# SPECIFICATION

## TITLE OF INVENTION: OPHTHALMIC SURGICAL APPARATUS

## FIELD OF THE INVENTION

The invention relates to ophthalmic surgical apparatus.

## BACKGROUND OF THE INVENTION

Cataract surgery includes removal of a central anterior part of a capsule of a lens of an eye. Cataract surgery requires removal of about 5.0 mm to 5.5 mm diameter central anterior part of a lens capsule preferably through a small corneal incision of 2.4 mm or less. The present golden standard is a manual surgical procedure known as Continuous Curvilinear Capsulorrhexis (CCC) employing shear forces starting from an initial induced opening in an anterior capsular surface. Considerable research and development have been invested in developing ophthalmic surgical apparatus for performing device induced automated capsulotomy procedures instead of manual CCC procedures. Exemplary ophthalmic surgical apparatus for capsulotomy procedures are described *inter alia* in France Patent No. 2,588,751 to Imbert, US Patent No. 4,367,744 to Sole, US Patent. No. 5,269,787 to Cozean, Jr. et al, US Patent No. 6,379,370 to Feinsod, US Patent No. 8,162,931 to Ben Nun, US Patent No. 8,235,978 to Ben Nun, US Patent No. 8,657,813 to Ben Nun et al., US Patent No. 9,173,771 to Keller, US Patent No. 9,532,903 to Ben Nun et al, US Patent No. 10,206,816 to Keller, US Patent No. 10,278,760 to Keller, US Patent No. 10,363,167 to Keller, US Patent No. 11,596,547 to Keller et al., US Patent No. 11,596,549 to Keller et al., US Patent No. 11,679,030 to Lum et al., US Patent No. 11,737,918 to Keller et al., US Patent Application Publication No. 2007/0191862 to Forrest, and US Patent Application Publication No. 2021/0212860 to Lee et al.

Descemet membrane transplants include a manual surgical procedure in which a recipient Descemet membrane is replaced by a harvested donor Descemet membrane. Descemet membrane transplants require removal of an about 8 mm diameter central part of a recipient Descemet membrane preferably through a small corneal incision of

2.4 mm or less. The central Descemet membrane part is removed by a range of ophthalmic surgical tools, for example, a Sinskey hook, and the like. Present surgical procedures include Descemet's Membrane Endothelial Keratoplasty (DMEK), Descemet Stripping Endothelial Keratoplasty (DSEK) and Descemet Stripping Automated Endothelial Keratoplasty (DSAEK). Such surgical procedures require removal of completely circular corneal tissue to perfectly match an intended donor graft but, in practice, removal of recipient Descemet membrane tissue is insufficiently accurate thereby increasing likelihood of subsequent partial or complete graft detachment.

There is a need for ophthalmic surgical apparatus for performing automated and centered completely circular incisions on eye tissue via small corneal incisions of about 2.4 mm or less.

## SUMMARY OF THE INVENTION

The present invention is directed towards ophthalmic surgical apparatus which can be configured for performing an automated capsulotomy or a comparable surgical procedure on a recipient eye's Descemet membrane hereinafter coined a descemetomy. The ophthalmic surgical apparatus includes an ophthalmic surgical handpiece supporting a compact cutting head which can be inserted through a 2.4 mm or less corneal incision into an eye's anterior chamber and manipulated inside the eye's anterior chamber for performing automated centered circular incisions on interior eye tissue. The ophthalmic surgical apparatus also includes a clinical practitioner operated power source for controlled activation of the ophthalmic surgical handpiece's cutting head. The power source typically has two or more activation modes for controlled activation of an ophthalmic surgical handpiece's cutting head in terms of electrical power rating, activation duration, and the like. Ophthalmic surgical handpieces are typically provided with cutting heads of different diameters, namely, an about 5 mm diameter for a capsulotomy and an about 8 mm diameter for a descemetomy.

