

Description

This invention relates to apparatus suitable for adjusting the shape of components of the eye and more particularly to making fixed changes in the corneal curvature.

Deviations from the normal shape of the corneal surface produce errors of refraction in the visual process. The 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 distance 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 flattened 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 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 steepened, thus the refraction of rays is greater as they 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 circle of diffusion and consequently 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. Recent research has been directed to operative techniques to change the refractive condition of the eye. Such techniques are generally referred to "keratorefractive techniques". Two such techniques are more particularly called keratophakia and keratomileusis. Keratomileusis involves the regrinding of a corneal lamella into a meniscus or hyperopic lens to correct myopia or hyperopia. A corneal optical lathe has been especially developed for this procedure and is also used in the keratophakia procedure, when a homograft ground into a convex lens is placed interlamellarly to correct aphakic hypermetropia. The homog-

raft tissue (corneal lamella) is frozen with carbon dioxide. The homograft is cut 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 and in keratophakia, it is the corneal stroma of a donor eye that is shaped by the lathe. These techniques have a broad application in the correction of high hyperopic and myopic errors. These procedures require radial cutting of the cornea about the periphery of the graft which weakens the cornea so that pressure from fluids below the incisions pushes up under the cuts and flattens the curvature of the cornea. This flattening of the cornea results in refractive errors to the eye not compensated for by the graft. Suturing in these operations also causes radial asymmetry of the cornea consequently promotes astigmatic error in this regard. Sutures also cause scarring of the corneal tissue, which scar tissue loses its transparency. Surgical correction of astigmatism is accomplished by asymmetrically altering the corneal curvatures. The effect of a peripheral distorting force may be easily visualized by imagining an inflated balloon with a spherical surface being compressed between the palms of the hands. Because the volume of air in the balloon is constant, the surface area remains constant. The previously spherical anterior surface is distorted meridionally as a result of compressing the diameter between the hands so that the curvature changes without changing the circumference of the surface. The meridian passing over the balloon between the extended fingers steepens, while the uncompressed meridian at right angles thereto flattens as its diameter lengthens in proportion to the shortening of the compressed diameter. This demonstrates the effect that may result from slight variations in the symmetrical patterns or intentional asymmetrical patterns attempted to be accomplished during surgical procedures and attendant suturing. It is thus seen that present procedures in keratorefractive techniques are best limited to situation 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 adjusting to this trauma.

In United States Patent Specification No. 3064643, there is disclosed a scleral brace which is used to induce changes in the curvature of the cornea. Such a brace is generally in the form of an annulus. However, the brace is placed on the outside of the eyeball beneath the eyelid. It will be apparent that such a brace is not implanted and is, therefore, liable to be displaced.

It is therefore an object of the present invention to provide a new and improved keratorefractive technique involving apparatus for changing the shape of the optical zone of the cornea to correct

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refractive error whereby a minimum disturbance is imposed on the eye system and the simplicity of the technique virtually eliminates the chance of error or further complications resulting from gross disturbances of the eye system.

In British Patent Specification No. 2095119, only published after the priority date of the present application, there is disclosed space maintainer, in the form of a ring, which is implantable into the cornea so as to flatten the cornea to correct myopia.

Summary of the Invention

With this and other objects in view, according to the present invention there is provided a device for implantation within the stroma of the eye to permit adjustment of the corneal shape, the device comprising a split ring shaped member made from resilient material and having a non circular cross section, one end of the member being shaped to facilitate its insertion and movement within the corneal tissue. In use, one end of the member is insertable in the cornea of the eye, the member then being moved in a circular path until its ends meet. Thereafter the ends of the member are adjustable relative to one another until the shape of the eye has assumed a desired curvature, whereupon the ends are fixedly attached to one another to maintain the desired curvature of the cornea.

In practice, the cross sectional shape of the device is ovaloid or ellipsoid such that, when inserted in the cornea, its major cross sectional axis is alignable with a corneal arc extending through the anterior pole of the cornea.

