(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
25 September 2014 (25.09.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/148922 A2

(51) International Patent Classification:
*G06F 17/50* (2006.01)

(21) International Application Number:
PCT/NZ2014/000046

(22) International Filing Date:
19 March 2014 (19.03.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
608439 19 March 2013 (19.03.2013) NZ

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

**Published**:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

(54) Title: AN IMPROVED CONTACT LENS AND IMPROVED METHOD OF FABRICATION OF CONTACT LENSES

(57) Abstract: A method of generating data for use in fabricating a contact lens for an eye is provided. Posterior lens data defining a posterior lens surface for the lens is generated dependent on ocular surface data generated by a scanner to represent the ocular surface of an eye. Anterior lens data defining an anterior surface for the lens to define optical properties for the lens is then generated. The anterior lens data is generated dependent on the posterior surface data. The posterior lens data is generated dependent on scanned data representing the ocular surface of an eye. Also provided is a contact lens with support surfaces which contact the eye in use and supported surfaces formed in relief in the posterior lens surface and which are supported by the support surfaces to minimise or avoid contact between the lens and features on the ocular surface.

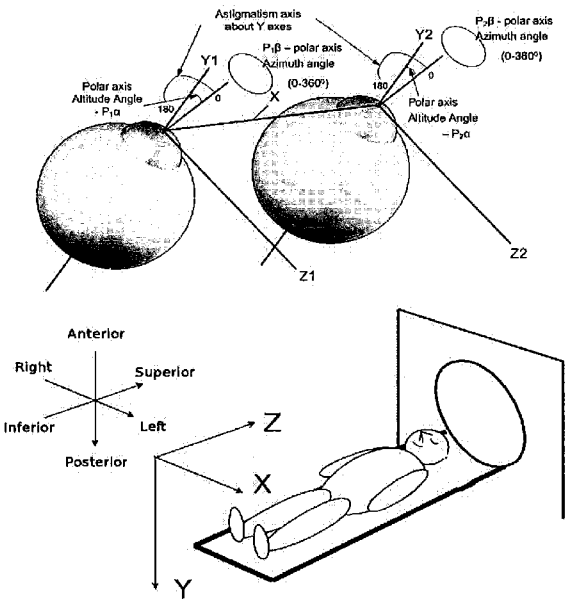


Figure 1

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# AN IMPROVED CONTACT LENS AND IMPROVED METHOD OF FABRICATION OF CONTACT LENSES

## Field

The present invention relates to contact lenses, such as a therapeutic contact lens. In particular the present invention relates to contact lenses suitable for eyes with irregular ocular surfaces.

## Background

Therapeutic contact lenses are designed to correct visual problems unresolved by spectacle lenses or by cosmetic soft lens corrections. They are distinguished from conventional lenses using spherical or aspherical geometrical optics to correct visual errors that have evolved during human development.

Rays of light are focused on the retina by a number of refractive interfaces beginning with the cornea that contributes more than 3 times the power of the ocular lens lying behind the pupil. If the ocular lens has developed cataract it may have been removed, a state known as aphakia.

In adult eyes a substitute known as an intraocular lens [IOL] is generally implanted behind the iris, producing a state of pseudo-aphakia. However for babies born with congenital cataract an IOL cannot be used as it may cause a sight threatening physiological response and a therapeutic contact lens must be used from the day of the operation forward, causing great stress for the child and the parents.

The power of IOL's, therapeutic or cosmetic contacts and spectacle lenses is ultimately determined by the length of the eye. If it is too short and the rays of light fall behind the retina, the eye is hyperopic. If the eye is too long then the eye is myopic.

The corneal surface contributes most of the power required to focus incoming rays of light onto the retina. If it is distorted by disease, injury or surgical intervention, the surface may become highly irregular and incapable of focussing the incoming rays, resulting in images that may be likened to looking through a piece of bathroom window glass. Spectacle lenses cannot focus vision through an eye with a badly damaged corneal surface.

Therapeutic contact lenses are conventionally manufactured from gas permeable rigid materials that have a high gaseous flux for oxygen and carbon dioxide to maintain the physiology of the corneal tissue by perfusion through the tear surface. The molecular structure of these rigid materials must be maintained for gas permeability; they are not thermoplastic and cannot be molded to conform to a surface. Custom-made contact lenses are typically manufactured to specifications that describe the path of the cutting tool for the lathe to shape the surfaces.

Contact lens specifications are currently defined by international convention and country standards, specifying a set of parameters such as radii of curvature and thickness. Contact lenses manufactured by the processes described by this invention are unable to be described by these conventions.

A common method of fitting a rigid lens to a normal eye is to measure the central curvature of the cornea with an optical instrument called a Keratometer. This provides a reading indicating the choice of a trial lens to be placed on the cornea. Sodium fluorescein instilled in the tears and excited by UV or cobalt blue light provides a fluorescent pattern that illustrates points of contact or clearance behind the trial lens. The fluorescent pattern is then optimized by the practitioner by observations of fittings of a range of trial lenses.

