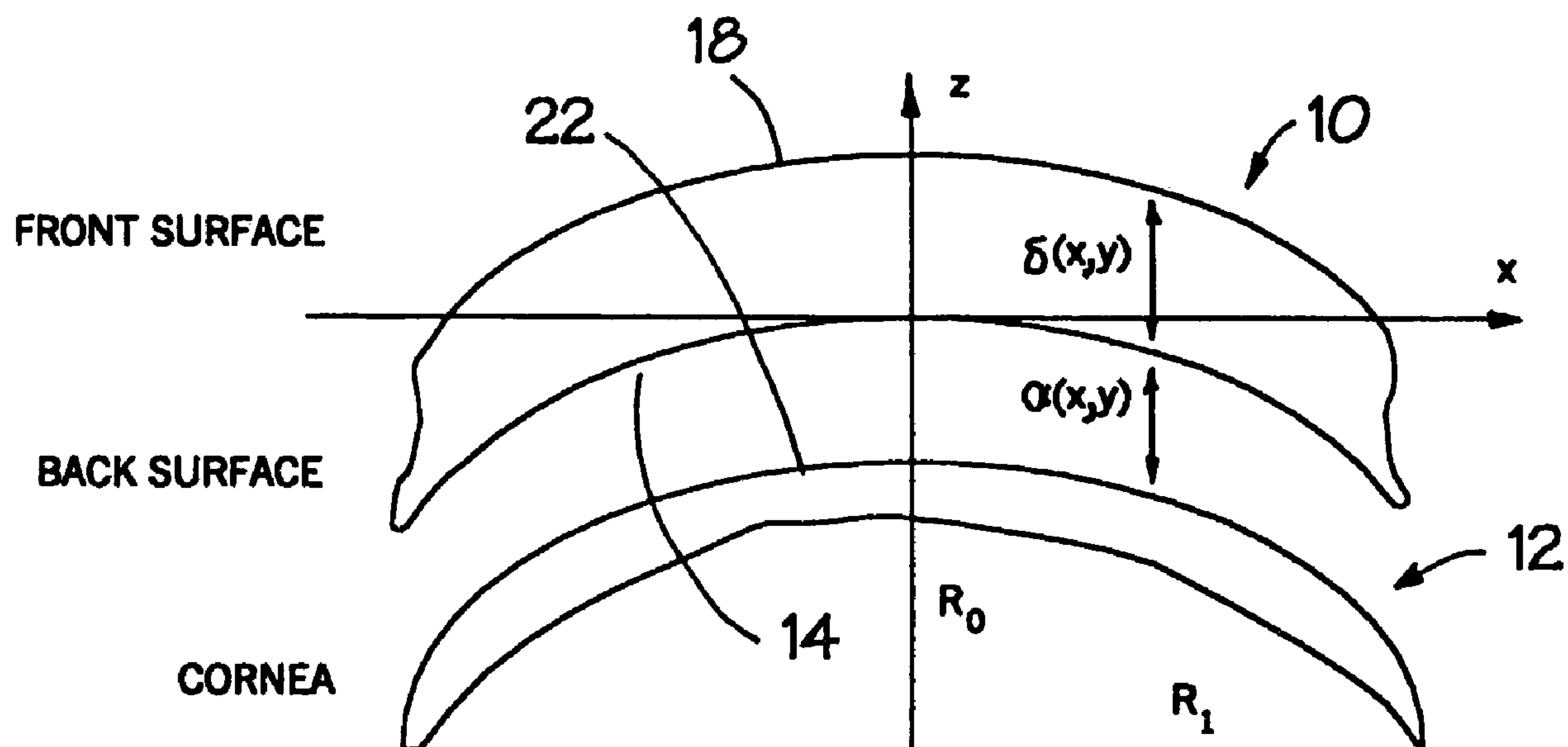




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(57) Abrégé/Abstract:

Methods for producing a junctionless ophthalmic lens are provided. Additionally, ophthalmic lenses having Functionless, three dimensional surfaces, for example, asymmetrical anterior (18) and/or posterior (14) surfaces, as well as molding tools used in the production of such lenses, are also provided. The method generally include providing sample data points to define a surface contour, and interpolating between these data points using an algorithm to produce a simulated three dimensional surface. The simulated three dimensional surface is used in producing an ophthalmic lens, for example, in cast molding a contact lens (10).



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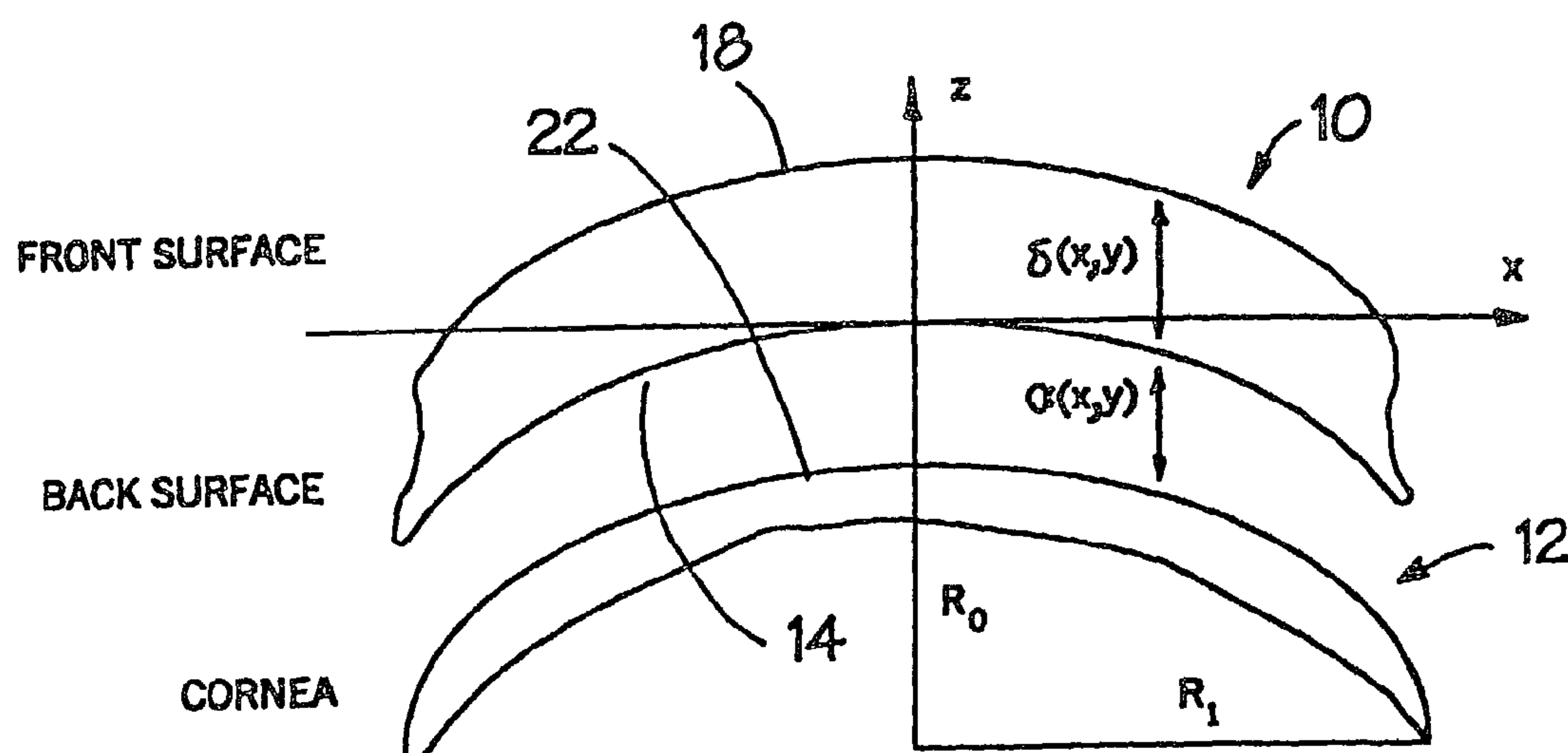
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(54) Title: JUNCTIONLESS OPHTHALMIC LENSES AND METHODS FOR MAKING SAME



(57) Abstract: Methods for producing a junctionless ophthalmic lens are provided. Additionally, ophthalmic lenses having Functionless, three dimensional surfaces, for example, asymmetrical anterior (18) and/or posterior (14) surfaces, as well as molding tools used in the production of such lenses, are also provided. The method generally include providing sample data points to define a surface contour, and interpolating between these data points using an algorithm to produce a simulated three dimensional surface. The simulated three dimensional surface is used in producing an ophthalmic lens, for example, in cast molding a contact lens (10).

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JUNCTIONLESS OPHTHALMIC LENSES AND
METHODS FOR MAKING SAME

The present invention generally relates to ophthalmic lens design and more specifically relates to junctionless ophthalmic lenses and methods for manufacturing ophthalmic lenses having junctionless, three dimensional surfaces.

5 Contact lens design typically involves a number of steps. The back surface, i.e. posterior surface, of the lens is frequently designed first based on the shape of the cornea and a desired cornea-lens fitting relationship. The front surface, i.e. anterior surface, of the lens is
10 constructed to obtain the necessary refractive correction for the eye and the desired lens performance. Such performance depends on a number of factors, including, but not limited to, lens mass distribution to provide effective eyelid interaction to achieve desired lens movement and
15 lens position, other configurational considerations to provide for the comfort of the lens wearer and the like.

 It is known that the surface topographies of a normal human cornea are often not spherical. For example, it is well known that the corneal surface of an eye has a curve
20 that generally flattens from the center of the cornea to the periphery. A typical approach to create a flatter peripheral lens surface and adequate edge clearance between the edge of the lens and the underlying cornea/conjunctiva, has been to generate a series of conic section curves, each
25 having a radius of curvature larger (i.e. flatter) than the preceding one. Both the anterior and posterior surfaces of conventional contact lens designs have been described in two dimensions by a series of rotationally symmetric surface segments. The surface segments may or may not be
30 offset from the axis of symmetry.

Conventionally designed lenses have been therefor described in two dimensions, such as by a series of

rotationally symmetric surface segments, and may be mathematically described thereby. The mathematical descriptions of two dimensional surface sections are made smooth and continuous by compositing, for example, splines or polynomials or blending of the sections. Such smooth, continuous surfaces can be considered to be free of junctions, or junctionless. Thus, ophthalmic lens surfaces with junctions have segments which intersect at discontinuities which can cause discomfort and/or one or more other reductions in lens performance. Thus, it is advantageous to provide an ophthalmic lens with one or more substantially junctionless surfaces.

Ducharme U.S. Patent No. 5,452,031 discloses a contact lens and method for manufacturing a contact lens having a smooth, junctionless surface. More specifically, the Ducharme patent discloses a method for defining the shape of the contact lens surface by relating the corneal surface to a reference curve. The reference curve may be derived from the use of piecewise polynomials and splines, based on point coordinates, resulting in a junctionless surface topography. A computer controlled lathe receives the spline data and generates a signal indicating the necessary lens form to be cut.

Vayntraub U.S. Patent No. 5,815,237 discloses a method for making a contact lens having a peripheral zone surface defined by an exponential function. Similarly, Vayntraub U.S. Patent No. 5,815,236 discloses a method for making a contact lens having a peripheral zone surface defined by a logarithmic function.

Although more closely approximating the curvature of a human eye than earlier spherically based contact lens forms, these now conventional lens computer aided design

methods, which are based on using polynomial and spline based interpolations, or exponential and logarithmic mathematical functions, result in a lens constrained to a two dimensional description of the surface topography.

5 The surface topography of a normal human cornea is often unique and includes areas of irregularity, asymmetry and asphericity that can not adequately be described in two dimensions. Likewise the lens anterior or posterior lens surface shape required to achieve optimal lens performance
10 cannot be adequately described in two dimensions. Particularly in such cases, conventional two dimensional computer aided lens design methods are insufficient.

 Designing a lens in two dimensions is inadequate when one or more of the posterior or anterior surfaces involves
15 an asymmetric component, that is a rotationally asymmetric component. Although computer controlled manufacturing techniques have facilitated manufacture of lenses in recent years, such techniques in practice have had only limited application and are inadequate in design and
20 production of lenses having one or more asymmetric components, particularly lenses for use in or on an eye, such as contact lenses, intraocular lenses and corneal onlay lenses. This is because current art in lens design necessarily requires assumptions and compromises to the
25 design by the averaging and compositing of many two dimensional surfaces. Such assumptions and compromises can result in reduced lens performance, both optically and based on user comfort.

 It would be advantageous to provide new ophthalmic
30 lenses and methods of designing and producing ophthalmic lenses which address one or more of the concerns with prior lenses, lens designs and production methods.

