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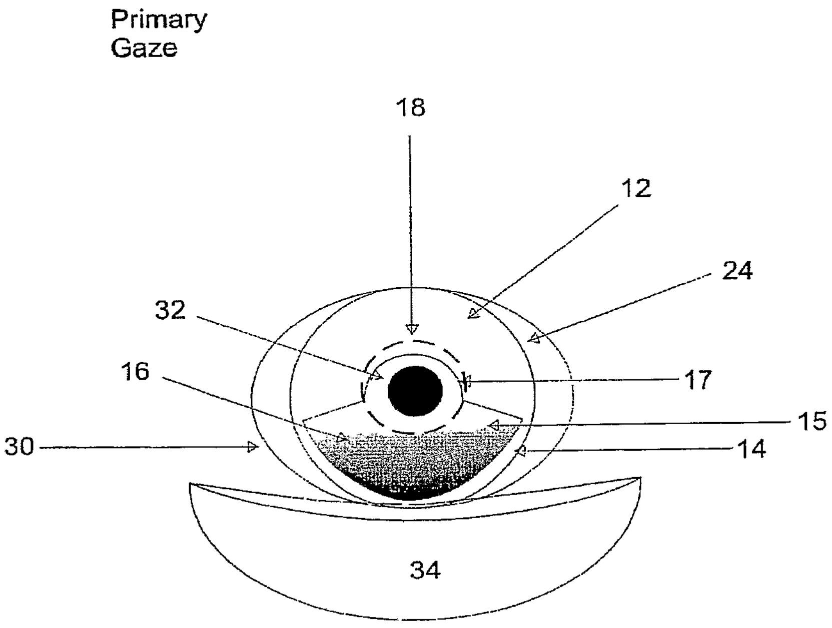
(54) Title: HYDRODYNAMIC MULTIFOCAL CONTACT LENS AND ASSOCIATED MANUFACTURING TECHNIQUES

Figure 1A



(57) Abstract: This invention pertains to a soft contact lens that has a body with a central zone aligned with the optical axis of the eye when a wearer wears the lens, In one embodiment the soft lens includes a chamber 17 that extends from a lower portion of the lens to its central axis and arranged so that when a person looks down, a fluid is squeezed from the reservoir 9 and changes the optical characteristics of the lens.

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Hydrodynamic Multifocal Contact Lens and Associated Manufacturing Techniques

BACKGROUND OF THE INVENTION

Field of the invention

This invention deals with the art of soft contact lens production for the purposes vision correction. More particularly, details designs and the methods to created a lens capable of dynamically altering the optical power of a soft contact lens, while in the eye, through gaze dependent use of fluid dynamics for the correction of refractive and accommodation deficiencies of the eye.

DESCRIPTION OF THE PRIOR ART

Some forty years ago, contact lenses (or contacts) started to be used as a common alternative to glasses to address both distance and near blurred vision. The two types of contact lenses that are presently in use are either

PMMA / Rigid Gas Permeable or Hydrophilic Soft contact lenses. Where soft contact design hold the majority of the retail market by a large margin.

Originally the lenses were produced to remedy only blurred distance vision from either near sighted or far sighted prescriptions. As the field matured more sophisticated designs become available to correct astigmatism (a football shaped eye) in addition to near and far sightedness.

As the age of contact lens wearing population matured the additional need for correcting near vision blur came into play. Generally the way in which contacts have achieved correcting both distance and near vision is either through a translating design or through what is called simultaneous vision designs.

Translating hard contact lenses designs work by having at least two separate optical zones (a bi-focal) in the lens and take advantage of the fact that they move around on the cornea. These lenses are fit such that the lower edge of the contact rests against the lower lid so that as the wearer looks from a distant object, downward to a near object, the lens stays stationary at the lower lid as the eye rotates downward behind the lens so as to be looking through the near vision portion of the contact. This effectively causes the lens to" translate" on the eye.

Simultaneous designs for both hard and soft contacts were developed to address how to focus on distance and near objects when a contact lens is fit to remain essentially in the same location with respect to the optical axis of the eye even during the blink. These lenses currently addressed this issue by creating multiple refractive surfaces disposed directly along the visual axis. Examples of designs used for this purpose include aspheric, diffractive, concentric power rings, and refractive islands. Unfortunately all of these designs focus light coming from different distances onto the retina simultaneously. This is why they are called simultaneous vision designs. As one could imagine these designs result in “double or multiple exposures” on the retina, which significantly degrade the quality of the retinal image. This is a classic example of attempting to engineer a static solution to a dynamic problem. In other words, the best solution is to create a contact lens, which would mimic the ability of the human eye to dynamically change its focus to whatever it is attending to.

It is the intent of this invention to address this very issue with the creation of a hydrodynamic gaze dependent multifocal contact lens.

SUMMARY OF THE INVENTION

Multifocal Contact Lens Containing a Hydrodynamic Reservoir

This present invention discloses various designs and the techniques to manufacture a contact lens capable of exhibiting new physical characteristics useful for dynamically adapting the focus of the eye. More specifically, multiple designs and the manufacturing techniques for production of a soft contact lens are disclosed that changes its refractive characteristics dynamically via gaze dependent pressure fluctuations induced by the eyelids on a reservoir of fluid contained inside the contact lens.

As discussed above, as the eyeball moves, the optical axes of a soft contact lens and the natural lens remain substantially coincident. Therefore, providing a contact lens having different refractive powers along different optical axes (as is the case with multifocal glasses) does not provide a solution to the problem of most patients. The present invention provides a solution to this problem by providing a lens that changes its optical characteristics (e.g., magnification power, its focal length, and/or refractive power dynamically and in situ. In particular, a soft contact lens is disclosed that includes a cavity with one or more flexible internal chambers arranged on the optical axis of the eye, and one reservoir filled with a fluid. Movement of the eye causes the fluid to selectively move between the reservoir and the cavity in a manner designed to provide in situ changes to the optical characteristics of the soft contact lens Preferably, the fluid is selected so that it is non toxic, ocular friendly, will not diffuse through the lens polymer and aids in the refractive changes to the contact lens. Examples of fluids meet these criteria may be a silicone oil or just saline solution.

According to one embodiment of this invention a contact lens includes a reservoir filled with fluid. For distant viewing, the bulk of the fluid generally remains outside the wearer's optical axis. The reservoir is constructed and arranged so that it undergoes compression by the natural force of apposition of the lid applied to the eye itself during downward gaze. This compression, forces fluid to move from the reservoir into the internal chambers, thereby dynamically changing the shape of the lens, and thereby dynamically altering the optical characteristics of the contact lens. Conversely, when the wearer returns his gaze forwardly, the compression forces from the lid are released and the fluid is returned to the reservoir, thereby allowing the lens to return to its natural shape. Thus, as described above, advantageously, in the present invention it is the position of gaze that determines the contact lens's optical characteristics in the field of vision. More specifically, the further the eye is in downward gaze the greater the change in the characteristics. Preferably, a downward gaze shortens the focal length of the contact thereby allowing objects at near to be in focus. In effect this creates a continuous variable multifocal contact lens. This can be accomplished through using fluid pressure to

1) Reshape the front surface of the contact into a steeper base curve;
2) Dynamically separate or alter two or more internal refractive surfaces of the contact lens, thereby producing in effect several coaxial lens;
3) Move an alternate index fluid into the visual axis;
4) Float an internal refractive surface into the visual axis;
5) Cause a combination of the above.

These principles may be used to provide other optical configurations as well. More specifically, the lens is constructed so that this wiping action of the lids causes a fluid within the reservoirs to shift toward or away from a subject's axis of gaze, thereby causing a corresponding change in the optical characteristics of the lens relative to the wearer's gaze. The movement of the fluid, or reshaping of the cavity, can change the optical characteristics of the lens, adjusting for the correction required for the user.

In another embodiment, the contact lens includes an internal cavity made up of a single peripheral reservoir combined with multiple chambers, or micro-channels or micro-tubes in the optic zone to allow for multiple small base cure changes instead of one large base curve change, thereby substantial decreasing the pressure and volume of fluid needed to induce those changes. Since the dimensional changes occurring to the contact lens have designed features that would allow maximum refractive changes under minimum lid pressure, the range of patients able to gain benefit from reservoir lenses increases dramatically, especially considering that the pressure of lid apposition to the eye decreases with age. This invention also broadens the population of potential beneficiaries to include emmetropic presbyopes (individuals who only need correction for reading and not for distance) but whose eyelid pressure is insufficient for the reservoir lenses in the prior art. This invention is beneficial to this population because current products diminish the clarity at distance, which makes those designs unacceptable to individuals who otherwise have clear distance vision.

In another embodiment, a diaphragm can be placed between the peripheral reservoir and the microtubules in the optic zone so that only fluid pressure and not the fluid itself is exchanged. This would allow the use of fluids with different characteristics, like index of refraction or viscosity, to be used in different areas of the contact lens.

