5,318,044 and 5,395,385, the subject matter and disclosures of which are also incorporated herein by reference.

The operation of the apparatus and the methods of surgery are accomplished by first taking optical measurements of the eye as to the shape of the cornea and to determine the refractive error. For example, the shape the cornea should have in the order for eye to be optically correct. Typically, a keratograph image using a placido ring target such as described in U.S. Patent 3,797,921 or in Refractive Keratotomy, supra is used. A topographic survey of the eye is made for comparison purposes and to provide the surgeon with the necessary information for correcting the refractive error. Once all of the preliminary information has been decided, the operation first proceeds by attaching the vacuum ring 52 to the bottom of the adapter 50. The sleeve 70 is then threaded into the adapter 50 and is assembled so that the lower end 72 of the sleeve 70 is withdrawn above the cornea 20. The vacuum ring 52 vacuum via conduit 54A
is activated and adjusted sufficient to maintain the ring 52 stable upon the eye. The vacuum to the adapter 50 by way of conduit 54B is then activated. Thereafter, sleeve 70 is rotated downwardly by the sleeve adjustment knob 76 in a clockwise direction. Rotation occurs in increments of 20μm to place the beveled bottom 72 of the sleeve 70 in close proximity of the cornea. Movement is slowly continued in increments until the bottom 72 touches the cornea. This will be immediately indicated by the establishment of vacuum pressure at the gauge on console 56 when the vacuum holes have been occluded, such as by a plug. After the initial contact, the sleeve 70 is advanced further, e.g., about 40μm to assure a good vacuum seal is established. The vacuum, by way of line 54B, is then released by the removal of the occlusion plug and the adapter/sleeve assembly is now positioned and ready for the next step.

The surgeon then by grasping the handle 150 places the micrometer assembly 80 into the top of the sleeve 70. The surgical knife 110 is then carefully placed into the bore 114 of the micrometer assembly 80 assuring that the blade surface does not contact any other surface in order to prevent inadvertent blade dulling. The micrometer nut 84 has been previously positioned to be at the top of its travel to assure that the blade is well above the cornea when inserted into the adapter/sleeve assembly. At this point the video imaging system is then inserted into the inner bore 114 of the surgical knife. The video camera 142 is designed to rest above the top of the surgical knife assembly. The video cable 144 is (or has been) attached and is inserted into the groove provided within the handle with the proximal end of the cable attached to the video
monitor 145. At this point the vacuum is now applied once again via conduit 54B to the adapter/sleeve assembly. The surgical knife 110 is slowly moved by rotating the nut 84 in a clockwise direction as for example 40μm at a time. In the preferred embodiment each individual marker line is 10μm. As the knife nears the cornea, the corneal surface will come into clear focus on the video monitor. Continued downward movement of the knife, for example, 20μm increments is continued until the knife touches an approximate 2mm area of corneal epithelium. The surgical knife is then rotated a few cycles in order to define and identify the touch zone diameter as will be shown on the monitor. The depth of cut is determined accurately by the surgeon utilizing the micrometer Vernier scale. The micrometer nut 84 is then lowered the amount of cut which has been previously established by a pre-prepared refractive algorithm look-up table based upon touch zone diameter, targeted correction and the final optical zone. After the desired ablation depth has been "dialed in" by the micrometer assembly 80, the process is initiated. In one embodiment, the procedure is manual, and therefore, under the absolute control of the surgeon, with the process being visible at all times on the video monitor 145. A typical, but not limiting process, begins by rotation of the surgical knife in an oscillatory manner making three to five full revolutions of the knife blade and then making a plurality, e.g., 5 oscillatory movements at a random rotational distance followed by three to five complete revolutions in the opposite direction. This concept is continued at the completion of which the vacuum provided through conduit 54B is released and the micrometer assembly 80 removed from the sleeve. At this point the surgeon
may use a surgical microscope which is swung into position over
the adapter sleeve assembly with connection being made to the
video monitor to observe the treated optical zone. The vacuum,
via conduit 54A, to the fixation ring is turned off and the
fixation ring and adapter ring assembly removed. The corneal
surface is then scrubbed, treated and measured. If further
correction is needed, the procedure is repeated.

