Title: HYDROGEL CONTACT LENS AND METHOD OF PRODUCING FOR CORRECTION OF HIGHER ORDER OPTICAL ABERRATIONS OF THE EYE

A method is described for correcting total optical aberration including higher order optical aberration in an eye of a subject. Data indicative of the wavefront error of the eye of the subject is measured. A trial contact lens is provided having a front surface, a back surface and a center, at least one of the front or back surface bearing indicia for determining the precise location and orientation of the trial contact lens when positioned on a cornea of a subject. The indicia include a first marking indicative of the center of the trial contact lens and a second marking identifying a predetermined bottom of the trial contact lens and an angular orientation of the contact lens from a vertical axis through the center of the cornea when the trial contact lens is positioned on the cornea of the subject. The precise location of the trial contact lens relative to the pupil visual axis of the subject is determined, including the offset distance between the center of the trial contact lens and the center of the pupil and the angular displacement of the trial contact lens with a vertical axis through the pupil of the subject with head positioned normally. A contact lens blank is manufactured to locate on the eye of the subject in the same position and orientation as the trial contact lens. The contact lens blank is provided with optical aberration correction for the subject by using the measured, data, the offset distance between the center of the trial contact lens and the center of the pupil and the relationship of the predetermined bottom of the trial contact lens and the bottom of the pupil of the subject relative to a horizontal ground so that the optical aberration correction is applied precisely on the contact lens blank for the optical aberration correction to be positioned correctly on the subject's pupil, thereby producing a vision-corrected contact lens.
HYDROGEL CONTACT LENS AND METHOD OF PRODUCING FOR CORRECTION OF HIGHER ORDER OPTICAL ABERRATIONS OF THE EYE

Field of the Invention

The present invention relates to contact lenses, particularly hydrogel contact lenses, and to correction of higher order optical aberrations of the eye.

Background of the Invention

Beginning with use of polished crystal magnifying lenses to assist vision in classical times, the science and practice of vision correction has improved and become more complex over the years. In the early renaissance, spectacles were invented in Venice by placing a pair of magnifying lenses in a frame that could be worn. At first, only aid for presbyopia, correction for the loss of accommodation by the eye's own lens, was available because only convex lenses were used. Then, with the introduction of concave lenses to the basic spectacle invention in the late renaissance, aid was offered to near sighted persons. However, until the middle of the 1800's, no correction was possible for astigmatism, another very common ocular error.

By the beginning of the twentieth century it was fully realized that the eye had aberrations above and beyond simple defocus and astigmatism, yet, there was no way to correct these errors with spectacle lenses. In the 1950's, rigid corneal contact lenses were introduced as practical eye correction devices and they corrected effects beyond those of defocus and astigmatism because the contact lenses had essentially replaced the natural corneal surface as the first
optical surface of the eye and, thus, could remove errors induced by that surface. However, such correction of higher order aberrations by rigid corneal contact lenses was always a serendipitous benefit and not a well-controlled correction.

In the 1990's, developments in the eye care field provided practical instruments to measure the higher order aberrations of the eye. Also, refractive surgical techniques involving ablation of the cornea with excimer laser systems were introduced that could create complex changes to the corneal shape. This, for the first time, offered the possibility of measuring and then correcting not only defocus and astigmatism in the eye but also higher order aberrations in a controlled way. Nevertheless, not all wish to undergo a surgical procedure to correct their vision.

Thus, it is desirable to be able to provide superior correction of the optical errors of the eye, including the higher order aberrations, using hydrogel contact lenses. Then, this correction of the higher order aberrations could be obtained without surgery.

U.S. Patent No. 5,114,628 describes a method for manufacturing contact lenses, especially individually fitted contact lenses. The topography of the eye is measured three-dimensionally, the geometry of the rear face of the lens is determined so as to fit the topography measured, the optical effect of a lachrymal lens which is formed between the rear face of the lens and the surface of the eye is determined, the geometry of the front face of the lens is
determined taking into account the optical effect of the lachrymal lens and the sight correction to be achieved, and the data so obtained for the lens geometry of the front and rear faces of the lens are stored and transferred to a control arrangement for the manufacture of the lens in a machine tool.

U.S. Patent No. 6,086,204 describes methods and devices that are needed to design and fabricate modified surfaces on contact lenses or on corneal tissue that correct the eye's optical aberrations beyond defocus and astigmatism. The patent discusses means for: 1) measuring the eye's optical aberrations either with or without a contact lens in place on the cornea, 2) performing a mathematical analysis on the eye's optical aberrations in order to design a modified surface shape for the original contact lens or cornea that will correct the optical aberrations, 3) fabricating the aberration-correcting surface on a contact lens by diamond point turning, three dimensional contour cutting, laser ablation, thermal molding, photolithography, thin film deposition, or surface chemistry alteration, and 4) fabricating the aberration-correcting surface on a cornea by laser ablation.

