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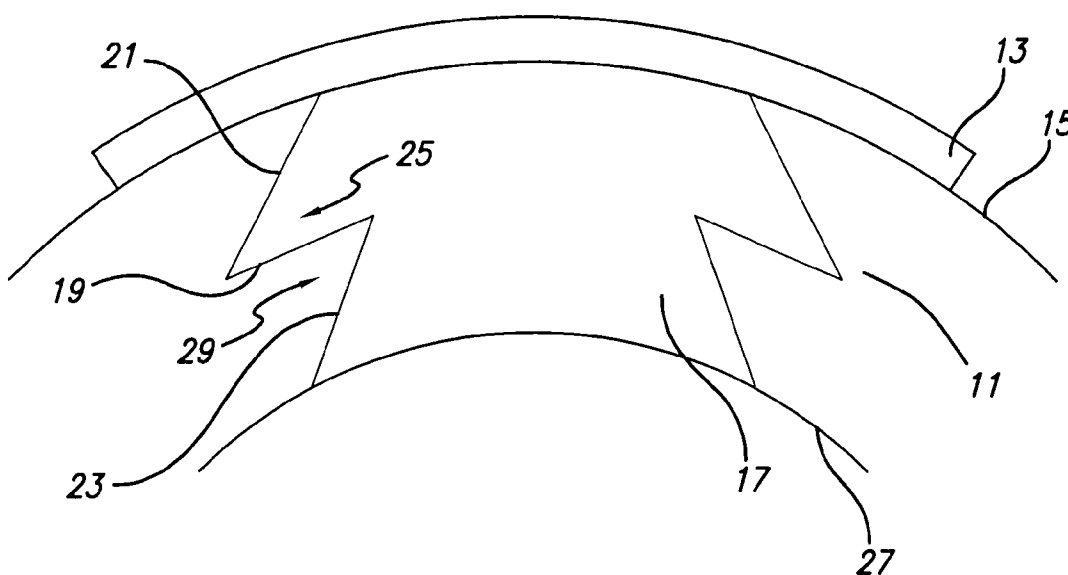
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[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR RESECTING CORNEAL TISSUE



(57) Abstract: A system and method of resecting corneal tissue for transplantation is disclosed. In each of the recipient cornea and the donor cornea, an annular incision is made at a predetermined incision depth. A first sidecut incision is made in each cornea, running from the outer periphery of the annular incision to one of the anterior corneal surface or the posterior corneal surface. The first sidecut incision forms an acute angle with the annular incision. A second sidecut incision is also made in each cornea, running from the inner periphery of the annular incision to the other of the anterior corneal surface or the posterior corneal surface. The second sidecut incision forms an acute angle with the annular incision. The combination of the incisions in each cornea resects corneal tissue from the recipient cornea and donor tissue from the donor cornea. The donor tissue is grafted into the recipient cornea.

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SYSTEM AND METHOD FOR RESECTING CORNEAL TISSUE

BACKGROUND OF THE INVENTION

[0001] The field of the present invention is systems and procedures for transplanting corneas.

[0002] A variety of techniques presently exist for performing corneal transplants. The tools used for the different techniques range from the traditional trephine to the more advanced laser surgical systems. Regardless of the technique or tool used for the transplant procedure, the overarching goal remains to provide the recipient with new corneal tissue while minimizing post-surgical complications such as induced astigmatism. Other desirable aspects of recent improvements include reducing the overall healing time and the likelihood of additional complications from wound ruptures.

[0003] One technique which attempts to use advanced laser surgical systems to help reduce post-surgical complications is disclosed in U.S. Patent No. 6,805,694. This technique relies on the theory that the inner and outer diameters of the undercut region should be chosen to have a specific ratio. Further, the theory postulates that the internal pressure of the eye will provide enhanced wound stability and reduce post-surgical complications by selection of an appropriate ratio. Unfortunately, when applied in actual transplant procedures, this theory does not rise up to meet expectations.

BRIEF SUMMARY OF THE INVENTION

[0004] The present invention is directed toward a system and method for resecting corneal tissue as part of a transplant procedure. In the system, a surgical laser emits a pulsed laser beam which is directed into the cornea by a focusing assembly. An interface provides a plurality of incision patterns for selection of a sidecut pattern which includes an annular region. The selected sidecut pattern is received by a controller which employs the focusing assembly to move the focal point of the pulsed laser beam and incise a donor cornea according to the sidecut pattern, placing the incision corresponding to the annular region at a predetermined depth from the anterior corneal surface. The controller also employs the focusing assembly to move the focal point and incise a recipient cornea according to the

sidecut pattern, again placing the incision corresponding to the annular region at the same predetermined depth from the anterior corneal surface.

