Title: INJECTABLE IRIS FIXATED INTRAOCULAR LENSES

Abstract: A refractive anterior chamber iris fixated intraocular lens including an optic portion having an outer peripheral edge and two or more but preferably two, three or four balanced haptic elements. Each haptic element is manufactured to have an inner portion and an outer free end portion for supporting the optic portion in a patient's eye. The inner portion of each haptic element is preferably permanently connected to the outer peripheral edge of the optic portion. Each haptic element also includes an aperture through which a fixation clamp is attached to or which a fixation clip is connected.
INJECTABLE IRIS FIXATED
INTRAOCULAR LENSES

FIELD OF THE INVENTION

The present invention relates to intraocular lenses (IOLs) and a method for making and using the same. More particularly, the present invention relates to anterior chamber iris fixated IOLs designed primarily for refractive correction in phakic eyes where the eye’s natural lens remains intact.

BACKGROUND OF THE INVENTION

Visual acuity deficiencies such as myopia (nearsightedness), hyperopia (farsightedness), presbyopia (age-related farsightedness), aphakia (absence of the crystalline lens of the eye) and astigmatism (irregular conformation of the cornea of the eye) are typically corrected through the use of refractive lenses such as spectacles or contact lenses. Although these types of lenses are effective in correcting a wearer’s eyesight, many wearers consider the lenses inconvenient. The lenses must be located, worn at certain times, removed periodically and may be lost or misplaced. The lenses may also be dangerous or cumbersome if the wearer participates in athletic activities or suffers an impact in an area near the eyes.
The use of surgically implanted anterior chamber IOLs as a permanent form of refractive correction has been gaining in popularity. IOL implants have been used for years in the anterior or posterior chamber of aphakic eyes as replacements for diseased natural crystalline lenses that have been surgically removed from the eyes. Many different IOL designs have been developed over past years and proven successful for use in aphakic eyes. The successful IOL designs to date primarily include an optic portion with supports therefor, called haptics, connected to and surrounding at least part of the optic portion. The haptic portions of an IOL are designed to support the optic portion of the IOL in the lens capsule, anterior chamber or posterior chamber of an eye once implanted.

Commercially successful IOLs have been made from a variety of biocompatible materials, ranging from more rigid materials such as polymethylmethacrylate (PMMA) to softer, more flexible materials capable of being folded or compressed such as silicones, certain acrylcs, and hydrogels. Haptic portions of the IOLs have been formed separately from the optic portion and later connected thereto through processes such as heat, physical staking and/or chemical bonding. Haptics have also been formed as an integral part of the optic portion in what is commonly referred to as "single-piece" IOLs.

Softer, more flexible IOLs have gained in popularity in recent years due to their ability to be compressed, folded, rolled or otherwise deformed.
Such softer IOLs may be deformed prior to insertion thereof through an incision in the cornea of an eye. Following insertion of the IOL in an eye, the IOL returns to its original pre-deformed shape due to the memory characteristics of the soft material. Softer, more flexible IOLs as just described may be implanted into an eye through an incision that is much smaller, i.e., 2.8 to 3.2 mm, than that necessary for more rigid IOLs, i.e., 4.8 to 6.0 mm. A larger incision is necessary for more rigid IOLs because the lens must be inserted through an incision in the cornea slightly larger than that of the diameter of the inflexible IOL optic portion. Accordingly, more rigid IOLs have become less popular in the market since larger incisions have been found to be associated with an increased incidence of postoperative complications, such as induced astigmatism.

After IOL implantation, both softer and more rigid IOLs positioned within the angle of the anterior chamber of the eye are subject to compressive forces exerted on the outer edges thereof, which typically occur when an individual squints or rubs the eye. Such compressive forces on angle positioned IOLs in either aphakic or phakic eyes may result in tissue damage, decenteration of the IOL and/or distortion of the visual image. Compressive forces exerted on an angle positioned IOL may also tend to cause movement of the IOL haptics and axial displacement of the IOL along the optical axis of an eye. Haptic movement and broad haptic contact in the angle of the anterior chamber of an eye has the potential to
cause damage to delicate structures within the eye such as the peripheral corneal endothelium, the trabecular meshwork and/or the iris. Movement of an IOL along the optical axis of an eye has the potential to cause the IOL to contact and damage the delicate corneal endothelial cell layer of the eye. Also, angle positioned IOLs of current designs, whether formed of either softer or more rigid materials, tend to deflect along the optical axis of an eye when the haptics are compressed. IOL manufacturers provide a wide range of IOL sizes to more precisely fit IOLs to each particular patient’s eye size. Providing a wide range of IOL sizes is an attempt to minimize the potential for haptic compression and the associated axial displacement of the IOL optic along the optical axis of an eye.