Summary of the Invention

New ophthalmic lenses and methods for ophthalmic lens design and manufacture have been discovered. The present lenses and methods offer significant advantages over conventional lenses and methods by providing ophthalmic lenses having substantially smooth, junctionless, three dimensional surfaces which may include one or more rotationally asymmetric components. Lenses produced by the methods in accordance with the invention may include, but are not limited to, ophthalmic lenses structured and adapted for use in or on an eye, for example, all types of contact lenses, such as toric contact lenses, monofocal and multifocal contact lenses and the like intraocular lenses (IOLs), such as anterior chamber IOLs, posterior chamber IOLs and the like, corneal onlay lenses, such as lenses affixed on the cornea, lenses placed or affixed in the cornea and the like. In addition, methods of the present invention may be utilized during corneal refractive laser surgery, for example in the shaping of the cornea.

The present invention provides methods for designing and manufacturing ophthalmic lenses having one or more substantially smooth, junctionless, three dimensional surfaces, for example, wherein the surface or surfaces may have one or more asymmetrical components. The scope of the present invention also includes such lenses, tooling inserts and mold sections used to manufacture such lenses, and methods of producing such tooling inserts and mold sections.

Advantageously, the present invention provides one or more additional, for example, relative to the prior art, degrees of freedom to control lens shape, surface contour, distribution of mass, optical power location and the like parameters within the lens design. Consequently, enhanced ophthalmic lens performance, for example, related to

comfort, fitting, vision and/or lens positioning are provided by the present invention.

It will be appreciated that the present methods are especially advantageous when applied to lens design where constraints of symmetry would otherwise present a disadvantage. For example, the methods are very well suited for the design of toric contact lenses, for example a toric contact lens including a posterior toric optical zone and an anterior surface shaped to provide the lens with appropriate optical power and a thickness profile facilitating lens orientation and stabilization in the form of a ballast.

Moreover, the present invention provides for enhanced reproducibility of the ophthalmic lens dimensions and surfaces. The present invention very effectively complements modern CNC lathes which have been used to produce ophthalmic lenses.

In one broad aspect of the present invention, methods for producing ophthalmic lenses are provided which generally comprise providing or specifying selected sample data points from a designated surface, for example, a designated corneal surface (the surface of the cornea of the wearer of the lens) or designated or desired anterior lens surface, interpolating between the sample data points using at least one algorithm to define a simulated three dimensional designated surface, preferably that has a relationship to, for example, is based at least in part on, the designated surface, and forming an ophthalmic lens having the simulated three dimensional designated surface. The simulated design surface preferably is sufficiently well defined, for example, in the interpolating step, to be a smooth, substantially junctionless three dimensional surface. In one embodiment, the simulated three dimensional surface is defined, during the interpolating step, using the sample data points and one or more factors

or relationships for one or more lens design parameters. Advantageously, the forming step is conducted so that the ophthalmic lens has the desired lens design parameters including, but not limited to, the desired optical
5 correction or corrections, size, configuration, space or gap between the cornea and posterior surface of the lens and other desired optical fitting relationships and the like.

Advantageously, the methods of the present invention
10 can be used to produce contact lenses having surfaces not constrained to contours defined by a two dimensional surface of rotation. Rather, the present lenses preferably are defined by one or more smooth, substantially
15 junctionless, three dimensional surfaces, including any rotationally asymmetric components unique or customized to the wearer's eye. This results in an improved lens/cornea fitting relationship and/or anterior surface shape that achieve desired physical, physiological lens movement and/or vision correction objectives.

20 In one aspect of the invention, ophthalmic lenses are provided and comprise lens bodies, preferably structured and adapted to be located in or on an eye, having anterior surfaces and generally opposing posterior surfaces. At least one of the anterior surface and the posterior surface
25 is a substantially smooth, junctionless, three dimensional surface. The junctionless surface may be an asymmetrical surface.

6a

In another aspect, the invention provides an ophthalmic lens comprising: a lens body structured and adapted to be located in or on an eye and having an anterior surface and a generally opposing posterior surface, wherein the lens body is a cast molded, soft hydrophilic lens body, and the anterior surface of the lens body is a substantially smooth, junctionless three dimensional asymmetrical surface having a varied surface topography with at least one contour that defines a substantially junctionless varying radial thickness of the lens body and further defining a ballast effective in providing lens orientation and lens stabilization when the ophthalmic lens is placed on a surface of an eye, and wherein the smooth, junctionless, three dimensional asymmetrical structure of the anterior surface facilitates lens comfort when the ophthalmic lens is placed on the surface of the cornea of the eye.

In another aspect, the invention provides an ophthalmic lens formed by the method comprising the steps of: providing a first tool having a surface generally corresponding to a posterior ophthalmic lens surface; positioning the first tool in a first molding apparatus; introducing a first moldable material into the first molding apparatus and subjecting the first moldable material to conditions effective to form a first mold section having a negative impression of the surface of the first tool; providing a second tool having a surface generally corresponding to an anterior ophthalmic lens surface; positioning the second tool in a second molding apparatus; introducing a second moldable material into the second molding apparatus and subjecting the second

6b

moldable material to conditions effective to form a second mold section having a negative impression of the surface of the second tool; assembling the first mold section and the second mold section to form a lens shaped cavity therebetween; and forming an ophthalmic lens in the lens shaped cavity of the assembled mold sections, wherein at least one of the steps of providing the first tool and providing the second tool comprises the steps of: obtaining sample data points from at least one three dimensional designated surface; interpolating between the sample data points using at least one algorithm to define a simulated three dimensional designated surface; and forming the simulated three dimensional designated surface on the first tool or the second tool.

15 In another aspect, the invention provides a method for producing a tooling insert useful in cast molding an ophthalmic lens, the method comprising: providing sample data points from at least one three dimensional designated surface; interpolating between the sample data points using at least one algorithm to define a simulated three dimensional designated surface; and forming the simulated three dimensional designated surface on a tooling insert blank.

25 In another aspect, the invention provides a method for reshaping a cornea of an eye, the method comprising: providing sample data points from a three dimensional corrected cornea surface; interpolating between the sample data points using at least one algorithm to produce a smooth, substantially junctionless simulated three dimensional surface; and providing an optical

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6c

correction to a cornea by shaping a surface of the cornea to approximate the simulated three dimensional surface.

In another aspect, the invention provides a method for producing an ophthalmic lens comprising the steps of:
5 providing selected sample data points from a designated corneal surface; interpolating between the sample data points using at least one algorithm to define a smooth, junctionless simulated three dimensional surface; and forming the ophthalmic lens having the simulated three
10 dimensional surface and having an anterior surface with a varied surface topography with at least one contour that defines a junctionless varying radial thickness of the ophthalmic lens, the structure of the varied surface topography of the anterior surface facilitating at least
15 one of lens orientation and lens stabilization when the ophthalmic lens is placed on a surface of a cornea of an eye.

Although, for illustrative purposes, the description of the present invention set forth herein emphasizes
20 contact lenses and methods relating to contact lenses, it is to be understood that the present invention is adapted to ophthalmic lenses in general, and preferably to ophthalmic lenses structured and adapted to be located in or on an eye, and to methods relating to such ophthalmic
25 lenses. All such lenses and methods are included within

the scope of the present invention.

The present invention may be adapted for use in producing ophthalmic lenses using any suitable processing technique or combination thereof. In one useful
5 embodiment, the present invention is utilized in conjunction with conventional cast molding techniques, for example in the initial design of a tooling insert having a surface generally corresponding to a desired lens surface. As is well known to those skilled in the art, a tooling
10 insert, or tool, is used to form a mold section which generally defines a negative impression of a surface of a final lens product.

For example, a tooling insert having a three dimensional, substantially junctionless surface designed by
15 a method of the invention, is positioned in a molding apparatus, such as a molding apparatus of conventional design. A moldable composition, such as a polymeric material or a composition of a polymeric material, is introduced into the molding apparatus and subjected to
20 conditions effective to form a mold section having a negative impression of the surface of the tool. The mold section formed by the tool may be either a back surface mold section, or a front surface mold section depending upon the tooling insert design. In other words, the
25 surface of the tool generally corresponds to a face, either a posterior or an anterior face of the ophthalmic lens to be formed.

As is conventional, the mold section is assembled with a complementary mold section to form a lens-shaped
30 cavity therebetween. A contact lens precursor material is introduced into the lens-shaped cavity. Upon demolding or removal from the mold sections, a lens product is obtained. As is typical, post formation processing steps may be employed to the demolded contact lens product. These steps
35 may include hydration, sterilization, packaging and the

like. These steps are well known and are not considered part of the present invention.

In accordance with the present invention, the tooling insert may include irregular or asymmetric surface contours that are customized or unique to the wearer's eye, or contours which are not definable as a substantially junctionless surface by a two dimensional curve or interpolation. The design of the tooling insert preferably is accomplished by a method comprising providing or specifying sample data points from a designated, three dimensional surface, for example, a designated corneal surface or a designated or desired anterior lens surface, interpolating between the data points using at least one algorithm to define a simulated three dimensional designated surface, and forming the simulated three dimensional surface on the tooling insert, for example, on a tooling insert blank.

In this embodiment of the invention, cast molded ophthalmic lenses, for example, contact lenses, are made having improved fit, and/or anterior surface shape and/or vision correction performance and/or other performance relative to conventional or prior art cast molded lenses, for example, that are conventionally produced using symmetric, conic or spherical inserts.

Alternative lens manufacturing techniques may be used in conjunction with the methods of the present invention. For example, the algorithm may be used in conjunction with lens surface forming tools, including but not limited to lathes or mills. The simulated designated three dimensional surface can be cut directly onto a lens blank, for example, using a computer driven surface cutting tool.

In another aspect of the present invention, methods for reshaping corneas are provided. Such methods comprise providing or specifying sample data points from a three dimensional corrected corneal surface, that is a corneal

surface to be provided to the cornea of a patient to obtain a desired result, such as a desired vision correction; interpolating between the sample data points using at least one algorithm to produce a smooth, substantially junctionless, simulated three dimensional surface; and providing an optical correction to a cornea by shaping the surface of the cornea to approximate the simulated three dimensional surface. In one useful embodiment, the methods further comprise providing sample data points from a three dimensional surface of the uncorrected surface of the cornea of the patient; and interpolating between the sample data points using at least one algorithm to produce a smooth, substantially junctionless, simulated three dimensional uncorrected surface, which is then employed in the providing step.

The present methods are effective to determine what degree of corneal reshaping is required to achieve a desired vision correction. The simulated three dimensional corrected corneal surface is the surface which will provide the desired correction, for example, vision correction. The uncorrected surface that is interpolated from the sample data points of the uncorrected cornea represents the surface of the cornea prior to reshaping. Thus, the degree of reshaping required to go from the original, uncorrected shape of the cornea to the desired or corrected shape of the cornea for a desired correction is determined.

The reshaping itself can be performed using any suitable method which can be adapted to be controlled in accordance with the present invention. In one particularly useful embodiment, the step of providing a correction includes ablating the surface of the cornea using a computer-driven laser system, such as is conventionally used in reshaping corneal surfaces. The step of providing a correction may include producing an asymmetrical surface on a corneal surface, for example, on a symmetrical corneal

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surface.

Each and every feature described herein, and each and every combination of two or more of such features, is included within the scope of the present invention provided that the features included in such a combination are not mutually inconsistent.

Brief Description of the Drawings

The advantages of the present invention will be more readily understood with reference to the following description when considered in conjunction with the appended drawing of which:

Fig. 1 shows a simplified, cross sectional representation of a contact lens on an eye surface;

Figs. 2a, 2b and 2c show, respectively, a front view representation including thickness data, a nominal radial thickness profile for a horizontal cross-section through the lens center and a side view of a rotationally symmetric, spherical contact lens designed in accordance with a method of the present invention. The regions bounded by broken lines (2a) designate transition regions between adjacent areas of substantially different surface types.

Figs 3a, 3b and 3c show, respectively, a front view representation including thickness data, a nominal radial thickness profile for a horizontal cross-section through the lens center and a side view of a rotationally asymmetric, toric contact lens designed in accordance with a method of the present invention. The regions bounded by broken lines (3a) designate transition regions between adjacent areas of substantially different surface types.

Fig 4 shows a front view representation, a cross-sectional view including thickness data of a complex design

contact lens designed in accordance with a method of the present invention. The regions bounded by broken lines designate transition regions between adjacent areas of substantially different surface types.

