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(54) Title: EPITHELIAL POCKET EXPANDING TOOL AND COMBINATION EPITHELIAL DELAMINATING DEVICE AND CORNEAL REFORMER

(57) Abstract: The described devices are useful in the field of ophthalmology. The devices and methods for using them involve separating or lifting corneal epithelium from the eye in a substantially continuous layer to form a flap or pocket. In particular, the devices generally utilize a non- cutting separator or dissector that is configured to separate the epithelium at naturally occurring cleavage surfaces in the eye, particularly between the epithelium and the corneal stroma (Bowman's membrane), specifically separating in the region of the lamina lucida. The dissector may oscillate during the noted separation. The separator or dissector may also have a structure that expands the epithelial pocket after formation. Independently, the separator or dissector may also include structure that alone or in combination with various energy sources, reforms the underlying cornea in a refractive procedure or treats other maladies. After such steps, the epithelium tissue member may then be replaced on the cornea or onto an ocular lens after placement of that ocular lens on the eye.

EPITHELIAL POCKET EXPANDING TOOL AND COMBINATION EPITHELIAL DELAMINATING DEVICE AND CORNEAL REFORMER

FIELD

[0001] The described devices are useful in the field of ophthalmology. The devices and methods for using them involve separating or lifting corneal epithelium from the eye in a substantially continuous layer to form a flap or pocket. In particular, the devices generally utilize a non-cutting separator or dissector that is configured to separate the epithelium at naturally occurring cleavage surfaces in the eye, particularly between the epithelium and the corneal stroma (Bowman's membrane), specifically separating in the region of the *lamina lucida*. The dissector may oscillate during the noted separation. The separator or dissector may also have a structure that expands the epithelial pocket after formation. Independently, the separator or dissector may also include structure that alone or in combination with various energy sources, reforms the underlying cornea in a refractive procedure or treats other maladies. After such steps, the epithelium tissue member may then be replaced on the cornea or onto an ocular lens after placement of that ocular lens on the eye.

BACKGROUND

[0002] Refractive surgery refers to a set of surgical procedures that change the native optical or focusing power of the eye. These changes alleviate the need for glasses or contact lenses that an individual might otherwise be dependent on for clear sight. The majority of the focusing power in the human eye is dictated by the curvature of the air-liquid interface, where there is the greatest change in the index of refraction. This curved interface is the outer surface of the cornea. The refractive power of this interface accounts for approximately 70% of the total magnification of the eye. Light rays that make up the images we see pass through the cornea, the anterior chamber, the crystalline lens, and the vitreous humor before they are focused on the retina to form an image. It is the magnifying power of this curved, air-corneal interface that provided the field of refractive surgery with the opportunity to surgically correct visual deficiencies.

[0003] Initial refractive surgical procedures corrected nearsightedness by flattening of the curvature of the cornea. The first largely successful procedure was called radial keratotomy (RK). RK was widely used during the 1970's and early 1980's where radially oriented incisions were made in the periphery of the cornea. These incisions allowed the peripheral cornea to bow outwards, consequently flattening the central optical zone of the cornea. This

was fairly easy and thus, popular, but it rarely did more than lessen one's dependency on glasses or contract lenses.

[0004] A largely flawed and failed procedure called epikeratophakia was developed in the era of RK. It is now essentially an academic anomaly. Epikeratophakia provided a new curvature to the outer curvature of the cornea by grafting onto the cornea a thin layer of preserved corneal tissue. Lyophilization is the preservation method used in epikeratophakia where the cornea is freeze-dried. The tissue is not acellularized but is rendered non-living. During the process of freeze drying, the cornea is also ground to a specific curvature.

[0005] The epikeratophakia lens was placed into the eye surgically. An annular 360° incision was placed into the cornea after completely removing the epithelium from where the epikeratophakic lens would sit. The perimeter of this lens would be inserted into the annular incision and held in place by a running suture. There were several problems with epikeratophakia: 1) the lenses remained cloudy until host stromal fibroblasts colonized the lens, which colonization possibly could take several months; 2) until migrating epithelium could grow over the incision site onto the surface of the lens, the interrupted epithelium was a nidus for infection; and 3) epithelium healing onto the surgical site sometimes moved into the space between the lens and the host cornea. Currently, epikeratophakia is limited in its use. It is now used in pediatric aphakic patients who are unable to tolerate very steep contact lenses.

[0006] Major industrial research efforts tried to produce a synthetic version of the epikeratophakic graft called the synthetic onlay in a synthetic epilens. Different synthetic polymers were used (hydroxyethylmethacrylate, polyethylene oxide, lidofilcon, polyvinyl alcohol). Hydrogels of these materials normally did not have a surface that was readily conducive to epithelial cells growing and adhering onto these synthetic surfaces. This was one of the major setbacks of synthetic onlays. Epithelial cells could not adequately heal onto these lenses.

[0007] Another problem with these synthetic lenses is that they did not adhere well to the surface of the eye. Conventional suturing was difficult and the use of biological glues was also flawed. Glues were not ideally biocompatible in the cornea.

[0008] Lastly, the permeability of these hydrogels was significantly limiting. Living epithelial cells on the surface had difficulty achieving adequate nutrition. Corneal epithelial nutritional flow is from the aqueous humor through the cornea out to the epithelial cells. In the end, industrial efforts failed to develop an adequate synthetic epikeratophakic lens.

[0009] Around the mid 1990's procedures that sculpt the cornea with lasers were sufficiently successful that they began to replace radial keratotomy. The first generation of laser ablation of the cornea was called photorefractive keratectomy (PRK). In PRK, an ablative laser (e.g., an excimer laser) is focused on the cornea to sculpt a new curvature into the surface. In PRK, the epithelium is destroyed when achieving a new outer surface curve. Over the ensuing post-operative days, the epithelium has to grow or heal back into place. This epithelial healing phase was problematic for most patients since the epithelially denuded and ablated cornea was painful. It is also initially difficult to see, and this "recuperative time" can last from days to a week or more.