The objectives of U.S. Patent 6,086,204 are accomplished by mathematical methods which analyze the wavefront slope data as well as the shape of the subject's original contact lens or corneal surface in order to design a modified surface shape for the original contact lens or cornea that corrects the aberrations. By the term "original optical surface" in U.S. Patent 6,086,204 is meant the anterior surface of either a contact lens placed on the cornea or, in the absence of a contact lens, the cornea itself. The steps in that mathematical
method are: 1) determining the normal vectors to the original contact lens or corneal surface, 2) from these normal vectors and the wavefront slope data, determine the partial derivatives of the surface for the modified contact lens or corneal surface that corrects the aberrations, and 3) fitting these partial derivatives of the aberration-correcting surface with the corresponding partial derivatives of a polynomial expression that best represents the aberration-correcting surface. From those methods, a mathematical expression for the aberration-correcting is obtained.

Finally, devices and methods are provided to fabricate the modified aberration-correcting surfaces designed by the mathematical methods described. For contact lenses, fabrication devices and methods mentioned include those of diamond point micro-machining, laser ablation, thermal molding, photolithography and etching, thin film deposition, and surface chemistry alteration. For corneal tissue resurfacing, fabrication devices and methods mentioned are those associated with laser ablation as used with photorefractive keratectomy (PRK) and laser in-situ keratomileusis (LASIK).

In U.S. 6,086,204, the subject is examined and data gathered for correcting optical aberration as follows. The examiner accurately positions the subject's eye so that the entering beam is accurately centered with respect to the subject's pupil. The positioning of the subject's eye with respect to the instrument beam is controlled by a mechanism consisting of an x-y-z translation stage that moves a chin and head rest used by the subject.
The subject is asked to look through an eyepiece at the point of light formed within the field stop, while the examiner adjusts the location of subject's eye so that the beam passes through the center of the pupil. Prior to taking a measurement, the examiner focuses the eyepiece trying to achieve the brightest and best-focused image of the array of focal spots seen on the computer monitor. When the instrument is aligned with respect to the patient's eye and a best-focus image is obtained, the operator presses a key which commands the computer to acquire an image of the array of spots. During a measurement session, as many as ten successive images may be acquired for subsequent averaging to improve the signal/noise ratio of the data. The image analysis program carries out the following steps: 1) subtracts "background" light from the image, 2) determines the x & y coordinates (in pixels) of the centroid for each of the focal spots, 3) subtracts the x & y pixel coordinate values from a corresponding set of reference values (obtained from a calibration with a diffraction-limited reference lens), 4) multiplies the difference values (in pixel units) by a calibration factor which gives for each location in the pupil the components in the x and y directions of the wavefront slope error measured in radians. The components of the wavefront slope error, labeled Bx and By, are the essential measurement data of the wavefront sensor.

As stated in U.S. Patent 6,086,204, the purpose of that invention is to design modifications to an initially known lens surface, described by z(x,y), which will correct the eye's optical aberrations measured with wavefront sensors through that surface. The mathematical equations needed for that task, which leads to a new lens surface described by z'(x,y), are described in
U.S. Patent 6,086,204, the entire disclosure of which is hereby incorporated by reference.

U.S. Patent 6,305,802 B1 describes a system and method for correcting optical aberration that integrates corneal topographic data and ocular wavefront data with primary ametropia measurements to create a soft contact lens design. Corneal topographic data is used to design a better fitting soft contact lens by achieving a contact lens back surface which is uniquely matched to a particular corneal topography, or which is an averaged shape based on the particular corneal topography. In the case of a uniquely matched contact lens back surface, the unique back surface design also corrects for the primary and higher order optical aberrations of the cornea. Additionally, ocular wavefront analysis is used to determine the total optical aberration present in the eye. The total optical aberration, less any corneal optical aberration corrected utilizing the contact lens back surface, is corrected via the contact lens front surface design. The contact lens front surface is further designed to take into account the conventional refractive prescription elements required for a particular eye.

Suitable wavefront correction of vision can enhance acuity and also can enhance vision under low-light conditions such as nighttime driving. Candidates for wavefront correction include those seeking “super vision” or enhanced nighttime vision, as well as people with keratoconus, irregular astigmatism, corneal scarring, or surgically induced irregularity, who are difficult or impossible to have their vision fully corrected by conventional
means. People with such difficult vision correction problems can be as much as 38% of the population. These people would experience limited improvements to their vision with today's spherocylindrical correction, whether contact lens or refractive surgery, that only addresses the lower three of the more than 18 orders of Zernike terms that express various orders of optical aberrations.

