

LENS DELIVERY SYSTEM CARTRIDGE

This application claims priority under 35 USC § 119 to U.S. provisional application Serial No. 61/026,805, filed on February 7, 2008.

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This invention relates to intraocular lenses (IOLs) and more particularly to cartridges for use with devices used to inject IOLs into an eye.

Background of the Invention

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The human eye in its simplest terms functions to provide vision by transmitting and refracting light through a clear outer portion called the cornea, and further focusing the image by way of the lens onto the retina at the back of the eye. The quality of the focused image depends on many factors including the size, shape and length of the eye, and the shape and transparency of the cornea and lens.

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When trauma, age or disease cause the lens to become less transparent, vision deteriorates because of the diminished light which can be transmitted to the retina. This deficiency in the lens of the eye is medically known as a cataract. The treatment for this condition is surgical removal of the lens and implantation of an artificial lens or IOL.

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While early IOLs were made from hard plastic, such as polymethylmethacrylate (PMMA), soft, foldable IOLs made from silicone, soft acrylics and hydrogels have become increasingly popular because of the ability to fold or roll these soft lenses and insert them through a smaller incision. Several methods of rolling or folding the lenses are used. One popular method is an injector cartridge that folds the lenses and provides a relatively small diameter lumen through which the lens may be pushed into the eye, usually by a soft tip plunger. The most commonly used injector cartridge design is illustrated in U.S. Patent No. 4,681,102 (Bartell), and includes a split, longitudinally hinged cartridge. Similar designs are illustrated in U.S. Patent Nos. 5,494,484 and

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5,499,987 (Feingold) and 5,616,148 and 5,620,450 (Eagles, et al.). In an attempt to avoid the claims of U.S. Patent No. 4,681,102, several solid cartridges have been investigated, see for example U.S. Patent No. 5,275,604 (Rheinish, et al.) and 5,653,715 (Reich, et al.).

5 These prior art devices were intended to inject an IOL into the posterior chamber of an aphakic eye through a relatively large (approximately 3.0 mm or larger) incision. Surgical techniques and IOLs have been developed that allow the entire surgical procedure to be performed through much smaller incisions, 2.4 mm and smaller. Such small incisions require that the IOL be compressed very tightly, and that the nozzle used
10 on the injection cartridge have very thin walls. The combination of a tightly compressed lens traveling through a very thin walled nozzle often results in the nozzle splitting during use. In addition, although the surgeon may make the incision a specific size, insertion and manipulation of the cartridge and the lens frequently stresses the incision walls, increasing the size of the incision as well as causing trauma to the surrounding tissue.

15 Accordingly, a need continues to exist for an intraocular lens injection cartridge capable of injection an IOL through a relatively small incision with reduced trauma to the tissue.

Brief Summary of the Invention

Embodiment of the present invention improves upon the prior art by providing a cartridge for an IOL delivery system that has a injector tip geometry designed to reduce applied stresses on the incision during insertion of the cartridge tip through the wound to reduce the likelihood of tearing or overstretching the wound during cartridge tip insertion and residence time in the wound while the lens is being delivered into the eye.

Accordingly an embodiment of the present invention seeks to provide a cartridge for a lens delivery system that has an injector tip geometry designed to reduce stresses on the wound incision.

A further embodiment of the present invention seeks to provide a cartridge for a lens delivery system that reduces post insertion wound trauma.

According to an aspect of the present invention, there is provided an intraocular lens delivery system cartridge, comprising: a body, and a tubular nozzle connected to the body and projecting distally from the body, the nozzle having a modified elliptical cross-section with a blend radius radii, the modified elliptical cross-section having a shape defined by: a portion of a decentered ellipse disposed in the first quadrant and the second quadrant of a Cartesian coordinate system, the portion of the decentered ellipse defined as a first curve; and a second curve defined as a mirror image of the first curve mirrored about the abscissa axis of the Cartesian coordinate system, the first curve and the second curve forming inflection points at locations where the first curve and the second curve intersect the abscissa axis of the Cartesian coordinate system; and the blend radii being formed at opposing ends of the elliptical shape proximate the inflection points, each blend radius defined as a portion of a circle joining the first curve and the second curve that is tangent to both the first curve and the second curve and that has a 90 degree tangent line at a point along the abscissa axis crossed by the blend radius wherein the blend radius is calculated from a desired incision size.