The ophthalmic surgical handpiece includes an ophthalmic surgical handpiece housing having a longitudinal ophthalmic surgical handpiece housing centerline, an ophthalmic surgical handpiece housing proximal end and an ophthalmic surgical

handpiece housing distal end. The ophthalmic surgical handpiece includes a long support rod and a short support rod longitudinally extending from the ophthalmic surgical handpiece housing distal end for supporting a cutting head. One support rod is selectively reciprocal between an extended position relative to the ophthalmic surgical handpiece housing and a retracted position relative to the ophthalmic surgical handpiece housing. In a top plan view of the cutting head, the cutting head is elastically deformable between a normally undeformed completely circular shape and an elliptical shape co-directional with the longitudinal ophthalmic surgical handpiece housing centerline. The cutting head includes a coated electrically conductive monolithic cutting ring having an exposed cutting ring rim for application to an eye tissue for thermally cutting a completely circular incision on internal eye tissue.

A clinical practitioner typically stands over a supine patient and holds the ophthalmic surgical handpiece of the present invention similar to holding a phacoemulsification unit's handpiece. The ophthalmic surgical handpiece preferably includes a topside finger-operated slide button for sliding the extendible-retractable support rod from a biased position in which the cutting head assumes its completely circular shape to its finger displaced position in which the cutting head assumes its longitudinally directed elliptical shape. For performing a capsulotomy, the exposed cutting ring rim is the cutting ring's lowermost cutting ring rim for pressing downwards on the central anterior part of the capsule of the lens of an eye. For performing a descemetomy, the exposed cutting ring rim is the cutting ring's uppermost cutting ring rim for pressing upwards on a Descemet membrane of an eye.

In the discussion, unless otherwise stated, adjectives such as "substantially" and "about" that modify a condition or relationship characteristic of a feature or features of an embodiment of the invention, are to be understood to mean that the condition or characteristic is defined to within tolerances that are acceptable for operation of the embodiment for an application for which it is intended. Unless otherwise specified, the terms 'about' and/or 'close' with respect to a magnitude or a numerical value may imply to be within an inclusive range of -10% to +10% of the respective magnitude or value.

The terms "proximal" and "distal" refer to locations which are correspondingly closer to a clinician performing a procedure and "distal" to locations which are located further therefrom.

The terms "longitudinal" and "axial" are interchangeable, and refer to an axis extending in the proximal and distal directions, unless otherwise expressly defined.

The terms "leading" and "trailing" refer to locations which are correspondingly closer to a clinician performing a procedure and further therefrom.

The terms "rearward" and "forward" refer to locations which are correspondingly closer to a clinician performing a procedure and further therefrom.

## BRIEF DESCRIPTION OF DRAWINGS

In order to understand the present invention and to see how it can be carried out in practice, preferred embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings, in which similar parts are likewise numbered, and in which:

Fig. 1 is a pictorial view of ophthalmic surgical apparatus for performing a capsulotomy, the ophthalmic surgical apparatus including an ophthalmic surgical handpiece having a cutting head assuming a non-deformed completely circular shape.

Fig. 2 is a close-up view of Figure 1's encircled area denoted 2.

Fig. 3 is a pictorial view of the Figure 1 ophthalmic surgical handpiece with its cutting head assuming an elastically deformed elliptical shape.

Fig. 4 is a close-up view of Figure 3's encircled area denoted 4.

Fig. 5 is an exploded view of the ophthalmic surgical handpiece.

Fig. 6 is a top plan view of a horizontal ophthalmic surgical handpiece's cutting head assuming a completely circular shape.

Fig. 7 is a longitudinal section of the cutting head along Figure 6's line 7-7.

Fig. 8 is a top plan view of a horizontal ophthalmic surgical handpiece's cutting head assuming an elliptical shape.

Fig. 9 is a close-up view of Figure 7's encircled area denoted 9.

Fig. 10 is a front elevation view of a horizontal ophthalmic surgical handpiece.

Fig. 11 is a pictorial view of alternative ophthalmic surgical apparatus for performing a capsulotomy, the ophthalmic surgical apparatus including an ophthalmic surgical handpiece having a cutting head assuming a non-deformed completely circular shape.

