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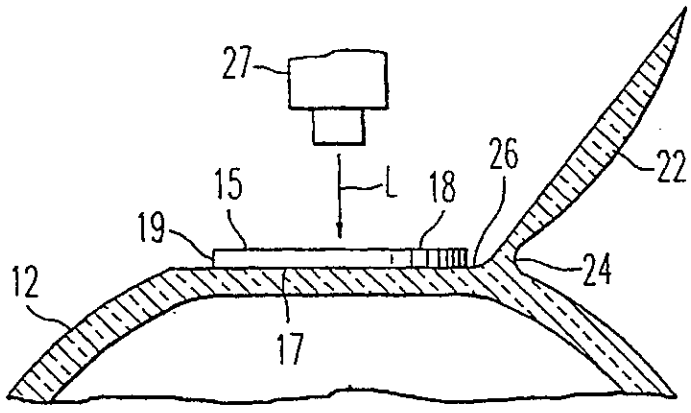
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(54) Title: A UNIVERSAL IMPLANT BLANK FOR MODIFYING CORNEAL CURVATURE AND METHODS OF MODIFYING CORNEAL CURVATURE THEREWITH

(57) Abstract

A universally sized blank (18) made of organic or synthetic material that can be placed on an exposed inner surface of a live cornea and ablated with a laser beam (L) to be altered to a particular shape. The blank (18) can be disk–shaped, annularly–shaped with a through opening, or any other suitable shape. A flap–like portion of the live cornea is removed to expose an inner surface of the cornea, and the blank (18) is positioned on the exposed inner surface of the eye. A laser beam (L) is directed onto a portion of the exposed inner surface (e.g., exposed at the opening in the blank), a portion of the blank (18), or both, based on the type of ametropic condition (i.e., myopia, hyperopia or astigmatism) of the eye needing correction, so that the laser beam (L) ablates those portions of the inner surface and/or blank (18) and thus reshapes the inner surface, the blank (18), or both.



A UNIVERSAL IMPLANT BLANK FOR MODIFYING CORNEAL CURVATURE AND METHODS OF MODIFYING CORNEAL CURVATURE THEREWITH

This is a continuation-in-part application of U.S. Patent Application Serial No. 08/845,448 filed April 25, 1997, the entire contents of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

Field of the Invention:

The present invention relates to a universal blank which is used to modify the curvature of a live cornea when implanted therein. The blank is made of synthetic or organic material, and can be shaped to the appropriate configuration while supported on an exposed inner surface of the cornea.

Description of the Related Art:

A normal emetropic eye includes a cornea, lens and retina. The cornea and lens of a normal eye cooperatively focus light entering the eye from a far point, i.e., infinity, onto the retina. However an eye can have a disorder known as ametropia, which is the inability of the lens and cornea to focus the far point correctly on the retina. Typical types of ametropia are myopia, hypermetropia or hyperopia, and astigmatism.

A myopic eye has either an axial length that is longer than that of a normal emetropic eye, or a cornea or lens having a refractive power stronger than that of the cornea and lens of an emetropic eye. This stronger refractive power causes the far point to be projected in front of the retina.

Conversely, a hypermetropic or hyperopic eye has an axial length shorter than that of a normal emetropic eye, or a lens or cornea having a refractive power less than that of a lens and cornea of an emetropic eye. This lesser refractive power causes the far point to be focused in back of the retina.

An eye suffering from astigmatism has a defect in the lens or shape of the cornea. Therefore, an astigmatic eye is incapable of sharply focusing images on the retina.

A common method of correcting myopia is to place a "minus" or concave lens in front of the eye in order to decrease the refractive power of the cornea and lens. In a similar manner, hypermetropic or hyperopic conditions can be corrected to a certain degree by placing a "plus" or convex lens in front of the eye to increase the refractive power of the cornea and lens. Lenses having other shapes can be used to correct astigmatism. The concave, convex or other shaped lenses are typically configured in the form of glasses or contact lenses. This technique, which involves the placement of lenses in front of the eye, is known as photorefractive keratectomy.

Although photorefractive keratectomy can be used to correct vision in eyes suffering from low myopia up to 6 diopters, or in eyes suffering from hypermetropic, hyperopic or astigmatic conditions which are not very severe, that method is ineffective in correcting vision in eyes suffering from sever forms of ametropia. For example, photorefractive keratectomy is less effective in correcting high myopia of 6 diopters or greater, and is also ineffective in

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correcting severe astigmatism and severe forms of hypermetropia or hyperopia.

However, surgical techniques exist for correcting these more severe forms of ametropia to a certain degree. For example, in a technique known as myopic keratomileusis, a microkeratome is used to cut away a portion of the front of the live cornea from the main section of the live cornea. The cut portion of the cornea is frozen and placed in a cryolathe where it is cut and reshaped. Altering the shape of the cut portion of the cornea changes the refractive power of this cut portion, which thus affects the location at which light entering the cut portion of the cornea is focused. The reshaped cut portion of the cornea is then reattached to the main portion of the live cornea. Hence, it is intended that the reshaped cornea will change the position at which the light entering the eye through the cut portion is focused, so that hopefully the light is focused on the retina, thus remedying the ametropic condition.

The myopic keratomileusis technique is known to be effective in curing myopic conditions within a range of 6 to 18 diopters. However, the technique is impractical because it employs very complicated and time consuming freezing, cutting and thawing processes. Furthermore, the technique is ineffective in correcting myopic conditions greater than 18 diopters.

Keratophakia is another known surgical technique for correcting sever ametropic conditions of the eye by altering the shape of the eye's cornea. In this technique an artificial organic or synthetic lens is implanted inside the cornea to thereby alter the shape of the cornea and thus change its refractive power. Accordingly, as with the myopic keratomileusis technique, it is desirable that the shape of the cornea be altered to a degree allowing light entering the eye to be focused correctly on the retina.

However the keratophakia technique is impractical, complicated, and expensive because it requires manufacturing or cutting a special lens prior to its insertion into the cornea. Hence, a surgeon is required to either maintain an assortment of many differently shaped lenses, or alternatively, must have access to expensive equipment, such as a cyrolathe, which can be used to cut the lens prior to insertion into the cornea.

Surgical techniques involving the use of ultraviolet and shorter wavelength lasers to modify the shape of the cornea also are known. For example, excimer lasers, such as those described in U.S. Patent No. 4,840,175 to Peyman, which emit pulsed ultraviolet radiation,

can be used to decompose or photoablate tissue in the live cornea so as to reshape the cornea.

Specifically, a laser surgical technique known as laser in situ keratomileusis (LASIK) has been previously developed by the present inventor. In this technique, a portion of the front of a live cornea can be cut away in the form of a flap having a thickness of about 160 to about 180 microns. This cut portion is removed from the live cornea to expose an inner surface of the cornea. A laser beam is then directed onto the exposed inner surface to ablate a desired amount of the inner surface up to 150-180 microns deep. The cut portion is then reattached over the ablated portion of the cornea and assumes a shape conforming to that of the ablated portion.

However, because only a certain amount of cornea can be ablated without the remaining cornea becoming unstable or experiencing outbulging (ectasia), this technique is not especially effective in correcting very high myopia. That is, a typical live cornea is on average about 500 microns thick. The laser ablation technique requires that at least about 200 microns of the corneal stroma remain after the ablation is completed so that instability and outbulging does not occur. Hence, this procedure cannot be effectively used to correct high myopia of greater than 15 diopters because in order to reshape the cornea to the degree necessary to alter its refractive power so as to sufficiently correct the focusing of the eye, too much of the cornea would need to be ablated.

Examples of known techniques for modifying corneal curvature, such as those discussed above, are described in U.S. Patent No. 4,994,058 to Raven et al., U.S. Patent No. 4,718,418 to L'Esperance, U.S. Patent No. 5,336,261 to Barrett et al., U.S. Patent No. 4,840,175 to Peyman, and a publication by Jose I. Barraquer, M.D. entitled "Keratomileusis and Keratophakia in the Surgical Correction of Aphakia".