These designs can be manufactured by many different techniques. Take for example, one variation of this embodiment, which could be created through a lamination of two halves of a contact lens one with a reservoir contour and one without or each with surface contours of half of the intended internal reservoir. Another variation of this lamination embodiment is a technique creating a sandwich of three contacts where the center contact would have a “punch out” in the shape of the intended reservoir while the other two contacts would seal the “punch out” into a reservoir. Another technique to create an internal reservoir is to pre-form a “balloon reservoir” and then encapsulate it inside a contact lens during the injection molding process. Another technique to create an internal reservoir is to use a laser (eg.eximer) to etch out either part of or the entire reservoir. Another technique yet would involve combining a fine spray of monomer with a fine spray of polymerization agent in the presence of UV light in order to build a contact lens by layered “print polymerization”. These techniques can also be used in combination.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A-1B	shows a contact lens with a fluid reservoir in accordance with this invention;
Figures 2A –2C	show, respectively, a side and cut away views of the structures within a contact lens capable of inducing refractive changes secondary to fluid displacement within an encapsulated fluid chamber;
Figures 3A –3K	show, respectively, differences in internal fluid volume between reservoirs designed with and without micro-channels tubules in the optic zone;
Figures 4A –4K	show, respectively, an alternate method of reshaping the front base curve by hydrodynamic circumferential compression of the optic zone;
Figures 5A-5C	show, respectively, a two layer lamination technique to create an internal fluid reservoir where the reservoir contour in placed on a internal convex surface, an internal concave surface and on both types of internal surfaces;

Figures 5D	show, a three layer lamination technique to create an internal reservoir;
Figures 7A –7D	show, alternate methods to fill the internal fluid reservoir;
Figures 8 - 9	show, respectively, a single and two step method of encapsulating a preformed balloon reservoir inside a contact;
Figures 10	show, a method to create an internal reservoir via lamination of wet gel injection molding;
Figures 11	shows, a production schematic to construct a contact lens containing hydrodynamic reservoir using a four piece mold via lamination of wet gel injection molding;
Figures 11A	shows, a production schematic to construct a contact lens containing hydrodynamic reservoir using a four piece mold to encapsulate a preformed balloon reservoir via lamination of wet gel injection molding;

Figures 12-12A	show, respectively a horizontal and vertical techniques of 3D print polymerization to construct a contact lens containing hydrodynamic reservoir;
Figures 13	shows, a laser etching technique to construct a contact lens containing hydrodynamic reservoir;

DETAILED DESCRIPTION OF THE INVENTION

This present invention discloses various designs and the techniques to manufacture a contact lens capable of exhibiting new physical characteristics useful for dynamically adapting the focus of the eye. More specifically, designs and the manufacturing techniques for production of a soft contact lens Figure 1 10 are disclosed that changes its refractive characteristics dynamically via gaze dependent pressure fluctuations induced by the eyelids Figure 1 34 on a reservoir of fluid Figure 1 16 contained inside the contact lens. The following example illustrates the general concept the invention.

In general this embodiment can be accomplished by creating a reservoir inside the contact lens through many different techniques. One technique for example, could be through a lamination process. This process may entail shaping two contact lens surfaces joined peripherally Figure 1B 8 to define a reservoir therebetween having predetermined shape Figure 1A 16. As shown in Fig. 1A, a lens 24 constructed in accordance with this invention is formed consisting of a shell having an upper section 12 that has the same characteristics as standard distant vision contact lens, which may or may not have any optical effects, and a lower section 14 that is formed with the reservoir 16. This reservoir 16 has a shaped somewhat like the letter D facing downward with an upwardly extending circular section 17 projecting into the center of the contact. The lower area 19 of reservoir 16 has a separation or clearance between its internal convex and concave surfaces while in area 17 the internal convex and concave surfaces have little to no clearance. When the contact 24 is placed into an eye 30, the reservoir 16 extends from the lower portion of the contact lens up into the visual axis that passes the pupil 32. The reservoir 16 is filled with non toxic, ocular friendly fluid, such as saline, contact lens lubricants, artificial tears or other non-toxic material such a silicone oil. In the area 17, defining the visual axis X-X, during primary gaze figure 2B PG, the inner back convex surface17A and inner concave front surface 17B of the reservoir 16 are in apposition. The outer most layer of the reservoir 17B is distensible as shown in Figure 2B. Upon insertion, the weight of the reservoir causes the lens to take the position shown in the Figures, i.e., with the reservoir disposed at the bottom portion of the lens.

When the person gazes straight forward for distant vision, they are looking along an optical axis X-X that passes through the optic zone 18, which is deposed in area 17 of reservoir 16. In this position, the fluid is primarily deposited in the lower portion 19 of the reservoir 16 as shown in Fig. 2A. In this configuration, the portion of the lens 24 through which the wearer is looking through 18 has either no optical effect on the wearer's vision, or is configured to provide distant vision.

In order to change to near vision, the eye is lowered from primary gaze Fig. 2A PG into a downward gaze Fig. 2B DG, where the pressure of the lower lid 34 on the contact lens 24 causes the fluid in area 19 of reservoir 16 to rise, thereby filling and expanding reservoir section 17, as shown in Figs. 2B. In other words, the lower lid 34, which normally applies pressure directly to the eyeball during downward gaze, now is used to compress the lower section of this reservoir figure 2B 19 and force the fluid up into the area 17 located in the visual optic zone 18. As a result, layer 17B of section 17 in Figure 2B is deformed to a steeper base curve causing a shift in the refractive power of the contact lens. The term ‘steepen’ is a term of the art and it relates to a distortion of a lens that causes the lens to become more convex. Advantageously, depending the depth of downward gaze, which controls the amount of fluid that reaches into section 17, which controls the overall change in front surface base curve, which induces the refractive power change of the contact lens, this lens is capable of producing a smooth progression of near addition power similar to that of a progressive lens. In essence what this does, for example, is to take a lens used to correct myopia and gradually makes it less minus by increasing its front base curve in the visual axis. (The same is true for a plus lens but instead of decreasing its power the increase of the base curve would increase its refractive power). This in turn creates a gaze dependent multifocal contact lens via in situ alteration of the base curve.

To return to distant vision focus, the wearer looks up which carries the contact lens up from behind the lower lid 34 releasing the pressure on the lower reservoir 19 and allowing the fluid from reservoir section 17 to flow down and return to section 19 of reservoir 16 in the bottom of the lens, away from the optical axis X-X. This action is further assisted by the upper lid which acts as a squeegee, (utilizing the same "force of apposition" during a blink), causing the upper section of the reservoir to empty back into the lower portion of the reservoir. This re-flattens the distended outer surface base curve of the contact lens 17B, placing surfaces 17A and 17B back in apposition, thereby returning the focus to distance.

Another embodiment disclosed is a technique to minimize the amount of hydrodynamic fluid used within the lens. This can be accomplished by converting the central optic zone reservoir from a single cavity Figure 3A #300 to a series of microchannels Figure 3F #310. Due to the fact that the diameter of each micro-channel is much smaller then that of the single chamber reservoir (Figures 3B vs 3G & 3D vs 3I), the sagita depth is greatly reduced figures 3C vs 3H & 3E vs 3J. Therefore the volume needed to inflate each micro-channel to the equivalent single reservoir base curve will be significantly reduced Figure 3K.

Additional when inflated, these micro-channels will act as an array of "plus cylinder bars" mimicking the focal length change induce by a larger single lens base curve change. This embodiment broadens the population and age range of potential beneficiaries to include individuals who whose eyelid pressure is insufficient for the single optic zone reservoir lenses.

Figs 4A-4F show a yet another embodiment of the invention. This embodiment also includes a reservoir 416 disposed at the bottom of contact lens 410 and having about the same size and shape as in the previous embodiments. However, the upper chamber 420 includes one or more annular micro-channels 411 encircling a sealed optic zone 419. The optic zone 419 is filled with a liquid, a gel, or a flexible solid. The annular microchannels 420 can exchange fluid or fluid pressure (through an appropriate diaphragm) from the reservoir 416 in the manner described for the other embodiments. When a wearer gazes straight forward for distant vision, he/she look along an optical axis that passes through section 419. In this position, the fluid in the surrounding ring 411 is primarily or totally disposed in the lower portion of the reservoir 416 as shown in Figs. 4A and 4C causing the circumferential ring to be in a non–expanded or deflated state. In this configuration, the portion of the lens 419 through which the wearer is looking is configured to provide either no optical effect on the wearer's vision or to provide distant vision.

In order to change to near vision, the eye is lowered, and the pressure of the lower lid 434 on the contact lens 410 causes the fluid in the reservoir 416 to rise, thereby filling and expanding the micro-channels 411 surrounding section 419, as shown in Figs. 4D- 4F. In other words, the lower lid 434, which normally applies pressure directly to the eyeball during downward gaze, now is used to compress the reservoir and force the fluid up into the circumferential micro-channel or ring 411. As a result, central optic zone 419 is inwardly compressed and deformed to a steeper base curve or a more convex lens surface causing a shift in the optical characteristics of the contact lens (see Figures 4D-4F). Advantageously, the depth of downward gaze defines the optical characteristic of the contact lens and will therefore dictate the progression of optical change in relation to that of the downward gaze. This creates a gaze dependent multifocal contact lens via in situ alteration of the base curve.

To return to distant vision focus, the wearer looks up, moving the contact lens up away from the lower lid 434, thereby releasing the pressure on the lower reservoir and allowing the fluid from the micro-channels 411 to flow back down into the peripheral reservoir 416. This action removes any deforming pressure on the central optic zone 419. This action is further assisted by the upper lid 436, which acts as a squeegee, (utilizing the same "force of apposition" during a blink), flattening the distended center optic zone 419 returning the focus to distance.

The optimum hydrodynamic fluid used in the lens should be physiologically inert, and unable to diffuse through the contact lens polymer and able to transmit oxygen. One embodiment of this invention uses a medical grade fluorinated silicone oils (eg. Silicone oil RMN3 mixture as used for an internal retinal tamponade for complicated retinal detachment repair). Another embodiment uses Flombins or porous microspheres that have had fluorinated silicone bonded to their surface. These small spheres are analogous to very small, very slick ball bearings on a string that in aggregate act as a fluid. But unlike a fluid they are so large they are unable to diffuse through the matrix of the contact lens polymer.

