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5 SEGMENTED PRE-FORMED INTRASTROMAL CORNEAL INSERTField of the Invention

This invention is a pre-formed intrastromal corneal insert. It is made of a physiologically
10 compatible polymer and may be used to adjust corneal curvature and thereby correct vision abnormalities. The insert or segment may also be used to deliver therapeutic or diagnostic agents to the interior of the cornea or of the eye. The insert subtends only a portion of a ring,
15 or "arc", encircling the anterior cornea outside of the cornea's field of view but within the frontal circumference of the cornea, but may be used in multiples to form complete arcs or to form constructs of varying thicknesses. The invention also includes both a
20 minimally invasive procedure for inserting one or more of the devices into the cornea as well as the thus-corrected eye.

Background of the Invention

25 Anomalies in the overall shape of the eye can cause visual disorders. Hyperopia ("farsightedness") occurs when the front-to-back distance in the eyeball is too short. In such a case, parallel rays originating greater than 20 feet from the eye focus behind the
30 retina. In contrast, when the front-to-back distance of eyeball is too long, myopia ("nearsightedness") occurs and the focus of parallel rays entering the eye occurs in front of the retina. Astigmatism is a condition which occurs when the parallel rays of light do not focus to a
35 single point within the eye, but rather have a variable

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the gel must simply conform to the shape of the intrastromal channel. However, it does show the concept of using arcuate channels containing a gel-based insert centered about the corneal to correct.

5 Temirov et al, "Refractive circular tunnel keroplasty in the correction of high myopia", Vestnik Oftalmologii 1991: 3-21-31, suggests the use of collagen thread as ICR material.

10 These publications do not suggest the introduction of pre-formed polymeric arcuate inserts into the cornea for the correction of various visual aberrations. Certainly the publications do not imply that the devices may be used to introduce therapeutic or diagnostic materials into the corneal intrastromal space.

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Summary of the Invention

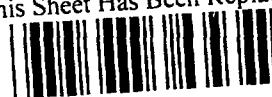
 This invention is a pre-formed polymeric insert suitable for insertion between the lamella of the corneal stroma. The insert is an arc-shaped segment of a ring
20 and may be used in isolation, in isolated multiples, in cooperative multiples, as segments in a larger assemblage encircling at least a portion of the cornea, or as assemblages to form constructs of varying thickness. The insert may be of one or more synthetic or natural
25 polymers, hydrophilic or hydrophobic, or may be a hybrid device comprising layered materials or it may be hollow.

 The insert may be adapted to be fillable with a biologic agent, drug or other liquid, emulsified, or time-release eye treatment or diagnostic material.

30 When the insert is a hybrid, both the inner and outer portions may comprise variously one or more high or low modulus, physiologically compatible polymers or a composite of a low modulus polymer and a high modulus polymer. The inner portion may comprise a gel or a

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made according to the invention which shows certain defined terms used in the description.

Each of Figures 4A, 4B, and 4C; 5A, 5B and 5C; 6A, 6B, and 6C; and 7A, 7B, and 7C, shows respectively a
5 front view ("A"), a cross section ("B"), a top view ("C") of various narrow point intracorneal inserts made according to the invention.

Figures 8A, 8B, and 8C show respectively a front view and two cross sections of a broad point
10 tapered intracorneal insert made according to the invention.

Figures 9A, 9B, and 9C show respectively a front view and two cross sections of a soft, filled intracorneal insert made according to the invention.

15 Figure 10 depicts a front view of an end-to-end assemblage of intracorneal segments having no end junctions between the inserts.

Figure 11 shows a front view of an end-to-end assemblage of intracorneal segments having junctions
20 between the inserts to hold them in a particular spatial relationship.

Figure 12 shows a partial cross-sectional view of an end-to-end assemblage of intracorneal segments which are strung on a filament to form a ring.

25 Figures 13A and 13B show respectively a front view and a cross section of an assemblage of intracorneal inserts made according to the invention which overlap at their ends to form a single monolithic device.

Figures 14A-14E and 15A-15F schematically
30 depict procedures for installing intracorneal inserts.

Description of the Invention

Prior to explaining the details of the inventive devices, a short explanation of the physiology
35 of the eye is needed to appreciate the functional

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The retina (18) is a part of the brain arising as an outgrowth from the fore-brain, with the optic nerve (24) serving as a fiber tract connecting the retina part of the brain with the fore-brain. A layer of rods and
5 cones, lying just beneath a pigmented epithelium on the anterior wall of the retina serve as visual cells or photoreceptors which transform physical energy (light) into nerve impulses.