Fig. 12 is a close-up view of Figure 11's encircled area denoted 12.

Fig. 13 is a pictorial view of the Figure 11 ophthalmic surgical handpiece with its cutting head assuming an elastically deformed elliptical shape.

Fig. 14 is a close-up view of Figure 13's encircled area denoted 14.

Fig. 15 is a pictorial view of ophthalmic surgical apparatus for performing a descemetomy, the ophthalmic surgical apparatus including an ophthalmic surgical handpiece having a cutting head assuming a normally non-deformed completely circular shape.

Fig. 16 is a close-up view of in Figure 15's encircled area denoted 16.

## DETAILED DESCRIPTION OF DRAWINGS

Ophthalmic surgical apparatus for performing a capsulotomy

Figure 1 to Figure 10 show ophthalmic surgical apparatus 10 for performing a capsulotomy. The ophthalmic surgical apparatus 10 includes a typically clinical practitioner handheld ophthalmic surgical handpiece 100 and a power source 200 connected to the ophthalmic surgical handpiece 100 by an electrical cable 201 for activating the ophthalmic surgical handpiece 100. An ophthalmic surgical handpiece 100 is typically a single use disposable item supplied in sealed sterile packaging. The power source 200 can be powered by a mains power supply, a rechargeable battery, and the like. The power source 200 is typically intended for repeated usage and foot operated by a clinical practitioner thereby freeing his hands. The power source 200 typically requires two foot depressions in quick succession for activating an ophthalmic surgical handpiece 100 to avoid inadvertent activation. The power source 200 typically includes an activation mode selector 202 for selecting an activation mode from two or more activation modes for activating an ophthalmic surgical handpiece 100. Activation modes differ in terms of electrical power rating, activation duration, and the like.

An ophthalmic surgical handpiece 100 includes an ophthalmic surgical handpiece housing 101 having a longitudinal ophthalmic surgical handpiece housing centerline 102 and assembled from a right-side ophthalmic surgical handpiece housing base 103 and a left-side ophthalmic surgical handpiece housing cover 104. From the point of view of a clinical practitioner holding the ophthalmic surgical handpiece 100 like a phacoemulsification unit's handpiece and his position relative to a supine patient for performing a capsulotomy, the ophthalmic surgical handpiece housing 101 includes a major handheld proximal housing section 106 with an ophthalmic surgical handpiece housing proximal end 107 which converges to an upwardly inclined minor distal housing section 108 with an ophthalmic surgical handpiece housing distal end 109 for facilitating access to an operated eye's anterior chamber. The major handheld proximal housing section 106 includes a finger-operated slide button 111 slidingly reciprocal between a distal position (see Figure 1) and a proximal position (see Figure 3) as denoted by an arrow A and typically biased to its distal position. The minor distal housing section 108 is preferably arcuately upwardly inclined. The ophthalmic surgical handpiece housing distal end 109 has an ophthalmic surgical handpiece housing distal end aperture 112.

The ophthalmic surgical handpiece 100 includes a long support rod 120 and a short support rod 130 both permanently longitudinally extending from the minor distal housing section 108 through the ophthalmic surgical handpiece housing distal end aperture 112 to support a shape configurable cutting head 140. In a top plan view of the shape configurable cutting head 140, the finger-operated slide button 111 is top-sided, the long support rod 120 has a stepped shape, the short support rod 130 is straight, and the cutting head 140 assumes either a completely circular shape or an elliptic shape co-directional with the longitudinal ophthalmic surgical handpiece housing centerline 102. On assuming a completely circular shape, the cutting head 140 preferably has a diameter D1 of about 5 mm for a capsulotomy and, on assuming its longitudinally directed elliptical shape, the cutting head 140 can be elongated to a variable length depending on the cutting head 140's ellipticity. The cutting head's maximal length is shorter than a theoretical straight length $\Pi$ D1/2 due to the width of the attachment

points of the long support rod 120 and the short support rod 130 and the cutting ring 140.