[0010] A subsequent variation of PRK corneal laser ablation, LASIK, has become very popular. The LASIK procedure, also known as laser in situ keratomileusis, is synonymous in the public mind with laser vision correction. In LASIK, an outer portion (or chord-like lens-shaped portion) of the cornea (80 to 150 microns thick) is surgically cut from the corneal surface. This is performed by a device called a microkeratome. The microkeratome is a device which cuts a circular flap from the surface of the cornea which remains hinged at one edge. This flap is reflected back and an ablative (excimer) laser is used to remove or to reform a portion of the exposed surgical bed. The flap is laid back into place. When this flap is laid back into place, the cornea achieves a new curvature because the flap conforms to the laser-modified surface. In this procedure, epithelial cells are not removed or harmed. The epithelial cells have simply been incised at the edge of this flap. When the flap is placed back onto the corneal bed, the epithelium heals back at the incision site. There is essentially no recuperative time and the results are almost immediate. Because there is very little surgical time (15 minutes for each eye) and because there are lasting and very accurate results, LASIK is currently considered the premier manner of performing refractive surgery.

[0011] The newest technique being evaluated in high volume refractive surgical practices and in some academic centers is a procedure called Laser Assisted Subepithelial Keratomileusis (LASEK). In LASEK, a "flap" is made of only epithelium. This layer of epithelium is lifted off the cornea in a manner similar to LASIK. The ablative laser is focused just on the surface of the denuded cornea (in the same manner as was done with PRK). However, this epithelial flap is left intact, i.e., epithelium is not destroyed. It is simply rolled back into place after formation of the re-curved anterior portion of the cornea, resulting in much less recuperative time than with PRK. Current methods of LASEK are not as good as LASIK but the results are better than with PRK.

[0012] The corneal epithelium is a multilayered epithelial structure typically about 50 ☒m in thickness. It is non-cornified. The outer cells are living, although they are squamous in nature. The basal epithelial cells are cuboidal and sit on the stromal surface on a structure known as Bowman's membrane. The basal cell layers is typically about 1 mil thick (0.001"). The basal cells produce the same keratins that are produced in the integument, i.e., skin. The basal epithelial cells express keratins 5 and 14 and have the potential to differentiate into the squamous epithelial cells of the corneal epithelium that produce keratins 6 and 9. The corneal epithelium has a number of important properties: 1) it is clear; 2) it is impermeable; 3) it is a barrier to external agents; and 4) it is a highly innervated organ. Nerves from the cornea directly feed into the epithelium, and thus, defects of this organ produce pain.

[0013] Epithelial cells are attached side-to-side by transmembrane molecules called desmosomes. Another transmembrane protein, the hemidesmosome, connects to collagen type 7 and is present on the basolateral surface of basal epithelial cells. Hemidesmosomes anchor epithelium to the underlying collagenous portion of the stroma. The junction between the epithelium and corneal stroma is referred to as basement membrane zone (BMZ).

[0014] When LASEK is performed, a physical well is placed or formed on the epithelium and filled with a selection of 20 percent ethanol and balanced salt solution. Contact with the solution causes the epithelial cells to lose their adherence at the BMZ, most likely by destroying a portion of that cell population. The epithelium is then raised by pushing the epithelium, e.g., with a Weck sponge, in a manner similar to striping a wall of paint. The exposed collagenous portion of the corneal stroma is then ablated to reshape its surface. A weakened epithelium is then rolled back into place to serve as a bandage. However, this "bandage" fails to restore the epithelium to its original state, i.e., it does not preserve the integrity of the epithelium, thereby reducing its clarity, impermeability to water, and barrier function. Furthermore, the ability of the epithelium to adhere to the corneal stromal surface is impaired.

[0015] U.S. Patent Nos. 6,099,541 and 6,030,398 to Klopotek describe an microkeratome apparatus and method for cutting a layer of corneal epithelium to prepare the eye for LASIK or other reshaping procedures. The epithelium, if replaced, is attached using surgical techniques.

[0016] None of the cited references shows or suggests my described devices.

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SUMMARY

[0024] The description includes mechanical non-cutting devices and methods to form a separation of the epithelium from the eye or to lift a generally continuous layer of epithelium from its supporting underlying structure. The epithelial delaminator is used to create an epithelial flap or a pocket. The flap or pocket may be used in conjunction with a refractive surgical procedure or with placement of refractive lens.

[0025] The epithelial delaminator may be mechanical in nature. Such mechanical delaminators lift epithelium in a generally continuous layer from the anterior surface of the eye by application of a dissecting, non-cutting, mechanical force. Mechanical delaminators specifically include blunt dissectors and wire-based dissectors having wires that are passive or active as applied to the eye.

[0026] Furthermore, the described devices and methods may be used variously to form epithelium tissue members such as pockets or flaps and to reform the underlying corneal surface without removing the device, de-epithelialize the cornea in preparation for a

reshaping or reforming procedure such as LASEK, to form a pocket for inclusion of a contact lens, or to expand a pocket so-formed if desired.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Figs. 1A – 1D show a schematicized version of a generalized method of using the generic devices described here.

[0028] Figs. 2A – 2E show various directional and cross-sectional views of the combination device for forming an epithelial tissue member and reforming a cornea beneath it.

[0029] Fig. 3A shows cross section of the combination corneal reforming device in a generalized placement of laser emission sites.

[0030] Fig. 3B shows a bottom view of the device of Fig. 3A.

[0031] Fig. 4 shows a section of corneal reforming device utilizing lasers and a heat absorptive and conductive contact layer.