FIG. 12 represents a motorized version of the invention and
comprises a support member 180 that is attached to an upper
support 181 for the surgical assembly via bearing assembly 182
and at the lower end to the micrometer lower body 82. A motor
184 has its output shaft 186 connected to pulley 188 driving a
belt 190 which connects to the surgical knife body 112 which
rests upon micrometer nut 202. A potentiometer 194 has its
output shaft 196 connected to a pulley 198 and belt 200 for
coupling to the micrometer nut 202 for the purpose of monitoring
the vertical positioning of the surgical knife blade and body
204.

As noted, in addition to its use as a primary mode of
altering the refraction of the eye by reprofiling the anterior
surface of the cornea, the apparatus of the present invention may
be used in conjunction with other known refractive techniques to
reprofile either the anterior or stromal cornea, to finish or
fine tune a procedure, or to otherwise expand, smooth or enhance
the cornea following a refractive procedure.

By way of illustration, FIG. 13 is a schematic depiction of
the process of anterior lamellar keratectomy utilizing the
concepts of this invention. In FIG. 13A a lamellar keratectomy
is performed upon cornea 20, having a given radius R, creating
the resected disc 200 which, in a preferred arrangement, remains hinged to the cornea at one side at point 201, creating a stromal bed 202. The stromal bed is then modified, as for example, to correct for myopia, creating a flatter curve 204 (dotted) by the use of, as for example, photorefractive keratectomy. In combination, or in lieu thereof, the apparatus of this invention may be used to surgically scrape the stromal bed in a manner to achieve the desired curve.

The resected disc is then returned to contact with the stromal bed and is sutured, which sutures are removed a few days thereafter. As a result, as for a myopic eye, the radius of curvature $R_2$ is now greater. It is to be understood, however, that the process is also adaptable to correct hyperopia depending upon the reforming of the stromal bed 202.

Accordingly, the invention can be used in combination with laser surgery or other refractive procedures without altering the refractive benefits of the procedures to either provide primary or secondary corneal reshaping or a finished surface more conducive to wound healing.

Without limitation, the present invention can be used in conjunction with any corneal refractive procedure used to alter the refractive characteristics of the cornea wherein the refractive procedure has produced a worked area upon the cornea. In accordance with the present invention, the apparatus described herein is rotated or oscillated upon the worked area of the cornea such that the worked area is further altered or is otherwise smoothed and enhanced.

For further example, the present invention can be used in conjunction with radial keratotomy to remove debris and smooth
and enhance the optical zone of the cornea after the radial incisions are made. The invention is further useful in combination with any photorefractive procedure to treat ablated surfaces. Still further, the invention can be employed in conjunction with the various keratomileusis procedures to either reprofile or finish the anterior surface of the cornea, an exposed stromal area or both.

The invention as thus described has wide application (1) as a primary means of reprofiling the cornea to correct refractive error, (2) as a secondary means used in combination with other procedures to more accurately shape the cornea, (3) as a method of smoothing an anterior or stromal corneal surface that has been corrugated, rippled, roughened or hardened during corneal surgery, such as by laser ablation, (4) as a means for dislocating debris from a worked area upon the cornea, (5) as a method of expanding the optical zone following a corneal refractive procedure on the anterior portion of the cornea, and (6) as a way of otherwise smoothing and enhancing the cornea or its optical zone after a refractive procedure.
WHAT IS CLAIMED IS:

1. An apparatus for reprofiling the anterior or stromal corneal portion of an eye of animals (including humans), said eye having a visual axis, to change the corneal radius and thus correct refractive errors, to finish or fine tune the cornea following a refractive correction procedure, or to otherwise expand, smooth or enhance the cornea following a refractive correction procedure, comprising:

   a scraping tool having at least one sharpened knife edge blade at its bottom end and having a central bore extending axially therethrough for viewing said cornea during reprofiling;

   a support assembly for attachment to said cornea coaxially to said visual axis, said support assembly adapted to coaxially receive said scraping tool and support said scraping tool above and upon said cornea;

   means for affecting the incremental vertical movement of said scraping tool coaxially relative to said visual axis of said cornea; and

   means for rotating or oscillating said scraping tool to scrape said anterior or stromal corneal portion to obtain a desired change in curvature.