[0005] In the method, the depth of an incision from the anterior corneal surface is initially determined. This incision depth is used for both the recipient cornea and the donor cornea, and in each cornea, an annular incision is made at the incision depth. A first sidecut incision is made running from the outer periphery of the annular incision toward one of the anterior corneal surface or the posterior corneal surface. A second sidecut incision is made running from the inner periphery of the annular incision toward the other of the anterior corneal surface or the posterior corneal surface. The angle of each sidecut incision to the annular incision may be acute, perpendicular, or obtuse. The combination of the incisions in each cornea resects corneal tissue from the recipient cornea and donor tissue from the donor cornea, respectively. The donor tissue is thereafter grafted into the recipient cornea. Following the graft, the donor tissue may be secured using a plurality of sutures, each preferably passing through the sidecut incision which is nearest the posterior surface of the recipient cornea.

[0006] The extent of the sidecut incisions depends upon whether the transplant is a full thickness corneal transplant or a partial thickness corneal transplant. In a full thickness transplant, each sidecut incision runs from the annular incision to one of the anterior corneal surface or the posterior corneal surface. A partial thickness transplant may be an anterior lamellar keratoplasty (ALK) or a posterior lamellar keratoplasty (PLK). In both procedures, a resection incision is made within the stromal tissue of each cornea. For the ALK procedure, the depth of the annular incision is between the anterior surface and the resection incision, whereas for the PLK procedure, the depth of the annular incision is between the posterior surface and the resection incision. Thus, in the ALK procedure, one of the sidecut incisions runs from the annular incision to the anterior surface and the other runs from the annular incision to the resection incision. Similarly, in the PLK procedure, one of the sidecut incisions runs from the annular incision to the posterior surface and the other runs from the annular incision to the resection incision.

[0007] Accordingly, an improved system and method for resecting corneal tissue as part of a transplant procedure are disclosed. Advantages of the improvements will appear from the drawings and the description of the preferred embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] In the drawings, wherein like reference numerals refer to similar components:

[0009] Fig. 1A & 1B illustrates a sectional view of a cornea with incisions made therein for a full thickness corneal tissue transplant;

5 [0010] Fig. 2 illustrates a sectional view of donor tissue grafted into a recipient cornea;

[0011] Fig. 3 illustrates a sectional view of incisions made in a cornea for a partial thickness ALK corneal tissue transplant;

[0012] Fig. 4 illustrates a sectional view of incisions made in a cornea for a partial thickness PLK corneal tissue transplant; and

10 [0013] Fig. 5 is a schematic view of a system for resecting corneal tissue.

DETAILED DESCRIPTION OF THE INVENTION

[0014] Turning in detail to the drawings, Fig. 1A illustrates the incisions made in a cornea 11 as part of a full thickness corneal transplant procedure. The same incisions are made in both the recipient cornea and the donor cornea, although the incisions in the donor cornea may be made approximately 1%-5% larger, or more preferably 2%-5% larger, than the incisions in the recipient cornea to account for shrinkage in the donor corneal tissue following resection. As part of the procedure, a contact lens 13 placed against the anterior corneal surface 15. This contact lens 13 deforms the cornea 11, forcing the anterior corneal surface 15 to take on the shape of the contact lens 13. Deformation of the cornea 11 in this manner provides multiple advantages which are well known to skilled artisans. For example, U.S. Patent No. 5,549,632, which is incorporated herein by reference, describes advantages gained in making laser incisions by deforming the shape of the cornea, particularly by applanation. U.S. Patent No. 6,863,667 and U.S. Pat. App. No. 11/258,399, both of which are incorporated herein by reference, describe patient interface devices which may be used to align the surgical laser with the recipient cornea for purposes of making accurate incisions.

[0015] Further, deformation of the cornea reduces the amount of physical data which needs to be collected for both the recipient cornea and the donor cornea prior to the transplant procedure. The physical data collected includes thickness measurements of both the recipient and donor corneas. These thickness measurements are used to develop a thickness profile of each cornea. Additional physical data may also be collected for each cornea. This thickness

profile, along with any other data needed for the procedure, may be obtained by any one of the many known methods for measuring the physical structure of the eye, with the preferred method being through optical coherence tomography (OCT). Many commercially available OCT scanners are capable of performing such measurements. One example is the Visante™ OCT scanning system, manufactured by Carl Zeiss Meditec, which has an office in Dublin, California. One advantage of the Visante™ OCT system is that it does not make contact with the cornea when performing the OCT scan.