There are several ways in which the hydrodynamic fluid will be introduced to the contact lens reservoir. One embodiment is to place a specified quantity in to the reservoir portion in the concave side of the external half of the contact lens Figure 7A prior to lamination. Another embodiment involves putting a very small hole Figure 7B 72 in the peripheral reservoir portion of the contact lens shell 70 prior to laminating or creating a channel Figure 7C 83 on the convex surface of contact lens shell 82 leading from the rim of the contact lens to the reservoir. Then, after laminating the two sides together, fill the reservoir through the front surface hole or rim channel with a syringe and microfill tip setup. Polymerizing a drop of raw monomer introduced into the hole or channel would then seal the filling port.

Another embodiment is to coat and fill both sides and the reservoir contour with a non-toxic ocular friendly raw monomer and then carefully polymerizes only the periphery and surface leaving a reservoir filled with liquid monomer, which would then act as the hydrodynamic fluid.

Yet another embodiment is to place a pre filled balloon (similar to breast augmentation implants) into the reservoir contour and then laminate the two contact shells together.

Utilizing the general concepts described above the following sections cover specific manufacturing techniques that produce an encapsulated fluid filled space inside a contact lens for the purposed of redistribution of fluid or fluid pressure from a peripheral storage zone to a central optic zone in order induce mechanical, physical and optical alterations of the refractive nature of the contact lens.

Multifocal Contact Lens Hydrodynamic Reservoir by Lamination Technique

As described above this embodiment intends to describe the technique to produce a reservoir within a contact lens capable of redistribution of fluid or fluid pressure from a peripheral storage zone to a central optic zone for the purposes of mechanical, physical and optical alteration of the refractive nature of the contact lens.

In this embodiment a contact lens with a central reservoir (Figure 1 #16) is created through the lamination of two halves of a contact lenses, one with a reservoir contour and one without or each with surface contours of half of the intended internal reservoir, while their respective external surfaces are contoured for fit, stabilize and to optically correct the patient's distance vision refractive disorder. These halves can be constructed via lath cutting, injection molding laser etching or layered "print polymerization".

Figures 5A-5C, show the process of laminate contacts together to create a central reservoir but each depict various placements for the reservoir. In

Figure 5A the contact lens shell 20 has its concave surface 27 configured to fit the cornea. Part of its convex surface 25 is configured to mate exactly with the concave surface 26 of contact lens shell 22. The remaining portion, area 21, is configured to contain a depression in the shape of the intended reservoir. Centrally, area 17 of the reservoir 16 in the optic zone region Figures 2A-C 18 has no real indentation or separation but deepens in the periphery in area 19. This configuration causes the 2 halves of the contact lens, when mated, to have a near zero clearance centrally Figure 2A 17 but a gap or space peripherally Figure 2A 19. Preferable this gap is configured to consist of a male contour Figure 5C 41 and female contour Figure 5C 43 such that when pressure is applied to area 2B 19 the gap will be closed and the fluid will be forced out into area 2B 17.

In all these examples the configurations allow the external surface radius or base curves in the optic zone to set the overall distance vision power of the contact lens. This is because the surfaces of both sides of the internal reservoir in central optic zone are in contact with one another, in the un-inflated state and therefore, optically, do not come in to play. This configuration also creates space peripherally Figure 2B 19 to “store” the hydrodynamic fluid which when the patient looks from primary gaze (Figure 2B PG) into downward gaze Figure 2b DG becomes compressed by the lower lid (LL) causing the fluid to flow up into the “zero clearance” area 17 of the reservoir 16 in the optic zone 18, vaulting the front radius Figure 2B 17B into a steeper base curve causing the lens to become optically more plus thereby aiding focusing at near.

Another variation of this lamination embodiment is a technique creating a sandwich of three contacts where the center contact would have a "punch out" Figure 5D 53 in the shape of the intended reservoir while the other two contacts 50 & 55 would seal in the "punch out" into a reservoir. The center punch out contact lens would taper from being very thin centrally to a thick peripheral zone or it could have no taper and central portions of the convex cure of 50 and/or the concave curve of 55 would bump out to fill the gap centrally between 52 and 55. (See Figure 5D 51& 56) In either case this configuration will yield a zero clearance centrally between the two outer sealing contacts but also creates space peripherally for the hydrodynamic fluid.

Multifocal Contact Lens Hydrodynamic Reservoir by Injection Molding Encasement

In this embodiment a hydrodynamic reservoir is created through polymerizing a raw monomer around a preformed balloon. This process will occur in a "wet gel" state, which allows the polymer to form in its hydrated equivalent expanded state. This prevents expansion issues that might of occurred between the hydrating polymer matrix and the encapsulated, a non expanding, balloon reservoir.

As seen in Figure 8 a balloon reservoir 80 is created to follow the contour of the intended finished contact lens. It is made of silicone and filled with a hydrodynamic substance like fluorinated silicone oil. It could also be made of a water-tight material and filled with saline similar to breast implants. Internally the balloon reservoir is designed to have near zero clearance 80ZC between the concave area 80A of reservoir 80 and the convex area of reservoir 80 in the region where it passes the optic zone of the contact lens and increasing space peripherally 80S. On its convex surface it could have strips of the contact lens polymer will act as spacers or suspension tethers so the cause the balloon to sit off the external mold's concave surface 85.

Once the balloon reservoir is in place or suspended between the ocular surface 82 contour mold and the external surface mold 84, the raw monomer can be injected and polymerization can take place. The finished product 86, a balloon encased inside a contact lens, would have the appearance of fruit suspended in gelatin.

A variation of this method would forgo the suspension of the balloon in favor of a two-step approach. The first step is to create the ocular surface half that incorporates the reservoir Figure 9 96. Then in step two, injection mold laminate the external surface onto the ocular surface balloon-reservoir skirt.

As seen in Figure 9 the balloon reservoir 90 is placed against the concave surface 91 of internal surface mold 92 the mold is closed by the ocular surface mold portion. Injection and polymerization of raw monomer creates the ocular surface balloon reservoir skirt 96. This skirt is then transferred to the external mold 98 where it receives its external surface 99 through injection mold lamination. The combination of the ocular surface/balloon reservoir skirt 96 and the external surface 99 yields the finished product 100. At this point the contact can be flushed of its expansion solution and hydrated.

Yet another variation of this embodiment is to create two sets of injection mold shells each with some of the surface contours that would make up an internal reservoir as well as external ocular fitting surfaces and optical components as illustrated in figure Figures 3, 4, 5 and 6. The general concept is depicted in Figure 10 where the mold 110 containing the ocular surface contour 112 is brought together with the mold 114 containing the smooth central laminating surface contour 116 to create the ocular surface shell 126. Concurrently to this formation the external shell 128, containing, on the concave surface, the reservoir contour 119B, with the contour for the micro filling channel 119C and on the convex external surface contour 124A, is formed by bringing together mold 118, containing the smooth convex middle laminate surface 120 and bump out reservoir contour 119 and the bump out fluid channel contour119A, with mold 122 containing the external convex surface contour 124. Shells 126 and 128 are then laminated together to yield contact lens 130 containing a reservoir 119D and micro-filling channel 119E. This reservoir is then filled with liquid silicone through microfil tipped syringe setup 132 and sealed by polymerizing a drop of monomer in the access channel.

This manufacturing process is further depicted in Figure 11 where mold 200 consists of four hinged sub-molds 110,114,118, 122. After the monomer is added to molds 110 and 118, mold 200 is folded over along the vertical hinge such that sub-molds 110 and 114 mate as do 118 and 122. Curing the monomer in each pair yields contact lens halves 126 and 128. After unfolding, monomer is carefully applied onto the convex surface of 126 and the concave surface of 128, making sure to follow the area of lamination as shown in Figure 1B. Mold 200 in then folded over along the horizontal hinge and a UV mask covering the entire reservoir is put in place. After curing the mold is unfolded and the reservoir is filled with hydrodynamic fluid. Introducing a drop of monomer and curing seals the filling port. Now the completed hydrodynamic multifocal contact 130 can be flushed of its expansion fluid, hydrated, labeled and shipped.

Figure 11A depicts a similar process except a balloon reservoir is laminated between 126 and 128.

Multifocal Contact Lens Hydrodynamic Reservoir by 3 Dimensional Printing Polymerization Technique

Unlike the technique described above this embodiment intends to describe a technique to partially polymerize raw contact lens monomer into a contact lens complete with a reservoir already filled with hydrodynamic fluid (eg. the remainder of the un-polymerized contact lens monomer) capable of redistribution of fluid or fluid pressure from a peripheral storage zone to a central optic zone for the purposes of mechanical, physical and optical alteration of the refractive nature of the contact lens.

As depicted in Figure 12, in order to create a contact lens in this manner it is necessary control the way in which the liquid monomer converts into a solid polymer. As mentioned above this process can be completed by heat, chemical or electromagnetic means. Both the heat and chemical methods do not lend themselves to be easily used to create fine detail during polymerization. On the other hand Ultra Violet (UV) light can easily be manipulated to act as a careful sculpting polymerization agent.

Similar to 3 dimensional printing where a 3 dimensional object is created by carefully fusing very thin layers on top on one another to build up a complete object, this embodiment discloses the use of an "Ink Jet" print head combined with UV light source to polymerize the spray immediately as it is being laid down. Advantageously, when the polymerization agent, from nozzle 148p of print head 148A, which is unfriendly to the eye, is discontinued, the polymerization process will stop leaving liquid filled areas in the shape of the central reservoir, which in turn allows the raw monomer to be used as the hydrodynamic fluid because it will contain no ocular toxic polymerization agents. This allows the lens to be filled as it is being built. It is also possible to completely discontinue spraying both the monomer and the polymerization agent and just add additional print head nozzles to fill the reservoir with hydrodynamic agents like silicone oils.