One cause irregular astigmatism is surgically induced corneal irregularity. The failure rate in this popular form of refractive surgery is reported to be 5%. With over a million people undergoing the procedures in the year 2001 alone, the number becomes significant: it has been estimated that up to 50,000 people would have unsatisfactory outcomes with LASIK in 2001. These people typically report glare, halo, ghosting, especially at night, and loss of contrast sensitivity. Such visual discomfort is generally caused by the induced higher order aberrations from the surgery, and is very difficult to be corrected with enhancement surgeries or conventional correction methods, leaving tens of thousands of people with subnormal vision.

This problem also seems to apply to other refractive surgeries such as RK (Radial Keratotomy) and PRK (Photorefractive Keratectomy). It has been reported that RK and PRK alike shifts the distribution of aberrations from third order dominance to fourth order dominance, and induces an increase in the total optical aberrations of the eye.
Thus, it continues to be desirable to provide efficient and economical methods and contact lenses for treating higher order aberrations to optical vision in people.

Summary of the Invention

The present invention recognizes that, with each step of improvement in the correction of vision, there has come the need to better control placement of the correction with respect to the eye. With the first spectacles, the vision correction was essentially the same even though the lenses were decentered with respect to the pupil of the eye or if the lenses were rotated. Only the distance the lenses were held from the eye was really important. This is because lenses to correct simple defocus are rotationally symmetric. When correction for astigmatism was added to that for defocus, freedom to rotate the lenses to an arbitrary orientation was lost although the correction was still quite insensitive to decentering. This is because lenses to correct astigmatism, although not rotationally symmetric, still retain a translational symmetry. However, when higher order corrections are added, all symmetry is lost and the correction must be well aligned with the pupil of the eye both with respect to centering, rotation and eye movement, thus, eliminating spectacles as an option.

The present invention provides this alignment with a trial contact lens and provides a process to find the correct orientation of the correction with respect to the eye for the contact lens as it naturally orients on the eye. In
accord with the present invention, a trial contact lens has a front surface, a back surface and a center. The front or back surface (or both) bears indicia for determining the precise location and orientation of the trial contact lens when positioned on a cornea of a subject. The indicia comprise (i) a first marking indicative of the center of the trial contact lens and (ii) a second marking identifying a predetermined bottom of the trial contact lens and an angular orientation (i.e., displacement) of the contact lens from a vertical axis through the center of the cornea when the trial contact lens is positioned on the cornea of the subject.

In certain preferred embodiments, the front surface of the trial contact lens has further comprises a slaboff surface positioned at the predetermined bottom of the lens. Preferably, the first marking comprises a ring having a diameter at least as large as the pupil of the subject, the ring being centered on the center of the contact lens. Also, preferably, the second marking comprises (i) an arrow shaped line located on a center axis of the lens and pointing in a direction of the predetermined bottom of the lens and (ii) two line markings located on a line through the center of the lens and perpendicular to said centerline, the two line markings being located on opposite sides of the center of the lens, thereby indicating a horizontal line when the center axis is vertical.

In certain embodiments, the first marking comprises a ring having a diameter at least as large as the pupil of the subject, the ring being centered on the center of the contact lens, and the second marking comprises (i) an arrow shaped line located on a center axis of the lens and pointing in a direction of
the predetermined bottom of the lens and (ii) two line markings located on a line through the center of the lens and perpendicular to said centerline, the markings being located on opposite sides of the center of the lens, thereby indicating a horizontal line when the center axis is vertical. Preferably, the set of markings extend outward from a perimeter of the ring.

The present invention also provides a method for correcting total optical aberration including higher order optical aberration in an eye of a subject, the method comprising: measuring data indicative of the wavefront error of the eye of the subject; providing a trial contact lens as described above; determining the precise location of the trial contact lens relative to the pupil of the subject, including the offset distance between the center of the trial contact lens and the center of the pupil and/or the angular displacement of the trial contact lens with a vertical axis through the pupil of the subject with head positioned normally when the trial contact lens is worn by the subject; manufacturing a contact lens that is structured and arranged to locate on the eye of the subject in the same position and orientation as the trial contact lens; and providing the contact lens with optical aberration correction for the subject by using the measured data, the offset distance between the center of the trial contact lens and the center of the pupil and/or the angular displacement of the trial contact lens with a vertical axis through the pupil of the subject with head positioned normally when the trial contact lens is worn by the subject so that the optical aberration correction is applied precisely on the corrected contact lens for the optical aberration correction to be positioned correctly on the subject's pupil.
In accord with the present invention, the process of creating a hydrogel contact lens that will correct the optical errors of the eye beyond the common sphero cylindrical errors (defocus and astigmatism) begins with the measurement of the errors of the eye using advanced refraction systems, often referred to "wavefront refractors". One example of such a refracting system is sold by Topcon Medical Systems, Inc., Paramus, New Jersey. Such devices are advanced automatic refractors that measure with higher data density than the usual automatic refractors and so can measure more complex errors than can the simpler refractors. The refraction information is usually presented in the form of a set of numbers known as Zernike coefficients. Zernike coefficients are a set of weighting values used with standardized Zernike polynomial functions. The sum of the weighted Zernike polynomial functions represents the wavefront error, expressed as an optical thickness, that must be removed to fully correct the vision of the eye. It may be thought of as an "error lens" which, if removed, removes the aberrations of the eye.