A continuing need therefore exists for improved methods to correct very severe ametropic conditions.

SUMMARY OF THE INVENTION

Accordingly, a primary object of the present invention is to provide a device which can be used to modify corneal curvature without experiencing the drawbacks associated with the

known techniques discussed above, to thus correct severe ametropic conditions.

Another object of the invention is to configure the device to be positioned on the surface of the cornea and reshaped while on the surface of the cornea so that the device need not be prefabricated or modified prior to placement on the cornea.

A further object of the invention is to provide a method for modifying the shape of a live cornea by using a device that can be placed on the surface of the live cornea and reshaped thereon.

Still a further object of the invention is to provide a method for modifying the shape of a live cornea by removing a layer of the live cornea to expose a surface underneath, placing a device on the exposed surface that can be reshaped while on the exposed surface, reshaping the device, the exposed surface, or both, and repositioning the layer over the remaining portion of the reshaped device so that the reshaped device, exposed surface, or both, influences the shape of the layer and thus the overall cornea.

Another object of the invention is to provide a method for modifying the shape of a live cornea by removing a layer of the live cornea to expose a surface underneath, placing a prefabricated device, such as an annularly-shaped device, on the exposed surface, and repositioning the layer of live cornea over the device to influence the shape of the layer and thus the overall cornea without the use of a laser to reshape the exposed surface of the cornea or the device.

The foregoing objects are basically obtained by providing a universally sized blank made of organic material, synthetic material, or a combination of organic and synthetic material, that can be placed on an exposed inner surface of a live cornea and ablated with a laser beam to be altered to a particular shape. The universally sized blank can be porous to allow oxygen and nutrients to pass there through. Also, the blank can be made from living cells such as a donor cornea of a human eye (e.g., as taken from an eye bank), or can be taken from a cultured cornea. The blank can be disk-shaped, annularly shaped having an opening therein, or any other suitable shape.

A flap-like portion of the live cornea is removed to expose the inner surface of the cornea. The blank is positioned on the exposed inner surface of the cornea, and a laser beam is directed, for example, onto the inner surface of the cornea exposed in the opening in the

blank, onto certain portions of the blank, or both, to ablate those portions of the inner surface, blank, or both, and thus reshape the inner surface, blank, or both, based on the type of ametropic condition (i.e., myopia, hyperopia or astigmatism) of the eye needing correction. The flap-like portion of the cornea is then repositioned over the remaining portion of the blank, so that the remaining portion of the blank, ablated inner surface, or both, influences the shape of the reattached flap-like portion of the cornea, thus modifying the curvature of the surface of the cornea. The universal blank can therefore be used to correct severe ametropic conditions, such as high myopia up to 35 diopters.

According to one aspect of the present invention, there is provided a blank, adaptable for use in modifying the curvature of a patient's live cornea, comprising:

a first surface adapted for placement directly on a surface of said patient's live cornea;

a second surface adapted to be exposed to a laser beam;

a wall surface, extending between said first and second surfaces; and defining an opening in said blank;

a first portion between said first surface and said second surface, said portion surrounding a majority of said opening and defining a first thickness; and

a second portion between said first surface and said second surface, said second portion having a second thickness, said second thickness being less than said first thickness;

said blank comprising a material whose properties permit light having a wavelength within the visible spectrum to pass therethrough and prevent substantially all light having a wavelength within the laser light spectrum from passing therethrough.

According to another aspect of the present invention, there is provided a method of modifying a blank, comprising the steps of:

separating a layer of said live cornea from the front of said live cornea;

moving said separated layer to expose an internal surface of said live cornea underneath said separated layer;

positioning a blank, having an opening therein, on said internal surface of said live cornea;

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directing a laser beam onto a portion of said blank to ablate said portion of said blank, while leaving an unablated portion of said blank on said internal surface of said live cornea; and

repositioning said separated layer of said live cornea back over said internal surface of said live cornea and said unablated portion of said blank, so that the shape of the internal surface and said unablated portion of said blank influences the shape of said repositioned separated layer of said live cornea.

Other objects, advantages, and salient features of the present invention will become apparent from the following detailed description, which, taken in conjunction with the attached drawings, discloses preferred embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Referring now to the drawings which form a part of the original disclosure:

Fig. 1 is a side elevational view in section taken through the center of an eye showing the cornea, pupil and lens;

Fig. 2 is a perspective view of an embodiment of a universal blank according to the present invention;

Fig. 3 is a front elevational view of the embodiment shown in Fig. 2;

Fig. 4 is a top elevational view of the embodiment shown in Fig. 2;

Fig. 5 is a side elevational view in section taken through the center of an eye showing formation of a flap-like structure at the front of the cornea;

Fig. 6 is a front elevational view of the cornea and flap-like structure as taken along lines VI-VI in Fig. 5;

Fig. 7 is a side elevational view in section taken through the center of an eye and showing the flap-like section positioned to expose an inner surface of the cornea;

Fig. 8 is an enlarged side elevational view in section taken through the center of an eye and showing placement of the embodiment of the universal blank shown in Fig. 2 on the exposed surface of the cornea;

Fig. 9 is an enlarged side elevational view in section taken through the center of an eye and illustrating the universal blank shown in Fig. 2 positioned on the exposed surface of the cornea;

Fig. 10 is a front elevational view of the cornea with the universal blank present on the exposed surface thereof as taken along lines X-X in Fig. 9;

Fig. 11 is an enlarged side elevational view in section taken through the center of the eye showing the cornea and the irradiation of a laser beam on the universal blank positioned on the exposed surface of the cornea;

Fig. 12 illustrates ablation of the center of the universal blank by the laser beam;

Fig. 13 is a reduced front elevational view of the ablated universal blank taken along lines XIII-XIII in Fig. 12;

Fig. 14 is an enlarged cross-sectional view of the blank and cornea as taken along lines XIV-XIV in Fig. 13;

Fig. 15 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the ablated universal blank shown in Fig. 14;

Fig. 16 is a side elevational view in section taken through the center of the eye illustrating ablation of the universal blank as well as a portion of the cornea below the blank by the laser beam;

Fig. 17 is a side elevational view in section taken through the center of the eye illustrating the flap-like portion repositioned over the remaining portion of the blank and ablated portion of the cornea;

Fig. 18 is a side elevational view in section taken through the center of the eye showing the cornea and the irradiation of a laser beam on other peripheral portions or the universal blank which is positioned on the exposed surface of the cornea;

Fig. 19 is a side elevational view in section taken through the center of the eye showing ablation of the portions of the universal blank by irradiation of the laser beam as shown in Fig. 18;

Fig. 20 is a reduced front elevational view taken along lines XX-XX in Fig. 19;

Fig. 21 is an enlarged cross-sectional view taken along lines XXI-XXI in Fig. 20;

Fig. 22 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank ablated by the laser beam as shown in Fig. 19;

Fig. 23 is a side elevational view in section taken through the center of the eye showing ablation of portions of the universal blank and the exposed surface of the cornea below the blank by irradiation of a laser beam;

Fig. 24 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank as ablated by the laser beam as shown in Fig. 23;

Fig. 25 is a side elevational view in section taken through the center of the eye showing ablation of multiple portions of the universal blank by irradiation of a laser beam;

Fig. 26 is a front elevational view of the ablated universal blank taken along lines XXVI-XXVI in Fig. 25;

Fig. 27 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank ablated by the laser beam as shown in Fig. 25;

Fig. 28 is a side elevational view in section taken through the center of the eye showing ablation of multiple portions of the universal blank and cornea by irradiation of a laser beam;

Fig. 29 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank as ablated by the laser beam as shown in Fig. 28;

Fig. 30 is a side elevational view in section taken through the center of the eye showing ablation of the universal blank in a nonsymmetrical manner by irradiation of a laser beam;