Other objectives, features and advantages of the present invention will become apparent with reference to the drawings, and the following description of the drawings and claims.

Brief Description of the Drawings

Figure 1 is a graph comparing the arc length for a circle, an ellipse and a straight line;

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Figure 2 is a graph illustrating theoretical incision size for various tip sizes; and

Figure 3 is an enlarged perspective view of the lens delivery system cartridge of the present invention.

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Detailed Description of the Preferred Embodiments

The present invention is directed to cartridge 10 having tip 12, tip 12 having a geometry designed to reduce stresses generated during insertion of an IOL into an eye. Although any incision size can be used, the dimensions given in the following discussion are based on a 2.0 mm incision or wound in the eye.

The action of inserting a cartridge tip 12 through an incision wound develops stresses at the wound edges that can result in trauma and tearing of the incision. The inventors have discovered that a correlation exists between the degree of wound stresses and cartridge tip geometry. Based on this discovery, the inventors determined that the incision or wound can be modeled as a deformable body having roughly an elliptical outer dimension with a major axis of approximately 2.0 mm and a minor axis of approximately 0.25 mm. In addition, the inventors determined that a cartridge tip 12 nozzle can be modeled as a rigid body with the assumption that no deformation of the tip 12 nozzle occurs during the insertion of an IOL into an eye and that any deformation occurs in the wound. As no actual tissue material properties are available, the material properties of the wound tissue can be modeled using the Arruda-Boyce material model. Assuming that the area of the tip 12 nozzle is larger than the area of the wound, the inventors applied a theoretical load to the inside of the wound to "stretch" the wound large enough to allow the nozzle tip 12 to enter. By lowering the theoretical load until the interior wound margins contact the entire outer peripheral surface of the tip 12, the residual strain, stress, stress distribution and contact pressure can be determined.

One skilled in the art understands that a circle or round cartridge tip has an aspect ratio of 1 because the height and width are equal. However, as the aspect ratio is reduced by shortening the height, the arc length changes which serves to reduce the degree of wound stretching by reducing the applied stresses at the wound edges as shown in FIG 1. One skilled in the art also understands that a straight line connecting height and width

results in the shortest distance between those points and represents the shortest “arc” length possible relative to applied stresses on the wound without creating a negative arc. Negative arc is undesirable because lens damage or undesirable folding can occur when a negative arc or non-curved geometry is used.

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The cross-sectional form of an ellipsoid, representing the injection tip 12 geometry, can be analyzed by using the ellipse shape factor. This shape factor ‘ε’ can remain constant to maintain the same form as the tip size is varied from 3.0 mm and below. By varying other parameter values, the form is maintained while reducing the periphery and resultant theoretical incision size as shown in Table 1 below and FIG. 2.

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This shape factor ε, also known as eccentricity, is further discussed below starting with the ellipse equation. A cross section of an ellipsoid in a plane parallel to coordinate axes forms an ellipse. In general, this 2D ellipse can be represented by the following equation:

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$$\frac{(x-h)^2}{a^2} + \frac{(y-k)^2}{b^2} = 1;$$

Where h, k represent the center of the ellipse, ‘a’ is the major axis and ‘b’ the minor axis.

The shape of an ellipse can be represented by its eccentricity, ε, defined as follows:

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$$\varepsilon = (1/a)\left(\sqrt{a^2 - b^2}\right);$$

where $0 < \varepsilon < 1$. The larger the value of ε is, the larger the ratio of a to b and the more elongated the ellipse becomes. Furthermore, for a given eccentricity value, if we know parameter ‘a’ or ‘b’ then the other parameter can be easily calculated using this equation.

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For completion, note that parameters ‘a’ and ‘b’ are constrained by the following equation:

$$c^2 = a^2 - b^2;$$

where $(\pm c, 0)$ represent the foci of the ellipse. Note that the cross section of the ellipse is modified in the sense that the center of the ellipse is not necessarily at the origin and is allowed to float. However, allowing for de-centration of the ellipse leaves a point of inflection, a sharp feature, when the part of the ellipse lying in quadrant I is revolved around the x-axis. To smooth out this point, a blend in radius is used so that the tangent to the point intersecting the x-axis is at 90 degrees. These two features, the decentered ellipse as well as a blend radius constitute the cross section of the modified ellipsoid configuration.

