METHOD OF FORMING A CORNEAL POCKET

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] The present application is a continuation-in-part of US application no. 10/980,717 filed November 3, 2004 and also claims the benefit of U.S. Provisional Patent Application No. 60/775,607, filed on Feb. 21, 2006.

BACKGROUND OF THE INVENTION

[002] The present invention generally relates to methods of forming a corneal pocket to receive intracorneal refractive lenses and, more particularly to configurations of corneal pockets to receive such lenses.

[003] Intraocular or intracorneal refractive lenses provide a viable alternative to spectacles and extra-ocular contact lenses for correcting deficiencies in visual acuity and refractive errors. Intraocular lenses (IOLs) of the prior art typically comprise an optical portion for refraction and a haptic portion for supporting the IOL in the anterior or posterior chamber of the eye. All or part of an IOL may be constructed from a deformable or flexible material. A deformable IOL has the advantage that it can be inserted in the eye via a smaller incision than an incision required to insert a non-deformable or rigid IOLs of comparable dimensions. Larger incisions in the eye have many disadvantages, including longer patient recovery times, astigmatism and increased risk of infection.

[004] However, the flexible nature of deformable IOLs typically presents problems both in maneuvering the IOL during an insertion procedure, and in retaining the IOL in the correct position within the eye. To prevent the risk of damage or necrosis of ocular tissue following contact with, or penetration by, a portion of an IOL, rigid and/or pointed structures should be avoided.

[005] Nevertheless, in an attempt to anchor the IOL in place within the eye,

prior art IOLs have used clasps, pointed tips, and the like which penetrate iris tissue. For example, US Patent No. 6,755,859 B2 to Hoffmann *et al.* discloses an intraocular lens having an optical portion and two or more haptic elements for supporting the optic portion in the eye via a tissue clasp on each haptic element. US Patent Application Publication No. US 2002/0103537 A1 (Willis *et al.*) discloses an intraocular lens having an optic and a haptic, wherein the distal end of the haptic includes a pointed tip constructed and arranged to penetrate the iris. In a second embodiment of Willis *et al.*, the intraocular lens is attached to the iris by a staple.

[006] US Patent Application Publication No. US 2004/0085511 A1 (Uno *et al.*) discloses an intraocular lens having at least one pore near the center of the optical part of the lens, and a plurality of grooves in the back surface of the lens in a region that will make contact with the crystalline lens. The grooves allow fluid to flow towards the pores, and the pores allow fluid to flow through the lens. The intraocular lens of Uno *et al.* may also have circumferentially spaced protrusions, arranged in the boundary between the optical part and the support part of the lens, in an attempt to separate the optical part of the IOL from the crystalline lens. The diameter of the pores is restricted by potential deterioration in optical characteristics of the optical portion, e.g., reflection of light incident on the periphery of the pores. The location of the protrusions is limited by their potential to interfere with or restrict deformability of the lens for insertion in the eye.

[007] US Patent No. 6,106,553 to Feingold discloses an intraocular lens having a shape that is predetermined with respect to a shape of the crystalline lens to form a spacing between at least part of the IOL and the crystalline lens. For example, the radius of arc of the posterior surface of an optic portion of the IOL may be smaller than the radius of arc of the posterior surface of a body portion of the IOL, so that the optic portion has a vaulted relationship to the anterior surface of the crystalline lens in the location of the pupil. In this relationship (e.g., Figure 28 of the '553 patent), the body portion of the IOL is in

contact with the crystalline lens at a position radially outward from the pupil. The IOL may have a circular groove that allows circulation of fluid in the eye (Figures 20 and 21 of the '553 patent).

[008] Intracorneal refractive lenses offer a number of advantages for correcting deficiencies in visual acuity. An intracorneal lens may be inserted into an opening in the cornea of an eye having visual abnormalities. Some previous cornea-based techniques have involved the surgical reshaping of inner portions of the cornea to correct visual deficiencies. However, such surgical reshaping is not reversible, resulting in some risk of creating permanent visual aberrations for the patient. In contrast, the procedures used with intracorneal lenses are reversible. Also, in typical surgical corneal reshaping surgery an entire flap of the cornea is lifted to permit access for further surgical modification of the cornea. In the surgery used to insert intracorneal lenses, a flap of the cornea is not lifted, but rather a pocket is formed in the corneal tissue, which leaves more of the corneal surface intact thereby simplifying healing. Nevertheless, the surgical preparation of such a pocket for an intracorneal lens is difficult to perform accurately. Also, some lenses which are available for such vision correction are not entirely satisfactory for a variety of reasons, including a tendency to shift out of position after placement, to impair transcorneal gas diffusion, to be excessively thick, or to be unable to correct presbyopis or astigmatism.