Because of the noted shortcomings of current IOL designs, there is a need for aphakic and phakic anterior chamber IOLs designed to eliminate haptic contact and movement in the angle of the anterior chamber and eliminate axial displacement of the IOL optic portion along the optical axis of the eye when compressive forces are exerted against the outer edges thereof. By eliminating an IOL’s haptic and optic movement within the angle and anterior chamber respectively, more certain refractive correction may be achieved and the risk of delicate tissue damage may be reduced.
SUMMARY OF THE INVENTION

An injectable anterior chamber iris fixated intraocular lens (IOL) made in accordance with the present invention has an optic portion with an outer peripheral edge and two or more but preferably two, three or four haptic elements for supporting the optic portion in a patient’s eye. Two, three or four haptic elements are preferred in the present invention to provide a balance between IOL stability and minimized points of fixation on the iris. A lens having two haptic elements is balanced or stabilized by having one haptic element formed on one edge of the optic portion and the second haptic element formed on an opposite edge of the optic portion. A lens having three haptic elements is balanced or stabilized preferably by having two spaced haptic elements formed on one edge of the optic portion and the third haptic element formed on an opposite edge of the optic portion for ease of passage through an inserter. Alternatively, a lens having three haptic elements may be balanced or stabilized by having each of the three haptic elements equally spaced around the periphery of the optic portion. A lens having four haptic elements is preferably balanced or stabilized by having two spaced haptic elements formed on one edge of the optic portion and two spaced haptic elements formed on an opposite edge of the optic portion for ease of passage through an inserter. Alternatively, a lens having four haptic elements may be balanced or stabilized by having each of the four haptic elements equally spaced around the periphery of
the optic portion. Each of the haptic elements on the optic portion is preferably of arcuate elongated or plate-like form designed to allow the IOL to be easily folded, rolled and/or compressed for implantation thereof within an eye through a relatively small incision preferably using an inserter. Each haptic element is manufactured with an attachment aperture preferably centered in an outer free end portion thereof for ease in securely attaching the same on the anterior surface of the iris of an eye. Each of the haptic elements also has an inner portion opposite the outer free end portion. The inner portion of the haptic element is preferably connected to or integrally formed with the outer peripheral edge of the optic portion of the IOL. Each haptic element includes a fixation clamp fitted through the attachment aperture formed in the outer free end portion or a fixation clip extending from the attachment aperture. The fixation clamps and fixation clips are designed to secure the IOL within the anterior chamber of an eye by securely engaging the relatively non-mobile outer peripheral edge of the iris of an eye.

Accordingly, it is an object of the present invention to provide intraocular lenses for use in aphakic and phakic eyes.

Another object of the present invention is to provide intraocular lenses for use in aphakic and phakic eyes, which eliminate anterior chamber angle contact.
Another object of the present invention is to provide intraocular lenses for use in aphakic and phakic eyes, which minimize axial displacement of the optic portions of the lenses along the optical axis of the eyes.

Another object of the present invention is to provide intraocular lenses that allow for increased ease of implantation thereof.

Another object of the present invention is to provide intraocular lenses that allow for implantation using an inserter.

Another object of the present invention is to provide intraocular lenses for use in aphakic and phakic eyes, which minimize damage to tissues in the interior of the eyes.

Still another object of the present invention is to provide intraocular lenses, which are resistant to decentration within the eyes.