Fig. 31 is a reduced front elevational view of the ablated universal blank taken along

lines XXXI-XXXI in Fig. 30;

Fig. 32 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank as ablated by the laser beam as shown in Fig. 30;

Fig. 33 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank after a portion of the periphery of the universal blank and a portion of the exposed surface have been ablated by a laser beam;

Fig. 34 is a side elevational view in section taken through the center of the eye showing a central portion of the exposed surface of the cornea being ablated by a laser beam;

Fig. 35 is a reduced front elevational view of the ablated exposed surface of the cornea taken along lines XXXV-XXXV in Fig. 34;

Fig. 36 is a side elevational view in section taken through the center of the eye and illustrating the universal blank shown in Fig. 2 position on the ablated exposed surface of the cornea and ablation of a central portion of the universal blank by a laser beam;

Fig. 37 is a side elevational view in section taken through the center of the eye showing the cornea and flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank as ablated by the laser beam as shown in Fig. 36;

Fig. 38 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank after a central portion of the universal blank and a central portion of the ablated exposed surface of the cornea have been ablated by a laser beam;

Fig 39 is a side elevational view in section taken through the center of the eye showing ablation of peripheral portions of the universal blank which is positioned in the ablated exposed surface of the cornea;

Fig. 40 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and remaining portion of the universal blank as ablated by the laser beam as shown in Fig. 39;

Fig. 41 is a side elevational view in section taken through the center of the eye showing the cornea and flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank after the periphery of the universal blank and a portion of the ablated exposed surface of the cornea surrounding the remaining portion of the blank have been ablated by a laser beam;

Fig. 42 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and a remaining portion of the universal blank which has been ablated in a nonsymmetrical manner by a laser beam;

Fig. 43 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank after a portion of the ablated exposed surface and universal blank have been ablated by a laser beam in a nonsymmetrical manner;

Fig. 44 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank of which multiple portions have been ablated by a laser beam;

Fig. 45 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank after multiple portions of the ablated portion of the exposed surface and multiple portions of the universal blank have been ablated by a laser beam;

Fig. 46 is a perspective view of another embodiment of a universal blank according to the present invention;

Fig. 47 is a front view of the embodiment shown in Fig. 46;

Fig. 48 is a bottom view of the embodiment shown in Fig. 46 as taken along lines XLVIII-XLVIII in Fig. 47;

Fig. 49 is a side elevational view in section taken through the center of the eye showing ablation of the exposed surface of the cornea by a laser beam to different depths;

Fig. 50 is a reduced front view of the cornea as taken along lines 50-50 in Fig. 49;

Fig. 51 is a side elevational view in section taken through the center of the eye showing the universal blank illustrated in Fig. 46 positioned on the exposed surface of the cornea after the exposed surface has been ablated as shown in Fig. 49;

Fig. 52 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank illustrated in Fig. 46 as ablated by the laser beam as shown in Fig. 51;

Fig. 53 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank shown in Fig. 46 after a central portion of the universal blank and a central portion of the ablated exposed surface of the cornea have been ablated by a laser beam;

Fig. 54 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank shown in Fig. 46 whose periphery has been ablated by a laser beam;

Fig. 55 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank after a portion of the periphery of the universal blank and a portion of the ablated exposed surface surrounding the remaining portion of the blank have been ablated by a laser beam;

Fig. 56 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank shown in Fig. 46 which has been ablated by the laser beam in a nonsymmetrical manner;

Fig. 57 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank shown in Fig. 46 after a portion of the universal blank and a portion of the ablated exposed surface have been ablated by the laser beam in a nonsymmetrical fashion;

Fig. 58 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank shown in Fig. 46 of which multiple portions have been by a laser beam;

Fig. 59 is a side elevational view in section taken through the center of the eye showing the cornea and the flap-like portion reattached over the exposed surface of the cornea and the remaining portion of the universal blank shown in Fig. 46 after multiple portions of the universal blank and multiple portions of the ablated exposed surface have been ablated by the laser beam;

Fig. 60 is a perspective view of another embodiment of a universal blank according to the present invention;

Fig. 61 is a front elevational view of the embodiment shown in Fig. 60;

Fig. 62 is a top elevational view of the embodiment shown in Fig. 60;

Fig. 63 is a perspective view of another embodiment of a universal blank according to the present invention, which is a variation of the embodiment shown in Fig. 60;

Fig. 64 is a front elevational view of the embodiment shown in Fig. 63;

Fig. 65 is a top elevational view of the embodiment shown in Fig. 63;

Fig. 66 is a front elevational view of a variation to the embodiments shown in Figs. 60 and 63;

Fig. 67 is a side elevational view in section taken through the center of an eye and showing placement of the embodiment of the universal blank shown in Fig. 60 on the exposed surface of the cornea;

Fig. 68 is an enlarged side elevational view in section taken through the center of an eye and illustrating the universal blank shown in Fig. 60 positioned on the exposed surface of the cornea;

Fig. 69 is an enlarged front elevational view of the cornea with the universal blank shown in Fig. 60 present on the exposed surface thereof as shown in Fig. 68;

Fig. 70 is a side elevational view in section taken through the center of the eye showing the cornea and the irradiation of a laser beam on the exposed surface of the cornea and on the universal blank shown in Fig. 60 positioned on the exposed surface of the cornea;

and

Fig. 71 is a side elevational view in section taken through the center of the eye illustrating the flap-like portion repositioned over the remaining portion of the universal blank shown in Fig. 60 and ablated portion of the cornea.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1 is a side elevational view in section taken through the center of an eye 10 which includes a cornea 12, a pupil 14 and a lens 16. If the cornea 12 and lens 16 do not cooperatively focus light correctly on the retina (not shown) of the eye to thus provide adequate vision, the curvature of the cornea can be modified to correct the refractive power of the cornea and thus correct the manner in which the light is focused with respect to the retina.

A universal blank 18 according to an embodiment of the present invention is illustrated in Figs. 2-4. As shown, the universal blank according to this embodiment is disk-shaped and has a uniform or substantially uniform thickness throughout, as illustrated specifically in Fig. 3. Specifically, the blank 18 has a first planar, substantially planar, or substantially curved surface 15, a second planar, substantially planar, or substantially curved surface 17, and a periphery 19. The surfaces 15 and 17 are arranged parallel or substantially parallel to each other with the periphery 19 being perpendicular or substantially perpendicular to one or both surfaces 15 and 17. Of course, the surfaces 15 and 17 and the periphery 19 need not be uniform but could have recesses, projections, raised portions, or any variation in shape and texture. Preferably, the universal blank 18 has a diameter of about 4 to about 9 mm and a thickness of between about 20 to about 500 microns. Of course, the diameter and thickness of the disk-shaped universal blank 18 can be of any practical size as would be appreciated by one skilled in the art. Furthermore, the universal blank need not be disk-shaped although it is preferred as shown in the embodiment of Figs. 2-4, but can be frusto-conical, oval, square, rectangle, or any practical shape as would be readily appreciated by one skilled in the art.

The blank 18 is preferably made of synthetic material, organic material, or a combination of both synthetic and organic material, that permits all or substantially all light

having a wavelength in the visible spectrum to pass through, but absorbs all or substantially all light having a wavelength in a laser light spectrum. For example, the blank 18 can be made of collagen, copolymer collagen, polyethylene oxide or hydrogel, or cross-linked organic material such as collagen, hyaluronic acid, mucopolysacoharide or glycoprotein, to name a few. The blank 18 is porous to allow oxygen and nutrients to pass therethrough. Also, the blank 18 can be made from a donor cornea of a human eye, or can be taken from a cultured cornea. However, the blank 18 is not limited to those materials, and can be made of any suitable material, such as those disclosed in U.S. Patent No. 4,994,058 to Raven et al., U.S. Patent No. 4,718,418 to L'Esperance, U.S. Patent No. 5,336,261 to Barrett et al., U.S. Patent No. 4,840,175 to Peyman, and a publication by Jose I. Barraquer, M.D. entitled "Keratomileusis and Keratophakia in the Surgical Correction of Aphakia", the disclosures of which are hereby incorporated by reference herein.