The use of a UV transparent mold in combination with changing the UV beam diameter will allow for very accurate sculpting of the liquid monomer into a sold contact lens containing an internal reservoir filled with un-polymerized monomer acting as the hydrodynamic fluid. As seen in Figure 12 the spray head 148 containing monomer nozzle 148M, polymerization agent nozzle 148P and an integrated UV light source 148UV is slowly spun around 145 inside mold 140 and the contact lens is slowly built up by successive passes as represented by Figures 142, 144, 146 respectively. As the spray head reaches the area in, which reservoir 143 is to be constructed, nozzle 148P of nozzle head 148A discontinues spraying the polymerization agent. This stops the conversion of monomer to polymer. In this way, over successive passes, with careful control of where and when the polymerization process takes place, the entire contact lens including the contoured walls of the intended reservoir within the center portion of the contact lens can be constructed while simultaneously "filling" the reservoir by means of just leaving the monomer in its unpolymerized, liquid state 143.

Figure 12A depicts a similar process except the contact lens is constructed vertically from the bottom to the top instead of horizontally from the front convex surface to the back concave surface.

Multifocal Contact Lens Hydrodynamic Reservoir by Laser Etching Technique

The embodiment of this technique described a method to produce a reservoir within a contact lens after it has been partially or even fully polymerized. As described above this reservoir is for the purposes of redistribution of fluid or fluid pressure from a peripheral storage zone to a central optic zone for the purposes of mechanical, physical and optical alteration of the refractive nature of the contact lens.

Similar to the process explored for the use in corneal refractive surgery this process uses for example an eximer laser focused on the internal structure of an already polymerized contact lens. As seen in Figure 13 the energy in beam 155 of laser 153 is focused inside a fully formed contact lens 150 to disrupt the molecular bonds of the polymer. As the beam in swept back and forth the contours of the intended internal fluid reservoir are created 154. This etching process could be used to hollow out a complete reservoir inside a contact 158, or just portions like micro-channels or could be used to create the intended contours of the reservoir on the surface of two half, which would then be laminated together to create a finished reservoir. Once the reservoir has been created, fluid can be introduced through a surface port created by the laser similar to Figures 7B&C or through injection 7D. The filling port can then be sealed with polymerizing a drop of raw contact lens monomer.

The preceding sections are a general description of how to create a hydrophilic contact lens which contains a fluid filled reservoir capable of redistribution of fluid or fluid pressure from a peripheral reservoir to a central optic zone for the purposes of mechanical, physical and optical alteration of the refractive nature of the contact lens. It is not meant to be an exhaustive or limiting only instructive on the general designs and construction techniques to create a contact lens capable of undergoing refractive changes induced by hydrodynamic forces. Obviously, to anyone skilled in the art, numerous variations, combinations or other modifications can easily be envisioned or implemented to the invention without departing from its scope as defined in the appended claims.

I claim:

1. A contact lens with variable focus comprising:

a lens body sized and shaped to fit over a portion of the eye of a person to improve the person's eye sight, said body being made of a soft material and having a first shape with a first optical characteristic and a second shape with a second optical characteristic, said lens body being responsive to pressure to selectively change between said first and second shapes.

2. The lens of claim 1 wherein said lens body is changed between said first and second shape by selectively steepening said shape.

3. The lens of claim 1 wherein said lens body defines a center axis and includes a reservoir disposed within the lens and being filled with a fluid, said reservoir including one section that is disposed away from the center axis of the lens, a second reservoir section extending over center axis of the eye, wherein the first shape is define with the second section being empty and the second shape being defined with the reservoir section being filled with said fluid.

4. The lens of claim 3 wherein said reservoir is filled with a liquid having the same index of refraction as the lens body.

5. The lens of claim 3 wherein said reservoir is filled with a liquid having an index of refraction different from that of the lens body.

6. The lens of claim 1 wherein said lens body is formed with a reservoir filled with a liquid, said reservoir being shaped and positioned to change the optical characteristic of the lens along a visual axis when a pressure is applied to the lens.

7. The lens of claim 6 wherein said lens body is adapted to change shape in response to a squeezing action from the eyelids of a wearer.

8. A soft contact lens comprising:

a round lens body having an upper portion including a visual axis through which a wearer is gazing and a lower portion when the lens body is disposed in an eye;

a reservoir formed within the lens body, said reservoir including a first section and a second section and being filled with a liquid, said reservoir cooperating with said lens body to provide the lens with one of a first optical characteristic and a second characteristic along said visual axis, based on the amount of fluid in said sections.

9. The soft contact lens of claim 8 wherein said reservoir is adapted to selectively steepen the curvature of the lens as said fluid is transferred from one section to another.

10. The soft contact lens of claim 9 wherein said fluid has the same index of refraction as said lens body.

11. The soft contact lens of claim 8 wherein said fluid has a different index of refraction then said lens body.

12 A soft contact lens comprising:

a disc-shaped body having a central portion selectively providing visual correction when worn by a person;

a fluid reservoir formed in said body away from said central portion and positioned to be selectively pressurized and depressurized by the person's eye lid as the person gazes downward and forward; and

a chamber with a micro-channel disposed in said central region and being filled with fluid having a pressure dependent on the pressure within said fluid reservoir, said micro-channel being arranged and constructed to change the optical characteristics of the lens by changing the curvature of said central region in response to changes in pressure of said reservoir,

13. The lens of claim 12 wherein said lens body is changed by said micro-channel between said first and second shape by selectively steepening or unsteepening said shape.

14. The lens of claim 12 wherein said reservoir is filled with a liquid having an index of refraction different from that of the lens body.

15. The lens of claim 12 wherein said lens body is adapted to change shape in response to a squeezing action from the eyelids of a wearer.

16. The lens of claim 12 further comprising a diaphragm positioned to transmit pressure between said reservoir and said chamber.

17. A soft contact lens comprising:

a round lens body having a central zone defining a visual axis through which a wearer is gazing when the lens body is disposed in an eye, and a lower portion;

a reservoir formed within the lower portion; and

a chamber disposed in said central zone and including at least one microchannel in fluid communication with said reservoir, said reservoir and said chamber cooperating with said lens body to provide the lens with one of a first optical characteristic and a second characteristic along said visual axis, based on the relative amount of fluid in said reservoir and said chamber.

18. The soft contact lens of claim 17 wherein said chamber is adapted to selectively steepen or unsteepen the curvature of the lens as said fluid is transferred between said chamber and said reservoir.

19. The soft contact lens of claim 17 wherein said visual axis passes through said first section and wherein when said first section is filled with liquid, said lens body and said reservoir cooperate to form a multi-lens path along said visual axis including a back portion of said lens body, said first section and a front portion of said lens body.

20. The soft contact lens of claim 17 wherein said visual axis passes through said first section and wherein when said first section is filled with liquid, said lens has an optical power that is primarily dependent on the optical characteristics of said fluid.

21. The soft contact lens of claim 17 wherein said lens body is shaped and constructed to shift said liquid between said reservoir and said central zone in response to a wearer looking straight or downward.

22. The lens of claim 17 wherein said lens body is adapted to respond to a wiping action of the wearer eyelids, said wiping action providing pressure on said lens body to cause liquid to shift between said reservoir and said central zone.

23. A method of making a contact lens comprising:

providing a first and a second shell, each shell having an inner and an outer surface, with at least one of said shells having an indentation on the inner surface;

laminating the shells together with the two inner surfaces facing each other to form a reservoir with said indentation; and

filling said reservoir with a fluid.

24. The method of claim 23 wherein said shells and said fluid have similar optical characteristics.

25. The method of claim 23 further comprising making an opening in said reservoir and filling said reservoir through said opening.

26. The method of claim 23 further comprising providing a balloon with said fluid and inserting said balloon between said shells prior to the lamination step.

27. The method of claim 23 wherein said shells are laminated using a polymer.

28. The method of claim 23 wherein first shell is constructed with its outer surface configured to rest on the eye of a person.