The vitreous body (26) is a transparent
10 gelatinous mass which fills the posterior four-fifths of the globe (11). At its sides it supports the ciliary body (16) and the retina (18). A frontal saucer-shaped depression (27) houses the lens.

The lens (21) of the eye is a transparent bi-
15 convex body of crystalline appearance placed between the iris (17) and vitreous body (26). Its axial diameter varies markedly with accommodation. A ciliary zonule (273), consisting of transparent fibers passing between the ciliary body (16) and lens (21) serves to hold the
20 lens (21) in position and enables the ciliary muscle to act on it.

Referring again to the cornea (12), this outermost fibrous transparent coating resembles a watch glass. Its curvature is somewhat greater than the rest
25 of the globe and is ideally spherical in nature. However, often it is more curved in one meridian than another giving rise to astigmatism. A central third of the cornea is called the optical zone with a slight flattening taking place outwardly thereof as the cornea
30 thickens towards its periphery. Most of the refraction of the eye takes place through the cornea.

Figure 2 is a more detailed drawing of the anterior portion of the globe showing the various layers of the cornea (12) making up the epithelium (31).
35 Epithelial cells on the surface thereof function to

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generally semicircular or arc-shaped channel is formed partially circling the cornea at the chosen radius. The dissector is then rotated in the opposite direction to withdraw it from the tunnel or channel thus formed. An
5 intrastromal segment is then introduced into the channel.

As is shown in Figure 3A, the arcuate segment (300) is a portion of the circle and subtends some specific amount of a circumference of the cornea (at some chosen radius) equal to a value of " α ", which value is
10 less than 360° , preferably less than 320° , most preferably less than 270° . I refer to this angle as the "arc angle". The value of " α " is dependent upon the indication to be resolved and the physical arrangement of the segment (or segments) as they are installed in the
15 eye. For instance, often the value of " α " is 60 to 90° for the correction of modest astigmatic aberrations. In any event, for definitional purposes, the opposite ends of a single "segment" do not meet when the segment is inserted into an intrastromal channel.

20 Similarly, if the segments are joined or used in conjunction with each other (such as are described in discussing Figures 10, 11, and 12 below) the value of " α " may be any of a wide range of values up to and including 360° or more.

25 Similarly, Figure 3B shows an orientation angle " β " of the segment as it is placed in the eye. Generally, the angle " β " is the angle between the tangent of the backside (302) of the segment (300) and the mean midline (304) of the eye. If the segment were (300) to be a
30 continuous ring encircling the cornea, it would be known as a cone angle. For convenience, the chosen conventions for thickness and width are shown on Figure 3B.

We have found that for the majority of uses to which these inserts are intended, the value of " β " may be
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polyvinylpyrrolidone (PVP), polyethylene oxide, or
polyacrylates, polyacrylic acid and its derivatives,
their copolymers and interpolymers, and the like as well
as biologic polymers such as crosslinked dextran,
5 crosslinked heparin, or hyaluronic acid.

In many instances, the intrastromal segments
may be hybrid, that is to say, the segments are made up
of a number of polymeric layers typically with a soft or
hydratable polymer on their outer surface. These hybrid
10 segments will be described with greater particularity
below. Partially hydrated or fully hydrated hydrophilic
polymers are typically slippery and consequently may
contribute to the ease with which the insert may be
introduced into the interlamellar tunnel. It is usually
15 desirable to (at least partially) hydrate the hybrid
intrastromal segment in that, otherwise, the intrastromal
segment during its traverse through the tunnel may
desiccate the path and begin to stick to the interior
wall of the tunnel. Suitable hydrophilic polymers
20 include polyhydroxyethylmethacrylate (pHEMA), N-
substituted acrylamides, polyvinylpyrrolidone (PVP),
polyacrylamide, polyglycerylmethacrylate,
polyethyleneoxide, polyvinyl alcohol, polyacrylic acid,
polymethacrylic acid, poly (N, N-dimethyl amino propyl-
25 N¹-acrylamide) and their copolymers and their
combinations with hydrophilic and hydrophobic comonomers,
crosslinks, and other modifiers. Thermoplastic hydrogels
include hydropolyacrylonitrile, polyvinyl alcohol
derivatives, hydrophilic polyurethanes, styrene-PVP block
30 copolymers and the like.