2. The apparatus according to claim 1, further comprising a means for viewing said cornea during reprofiling, said means being insertable into said central bore of said scraping tool.

3. The apparatus according to claim 2, wherein said means for viewing comprises a magnifying stem for use in conjunction with a surgical microscope.
4. The apparatus according to claim 2, wherein said means for viewing comprises an optical viewer having an elongated sleeve insertable into said central bore of said scraping tool, a lens, a video camera, and means to connect said camera to a video monitor.

5. An apparatus for reprofilling the anterior or stromal corneal portion of an eye of animals (including humans), said eye having a visual axis, to change the corneal radius and thus correct refractive errors, to finish or fine tune the cornea following a refractive correction procedure, or to otherwise expand, smooth or enhance the cornea following a refractive correction procedure, comprising:

   a transparent, resilient vacuum ring for attachment to said cornea coaxially to said visual axis;

   an adapter for attachment to said vacuum ring, said adapter having conduits for vacuum communication with said vacuum ring;

   a rotatable sleeve having a central bore axially extending therethrough for threadable engagement with said adapter, said rotatable sleeve having a lower end for making sealed contact with said cornea;

   means to provide an independently controllable vacuum to said vacuum ring and to the interior of said sleeve;

   a micrometer assembly, said micrometer assembly having a lower piece for coaxial engagement with said central bore of said sleeve and a micrometer nut for affecting incremental vertical movement of said assembly coaxially relative to a visual axis of said cornea; said lower piece and said micrometer nut having a central bore axially extending therethrough; and
a scraping tool having a cylindrical body with a central
bore, said body adapted to be received within said central bores
of said lower piece of said micrometer assembly and said
micrometer nut, said scraping tool having, at its upper end, an
enlarged grip which rests upon said micrometer nut, and at least
one sharpened knife edge substantially planar blade at its bottom
end for scraping said anterior or stromal corneal portion.

6. The apparatus of claim 5, wherein said lower piece of
said micrometer assembly is threadably connected with said
central bore of said sleeve.

7. The apparatus of claim 5, wherein said lower piece of
said micrometer assembly is integrally joined to said sleeve such
that said lower piece and said sleeve are one piece.

8. The apparatus according to claim 5, further comprising
a means for viewing said cornea during reprofiling, said means
being insertable into said central bore of said scraping tool.

9. The apparatus according to claim 8, wherein said means
for viewing comprises a magnifying stem for use in conjunction
with a surgical microscope.

10. The apparatus according to claim 8, wherein said means
for viewing comprises an optical viewer having an elongated
sleeve insertable into said central bore of said scraping tool,
a lens, a video camera, and means to connect said camera to a
video monitor.
11. The apparatus according to claim 10, further comprising
a hand held support for retaining said micrometer assembly and
means affixed to said hand held support to provide a controllable
light source adjacent said vacuum ring and sleeve assembly.

12. The apparatus of claim 10, further comprising means for
duplicating manual-like motion to impart to said scraping tool
a rotating or oscillating motion about a vertical axis that is
substantially coaxial with said visual axis.

13. The apparatus of claim 1, further comprising means for
duplicating manual-like motion to impart to said scraping tool
a rotating or oscillating motion about a vertical axis that is
substantially coaxial with said visual axis.