5 Figs. 5a and 5b show three dimensional representations of, respectively, a rear surface/cornea separation (α) and a radial thickness (δ) profile for the radially symmetric lens of Figs 2a-2c;

10 Figs. 6a and 6b show three dimensional representations of, respectively, a rear surface/cornea separation (α) and a radial thickness (δ) profile for the toric lens of Figs 3a-3c; and

15 Fig. 7a and 7b show three dimensional representations of, respectively, a rear surface/cornea separation (α) and a radial thickness (δ) profile for the complex design lens of Fig. 4.

Fig. 8 is a schematic diagram illustrating one method for producing lenses in accordance with the present invention.

20 **Detailed Description of the Drawings**

The present invention is directed to ophthalmic lenses and methods for designing and producing such lenses, including but not limited to monofocal, multifocal and toric contact lenses, intraocular lenses, corneal inlay
25 lenses and other ophthalmic lenses.

For the sake of simplicity and illustrative clarity, the following detailed description will be directed primarily to the design of contact lenses. It will be appreciated by persons of ordinary skill in the art that
30 the methods in accordance with the invention, possibly with one or more appropriate modifications thereto, can be utilized in the design of these and other types of lenses.

In accordance with a method of the invention, an

ophthalmic lens is designed using a mathematical algorithm and a limited number of specifications to achieve a single, continuous, non-compositing mathematical surface in three dimensional space.

5 More particularly, after a corneal shape is determined for a population or a selected patient, a posterior surface of a contact lens is designed by interpolating between sample scattered data points using a mathematical algorithm, preferably including relationships directed to
10 one or more parameters desired for the resulting lens to have, for example, the space or gap between the cornea and the posterior surface of the lens, as described elsewhere herein, to produce a simulated three dimensional surface (posterior lens surface), for example, that is based at
15 least in part on the corneal shape, such as closely approximating one or more of the varying curvatures of the cornea. Thickness data as well as specifications or relationships or for one or more lens performance requirements or parameters, as described elsewhere herein,
20 are provided and, in conjunction with the selected mathematical algorithm, define a three dimensional surface (anterior lens surface) having a desired thickness profile.

The simulated three dimensional surfaces can be formed onto a lens using conventional manufacturing techniques,
25 for example by cast molding techniques. Moreover, the present invention complements the use of modern CNC lathes.

By using this approach as detailed herein, anterior and/or posterior lens surfaces can be designed, preferably without substantial compromise.

30 Referring now to Fig. 1, a simplified, vertical cross sectional view of a contact lens 10 and cornea 12 is shown, taken across x and z coordinate axes, with the y-axis being directed into the page. The lens 10 includes a back surface (i.e. posterior surface) 14, that is tangential to
35 the x and y axes at (0,0,0). The cornea 12 lies a distance

α mm below a center of the back surface 14 of the lens 10, and a front surface (i.e. anterior surface) 18 lies a distance δ mm above the cornea 12. The cornea has a surface 22 that is ellipsoidal with semi-axial lengths R_0 and R_1 , as further described herein.

Any contact lens can be designed using the present invention.

For example, turning now to Figs 2a-2c, a rotationally symmetric, single vision contact lens 30 is shown, to represent one of the most simplest contact lens designs.

The present invention is particularly advantageous in the design and production of more complex, rotationally asymmetric lenses. For example, Figs. 3a-3c show a toric contact lens 40, specifically a prism ballast toric lens, designed in accordance with the invention.

Figs. 4a-4c show a very complex lens design, produced in accordance with the present invention. This complex lens 50 includes asymmetrical three dimensional surface components that can not be satisfactorily designed using conventional two dimensional methods and techniques.

Lens design using the present invention more specifically comprises the following steps. A corneal shape of a patient is first determined. A selected number of sample data points representing the cornea are provided using conventional means. A desired fitting relationship of the lens back surface to the cornea is then specified to meet the wearer's physiological, physical and/or optical requirements. A simulated three dimensional surface is then defined using an algorithm to interpolate between the data points. This simulated three dimensional surface can be formed on a tooling insert, or directly onto a lens posterior surface, for example by using a computer driven surface cutting tools, mills or lathes.

Next, an anterior surface of the lens is designed.

Particularly, key lens thickness data points are specified to achieve the desired clinical performance, e.g. vision correction, rotational orientation of a toric lens and the like. Examples of such thickness data for the three lens types are shown in Figs 2a-2b, Figs. 3a-3b, and Fig 4. The anterior surface of the lens is now designed by using an algorithm in conjunction with the key lens thickness data.

The outcomes of the construction of posterior and anterior surfaces, in accordance with a method of the invention, of the three lens types are demonstrated by the three dimensional schematic representations in Figs. 5a - 7b. More specifically, Figs 5a, 6a and 7a show rear surface/cornea separation of the three lens types, and Figs. 5b, 6b and 7b show radial thickness profiles of the three lens types.

Turning now specifically to Figs. 7a and 7b, the complex lens design 50 is shown as smooth and substantially junctionless, despite the varied surface topography thereof. Those of skill in the art will appreciate that this complex lens design cannot be produced using conventional two dimensional mathematically based lens design techniques and methods. It is further noted that the contours of the lens surface shown in Fig 7b can not be produced using offset rotationally symmetric curves and other sophisticated current design methods.

The step of providing sample data points may be accomplished using conventional techniques and equipment in which sample data points, for example, sagittal depths, can be designated, supplied or selected, for representing the designated surface.

As will be appreciated by those skilled in the art, the task of mathematically representing a surface smoothly in three dimensions, given a limited number of scattered data points and specifications, can be accomplished by many methods and for particular shapes and design

specifications. It is known that one algorithm may provide a better description than another, for example by providing different degrees of accuracy. The present invention can be exemplified by three algorithms, which follow hereinafter, although it is recognized that the present invention is not limited to any particular algorithms or combinations of algorithms.

The step of forming the lens surface having the three dimensional contour may include shaping a lens using a computer driven mill or lathe or other suitable cutting tool. The simulated three dimensional surface may be inputted in digital form into a computer driven lathe, and the lathe programmed to cut the junctionless, three dimensional surface into a lens blank, a tooling insert (for example in cast molded lenses), or a cornea (for example during laser surgery).

The central portion of an ophthalmic lens is typically referred to as the "optical zone" of the lens in that it provides the optical correction. Depending on the wearer, the optical zone may be described by a spherical conic section, or it may be another, more complicated configuration, such as a toric optical zone. The present invention is especially advantageous in design of toric contact lenses, as well as even more complex designs.

Contact lenses having a toric optical zone (commonly referred to as "toric contact lenses") are commonly used to correct refractive abnormalities of the eye relating to astigmatism. Astigmatism may be associated with other refractive abnormalities, such as myopia (nearsightedness), and hypermetropia (farsightedness), presbyopia and the like. Toric contact lenses can be prescribed with one or more spherical corrections.

Whereas spherical contact lenses may freely rotate on the eye, toric contact lenses typically include a ballast, or a thickened lens section, to inhibit rotation of the

lens on the eye such that the cylindrical axis of the toric zone remains generally aligned with the axis of the astigmatism. The ballast provides an asymmetric component to the lens that can be addressed by the present invention.

5 With particular reference to Fig. 8, the present invention further includes tools or tooling inserts 112 and 113 useful for cast molding a posterior surface and an anterior surface, respectively, of an ophthalmic lens. The tooling inserts 112 and 113 are adapted to be placed in
10 molding apparatus 115 and 116 in forming a first mold section or half 117 and a second mold section or half 118, each having a negative impression of a surface of the respective tooling insert. The surfaces of the inserts 112 and 113 are substantially smooth, junctionless three
15 dimensional asymmetrical surfaces corresponding to a desired ophthalmic lens posterior surface and anterior surface, respectively. The mold sections or halves 117 and 118 are assembled together to form an assembled mold 120, which defines a lens-shaped cavity. A
20 polymerizable/curable monomer composition is placed in the cavity and is processed, e.g., polymerized and/or cured, to form a contact lens. Such processing may be conventional and well known in the art and, therefore, needs not be described in detail. The lens is demolded and may be
25 subjected to conventional additional processing steps, such as sterilization, packaging and the like.

Tool inserts and molding sections produced by such tool inserts, as described herein, are within the scope of the present invention.

30 In another embodiment of the invention, a method for reshaping the cornea of an eye is provided. The method generally comprises selecting or designating sample data points representing a corrected corneal surface of an eye of a patient, e.g., human being, and interpolating, using
35 at least one algorithm, between the sample data points, to

17

produce a substantially smooth, continuous, three dimensional surface. Preferably, sample data points from a three dimensional surface of the uncorrected surface of the patient's cornea are obtained and are interpolated between using at least one algorithm to produce a smooth, substantially junctionless simulated three dimensional uncorrected surface. Using a conventional computer driven laser system supplied with the simulated surface contour, and preferably the simulated uncorrected surface contour, the cornea is reshaped to approximate the simulated surface contour. In this embodiment of the invention, the method can be used with conventional corneal refractive laser surgical systems to alter the refractive capabilities of the eye by selectively ablating or reshaping the corneal stromal tissue, and in some cases, following temporary removal of an anterior corneal flap. The method is useful in producing an asymmetric surface. such as a corneal surface, for example, to correct astigmatism, in providing custom corneal shaping for improved optical correction, in providing a correction centered over the corneal apex which is often not aligned with the pupil center and the like.

The following non-limiting Examples illustrate certain aspects of the invention.

EXAMPLES

Designing a toric lens based on a method of the present invention

The steps to be employed to design a toric contact lens in accordance with the present invention include:

- (1) Determine a corneal shape.
- (2) Select and represent a desired lens/cornea fitting relationship.
- (3) Specify a posterior surface including a toric

optical zone.

(4) Use Algorithm X to represent the posterior surface of the lens in three dimensions.

(5) Specify center thickness of the lens.

5 (6) Select an optical power of the lens.

(7) Determine lens mass distribution (selected sample points).

10 (8) Use Algorithm X to represent the anterior surface of the lens in three dimensions, including a graphical representation.

Algorithm X can be any suitable algorithm effective for interpolation to provide the desired simulated three dimensional surfaces. Three such mathematical methods using suitable algorithms used in interpolation between
15 data points are provided and discussed below.

INTERPOLATION METHODS

Generally speaking, a list of n data points and their values $(z_1 \dots z_n) = [z(x_1, y_1), \dots, z(x_n, y_n)]$ is specified which constitutes an incomplete representation of the
20 unknown underlying surface $f^*(x, y)$. Overall, an interpolating function $f(x, y)$ is chosen for which $f(x_i, y_i) = z_i, i=1, \dots, n$ and $f \rightarrow f^*$ monotonically as $n \rightarrow \infty$.

It has been assumed that the smoothness of the underlying surface f^* is generally considered to be at
25 least C^1 (or possibly piecewise C^1), and this assumption is built into the mathematical formation.

I. THE SHEPARD METHOD (Shepard 1968)

In the basic Shepard method, the interpolated value ϕ at any point (x, y) is defined by a weighted sum of the data
30 points, where the weighting is proportional to the inverse square of the distance between (x, y) and the data points.

In its simplest form, the algorithm can be represented

by the equation

$$\phi(x, y) = \frac{\sum_{i=1}^N h_i |(x, y) - (x_i, y_i)|^{-2}}{\sum_{i=1}^N |(x, y) - (x_i, y_i)|^{-2}}$$

where h_i is the i th data point, (x_i, y_i) its position, and N is the number of data points.

II. THE INTERPOLATION METHOD (Cline and Renka, 1984)

5 The following is a summary description of the
interpolation method hereinafter referred to as the CR
scheme; this method is described more fully in, Cline A.K.
and Renka, R.J., "A Storage-efficient Method for
Construction of A Thiessen Triangulation", Rocky Mountain
10 J. Math. 14(1), 119-139 (1984); Renka, R.J. and Cline,
A.K., "A Triangle-based C^1 Interpolation Method", Rocky
Mountain J. Math. 14(1) 223-237 (1984); and Renda R.J.,
"Algorithm 624: Triangulation and Interpolation At
Arbitrarily Distributed Points In The Plane"; ACM Trans.
15 Math, Software 10(4) 440-442 (1984).

The CR scheme comprises the following steps:

a. Partition the convex hull associated with the set
20 of known data points $\{(x_1, y_1), \dots, (x_n, y_n)\}$ into triangles
(CR Step 1).

b. Estimate the partial derivatives of the interpolating function $f(x,y)$ at each data point (CR Step 2).

5 c. For any arbitrary point (x_0, y_0) in the convex hull, the value of the interpolating function $f(x_0, y_0)$ can then be calculated using the data values and partial derivatives at each of the vertices of the triangle containing (x_0, y_0) . The calculation is based on a cubic surface capping the triangle (CR Step 3).

10 **STEP 1. Triangulation.**

Let S be the set of nodes (data points) $\{(x_1, y_1), \dots, (x_n, y_n)\}$, where $n \geq 3$ and $(x_i, y_i) \neq (x_j, y_j)$ for $i \neq j$. N_i is used to denote the node (x_i, y_i) . Let H be the convex hull of S .