These and other objectives and advantages of the present invention, some of which are specifically described and others that are not, will become apparent from the detailed description, drawings and claims that follow, wherein like features are designated by like numerals.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a schematic representation of the interior of a phakic human eye including a natural lens and a refractive IOL implanted in the anterior chamber of the eye;
FIGURE 2 is a plan view of an IOL with two haptics made in accordance with the present invention;

FIGURE 3 is a side view of the IOL of Figure 2;

FIGURE 4 is a plan view of an IOL with three haptics made in accordance with the present invention;

FIGURE 5 is a side view of the IOL of Figure 4;

FIGURE 6 is a plan view of an IOL with four haptics made in accordance with the present invention;

FIGURE 7 is a side view of the IOL of Figure 6;

FIGURE 8 is an enlarged plan view of the fixation clamp of the IOL of Figure 2;

FIGURE 9 is an enlarged side view of the fixation clamp of Figure 8;

FIGURE 10 is a side cross-sectional view of the haptic element of Figure 5 taken along line 10-10;

FIGURE 11 is a perspective view of a surgical forceps;

FIGURE 12 is a perspective view of a surgical retractor;

FIGURE 13 is a plan view of an IOL with two haptics made in accordance with the present invention;

FIGURE 14 is a plan view of an IOL with three haptics made in accordance with the present invention; and
FIGURE 15 is a plan view of an IOL with four haptics made in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 illustrates a simplified diagram of an eye 10 showing landmark structures relevant to the implantation of an intraocular lens of the present invention. Eye 10 includes an optically clear cornea 12 and an iris 14 with a relatively non-mobile peripheral edge 40. A natural crystalline lens 16 and a retina 18 are located behind iris 14 of eye 10. Eye 10 also includes anterior chamber 6 with angle 7 located in front of iris 14 and a posterior chamber 8 located between iris 14 and natural lens 16. An IOL 26, such as that of the present invention, is preferably implanted in anterior chamber 6 to correct refractive errors while healthy natural lens 16 remains in place (phakic application). However, IOL 26 likewise may be implanted in anterior chamber 6 of aphakic eyes where the natural lens 16 has been removed. Eye 10 also includes an optical axis OA-OA that is an imaginary line that passes through the optical center 20 of anterior surface 22 and posterior surface 24 of lens 16. Optical axis OA-OA in the human eye 10 is generally perpendicular to a portion of cornea 12, natural lens 16 and retina 18.

The IOL of the present invention, as best illustrated in Figures 2, 4, 6 and 13 through 15 identified by reference numeral 26, is designed for
implantation in anterior chamber 6 of a patient’s aphakic or phakic eye 10. IOL 26 has an optic portion 28 with an outer peripheral edge 30. Preferably integrally formed on peripheral edge 30 of optic portion 28 are two or more but preferably two, three or four separate arcuate elongated or plate-like haptic elements 32. Each haptic element 32 is manufactured to have an inner portion 34 and an outer free end portion 36. Inner portions 34 of haptic elements 32 are preferably integrally formed with and permanently connected to outer peripheral edge 30 of optic portion 28. Alternatively however, inner portions 34 of haptic elements 32 may be attached to optic portion 28 by staking, chemical polymerization or other methods known to those skilled in the art. Each haptic element 32 also includes at outer free end portion 36, a fixation clamp 38 or alternatively a fixation clip 39 designed to engage relatively non-mobile outer peripheral edge 40 of iris 14 in anterior chamber 6. In accordance with the present invention, IOL 26 is held in proper position in anterior chamber 6 through constant compressive forces exerted by fixation clamps 38 or fixation clips 39 on relatively non-mobile outer peripheral edge 40 of iris 14. Iris fixation of IOL 26 is desired to avoid haptic element 32 contact and damage to delicate tissues within angle 7 of eye 10.