In another aspect, the present invention provides a device suitable for inserting such an adjustment device into the cornea. Such an insertion device comprises a spiral-shaped member capable of being inserted into the cornea of the eye and having overlapping end portions, one end of the spiral shaped member being rounded to facilitate, in use, its movements along a circular path in the tissue of the cornea, there being means at said one end for releasably attached said one end of said adjustment member. By providing such an arrangement, such one end is movable in a circular path about the interior of the cornea until it reaches the insertion point, whereupon the one end of the adjustment member is releasably attachable to the one end of the spiral shaped member. The spiral-shaped member can then be moved in a reversed circular path, thereby pulling the now-attached adjustment device behind it, until the one end of the spiral-shaped member has returned to the insertion point. At this time, the one end of the adjustment member has also circularly moved about the interior of the cornea until its one leading end has reached the insertion point to implant the adjustment member in the cornea and withdraw the spiral-shaped member. The corneal curvature adjusting procedure and ring end fixing procedure are then performed.

In a preferred embodiment of the invention the

shape of the one leading end of the spiral shaped member is asymmetrically rounded into a sled shape. In use, this maintains a transverse bias on the one end during movement thereof within the corneal tissue.

In a still further aspect, the present invention provides a device for holding such an insertion device. The holding device comprises an elongate member having at least a portion of the surface of one end formed to facilitate rotation thereof by a user, the other end having a concave surface whose axis is coaxial with that of the elongate member, the concave surface having a groove therein for holding the insertion device, and means for generating a magnetic field near said other end of said elongate member to hold the insertion device in the groove. This magnetic force also pulls, in use, the spiral-shaped member toward the anterior of the corneal stroma into which it is being inserted. In addition, a pin may extend outwardly from the groove and serves to engage a blunt trailing end of the spiral shaped member as it is being inserted to further facilitate its movement in and about the cornea as the holder is rotated. Also, a cylindrical sleeve may be fitted over a portion of the elongate cylindrical member to facilitate holding the holding device steady as the cylindrical member is rotated in the adjustment member insertion procedure.

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 an eye system showing adjustment of the cornea to steepen the corneal slope;

Fig. 3 is a schematic illustration of an eye system showing adjustment of the cornea to flatten the corneal slope;

Fig. 4 is a more detailed schematic illustration of a horizontal section of the frontal portion of the eye showing an adjustment member positioned in the stroma of the cornea;

Fig. 5 is a plan view of a spiral-shaped member suitable for inserting the adjustment member into the cornea, the end portion of the spiral-shaped member being shown.

Fig. 6 is a plan view of an adjustment member showing its end portions;

Fig. 7 is an elevational view showing the inserting ends of the respective spiral-shaped member and adjustment member positioned for receiving a releasable connecting clip;

Fig. 8 is an elevational view of the adjustment member taken along lines 8—8 of Fig. 6;

Fig. 9 is a partial perspective view of the cornea of an eye with incisions for receiving the insertion and adjustment member, the members being positioned for releasable attachment to one another just prior to implanting the adjustment member,

Fig. 10 is a side elevational cross sectional view of a device for holding and rotating the insertion device; and

Fig. 11 is a schematic representation of a

cornea-scope type image superimposed with a target image for comparing the present shape of the cornea with a desired shape to permit accurate fixing of the adjustment ring to fix the shape of the cornea.

Description of the Preferred Embodiment

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 of 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 21, 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 its periphery. Most of the refraction of the eye takes place on the surface of the cornea.

Referring 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. 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 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.

The apparatus of the present invention is concerned with a system suitable for adjusting an annular chord of the cornea as suggested by the processes shown in Figs. 2 and 3 to thereby correct refractive errors of the eye. Again referring to Fig. 4 a member 47, having an ovaloid cross sectional shape is shown implanted in the stroma layer of the cornea. By adjusting the diameter of such a member in the cornea and fixing that diameter at a discrete value, the rays refracted by the cornea and other eye components can be brought to focus directly on the retina 18. Such a member placed approximately at the 8 mm chord of the cornea provides a means for making such a corrective adjustment. Apparatus and methods for making this adjustment are hereinafter described.

Referring now to Figs. 6 and 8 of the drawings, the adjusting member 47 is comprised of a generally circular member having split end portions 48 and 49. The split ring member is comprised of a material which has sufficient stiffness to maintain its generally circular shape and sufficient resiliency to permit its ends 48 and 49 to be adjusted relative to one another to thereby enlarge or decrease the normal diameter of the ring at rest. The material should have properties that render it physiologically compatible with the tissue of the cornea. Two such materials are plastic type materials sold under the trade names PLEXIGLASS and SAUFLON. The cross sectional shape of the member is that of an oval generally dimensioned to be about 1 mm across its major axis and .2 mm across its minor axis. The one insertion end or leading end 48 of the adjusting member is tapered asymmetrically to a rounded tip end (see Fig. 7).