14. A method of reprofiling the anterior or stromal corneal
portion of an eye of animals (including humans), said eye having
a visual axis, to change the corneal radius and thus correct
refractive errors, to finish or fine tune the cornea following
a refractive correction procedure, or to otherwise expand, smooth
or enhance the cornea following a refractive correction
procedure, comprising the steps of:
positioning a support assembly to said cornea coaxially to
said visual axis, said support assembly adapted to coaxially
receive a scraping tool and support said scraping tool above and
upon said cornea;
positioning said scraping tool within said support assembly,
said scraping tool having at least one sharpened knife edge blade
at its bottom end and having a central bore extending axially therethrough for viewing said cornea during reprofiling; incrementally and vertically advancing said scraping tool coaxially relative to said visual axis of said cornea; and rotating or oscillating said scraping tool to scrape said anterior or stromal corneal portion to obtain a desired change in curvature.

15. The method according to claim 14, further comprising a means for viewing said cornea during reprofiling, said means being insertable into said central bore of said scraping tool.

16. The method according to claim 15, wherein said means for viewing comprises a magnifying stem for use in conjunction with a surgical microscope.

17. The method according to claim 15, wherein said means for viewing comprises an optical viewer having an elongated sleeve insertable into said central bore of said scraping tool, a lens, a video camera, and means to connect said camera to a video monitor.

18. A method of reprofiling the anterior or stromal corneal portion of an eye of animals (including humans), said eye having a visual axis, to change the corneal radius and thus correct refractive errors, to finish or fine tune the cornea following a refractive correction procedure, or to otherwise expand, smooth or enhance the cornea following a refractive correction procedure, comprising the steps of:
positioning a vacuum ring upon the cornea and coaxial to a visual axis of said cornea;

positioning an adapter upon said vacuum ring, said adapter having conduits for vacuum communication with said vacuum ring; threadably engaging a rotatable sleeve having a central bore axially extending therethrough with said adapter, said rotatable sleeve having a lower end for making sealed contact with said cornea;

supplying a first vacuum to said ring, and a second vacuum to an interior of said sleeve;

positioning a micrometer assembly upon said sleeve, said micrometer assembly having a lower piece for coaxial engagement with said central bore of said sleeve and a micrometer nut for affecting incremental vertical movement of said assembly coaxially relative to a visual axis of said cornea, said lower piece and said micrometer nut having a central bore axially extending therethrough;

positioning, upon said micrometer nut and within said central bores of said lower piece and said micrometer assembly, a corneal scraping tool having a sharpened knife edge substantially planar blade such that said knife edge is perpendicular to said visual axis of said cornea; and turning said scraping tool to scrape said anterior or stromal corneal portion to obtain a desired change in curvature.

19. The method of claim 18, wherein said lower piece of said micrometer assembly is threadably connected with said central bore of said sleeve.
20. The method of claim 18, wherein said lower piece of said micrometer assembly is integrally joined to said sleeve such that said lower piece and said sleeve are one piece.

21. The method according to claim 18, further comprising a means for viewing said cornea during reprofiling, said means being insertable into said central bore of said scraping tool.

22. The method according to claim 21, wherein said means for viewing comprises a magnifying stem for use in conjunction with a surgical microscope.

23. The method according to claim 21, wherein said means for viewing comprises an optical viewer having an elongated sleeve insertable into said central bore of said scraping tool, a lens, a video camera, and means to connect said camera to a video monitor.

24. The method according to claim 23, further comprising a hand held support for retaining said micrometer assembly and means affixed to said hand held support to provide a controllable light source adjacent said vacuum ring and sleeve assembly.

25. The method of claim 18, further comprising means for duplicating manual-like motion to impart to said scraping tool a rotating or oscillating motion about a vertical axis that is substantially coaxial with said visual axis.
26. A method of reprofiling a cornea, which comprises:
   (a) performing a lamellar keratectomy to obtain a corneal lamella and reveal a stromal bed;
   (b) scraping said stromal bed to obtain a desired curvature; and
   (c) replacing said corneal lamella upon said stromal bed.