The long support rod 120 has a long support rod proximal end 121 and a long support rod distal end 122. The long support rod 120 constitutes a stationary support rod having a fixed length L1 of about 10 mm measured from the ophthalmic surgical handpiece housing distal end aperture 112. The short support rod 130 has a short support rod proximal end 131 and a short support rod distal end 132. The short support rod 130 constitutes an extendible-retractable support rod reciprocal by the finger-operated slide button 111 between an extended position (see Figure 6) and a retracted position (see Figure 8) correspondingly having a length L2 and a length L3 < L2 as measured from the ophthalmic surgical handpiece housing distal end aperture 112. The short support rod 130 is typically biased to its extended position corresponding to the finger-operated slide button 111's distal position whereupon the cutting head 140 assumes its completely circular shape.

In the cutting head's top plan view, the long support rod proximal end 121 and the short support rod proximal end 131 are spaced apart and the long support rod distal end 122 and the short support rod distal end 132 define a longitudinal cutting head centerline 140A co-directional with the longitudinal ophthalmic surgical handpiece housing centerline 102. The short support rod 130 and the longitudinal cutting head centerline 140A are preferably co-linear with the longitudinal ophthalmic surgical handpiece housing centerline 102. Accordingly, in the cutting head's top plan view, on the cutting ahead 140 assuming its completely circular shape, the longitudinal cutting head centerline 140A constitutes a diameter of the cutting head 140 and, on assuming its longitudinally directed elliptical shape, the longitudinal cutting head centerline 140A constitutes a major axis of the cutting head 140.

The minor distal housing section 108 is upwardly inclined with respect to the major handheld proximal housing section 106 in Figure 10's front elevation view of a horizontal ophthalmic surgical handpiece 100 such that the longitudinal cutting head centerline 140A preferably subtends an included angle $\alpha$ of about 135° with the horizontal longitudinal ophthalmic surgical handpiece housing centerline 102 similar to the angulation of Utrata capsulorrhexis forceps.

The ophthalmic surgical handpiece 100 includes electrical wiring 113 extending through the ophthalmic surgical handpiece housing 101 and the long support rod 120 to the long support rod distal end 122. The electrical wiring 113 is channeled along the right-side ophthalmic surgical handpiece housing base 103 and includes a junction box 114 secured by a cover 116. The ophthalmic surgical handpiece 100 includes electrical wiring 117 extending through the ophthalmic surgical handpiece housing 101 and the short support rod 130 to the short support rod distal end 132. The electrical wiring 117 includes an elongated junction box 118 reciprocal along the longitudinal ophthalmic surgical handpiece housing centerline 102 under the action of the finger-operated slide button 111. The ophthalmic surgical handpiece 100 typically includes a biasing mechanism 119 for biasing the elongated junction box 18 in a distal direction for biasing the finger-operated slide button 111 to its distal position. The biasing mechanism 119 can be constituted by a compression spring, and the like. Accordingly, the electrical wiring 117 has some spare length in the ophthalmic surgical handpiece housing 101 in the finger-operated slide button's 111 proximal position.

The cutting head 140 includes an electrically conductive monolithic cutting ring 141 typically made from super elastic metal, for example, nitinol. The cutting ring 141 has a generally rectangular cross section in Figure 7's longitudinal section with a height to width aspect ratio of at least 4:1 for affording structural rigidity. Typical dimensions of the cutting ring 141 are height H of about 350μm and width W of about 60μm. The monolithic term emphasizes the cutting ring 141 is a single gapless complete ring as opposed to a rectangular cutting strip having two opposite ends which are joined together to form a ring. The cutting ring 141 has an uppermost cutting ring rim 142 and a lowermost cutting ring rim 143 facing away from the finger-operated slide button 111 for intimate completely circular contact on a central anterior part of the capsule of the lens of an eye intended for a capsulotomy. The electrical wiring 113 and the electrical wiring 117 are electrically connected to the uppermost cutting ring rim 142.