The required functional characteristics of haptic elements 32 to maintain adequate compressive forces on iris 14, are achieved through the
unique design thereof. IOL 26 has arcuate elongated haptic elements 32 as illustrated in Figures 2, 6, 13 and 15 or plate-like haptic elements 32 as illustrated in Figures 4 and 14 each formed with a suitably sized attachment aperture 44 therethrough. Fixation clamps 38, which are positioned through suitably sized attachment aperture 44 either before or after IOL 26 implantation within an eye 10, include two interlocking smooth, serrated or toothed edges 80 as best illustrated in Figures 2, 4, 6, 8 and 9. Smooth, serrated or toothed edges 80 of fixation clamps 38 may be separated or spread apart along plane 48-48 by inserting tips 92 of surgical retractor 90, illustrated in Figure 12, within interior edge 83. Interior edge 83 defines center aperture 50 of fixation clamp 38. By then opening or spreading apart tips 92 of retractor 90 with a force moving handles 94 into contact with one another, smooth, serrated or toothed edges 80 are opened. Alternatively, smooth, serrated or toothed edges 80 of fixation clamps 38 may be separated or spread apart along plane 46-46 in a shearing mode using similar surgical tools and techniques. Likewise smooth, serrated or toothed edges 80 of fixation clamps 38 may be separated or spread apart by placing spaced tips 98 of surgical forceps 96 as illustrated in Figure 11 on the outer edge 81 of fixation clamp 38. A compressive force is then applied to handles 95 of surgical forceps 96 in an attempt to bring spaced tips 98 in closer proximity to one another. The compressive force applied to outer edge 81 of fixation
clamp 38 by spaced tips 98, serve to open smooth, serrated or toothed edges 80. Once smooth, serrated or toothed edges 80 are separated or opened, the same may be placed on or in contact with the relatively non-mobile peripheral edge 40 of iris 14 and allowed to return to their original closed position. In closing, smooth, serrated or toothed edges 80 pinch or pierce relatively non-mobile peripheral edge 40 of iris 14 for reliable secure attachment thereto. Preferably smooth, serrated or toothed edges 80 of fixation clamps 38 are oriented in a plane perpendicular to the optical axis OA—OA of eye 10 when secured to iris 14 for better tolerance by iris 14 and easier surgical handling during the clamping process. Because fixation clamps 38 are relatively small in size, IOL 26 may be implanted in an eye 10 through a relatively small incision, such as less than 4.0 mm, using an inserter without tearing off fixation clamps 38. However, fixation clamps 38 may optionally be placed through attachment apertures 44 after implantation of IOL 26.

As an alternative to utilizing fixation clamps 38 for stabilization of IOL 26, fixation clips 39 as illustrated in Figures 13 through 15 may be utilized. Fixation clips 39 are formed on outer free end portions 36 of haptic elements 32 and extend from attachment aperture 44 to free edge 100. Fixation clips 39 have two smooth, serrated or toothed edges 102 for attachment to relatively non-mobile peripheral edge 40 of iris 14. Smooth, serrated or toothed edges 102 of fixation clips 39 may be separated or
spread apart along plane 48-48 by inserting tips 92 of surgical retractor 90, illustrated in Figure 12, within attachment aperture 44. By then opening or spreading apart tips 92 of retractor 90 with a force moving handles 94 into contact with one another, smooth, serrated or toothed edges 102 are opened. Alternatively, smooth, serrated or toothed edges 102 of fixation clips 39 may be separated or spread apart along plane 46-46 in a shearing mode using similar surgical tools and techniques. Likewise smooth, serrated or toothed edges 102 of fixation clips 39 may be separated or spread apart by placing spaced tips 98 of surgical forceps 96 as illustrated in Figure 11 on free edge 100. Spaced tips 98 are positioned so that attachment aperture 44 lies there between. Compressive force is then applied to handles 95 of surgical forceps 96 in an attempt to bring spaced tips 98 in closer proximity to one another. The compressive force applied to free edge 100 of fixation clip 39 by spaced tips 98 serves to open smooth, serrated or toothed edges 102. Once smooth, serrated or toothed edges 102 are separated, the same may be placed on or in contact with the relatively non-mobile peripheral edge 40 of iris 14 and allowed to return to their original closed position. In closing, smooth, serrated or toothed edges 102 pinch or pierce relatively non-mobile peripheral edge 40 of iris 14 for reliable secure attachment thereto. Preferably smooth, serrated or toothed edges 102 of fixation clips 39 are oriented in a plane perpendicular to the optical axis OA—OA of eye 10 when secured to iris 14 for better tolerance by iris 14 and easier surgical handling during the fixation process. Because
fixation clips 39 are formed in haptic elements 32, IOL 26 may be easily
implanted in an eye 10 through a relatively small incision, such as less than
4.0 mm, using an inserter.