15 A triangulation of S is a set of triangles T with the following properties: (i) each triangle contains exactly three nodes, (ii) the interior regions of the triangles are pairwise disjoint, and (iii) every point in H is contained in some triangle of T .

20 To maximize the accuracy of Steps (ii) and (iii) above, construct a triangle that is as nearly equiangular as possible. To do this, define an arc as the undirected line segment $N_i \leftrightarrow N_j$, $i \neq j$, joining two vertices of a triangle in T . An arc $N_i \leftrightarrow N_j$ is locally optimal if it
25 lies on the boundary of H or if the quadrilateral defined by a pair of adjacent triangles that share nodes is not strictly convex.

The triangulation required is one in which all arcs are locally optimal. The resulting triangulation is called
30 a Thiessen triangulation, or a Delaunay triangulation. Cline and Renka (1984) give the following algorithm for

producing a Thiessen triangulation.

- 5 • For each node N_i , define the Thiessen region associated with N_i to be the set of points (x,y) which satisfy $| (x,y) - N_i | < | (x,y) - N_j |$ for all $i \neq j$.
- 10 • A pair of nodes N_1, N_2 are said to be Thiessen neighbours iff their corresponding Thiessen regions share at least one point. If the regions share exactly one point, N_1 and N_2 are called weak Thiessen neighbours, if they share two or more points, they are called strong Thiessen neighbours.
- 15 • Connect all pairs of strong Thiessen neighbours, and arbitrarily choose $k - 3$ nonintersecting arcs connecting weak neighbours when k nodes lie on a common circle ($k \geq 4$).

STEP 2. Estimate partial derivatives of the interpolating function $f(x,y)$ at each data point.

20 After performing the triangulation, the next step in the CR scheme is to determine the partial derivatives of the interpolating functions at each node.

The value of the following partial derivative vectors are to be found:

(1)

$$D_{(x,y)} = \left(\frac{\partial f}{\partial(x,y)}(x_1, y_1), \dots, \frac{\partial f}{\partial(x,y)}(x_n, y_n) \right)$$

25 Such vectors minimize the L_2 norm of the linearized

curvature over H of the interpolating function $f(x,y)$. This leads directly to the problem of finding the value of the partial derivatives (1) which minimize the quadrilateral functional

5 (2)

$$Q_k(D_x, D_y) = \int_{P_k} \left\{ \left(\frac{\partial^2 f}{\partial x^2} \right)^2 + 2 \left(\frac{\partial^2 f}{\partial x \partial y} \right)^2 + \left(\frac{\partial^2 f}{\partial y^2} \right)^2 \right\} dx dy$$

where P_k is the patch of triangles containing node k . As described in Renka and Cline (1984), equation (2) leads to a linear system

10 (3)

$$\frac{\partial Q_k}{\partial D_x} = 0, \frac{\partial Q_k}{\partial D_y} = 0$$

which is solved by a block Gauss-Seidel method to recover the required derivatives D_x and D_y .

STEP 3. Sampling.

15 For any arbitrary point in the convex hull, the value of the interpolating function can be calculated using the data values and partial derivatives at each of the vertices of the triangle containing the arbitrary point. The calculation is based on a cubic surface capping the
20 triangle.

The previous two steps have constructed the skeleton of the interpolating function at the known data points of the surface. In the absence of an elementary formula for

the underlying surface, the mathematical description of the surface will be complete when the algorithm representing $f(x,y)$ returns a reasonable value for any $(x,y) = (x_0,y_0)$ in the region of interest.

5 This process is a common one in interpolation and finite-element analysis, and therefor will not be described in detail herein. In summary, the value of $f(x_0,y_0)$ for some $(x_0,y_0) \in H$ is calculated by a procedure due to Lawson (1976). On the triangle T containing (x_0,y_0) , the local
10 structure of f is represented by the cubic element $F(x,y)$ spanning the triangle, so that $f(x_0,y_0) = F(x_0,y_0)$. The local element F has the following properties:

1. F is a true cubic (not bicubic) in each of the three subtriangles of equal area formed by
15 connecting the vertices to the barycenter of the triangle containing (x_0,y_0) .

2. F is C^1

3. On each triangle edge, $N_i \leftrightarrow N_j$, F is a
20 Hermite cube interpolate of z_i, z_j and their directional derivatives at the endpoints N_i and N_j . Furthermore, the derivative of F in the direction normal to $N_i \leftrightarrow N_j$ interpolates the normal derivative at N_i and N_j .

25 The last two properties guarantee the C^1 continuity across triangle borders (and hence over the whole region H), since the derivatives at any point on a triangle side are completely determined by their values at the endpoints of the side.

With the construction of local cubic elements F , values lying between the local known data points can be determined. The surface is thus knowable at any point in the region covered by the data.

5 III. INTERPOLATION METHOD (THE BICUBIC SPLINE)

This interpolation method, described in Dierck, P., "An Algorithm for Surface Fitting With Spline Functions", IMA Journal of Numerical Analysis, v.1, pp. 267-283 (1981), calculates a smooth, bicubic spline approximation $\phi(x, y)$ to the set of scattered data points (x_i, y_i, h_i) weights w_i , where $i = 1 \dots N$. The spline is given the B-spline representation

(4)

$$\phi(x, y) = \sum_k \sum_l c_{kl} Q_k(x) P_l(y)$$

15 where $Q_k(x)$ and $P_l(y)$ are normalized cubic B-splines defined on an interactively calculated set of knots, and the coefficients c_{kl} are to be determined.

At the k th iteration, the current knot set is used to fit a bicubic spline to the data in a least - squares
20 sense. The residual variance

(5)

$$\theta = \sum_{i=1}^N w_i^2 (h_i - \phi_k(x_i, y_i))^2$$

is then calculated. If θ is greater than a user-specified non-negative limit S , the knot set is refined by adding extra knots in regions where the fit is most poor (that is, where θ is largest) to produce the knot set for the $(k + 1)$ th iteration. After many such iterations, the criterion $\theta \leq S$ is satisfied, the set of knots is accepted.

The final approximation to the surface is then calculated as the solution to the optimization problem of finding the coefficients in equation (4) that minimizes a global smoothness measure subject to the constraint $\theta < S$.

Although there has been hereinabove described specific ophthalmic lenses having a junctionless, three dimensional surface, and methods for producing same, in accordance with the present invention, for the purpose of illustrating the manner in which the present invention may be used to advantage, it should be appreciated that the invention is not limited thereto.

While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced within the scope of the following claims.

CLAIMS:

1. An ophthalmic lens comprising:

a lens body structured and adapted to be located in or on an eye and having an anterior surface and a generally opposing posterior surface, wherein the lens body is a cast molded, soft hydrophilic lens body, and the anterior surface of the lens body is a substantially smooth, junctionless three dimensional asymmetrical surface having a varied surface topography with at least one contour that defines a substantially junctionless varying radial thickness of the lens body and further defining a ballast effective in providing lens orientation and lens stabilization when the ophthalmic lens is placed on a surface of an eye, and wherein the smooth, junctionless, three dimensional asymmetrical structure of the anterior surface facilitates lens comfort when the ophthalmic lens is placed on the surface of the cornea of the eye.

2. The ophthalmic lens of claim 1 wherein the posterior surface is a further substantially smooth, junctionless three dimensional asymmetrical surface.

3. The ophthalmic lens of claim 1 or 2 wherein the lens body is a contact lens, intraocular lens or corneal onlay lens.

4. An ophthalmic lens formed by the method comprising the steps of:

providing a first tool having a surface generally corresponding to a posterior ophthalmic lens surface;

positioning the first tool in a first molding apparatus;

introducing a first moldable material into the first molding apparatus and subjecting the first moldable material to conditions effective to form a first mold section having a negative impression of the surface of the first tool;

providing a second tool having a surface generally corresponding to an anterior ophthalmic lens surface;

positioning the second tool in a second molding apparatus;

introducing a second moldable material into the second molding apparatus and subjecting the second moldable material to conditions effective to form a second mold section having a negative impression of the surface of the second tool;

assembling the first mold section and the second mold section to form a lens shaped cavity therebetween; and

forming an ophthalmic lens in the lens shaped cavity of the assembled mold sections, wherein at least one of the steps of providing the first tool and providing the second tool comprises the steps of:

obtaining sample data points from at least one three dimensional designated surface;

interpolating between the sample data points using at least one algorithm to define a simulated three dimensional designated surface; and

forming the simulated three dimensional designated surface on the first tool or the second tool.

5. The ophthalmic lens of claim 4 wherein the simulated three dimensional designated surface defined in the step of interpolating is a substantially smooth, junctionless, simulated three dimensional designated surface.

6. The ophthalmic lens of claim 4 or 5 wherein the step of forming the simulated three dimensional designated surface comprises the step of using the at least one algorithm in conjunction with a surface forming tool.

7. The ophthalmic lens of any one of claims 4 to 6 wherein the at least one three dimensional designated surface comprises a corneal surface and the simulated three dimensional designated surface is formed on the first tool.

8. The ophthalmic lens of any one of claims 4 to 6 wherein the at least one three dimensional designated surface comprises the anterior ophthalmic lens surface and the simulated three dimensional designated surface is formed on the second tool.

9. The ophthalmic lens of any one of claims 4 to 8 wherein the simulated three dimensional surface includes an asymmetrical surface form.

10. The ophthalmic lens of claim 8 wherein the anterior ophthalmic lens surface is represented by anterior surface data points measuring thicknesses of the ophthalmic lens at least in part in reference to at least one of a corneal surface and the posterior ophthalmic lens surface.

11. The ophthalmic lens of any one of claims 4 to 9 which is a contact lens, intraocular lens, or corneal onlay lens.

12. A method for producing a tooling insert useful in cast molding an ophthalmic lens, the method comprising:

providing sample data points from at least one three dimensional designated surface;

interpolating between the sample data points using at least one algorithm to define a simulated three dimensional designated surface; and

forming the simulated three dimensional designated surface on a tooling insert blank.

13. The method of claim 12 wherein the at least one three dimensional designated surface is a corneal surface.

14. The method of claim 12 wherein the simulated three dimensional designated surface corresponds generally to a posterior surface of the ophthalmic lens.

15. The method of claim 12 wherein the simulated three dimensional designated surface corresponds generally to an anterior surface of the ophthalmic lens.

16. The method of any one of claims 12 to 15 wherein the simulated three dimensional designated surface defined in the step of interpolating is a substantially smooth, junctionless, simulated three dimensional designated surface.

17. The method of any one of claims 12 to 16 wherein the step of forming the simulated three dimensional designated surface comprises the step of using the at least one algorithm in conjunction with a computer driven lathe.

18. The method of any one of claims 12 to 17 wherein the at least one three dimensional designated surface is an asymmetrical surface.

19. A method for producing an ophthalmic lens comprising the steps of:

providing selected sample data points from a designated corneal surface;

interpolating between the sample data points using at least one algorithm to define a smooth, junctionless simulated three dimensional surface; and

forming the ophthalmic lens having the simulated three dimensional surface and having an anterior surface with a varied surface topography with at least one contour that defines a junctionless varying radial thickness of the ophthalmic lens, the structure of the varied surface topography of the anterior surface facilitating at least one of lens orientation and lens stabilization when the ophthalmic lens is placed on a surface of a cornea of an eye.

20. The method of claim 19 which further comprises defining desired lens design parameters of the ophthalmic lens, and the forming step is conducted so that the ophthalmic lens has the desired lens design parameters.

21. The method of claim 19, comprising the steps of:

providing a first tool having a surface corresponding to the posterior ophthalmic lens surface;

positioning the first tool in a first molding apparatus;

introducing a first moldable material into the first molding apparatus and subjecting the first moldable material to conditions effective to form a first mold section having a negative impression of the surface of the first tool;

providing a second tool having a surface corresponding to the anterior ophthalmic lens surface;

positioning the second tool in a second molding apparatus;

introducing a second moldable material into the second molding apparatus and subjecting the second moldable material to conditions effective to form a second mold section having a negative impression of the surface of the second tool;

assembling the first mold section and the second mold section to form a lens shaped cavity between the first mold section and the second mold section; and

forming the ophthalmic lens in the lens shaped cavity of the assembled mold sections, wherein at least one of the steps of providing a first tool and providing a second tool comprises the steps of:

obtaining sample data points from at least one three dimensional designated surface;

interpolating between the sample data points using at least one algorithm to define the simulated three dimensional designated surface; and

forming the simulated three dimensional designated surface on the first tool or the second tool.

22. The method of claim 21 wherein the simulated three dimensional designated surface defined in the step of interpolating is a smooth, junctionless, simulated three dimensional designated surface.