The cutting head 140 includes a thermal, electrical protective coating 144 for initially coating the entire cutting ring 141 before subsequent trimming to expose the lowermost cutting ring rim 143. Suitable thermal, electrical protective coatings 144 include parylene, and the like. The thermal, electrical protective coating 144 can have

a thickness of about 50 μm. Such protective coatings also beneficially reduce friction on insertion of a cutting head 140 through a corneal opening into an eye and removal therefrom. The lowermost cutting ring rim 143 can optionally be chamfered to provide a sharpened lowermost cutting ring rim 143 for facilitating a capsulotomy (see Figure 9).

A clinical practitioner performs a capsulotomy as follows:

1) Makes a 2.4 mm or less corneal incision in an eye and fills it with viscoelastic material of any clinically required viscosity.

2) Removes the ophthalmic surgical handpiece from its sealed sterile packaging. The ophthalmic surgical handpiece is typically supplied with its finger-operated slide button in its biased distal position such that the cutting head assumes its non-deformed completely circular shape.

3) Slides the finger-operated slide button to its proximal position for temporarily elastically deforming the cutting head to its elliptical shape.

4) Inserts the extended cutting head through the corneal incision into the eye's anterior chamber.

5) Releases the finger-operated slide button which is urged to its biased distal position such that the cutting head reverts to its non-deformed completely circular shape.

6) Depresses the cutting head's exposed lowermost cutting ring rim on the central anterior part of the capsule of the lens of the eye.

7) Operates the power source to activate the cutting ring for automatically thermally cutting a centered 5 mm diameter circle in the lens anterior capsule.

8) Gently elevates the cutting ring from the lens surface.

9) Slides the finger-operated slide button to its proximal position again for temporarily elastically deforming the cutting head to its elliptical shape.

10) Removes the cutting head from the operated eye via the same incision.

11) Releases the finger-operated slide button which is urged to its biased distal position such that the cutting head reverts to its non-deformed completely circular shape.

12) Discards the ophthalmic surgical handpiece.

13) Adds viscoelastic material to the anterior chamber and uses standard Utrata forceps for removing the 5 mm diameter central anterior part of the lens capsule from the operated eye.

Figure 11 to Figure 14 show an ophthalmic surgical apparatus 10 including an ophthalmic surgical handpiece 300 for performing a capsulotomy. The ophthalmic surgical handpiece 300 has a similar construction as the ophthalmic surgical handpiece 100 and therefore similar parts are likewise numbered. The latter 300 differs from the former 100 insofar as the long support rod 120 constitutes an extendible-retractable support rod and the short support rod 130 constitutes a stationary support rod. Accordingly, the finger-operated slide button 111 reciprocates the long support rod 120 as denoted by arrow B between a retracted position in which the cutting head 140 assumes its completely circular shape (see Figure 11 and Figure 12) and an extended position in which the cutting head 140 assumes its longitudinally directed elliptical shape (Figure 13 and Figure 14). The finger-operated slide button 111 is preferably biased to its proximal position in which the cutting head 140 assumes its completely circular shape. The ophthalmic surgical handpiece 300 includes electrical wiring enabling the extension of the long support rod 120.

Ophthalmic surgical apparatus for performing a descemetomy

Figure 15 and Figure 16 show an ophthalmic surgical handpiece 400 for performing a descemetomy. The ophthalmic surgical handpiece 400 has a similar construction as the ophthalmic surgical handpiece 100 and therefore similar parts are likewise numbered. The latter 400 differs from the former 100 insofar as the latter 400's cutting head 140 has an exposed uppermost cutting ring rim 142 facing the same direction as the finger-operated slide button 111 for completely circular contact on a Descemet membrane. In other words, the latter 400's cutting head 140 is reversed with respect to the former 100's cutting head 140. Accordingly, the electrical wiring 113 and the electrical wiring 117 are electrically connected to the lowermost cutting ring rim 143. And second, the ophthalmic surgical handpiece 400's cutting head 140 has a larger diameter than the ophthalmic surgical handpiece 100's cutting head 140. The

ophthalmic surgical handpiece 400's cutting head 140 typically has a non-deformed completely circular diameter D2 of about 8 mm.