This data for this correction or "error lens" is expressed with respect to the visual axis or the pupil center. Information also is needed to tell where the visual axis or the pupil center lies within the hydrogel contact lens so that the correction may be correctly placed on that contact lens. To accomplish this, a trial contact lens having the same shape as the final vision-corrected contact lens, but with orientation marks on it, is used for fitting the patient and taking measurements for manufacturing the vision-corrected contact lens. This trial contact lens is placed on the eye and allowed to stabilize with respect to the eye. Then a photograph is taken of the eye/lens combination allowing the pupil of
the eye and the alignment marks on the lens to be seen simultaneously. The
lens has taken its customary position so, by noting the angle between the
orientation marks and local horizontal (accomplished by insuring the camera is
held level and the person has taken a natural eye and head position), a
rotation correction angle is made available. Centering marks on the lens allow
the position of the pupil center with respect to the lens to be assessed.

The design of the contact lens should preferably be such that little if any
change in centering occurs during wear and that the lens does not rotate
during wear. If this is not the case, the correction will not be optimal. Thus, it
also is preferable that the trial contact lens and final vision-corrected contact
lens have the same centering and rotational stability characteristics.

When the refractive error information and the lens orientation have been
collected, the lens can be made. The lenses may be made in any conventional
way. For example, a single point diamond tool lathe with ability to turn
complex shapes can be used to create the front surface of the lens on a
dehydrated lens. One example of such a lathe is manufactured by DAC
International of Carpenteria, CA. The lens can be created by turning the front
surface using the special lathe on a standard dehydrated contact lens button
and then turning a conventional back surface to the lens to create a finished
lens. The lens also can be created by turning the front surface on a semi-
finished cast molded lens whose back surface is created in a finished geometry
in the molding process and remains attached to the back surface mold during
process of turning the front surface. The lens is subsequently hydrated to create a finished hydrogel lens.

In the another method, a hydrogel contact lens blank with the proper characteristics is affixed to a hold fixture and the front surface of the lens is shaped using an excimer laser system of the same type used to ablate the human cornea during a surgical refractive correction procedure. In yet another method, a semi-finished cast molded lens in the dehydrated state, attached to the back surface mold and with a finished front surface has its front surface shaped by an excimer laser system. The lens is then detached from the mold and hydrated.

In one preferred method, a master for the aberration corrected lens is made using, for example, a single point diamond tool lathe, or the like. The master is then used to make a mold for cast molding the hydrogel lens. This method permits the subject to use disposable contact lenses.

Brief Description of the Drawings

FIG. 1 is a cross-sectional view of a hydrogel contact lens.

FIG. 2 is a plan view of the hydrogel contact lens showing alignment markings in accord with the present invention.

Detailed Description Of The Invention Including Preferred Embodiments

Both the trial contact lens and the finished vision-corrected contact lens must be designed and made to provide the same orientation. Thus, in accord
with the present invention, the trial contact lens and the finished vision-corrected contact lens are provided with a like set of orientation markings. A preferred design to maintain orientation provides a lens wherein the optical center of the front surface in the optical zone is displaced about 0.15 mm along the vertical axis from the optical center of the back surface and, in addition, a "slaboff" region preferably is created on the inferior edge of the lens. However, it should be realized that other displacements can be suitable. Further, it can be preferred to utilize a dynamically stabilized, double slaboff design. Alternatively, the lens orientation can be stabilized using a prism ballast.

As illustrated in FIG. 1, a contact lens 1 (shown in vertical cross section) has the back surface center of curvature 3, which is located on back surface optical axis 6, is 0.15 mm above the front surface center of curvature 4, which is located on the optical axis of the front surface 7. The front surface 2 of the lens continues from the top of the lens until it joins the "slaboff" surface 5, the center of curvature 8 of which is located on back surface optical axis 6. This hydrogel contact lens cross section design causes the lens to orient itself on the eye via the action of the lids during the natural blink process so that the "slaboff" is essentially located inferiorly, provided that the lens is sufficiently thin and flexible.