[0016] Three incisions, an annular incision 19 and two sidecut incisions 21, 23, are made in the cornea 11 to resect the corneal tissue 17. These incisions may be made separately, one at a time, or they may be made concurrently. The combined incisions result in corneal tissue being resected from the recipient cornea, and donor tissue being resected from the donor cornea. All incisions are preferably made using a pulsed laser beam having ultra-short pulses, preferably in the femtosecond range. The laser may be of the type described in U.S. Patent No. 4,764,930, producing an ultra-short pulsed beam as described in one or both of U.S. Patent No. 5,984,916 and U.S. Patent No. RE37,585. The disclosures of the aforementioned patents are incorporated herein by reference in their entirety. Commercial lasers capable of performing the incisions are available from IntraLase Corp. of Irvine, California.

[0017] The annular incision 19 is located at a predetermined depth from the anterior corneal surface 15. To facilitate the resection and grafting process, the entire annular incision 19 is at a uniform distance from the anterior corneal surface 15, although such uniformity of depth is not required. Further, for simplicity the annular incision 19 is described as being defined by an inner radius and an outer radius, although such is not necessary. It is sufficient for this incision to be formed by an inner perimeter and an outer perimeter, both perimeters being of any desired shape. More complex shapes, however, can add significantly to the complexity of the procedure. Various techniques are known for making the annular incision 19 at a uniform distance from the anterior corneal surface 15. For example, the techniques disclosed in U.S. Patent No. 5,993,438, U.S. Patent No. 6,730,074, and U.S. Patent Publication No. 20050245915 may be readily adapted to make the desired annular incision 19. Other techniques known to skilled artisans may also be employed.

[0018] The first sidecut incision 21 runs from the outer periphery of the annular incision 19 to the anterior corneal surface 15. An acute angle is formed at the juncture 25 of the first

sidecut incision 21 and the annular incision 19. The second sidecut incision 23 runs from the inner periphery of the annular incision 19 to the posterior corneal surface 27. An acute angle is also formed at the juncture 29 of the second sidecut incision 23 and the annular incision 19. Alternatively, the angle between each of the sidecut incisions and the annular incision may be perpendicular or obtuse.

[0019] Fig. 1B illustrates an alternative configuration for the sidecut incisions 21', 23' made in the cornea 11 with respect to the annular incision 19. Here, the first sidecut incision 21' runs from the inner perimeter of the annular incision 19 to the anterior corneal surface 15, and the second sidecut incision 23' runs from the outer perimeter of the annular incision 19 to the posterior corneal surface 27.

[0020] The donor tissue 31 is shown grafted into the recipient cornea 33 in Fig 2. Sutures 35, 37 are placed to secure the donor tissue 31 to the recipient cornea 33. Two different techniques for placement of sutures are shown. The first suture 35 is placed through the sidecut incision 39 which runs between the annular incision 41 and the posterior corneal surface 43. The second suture 37 is placed through the sidecut incision 45 which runs between the annular incision 41 and the anterior corneal surface 47. Both locations of sutures are believed to be equally as effective for securing the donor tissue 31 to the recipient cornea 33. Further, neither location is believed to be more likely than the other to induce astigmatism during the healing process.

[0021] Fig. 3 illustrates how the incision configuration described above may be adapted for an ALK procedure. For the ALK process, a resection incision 51 is made in the cornea 53 at a predetermined resection depth, and the annular incision 55 is made at a depth which lies between the resection depth and the anterior corneal surface 57. The first sidecut incision 59 is made in the same manner as is described above. The second sidecut incision 61, however, runs from the annular incision to the resection incision 51. The donor tissue may be secured to the recipient cornea by either of the techniques described above.

[0022] Fig. 4 illustrates how the incision configuration described above may be adapted for an PLK procedure. For the PLK process, a resection incision 63 is made in the cornea 65 at a predetermined resection depth, and the annular incision 67 is made at a depth which lies between the resection depth and the posterior corneal surface 69. The first sidecut incision 71 is made in the same manner as is described above. The second sidecut incision 73, however,

runs from the annular incision to the resection incision 63. In a PLK procedure, sutures are not necessary to secure the donor tissue to the recipient cornea.

[0023] Referring to Fig. 5, a surgical system is shown which may be used to incise both a donor cornea or a recipient cornea. Alternatively, two similarly configured systems may be used to incise each respective cornea. A femtosecond surgical laser 81 generates a pulsed laser beam 83 and directs that beam into the focusing assembly 85, which in turn focuses the pulsed beam 83 into the cornea 87. A contact lens 89 is placed over the cornea to deform the anterior corneal surface as described above. Where different contact lenses are used with the donor cornea and the recipient cornea, the posterior curvature, i.e., the side of the contact lens that is placed against the anterior corneal surface, is the same for each contact lens. The controller 91 is a programmable computer which precisely controls the location of the beam focal point within the cornea 87 according to parameters received from the surgeon interface 93. The interface 93 presents the surgeon with several incision patterns from which the desired sidecut pattern is selected. The selected pattern is received by the controller 91, which uses the pattern to incise both the donor cornea and the recipient cornea, placing the annular region of the selected pattern at a predetermined depth from each respective anterior corneal surface. The contact lenses which are used to deform each of the corneas as part of this procedure preferably have the same curvature on the posterior surface, i.e., the surface placed in contact with the anterior corneal surface.