[0032] Fig. 5 shows a device similar to that of Fig. 4, but instead including discrete, heat conducting members.

[0033] Figs. 6 and 7 depict examples of formations of discrete, heat conducting sites suitable for use with the variation shown in Fig. 5.

[0034] Fig. 8A depicts an RF device in which the dissector (shown in Fig. 8B) comprises a number of RF-receiving sites that are heated upon application of RF, and an external RF antenna source having selectable RF transmission sites for cooperatively heating the receiving sites situated upon the dissector. The antenna source is shown in a bottom view in Fig. 8C.

[0035] Figs. 9A and 9B show additional variations of the combination RF source dissector.

[0036] Fig. 10 shows a combination dissector that includes a number of thermal heat sources.

[0037] Fig. 11 shows a side, sectional view of a device similar to that in Fig. 10, but also having discrete heat conduction sites.

[0038] Figs. 12A and 12B provide a side view of a dissector that is configured to form and to expand an epithelial pocket.

[0039] Figs. 13A and 13B show cross-sectional views of dissector such as that found in Figs. 12A and 12B with a hinged rotation member.

[0040] Figs. 14A and 14B show side, sectional views of a dissector having a hydraulically expandable member.

[0041] Figs. 15A and 15B show side, sectional views of expandable dissector that expands in the center of the device.

DETAILED DESCRIPTION

[0042] For any integument surface such as the skin, respiratory epithelium, gut epithelium, and cornea, there is an epithelial cell layer that is adherent to an underlying basement membrane. When epithelium is separated from its basement membrane and underlying collagenous tissue, a subepithelial blister is formed. In general, gross separation less than 1mm in diameter is known as vesiculation and separation greater than 1 millimeter in diameter, a true blister.

[0043] A continuous layer of corneal epithelium may be separated from or lifted from the anterior surface of the eye by applying various mechanical forces to this anterior surface, or to the basal cell layer, or to the junction between the basal cell layer and the Bowman's Layer or membrane (the "lamina lucida"). The term "continuous" as used herein means "uninterrupted". The term "mechanical force" as used herein refers to any physical force produced by a person, instrument, or device. Examples of mechanical forces include suction, shearing, and blunt forces.

[0044] Mechanical forces are applied to epithelium such as corneal epithelium by epithelial delaminators. As used herein, the term "epithelial delaminator" refers to any instrument or device that separates epithelium from the basement membrane by application of a mechanical force. Epithelium may also be separated from or lifted from the anterior surface of the eye by contacting the surface with a chemical composition that induces separation of the epithelium from the underlying stroma.

COMBINATION DISSECTOR AND CORNEA REFORMING DEVICE

[0045] Figs. 1A – 1D show, in a collective sense, a process for using the described combination dissector and corneal reforming device.

[0046] Fig. 1A provides a side view of an eye (200) and the approach of combination dissector-corneal reformer (202) as described below. The leading edge (204) and other appropriate edges of combination dissector (202) are configured in such a way that it is sufficiently blunt that, when passing axially along the corneal surface after having penetrated the epithelium, that it will not cut or remove tissue from the anterior surface of the cornea,

i.e., Bowman's membrane. The dissector-reformer (202) may be oscillated from side to side or axially, if so desired by the designer. Generally, the device provides an epithelial tissue member that remains attached to the cornea at at least some portion of the edge of the separated epithelial tissue, perhaps in a pocket-shaped form.

[0047] Fig. 1B shows, in a cross section, the placement of the dissector body (208) beneath the epithelium (210) to form, in this variation, a pocket-shaped epithelial tissue member (206).

[0048] Fig. 1C shows the blade body (208) positioned on eye (200) with the opening (212) to the epithelial pocket or epithelial tissue member (206) with the combination dissector-corneal reformer still in place.

[0049] With the dissector-corneal reformer (202) situated in Fig. 1C, the device may be used to apply energy in very specific ways to the corneal surface to reform its shape. Variations of my device appropriate for so-changing the shape of the corneal surface will be discussed below. Alternatively, if the device is one which is suitable for expanding the epithelial pocket (206), the expansion step may take place at this time. A description of the expander variation of my device will also be found below.

[0050] Fig. 1D shows a step of withdrawing combination device (202) from eye (200) leaving whatever results of any steps practiced. The epithelial member (206) closes over the eye and, as is its nature, will provide some amount of healing to the cornea.

[0051] Figs. 2A – 2E show one variation of the combined dissector and corneal reformation device.

[0052] Fig. 2A shows a perspective view of a generalized version of the combination device (220) having a blade body (222) and a blade edge (224). Again, the blade may be oscillated from side to side or axially or in any combination of the two directions. The edge (224) is, again, sufficiently blunt that although it will initially penetrate the epithelial layer of the eye, it will not cut tissue from the underlying cornea.

[0053] Fig. 2B shows, in cross section, the device shown in Fig. 2A. Visible on the cornea side (226) of dissector body (222) are a number of or an array of energy-emitting points (228) (better seen in the bottom view (Fig. 2D)).

[0054] These energy-emitting sites (228) may be any variety of types. For instance, they may be laser diodes (e.g., such as those manufactured by Tyco Electronics, Laser Diode Incorporated, Sanyo, or Sony) and chosen to emit light of a wavelength that interacts with the collagen of the cornea or with an introduced dye to generate or to provide sufficient heat at

the noted or desired site placement of the diode within the device to result in reforming of the nearby or adjacent corneal tissue.

[0055] The reforming light source may alternatively be placed remotely to the blade body (222) and the light introduced to the exit points (228) through fiber optics. Energy conduits (230) are shown in the support (232). As shown in the cross-section of support (232), conduits (230) may be electrically conductive wire or ribbon if the energy sources are light-emitting or resistive thermal sources and located in the blade body (222) or may be fiber optic in nature if the energy source is remote from blade body (222). Indeed, the energy conduits may be fluidic in nature allowing passage of heated, cooled, or reactive fluids their passage to the eye surface.