As shown in Fig. 8, the major axis of the oval member 47 is formed at an angle sloping inwardly to the center of the member. The angular disposition of the major axis of the ovaloid member corresponds to the intended implantation position of the member 47 in the cornea. The member is implanted in the stroma 32 of the cornea as shown in Fig. 4. One function of the stroma is to transfer fluids through the eye. In order to minimize the effect of the implanted member 47 on the transfer of fluids, the member is positioned so that its major axis is parallel to the lamellae of the stroma. Thus the member is implanted at a slope corresponding to the slope of the corneal arc extending through the anterior

pole 20 (Fig. 1) of the cornea. This slope of the adjusting member also corresponds to the direction of lamellae within the corneal stroma. By orienting the member thus, the member may be inserted between the lamellae to produce a minimum of trauma to the eye. During the development of this procedure, a circular adjusting member was used. It was found however that the circular member, when expanded or contracted to adjust its size (see Figs. 2 and 3), creates a sufficient pressure between the corneal tissue and the member, to cause the member to cut through the tissue. By utilizing an ovaloid shape and orienting the major axis of the ovaloid as shown in Fig. 4, and enlarged surface is presented in the direction of pressure of the ring to prevent cutting of the tissue. Thus the major axis of the member acts against the lamellae of the stroma in the direction of pressure and the minor axis is aligned with the lamellae to provide a minimum of interruption to fluid flow.

Fig. 5 of the drawings shows an insertion device in the form of a spiral-shaped insertion member 51 which is circular in cross section and has overlapping split end portions 52 and 53. The ends of the member overlap approximately one half a diameter of the member. Member 51 may be constructed of a metallic material such as stainless steel and in any event a magnetic material for purposes to be hereinafter described. Member 51 also is provided with an asymmetrically rounded end portion 52 having a lower tapered surface to resemble the shape of a sled runner. The trailing end 53 of the member 51 has a blunt end surface 54.

Referring now to Fig. 7 both the insertion member 51 and the adjustment member have transverse substantially vertical holes 56 and 57 respectively through their ends, near the tip ends thereof. Longitudinal grooves 58 are formed in the top surface of each of the members 47, 51 and extend from the holes 56, 57 to the respective tip ends of the rings. An inverted U-shaped clip member 61 is shown positioned in Fig. 7 for reception of its downwardly projecting leg portions 62 into the holes 56 and 57 of the insertion and adjusting members respectively and its body portion 63 into the longitudinal grooves 58 in the top end of the respective members.

Referring to Fig. 10 of the drawings, an insertion member holding and rotating apparatus 71 is shown including a solid cylindrical rotating member 72 having a knurled upper end surface 73. The cylindrical rotating member 72 is slip-fitted with a cylindrical holding sleeve 74 to permit relative rotation between the member 72 and sleeve 74. The lower end of the rotating member 72 has a concentrically arranged concave surface 76 having its concave shape as well as the proportions of the surface 76 arranged to be matingly received over the anterior corneal surface of the eye. An annular groove 77 is formed in the concave surface 76 near the peripheral edge of the rotating member 72. This groove 77 is sized to receive and hold the inser-

tion member at its nominal diameter for insertion into and around the cornea at the 8 mm chord of the eye as shown in Fig. 4. This chord is located within a plane across the cornea which measures approximately 8 mm in diameter. Thus the groove 77 itself has an internal diameter of approximately 8 mm. The rotatable holding member 72 is constructed of a magnetized material or has a means for being magnetized. The magnetic nature of the member 72 holds the member 51 in place on the tool during the kerato-refractive procedure to be described. A small pin 78 is vertically arranged to project downwardly from a point in the groove. This pin contacts the trailing blunt end 54 of the insertion member.