The subject IOL 26 is preferably produced having an optic portion
28 approximately 4.5 to 9.0 mm, but preferably approximately 5.0 to 6.0
mm and most preferably 5.5 mm in diameter and approximately 0.5 mm to
1.0 mm, but preferably approximately 0.6 to 0.8 mm and most preferably
0.7 mm in thickness at peripheral edge 30. Haptic elements 32 extend in a
substantially arcuate elongated or plate-like configuration and will increase
or decrease in length depending upon the diameter of optic portion 28. As
the diameter of optic portion 28 increases, the length of haptic elements 32
decrease. Likewise, as the diameter of optic portion 28 decreases, the
length of haptic elements 32 increase. In general, haptic elements 32 are
formed to be approximately 2.6 to 6.0 mm, but preferably approximately 3.4
to 5.0 mm and most preferably approximately 4.2 mm in length measuring
from the center of inner portion 34 to the center tip 82 of outer free end
portion 36. The overall diameter of IOL 26 is approximately 6.0 to 10.0
mm, but preferably approximately 7.0 to 9.0 mm, and most preferably
approximately 8.0 mm. Haptic elements 32 are preferably
vaulted as illustrated in Figures 3, 5 and 7 so optic portion 28 lies in a
different but parallel plane to that of center tips 82 of haptic elements 32.
Such vaulting of IOL 26 allows appropriate fixation thereof to relatively non-
mobile peripheral edge 40 of iris 14 while avoiding contact between the
posterior surface 76 of optic portion 28 and mobile portions 9 of iris 14. A vault of approximately 0.5 to 1.0 mm measuring between posterior surface 76 of optic portion 28 and center tips 82 of haptic elements 32 is preferred for central placement of IOL 26 between iris 14 and corneal endothelium 4. Arcuate elongated haptic element 32 as illustrated in Figures 2 and 6 is approximately 0.5 to 2.5 mm, but preferably approximately 1.0 to 2.0 mm and most preferably 1.6 mm in length; approximately 0.2 to 1.0 mm, but preferably approximately 0.3 to 0.7 mm and most preferably approximately 0.46 mm in thickness in plane 46-46 and approximately 0.5 to 2.0 mm, but preferably approximately 0.75 to 1.75 mm and most preferably approximately 0.75 to 1.50 in width in plane 48-48. Arcuate plate-like haptic element 32 as illustrated in Figure 4 is approximately 0.5 to 2.5 mm, but preferably approximately 1.0 to 2.0 mm and most preferably 1.6 mm in length; approximately 0.2 to 1.0 mm, but preferably approximately 0.3 to 0.7 mm and most preferably approximately 0.46 mm in thickness in plane 46-46 and varies in width in plane 48-48 from approximately 0.1 to 3.0 mm, but preferably approximately 0.2 to 2.5 mm and most preferably approximately 0.2 to 2.0 mm. Fixation clamps 38 are preferably manufactured in an overall circular ring-like form with an exterior diameter of approximately 0.2 to 1.0 mm, but preferably approximately 0.4 to 0.6 mm and most preferably approximately 0.5 mm, and an interior diameter of approximately 0.05 to
0.5 mm, but preferably approximately 0.1 to 0.4 mm and most preferably approximately 0.3 mm. The cross-section diameter of fixation clamps 38 is preferably approximately 0.1 to 0.3 mm but most preferably approximately 0.2 mm throughout its length to ensure adequate strength. The diameter of attachment apertures 44 may be the same or differ and is preferably approximately 0.125 to 0.5 mm but most preferably approximately 0.225 mm. The length of fixation clips may be the same or differ and is preferably approximately 0.1 to 0.3 mm but most preferably approximately 0.2 mm to ensure adequate strength.

The desired functional characteristics of IOL 26 may likewise be achieved or enhanced by incorporating a stiffening element 60, in the shape of a ribbon, in one or more haptic elements 32, as illustrated in Figure 10. Stiffening element 60 may be positioned in haptic element 32 so that flat face 62 is oriented parallel to the dimension 48-48. Stiffening element 60 functions in a manner similar to that of an I-beam in construction to prevent movement of IOL 26 along optical axis OA-OA.

Stiffening element 60 is formed of a less flexible material than that of IOL 26. Suitable materials for stiffening element 60 include but are not limited to polyimides, polyolefins, high-density polyethylenes, polyesters, nylons, metals or any biocompatible material with suitable stiffening characteristics. Stiffening element 60 may be used in conjunction with
haptic elements 32 described above or in cases where a thinner haptic
design is desired while still achieving the desired functional characteristics.