[0024] Thus, a method of transplanting corneal tissue is disclosed. While embodiments of this invention have been shown and described, it will be apparent to those skilled in the art that many more modifications are possible without departing from the inventive concepts herein. The invention, therefore, is not to be restricted except in the spirit of the following claims.

WHAT IS CLAIMED IS:

1 1. A method of transplanting donor tissue from a donor cornea to a
2 recipient cornea, the method comprising:
3 determining an incision depth from an anterior corneal surface;
4 making an annular incision at the incision depth in each of the donor cornea
5 and the recipient cornea;
6 making a first sidecut incision in each of the donor cornea and the recipient
7 cornea, the first sidecut incision running from an outer periphery of the annular incision to
8 one of the anterior corneal surface or a posterior corneal surface;
9 making a second sidecut incision in each of the donor cornea and the recipient
10 cornea, the second sidecut incision running from an inner periphery of the annular incision to
11 the other of the anterior corneal surface or a posterior corneal surface, wherein a combination
12 of the incisions in each of the recipient cornea and the donor cornea resects corneal tissue
13 from the recipient cornea and resects the donor tissue from the donor cornea, respectively;
14 grafting the donor tissue into the recipient cornea.

1 2. The method of claim 1, wherein the first sidecut incision forms a first
2 acute angle with the annular incision.

1 3. The method of claim 1, wherein the second sidecut incision forms a
2 second acute angle with the annular incision.

1 4. The method of claim 1 further comprising securing the donor tissue to
2 the recipient cornea with a plurality of sutures, at least one of the sutures passing through one
3 of the first sidecut incision or the second sidecut incision, whichever is nearer the posterior
4 corneal surface.

1 5. The method of claim 1, wherein the incisions are made using a surgical
2 laser.

1 6. The method of claim 1 further comprising placing a contact lens
2 against the anterior corneal surface of each of the recipient cornea and the donor cornea prior
3 to making the incisions in each cornea, wherein the contact lens is adapted to conform the
4 anterior corneal surface to a shape of the contact lens.

1 7. The method of claim 6, wherein the contact lens applanates the anterior
2 corneal surface.

1 8. The method of claim 1, wherein the annular incision is at a uniform
2 distance from the anterior corneal surface.

1 9. A method of transplanting donor tissue from a donor cornea to a
2 recipient cornea, the method comprising:
3 determining a first incision depth from an anterior corneal surface;
4 determining a second incision depth from the anterior corneal surface, wherein
5 the second incision depth is less than the first incision depth;
6 making a resection incision at the first incision depth in each of the donor
7 cornea and the recipient cornea;
8 making an annular incision at the second incision depth in each of the donor
9 cornea and the recipient cornea;
10 making a first sidecut incision in each of the donor cornea and the recipient
11 cornea, the first sidecut incision running from an outer periphery of the annular incision to
12 one of the anterior corneal surface or the resection incision, wherein the first sidecut incision
13 forms a first acute angle with the annular incision;
14 making a second sidecut incision in each of the donor cornea and the recipient
15 cornea, the second sidecut incision running from an inner periphery of the annular incision to
16 the other of the anterior corneal surface or the resection incision, wherein the second sidecut
17 incision forms a second acute angle with the annular incision, and wherein a combination of
18 the incisions in each of the recipient cornea and the donor cornea resects corneal tissue from
19 the recipient cornea and resects the donor tissue from the donor cornea, respectively;
20 grafting the donor tissue into the recipient cornea.

1 10. The method of claim 9 further comprising securing the donor tissue to
2 the recipient cornea with a plurality of sutures, at least one of the sutures passing through one
3 of the first sidecut incision or the second sidecut incision, whichever is nearer a posterior
4 corneal surface.

1 11. The method of claim 9, wherein the incisions are made using a surgical
2 laser.

1 12. The method of claim 9 further comprising placing a contact lens
2 against the anterior corneal surface of each of the recipient cornea and the donor cornea prior
3 to making the incisions in each cornea, wherein the contact lens is adapted to conform the
4 anterior corneal surface to a shape of the contact lens.