A preferred orientation marking is illustrated in FIG. 2. A colored ring 10 is printed on the contact lens 9. In this example, the ring is a blue ring, 10 mm in diameter, and is centered with outer edge of the lens, the diameter of which is 14.5 mm. Two printed alignment marks 11, 12 are located on the horizontal
axis and are attached to the ring. Another alignment mark in the form of an arrow 13 is printed (joined to the ring) at 90 degrees from the horizontal marks and is located in the area of the "slaboff" and to indicate the bottom of the lens. The boundary between the optical zone of the lens and the "slaboff" area is indicated by curved line 14. The ring and alignment marks can be provided by any means capable of providing a mark that is visible under predetermined conditions, including etching, engraving, and molding into the lens. Printing can use indicators that are visible only under a predetermined frequency of irradiation. In a preferred embodiment the arrow can be part of the right horizontal alignment mark instead of a separate mark. Rotation of the trial lens is measured then from the zero axis position instead of from the vertical axis when using the separate arrow 13.

The information necessary to shape the front surface of the hydrogel contact to give full optical correction of the eye consists of (i) characterization of the wavefront error of the eye, typically given as a set of Zernike polynomial function coefficients along with the pupil diameter used to create these coefficients, (ii) the index of refraction of the hydrated contact lens material, (iii) the offset of the pupil center (or the visual axis) from the center (or the visual axis) of the hydrogel contact lens when it is worn by the patient and (iv) the rotation of the lens from horizontal (or vertical) when worn. The Zernike coefficients are then used to calculate the wavefront error over the surface of the pupil in terms of optical path length. The optical path lengths are then converted to effective path length in lens material by multiplying the optical path length values by the quantity (the index of refraction of hydrated lens
material equals 1). Starting with a lens blank, for example, which is designed, for example, to have zero optical power, the path lengths at each location on the lens front surface of the lens (which is located over the pupil of the eye when the vision-corrected contact lens is positioned on the eye) provides the amount of hydrated lens material that should be removed from the lens blank to make the vision-corrected contact lens. The procedure also can use (perhaps, preferably) a lens blank having a predetermined spherical, spherical plus cylindrical (i.e., spherical plus astigmatic), or spherical equivalent optical power, the particular lens blank being selected based on the optical correction required by the specific patient.

Thus, the contact lens fitter (i.e., for example, ophthalmologist or optometrist) can have a set of trial contact lenses having various optical corrections, for example, from plus 15 diopters to minus 15 diopters in 0.25 diopter increments. The fitter selects the trial lens having base optical correction closest to the optical correction needed for the patient and obtains the wavefront error of the eye with that trial lens. The final vision-corrected lens is made having both the base optical correction and correction for wavefront error of the eye.

The method of deriving a mathematical expression for the wavefront from directional ray information is described by Liang et al. in the *Journal of the Optical Society of America A*, Vol. 11, pp. 1949-1957 (1994). First, the wavefront is expressed as a series of Zernike polynomials with each term weighted initially by an unknown coefficient. Zernike polynomials are described
in "Standards for Reporting the Optical Aberrations of Eyes" by L. N. Thibos in OSA TOPS Vol. 35 Vision Science and Its Applications 232-244 (Optical Society of America, Washington, DC; 2000). Next, partial derivatives (in x and y) are calculated from the Zernike series expansion. Then, these partial derivative expressions respectively are set equal to the measured wavefront slopes in the x and y directions obtained from the wavefront sensor measurements. Finally, the method of least-squares fitting of polynomial series to the experimental wavefront slope data is employed which results in a matrix expression which, when solved, yields the coefficients of the Zernike polynomials. Consequently, the wavefront, expressed by the Zernike polynomial series, is completely and numerically determined numerically at all points in the pupil plane. The least-squares fitting method is discussed in Chapter 9, Section 11 of Mathematics of Physics and Modern Engineering by Sokolnikoff and Redheffer (McGraw-Hill, New York, 1958).

Those skilled in the art of making contact lenses know how to design a zero power trial contact lens. As an example, for a lens with a back surface with radius of curvature equal to 8.3 mm, a center thickness of 0.04 mm and an index of refraction of 1.433, a zero power lens is found to have a front surface curvature of 8.31 mm. A trial contact lens having a base optical corrective power also can be readily designed by those skilled in the art.

When the contact lens front surface is shaped in the dehydrated state allowance must be made for the expansion and change in index of refraction that comes with hydration. A hydrogel lens typically expands in an almost
isotropic manner. Therefore, it is usually sufficient to use a single expansion factor for all dimensional changes. Associated with each position on the contact lens front surface is an amount of hydrated material removal necessary to achieve the optical correction. The coordinates of each point change by the inverse of the expansion factor as the lens shrinks as it dehydrates, typically a factor of 1.26 for a conventional 43% water content material. Thus, as is well known to those skilled in the art, a coordinate transformation must be made in the instructions for surface shaping to account for this effect. At the same time, the lens thins by the same factor so the amount of material at each transformed coordinate position must be reduced by the same factor.