29. The method of claim 23 wherein said indentation is made in said first shell.

30. The method of claim 23 wherein each shell is made with a respective indentation.

Figure 1A

Primary
Gaze

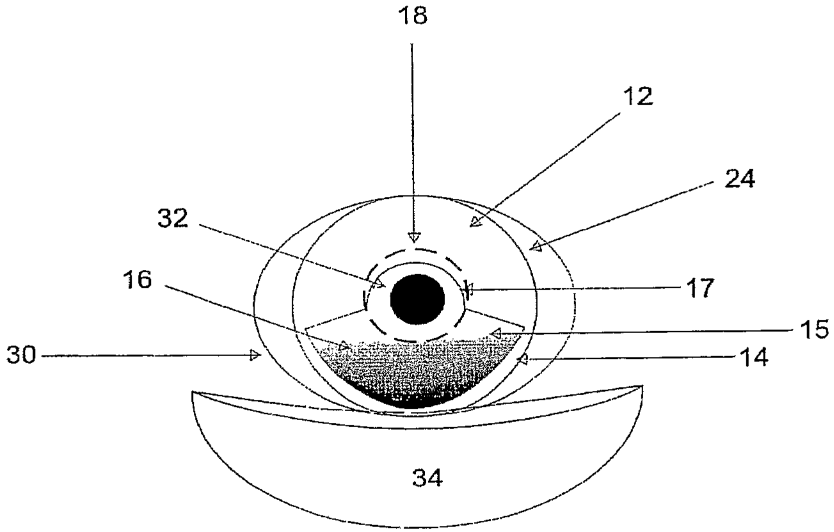


Figure 1B

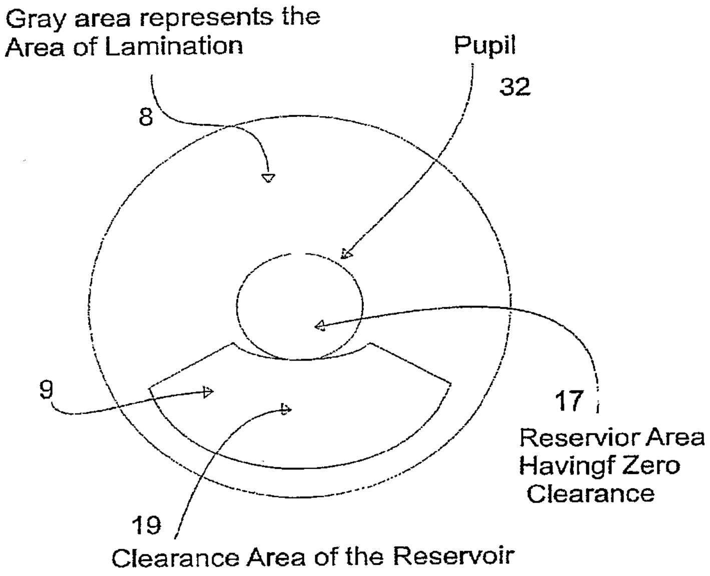


Figure 2A

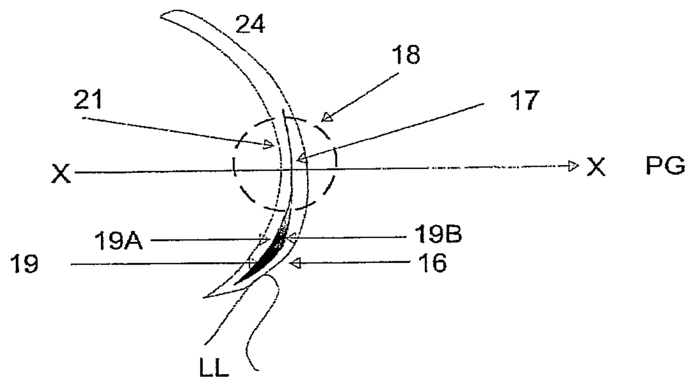


Figure 2B

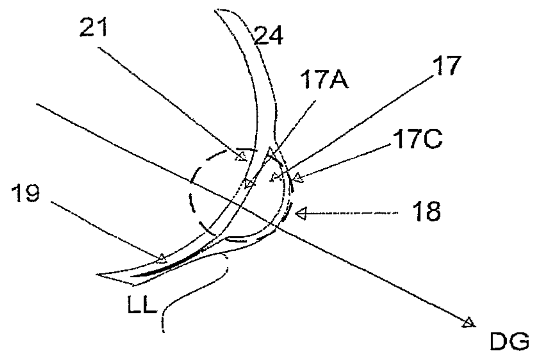


Figure 2C

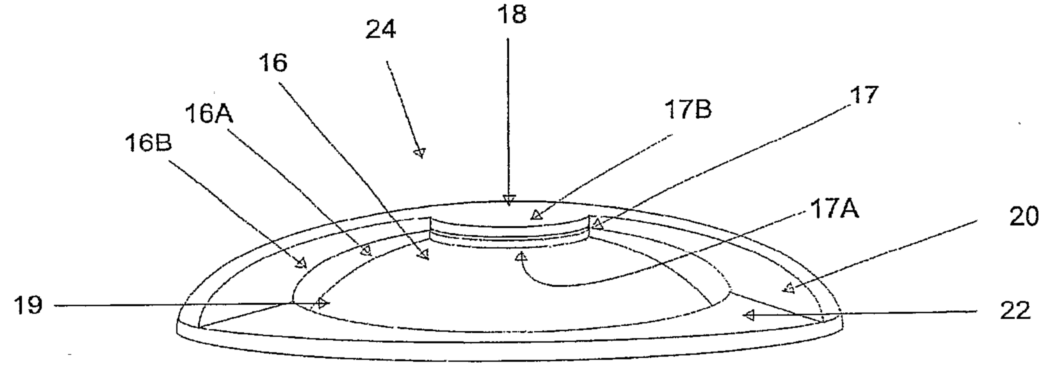


Figure 3

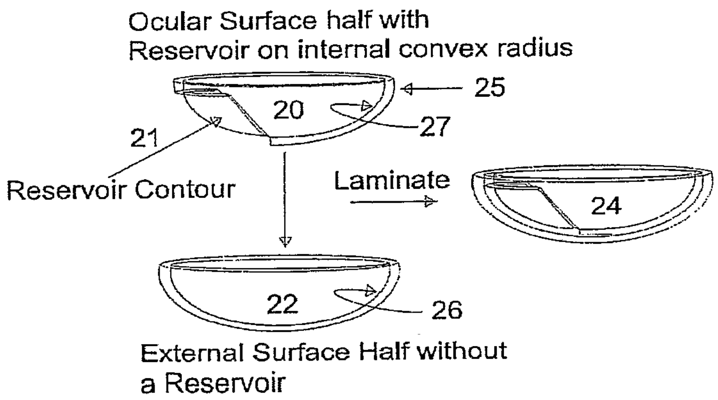
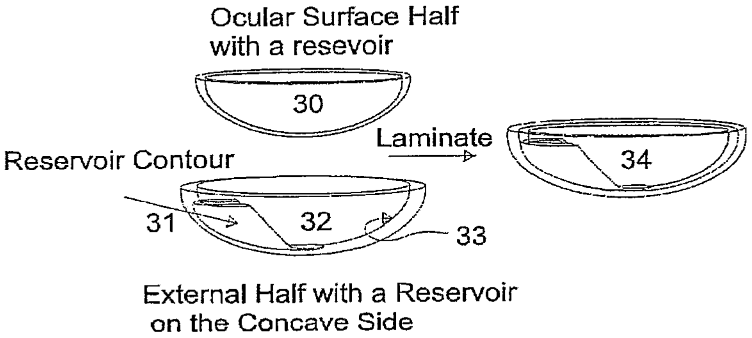


Figure 4



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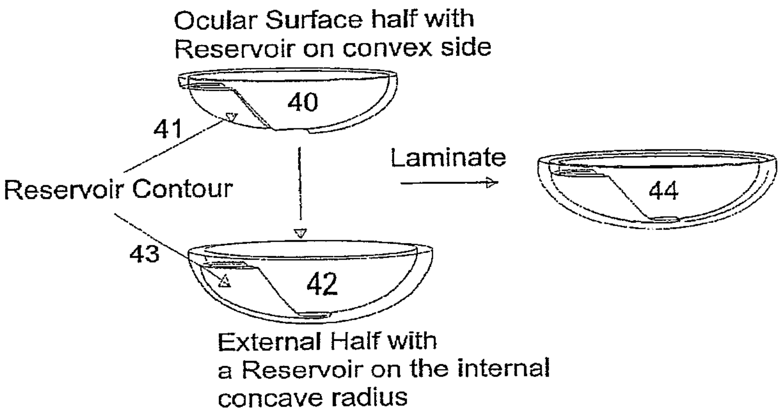
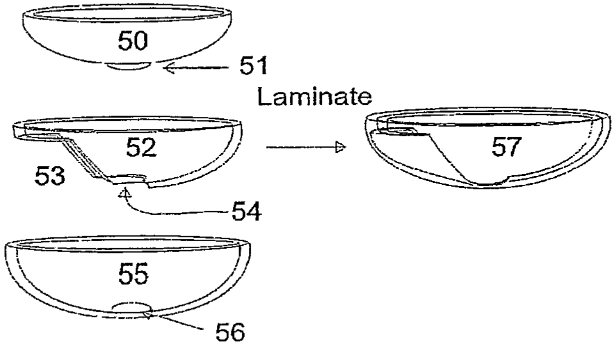