1 13. The method of claim 12, wherein the contact lens applanates the
2 anterior corneal surface.

1 14. The method of claim 9, wherein the annular incision is at a uniform
2 distance from the anterior corneal surface.

1 15. The method of claim 9, wherein the resection incision is at a uniform
2 distance from the anterior corneal surface.

1 16. A method of transplanting donor tissue from a donor cornea to a
2 recipient cornea, the method comprising:
3 determining a first incision depth from an anterior corneal surface;
4 determining a second incision depth from the anterior corneal surface, wherein
5 the second incision depth is greater than the first incision depth;
6 making a resection incision at the first incision depth in each of the donor
7 cornea and the recipient cornea;
8 making an annular incision at the second incision depth in each of the donor
9 cornea and the recipient cornea;
10 making a first sidecut incision in each of the donor cornea and the recipient
11 cornea, the first sidecut incision running from an outer periphery of the annular incision to
12 one of a posterior corneal surface or the resection incision, wherein the first sidecut incision
13 forms a first acute angle with the annular incision;
14 making a second sidecut incision in each of the donor cornea and the recipient
15 cornea, the second sidecut incision running from an inner periphery of the annular incision to
16 the other of the posterior corneal surface or the resection incision, wherein the second sidecut
17 incision forms a second acute angle with the annular incision, and wherein a combination of
18 the incisions in each of the recipient cornea and the donor cornea resects corneal tissue from
19 the recipient cornea and resects the donor tissue from the donor cornea, respectively;
20 grafting the donor tissue into the recipient cornea.

1 17. The method of claim 16 further comprising securing the donor tissue to
2 the recipient cornea with a plurality of sutures, at least one of the sutures passing through one
3 of the first sidecut incision or the second sidecut incision, whichever is nearer the posterior
4 corneal surface.

1 18. The method of claim 16, wherein the incisions are made using a
2 surgical laser.

1 19. The method of claim 16 further comprising placing a contact lens
2 against the anterior corneal surface of each of the recipient cornea and the donor cornea prior
3 to making the incisions in each cornea, wherein the contact lens is adapted to conform the
4 anterior corneal surface to a shape of the contact lens.

1 20. The method of claim 19, wherein the contact lens applanates the
2 anterior corneal surface.

1 21. The method of claim 16, wherein the annular incision is at a uniform
2 distance from the posterior corneal surface.

1 22. The method of claim 16, wherein the resection incision is at a uniform
2 distance from the posterior corneal surface.

1 23. A system for resecting donor tissue and corneal tissue prior to
2 transplantation, the system comprising:
3 a surgical laser adapted to emit a pulsed laser beam;
4 a focusing assembly adapted to focus the pulsed laser beam into a cornea;
5 an interface adapted to provide a plurality of incision patterns for selection of
6 a sidecut pattern which includes an annular region; and
7 a controller in communication with the interface to receive the sidecut pattern,
8 the controller being adapted to move a focal point of the pulsed laser beam within a donor
9 cornea using the focusing assembly,
10 direct the focal point of the pulsed laser beam to make a first sidecut incision
11 in the donor cornea according to the sidecut pattern, wherein the annular region of the sidecut
12 pattern is incised at a predetermined depth from a donor anterior corneal surface,

13 move the focal point of the pulsed laser beam within a recipient cornea using
14 the focusing assembly,
15 direct the focal point of the pulsed laser beam to make a second sidecut
16 incision in the recipient cornea according to the sidecut pattern, wherein the annular region of
17 the sidecut pattern is incised at the predetermined depth from a recipient anterior corneal
18 surface.