23. The method of claim 21 or 22 wherein the step of forming the simulated three dimensional designated surface comprises the step of using the at least one algorithm in conjunction with a surface forming tool.

24. The method of any one of claims 21 to 23 wherein the at least one three dimensional designated surface comprises a corneal surface and the simulated three dimensional designated surface is formed on the first tool.

25. The method of any one of claims 21 to 23 wherein the at least one three dimensional designated surface comprises the anterior ophthalmic lens surface and the simulated three dimensional designated surface is formed on the second tool.

26. The method of any one of claims 19 to 25 wherein the simulated three dimensional surface includes an asymmetrical surface form.

27. The method of any one of claims 19 to 26 wherein both the step of providing a first tool and the step of providing a second tool comprise the steps of obtaining

sample data points, interpolating between sample data points and forming the respective simulated three dimensional designated surface on the first tool and the second tool.

28. The method of claim 23 wherein the anterior ophthalmic lens surface is represented by anterior surface data points measuring thicknesses of the ophthalmic lens in reference to at least one of a corneal surface and the posterior ophthalmic lens surface.

29. The method of any one of claims 19 to 28 wherein the ophthalmic lens is a contact lens, intraocular lens or corneal onlay lens.

30. The method of any one of claims 19 to 28 wherein the step of forming an ophthalmic lens includes providing the anterior surface with the varied surface topography with at least one contour that further defines a ballast effective in providing at least one of lens orientation and lens stabilization when the ophthalmic lens is placed on a surface of an eye.

31. The method of claim 30 wherein the step of forming the ophthalmic lens comprises forming a toric contact lens.

32. The method of claim 30 wherein the step of forming the ophthalmic lens comprises forming a multifocal contact lens.

33. The method of any one of claims 29 to 32 wherein the step of forming the ophthalmic lens comprises forming a cast molded, soft hydrophilic ophthalmic lens.