Suitable materials for the production of the subject IOL 26 include
but are not limited to foldable or compressible materials, such as but not
limited to silicone polymers, hydrocarbon and fluorocarbon polymers,
hydrogels, soft acrylic polymers, polyesters, polyamides, polyurethane,
silicone polymers with hydrophilic monomer units, fluorine-containing
polysiloxane elastomers and combinations thereof. It is preferred that IOL
26 be of a bicomposite material design whereby the optic 28 and possibly a
portion of haptic elements 32 are manufactured from a compressible or
foldable material such as but not limited to a silicone or hydrogel material
such as but not limited to 2-hydroxyethyl methacrylate (HEMA) and 6-
hydroxyhexyl methacrylate (HOHEXMA), i.e., poly(HEMA-co-HOHEXMA).
The haptic elements 32 or at least a portion thereof, including fixation clips
39 if formed therein, are manufactured from a relatively more rigid material
such as but not limited to a relatively more rigid hydrogel,
polymethylmethacrylate (PMMA) or a polyimide but preferably PMMA due
to its ready availability. Another option, as illustrated in Figures 4 and 14,
IOL 26 may be manufactured as described in U.S. Patent Nos. 5,217,491
and 5,326,506 incorporated herein in their entirety by reference. In such a
case, optic portion 28 and at least a portion of haptic elements 32 are
manufactured from a foldable or compressible material such as but not
limited to silicone polymers, hydrocarbon and fluorocarbon polymers, hydrogels, soft acrylic polymers, polyesters, polyamides, polyurethane, silicone polymers with hydrophilic monomer units, fluorine-containing polysiloxane elastomers and combinations thereof. The remaining outer free end portions 36 of haptic elements 32, including fixation clips 39 if formed therein, are manufactured from a relatively more rigid material such as but not limited to a relatively more rigid hydrogel, PMMA or a polyimide. For the manufacture of fixation clamps 38, a relatively more rigid hydrogel, PMMA, polyimide, suitably strong composite material or suitably metal such as but not limited to surgical steel or titanium is preferred. Poly(HEMA-co-HOHEXMA) is the preferred material for the manufacture of the optic portion 28 of IOL 26 due to its equilibrium water content of approximately 18 percent by weight, and high refractive index of approximately 1.474, which is greater than that of the aqueous humor of the eye, i.e., 1.33. A high refractive index is a desirable feature in the production of IOLs to impart high optical power with a minimum of optic thickness. By using a material with a high refractive index, visual acuity deficiencies may be corrected using a thinner IOL. A thin IOL, such as that of IOL 26, is particularly desirable in phakic applications to minimize potentially harmful contact between the IOL 26 and the iris 14 and/or the corneal endothelium 4. Poly(HEMA-co-HOHEXMA) is also a desirable material in the production of IOLs 26 due to its mechanical strength, which
is suitable to withstand considerable physical manipulation. Poly(HEMA-co-HOHEXMA) also has desirable memory properties suitable for IOL use. IOLs manufactured from a material possessing good memory properties such as those of poly(HEMA-co-HOHEXMA) unfold in a controlled manner in an eye, rather than explosively, to its predetermined shape. Explosive unfolding of IOLs is undesirable due to potential damage to delicate tissues within the eye. Poly(HEMA-co-HOHEXMA) also has dimensional stability in the eye.

Although the teachings of the present invention are preferably applied to soft or foldable IOLs formed of a foldable or compressible material, the same may also be applied to harder, less flexible lenses formed of one or more relatively rigid materials such as but not limited to polymethylmethacrylate (PMMA) if implantation thereof through a relatively small incision or through an inserter such as that described in U.S. Patent Numbers 5,873,879, 5,860,986 and 5,810,834, incorporated herein in their entirety by reference, is not desired.

Optic portion 28 of IOL can be a positive powered lens from 0 to approximately +40 diopters or a negative powered lens from 0 to approximately −30 diopters. Optic portion 28 may be biconvex, plano-convex, plano-concave, biconcave or concave-convex (meniscus), depending upon the power required to achieve the appropriate central and peripheral thickness for efficient handling.
Optic portion 28 of the subject IOL 26 may optionally be formed with a glare reduction zone 56 of approximately 0.25 to 0.75 mm but more preferably approximately 0.3 to 0.6 mm and most preferably 0.5 mm in width adjacent outer peripheral edge 30 for reducing glare when outer peripheral edge 30 of IOL 26 is struck by light entering eye 10 during high light or at other times when pupil 58 is dilated. Glare reduction zone 56 is typically fabricated of the same material as optic portion 28, but may be opaque, roughened, textured, colored or patterned in a conventional manner to block or diffuse light in plane with optical axis OA-OA.