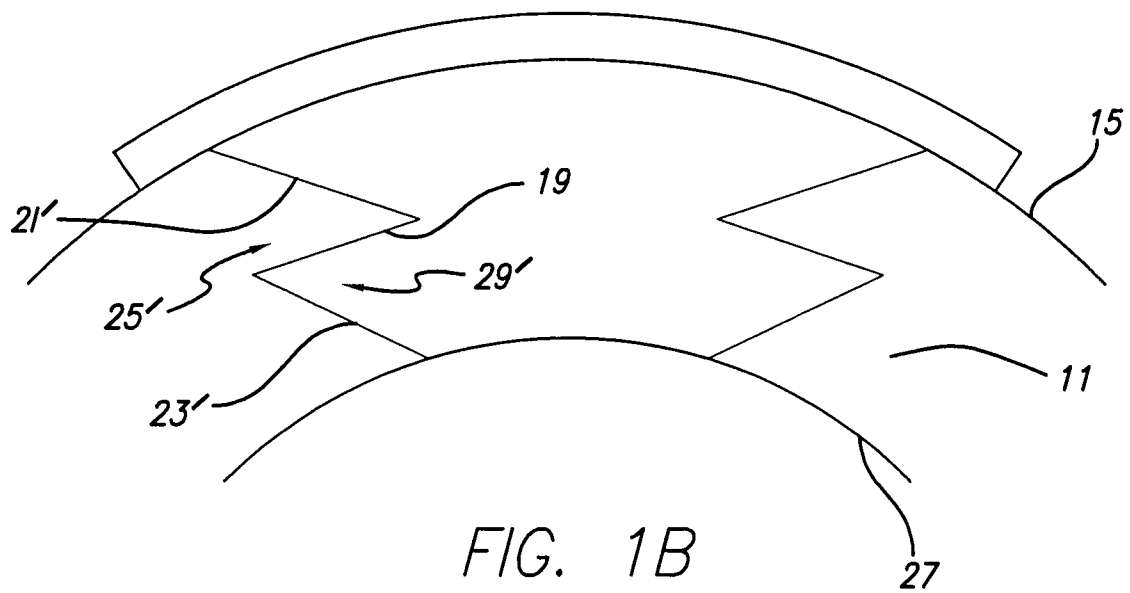
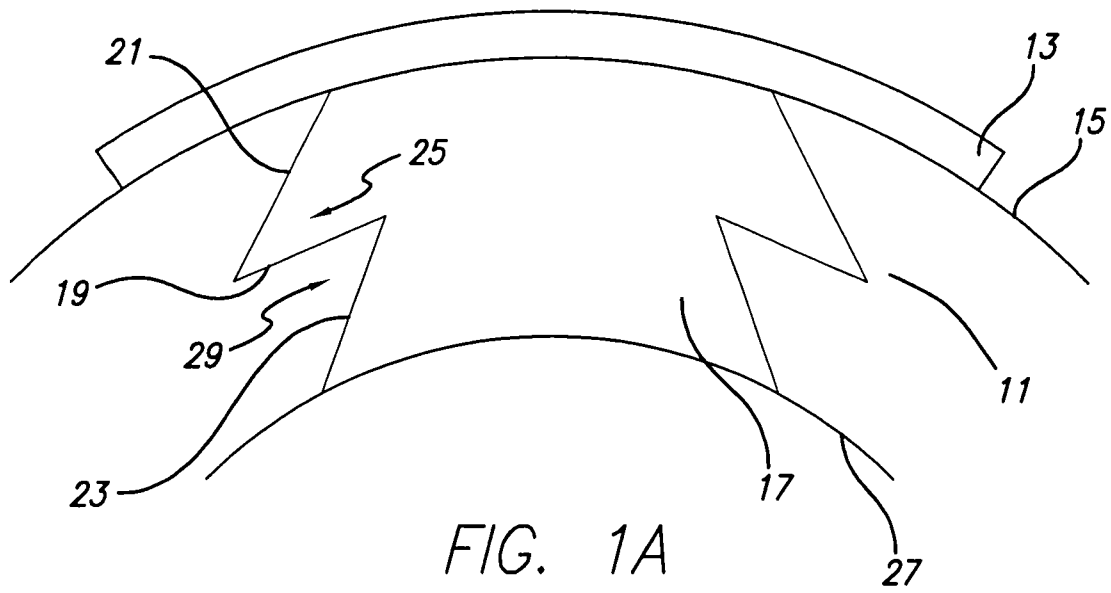
1 24. The system of claim 23, wherein at least one of the incision patterns
2 further includes a first sidecut region running from an outer periphery of the annular region
3 toward one of a posterior corneal surface or the anterior corneal surface, wherein the first
4 sidecut region forms a first acute angle with the annular region, and a second sidecut region
5 running from an inner periphery of the annular region toward the other of the posterior
6 corneal surface or the anterior corneal surface, wherein the second sidecut region forms a
7 second acute angle with the annular incision.

1 25. The system of claim 23, wherein the first sidecut region forms a first
2 acute angle with the annular region.

1 26. The system of claim 23, wherein the second sidecut region forms a
2 second acute angle with the annular region.

1 27. The system of claim 23 further comprising:
2 a first contact lens adapted to be placed against the donor anterior corneal
3 surface, the first contact lens being adapted to conform the donor anterior corneal surface to a
4 shape of the first contact lens; and
5 a second contact lens adapted to be placed against the recipient anterior
6 corneal surface, the second contact lens being adapted to conform the recipient anterior
7 corneal surface to a shape of the second contact lens, wherein the first and second contact
8 lenses have identical posterior surface curvatures.

1 28. The system of claim 27, wherein the first contact lens applanates the
2 donor anterior corneal surface.