[0056] Fig. 2C shows a top view of the device shown in Fig. 2A.

[0057] Figs. 3A and 3B show one variation of my combination device in which laser diodes (228) are mounted in blade body (222), specifically emitting light from the side (229) of the blade body (222) adjacent the epithelium when the blade is located beneath the epithelium. The light-emitting laser diodes (228) emanate directly from their location and shine directly onto and impinge upon the cornea for reformation of the shape of that cornea. Opaque fluid or one containing a heat absorptive and heat conductive material, such as a slurry of small particles of biocompatible metal, e.g., platinum or gold, may be introduced into the eye beneath the blade body during use to enhance absorption of the light and its conversion into heat. In this variation, energy conduits (232) are simply electrical conductors that power the diodes (228).

[0058] It should be apparent that once the needed correction for the eye has been determined, the sequence of number of, and position of the diodes to be activated is a routine determination. The diodes may be independently fired as necessary for the appropriate correction. They may be sequentially fired, at some positions more than others, to achieve desired correction for, e.g., various ocular aberrations such as myopia, astigmatism, or even presbyopia. Again, depending upon the nature of the energy source chosen, this arrangement may be used either for introduction of light for corneal reformation or heat for corneal reformation or for light to produce heat for corneal reformation.

[0059] Fig. 4 shows a variation of my described device (230) in which laser diodes (232) are placed behind a light absorptive, heat conductive member (234). In the variation shown in Fig. 4, conductor (234) may be substantially continuous in a region intended to cover a specific region of the cornea that the user wishes to reform. In this variation, selected members of a collection of laser diodes are activated and provide light to the absorber-

conductor (234). The absorber-conductor (234) absorbs the light and is thereby heated in the region of the diode. Clearly, the warmed or heated region of conductor (234) in turn heats the cornea for reformation of the adjacent corneal tissue. The device operates similarly when the light source is remotely located and the energy is introduced onto the conductor (234) via optical fibers.

[0060] Fig. 5 provides a cross section of a blade body (240) that is similar in design and construction to that seen in Fig. 4. In this variation, the conductors ((242) larger, (244) smaller) are heated by laser diodes (232). Figs. 6 and 7 show two variations of the design found in Fig. 5. As seen in Figs. 6 and 7, these discrete absorber-conductors (244, 246) may be situated or placed in the blade body in various patterns suitable for the user to treat the cornea to correct vision as desired. Again, the patterns may be chosen so to treat a specific type of ocular aberration or the patterns may be generalized so that the application of heat may be selected or regionalized during the time that the dissector body is in contact with the cornea and is beneath the epithelium. That is to say that treatment of myopia might be had by heating only the regions of the cornea in the periphery of the cornea. The size of the various absorber-conductors (244, 246) and their separation may be provided by a skilled designer depending only upon the necessity for isolation of the various, discrete absorber-conductors from each other and the size of the corneal region to be treated. Again, materials having high absorptivity and high thermal conductivity are quite suitable. The clear choices for such material candidates include members of the noble metals group of the Mendelev table, e.g., platinum, rhodium, and the like and gold and various alloys of these metals. The absorptivity of the absorber-conductors may, of course, be adjusted by surface treatment, such as by blackening an otherwise reflective surface for enhanced absorption of light.

[0061] Figs. 8A, 8B, and 8C provide a description of another variation of the combination dissector-corneal reformer. In this variation, the device utilizes radio frequency (RF) to effect the corneal reformation or modification. Essential to understanding this variation is the knowledge that there are two cooperating pieces of the device. One is an RF transmitter provided exterior to the eye and the other piece, the dissector, contains one or more susceptors or RF receivers or members of an "antenna array" that receives the RF and upon doing so is locally heated. The heated susceptors are heated by the RF and that heat is conducted to the anterior surface of the cornea to be reformed.

[0062] Fig. 8A shows the placement of various components in use. It is a cross section of the various components. The anterior region of the eye (300) with its various lamellar components is depicted. The dissector blade body (304) with the various discrete energy-

receiving regions or susceptors (306) is also shown. Each of these susceptors (306) is of material, e.g., a ferromagnetic metal or alloy, that when placed in a site to receive RF will become heated. The material may be chosen and engineered in such a way as to provide modest or controllable temperature rises by mixtures with other materials, e.g., phase change materials such as paraffins or salts designed to absorb significant heat at specific temperatures, or may be physically treated to provide a smooth temperature gradient cross device, e.g., by granulation and mixing of different crystalline particulate materials, each having different melting points. It may be preferable to thermally insulate each discrete member from the next if the isolation of effect upon the cornea is desired. Similarly, isolation of the RF emitting regions on the antenna wand (310) (in Figs. 8A and 8C).

[0063] Returning to Fig. 8A, the antenna component (310) with its multiple discrete antenna sections (312) is shown to be exterior to the epithelium (314). The dissector with RF receiving elements or susceptors (306) is shown to be positioned between epithelium (314) and cornea (300).

[0064] In operation, this variation might operate in the following fashion: one discrete antenna, e.g., (310a) would be activated and begin transmitting RF. Because of its relative proximity, susceptor (306a) would be heated. The heat from susceptor (306a) would be conducted to the nearby cornea causing contraction in region (316), thereby further causing a revision of the shape of the cornea and changing its refractive properties. As is the case with LASIK or LASEK or PRK, the careful planning of the imposition of light and heat upon the cornea changes the refraction properties of the margin of the cornea for the purpose of improving the vision in the eye.