The subject IOL 26 and separate fixation clamps 38 if desired, may be molded using removable molds as known to those skilled in the art. Alternatively, IOL 26 and separate fixation clamps 38 if desired, may be manufactured by first producing discs from one or more materials of choice as described in U.S. Patent Nos. 5,217,491 and 5,326,506 each incorporated herein in its entirety by reference. IOL 26, and separate fixation clamps 38 if desired, may then be machined from the material discs in a conventional manner. Once machined, IOL 26 with fixation clips 39 or IOL 26 and separate fixation clamps 38 may be polished, cleaned, optionally assembled if using fixation clamps 38, sterilized and packaged by a conventional method known to those skilled in the art.

The subject IOL 26 is used in eye 10 by creating an incision in cornea 12, inserting IOL 26 in anterior chamber 6 preferably using an
inserter if desired, extending fixation clamps 38 through attachment apertures 44 if not already assembled, opening smooth, serrated or toothed edges 80 with a surgical instrument, allowing smooth, serrated or toothed edges 80 to close and pinch and/or pierce relatively non-mobile peripheral edge 40 and closing the incision in accordance with methods known to those skilled in the art.

Alternatively, the subject IOL 26 is used in eye 10 by creating an incision in cornea 12, inserting IOL 26 in anterior chamber 6 preferably using an inserter if desired, opening smooth, serrated or toothed edges 102 with a surgical instrument, allowing smooth, serrated or toothed edges 102 to close and pinch and/or pierce relatively non-mobile peripheral edge 40 and closing the incision in accordance with methods known to those skilled in the art.

IOL 26 of the present invention provides for a refractive lens suitable for use in anterior chamber 6 of eye 10. IOL 26 has haptic elements 32 with functional characteristics that minimize or eliminate axial displacement along optical axis OA-OA of eye 10 and lens contact in the angle 7 of anterior chamber 6 thereby preventing damage to delicate eye tissues such as the trabecular meshwork 17 and the corneal endothelium 4. IOL 26 designed as described herein is also advantageous because one or a few lens sizes suitably fit eyes 10 of most sizes since the position of attachment to iris 14 may be varied slightly. By providing a "universal" lens such as
that of the present invention, clinical risks to patients due to improperly sized lenses in angle 7 are minimized. Likewise, manufacturers’ need to produce IOLs of many sizes to fit eyes of many sizes is eliminated, thus reducing production and inventory costs associated therewith.

Ophthalmologists also benefit from subject IOL 26 in that time is saved by eliminating the need to determine each patient’s particular eye size and costs associated with maintaining large inventories of varying sized lenses.

While there is shown and described herein certain specific embodiments of the present invention, it will be manifest to those skilled in the art that various modifications may be made without departing from the spirit and scope of the underlying inventive concept and that the same is not limited to the particular forms herein shown and described except insofar as indicated by the scope of the appended claims.
We claim:

1. An anterior chamber iris fixated intraocular lens to be implanted within an eye generally perpendicular to the eye's optical axis through a small incision comprising:
   - an outer peripheral edge defining an optic portion,
   - two or more haptic elements permanently connected to the outer peripheral edge, and
   - a fixation clip in direct contact with an aperture in each said haptic elements or a fixation clamp for attachment through an aperture in each haptic element, whereby the fixation clamp may be attached through the aperture in each haptic element following implantation of the lens or are sized to allow for implantation of the lens while assembled through the aperture.

2. The intraocular lens of claim 1 wherein the haptic elements and the optic portion are both formed of a foldable or compressible material.

3. The intraocular lens of claim 1 wherein the haptic elements and the optic portion are formed from differing materials.
4. The intraocular lens of claim 1 wherein the haptic elements, the fixation clamps or fixation clips and the optic portion are formed from the same or differing materials.

5. The intraocular lens of claim 1 wherein the fixation clamps or fixation clips are made from a material relatively more rigid than that of the optic portion.

6. The intraocular lens of claim 1 wherein the fixation clamps or fixation clips are formed from a material relatively more rigid than that of the haptic elements.