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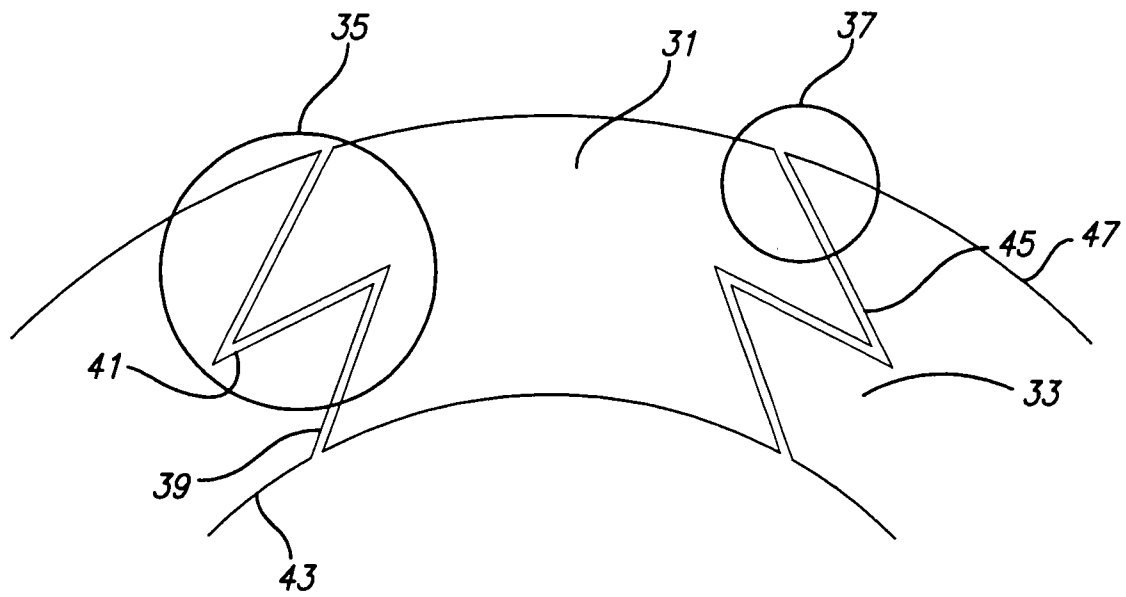