The method of implanting an adjusting member 47 within the cornea of the eye will now be described: First, a determination is made, by taking optical measurements of the eye, so as to what shape the cornea should have in order for that eye to operate in an optically correct manner. Fig. 11 shows a target image comprised of indicia 81. This target grid 81 may be made by reflecting light from placido rings from a standard spherical surface the same size as the eye in question and at a fixed distance. An image is made of this "correct" topographic map of the eye, referred to herein as a target or target image. The target indicia is in the form of vertical lines or grids 81 as shown in Fig. 11 which of course may be drawn in other radial meridians as well as the horizontal meridian as shown. The spacings between the grids 81 represents a topographic survey of an eye having a corrected curvature, as pertains to the specific eye in question.

An insertion member 51 is next placed in the groove 77 on the concave surface 76 of the rotatable holding member 72. The blunt end 54 of member 51 is contacted against the pin 78 extending outwardly from the groove. The magnetic attraction between the magnetic member 72 and steel member 51 holds the member in place on the end of the member 72. Next, working under a surgical microscope, a small (approximately 1 mm long and .2 mm deep) incision 82 (Fig. 9) is made in the cornea through the epithelium and Bowman's membrane. This incision is approximately the same size as the adjusting member to be implanted. The leading end 52 of the insertion member 51 is then moved through the incision and into the stroma of the cornea. The holding member 72 is then rotated to progressively thread the member around the cornea between the adjacent lamellae within the anterior portion of the stroma. The lamellae of fibrils near the anterior of the stroma are more loosely formed, making this a desirable location in the stroma for insertion of the insertion member and for implantation of the adjusting member. The sled shaped nose portion on the end 52 of the insertion member causes the end 52 to be continuously biased upwardly sufficiently to maintain the end 52 in a path in the anterior lamellae of the stroma. The magnetic force between the holder 72 and the insertion member also causes the insertion

member to maintain its path within the anterior lamellae. Rotation of the holding member 72 is continued with the pin 78 and magnetic attraction between the member 51 and holder 72 serving to drive the member about the cornea until the end portion 52 reaches the incision 83. At this time, a second incision (Fig. 9) is made perpendicular to the first incision, with the second incision being approximately 1 mm long. In any event the second incision extends from a position just above the hole 57 in the insertion member to a normal intersection with the first incision 83. The leading end 48 of the adjusting member 47 is then brought into position with its tip end adjacent the tip 52 of the insertion member now lying below the corneal surface. As shown in Fig. 7, the clip member or link 61 is now placed with its leg portions 62 projecting into the holes 56 and 57 in the respective adjusting and insertion members and the body portion 63 of clip 61 is passed through the second incision 82 into position in the grooves 58 in the top side of the respective members.

Next the holding member 72 is rotated in an opposite direction pulling the leading end 48 of the adjusting member through the incision 83 and around the circular path previously made by the insertion of the insertion member. The insertion member is moved in reverse rotation with the member 72 by means of the magnetic force between the holder 72 and member 51. The plastic adjusting member 47 is pulled by the metal insertion member. As the adjusting member 47 is drawn into the cornea, the insertion member is being progressively withdrawn or "backed-out" until the leading end 48 of the adjusting member is brought circularly back around to the incision 83, at which time the insertion member is fully withdrawn. The link 61 is then removed from the holes 56, 57 and slots 58 to release the connection between the insertion and adjusting member. The tip ends of the split ends 48, 49 of the adjusting member are then grasped, such as by the ends of an adjustable caliper, and adjusted longitudinally endwise relative to one another to adjust the diameter of the member and thereby bring the shape of the cornea into coincidence with the indicia 81 on the target image (Fig. 11). Also shown in Fig. 11 is an image of somewhat concentric circles 83 similar to that projected from a viewing surface by a corneoscope. The rings are produced by reflecting light from placido rings onto the present corneal surface being worked on. The distances from placido rings to cornea to image surface is the same as for constructing the target image. The concentricity and spacings of the rings 83 represents the topography of the eye being worked on. By superimposing the rings 83 onto the target image while adjustment of the ends of the adjusting member 47 is taking place, perfect correction of the corneal shape may be effected by manipulating the ends of the adjusting member until the indicia 81 and circles 83 are brought into coincidence. The ends 48, 49 of the

adjusting member 47 are then fixed together such as by gluing or the like to permanently fix the correct shape of the cornea.