If the lens is to be shaped by an excimer laser system, the semi-finished lens preferably is designed to have basic optical correction, i.e., a selected spherical, spherical plus cylindrical, or spherical plus astigmatic, or spherical equivalent optical correction (or can be a zero power lens) when hydrated. It is preferred that the semi-finished lens have an optical correction as close as possible to the basic corrective power need by the patient and that the initial front surface preferably is of optical quality. This quality is preferred because the laser only removes the material necessary to create the correction and any roughness or optical imperfection in the initial lens surface is not corrected merely by the procedure for correcting the higher order aberrations. It typically is an advantage to start with a partial optical correction molded into the lens and, then, only add a correction to it as determined by a fitting on the patient. This speeds the final process and can add precision in center thickness control to the final product.
It is preferred to start with a lens close to the final shape when doing the initial trial fitting and when making the finished lens. The closer the trial and finished lens are, the better the trial lens will predict the alignment of the finished lens. The manufacturing process is faster and better when little material need be removed. Further, if a great amount of material must be removed from the semi-finished lens, then care must be taken to provide sufficient lens material to start so that holes and very thin spots are not created in the lens during finishing.

If the lens is to be shaped by a single point diamond lathe, the front surface need not have as high optical quality because the lathe controls the total final geometry. Instruction to the lathe must include, not only the amount of material to be removed to provide the correction but also, the information on the underlying lens blank surface geometry that was used as the trial lens, because the lathe must also create this underlying shape. In practice, the surface instructions for the underlying surface and the overlying correction are combined into one set of lathe instructions.

In practice using one embodiment of the invention, a patient in need of vision correction is examined by a trained professional, typically an ophthalmologist or optometrist. The patient is fitted with a trial lens, preferably a lens that has required spherical optical power to correct the patient’s vision. With the trial lens in place, an eye refractor is used to determine optical aberration. The information received from the measuring refractor instrument
will consist of a set of numbers. The radius of the pupil of the eye is used to
generate a set of numbers known as the Zernike coefficients. The further set of
four numbers consists of the horizontal and vertical displacements of the center
of the pupil from the geometric center of the trial lens, the rotation of the trial
lens from local horizontal and the power of the trial lens, given in diopters.

The numbers are used in the following way. The set of Zernike
coefficients, along with the value of the radius of the pupil used to generate
them, are used to reconstruct a surface. That surface is the wavefront error
measured by the instrument. This is done by choosing a polar coordinate
system grid, one that is sized for the lathe system to be used, and calculating
the height of the surface at each point in the grid as follows.

The Zernike functions can be written as a product of a radial polynomial
function, \( R_n^{[m]} \), a meridional function, \( M_n^m \) and a normalization function \( N_n^m \).
These are normally given by

\[
Z_n^m = N_n^m R_n^{[m]}(\rho) M(m\theta)
\]

where

\[
\rho = \frac{r}{a}
\]

\( r \) is the value of the radial position coordinate

\( a \) is the value of the pupil radius

(NOTE: For this representation, the value of the radial variable \( \rho \), a
dimensionless number, always is from 0.0 to 1.0)

\[
N_n^m = \sqrt{\left(2 - \delta_{0m}\right)(n + 1)} \quad \text{where } \delta_{0m} = 1 \text{ if } m=0, \delta_{0m} = 0 \text{ if } m \text{ is not } 0
\]
(3) 
\[ R_n^{[m]}(\rho) = \sum_{s=0}^{0.5(n-|m|)} \frac{(-1)^s(n-s)!}{s!(0.5(n+|m|)-s)!(0.5(n-|m|)-s)!} \rho^{n-2s} \]

(4) \[ M(n, m) = \cos(m\theta) \text{ if } m \geq 0 \]
\[ M(n, m) = \sin(m\theta) \text{ if } m < 0 \]

The surface or wavefront, described by using a finite set of the above functions within a circular aperture whose radius is a, is given by the sum

(5) \[ S(r, \theta) = \sum c_n Z_n = \sum S_n \]

where the values \( c_n \) are the values of the coefficients given in the data set.

The values \( S(r, \theta) \) represent the change in optical path length needed at the point \((r, \theta)\) on the lens to correct the error in the eye. These values must be converted to value of lens material removed for them to be useful as lathe instructions. If \( n \) is the index of refraction of a material and that material forms an interface with air whose index of refraction is 1.0, the change in the optical path length of light passing through the material when a thickness of the material \( x \) is removed from the surface is \((n-1)x\). Therefore, if one desires to remove an optical path-length \( S(r, \theta) \), the amount of material to remove, \( T(r, \theta) = S(r, \theta)/(n-1) \). The value of \( n \) to choose for a hydrated Optifilcon-A® lens happens to be 1.433, the hydrated thickness is the value found with Equation (5) divided by 0.433.