The intrastromal segment may be lubricated with
suitable ocular lubricants such as hyaluronic acid,
methylethyl cellulose, dextran solutions, glycerine
solutions, polysaccharides, or oligosaccharides upon its
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to the invention. Although these drawings show narrow points on the inventive inserts, such points are not a critical aspect of the invention. The ends of the inserts may be tapered in both width and thickness, in one or the other of those axes, or may be blunt. Other variations of the ends will be discussed below to the extent necessary to understand the invention. These inserts are "pre-formed" or "pre-shaped". By the use of these terms, I mean that the insert has sufficient structural integrity to approximate in shape some portion of the intrastromal channel into which it is to be placed.

Figure 4A shows a front view of a pre-shaped intracorneal insert (400) having ends (402). The intracorneal insert tapers both in width and in thickness to narrow points (402). Viewed in cross section in Figure 4B, the generally smooth convex front surface (404) and planar rear surface (406) may be seen. Figure 4C shows a side view of the segment or insert. Some care must be taken in using an insert having such narrowly pointed ends since such inserts are intended to be introduced into a previously created intrastromal channel. Points of great sharpness may wander in direction from the desired channel.

Figure 5A shows a front view of an intracorneal insert (500) having ends (502). Again, the intracorneal insert tapers both in width and in thickness to narrow points (502). Viewed in cross section in Figure 4B, the generally hexagonal shape may be seen. The surfaces most adjacent the anterior surface of the eye and the side just opposite are generally the two longer of the sides. Those generally planar front surface (504) and planar rear surface (506) may be seen. Our previous experience with Intracorneal Rings ("ICRs") has demonstrated that the use of such a shape in the cornea is generally less

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elasticity is considered to be greater in value than about 3.5 kpsi, preferably 5-12 kpsi, and most preferably 8-10 kpsi. These high modulus of elasticity polymers are discussed above.

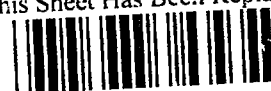
5 If hydratable polymers are chosen for the outside layers, the extent to which those outer layers swell upon hydration is dependent upon the type of polymer chosen and, when the polymer is hydratable, upon the amount of cross-linking found in the outer layers
10 (702) and (706), and upon the thickness of the layer. Generally speaking, the more highly linked the hydratable polymer, the smaller the amount of volume change upon hydration. Conversely, a polymer having only sufficient cross-linking for strength in the service in which this
15 device is placed, will have a somewhat lower level of cross-linking. Alternatively, a substantially nonswellable polymer system may be formed of a hydrogel physically interpenetrated by another polymer which does not hydrate, e.g., polyHEMA.

20 The thickness of the outer layer depends in large function upon the intended use of the intrastromal segment. If the outer layer is used to provide a swellable outer layer which does not add significantly to the size of the intrastromal segment or is used
25 functionally as a lubricant layer, the other layer may be quite thin -- even to the point of a layer of minimum coverage, perhaps as thin as a single molecular layer.

 Of course, the inner and outer layers need not be, respectively, low modulus and high modulus polymers
30 but may instead be multiple layers of low modulus polymers including an outer hydrophilic polymer layer and an inner hydrophobic polymer; a variety of hydrophilic polymers; etc.

 Additionally, the inventive device shown in
35 Figures 7A to 7C need not have a inner (704) and outer

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Figure 9C shows the inner cavity (904) which may be filled with a biologic, a drug or other liquid, or biologically active eye treatment material. These devices may be tied or pinched or crimped or otherwise
5 connected at their point of insertion by known techniques.

The shell (902) may be injected with a settable soft polymer core, allowed to expand to a desired thickness, and set. Polymeric gels which do not
10 polymerize in situ are preferred. Suitable injectable polymers are well known but include polyHEMA hydrogel, cross-linked collagen, cross-linked hyaluronic acid, siloxane gels, and organic-siloxane gels such as cross-linked methyl vinyl siloxane gels.

Figure 10 shows a variation of the invention in which an assemblage of the inventive intrastromal segments (950) are formed into a polymeric ring or, at least, into an assemblage which totals no more than 360° of corneal circumference when assembled into the
20 intracorneal space. The two segments (950) depicted in Figure 10 may be of any of the individual variations shown in the Figures above and need not be connected in any way. The segments may be of similar or quite different configurations depending upon the indication to
25 be remedied. Additionally, they may be inserted in separately produced intrastromal channels which may, or may not, be in communication within the cornea. Such individual insertion will be discussed in more detail below.