7. The intraocular lens of claim 1 wherein said lens is formed from a material selected from the group consisting of silicone polymers, hydrocarbon and fluorocarbon polymers, hydrogels, soft acrylic polymers, polyester, polyamides, polyurethane, silicone polymers with hydrophilic monomer units, fluorine-containing polysiloxane elastomers and combinations thereof.

8. The intraocular lens of claim 1 wherein said lens optic portion and haptics are formed from a hydrogel material and said iris fixation clamps or fixation clips are formed from polymethylmethacrylate.
9. The intraocular lens of claim 1 wherein said lens is formed from a hydrogel material which is 18 percent by weight water.

10. The intraocular lens of claim 1 wherein said lens is formed from poly(HEMA-co-HOHEXMA) with the exception of the fixation clamps or fixation clips formed from polymethylmethacrylate.

11. The intraocular lens of claim 1 wherein said lens and possibly a portion of each of said haptics are formed from one or more materials selected from the group consisting of silicone polymers, hydrocarbon and fluorocarbon polymers, hydrogels, soft acrylic polymers, polyester, polyamides, polyurethane, silicone polymers with hydrophilic monomer units, fluorine-containing polysiloxane elastomers and combinations thereof, at least a portion of said haptics are formed from the same or different materials selected from the group consisting of relatively rigid hydrogels, polymethylmethacrylate and polyimides and said fixation clamps are formed from a material selected from the group consisting of relatively rigid hydrogels, polymethylmethacrylate polyimides, composite materials and metals.

12. The intraocular lens of claim 1 wherein said lens optic portion is formed from a material having a refractive index above 1.33.
13. The intraocular lens of claim 1 wherein said lens optic portion is formed from an acrylic material.

14. The intraocular lens of claim 1 wherein said lens optic portion is formed from a silicone material.

15. The intraocular lens of claim 1 wherein a glare reduction zone is formed adjacent to the outer peripheral edge of the optic portion.

16. The intraocular lens of claim 1 wherein one or more of said haptic elements includes a stiffening element having a greater resistance to bending in a plane generally perpendicular to an eye's optical axis than in a plane generally parallel to the eye’s optical axis.

17. The intraocular lens of claim 1 wherein the haptic element includes a stiffening element formed from a material selected from the group consisting of polyimide, polyolefin, high-density polyester, nylon and metal.

18. The intraocular lens of claim 1 wherein the fixation clamp or fixation clip is manufactured from a relatively rigid hydrogel, polymethylmethacrylate or a polyimide.
19. A method of manufacturing the intraocular lens of claim 1 comprising:
   forming a first disk from one or more suitable materials,
   optionally forming one or more additional disks from one or more suitable materials, machining said lens from said first disk, and
   optionally machining one or more fixation clamps from said additional disks.

20. A method of manufacturing the intraocular lens of claim 1 comprising:
   molding said lens and optionally said fixation clamps of the same or different suitable materials in removable molds, and
   removing said lens and optionally said fixation clamps from said molds.

21. A method of using the intraocular lens of claim 1 comprising:
   creating an incision in a cornea of an eye,
   inserting said intraocular lens in an anterior chamber of said eye,
   and
   securing said intraocular lens within the anterior chamber.
22. A method of using the intraocular lens of claim 1 comprising:
creating an incision in a cornea of an eye,
inserting said intraocular lens in an anterior chamber of said eye
using an inserter, and
securing said intraocular lens within the anterior chamber using
fixation clamps.

23. A method of using the intraocular lens of claim 1 comprising:
creating an incision in a cornea of an eye,
inserting said intraocular lens into an anterior chamber of said eye
using an inserter,
extending a fixation clamp through said aperture in each haptic
element, and
securing said lens within the anterior chamber using said fixation
clamps.

24. A method of using the intraocular lens of claim 1 comprising:
creating an incision in a cornea of an eye,
inserting said lens with fixation clamps attached thereto into an
anterior chamber of said eye using an inserter, and
securing said lens within the anterior chamber using said fixation
clamps.
25. A method of using the intraocular lens of claim 1 comprising:
creating an incision in a cornea of an eye,
inserting said intraocular lens into an anterior chamber of said eye
using an inserter, and
securing said intraocular lens within the anterior chamber using said
fixation clips.