The blank 18 is configured to be placed directly on an exposed inner surface of the cornea of the eye. In order to expose this inner surface of the cornea of the eye, a thin layer of the live cornea must be removed. To remove the layer of the cornea, a procedure is performed in which, for example, an incision 20 is made in the front portion of the cornea, as shown in Fig. 5. This incision 20 is made so as to separate thin layer 22 of the cornea from the remaining portion of the cornea 12. The incision can be made with a scalpel, keratome, excimer laser, or any type of surgical cutting instrument known to one skilled in the art. The layer 22 can also be separated from the surface of the live cornea by any other method which may not involve making an actual incision in the cornea as may be appreciated by one skilled in the art.

The layer 22 of the cornea can be completely removed from the remaining portion of the cornea 12. However, as shown in Figs. 5 and 6, it is preferable that the layer 22 of the cornea remain attached to the main portion of the live cornea 12 by an attaching or hinging portion 24 Accordingly, as shown in Fig. 7, the layer 22 of the cornea is formed as a flap-like layer that is pivotally moveable about the attaching portion 24 to expose an inner surface 26 of the cornea. The layer 22 typically can be of any practical thickness, for example, 160 microns.

The universal blank 18 is then used to modify the curvature of the cornea in the following manner.

As shown in Figs. 8 and 9, the flap-like layer 22 is positioned so as to expose the inner surface 26 of the cornea. The blank 18 is then positioned on the exposed surface of the cornea at a position deemed suitable by the person performing the cornea modifying technique. Typically, as shown in Fig. 10, the blank 18 is positioned centrally or substantially centrally on the exposed surface 26 with the central longitudinal axis of the blank substantially coincident with the central optical axis of the eye. Of course, the blank 18 need not be positioned centrally on the exposed surface 26 as shown, but rather, its central longitudinal axis can be offset from the central optical axis of the eye.

Once positioned on the exposed surface 26 of the cornea 12, the shape of the universal blank can be modified sufficiently to influence the shape of the flap-like layer 22 and to thus change the refractive power of the flap-like layer sufficiently to correct the abnormality of the eye 10. Generally, every 10 micron change in curvature of the cornea will change the refractive power of the cornea by 1 diopter.

For example, as shown in Figs. 11-14, a laser beam L is directed to the first upper surface 15 of the blank 18 that is opposite to the second lower surface 17 of the blank 18 that is supported on the exposed surface 26 of the cornea 12. The laser beam L can be emitted from any type of laser 27 typically used in eye surgery methods, such as an excimer laser 27 or the like as described in U.S. Patent No. 4,840,175.

As shown in Fig. 12, the laser beam L will begin to ablate or erode an area 32 of the blank 18 to which the laser beam is directed. Again, the area of the blank 18 to which the laser beam L is directed and which is ablated is selected to remedy a specific type of abnormality from which the eye is suffering.

For example, if the blank is being used to correct a myopic condition, the laser beam L will be directed toward a central area 32 of the blank 18 so as to ablate that central area 32. As shown in Fig. 13, for example, the blank 18 is disk-shaped, and the area 32 that is ablated is circular in top plan view and is at least initially in the form of a substantially hemispheric recess. Of course, the shape of the ablated area can be any desired shape necessary to effect correction of the particular abnormality of the eye.

As stated previously, the blank 18 is made of a material that will absorb all or substantially all light having a wavelength within the laser light spectrum. Therefore, when

the laser beam L is irradiated onto the blank 18, none or substantially none of the laser beam will pass through the blank 18 to ablate any portion of the cornea 12. However, as also previously stated, the material of the blank 18 will allow all or substantially all light having a wavelength within the visible light spectrum to pass therethrough.

Hence, as shown in Fig. 14, the laser beam L can be directed to the blank 18 until the ablated central area 32 becomes a hole with a frustoconical wall which passes entirely through the blank 18 to expose a portion 34 of the surface 26 of the cornea 12. Of course, the hole can have a cylindrically or substantially cylindrically shaped wall, or any other shape as would be formed by the laser beam L. As shown in Fig. 14, none or essentially none of the surface 26 of the cornea has been ablated by the laser beam.

After the laser ablation process has been completed, the flap-like layer 22 of the cornea is repositioned over the remaining portion of the blank 18 and the surface 26 of the cornea 12 as shown, for example, in Fig. 15. As illustrated, the shape of the remaining portion of the blank 18 will influence the shape of the flap-like layer 22 when the flap-like layer is repositioned over the remaining portion of the blank 18 and surface 26 of the cornea 12. Hence, the refractive power of this flap-like layer 22 will be changed due to this change in shape. The flap-like layer 22 can be reattached to the cornea 12 by any known techniques such as suturing or the like.

Because the material of the blank 18 is transparent or essentially transparent to light having a wavelength within the visible light spectrum, visible light will pass through the remaining portion to the blank 18 and enter the eye 12. However, because the reshaped flap-like layer 22 has a different refractive power, the flap-like layer 22 will refract the light passing therethrough differently than prior to the reshaping. Therefore, in cooperation with the lens 16 (see Fig. 1), this reshaped layer 22 will focus the light in the appropriate manner on the retina, thus correcting the ametropic condition of the eye.

It is further noted that the laser 27 can be used to reduce the overall thickness of the blank 18 prior to shaping the blank. For instance, the blank 18 can initially be about 500 microns thick for ease of handling. Then, once the blank 18 is positioned on the exposed inner surface of the cornea in the manner described above, the inner beam L can be directed to the upper surface 15 of the blank so as to reduce the overall thickness of the blank 18 as desired.

Hence, a 500 micron thick blank can be reduced, for example, to about 100 microns or any suitable thickness by the laser beam L before the laser beam L is used to sculpt the blank 18 to a particular shape as shown, for example, in Figs. 11-15.

Additionally, based on the severity of the abnormality from which the eye is suffering, it may be determined that the surface of the cornea must be reshaped more extensively. In this event, as shown in Fig. 16, the laser beam L can be irradiated onto the area 32 of the blank 18 until the area 32 of the blank 18 is completely ablated by the laser beam and becomes a hole that passes entirely through the blank 18. Afterward, the laser beam L is directed onto the exposed portion of the surface 26 of the cornea so as to ablate a portion 36 of that surface.

Accordingly, as shown in Fig. 17, when the flap-like layer is repositioned over the remaining portion of the blank 18 and the surface 26 of the cornea 12, the ablated portion 36 of the surface of the cornea 26 will also influence the shape of the repositioned flap-like layer 22. By using this technique, it is not necessary that the thickness of the blank 18 be changed in order to provide a more substantial change in the shape of the flap-like layer 22.

Alternatively, if the blank 18 is being used to correct a high hyperopia condition, the laser beam L can be directed toward the outer perimeter of the blank as shown, for example, in Figs. 18-21. As discussed above, the blank 18 is made of a material which will absorb all or substantially all of the laser beam. Therefore, as shown in Fig. 19 specifically, the blank 18 will be ablated by the laser beam, but none or substantially none of the surface 26 of the cornea 12 below the ablated area 38 of the blank will be ablated.

The laser beam L can be irradiated onto the ablated area 38 of the blank 18 until that area 38 is ablated down to the surface 26 of the cornea on which the blank 18 is positioned, and the remaining portion of blank 18 thus has a frustoconical shape. Of course, the blank 18 can be shaped in any manner by the laser beam L. As shown in Fig. 22, the flap-like layer 22 is then repositioned over the remaining portion of the blank 18 so that the remaining portion of the blank 18 influences the shape of the repositioned flap-like layer 22. Since the material of the blank 18 is transparent or substantially transparent to light having a wavelength in the visible light spectrum, visible light will pass through the remaining portion of the blank 18. However, because the reshaped flap-like layer 22 has a different refractive power, the flap-like layer 22 will refract the light passing therethrough differently than prior to the reshaping.