[0065] Fig. 9A shows another partial cross section of a blade body (350) having integrated discrete RF emission members coupled with discrete RF susceptors (354) in the same body (350).

[0066] Fig. 9B shows another variation of the blade body (360) that utilizes RF emitters (362) that pass RF energy directly into the cornea for reformation. Each of the RF emitting regions in each of these variations may be independently caused to emit RF energy or may be used in unison or in patterns, both spatial patterns and time-wise patterns, to effect the desired refractive change in the cornea.

[0067] Fig. 10 shows another variation in which blade body (370) is equipped with discrete electrically resistive heating elements (372). In this variation, a single addressable lead (374) goes to each resistive, heating element (372). The return line for the current flow takes place via a common bus (376).

[0068] In a similar concept, Fig. 11 depicts a blade body (380) having a number of resistive heating elements (372) that in this case are each adjacent a heat conductor (374) that is able to focus or to defocus the application of heat to the adjacent cornea.

[0069] In summary, the generic combination device here is one that is able to separate the epithelium from the cornea and to cause or to take part in refractive procedure prior to its retraction from beneath the epithelial tissue.

EPITHELIAL TISSUE MEMBER EXPANSION DEVICE

[0070] In some instances, the volume of the epithelial tissue member or pocket formed is insufficient to allow introduction of other treatment devices into the pocket. Some type of larger device may simply be needed.

[0071] Fig. 12A provides a generic description of the function of the device. Generally, the expander (400) includes a blunt tip (402) permitting penetration of the epithelium and separation of the epithelial tissue from the cornea without cutting the corneal tissue. Additionally, the blade body region (404) is at least partially expandable as shown by arrows (406) in Fig. 12B. This movement may be caused by hydraulic actuation, electrical movement (motor or heating of a pre-formed shaped-memory nitinol member), or other motive actuators.

[0072] Fig. 13A shows one variation (406) including an inflatable balloon (408) situated in an interior space between two members: a movable, epithelium-side member (410) and a stationary cornea side member (412).

[0073] Fig. 13B provides a cross section, side view of the blade body (406) with the interior balloon (408) expanded.

[0074] Fig. 14A shows a similar variation (430) in which the inflatable balloon (432) is in contact with the epithelium during the introduction of the blade body (430) and its subsequent expansion. Fig. 14B shows the expanded balloon (432). Although not required, constructing the balloon from a hard slippery material, e.g., NYLON or TEFLON, the type often used in constant diameter cardiovascular balloons, may provide some advantages.

[0075] Finally, Figs. 15A and 15B shows cross-sectional views of another variation (440) in which the epithelium side surface of blade body (442) expands from the center rather than via a leading hinge as has been the case shown in Figs. 12A through 14B. Fig. 15A shows the blade (440) prior to expansion and Fig. 15B shows the blade (440) after expansion.

CLAIMS

I CLAIM AS MY INVENTION:

1. A device for opening and expanding an epithelial pocket comprising:

an edge for providing an opening in the epithelium and separating at least a portion of the epithelium from the cornea without cutting the cornea, and

a first surface situated adjacent the epithelium and a second surface situated adjacent the cornea when the edge has separated the epithelium from the cornea and which first and second surfaces are movable away from each other after first separating at least a portion of the epithelium from the cornea.

2. The device of claim 1 further comprising an actuator configured to move the first surface from the second surface.

3. The device of claim 2 wherein the actuator comprises an inflatable balloon.

4. The device of claim 2 wherein the actuator comprises the first surface, the second surface, or the first surface and the second surface.

5. The device of claim 2 wherein the actuator is hydraulically placed.

6. The device of claim 2 wherein the actuator is electrically actuated.

7. The device of claim 2 wherein the actuator is mechanically actuated.

8. The device of claim 1 where at least one of the first surface, second surface, or edge are at least partially lubricious.

9. A corneal reformation device for changing the shape of a cornea on an eye having a cornea and an epithelium comprising:

an edge configured to provide an opening in the epithelium and further configured to separate at least a portion of the epithelium from the cornea without cutting the cornea and form an epithelial tissue member, and

a corneal reformer member configured to reform the cornea while situated adjacent the cornea and at least partially beneath the separated epithelial tissue member.

10. The device of claim 9 wherein the corneal reformer comprises one or more light sources.

11. The device of claim 9 wherein the corneal reformer comprises one or more heat sources.

12. The device of claim 9 wherein the corneal reformer comprises one or more heat and light sources.

13. The device of claim 9 wherein the corneal reformer comprises one or more energy absorptive, conductive members placeable adjacent the cornea during reformation configured to rise in temperature during reformation to reform the cornea.

14. The device of claim 10 wherein the corneal reformer comprises one or more energy absorptive, conductive members placeable adjacent the cornea during reformation and configured to absorb light and to rise in temperature during reformation to reform the cornea.

15. The device of claim 11 wherein the corneal reformer comprises one or more energy absorptive, conductive members placeable adjacent the cornea during reformation and configured to absorb heat and to rise in temperature during reformation to reform the cornea.

16. The device of claim 12 wherein the corneal reformer comprises one or more energy absorptive, conductive members placeable adjacent the cornea during reformation and configured to absorb light and heat and and to rise in temperature during reformation to reform the cornea.

17. The device of claim 9 wherein the corneal reformer further comprises one or more fluid sources and is configured to absorb light and heat to rise in temperature during reformation to reform the cornea.

18. The device of claim 9 wherein the corneal reformer comprises one or more RF susceptors placeable adjacent the cornea during reformation and configured to absorb RF energy from an RF energy source and to rise in temperature during reformation to reform the cornea.

19. The device of claim 18 further comprising an RF energy source configured to cooperatively direct RF energy to the one or more RF susceptors of the corneal reformer to reform the cornea.