[009] US Patent 6,599,305 to Feingold discloses a corneal-pocket keratome device to create a corneal pocket and a lens to be inserted and retained in the corneal pocket to effect correction. The corneal-pocket keratome creates a pocket of precise dimensions in the cornea. The corneal-pocket keratome includes a drive unit having cutting head elements which contact the subject eye during corneal pocket formation, and also includes a blade assembly that oscillates laterally while extending forward into the cornea to form the pocket. Intracorneal lenses are also disclosed in US Patent 6,599,305 which may include a feature to impede accidental lens movement after the lens is disposed

within the corneal pocket, such features may include a swelling after insertion or a circumferential irregularity.

[0010] As can be seen, there is a need for a method for correcting visual abnormalities through surgical implantation of an appropriate corrective lens within the cornea in a precisely predictable and repeatable manner and in such a way that the lens will remain properly positioned and oriented. There is also a need for a method of correcting visual abnormalities which can be reversed and which enables correction of a wide range of visual abnormalities. There is a further need for a method of inserting an intracorneal lens, such that it can be held at a desired intracorneal location, without penetrating or damaging other ocular tissue. There is also a need for a method of creating a corneal pocket and configurations of such pocket that effectively position and hold a variety of intracorneal lenses.

SUMMARY OF THE INVENTION

[0011] In one aspect of the present invention, there is provided a method for correcting vision of a patient, comprising providing a refractive intracorneal lens, wherein the intracorneal lens comprises an optical portion and a haptic portion, and wherein the haptic portion is corrugated; forming a corneal pocket in an eye of the patient; and inserting the intracorneal lens in the corneal pocket.

[0012] In yet another aspect of the present invention, there is provided a method for correcting vision of a patient comprising providing a refractive intracorneal lens; forming with a laser a corneal pocket in a cornea of the patient; and inserting the lens in the corneal pocket.

[0013] In a further aspect of the present invention, a corneal pocket comprises an arced portion; and a straight portion adjacent the arced portion.

[0014] In an additional aspect of the present invention, a corneal pocket in a cornea comprises a straight portion extending across an entirety of the cornea.

[0015] These and other features, aspects, and advantages of the present

invention will become better understood with reference to the following drawings, description, and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Figure 1 is a sectional view of the anterior portion of an eye having a corrugated lens disposed within the cornea of the eye, according to an embodiment of the invention;

[0017] Figure 2 is a sectional view of the anterior portion of an eye having an lens disposed within the cornea of the eye, according to another embodiment of the invention;

[0018] Figure 3 schematically represents a series of steps involved in a method for inserting an lens in the cornea of a patient, according to another embodiment of the invention;

[0019] Figure 4 is a cross-sectional view of a corneal pocket according to an embodiment of the present invention; and

[0020] Figures 5A-5I depict exemplary configurations of a corneal pocket according to various embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0021] The following detailed description is of the best currently contemplated modes of carrying out the invention. The description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the invention, since the scope of the invention is best defined by the appended claims.

[0022] Broadly, the present invention relates to methods for correction of a visual deficiency of a patient. The present invention also relates to methods for insertion of an intracorneal lens in a corneal pocket in a patient's eye. The present invention still further relates to corneal pockets configured to facilitate

the insertion of an intracorneal lens therein.

[0023] In contrast to the prior art, in some embodiments of the present invention a variety of different corneal pocket shapes may be employed to further enhance the ease of insertion of an intracorneal lens, and to maximize the surface of the cornea which is left intact thereby facilitating healing.