While particular embodiments of the present invention have been shown and described, it is apparent that changes and modifications may be made without departing from this invention in its broader aspects.

Claims

1. A device for implantation within the stroma of the eye to permit adjustment of the corneal shape, the device comprising:

a split ring shaped member (47) made from resilient material and having a non-circular cross-section, one end (48) of the member being shaped to facilitate its insertion and movement within the corneal tissue.

2. A device as claimed in claim 1, characterised in that the one end (48) of the member has means thereon for connecting said adjusting member to an insertion device.

3. A device as claimed in claim 2, characterised in that the connecting means includes a hole (57) at said one end (48) of the member and a longitudinal slot (58) in the outer surface of the adjusting member (47) connecting the hole (56) to the one end (48) of the member.

4. A device suitable for inserting into the cornea an adjustment device in accordance with claims 1 to 3 comprising:

a spiral-shaped member (51) capable of being inserted into the cornea of the eye and having overlapping end portions (52, 53); one end (52) of the spiral-shaped member (51) being rounded to facilitate, in use, its movement along a circular path in the tissue of the cornea, there being means (56) at said one end (52) for releasably attaching said one end (48) of said adjustment member (47).

5. A device as claimed in claim 4 wherein said one end (52) of said spiral-shaped member (51) is asymmetrically rounded in a sled shape to bias said spiral shaped member (51) in a direction which is transverse, in use, to its path of movement as it moves within the corneal tissue.

6. A device as claimed in claim 4 or 5, characterised in that said spiral-shaped member (51) is substantially circular in cross sectional shape.

7. A device as claimed in any one of claims 4 to 6 characterised in that the connecting means includes a hole (57) near said one end of said spiral-shaped member (51) and a longitudinal slot (58) in the upper-facing surface of said spiral-shaped member (51) extending from said hole (57) to the tip end of said one end of said spiral-shaped member (52).

8. A device for holding an insertion device in accordance with any one of claims 4 to 7 when the insertion device is made of magnetic material comprising:

an elongate member (72) having at least a portion of the surface (73) of one end formed to facilitate rotation thereof by a user, the other end

having a concave surface (76) whose axis is coaxial with that of the elongate member (72), the concave surface (76) having a groove (77) therein for holding the insertion device, and means for generating a magnetic field near said other end of said elongate member (72) to hold the insertion device in the groove (77).

9. A device as claimed in claim 8 characterised in that concentric groove means (77) are formed in said concave surface (76).

10. A device as claimed in claim 9 wherein said groove means (77) is arranged to receive the spiral-shaped insertion member (51) and further including pin means (78) extending outwardly from said groove (77) for engaging one end of said insertion member (51).

11. A device as claimed in claim 10 characterised in that said elongated member (72) is cylindrical and further including circular sleeve means (74) arranged for receiving said elongated member (72) therein.

12. An apparatus comprising an adjustment device in accordance with any one of claims 1 to 3, an insertion device in accordance with any one of claims 4 to 7, a holding device in accordance with any one of claims 8 to 11 and means (56, 57, 61, 62) for connecting respective end portions of the adjustment device and the insertion device.

Patentansprüche

1. Vorrichtung zum Einsetzen in das Bindegewebe des Auges zur Korrektur der Hornhautkrümmung, beinhaltend ein ringförmiges, geschlitztes Korrekturteil (47) aus elastischem Material mit einem von der Kreisform abweichenden Querschnitt, wobei ein Ende (48) dieses Bauteils derart geformt ist, daß es leicht in das Hornhautgewebe einführbar und dort verschiebbar ist.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß das eine Ende (48) des Korrekturteils Einrichtungen zur Verbindung mit einem Einführungsteil aufweist.

3. Vorrichtung nach Anspruch 2, dadurch gekennzeichnet, daß die Verbindungseinrichtungen eine Bohrung (57) am genannten Ende (48) des Korrekturteils haben, sowie eine Längsrille (58) in der äußeren Oberfläche des Bauteils (47), die sich von der Bohrung (57) zum Ende (48) des Bauteils erstreckt.