FIG. 2

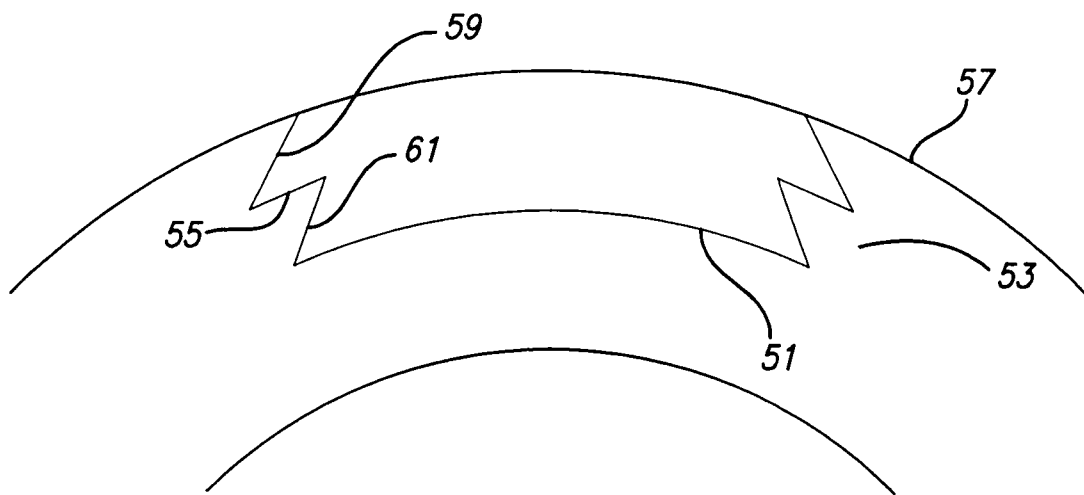


FIG. 3

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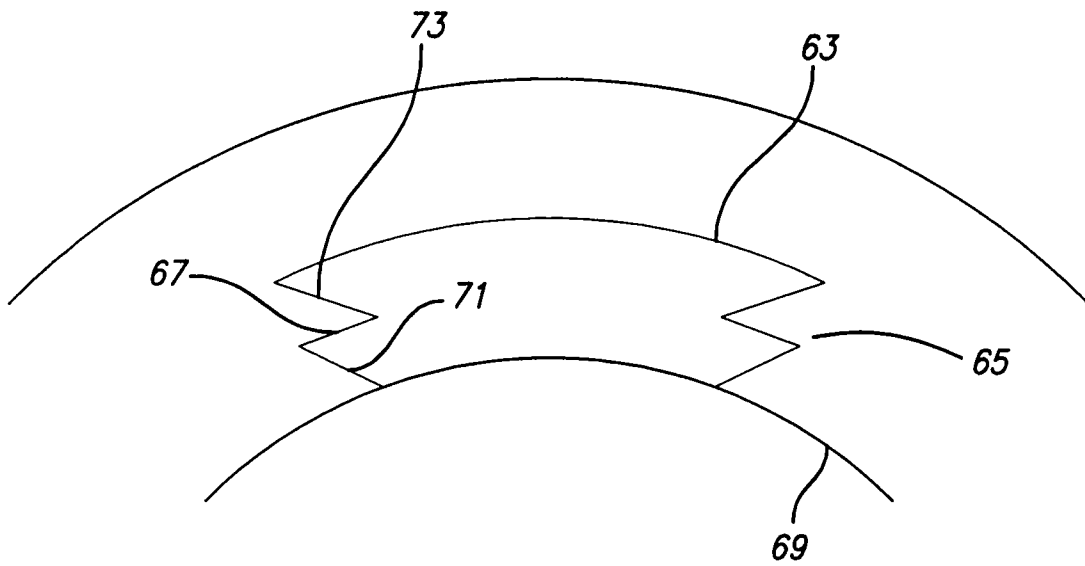


FIG. 4

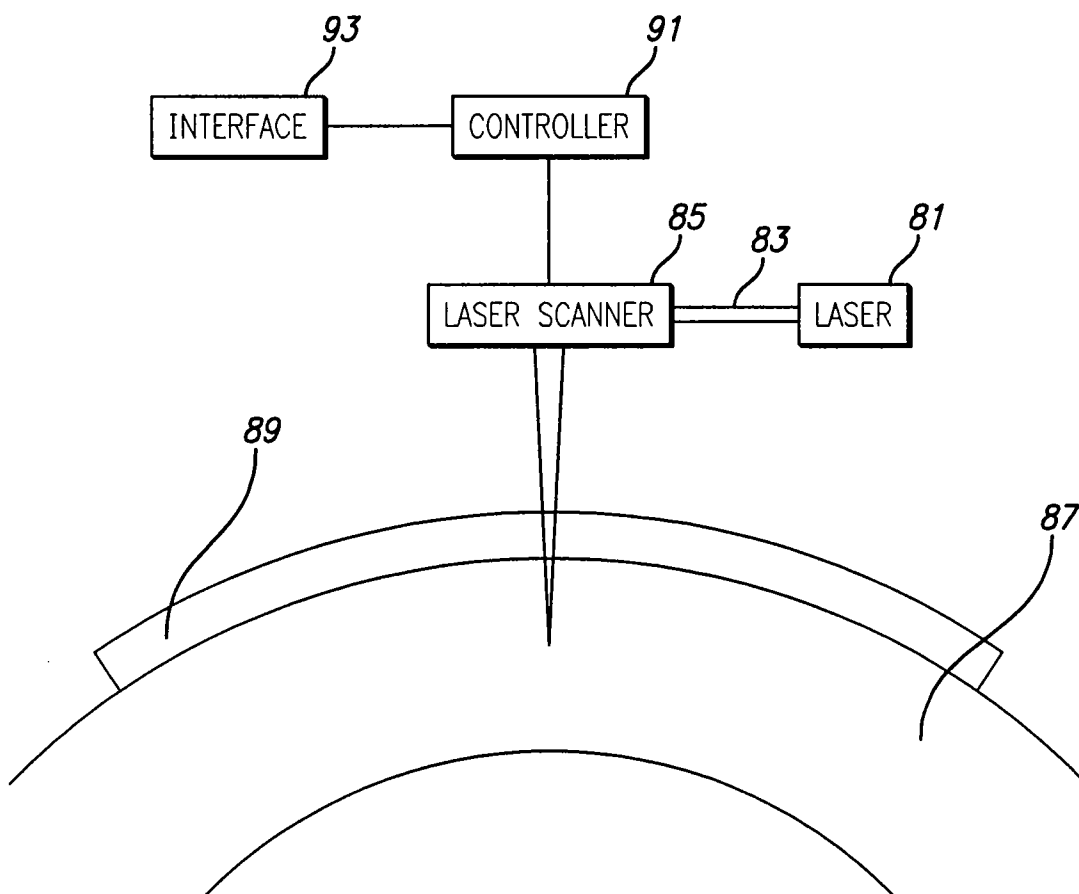


FIG. 5