Figure 6



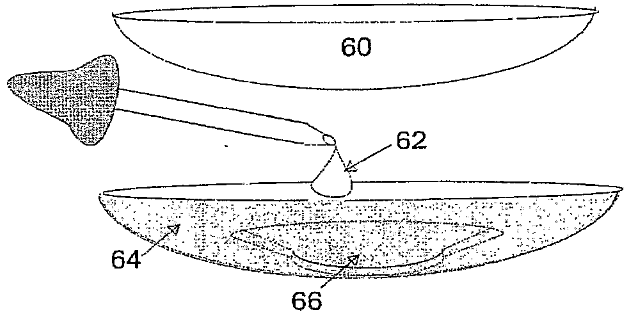


Figure 7A

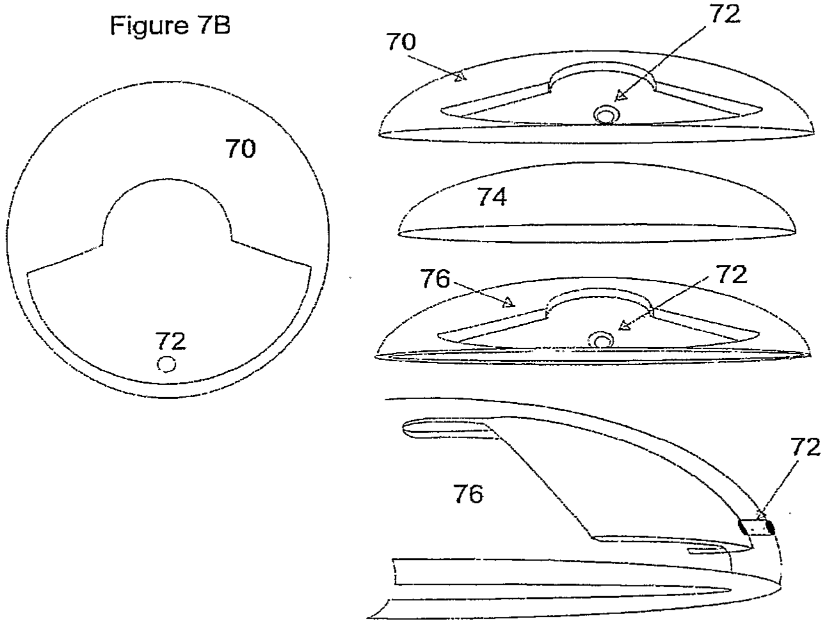


Figure 7B

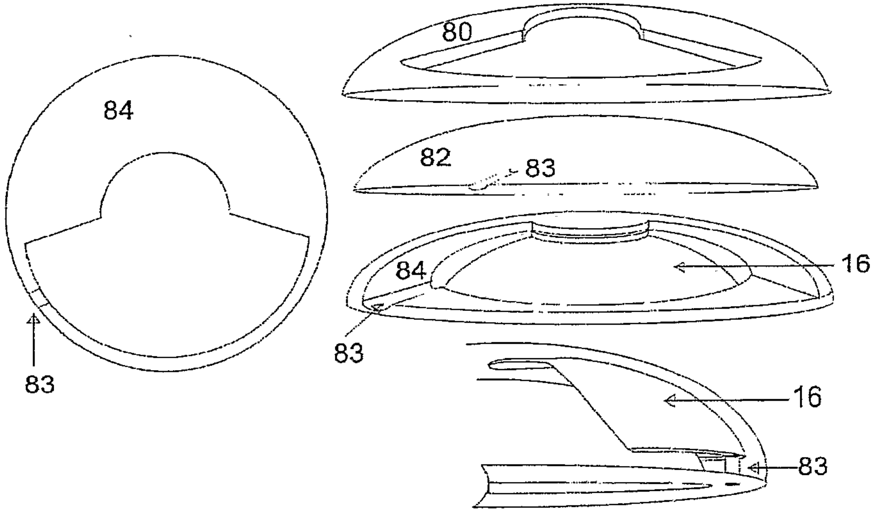


Figure 7C

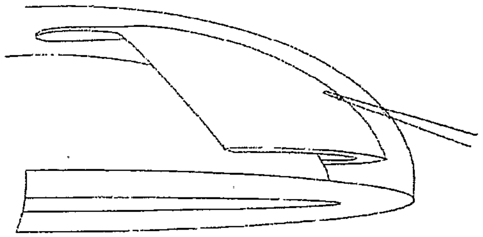
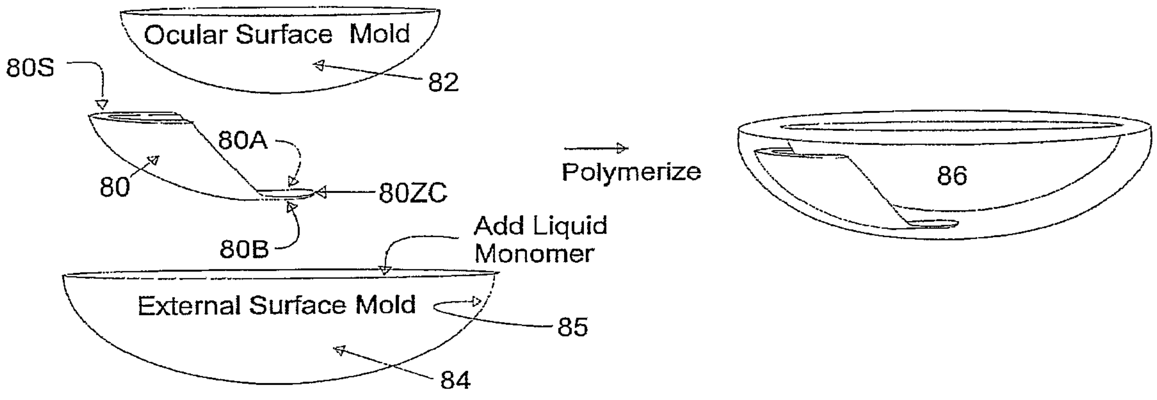


Figure 7D

Figure 8



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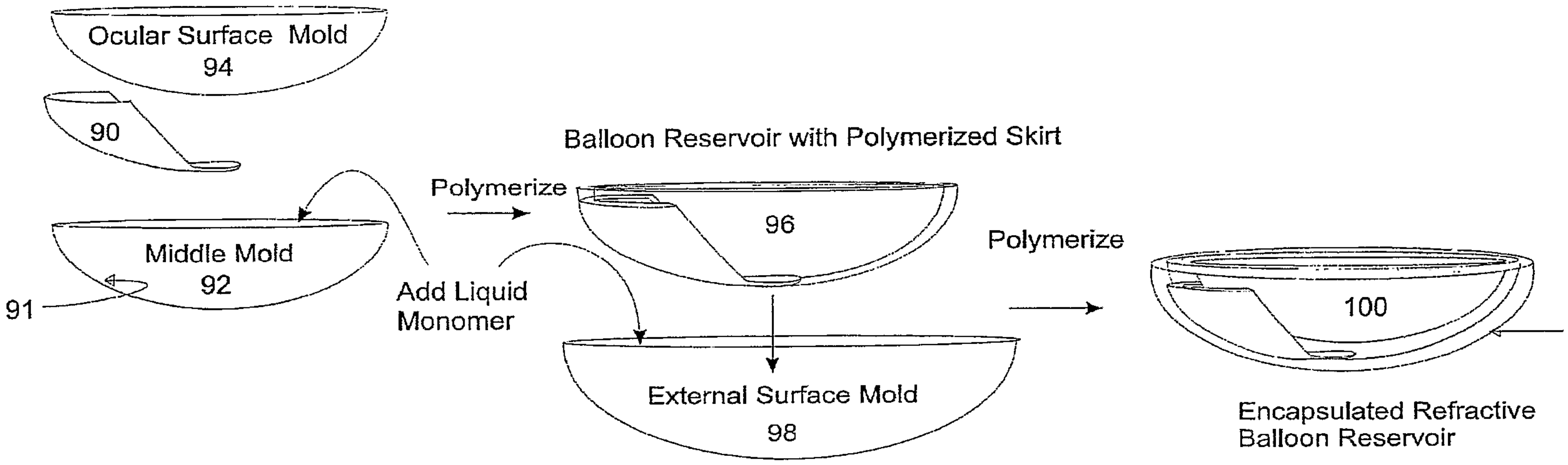

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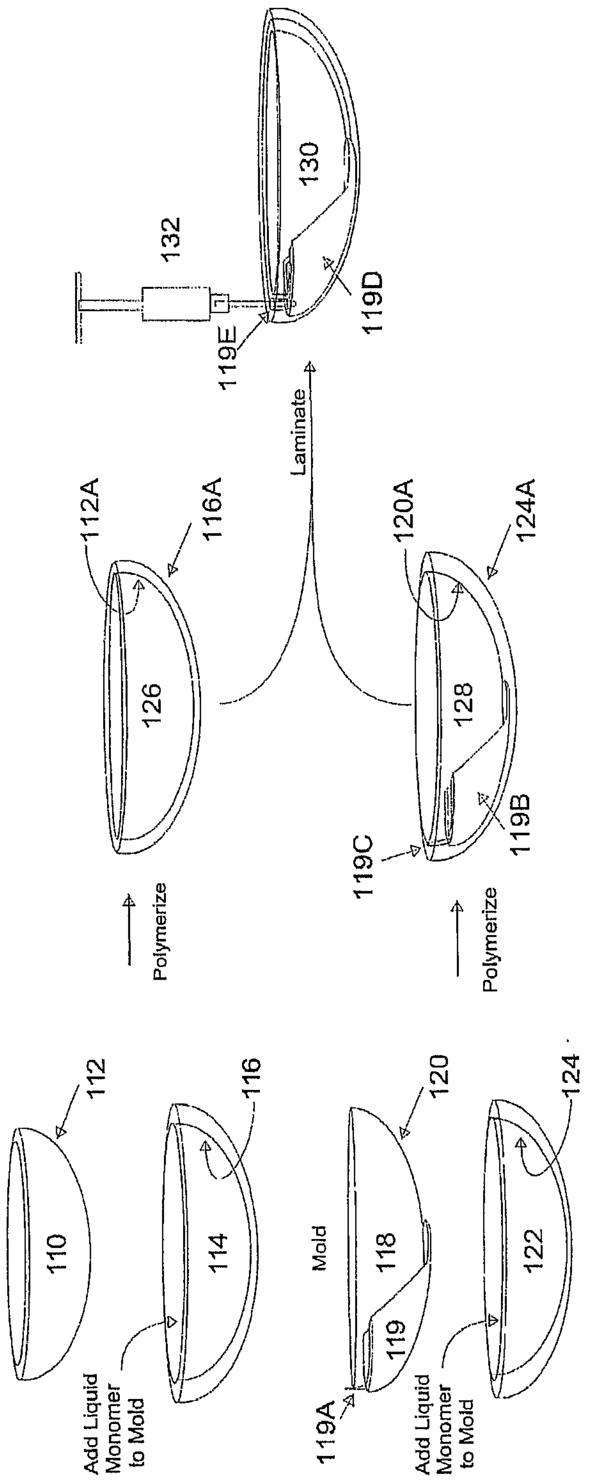
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112
Add Liquid Monomer to Mold
114
116
Mold
118
119
119A
120
Add Liquid Monomer to Mold
122
124
Polymerize
Polymerize
126
112A
116A
128
119B
119C
120A
124A
Laminate
130
132
119D
119E