27. A method of reprofiling a cornea, which comprises:
   (a) performing a lamellar keratectomy to obtain a corneal lamella and reveal a stromal bed;
   (b) using a scraping tool to modify said stromal bed and obtain a desired curvature; and
   (c) replacing said corneal lamella upon said stromal bed.

28. A method of reprofiling a cornea, which comprises:
   (a) performing a lamellar keratectomy to obtain a corneal lamella and reveal a stromal bed;
   (b) reshaping said stromal bed by laser photoablation to obtain a modified stromal bed of a desired curvature;
   (c) smoothing the surface of said modified stromal bed by rotating or oscillating a scraping tool upon said surface; and
   (d) replacing said corneal lamella upon said stromal bed.
29. A method of reprofiling a cornea, which comprises:
   (a) resecting a portion of said cornea in a manner such that said resected portion remains hinged to said cornea at one point;
   (b) folding said resected portion up and away from said cornea to reveal a stromal bed;
   (c) reshaping said stromal bed by laser photoablation to obtain a modified stromal bed of a desired curvature;
   (d) smoothing the surface of said modified stromal bed by rotating or oscillating a scraping tool upon said surface; and
   (e) folding said resected portion back over said modified stromal bed.

30. A method of smoothing a corneal surface that has been corrugated, rippled, roughened or hardened due to the performance of a corneal refractive procedure, which comprises rotating or oscillating a scraping tool upon said corrugated, rippled, roughened or hardened surface until said surface is smoothed.

31. A method of dislocating debris from a corneal surface that has been corrugated, rippled, roughened or hardened due to the performance of a corneal refractive procedure, which comprises the steps of rotating or oscillating a scraping tool upon said debris-containing surface until said debris is dislodged.
32. A method of reprofiling a cornea, which comprises:
   (a) resecting a portion of said cornea in a manner
       such that said resected portion remains hinged to
       said cornea at one point;
   (b) folding said resected portion up and away from
       said cornea to reveal a stromal bed;
   (c) performing a corneal refractive procedure to
       obtain a modified stromal bed of a desired
       curvature;
   (d) smoothing the surface of said modified stromal
       bed by rotating or oscillating a scraping tool
       upon said surface; and
   (e) folding said resected portion back over said
       modified stromal bed.

33. A method of enhancing the optical zone of a cornea,
    which comprises the steps of performing a corneal refractive
    procedure followed by rotating or oscillating a scraping tool
    upon the surface of said cornea, whereby said optical zone is
    smoothed and expanded.

34. An improved method of reprofiling a cornea wherein a
    corneal refractive procedure is performed to alter the refractive
    characteristics of said cornea, said procedure producing a worked
    area upon said cornea, the improvement comprising rotating or
    oscillating a scraping tool upon said worked area of said cornea
    such that said worked area is smoothed and enhanced.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61F9/00

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
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<td>EP,A,0 303 174 (GRIESEHABER) 15 February 1989 see the whole document</td>
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<td>Y</td>
<td>US,A,4 526 171 (SCHACHAR) 2 July 1985 see the whole document</td>
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<td>A</td>
<td>DE,A,37 07 004 (KRUMEICH) 15 September 1988 see abstract; claims; figures</td>
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<td>A</td>
<td>EP,A,0 208 950 (GRÜNDLER) 21 January 1987 see abstract; claims 1.9; figures 1.4</td>
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Further documents are listed in the continuation of box C. Patent family members are listed in annex.

This is a special category of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

Date of the actual completion of the international search: 25 April 1996

Date of mailing of the international search report: 08.05.96

Name and mailing address of the ISA:
European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Fax (+ 31-70) 340-3016

Authorized officer: Klein, C

Form PCT/ISA/310 (second sheet) (July 1993)
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INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 14–34
   because they relate to subject matter not required to be searched by this Authority, namely:
   PCT Rule 39.1(iv) Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:  
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:  
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:  

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (1)) (July 1992)
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