4. Vorrichtung zum Einsetzen einer Korrekturvorrichtung nach den Ansprüchen 1 bis 3 in die Hornhaut, beinhaltend ein spiralförmiges Bauteil (51), das in die Hornhaut des Auges eingeführt werden kann, mit überlappenden Endabschnitten (52, 53), wobei ein Ende (52) des spiralförmigen Bauteils (51) abgerundet ist, um seine Bewegung in einer kreisförmigen Bahn in Hornhautgewebe zu erleichtern, und wobei Mittel (56) an diesem Ende (52) zur lösbaren Verbindung mit dem Ende (48) des Korrekturteils (47) vorgesehen sind.

5. Vorrichtung nach Anspruch 4, wobei dieses Ende (52) des spiralförmigen Einführungsteils (51) asymmetrisch schiffenförmig abgerundet ist, um diesem spiralförmigen Einführungsteil (51)

adjusting member 47 are then fixed together such as by gluing or the like to permanently fix the correct shape of the cornea.

While particular embodiments of the present invention have been shown and described, it is apparent that changes and modifications may be made without departing from this invention in its broader aspects.

Claims

1. A device for implantation within the stroma of the eye to permit adjustment of the corneal shape, the device comprising:

a split ring shaped member (47) made from resilient material and having a non-circular cross-section, one end (48) of the member being shaped to facilitate its insertion and movement within the corneal tissue.

2. A device as claimed in claim 1, characterised in that the one end (48) of the member has means thereon for connecting said adjusting member to an insertion device.

3. A device as claimed in claim 2, characterised in that the connecting means includes a hole (57) at said one end (48) of the member and a longitudinal slot (58) in the outer surface of the adjusting member (47) connecting the hole (56) to the one end (48) of the member.

4. A device suitable for inserting into the cornea an adjustment device in accordance with claims 1 to 3 comprising:

a spiral-shaped member (51) capable of being inserted into the cornea of the eye and having overlapping end portions (52, 53); one end (52) of the spiral-shaped member (51) being rounded to facilitate, in use, its movement along a circular path in the tissue of the cornea, there being means (56) at said one end (52) for releasably attaching said one end (48) of said adjustment member (47).

5. A device as claimed in claim 4 wherein said one end (52) of said spiral-shaped member (51) is asymmetrically rounded in a sled shape to bias said spiral shaped member (51) in a direction which is transverse, in use, to its path of movement as it moves within the corneal tissue.

6. A device as claimed in claim 4 or 5, characterised in that said spiral-shaped member (51) is substantially circular in cross sectional shape.

7. A device as claimed in any one of claims 4 to 6 characterised in that the connecting means includes a hole (57) near said one end of said spiral-shaped member (51) and a longitudinal slot (58) in the upper-facing surface of said spiral-shaped member (51) extending from said hole (57) to the tip end of said one end of said spiral-shaped member (52).

8. A device for holding an insertion device in accordance with any one of claims 4 to 7 when the insertion device is made of magnetic material comprising:

an elongate member (72) having at least a portion of the surface (73) of one end formed to facilitate rotation thereof by a user, the other end

having a concave surface (76) whose axis is coaxial with that of the elongate member (72), the concave surface (76) having a groove (77) therein for holding the insertion device, and means for generating a magnetic field near said other end of said elongate member (72) to hold the insertion device in the groove (77).

9. A device as claimed in claim 8 characterised in that concentric groove means (77) are formed in said concave surface (76).

10. A device as claimed in claim 9 wherein said groove means (77) is arranged to receive the spiral-shaped insertion member (51) and further including pin means (78) extending outwardly from said groove (77) for engaging one end of said insertion member (51).

11. A device as claimed in claim 10 characterised in that said elongated member (72) is cylindrical and further including circular sleeve means (74) arranged for receiving said elongated member (72) therein.

12. An apparatus comprising an adjustment device in accordance with any one of claims 1 to 3, an insertion device in accordance with any one of claims 4 to 7, a holding device in accordance with any one of claims 8 to 11 and means (56, 57, 61, 62) for connecting respective end portions of the adjustment device and the insertion device.

Patentansprüche

1. Vorrichtung zum Einsetzen in das Bindegewebe des Auges zur Korrektur der Hornhautkrümmung, beinhaltend ein ringförmiges, geschlitztes Korrekturteil (47) aus elastischem Material mit einem von der Kreisform abweichenden Querschnitt, wobei ein Ende (48) dieses Bauteils derart geformt ist, daß es leicht in das Hornhautgewebe einführbar und dort verschiebbar ist.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß das eine Ende (48) des Korrekturteils Einrichtungen zur Verbindung mit einem Einführungsteil aufweist.