[0024] Figure 1 is a sectional view of the anterior portion of an eye 100''' having a corrugated intracorneal lens 10 disposed therein, according to an embodiment of the invention. In the embodiment of the invention shown in Figure 1, lens 10 may be disposed within cornea 110, which may partially enclose the anterior chamber 114. Also shown in Figure 1 is an iris 108. . As an example, lens 10 may be inserted within cornea 110 following formation of a corneal pocket, which may be formed, e.g., using a laser or corneal-pocket keratome device as disclosed in the aforementioned US Patent No. 6,599,305, the disclosure of which is incorporated by reference herein in its entirety. For insertion in cornea 110, lens 10 may have a haptic portion 30, which may be opaque and may be located outside the optical zone of the eye 100''', whereby interference with the vision of the patient by haptic portion 30 may be avoided. In an alternative embodiment, the haptic portion may be eliminated, whereby lens 10/10'' may consist essentially of optical portion 20 (see, e.g., Figure 2).

[0025] Optical portion 20 is not restricted to the configuration shown in the drawings, but may have various shapes, such as circular or oval, wherein optical portion 20 may be elongated in the horizontal direction (x axis) or shortened in the vertical direction (y axis). In some embodiments, optical portion 20 may have a doughnut-like configuration. The size and shape of the lens 10 may, in some cases, determine the size and shape of the corneal pocket. Various embodiment of such cornea pockets are described below and shown in Figures 5A-5I.

[0026] The lens 10 preferably may be formed of a biocompatible material that permits sufficient gas diffusion to allow adequate oxygenation of internal eye tissues. Such materials may include silicone, hydrogels, urethanes or acrylics.

It also may be desirable that the lens be made of a hydrophilic material which swells somewhat when hydrated. Such materials, for example, hydrogels, are well known and are used in some present contact lenses.

[0027] The optical characteristics of optical portion 20 may be selected for correcting various visual deficiencies, including without limitation: myopia (short sightedness), hypermetropia (long sightedness), presbyopia and astigmatis. As an example, optical portion 20 may have a diopter power or value in the range of from +15 to -30. Optical portion 20 may be customized for a particular patient to provide optical characteristics to correct a specific visual defect of a patient. Optical portion 20 may be multi-focal. Lens 10 may also be provided as an off-the-shelf unit with pre-determined optical characteristics. It is to be understood that the present invention is not limited to treatment of the aforementioned visual defects, and that treatment of other eye conditions is also within the scope of the invention.

[0028] Haptic portion 30 may surround optical portion 20 and may be corrugated. Haptic portion 30 may vary in the number and configuration of corrugations and may be adapted for supporting optical portion 20 and for holding lens 10 in a desired position in the cornea 110. Typically, the number of corrugations within haptic portion 30 may be in the range of from 1 to about 5. In general, a larger number of corrugations of haptic portion 30 may lead to increased flexibility and increased deformability in the horizontal direction. Further, haptic portion 30 may have corrugations oriented in directions other than those shown in Figure 1. Increased rigidity of haptic portion 30 may provide improved retention of lens 10 in a desired intracorneal location. Deformation of lens 10 allows its insertion into the cornea of a patient via a small (about 3 mm) incision. Corrugation of haptic portion 30 may cause lens 10 to behave like a spring when distorted, from a relaxed configuration to a flexed configuration.

[0029] Figure 2 is a sectional view of the anterior portion of an eye 100''' having a lens 10" disposed therein, according to another embodiment of the

invention. Lens 10" may comprise an optical portion 20. At least a portion of haptic portion 30 (e.g., Figure 1) may be missing or removed in lens 10". As an example, lens 10" may have either no haptic portion, or a vestigial haptic portion 30 (Figure 2). Lens 10" may be inserted within cornea 110 following formation of a corneal pocket, for example, as described with reference to Figure 1. Optical portion 20 in the embodiment of Figure 2 may have various features, characteristics, and elements in common with other embodiments of the present invention as described hereinabove. For example, an optical portion 20 for insertion in cornea 110 may have a doughnut-like configuration comprising a peripheral optic zone 22 having optical power and an inner non-optic zone 24 having no optical power.