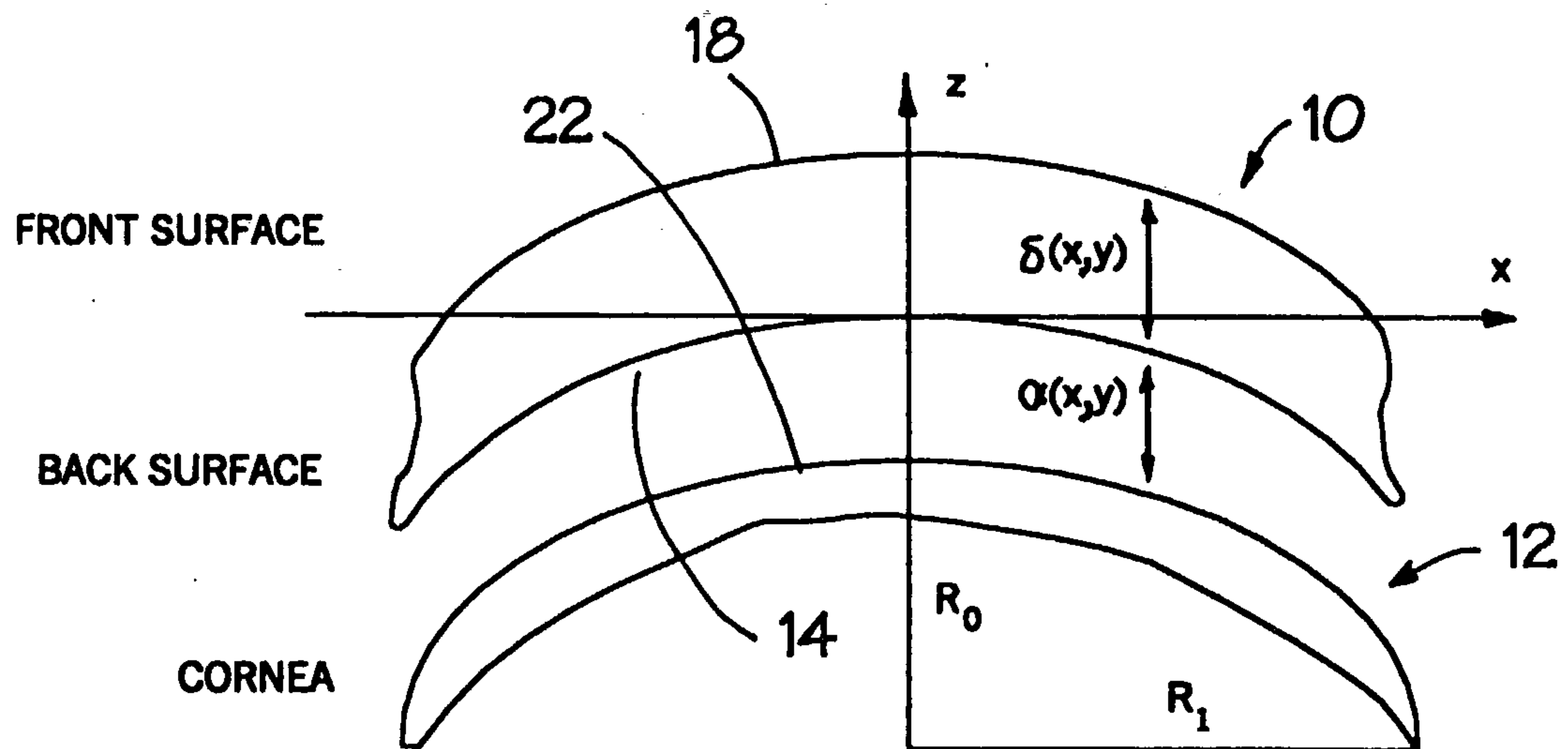


Fig. 1

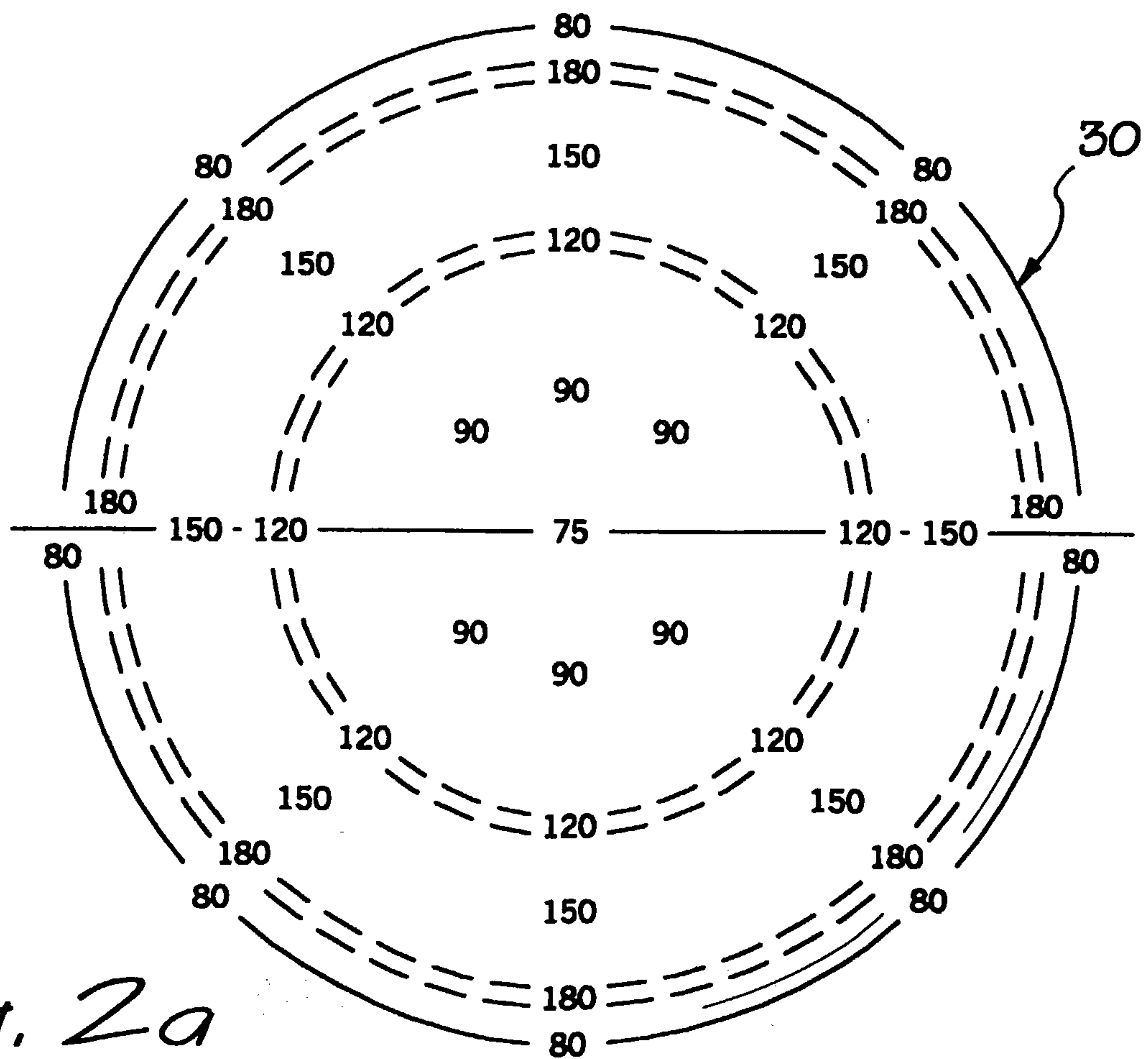
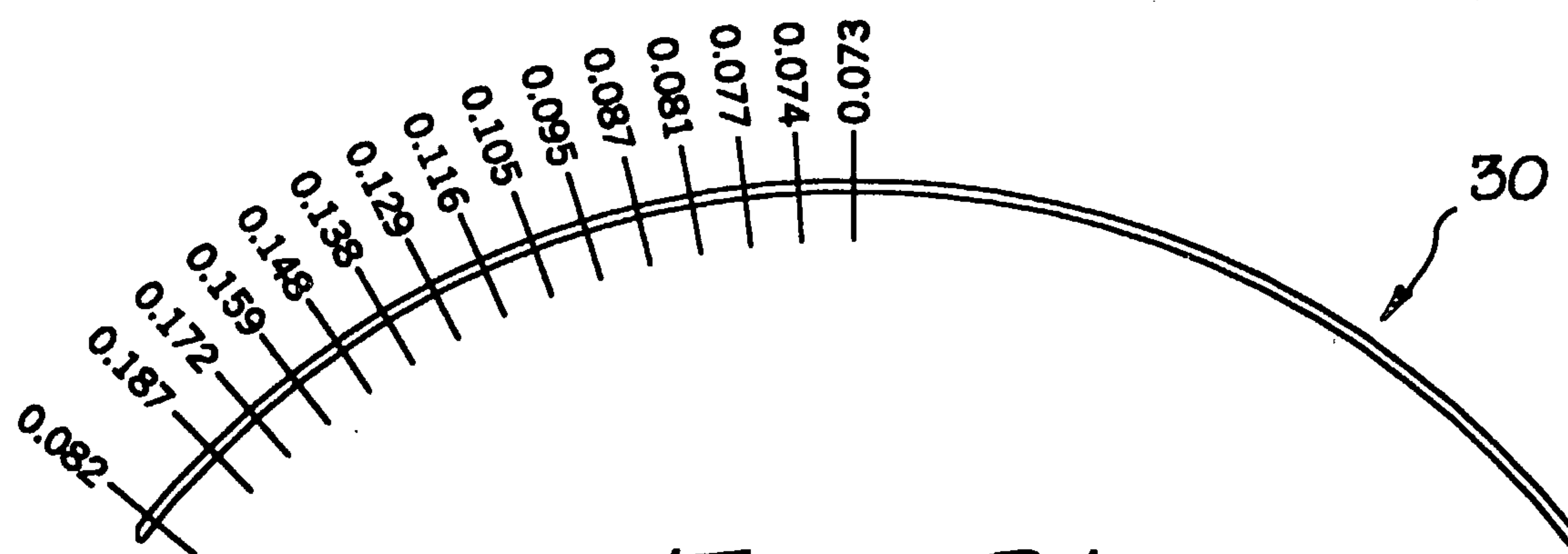
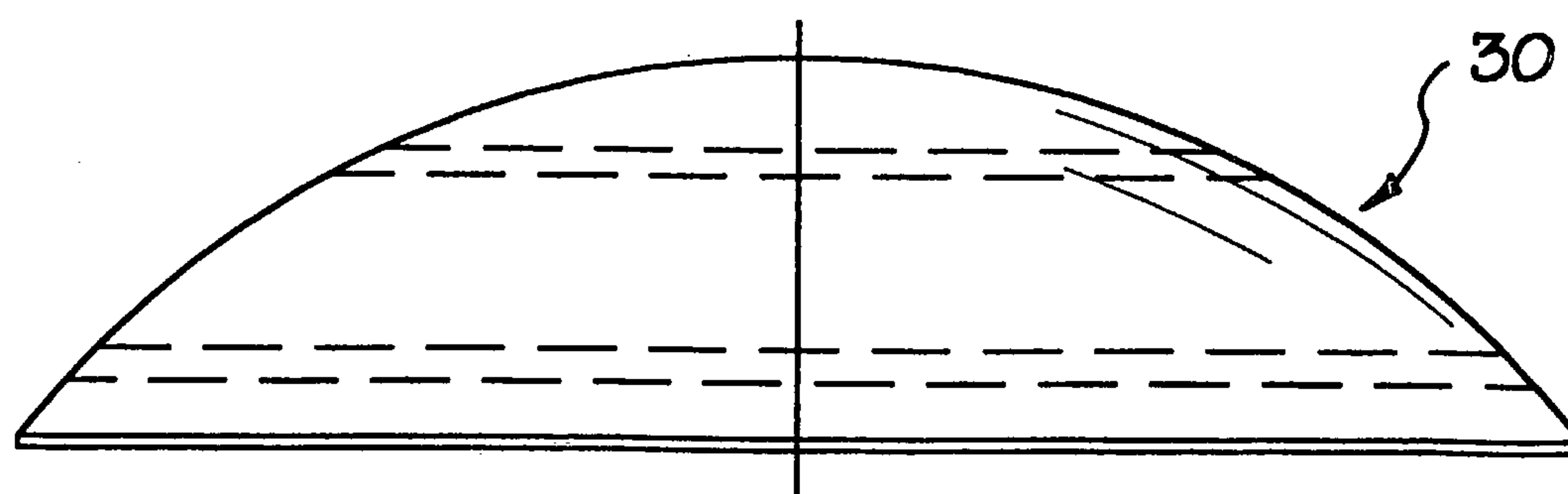
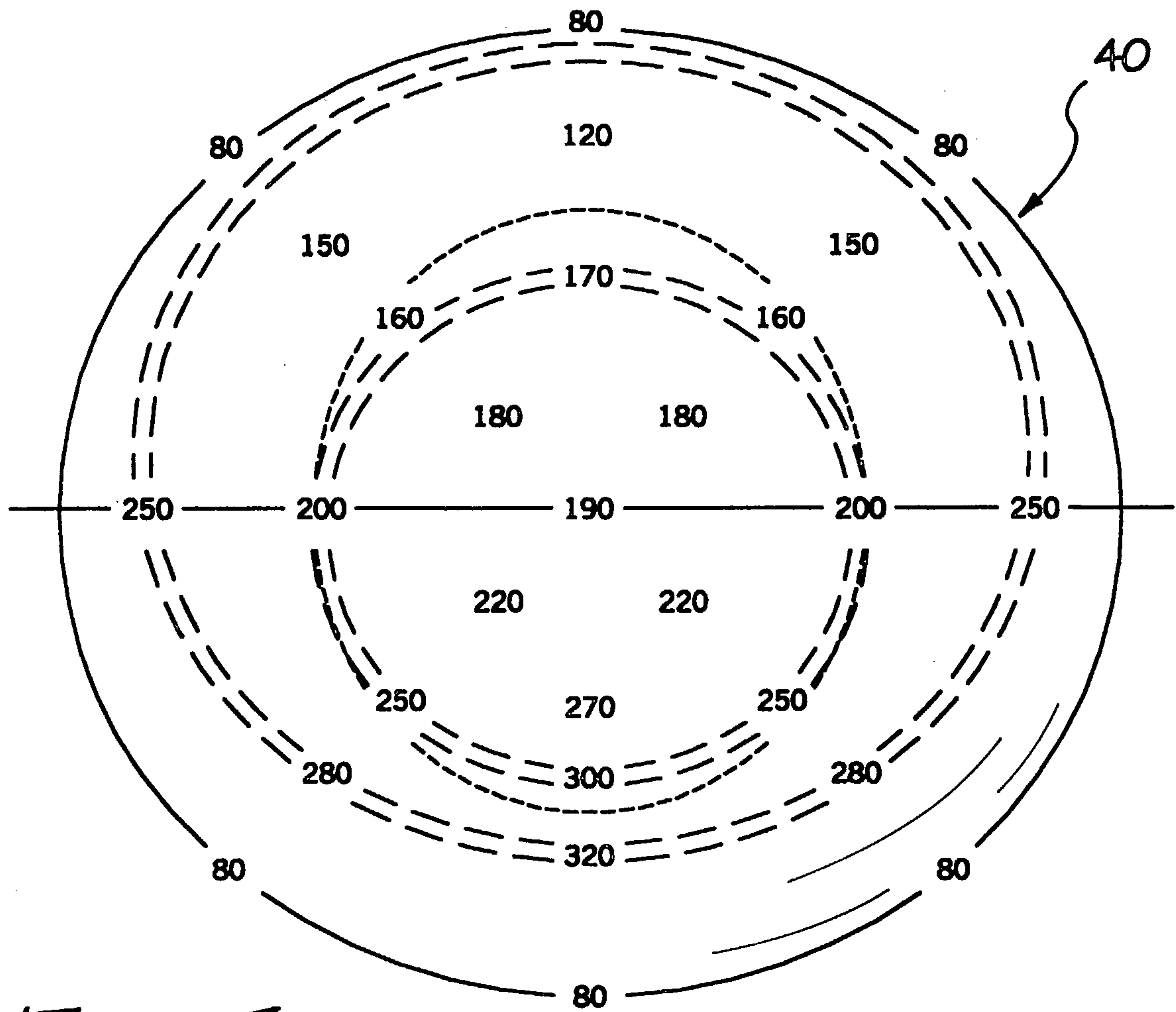