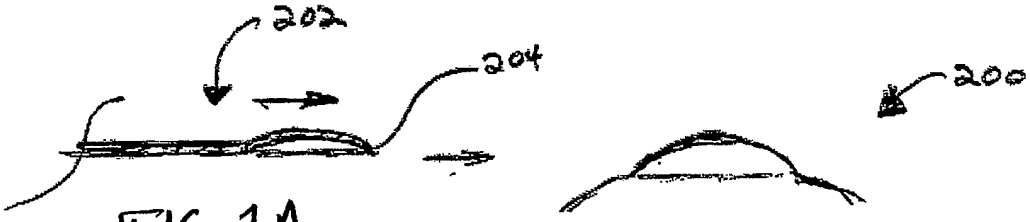


FIG. 1A

. 1A

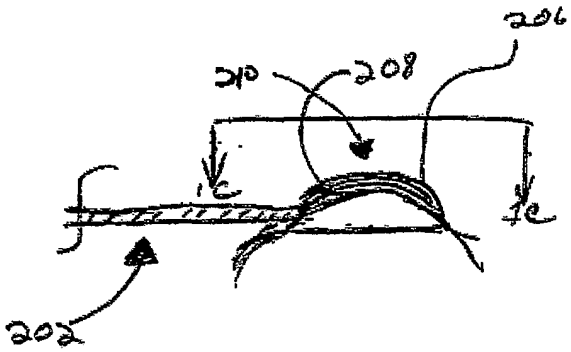


Fig 1B

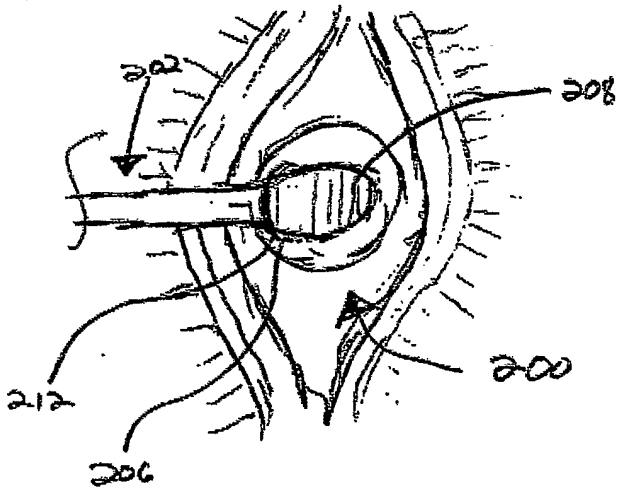


Fig 1C



Fig 1D

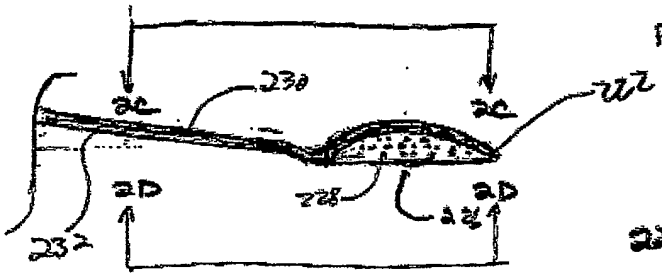


Fig 2B

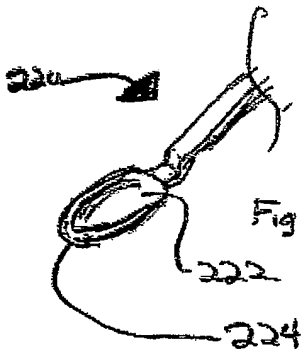


Fig. 2A

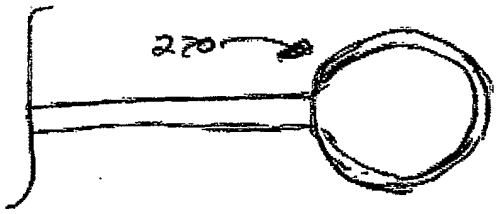


Fig 2C

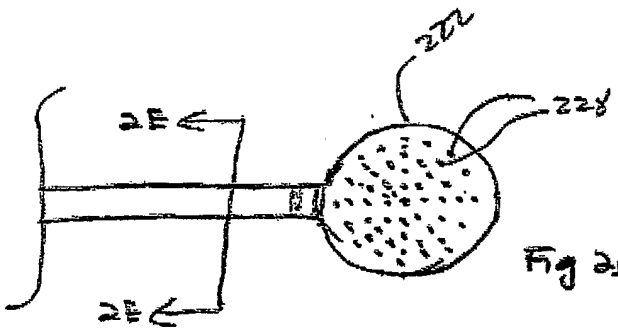


Fig 2D



Fig 2E

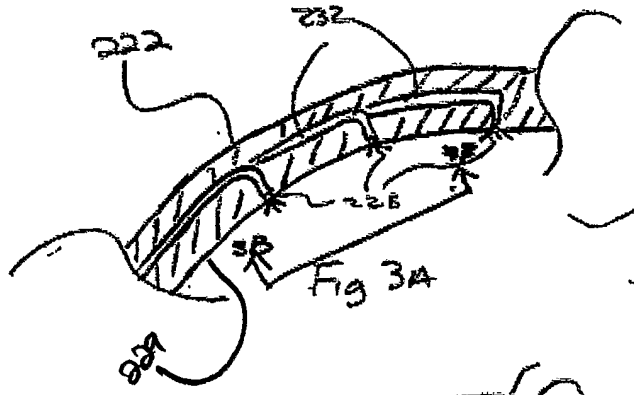