Figure 11

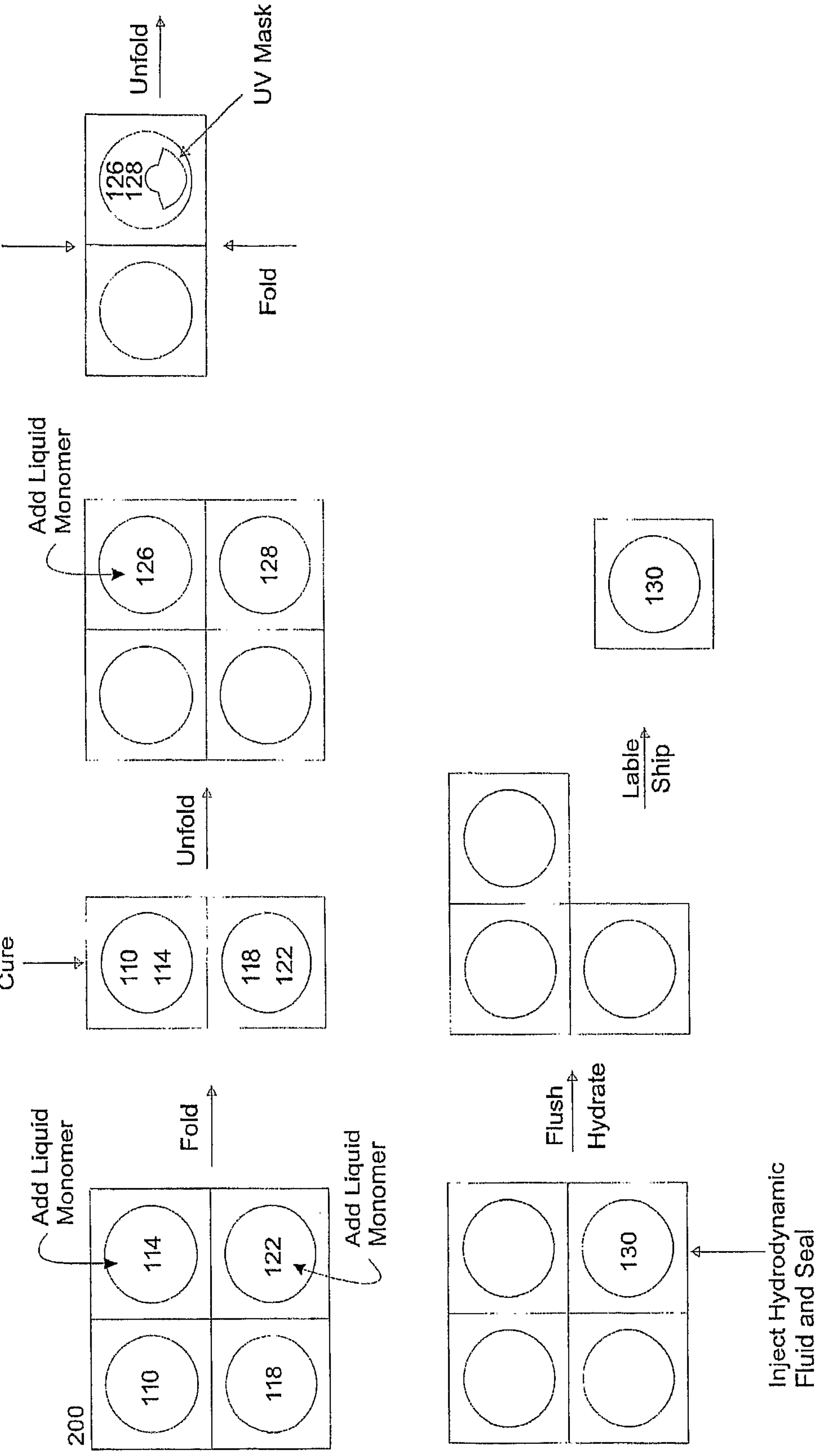
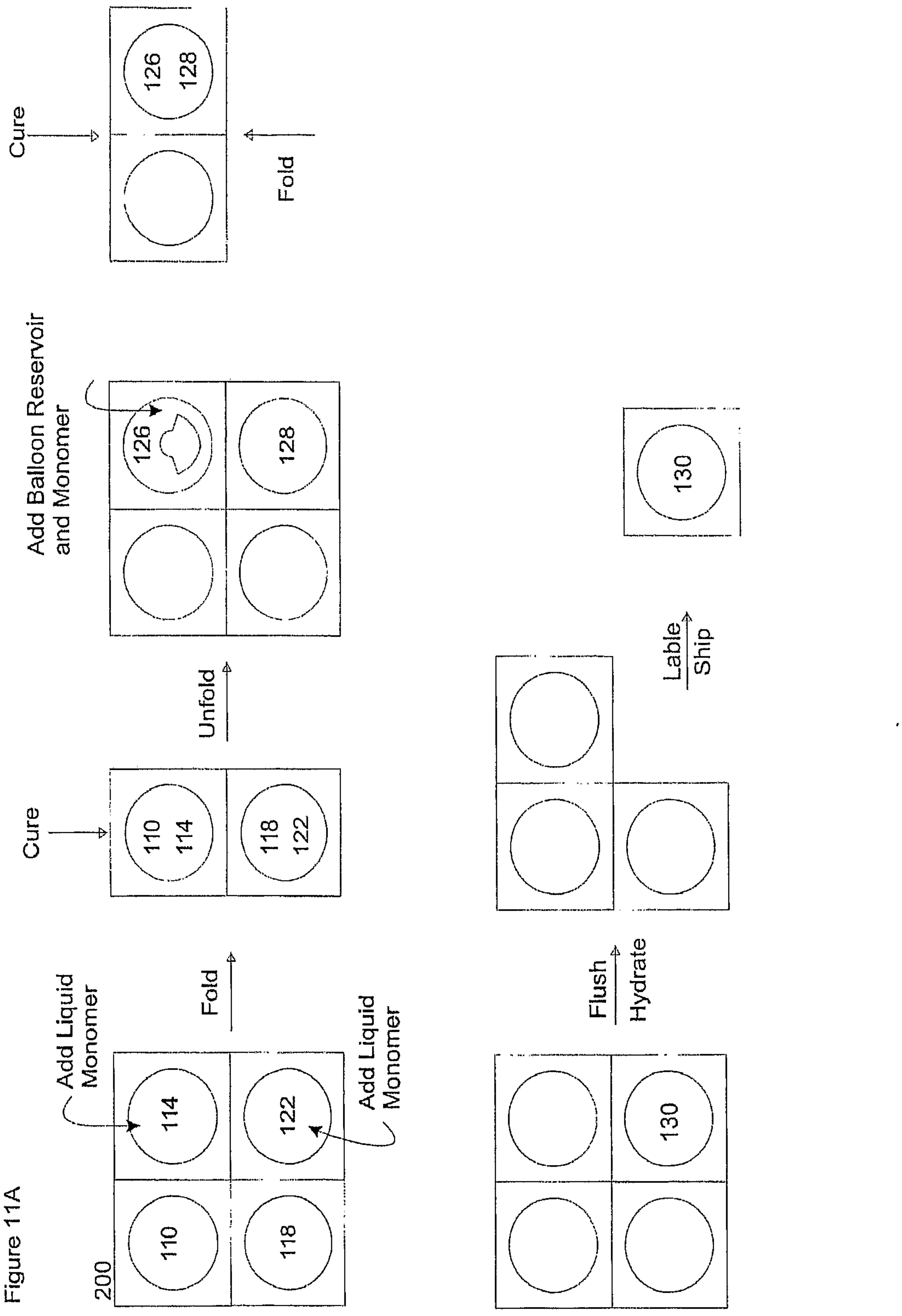

200
110
114
118
122
Add Liquid Monomer
Add Liquid Monomer
Fold
Cure
110
114
118
122
Unfold
Add Liquid Monomer
126
128
Cure
126
128
UV Mask
Fold
Unfold
Inject Hydrodynamic Fluid and Seal
130
Flush
Hydrate
Lable
Ship
130