The lathe cuts a de-hydrated lens that will swell as it hydrates so one need not cut as much material as found above. Indeed, the amount of material
to remove at a location \((r, \theta)\) is the value found above divided by the material expansion constant, \(E\). For Optisolcon-A®, for instance, this is 1.26, so that amount of material removed becomes

\[
T(r, \theta) = \frac{S(r, \theta)}{(n-1)E} = \frac{S(r, \theta)}{(0.433 \times 1.26)}
\]

This gives the thickness change values if the correction where to be centered in the lens and aligned with local horizontal, but in general they are not. The preferred way to deal with this decentration and rotation problem is to use a method in which the Zernike coefficients are transformed so that they represent the surface in a new coordinate system that is decentered and rotated from the original. Once determined, it is these coefficients, not that ones sent from the measuring refraction device, that are used in Equation (5).

Modifying an un-hydrated lens with a lathe is a sculpture process and so material can only be removed, not added. However the thickness values given by \(T(r, \theta)\) can taken both positive and negative values so to insure that all values are negative, indicating material removal, a constant value equal to the most positive value of \(T(r, \theta)\), is removed from all values. This does not alter the corrective effect, it merely moves the surface “downward” with respect to the underlying predicate lens.

However, the corrective surface, modified so that all values are equal to or less than zero goes out to a certain diameter and then stops. But in the actual lens this surface must blend smoothly into the predicate lens surface. To accomplish this blend a transition zone is created between the edge of the
correction zone and the unaltered predicate front surface. There are a number of ways to create a transition zone but the preferred way is to extend the correction surface out to the edge of the chosen transition zone with a smooth continuation of the correction surface by using the method of resizing the coefficients. This is done with an analytical technique that creates a set of coefficients from an original set appropriate for an enlarged pupil diameter. This method guarantees that the area with in the original surface is not changed when the surface is reconstructed with the new coefficient set and guarantees that the added surface area joins smoothly to the original area. This resizing step is actually done before the translation and rotation step discussed above is done and it is the resized coefficients that are translated and rotated.

Then, a transition mask is created with the following characteristics. The mask is created with the same location values as are used to generate the translated and rotated surface. At each location with in the correction area, the mask is given a value 1.0. In the peripheral, transition area the mask takes values that decrease smoothly in radial directions from the center of the correction area and become 0 at and beyond the edge of the transition area. This mask, an array of value with one-to one correspondence with the expanded correction area, also an array of values, it multiplied on a point-by-point basis with the expanded correction array. The total effect is to cause no change in the correction area and to smoothly blend the surface to zero (no change) at the edge of the transition area.
The final step is to generate a point file for the front surface of the predicate lens, using the known value for the trial lens power used, and add to it the blended correction area points file. The result is the surface that the lathe must cut.

This information is provided to the lathe and a lens is made. The lens is provided to the patient and provides total vision correction to the patient.

The present invention has been described in detail with reference to preferred embodiments thereof. However, it will be appreciated that those skilled in the art may make modifications and improvements within the scope of the claims. For example, numerical values used in the description are merely illustrative and can be changed to meet the requirements of particular subjects. Materials having various degrees of hydration can be used with the invention. Any known techniques for manufacturing contact lenses can be used with the present invention. The indicia on the trial contact lens for determining the precise location and orientation preferably are visible. However, the markings can be visible only under selected conditions not typically found in everyday use. Also, the markings can take alternative configurations, as long as the desired result is obtained. Also, the information determined by the eye refractor can be used to make a mold for forming the contact lens, instead of making the lens directly. Those skilled in the art can readily manufacture the vision corrected lens by various well known methods.
As used herein, the term "slaboff" region means a region of the contact lens having a discontinuous change in thickness as a result of a change in the radius of the surface, the result causing the lens to be stably oriented by the normal blinking of the eye.
What is claimed is:

1. A trial contact lens having a front surface, a back surface and a center, at least one of the front or back surface bearing indicia for determining the precise location and orientation of the trial contact lens when positioned on a cornea of a subject, said indicia comprising a first marking indicative of the center of the trial contact lens and a second marking identifying a predetermined bottom of the trial contact lens and an angular orientation of the contact lens from a vertical axis through the center of the cornea when the trial contact lens is positioned stably on the cornea of the subject.

2. The trial contact lens of claim 1, the front surface of the lens further comprising a slaboff surface positioned at the predetermined bottom of the lens.

3. The trial contact lens of claim 1, wherein said first marking comprises a ring having a diameter at least as large as the pupil of the subject, the ring being centered on the center of the contact lens.

4. The trial contact lens of claim 1, wherein said second marking comprises (i) an arrow shaped line located on a center axis of the lens and pointing in a direction of the predetermined bottom of the lens and (ii) two line markings located on a line through the center of the lens and perpendicular to said centerline, the two line markings being located on opposite sides of the center of the lens, thereby indicating a horizontal line when the center axis is vertical.
5. The trial contact lens of claim 1, wherein said first marking comprises a ring having a diameter at least as large as the pupil of the subject, the ring being centered on the center of the contact lens, and wherein said second marking comprises (i) an arrow shaped line located on a center axis of the lens and pointing in a direction of the predetermined bottom of the lens and (ii) two line markings located on a line through the center of the lens and perpendicular to said centerline, the two line markings being located on opposite sides of the center of the lens, thereby indicating a horizontal line when the center axis is vertical.