Therefore, in cooperation with the lens 16 (see Fig. 1), this reshaped layer 22 will focus the light in the appropriate manner on the retina, thus correcting the ametropic condition of the eye.

If a more substantial modification of the shape of the cornea is necessary to correct a more severe ametropic condition, the laser beam L can be directed onto the surface 26 of the cornea 12 in order to ablate a portion 40 of that surface 26 as shown, for example, in Fig. 23. As shown in Fig. 24, when the flap-like layer is repositioned over the remaining portion of the blank 18 and the surface 26 of the cornea 12, the ablated portion 40 of the surface 26 will also influence the shape of the repositioned flap-like layer 22. Accordingly, the thickness of the blank 18 need not be increased in order to increase the degree to which the flap-like layer 22 is reshaped. High myopic conditions up to 35 diopter can be corrected by using this technique.

As discussed above, any portion or portions of the blank 18 can be ablated to a degree necessary to correct the ametropic condition of the eye. For example, as shown in Figs. 25 and 26, the laser beam L can be directed toward a central area 32 of the blank 18 and also toward the 38 of the blank 18 to ablate inner and outer areas 32 and 38. As shown in Fig. 27, when the flap-like layer 22 is repositioned over the surface 26 of the cornea and the remaining portion of the blank 18, the remaining portion of the blank 18 will influence the shape of the flap-like layer 22.

As further shown in Fig. 28, any portion or amount of the exposed surface of the cornea 26 can be ablated as well, as long as a sufficient amount (e.g., 200 microns) of cornea is left remaining so that the remaining cornea does not experience instability or outbulging (ectasia). As illustrated, the laser beam L can be directed toward the surface 26 of the cornea underneath the ablated portions 32 and 38 of the blank 18 to ablate those portions 36 and 40 of the surface 26 of the cornea 12. Accordingly, as shown in Fig. 29, the remaining portion of the blank 18 and the ablated portions 36 and 40 of the surface 26 of the cornea 12 will influence the shape of the flap-like layer 22 when the flap-like layer 22 is repositioned over the remaining portion of the blank 18 and surface 26 of the cornea.

As illustrated in Fig. 30, the laser beam L can be directed onto the blank 18 to ablate the blank in a nonsymmetrical manner. This type of shaping of the blank 18 is usually done to correct an astigmatic condition of the eye. For example, the blank can be sculpted to assume a

substantially hemispherical shape resembling one-half of an egg as cut along the longitudinal axis of the eye. In other words, the blank 18 can assume a substantially hemispherical shape having a varying radius. As can be appreciated from Fig. 31, only a portion 42 of the right-side periphery of the blank 18 is ablated. Accordingly, as shown in Fig. 32, the remaining portion of the blank 18 will influence the shape of the flap-like layer 22 when the flap-like layer 22 is repositioned over the remaining portion of a blank 18 and surface of the cornea 26.

As shown in Fig. 33, any portion or amount of the exposed surface of the cornea 26 can be ablated in a nonsymmetrical manner as well, as long as a sufficient amount of cornea (e.g., about 200 microns) is left remaining so that the remaining cornea does not experience instability or outbulging (ectasia). In this event, the laser beam L is directed onto the portion of the disk 18 to be ablated, and after that portion has been ablated, the laser beam L is directed onto the surface of the cornea 26 below the ablated portion of the blank in a manner similar to that described, for example, with regard to Fig 16 until a portion 44 of the surface 26 is ablated. Then, as shown in Fig. 33, the flap-like layer 22 is repositioned over the remaining portion of the blank 18 and the surface 26 of the cornea so that the remaining portion of the blank 18 and the ablated portion 44 of the surface 26 of the cornea 12 will influence the shape of the flap-like layer 22.

Fig. 34 shows another embodiment of the method for using a universal blank according to the present invention. As illustrated, after the flap-like layer 22 has been positioned as shown in Fig. 7 to expose the inner surface 26 of the cornea, that surface 26 can be ablated by a laser beam before the blank 18 is positioned thereon. Specifically, the laser beam L is directed onto that exposed surface 26 to ablate the cornea 12 down to a particular depth. Typically, since the thickness of an average cornea is approximately 500 microns, the surface 26 can be ablated to any amount up to a depth of about 300 microns, which would leave a sufficient amount (e.g., about 200 microns) of cornea left remaining so that the cornea does not experience instability or outbulging as discussed above.

The ablated section 46 of the surface 26 can be symmetrical about the center of the front portion of the cornea as shown in Fig. 35. Preferably, the shape of the ablated section 46 will coincide with the shape of the blank 18 that is used in modifying the cornea. In the example illustrated in Fig. 36, the blank 18 is disk-shaped and hence, the ablated section 46 is

circular. Furthermore, the diameter of the ablated section will coincide or substantially coincide with the diameter of the disk 18. Of course, the shape of the ablated section 46 can be asymmetrical, for example, and can vary to accommodate a disk having any shape as would be appreciative by one skilled in the art. Furthermore, the center of the ablated section need not coincide with the optical axis of the eye, but rather could be offset from the optical axis. The edge 48 of the ablated section 46 will abut against the periphery 19 of the disk as shown in Fig. 36, thereby preventing or substantially preventing the disk 18 from moving laterally on the surface 26 of the cornea. However, the edge 48 need not contact the entire periphery 19 to achieve this function.

As shown in Fig. 37, the disk 18 can be ablated in the manner discussed above with regard to Figs. 11-14 so that a recess or hole is formed in the center or substantially in the center of the blank 18. In the example shown in Fig. 37, the ablation is stopped at the exposed ablated section 46 of the surface 26 so that none or substantially none of the ablated section 46 is further ablated. The flap-like layer 22 is then repositioned over the remaining portion of the blank 18 so that the remaining portion of the blank 18 and the central portion 50 of the exposed ablated section 46 influences the shape of the repositioned flap-like layer 22.

Alternatively, as shown in Fig. 38, the laser beam L can be directed onto the blank 18 and the exposed ablated section 46 in a manner similar to that described above with regard to Fig. 16. By doing this, a portion 52 of the ablated section 46 of the exposed surface 26 is further ablated. The ablated section 46 can be ablated by any amount as long as a sufficient amount (e.g., about 200 microns) of cornea 12 is left remaining. In this example, the remaining portion of the blank 18 and the ablated portion 52 of the exposed ablated section 46 influences the shape of the flap-like layer 22 when the flap-like layer is repositioned over the blank 18 and the exposed surface 26 of the cornea.

As shown in Fig. 39, the periphery of the blank 18 can be ablated in the manner similar to that discussed above with regard to Fig. 21. As shown, none or substantially none of the previously ablated surface 46 of the exposed surface 26 is ablated by the laser beam. Accordingly, as shown in Fig. 40, the remaining portion of the blank 18 and the ablated section 46 of the exposed surface of the cornea influences the shape of the flap-like layer 22 when the flap-like layer is repositioned over the blank and the exposed surface 26.

Alternatively, as shown in Fig. 41, a portion 54 of the ablated section 46 of the exposed surface 26 can be further ablated by the laser beam. In this event, when the flap-like layer 22 is repositioned over the exposed surface 26 and the remaining portion 18 of the blank, the ablated portion 54 and remaining portion of the blank 18 influence the shape of the flap-like layer 22.

As further shown in Figs. 42 and 43, a portion of the blank 18 alone or a portion of the blank 18 and a portion 56 of the ablated section 46 of the exposed surface 26 of the cornea 12 can be ablated in a nonsymmetrical manner. Accordingly, when the flap-like layer 22 is repositioned over the exposed surface 26 and the remaining portion of the blank, the shape of the remaining portion of the blank 18 and the ablated portion 56 influence the shape of the flap-like layer 22.