Figure 11 shows a similar assemblage in which the intracorneal segments (952) are held together using open holes (954) and a clip (956) which may be a simple wire or other suitable joining device. An assemblage such as is seen in Figure 11 may be advantageously

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Insertion of the inventive device is a reasonably simple surgical procedure. An entry slit (804) is made radially into the cornea. A dissector blade is introduced into the entry slit (804) and turned in the direction of the arrow (806) to form a partial intrastromal channel of a desired length. A second entry slit (808) may then be made in the cornea and a second intrastromal channel be made in the direction of the arrow (810).

Figure 14C shows the introduction of the first inventive segment (812) into the first entry slit (808). Figure 14C shows the first segment (812) in its final resting position and the introduction of the second segment (814) into the second entry slit (808). Finally Figure 14E shows both first segment (812) and second segment (814) in their final position within the cornea. This demonstrates the flexibility of the procedure in that either left or right "hand" insertion is appropriate and the intrastromal channel need not be a complete circle about the cornea. Further, it should be noted that the first segment (812) and the second segment (814) may be of differing diameters or of differing arc lengths depending upon the indication to be resolved.

Figures 15A-15F schematically portray a method for the insertion of the segments described above in which partial arc segments are introduced into separate sections of the corneal circumference outside of the "sight" area of that cornea through a single entry slit.

Figure 15A shows the making of the initial entry slit (840) radially into the cornea. A dissector blade is introduced into the entry slit (840) and turned in the direction of the arrow (842) to form a partial intrastromal channel of a desired length. As is shown in Figure 15B, a second intrastromal channel is made in the direction of the arrow (844) from the same entry slit (842).

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myopic correction is needed, segments of between about 20° and 90°, preferably between about 20° and 60° may be used. Where treatment of astigmatism and myopia is required, segments of between about 45° and 160°,
5 preferably between about 60° and 90° may be used. For the treatment of myopia where no astigmatic enhancement is required, segments of between about 90° and 360°, preferably between about 90° and 270° may be used.

The terms and expressions which have been used
10 in the description above are used only as terms of description and not of limitation. There is no intention of excluding equivalents of the features shown or described. It is recognized that one having ordinary skill in this art would perceive equivalence to the
15 inventions claimed below, which equivalence would be within the spirit of the invention as expressed above.

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I CLAIM AS MY INVENTION:

1. An intrastromal corneal insert suitable for introduction into the corneal stroma comprising a pre-shaped, physiologically compatible, polymeric segment adapted for introduction into an intrastromal intracorneal channel and having an arc angle less than 360° when inserted into the intrastromal channel.

5 2. The insert of claim 1 where the segment comprises an arc angle of less than about 320° .

3. The insert of claim 2 where the segment comprises an arc angle of less than about 270° .

10 4. The insert of claim 3 where the segment comprises an arc angle of 20 to 90° .

5. The insert of claim 2 where the segment comprises a low modulus physiologically compatible polymer.

15 6. The insert of claim 5 where the low modulus physiologically compatible polymer is selected from polyhydroxyethylmethacrylate (Poly-HEMA), polyvinylpyrrolidone (PVP), polyethylene oxide, or polyacrylates, polyacrylic acid and its derivatives, their copolymers and interpolymers, silicones, crosslinked dextran, crosslinked heparin, or hyaluronic acid.

20 7. The insert of claim 5 where the low modulus physiologically compatible polymer is selected from hydratable polymers which swell upon hydration, hydratable polymer systems which do not swell upon hydration, and elastomers.



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hydratable polymer systems which do not swell upon hydration, and elastomers.

8. The insert of claim 2 where the segment
5 comprises comprises a polymer having a high modulus of elasticity.

9. The insert of claim 8 in which the polymer
having a high modulus of elasticity comprises a polymer
10 selected from PMMA, TEFLON, polysulfones, polycarbonate, epoxies, a polyolefin selected from polyethylene, polypropylene, polybutylene, mixtures, or interpolymers.

10. The insert of claim 1 having a hollow
15 inner fillable portion.

11. The insert of claim 10 where the hollow inner portion is fillable with a liquid.

12. The insert of claim 10 where the hollow inner portion is at least partially filled with a gel or a settable polymer, a drug or a biologic agent.

13. The insert of claim 12 where the gel or
25 settable polymer is selected from polyHEMA hydrogel, cross-linked collagen, cross-linked hyaluronic acid, siloxane gels, polyvinyl pyrrolidone, and organic-siloxane gels.

14. The insert of claim 5 additionally comprising a drug or biologic agent.

15. The insert of claims 12 or 14 where the drug is selected from dexamethasone, heparin,
35 corticosteroids, antimitotics, antifibrotics,



25. The insert of claim 23 where at least one polymeric layer comprises a high modulus physiologically compatible polymer.

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