[0030] Figure 3 schematically represents a series of steps involved in a method 400 for inserting a lens in the cornea of a patient, according to another embodiment of the invention, wherein step 402 may involve providing a lens. The lens, e.g., an intracorneal lens provided in step 402, may have features generally as described hereinabove. As an example, the lens provided in step 402 may include an optical portion having a peripheral optic zone having optical power, and an inner non-optic zone having no optical power. In some embodiments, the lens provided in step 402 may lack a haptic portion, e.g., the lens may consist essentially of an optical portion. The lens may be inserted in the cornea for correcting vision of the patient. The lens provided in step 402 may be adapted to be deformable in order to facilitate insertion of the lens in the cornea.

[0031] Step 404 may involve forming an incision in the cornea of the eye. Step 404 may involve forming a corneal flap or a corneal pocket. The formation of corneal flaps and corneal pockets are known in the art of eye surgery. As an example, a corneal flap may be formed using a laser. The laser may be used and guided under computer control, as is well known in the art. A corneal flap may be formed by methods similar to those used during LASIK (laser-assisted *in-situ* keratomileusis) procedures. A corneal pocket may be formed by

tunneling in the cornea, for example, using a microkeratome having an oscillating metal blade. A corneal-pocket keratome device was disclosed in US Patent No. 6,599,305, the disclosure of which is incorporated by reference herein in its entirety. In alternative embodiments, a corneal pocket may be formed by a laser. Alternatively, a corneal pocket may be formed manually by the surgeon using hand-held instruments. An exemplary corneal pocket 116 formed by an incision is depicted in cross-section in Figure 4.

[0032] Step 406 may involve inserting the lens in the cornea (see, for example, Figure 2). In alternative embodiments, step 406 may involve inserting the lens within a corneal pocket. Step 406 may further involve temporarily deforming the lens preparatory to introducing the lens into the eye. The lens may be deformed by rolling, folding, and the like. The lens of the invention may have prescribed memory characteristics that allow the lens to return to its original size and configuration after insertion in the eye, while retaining the optical characteristics of the optical portion. Corrugations of the haptic portion of the lens may facilitate maneuvering the lens during step 406 by providing rigidity to the lens and by allowing the surgeon to grasp the haptic portion by the corrugations. As described above, the lens may be made of a hydrophilic material which swells when hydrated. The lens may be inserted fully hydrated to elastically fit into a corneal pocket, or while at least partly dehydrated such that subsequent hydration helps secure the fit in the pocket.

[0033] Various configurations of corneal pockets may be employed in the present invention, such as those pockets 116 depicted in Figures 5A to 5I which are top views of the pockets 116 formed in the cornea 110. The various configurations are adapted to be used with lenses of various shapes and sizes. The corneal pockets 116 also are configured to facilitate the insertion of the lens and to minimize the size of the incision for improved post-surgical healing of the cornea.

[0034] The corneal pockets shown in Figures 5A to 5G and 5I include an arced portion 118 near a center of the pocket, in addition to a straight portion

120 adjacent to the arced portion 118. In Figure 5H, the corneal pocket includes a straight portion 122 extending across the entirety of the cornea.

[0035] In conjunction with the corneal pocket, a release area 124 (depicted in Figures 5D-5H as arced lines) may be optionally provided in the cornea 110 so as to provide a means of expansion and contraction when inserting and positioning the lens in the corneal pocket. The arcuate incision in combination with the pocket may also reduce the induced astigmatism Release areas 124 may comprise incisions made into the cornea 110. These arcuate incisions are made by the laser at the same time as the pocket being created, so that the patient may not need to come back to the surgeon to enhance its vision due to astigmatism.

[0036] As can be appreciated by those skilled in the art, the present invention may provide a method for correcting the vision of a patient with a refractive intracorneal lens that may be easily inserted into a corneal pocket. The intracorneal lens may be effectively positioned and held in place by the use of corrugated haptic region. A variety of corneal pocket configurations may be used accommodate various corneal lens shapes and sizes.

[0037] It should be understood, of course, that the foregoing relates to exemplary embodiments of the invention and that modifications may be made without departing from the spirit and scope of the invention as set forth in the following claims.

WE CLAIM:

1. A method for correcting vision of a patient, comprising:

providing a refractive intracorneal lens, wherein said intracorneal lens comprises an optical portion and a haptic portion, and wherein said haptic portion is corrugated;

forming a corneal pocket in an eye of said patient; and

inserting said intracorneal lens in said corneal pocket.