Figure 11A


200
110
114
118
122
Add Liquid Monomer
Add Liquid Monomer
Fold
Cure
110
114
118
122
Unfold
Add Balloon Reservoir and Monomer
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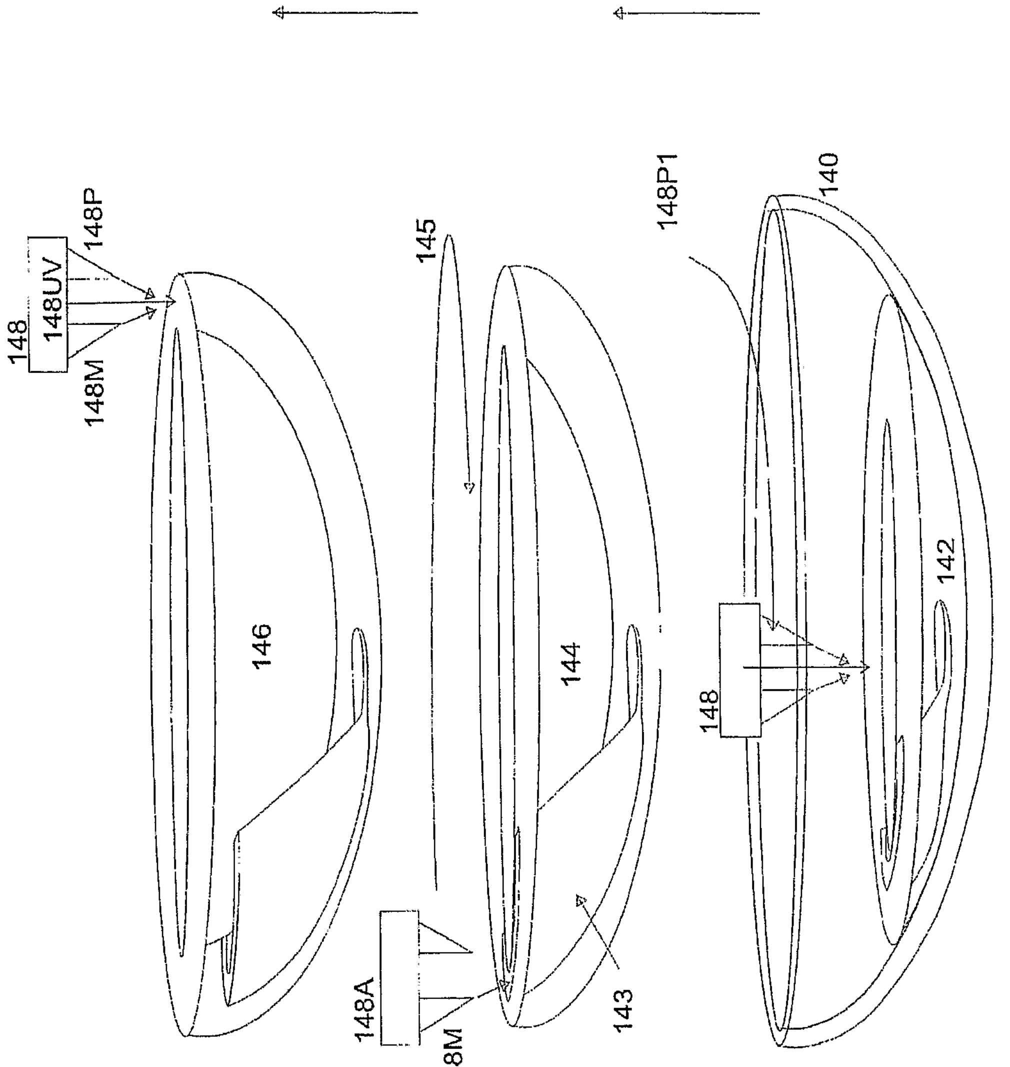
128
Cure
126
128
Fold
Flush
Hydrate
130
Lable
Ship
130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148A
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148P1
140
142
148

Figure 12

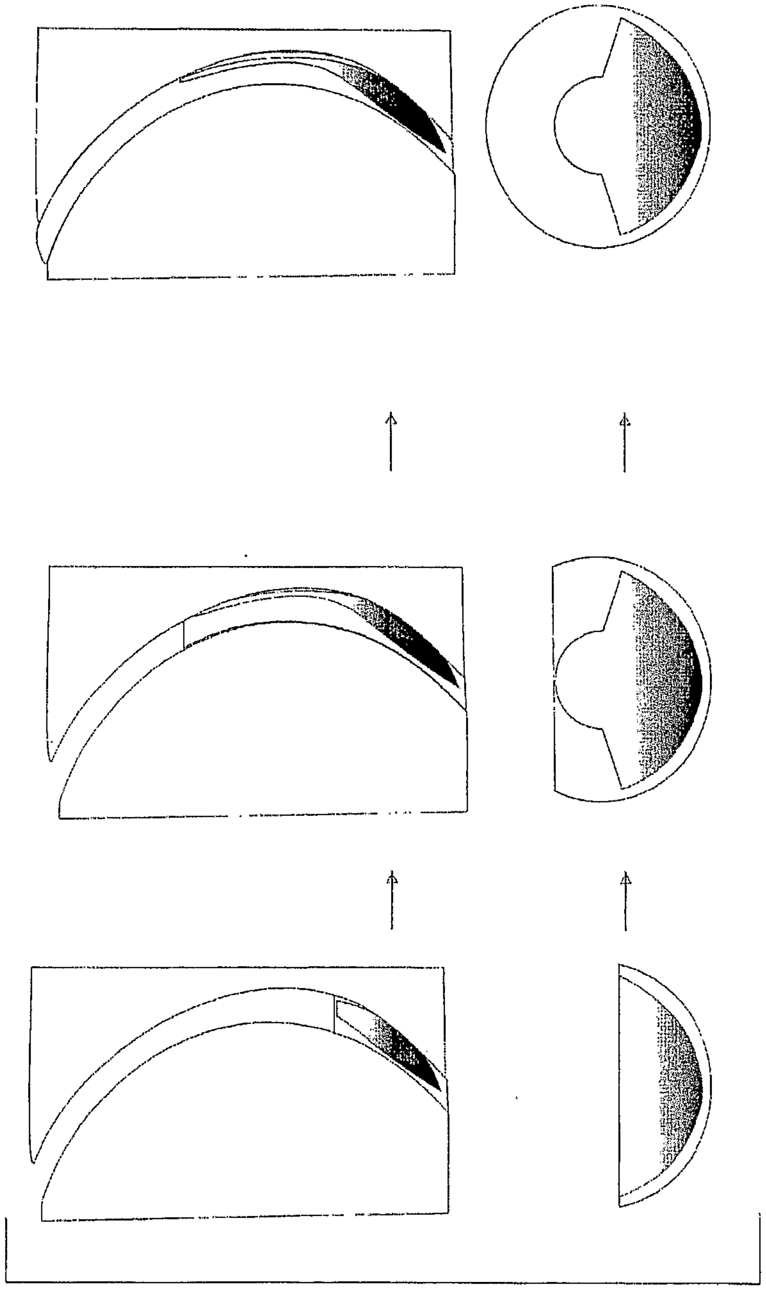

Figure 12A

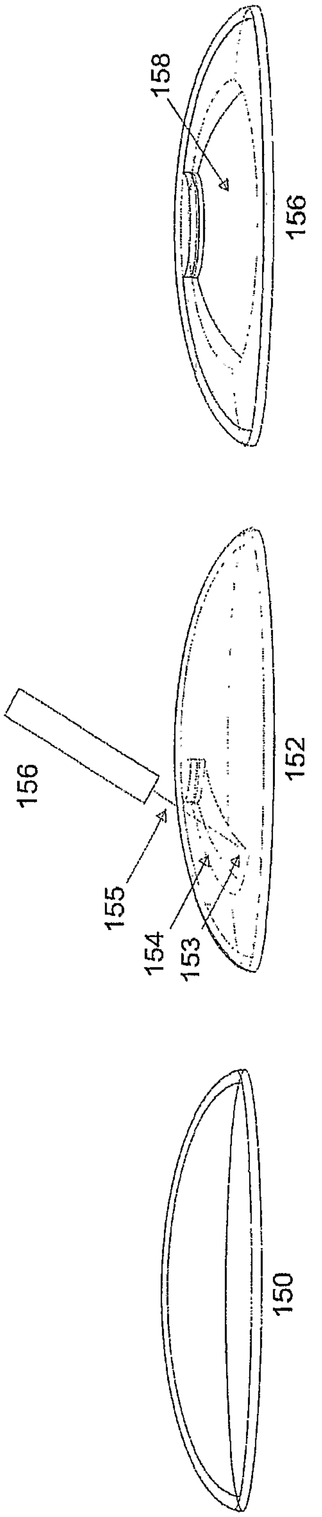

Figure 13

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US07/72640

A. CLASSIFICATION OF SUBJECT MATTER

IPC: **G02C 7/04**(2006.01)

USPC: 351/160R,160H,161

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 351/160R,160H,161

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO, JPO, Derwent, IBM Technical Database

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,702573 A (Morstadt) 27 October 1987 (27.10.1987) Abstract, Figures 1-4, col. 1, lines 30-60	1-2 ----------- 6-7
X --- Y	US 4,477,158 (Pollock et al) 16 October 1984 (16.10.1984) Figures 16-19, Col. 17, lines 3-22; Numerals 34, 36, 72	8-11,17-22,23-25,27-30 ----------- 6-7
A	US 4,174,156 A 13 November 1979 (13.11.1979) Whole Document	1-30
A	US 3,973,838 A 10 August 1976 (10.8.1976) Whole Document	1-30

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

29 May 2008 (29.05.2008)

Date of mailing of the international search report

25 JUN 2008

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Authorized officer

Ricky Mack

Telephone No. 571-272-2000

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US07/72640

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

Group I, claim(s) 1-7, drawn to a contact lens including the details of the whole lens's body being flexible such that it provides two optically different shapes when pressure is applied classified in US class/subclass 351/160R.

Group II, claim(s) 8-11, drawn to a soft contact lens including the details of a reservoir formed within the lens body including two distinct sections classified in US class/subclass 351/160R.

Group III, claim(s) 12-22, drawn to a soft contact lens including the details of a microchannel within the lens body classified in US class/subclass 351/160R.

Group IV, claim(s) 23-30, drawn to a method of making a contact lens classified in US class/subclass 351/177.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I cites the technical feature of a whole lens body which changes shape between two specific shapes with two separate sets of optical characteristics. Group II cites the technical feature of a reservoir with two separate sections included within the body of the soft contact lens. Group III cites the technical feature of a micro-channel within the body of the soft contact lens. Group IV cites the technical feature of laminating two shells together in order to form a contact lens. Given the above cited technical features it is clear that the groups I-IV have mutually exclusive subject matter, and therefore, lack unity of invention.