Fig 3A

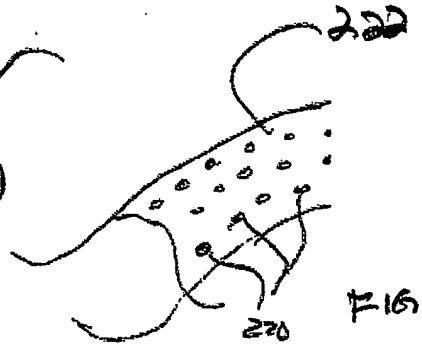


FIG 3B

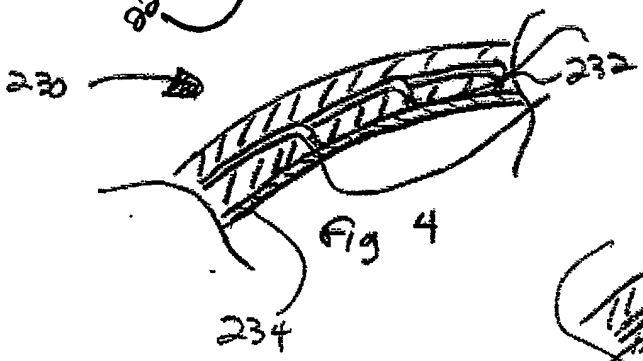


Fig 4

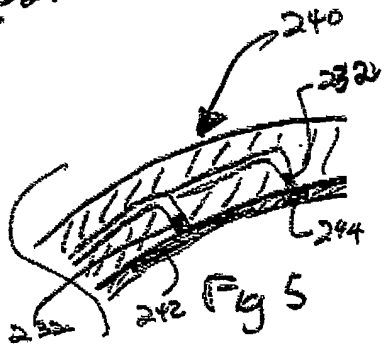


Fig 5

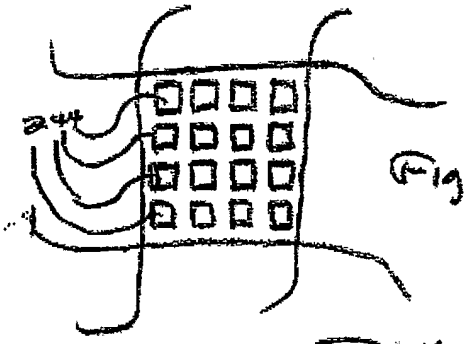


Fig 6

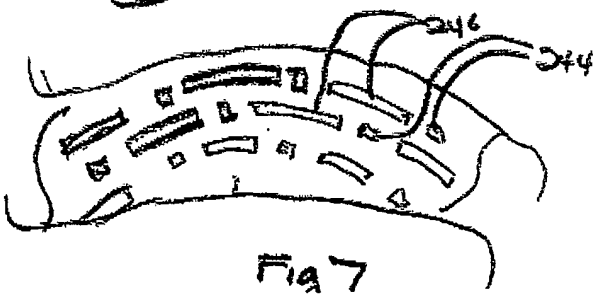


Fig 7

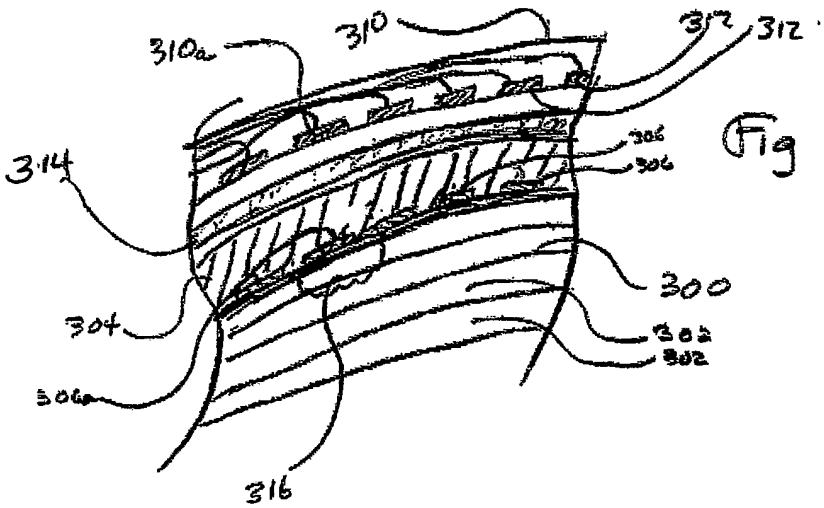


Fig 8A

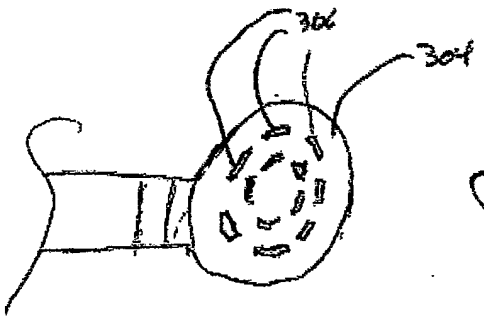


Fig 8B



Fig 8C

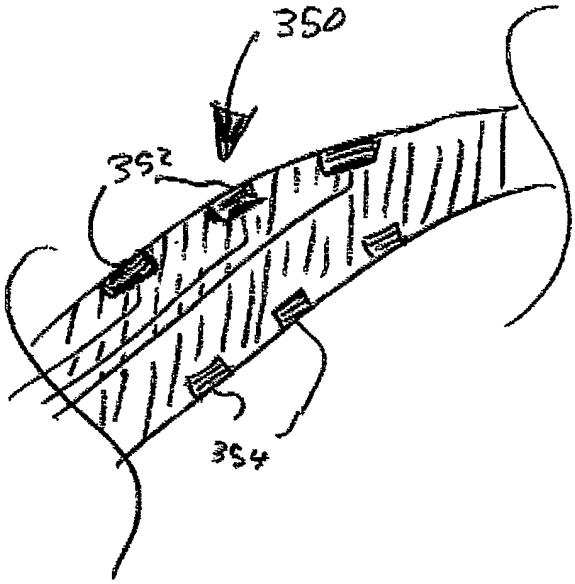