3. Vorrichtung nach Anspruch 2, dadurch gekennzeichnet, daß die Verbindungseinrichtungen eine Bohrung (57) am genannten Ende (48) des Korrekturteils haben, sowie eine Längsrille (58) in der äußeren Oberfläche des Bauteils (47), die sich von der Bohrung (57) zum Ende (48) des Bauteils erstreckt.

4. Vorrichtung zum Einsetzen einer Korrekturvorrichtung nach den Ansprüchen 1 bis 3 in die Hornhaut, beinhaltend ein spiralförmiges Bauteil (51), das in die Hornhaut des Auges eingeführt werden kann, mit überlappenden Endabschnitten (52, 53), wobei ein Ende (52) des spiralförmigen Bauteils (51) abgerundet ist, um seine Bewegung in einer kreisförmigen Bahn in Hornhautgewebe zu erleichtern, und wobei Mittel (56) an diesem Ende (52) zur lösbaren Verbindung mit dem Ende (48) des Korrekturteils (47) vorgesehen sind.

5. Vorrichtung nach Anspruch 4, wobei dieses Ende (52) des spiralförmigen Einführungsteils (51) asymmetrisch schlittenförmig abgerundet ist, um diesem spiralförmigen Einführungsteil (51)



bei seiner Verwendung eine Richtung quer zu seinem Bewegungsweg in dem Hornhautgewebe zu geben.

6. Vorrichtung nach Anspruch 4 oder 5, dadurch gekennzeichnet, daß das spiralförmige Einführungsteil (51) einen im wesentlichen, kreisförmigen Querschnitt aufweist.

7. Vorrichtung nach einem der Ansprüche 4 bis 6, dadurch gekennzeichnet, daß die Verbindungsmittel eine Bohrung (57) in der Nähe des einen Endabschnittes des spiralförmigen Einführungsteils (51) aufweisen, sowie eine Längsrille (58) in der oberen Oberflächenseite, der sich von der Bohrung (57) zur Spitze des Endabschnittes des spiralförmigen Einführungsteils (51) erstreckt.

8. Vorrichtung zum Halten eines Einführungsteils gemäß eines der Ansprüche 4 bis 7 wobei das Einführungsteil aus magnetischem Material besteht, mit einem länglichen Teil (72), dessen Oberfläche zumindest teilweise so gestaltet ist, daß die Drehung durch den Benutzer erleichtert wird, wobei das andere Ende eine konkave Oberfläche (76) aufweist, deren Achse koaxial mit der Achse des länglichen Teils (72) verläuft, wobei die konkave Oberfläche (76) eine Nut (77) zur Aufnahme des Einführungsteils aufweist, und wobei Einrichtungen zur Erzeugung eines Magnetfeldes in der Nähe dieses anderen Endes des länglichen Teils (72) vorgesehen sind, um das Einführungsteil in der Nut (77) zu halten.

9. Vorrichtung nach Anspruch 8, dadurch gekennzeichnet, daß konzentrische Nuten (77) in der konkaven Oberfläche (76) ausgebildet sind.

10. Vorrichtung nach Anspruch 9, wobei diese Nuten (77) zur Aufnahme des spiralförmigen Einführungsteils (51) angeordnet sind und wobei sich Zapfen (78) von dieser Nut (77) nach außen erstrecken um ein Ende des Einführungsteils (51) zu erfassen.

11. Vorrichtung nach Anspruch 10, dadurch gekennzeichnet, daß der längliche Teil (72) zylindrisch ist und kreisförmige Mittel aufweist, die zur Aufnahme des länglichen Teils (72) angeordnet sind.

12. Anordnung mit einem Korrekturteil gemäß einem der Ansprüche 1 bis 3, einem Einführungsteil gemäß einem der Ansprüche 4 bis 7, einer Haltevorrichtung gemäß einem der Ansprüche 8 bis 11, sowie Vorrichtungen (56, 57, 61, 62) zur Verbindung zugehöriger Endabschnitte des Korrekturteils und des Einführungsteils.