The use of the ophthalmic surgical handpiece 400 is similar to the use of the ophthalmic surgical handpiece 100 except that the ophthalmic surgical handpiece 400's cutting head 140 is upwardly pressed against a recipient Descemet membrane for thermally cutting a completely circular incision in a recipient eye's Descemet membrane. Thereafter, Descemet membrane tissue bounded by the completely circular incision is scrapped from the eye's cornea.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications, and other applications of the invention can be made within the scope of the appended claims.

# CLAIMS

1. An ophthalmic surgical handpiece for use with a clinical practitioner operated power source for providing electrical energy, the ophthalmic surgical handpiece comprising:

a) an ophthalmic surgical handpiece housing having a longitudinal ophthalmic surgical handpiece housing centerline, an ophthalmic surgical handpiece housing proximal end and an ophthalmic surgical handpiece housing distal end;

b) a long support rod longitudinally extending from the ophthalmic surgical handpiece housing distal end, and having a long support rod proximal end and a long support rod distal end;

c) a short support rod longitudinally extending from the ophthalmic surgical handpiece housing distal end, and having a short support rod proximal end and a short support rod distal end;

d) a finger-operated slide button slidable between a proximal position and a distal position for correspondingly sliding one support rod of the long support rod and the short support rod between a retracted position and an extended position relative to the ophthalmic surgical handpiece housing; and

e) a cutting head including a coated electrically conductive monolithic cutting ring having an exposed cutting ring rim for application to eye tissue,

the cutting head being mounted on the short support rod distal end and the long support rod distal end thereby defining a longitudinal cutting head centerline,

the cutting head being configurable in a top plan view between a completely circular shape and an elliptical shape co-directional with the longitudinal ophthalmic surgical handpiece housing centerline,

the arrangement being such that in the cutting head's top plan view, the long support rod proximal end and the short support rod proximal end are spaced apart and, in one position of the finger-operated slide button, the cutting head assumes its completely circular shape, and in the other position of the finger-operated slide button, the cutting head assumes its elliptical shape,

wherein, in use, on assuming its completely circular shape, the cutting ring being activated by the power source for thermally cutting a completely circular incision on the eye tissue.

2. The ophthalmic surgical handpiece according to claim 1 wherein the ophthalmic surgical handpiece housing includes a major handheld proximal housing section converging to a minor distal housing section such that the longitudinal cutting head centerline subtends an included angle $\alpha$ of about 135° with the longitudinal ophthalmic surgical handpiece housing centerline in a front elevation view of a horizontal ophthalmic surgical handpiece.

3. The ophthalmic surgical handpiece according to either claim 1 or 2 and further comprising a biasing mechanism for biasing the finger-operated slide button to one position of its proximal position and its distal position for urging the cutting head to its completely circular shape.

4. The ophthalmic surgical handpiece according to any one of claims 1 to 3 wherein the finger-operated slide button reciprocates the short support rod between an extended position and a retracted position.

5. The ophthalmic surgical handpiece according to any one of claims 1 to 3 wherein the finger-operated slide button reciprocates the long support rod between an extended position and a retracted position.

6. The ophthalmic surgical handpiece according to any one of claims 1 to 5 wherein the finger-operated slide button is top-sided on the ophthalmic surgical handpiece housing in the cutting head's top plan view and the cutting head includes an exposed lowermost cutting ring rim facing away from the finger-operated slide button for performing a capsulotomy.

7. The ophthalmic surgical handpiece according to any one of claims 1 to 5 wherein the finger-operated slide button is top-sided on the ophthalmic surgical handpiece

housing in the cutting head's top plan view and the cutting head includes an exposed uppermost cutting ring rim facing the same direction as the finger-operated slide button for performing a descemetomy.

8. Ophthalmic surgical apparatus comprising

a) an ophthalmic surgical handpiece according to any one of claims 1 to 7; and

b) a power source for activating the ophthalmic surgical handpiece's cutting head.

9. The ophthalmic surgical apparatus according to claim 8 wherein the power source has an activation mode selector for selecting an activation mode of at least two activation modes for activating the ophthalmic surgical handpiece's cutting head.