Fig 9A

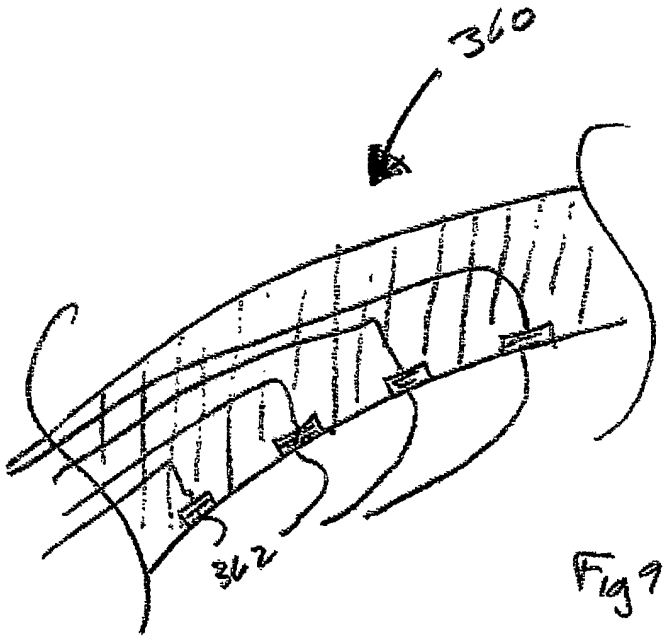


Fig 9B

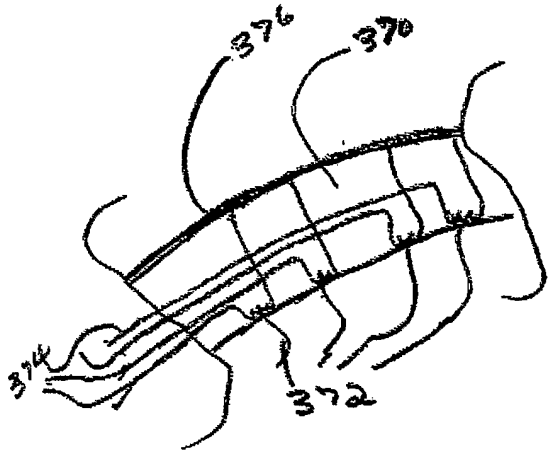


Fig 10

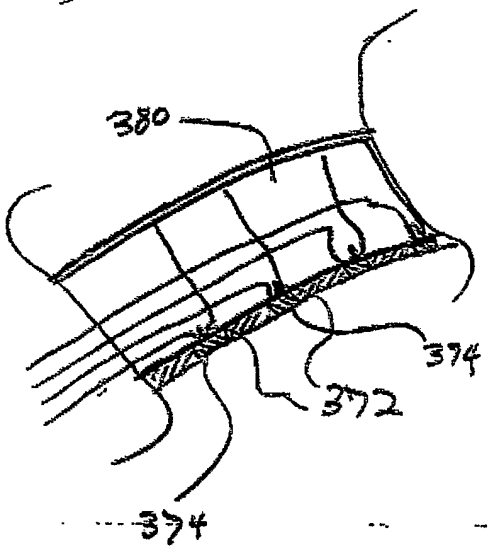


Fig 11



Fig 12A



Fig 12B

Fig. 13A

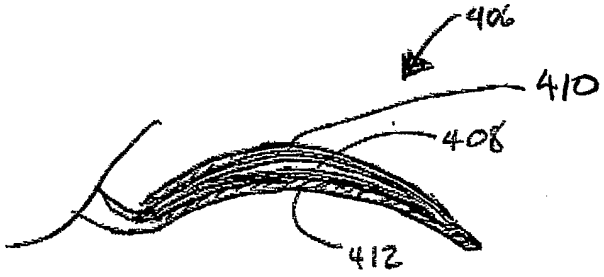
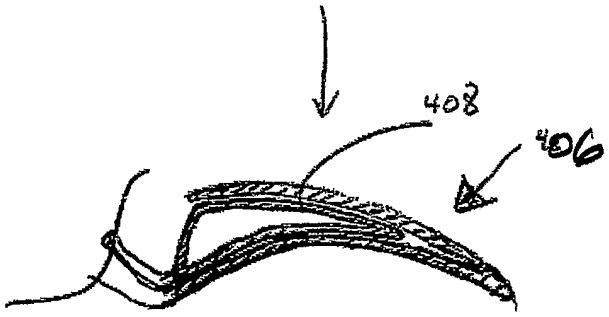


Fig. 13B



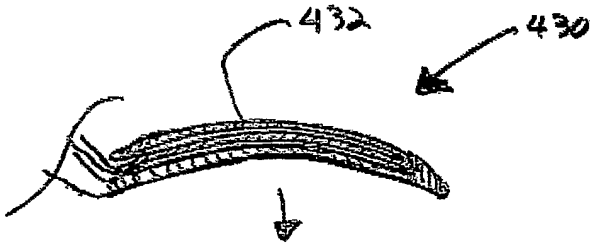


Fig. 14A



Fig. 14B

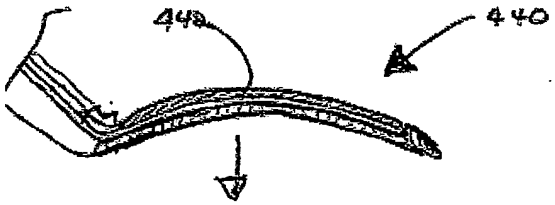


Fig. 15A



Fig. 15B