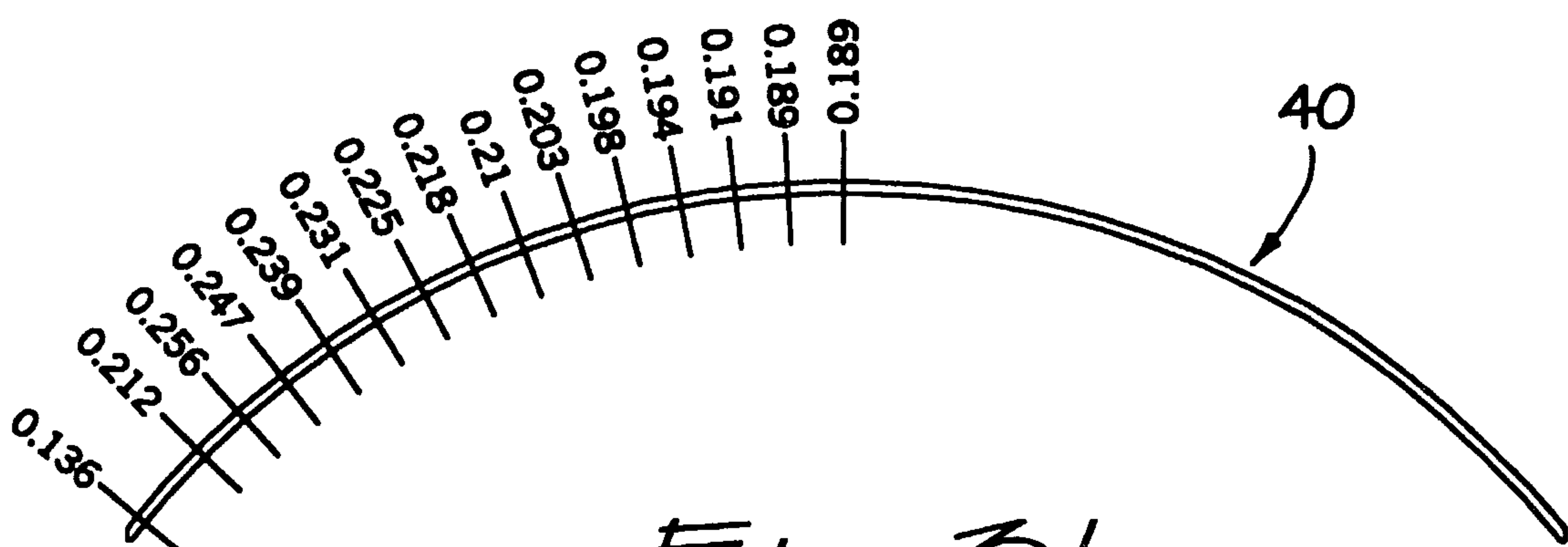
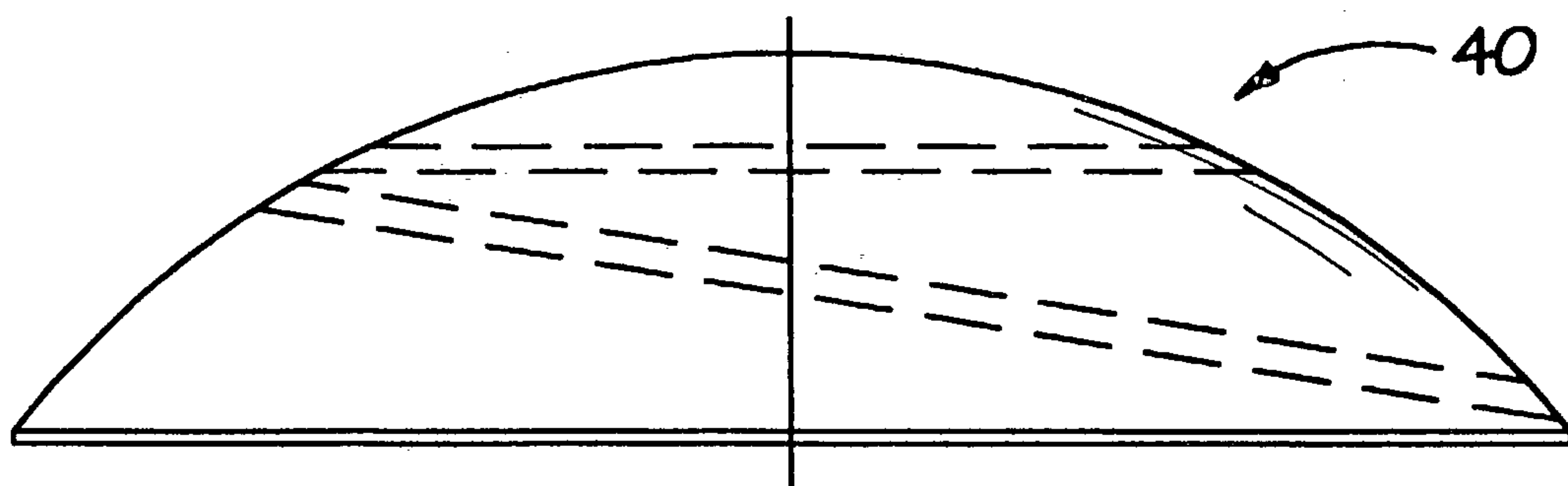
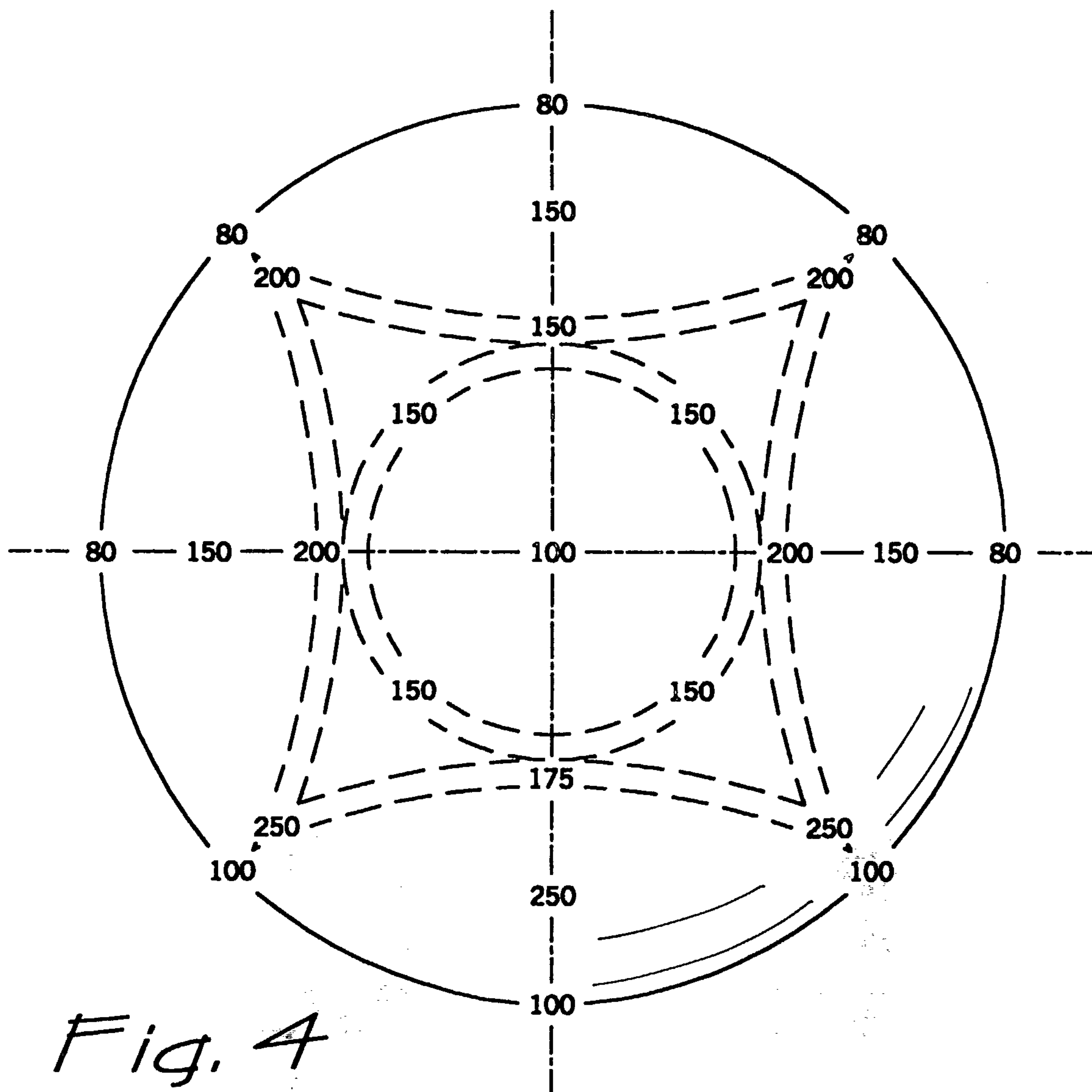
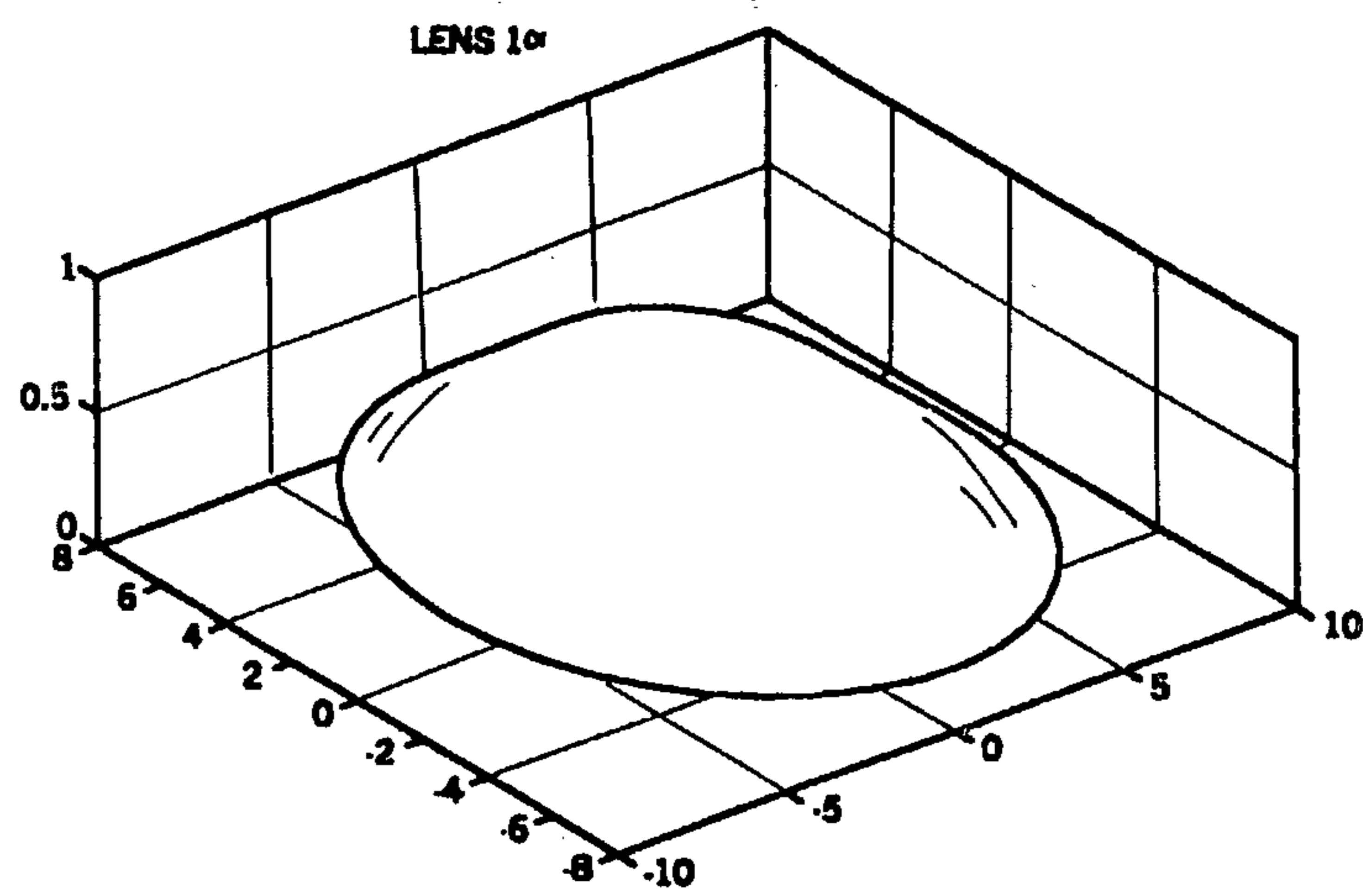
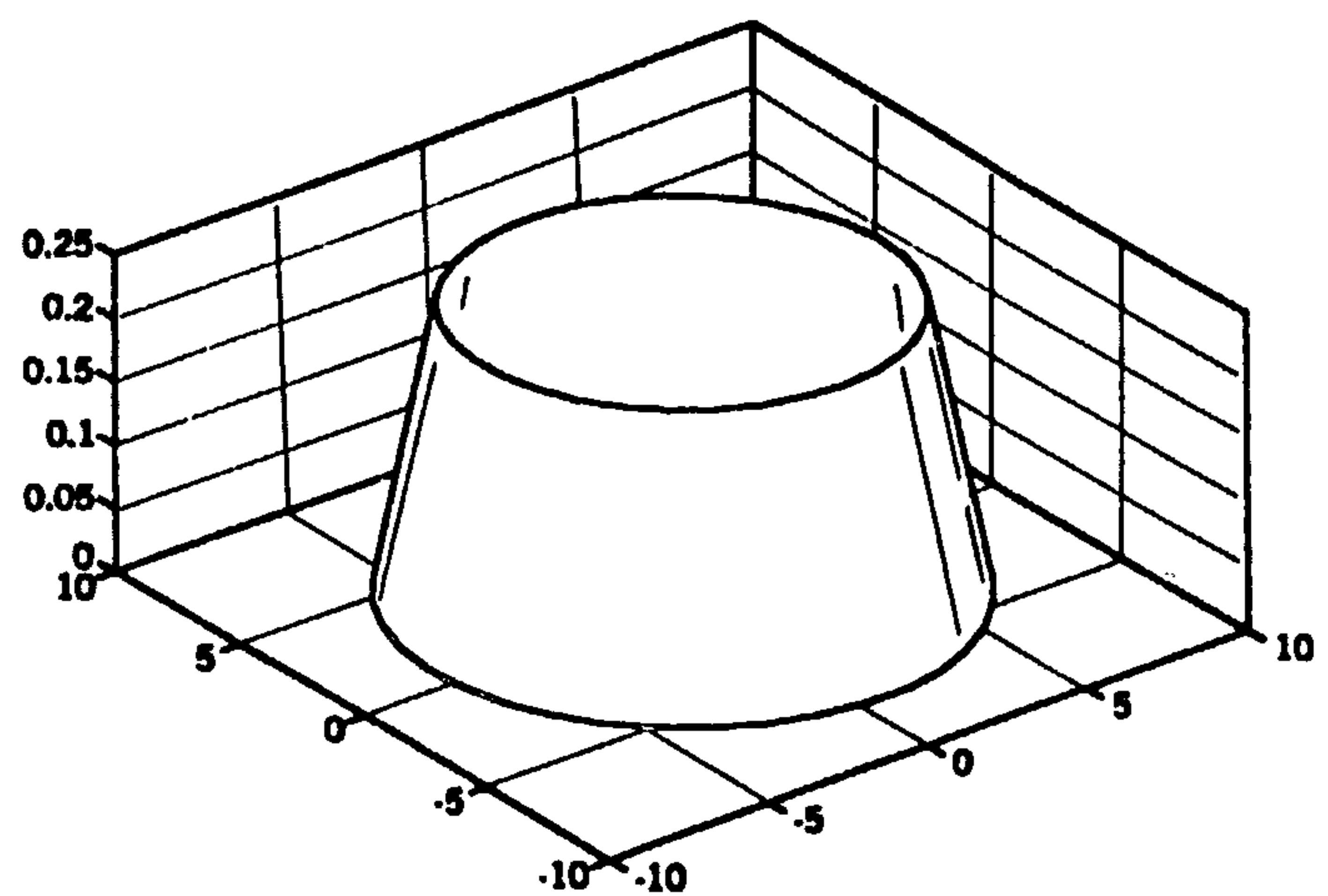
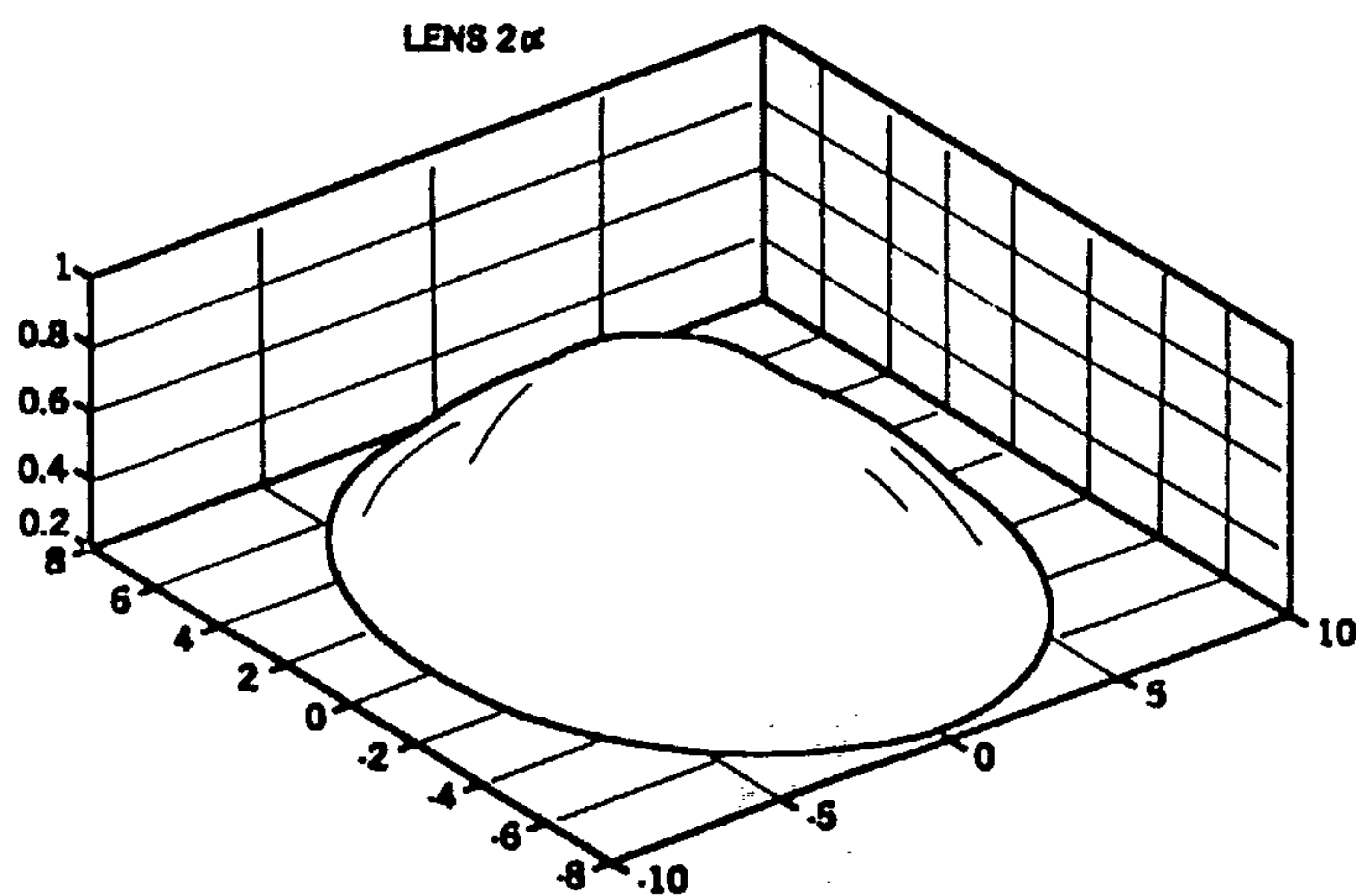