6. The trial contact lens of claim 5, wherein the line markings extend outward from a perimeter of the ring.

7. The trial contact lens of claim 1, wherein said first and second markings are visible under predetermined lighting conditions.

8. A method for correcting total optical aberration including higher order optical aberration in an eye of a subject, the method comprising:

   measuring data indicative of the wavefront error of the eye of the subject;
   providing a trial contact lens having a front surface, a back surface and a center, at least one of the front or back surface bearing indicia for determining the precise location and orientation of the trial contact lens when positioned on a cornea of a subject, said indicia comprising a first marking indicative of the center of the trial contact lens and a second marking identifying a
predetermined bottom of the trial contact lens and an angular orientation of the contact lens from a vertical axis through the center of the cornea when the trial contact lens is positioned on the cornea of the subject;

determining the precise location of the trial contact lens relative to the pupil visual axis of the subject, including the offset distance between the center of the trial contact lens and the center of the pupil and the angular displacement of the trial contact lens with a vertical axis through the pupil of the subject with head positioned normally;

manufacturing a contact lens blank that is structured and arranged to locate on the eye of the subject in the same position and orientation as the trial contact lens; and

providing the contact lens blank with optical aberration correction for the subject by using the measured data, the offset distance between the center of the trial contact lens and the center of the pupil and the angular displacement of the trial contact lens with a vertical axis through the pupil of the subject with head positioned normally to produce a vision-corrected contact lens so that the optical aberration correction is applied precisely on the contact lens blank for the optical aberration correction to be positioned correctly on the subject's pupil when wearing the vision-corrected contact lens.

9. The method of claim 8, wherein the trial contact lens is designed to have zero optical corrective power.

10. The method of claim 9, wherein the trial contact lens and the contact lens blank have the same optical corrective power.
11. The method of claim 8, wherein the trial contact lens is designed to have a sphero-cylindrical optical corrective power selected for a particular subject to be fitted.

12. The method of claim 11, wherein the trial contact lens and the contact lens blank have the same optical corrective power.

13. The method of claim 8, wherein the front surface of the trial contact lens further comprises a slaboff surface positioned at the predetermined bottom of the lens.

14. The method of claim 8, wherein said first marking of the trial contact lens comprises a ring having a diameter at least as large as the pupil of the subject, the ring being centered on the center of the contact lens.

15. The method of claim 8, wherein said second marking of the trial contact lens comprises (i) an arrow shaped line located on a center axis of the lens and pointing in a direction of the predetermined bottom of the lens and (ii) two line markings located on a line through the center of the lens and perpendicular to said centerline, the two line markings being located on opposite sides of the center of the lens, thereby indicating a horizontal line when the center axis is vertical.
16. The method of claim 8, wherein said first marking of the trial contact lens comprises a ring having a diameter at least as large as the pupil of the subject, the ring being centered on the center of the contact lens, and

wherein said second marking of the trial contact lens comprises (i) an arrow shaped line located on a center axis of the lens and pointing in a direction of the predetermined bottom of the lens and (ii) two line markings located on a line through the center of the lens and perpendicular to said centerline, the two line markings being located on opposite sides of the center of the lens, thereby indicating a horizontal line when the center axis is vertical.

17. The method of claim 16, wherein the line markings extend outward from a perimeter of the ring.

18. The method of claim 8, wherein said first marking said first and second markings of the trial contact lens are visible under predetermined lighting conditions.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : G02C 7/04
US CL : 351/160R, 162, 172
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, 162, 172
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
BRS EAST Search
Electronic database consulted during the international search (name of database and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>US 5,872,613 (Blum et al) 16 February 1999 (16.02.1999), column 4, lines 13-20, column 7, lines 44-50.</td>
<td>1 and 7</td>
</tr>
<tr>
<td>Y</td>
<td>US 4,286,133 (Fisher et al) 19 May 1981 (19.05.1981), column 5, lines 41-53.</td>
<td>1 and 8-11</td>
</tr>
<tr>
<td>Y</td>
<td>US 4,322,139 (Wichterle) 30 March 1982 (30.03.1982), Figure 2, column 6, lines 1-5 and 14-15.</td>
<td>1 and 3-6</td>
</tr>
<tr>
<td>Y</td>
<td>US 5,062,701 (Drazba et al) 5 November 1991 (05.11.1991), Figure 4.</td>
<td>1 and 2</td>
</tr>
</tbody>
</table>

Are further documents are listed in the continuation of Box C. See patent family annex.

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