Also, as further shown in Figs. 44 and 45, multiple portions of the blank 18 alone or multiple portions of the blank and multiple portions 58 of the ablated section 46 of the exposed surface 26 can be ablated by the laser beam. Accordingly, the remaining portion of the blank 18, and the ablated portions 58 of the ablated section 46 of the exposed surface influence the shape of the flap-like layer 22 when the flap-like layer is repositioned over the remaining portion of the blank 18 and the exposed surface 26.

Another embodiment of the universal blank according to the present invention is shown in Figs. 46-48. Specifically, the blank 60 shown in Fig. 46 has a large portion 62 and a small portion 64. The large portion 62 can have any practical size and shape as could the blank 18 shown in Fig. 2 as discussed above, and can be made of the same type of materials as the blank 18.

In the example shown in Fig. 46, the large portion 62 of the blank 60 is disk-shaped and has a diameter of about 4 to about 9 millimeters and a thickness of between about 20 and about 500 microns. Of course, the diameter and thickness of the blank 60 can be of any practical size that would be appreciated by one skilled in the art.

As further illustrated in Figs. 47 and 48, the small portion 64 of the blank 60 is also disk-shaped, but has a small diameter than the large portion 62. The diameter of small portion 64 can be any practical size, such as a small disk-shaped projection having a nominal diameter up to a disk-shaped projection having a diameter only a fraction smaller than the diameter of

the large shaped portion 62. Of course, the small portion 64 need not be disk-shaped, but can have any practical shape as would be appreciative by one skilled in the art. Furthermore, the large portion 62 and small portion 64 can have shapes different from each other. Hence, for example, the large portion 62 can be disk-shaped while the small portion 64 can be oval or rectangularly shaped.

The large portion 62 has a first planar or substantially planar surface 63, a second planar or substantially planar surface 65, and a periphery 66. The surfaces 63 and 65 can be parallel or substantially parallel to each other, and the periphery 66 can be perpendicular to one or both of the surfaces 63 and 65. Of course, the surfaces 63 and 65 and the periphery 66 need not be smooth but can have projected portions, recesses or any type of texture.

The small portion 64 is integral with or attachable to the large portion 62 and a planar or substantially surface 68 and a periphery 69. The surface 68 can be parallel or substantially parallel to one or both of the surfaces 63 and 65 of the large portion 62, and the periphery 69 could be perpendicular or substantially perpendicular to the surface 68. Of course, the surface 68 and periphery 69 need not be smooth but can have projected portions, recesses or any type of texture.

An embodiment of a method for using the universal blank 60 according to the present invention is shown in Fig. 49. Specifically, the surface of the cornea 26 that has been exposed by forming and positioning the flap-like layer 22 in the manner discussed above is ablated in the manner shown in Fig. 49. That is, the exposed surface 26 is ablated to different depths so as to assume a shape which can accommodate the blank 60. Hence, an outer section 70 of the exposed surface 26 is ablated to a first depth, while an inner section 71 is ablated to a second depth greater than the first depth. The depths of the ablated inner and outer sections 70 and 71 can be any amount which would allow a sufficient amount of cornea 12 (e.g., about 200 microns) to remain so that the remaining cornea does not experiencing distortion or outbulging. It is noted that this step-shaped blank 60 provides an advantage over a uniformly shaped blank 18 in this regard, because less volume of cornea can be ablated to form a recess which will accommodate the smaller portion 64 of the blank 60 and thus point the blank 60 from shifting on the surface of the cornea. That is, the volume of cornea removed to form section 71 is less than the volume of cornea removed to form section 46 (Fig. 34).

As shown in Fig. 51, the blank 60 is positioned on the ablated sections 70 and 71 of the exposed surface 26 so that the surface 68 of the small portion 64 of the blank 60 contacts or substantially contacts the ablated section 71 while the surface 65 of the large portion 62 of the blank 60 contacts or substantially contacts the ablated section 70 as shown. As further shown, an edge 72 of the ablated section 71 contacts the periphery 66 of the large portion of the blank 60, while an edge 74 of the ablated section 71 contacts the periphery 69 of the small portion 64 of the blank 60. Of course, the sizes and shapes of the ablated section 70 and 71 can be made to conform or substantially conform with the sizes and shapes of the large and small portions 62 and 64, respectively, of the blank 60, and can thus be any practical size and shape as would be appreciated by one skilled in the art. Also, the ablated sections 70 and 71 need not be made symmetrical about the central optical axis of the eye, but rather, could be offset from the central optical axis of the eye and from each other. The edges 72 and 74 of the ablated sections 70 and 71, respectively, can contact the peripheries 66 and 69, respectively, in their entirety or at various locations.

As further shown in Fig. 51, the laser beam L is irradiated onto the blank 60 in a manner similar to that described above with regard to Figs. 11-14 to ablate a central or substantially central portion of the blank 60 as shown in Fig. 52. That ablated portion can be, for example, a substantially hemispherical recess as discussed above with regard to Figs. 11-14. As further shown in Fig. 52, none or substantially none of the ablated section 71 is further ablated by this laser beam. Accordingly, the surface of the ablated section 71 and the remaining portion of the blank 60 influence the shape of the flap-like layer 22 when the flap-like layer 22 is repositioned over the blank 60 and the exposed surface 26.

Alternatively, shown in Fig. 53, a portion 76 of the ablated section 71 below the ablated portion of the blank 60 can be further ablated by the laser beam to any depth which would allow a sufficient amount (e.g., about 200 microns) of the cornea 12 to remain. Accordingly, the ablated portion 76 and remaining portion of the blank 60 influence the shape of the flap-like layer 22 when the flap-like layer 22 is repositioned back over the exposed surface 26 and the remaining portion of the disk 60.

As further shown in Fig. 54, multiple portion of the blank 60 can be ablated in a manner similar to that in which the blank 18 is ablated as described, for example, with respect

to Figs. 18-22 above. Furthermore, as shown in Fig. 55, the laser beam can be directed onto the ablated section 70 of the exposed surface 26 to ablate portion 78 of that ablated section 70. Accordingly, as shown in Fig. 54, the remaining portion of the blank 60 and the ablated section 70 influence the shape of the flap-like layer 22 when the flap-like layer 22 is repositioned over the exposed surface 26 and the remaining portion of the blank 60. Conversely, as shown in Fig. 55, the remaining portion of the blank 60 and the further ablated portion 78 of the ablated section 70 of the exposed surface 26 influence the shape of the flap-like layer 22 when the flap-like layer 22 is repositioned over the exposed surface 26 in the remaining portion of the blank 60.

As further shown in Figs. 56 and 57, the blank 60 and ablated section 70 of the exposed surface 26 can be ablated by the laser beam in a nonsymmetrical manner. Accordingly, as shown in Fig. 56, the remaining portion of the blank 60 and the ablated section 70 influence the shape of the flap-like layer 22 when the flap-like layer is repositioned over the surface 26 in the remaining portion of the blank 60. As shown in Fig. 57, the nonsymmetrical ablated portion 80 and the remaining portion of the blank 60 influence the shape of the flap-like layer 22 when the flap-like layer is repositioned over the exposed surface 26 and the remaining portion of the blank 60.

As shown in Figs. 58 and 59, the blank 60 and ablated section 70 can be ablated at multiple locations in a manner similar to that in which the blank 18 and surface 26 are ablated as described above with regard to Figs. 25-29. Accordingly, as shown in Fig. 58, the remaining portion of the blank 60 and the ablated sections 70 and 71 of the exposed surface 26 influence the shape of the flap-like layer 22 when the flap-like layer 22 is repositioned over the exposed surface 26 and the blank 60. Alternatively, as shown in Fig. 59, the further ablated portion 82 of the ablated section 70, the further ablated portion 84 of the ablated section 71, and the remaining portion of the blank 60 influence the shape of the flap-like layer 22 when the flap-like layer 22 is repositioned over the remaining portion blank 60 and the exposed surface 26.