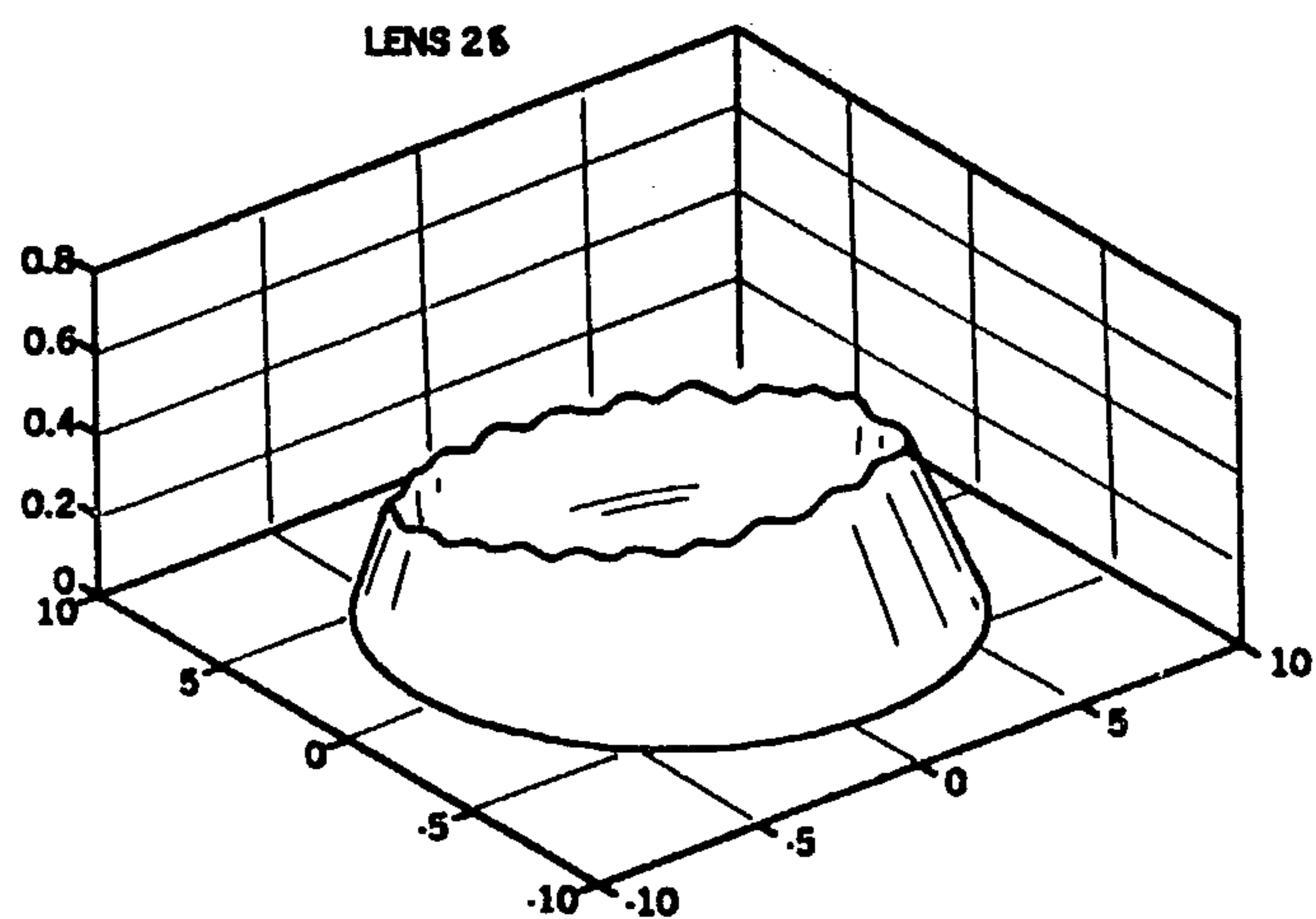
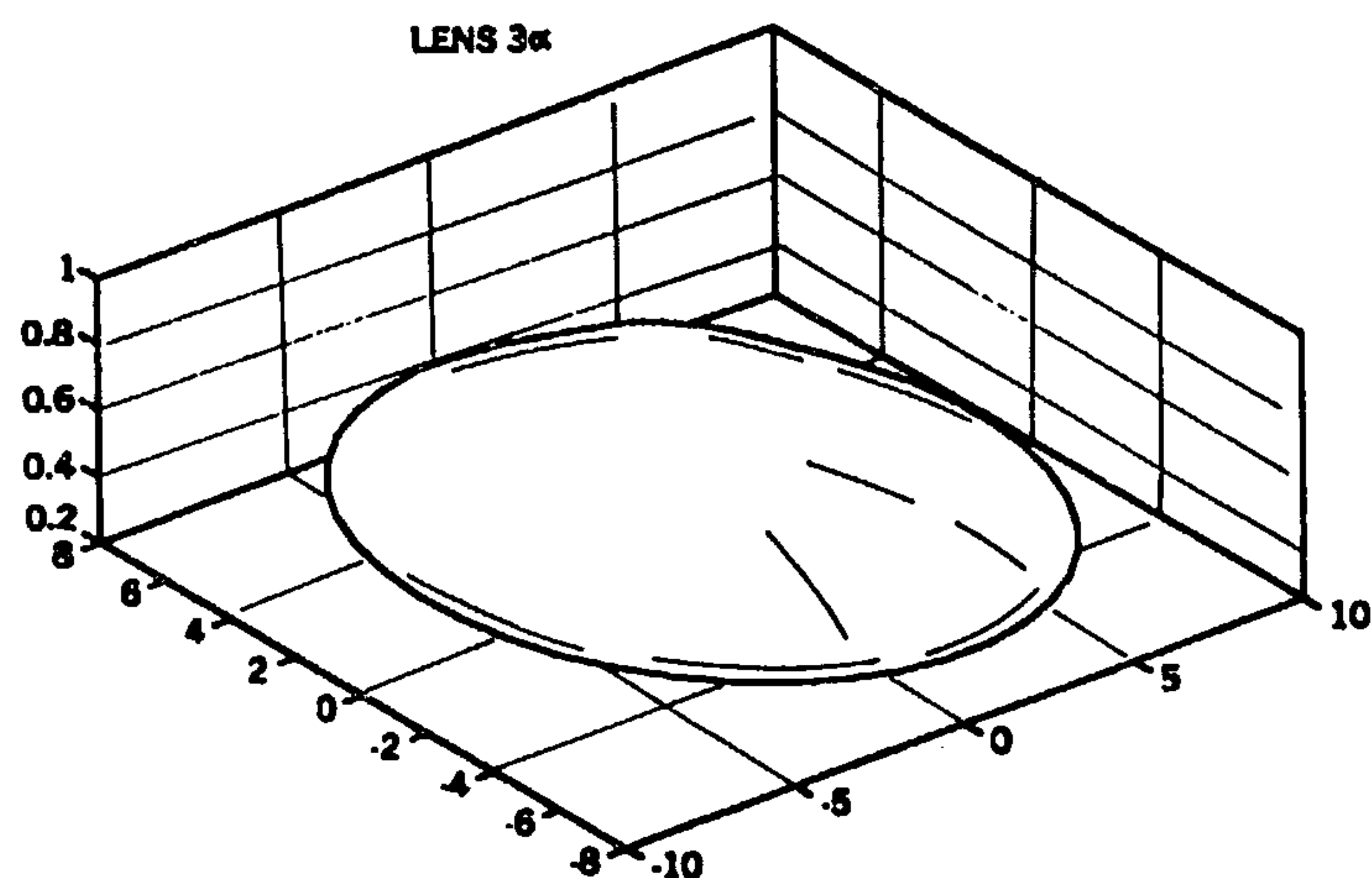
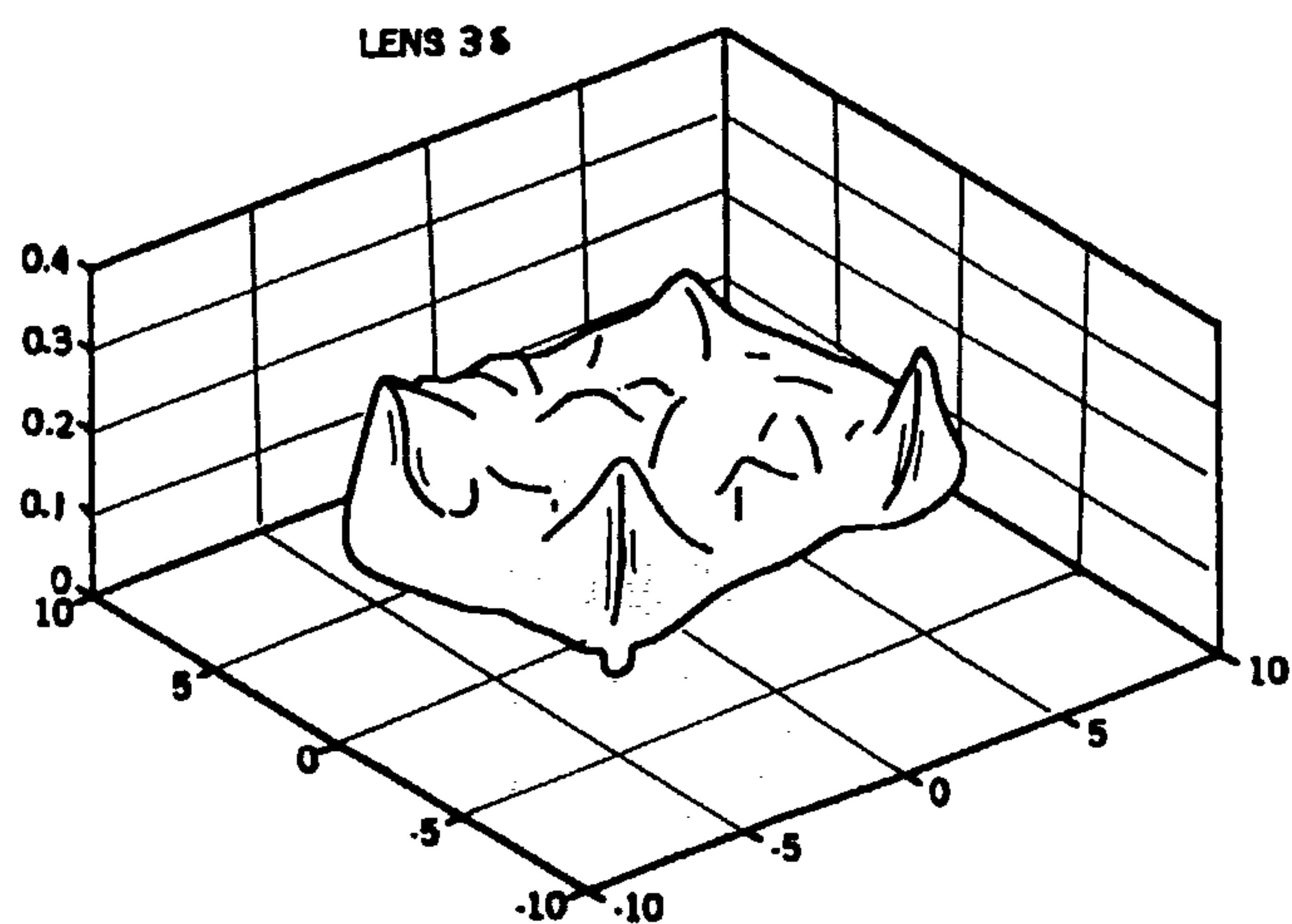
Fig. 2a

*Fig. 2b**Fig. 2c*

*Fig. 3a**Fig. 3b*

*Fig. 3c**Fig. 4*

*Fig. 5a**Fig. 5b**Fig. 6a*

*Fig. 6b**Fig. 7a**Fig. 7b*