An alternate form to the above ellipse equation can be represented as,

$$Ax^2 + Bxy + Cy^2 + Dx + Ey + F = 0;$$

where $B^2 < 4AC$ and all coefficients are real. This equation can be converted to the first equation by completing squares and obtaining a form that displays the center of the ellipse as well as the lengths of major and minor axes.

Using the above guidelines, these parameters can be calculated. The elliptic curve in quadrant 1 was fitted to a general ellipse and it was found that $(h, k) = (0.0, -0.13)$, and $(a, b) = (0.95, 0.72)$. The eccentricity e was then calculated to be 0.65. Given this eccentricity, if either of the two axial dimensions of the ellipse is to be changed, then the other can be calculated with the above equation. Generally, the blend radius at the point of inflection can be chosen to be the smallest possible circle that is tangent to both the curve above and below and has a 90 deg. tangent line at the point crossing the x-axis, such as circle 100 of FIGURE 4.

An example of the application of the determined minimum arc length, aspect ratio and blend radius described above can be seen in Table 1 below where typical values for each of the variables are shown. The table defines typical modified ellipsoid values as a function of incision size. Incision sizes of 1.0, 2.0 and 3.0mm are used to demonstrate the

relationship when the ArcLength width and Ellipse eccentricity are held constant. Applying these values to cartridge tip designs result in the maximum internal volume relative to the minimum arc length which in combination results in significantly reduced strain at the incision wound edges while minimizing the degree of lens compression and resultant lens injection forces.

Table 1: Modified Ellipsoid typical dimensions as a function of Incision size.

Incision Size (mm)	Ellipse Major Axis, a (mm)	Ellipse Minor Axis, b (mm)	Ellipse Eccentricity, ϵ	ArcLength (mm)	ArcLength /Width	Blend Radius (mm)
1.0	0.392	0.30	0.65	1.087	1.386	0.2
2.0	0.784	0.60	0.65	2.174	1.386	0.4
3.0	1.176	0.90	0.65	3.261	1.386	0.6

The steps outlined above result in a design for cartridge tip 12 that provides the maximum internal volume relative to the minimum arc length. This combination results in significantly reduced strain at the incision wound edges while minimizing the degree of lens compression and resultant lens injection forces. The invention described within provides injector cartridge 10 or nozzle tip 12 shape that reduces the force required to insert cartridge tip 12 through the wound due to the reduced aspect ratio and arc length. In addition, this curved form facilitates reduced wound trauma and potential for lens damage through elimination of sharp external and internal features or transition points.

While certain embodiments of the present invention have been described above, these descriptions are given for purposes of illustration and explanation. Variations, changes, modifications and departures from the systems and methods disclosed above may be adopted without departure from the scope or spirit of the present invention.

Claims:

1. An intraocular lens delivery system cartridge, comprising:
a body, and
5 a tubular nozzle connected to the body and projecting distally from the body, the nozzle having a modified elliptical cross-section with a blend radius radii, the modified elliptical cross-section having a shape defined by:
 - 10 a portion of a decentered ellipse disposed in the first quadrant and the second quadrant of a Cartesian coordinate system, the portion of the decentered ellipse defined as a first curve; and
 - 15 a second curve defined as a mirror image of the first curve mirrored about the abscissa axis of the Cartesian coordinate system, the first curve and the second curve forming inflection points at locations where the first curve and the second curve intersect the abscissa axis of the Cartesian coordinate system; and
 - 20 the blend radii being formed at opposing ends of the elliptical shape proximate the inflection points, each blend radius defined as a portion of a circle joining the first curve and the second curve that is tangent to both the first curve and the second curve and that has a 90 degree tangent line at a point along the abscissa axis crossed by the blend radius wherein the blend radius is calculated from a desired incision size.
- 25 2. The cartridge of claim 1, wherein the elliptical cross-section has an ellipse eccentricity of 0.65.
3. The cartridge of claim 1, wherein the elliptical cross-section has an arc length width of 1.386.