Another embodiment of the universal blank according to the present invention is shown in Figs. 60-62. Specifically, the blank 86 is annular or ring-shaped having an upper planar, substantially planar or substantially curved surface 88, a lower planar, substantially

planar surface or substantially curved 90, an outer wall 92 and an inner wall 94 defining an opening 96 through the blank 86. The opening 96 can be circular in shape, as shown, or any suitable shape such as oval, multi-sided (e.g., square, rectangular, triangular), and so on. The opening 96 also need not pass entirely through the blank 86 as shown, but can be a recess in the blank 86. The surfaces 88 and 90 can be parallel or substantially parallel to each other, or at any suitable angle, and either the outer wall 92, the inner wall 94, or both, can be perpendicular to one or both of the surfaces 88 and 90, or can be at any suitable angle with respect to the surfaces 88 and 90. Also, the surfaces 88 and 90, the outer wall 92 and inner wall 94 need not be smooth, but can have projected portions, recesses or any type of texture or degree of curvature, and can have any shape such as concave, convex, toric, and so on.

The blank 86 can be made of the same types of materials as blanks 18 and 60 discussed above. Typically, the blank 86 has an outer diameter within a range of about 4 mm to about 11 mm, and opening 96 has a diameter of about 0.1 mm to about 10 mm, depending on the size of the outer diameter. Furthermore, the blank 86 can have a thickness ranging from about 10 μm to about 1000 μm, with a thickness of about 144 μm being a suitable exemplary thickness. In general, about 12 μm of blank thickness provides a correction of about 1 diopter. Hence, a 144 μm thick blank provides for a correction of about 12 diopters.

Also, the blank itself can have any suitable shape, such as oval, square, rectangular, polygonal, and so on. As shown, for example, in Figs. 63-65, the blank can be an oval shaped blank 98 having an upper surface 100, a lower surface 102, an outer wall 104 and an inner wall 106 defining an opening 108 through the blank 98 which, like opening 96, can be circular, oval, or any other suitable shape, and can pass entirely through the blank 98 or be a recess in the blank 98. Blank 98 can be made of the same types of materials as blanks 18, 60 and 86 discussed above, and can have similar dimensions. That is, the largest overall outer diameter of blank 98 can range from about 4 mm to about 11 mm, and the largest overall diameter of opening 108 can range from about 0.1 mm to about 10 mm, depending on the size of the outer diameter.

Furthermore, the blank 98 can have a thickness ranging from about 10 μm to about 1000 μm, with a thickness of about 144 μm being a suitable exemplary thickness. Also, the surfaces 100 and 102 can be parallel or substantially parallel to each other, or at any suitable

angle, and either the outer wall 104, the inner wall 106, or both, can be perpendicular to one or both of the surfaces 100 and 102, or can be at any suitable angle with respect to the surfaces 100 and 102. Also, as with blank 100, the surfaces 100 and 102, the outer wall 104 and inner wall 106 need not be smooth, but can have projected portions, recesses or any type of texture or degree of curvature.

In addition, as shown in Fig. 66, either of blanks 86 and 98 can have a varying thickness ranging from about 20 μm to about 500 μm, which is especially useful in correcting astigmatic conditions. Furthermore, the blanks 86 and 98 need not be completely annular. That is, blanks 86 and 98 can include a gap 110 and 112, respectively, as shown in Figs. 62 and 65, which can be of any suitable width. The gaps 110 and 112 can be wedge-shaped as shown. That is, the surfaces 114 and 116 forming gap 110 can extend angularly with respect to each other as shown. Alternatively, gap 110 can be slot-like, with the surfaces 114 and 116 extending parallel or substantially parallel to each other. Likewise, the surfaces 118 and 120 forming gap 112 can extend angularly with respect to each other as shown. Alternatively, gap 112 can be slot-like, with the surfaces 118 and 120 extending parallel or substantially parallel to each other. The surfaces 114, 116, 118 and 120 can be smooth, or can have projections or any suitable texture. Also, instead of gaps, the regions designated by 110 and 112 can be regions in which the thickness of the respective blanks 86 and 98 are greater than or less than the overall thickensses of the remainder of the respective blanks 86 and 98.

An embodiment of a method for using the universal blanks 86 and 98 according to the present invention is shown in Figs. 67-71, which is similar to the methods described above regarding blank 18. For exemplary purposes, Figs. 67-71 illustrate blank 86. However, blank 98 is used in a similar manner.

Specifically, a flap-like layer 22 having a diameter of about 8 mm to about 9 mm and a thickness of about 160 μm is separated from the cornea 12 in the manner described above to expose a surface 26. As shown in Figs. 67-69, the blank 86 is positioned on the exposed surface 26 so that the surface 90 contacts the surface 26. Typically, the blank 86 (or 98) is positioned on the surface 26 so that its center is substantially aligned with the optical axis of the eye 10. However, the blank 86 (or 98) can be placed at any location on surface 26.

As further shown in Fig. 70, the laser beam L is irradiated onto the portion of the

exposed surface 26 which remains exposed by the opening 96 (or 108) in the blank 86 (or 98), and ablates that portion of the surface 26. Alternatively or in addition, the laser beam L can be irradiated onto the blank 86 (or 98) to ablate a portion of the blank. Typically, the portion of the blank 86 (or 98) that is ablated is that which includes inner wall 94 (or 106), thus enlarging the diameter of opening 96 (or 108).

Accordingly, as shown in Fig. 70, a portion 122 of the surface 26, a portion 124 of the blank 86 (or 98), or both are ablated by the laser beam L. The surface 26 of the cornea 12 can be ablated up to any suitable depth as discussed above, to correct for the vision disorder as appropriate. Also, the portion of the blank 86 (or 98) can be ablated entirely, or by a desired amount, to correct for the vision disorder as appropriate. It is further noted that the ablation of the exposed surface 26 and blank 86 (or 98) need not occur evenly. That is, some of the exposed surface 26 can be ablated to a larger depth than other portions of the exposed surface 26 being ablated. Likewise, some of the blank 86 (or 98) can be ablated to a depth greater than that to which other portions of the blank are ablated. In any event, the degree to which the exposed surface 26 of the cornea 12 and, if necessary, the blank 86 (or 98) is ablated is dependent on the severity of the vision disorder being corrected, as well as the type of vision disorder (e.g., myopia, hyperopia or astigmatism).

Once the desired amount of ablation has occurred, the flap-like layer 22 is repositioned over the blank 86 (or 98) and exposed surface 26 as shown in Fig. 71. In a manner similar to that described above, the flap-like layer 22 rests on the blank 86 (or 98) and surface 26 in a relaxed state. Accordingly, the ablated surface 26 and the remaining portion of the blank 86 (or 98) influence the shape of the flap-like layer 22 when the flap-like layer 22 is repositioned over the blank and the exposed surface 26. The new shape assumed by the flap-like layer 22 thus corrects the refractive power of the eye 10 as necessary to correct the vision disorder.

Another embodiment of the universal blank shown in Figs. 60-62, for example, allows for the specific parameters of the blank to be prefabricated, such as by ablation by an excimer laser or shaping in a cryolathe, so that the lower (posterior) surface 90 of the blank 86 has the same or similar radius of curvature as the preoperative live cornea. The upper (anterior) surface 88 may have a curvature which is concave, convex, toric or parallel in relation to posterior surface 90, or any other suitable curvature. Posterior surface 90 can also have any of

these curvatures if desired. The thickness of the blank 86, the curvature of anterior surface 88, the length of the gap 110 (or thickness of the region between surfaces 118 and 120) can be prefabricated to correct ametropia and astigmatism without the use of laser ablation. The universal blank having the shape shown in Fig. 63-65 can have similar prefabricated characteristics, as desired.