Revendications

1. Un dispositif pour implantation à l'intérieur du strama de l'oeil pour permettre le réglage de la forme de la cornée, ce dispositif comportant: un élément en forme de bague fendue (47) réalisé en matière élastique et ayant une section transversale non circulaire, une extrémité (48) de l'élément étant façonnée pour faciliter son introduction et son mouvement à l'intérieur du tissu de la cornée.

2. Un dispositif selon la revendication 1, caractérisé en ce que l'extrémité (48) de l'élément

comporte des moyens pour relier ledit élément de réglage à un dispositif d'introduction.

3. Un dispositif selon la revendication 2, caractérisé en ce que les moyens de liaison comprennent un perçage (56) dans ladite extrémité (48) de l'élément et une fente longitudinale (58) dans la surface extérieure de l'élément de réglage (47) reliant le perçage (56) à l'extrémité (48) de l'élément.

4. Un dispositif adapté à l'introduction dans la cornée d'un dispositif de réglage selon les revendications 1 à 3, comportant: un élément en forme de spirale (51) pouvant être introduit dans la cornée de l'oeil et présentant des parties d'extrémité en recouvrement (52, 53), une extrémité (52) de l'élément en forme de spirale (51) étant arrondie pour faciliter, lors de l'utilisation, son mouvement suivant un parcours circulaire dans le tissu de la cornée, des moyens (56) existant à ladite extrémité (52) pour lier de façon amovible ladite extrémité (48) dudit élément de réglage (47).

5. Un dispositif selon la revendication (4), dans lequel ladite extrémité (52) dudit élément en forme de spirale (51) est arrondie de façon dissymétrique en forme de traîneau pour pousser ledit élément en forme de spirale (51) dans une direction qui est transversale, en cours d'utilisation, à la trajectoire de son mouvement lorsqu'il se déplace à l'intérieur du tissu de la cornée.

6. Un dispositif selon la revendication 4 ou la revendication 5, caractérisé en ce que ledit élément en forme de spirale (51) présente en section transversale une forme sensiblement circulaire.

7. Un dispositif selon l'une quelconque des revendications 4 à 6, caractérisé en ce que le moyen de liaison comprend un perçage (57) proche de ladite extrémité dudit élément en forme de spirale (51) et une fente longitudinale (58) dans la surface supérieure dudit élément en forme de spirale (51) s'étendant dudit perçage (57) au bout extrême de ladite extrémité dudit élément en forme de spirale (52).

8. Un dispositif pour maintenir un dispositif d'introduction selon l'une quelconque des revendications 4 à 7 quand le dispositif d'introduction est réalisé en matière magnétique, comportant: un élément allongé (72) ayant au moins une partie de la surface (73) d'une extrémité façonnée pour faciliter sa rotation par un utilisateur, l'autre extrémité présentant une surface concave (76) dont l'axe est en coïncidence avec celui de l'élément allongé, la surface concave (76) présentant une rainure (77) pour maintenir le dispositif d'introduction, et des moyens pour produire un champ magnétique près de ladite autre extrémité dudit élément allongé (72) pour maintenir le dispositif d'introduction dans la rainure (77).

9. Un dispositif selon la revendication 8, caractérisé en ce que les moyens à rainure concentrique (77) sont formés dans ladite surface concave (76).

10. Un dispositif selon la revendication 9, dans lequel lesdits moyens à rainure (77) sont disposés



pour recevoir l'élément d'introduction en forme de spirale (51) et comportent en outre des moyens en saillie (78) s'étendant vers l'extérieur à partir de ladite rainure (77) pour s'engager dans une extrémité dudit élément d'introduction (51).

11. Un dispositif selon la revendication 10, caractérisé en ce que ledit élément allongé (72) est cylindrique et comporte en outre un manchon circulaire (74) agencé pour recevoir intérieurement ledit élément allongé (72).

12. Un appareil comportant un dispositif de réglage selon l'une quelconque des revendications 1 à 3, un dispositif d'introduction selon l'une quelconque des revendications 4 à 7, un dispositif de maintien selon l'une quelconque des revendications 8 à 11 et des moyens (56, 57, 61, 62) pour relier des parties d'extrémité respectives du dispositif de réglage au dispositif d'introduction.



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