2. The method of Claim 1 wherein said step of inserting said corneal lens further comprises:

deforming said intracorneal lens from an extended configuration to a deformed configuration prior to inserting said intracorneal lens, and

releasing said intracorneal lens wherein it returns to said extended configuration after insertion into said corneal pocket.

3. The method of Claim 1 wherein said step of forming a corneal pocket further comprises forming said corneal pocket using a laser.

4. The method of Claim 1 said step of forming a corneal pocket further comprises forming said corneal pocket using a microkeratome.

5. The method of Claim 1 wherein the intracorneal lens is made of a hydrophilic material and is partially hydrated such that said lens swells after insertion in said corneal pocket.

6 The method of Claim 1 further comprising forming at least one release area in the cornea.

7. The method of Claim 1 wherein said step of forming a corneal

pocket further comprises forming a corneal pocket having an arc shaped portion and a straight portion.

8. The method of Claim 1 wherein said step of forming a corneal pocket comprises forming a corneal pocket having parallel straight portions.

9. A method for correcting vision of a patient, comprising:

providing a refractive lens having an optical portion and a haptic portion;

forming with a laser a corneal pocket in a cornea of the patient; and

inserting said lens in the corneal pocket.

10. The method of Claim 9 wherein said step of providing a refractive lens further comprises providing a refractive lens having an optical portion and a haptic portion which is at least partially opaque.

11. The method of Claim 10 wherein said step of providing a refractive lens further comprises providing a refractive lens having a haptic portion that is corrugated.

12. The method of Claim 9 wherein said step of inserting said lens further comprises:

deforming said lens from an extended configuration to a deformed configuration prior to inserting said lens, and

releasing said lens wherein it returns to said extended configuration after insertion into said corneal pocket.

13. The method of Claim 9 wherein the lens is comprised of a hydrophilic material that is partially hydrated such that the lens swells after

insertion in said corneal pocket.

14. The method of Claim 9 further comprising forming at least one release area in the cornea of said patient.

15. The method of Claim 14 wherein the step of forming at least one release area in said cornea further comprises forming an arc-shaped release area.

16. The method of Claim 9 wherein said step of forming a corneal pocket further comprises forming a corneal pocket having an arc-shaped portion and a straight portion.

17. The method of Claim 9 wherein said step of forming a corneal pocket comprises forming a corneal pocket having parallel straight portions.

18. A corneal pocket, comprising:
an arced portion; and
a straight portion adjacent the arced portion.

19. The corneal pocket of Claim 18 wherein said straight portion includes a straight portion extending radially away from said arced portion.

20. The corneal pocket of Claim 19 wherein said straight portion further comprises first and second straight portions extending radially from said arced portion and being disposed on opposite sides of said arced portion.

21. The corneal pocket of Claim 18 wherein said straight portion comprises parallel edges extending radially away from said arced portion.

22. The corneal pocket of Claim 18 wherein said straight portion comprises nonparallel edges extending away from said arced portion.

23. The corneal pocket of Claim 18 further comprising at least one release portion separated from the arced portion and said straight portion.

24. The corneal pocket of Claim 23 wherein said release portion comprises an arc shaped corneal incision.

25. The corneal pocket of Claim 28 wherein said corneal pocket is formed by a laser or by a microkeratome.

26. A corneal pocket in a cornea, comprising:
a straight portion extending across an entirety of the cornea.

27. The corneal pocket of Claim 26 further comprising at least one release portion separated from said straight portion.

28. The corneal pocket of Claim 27 wherein said release portion is an arc-shaped corneal incision.

29. The corneal pocket of Claim 26 wherein said corneal pocket is formed by a laser or by a microkeratome.

30. A method for correcting vision of a patient, comprising:
providing a refractive intracorneal lens, wherein said intracorneal lens comprises an optical portion;
forming a corneal pocket in an eye of said patient; and
inserting said intracorneal lens in said corneal pocket.

31. A method for correcting vision of a patient, comprising:

providing a refractive intracorneal lens, wherein said intracorneal lens comprises an optical portion and non optical portion;

forming a corneal pocket in an eye of said patient; and

inserting said intracorneal lens in said corneal pocket