The prefabricated blank 86 (as well as blank 98) can then be used in a manner similar to that described above. That is, the flap-like layer 22 having a diameter of about 8 mm to about 9 mm and a thickness of about 160 μm is separated from the cornea 12 in the manner described above to expose a surface 26. The blank 86 is positioned on the exposed surface 26 so that the surface 90 contacts the surface 26. Typically, the blank 86 (or 98) is positioned on the surface 26 so that its center is substantially aligned with the optical axis of the eye 10. However, the blank 86 (or 98) can be placed at any location on surface 26.

The flap-like layer 22 is then repositioned over the blank 86 (or 98) and exposed surface 26. In a manner similar to that described above, the flap-like layer 22 rests on the blank 86 (or 98) and surface 26 in a relaxed state. Accordingly, the exposed surface 26 and the prefabricated blank 86 (or 98) influence the shape of the flap-like layer 22 when the flap-like layer 22 is repositioned over the blank and the exposed surface 26, without ablating any portion of the flap-like layer 22, the blank 86 (or 98), or exposed surface 22. The new shape assumed by the flap-like layer 22 thus corrects the refractive power of the eye 10 as necessary to correct the vision disorder.

In addition, blanks 18 and 60 can be prefabricated in a manner similar to blank 86, and used in a manner similar to blank 86 without laser ablation as described above.

Once the flap-like layer 22 and surface 26 heal, the patient's eyesight can be tested. If it is determined that the vision disorder has not be satisfactorily corrected, the flap-like layer 22 can be again separated from the cornea 12, and the surface 26 and/ or blank 86 (or 98) can be further ablated as necessary. Also, if deemed appropriate, an additional blank or blanks having the same or different shape and characteristics of the existing blank can be stacked on the surface 88 (or 100) of the blank 86 (or 98), and the additional blank or blanks can be ablated as necessary. The flap-like layer 22 can be then repositioned over the blank and surface 26, allowed to heal, and the eyesight can again be tested. The steps of removing the

flap-like layer 22 and ablation, as well as the addition of more blanks, can be repeated as many times as necessary to properly correct the vision disorder. It is desirable that vision up to 20/15 or 20/10 can be achieved.

Due to the presence of openings 88 and 108 in blanks 86 and 98, respectively, blanks 86 and 98 each uses less material than a solid blank (e.g., blank 18 discussed above) having the same overall diameter and thickness. Moreover, because the openings are already present in the blanks 86 and 98, it may only be necessary to ablate the exposed surface of the cornea through the opening in the blank to achieve the appropriate corneal modification. In this event, less laser usage and thus, less overall surgical time, is required.

Although only a few exemplary embodiments of this invention have been described in detail above, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the following claims.

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CLAIMS:

1. A blank, adaptable for use in modifying the curvature of a patient's live cornea, comprising:

a first surface adapted for placement directly on a surface of said patient's live cornea;

a second surface adapted to be exposed to a laser beam;

a wall surface, extending between said first and second surfaces; and defining an opening in said blank;

a first portion between said first surface and said second surface, said portion surrounding a majority of said opening and defining a first thickness; and

a second portion between said first surface and said second surface, said second portion having a second thickness, said second thickness being less than said first thickness;

said blank comprising a material whose properties permit light having a wavelength within the visible spectrum to pass therethrough and prevent substantially all light having a wavelength within the laser light spectrum from passing therethrough.

2. A blank according to claim 1, wherein said material is adapted to be ablated by laser light.

3. A blank according to claim 1, wherein the thickness of said blank is within a range of about 10 to about 1000 microns, and a maximum length of at least one of said first and second surfaces of said blank is within a range of about 4 mm to about 11 mm.

4. A blank according to claim 1, wherein said blank is annularly-shaped having said first and second surfaces on opposite sides thereof, the thickness of said blank is within a range of about 10 to about 1000 microns, the diameter of said blank is within a range of about 4 mm to about 11 mm, and the diameter of said opening is within a range of about 0.1 mm to about 10 mm.

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5. A blank according to claim 1, wherein said material is one of organic material and synthetic material.

6. A blank according to claim 1, wherein said material is one of collagen, copolymer collagen, polyethylene oxide and hydrogel.

7. A blank according to claim 1, wherein said material includes one of the following cross-linked organic materials: collagen, hyaluronic acid, mucopolysaccharide and glycoprotein.

8. A blank according to claim 1, wherein said blank has a substantially uniform thickness between said first and second surfaces.

9. A blank according to claim 1, wherein said first and second surfaces each are substantially planar surfaces, or substantially curved surfaces.

10. A blank according to claim 9, wherein said first and second surfaces are substantially parallel to each other.

11. A blank according to claim 9, wherein said second surface is convex, concave, or toric in relation to said first surface.

12. A blank according to claim 1, wherein said wall surface extends at an angle other than 0° with respect to said first and second surfaces.

13. A blank according to claim 1, wherein said wall surface is convex, concave or toric.

14. A blank according to claim 1, wherein said wall surface extends substantially perpendicularly with respect to at least one of said first and second surfaces.

15. A blank according to claim 14, wherein said wall surface extends substantially

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perpendicular with respect to said first and second surfaces.

16. A blank according to claim 1, wherein said blank is annularly-shaped.

17. A blank according to claim 1, wherein said blank is oval-shaped.

18. A blank according to claim 1, wherein said wall surface defines said opening as a substantially circularly-shaped opening.

19. A blank according to claim 1, wherein said wall surface defines said opening as an oval-shaped opening.

20. A blank according to claim 1, wherein said second thickness is zero.

21. A blank according to claim 1, wherein said second portion has a first edge and a second edge, said first and second edges extending from said opening to a periphery of said blank.

22. A blank according to claim 21, wherein said first and second edges extend substantially parallel to each other.

23. A blank according to claim 21, wherein said first and second edges extend at angularly with respect to each other.

24. A blank according to claim 21, wherein said first and second edges are smooth.

25. A blank according to claim 1, wherein said first and second edges have projections thereon.

26. A method of modifying a blank, comprising the steps of:

separating a layer of said live cornea from the front of said live cornea;

moving said separated layer to expose an internal surface of said live cornea underneath said separated layer;

positioning a blank, having an opening therein, on said internal surface of said live cornea;

directing a laser beam onto a portion of said blank to ablate said portion of said blank, while leaving an unablated portion of said blank on said internal surface of said live cornea; and

repositioning said separated layer of said live cornea back over said internal surface of said live cornea and said unablated portion of said blank, so that the shape of the internal surface and said unablated portion of said blank influences the shape of said repositioned separated layer of said live cornea.

27. A method according to claim 26, wherein the separating step comprises one of the following steps:

directing a laser beam onto said live cornea to separate said separated layer from said live cornea; and

using a blade to cut an incision into said live cornea to separate said separated layer from said live cornea.

28. A method according to claim 26, wherein the separating step comprises the step of forming said separated layer as a flap having an attaching portion which remains attached to said live cornea.

29. A method according to claim 28, wherein the separated layer moving step comprises the step of moving said separated layer about said attaching portion to expose said internal surface.

30. A method according to claim 26, wherein the laser beam directing step

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comprises the step of directing said laser beam onto said blank to ablate said portion of said blank without ablating substantially any of said internal surface.

31. A method according to claim 26, wherein said portion of said blank includes surfaces of said blank defining said opening in said blank.

32. A method according to claim 26, wherein the laser beam directing step comprises the step of directing said laser beam onto said internal surface to ablate said portion of said internal surface without ablating substantially any of said blank.

33. A method according to claim 26, wherein the laser beam directing step comprises the step of directing said laser beam onto said blank and onto said inner surface to ablate said portion of said blank and said portion of said internal surface.

34. A method according to claim 26, wherein said blank is annular-shaped.

35. A method according to claim 26, wherein said blank is oval-shaped.