Topographers 'grab' an image and graphically derive parameters for a central zone of the cornea limited to about 10mm diameter. They do not provide an absolute measurement, rather they graphically interpret a reflected image from, or transmission through the cornea that is frequently corrupted by poor reflectivity from the surface. Topographical images frequently do not provide

critical information where it is most needed for fitting, for example at a discontinuous junction or scar on the cornea; the output is variable and dependent upon the quality of the tear film and the position of the lids. The required data may be under the lids and beyond the measured area.

Topographers provide simulation programs to enable the selection of a trial lens, and provide a useful starting point. However they are of limited value when fitting therapeutic contact lenses, particularly if the practitioner wishes to improve the fitting of these lenses by departing from the lens manufacturer's specifications.

Topographers cannot be used on babies, for example, so observational, skill based methods have been the only option until the embodiments of the invention.

There has been a move in recent years towards semi scleral lens designs, often 14mm to 16mm or more in diameter because of their advantages when fitting decentered cones and grafts. These lenses are restrained in the eye by the lids and can be used for sport and in dusty occupations.

Topgraphers using the placedo disc principle are restricted to an area of approximately 10mm in diameter, often restricted in the vertical meridian by a drooping upper lid, disruption from eyelashes or the quality of the tear film. Relying on the reflection from the corneal surface, the quality of the image is compromised by scar tissue that scatters the light, or wayward reflected rays from abrupt changes in the surface, for example the margin of graft or trauma scar. The quantitative values available to the therapeutic lens fitter relies on the quality of the image and is subject to interpretation by the manufacturer of the topographer who uses proprietary algorithms. Absolute values over the whole surface area to be fitted are essential for surface modelling.

Instrumentation utilising scanning systems are an alternative but they but they provide slices of information through the cornea and to a limited extent the sclera, but the processing time is significant between scans during which time the eye can shift and the reference plane is lost.

Therapeutic lenses were traditionally machined with modified watchmaker's lathes, providing a scale and accuracy for their manufacture. The lathes were modified to allow the cutting tool to describe arcs of predetermined radii to fit the shape of the eye, with the desired optical and peripheral parameters to support the lens. The surfaces were subsequently polished to remove the tooling tracks.

Rigid lenses are now almost universally machined with CNC controlled lathes, utilising diamond tools, finely honed and with careful control of cutting speeds the surfaces do not require polishing.

Distortions of the rear surfaces of contact lenses to optimise the fit on the eye for comfort and stability, have been limited to machining conic sections with the minor and major axes at $90^0$ to each other. Because these axes may be only an approximation for a grossly distorted eye, the patient's tolerance of the lens may be very limited using these formats.

More recently additional control factors have been added to the designs by specifying adjustments to quadrants of the lenses using 'reverse' contours, but the symmetry imposed by quadrants continues to restrict fittings to less extreme corneal surfaces

When fitting conventional lenses, the physical parameters of the lens may be inferred by observing with slitlamp biomicroscope, the relationship of the surfaces of the lens to the irregular surfaces of the eye.

Frothing or bubbles under the lens and the position of the lens in all directions of gaze, influenced by lid pressure assists the practitioner to clinically assess how the design behaves.

Information from the excitation of Sodium Fluorescein in the tears to glow green, highlights areas of clearance and pressure behind the lens, that may be interpreted by the practitioner for adjustments to conventional lens parameters that define conic sections. Conversion of observations to physical parameters is not an exact science; it is acquired by training and practice. The imprecise

nature of this process results in many poor fittings, numerous trials and prolonged chair time.

Furthermore, the skill base for fitting therapeutic lenses is declining because young practitioners almost exclusively dispense soft contact lenses and do not gain expertise fitting normal eyes with rigid lenses. They cannot therefore be expected to practice to a high standard, fitting complex corneal distortions with therapeutic lenses. It is an object of some aspects of the present invention to provide a method of fabricating contact lenses that reduce the need for trial lenses.

It is an object of some aspects of the present invention to provide a contact lenses and/or a method of fabrication of contact lenses which are improved for eyes that may be harmed if the ocular surface is compromised.

It is an object of aspects of the present invention to provide a method of fabrication contact lenses which are better customised for given eyes.

As used herein, the term, 'topometrical' refers to the process of metrication of the surface, derived from Cartesian co-ordinates, whereas 'topographical' is the graphical interpretation of the surface derived from the co-ordinates and interpreted by algorithms applied by the manufacturer's software used in their medical devices known as topographers.

**Summary of the Invention**

Aspects of the invention provide a method of fabricating a contact lens for an eye using scan data generated by a scanner, the scan data defining an ocular and/or corneal surface of the eye.

Aspects of the invention provide a method of fabricating a contact lens for an eye using scan data to form a posterior surface of the lens which is complimentary to the ocular surface of the eye.

Aspects of the present invention provide a method of generating topometric data defining an ocular surface of an eye for the fabrication of a contact lens

the method including taking a molded impression of an ocular surface of an eye.

Aspects of the present invention provide a method of generating topometric data defining an ocular surface of an eye for the fabrication of a contact lens the method including scanning a mold of an ocular surface of the eye.

Aspects of the present invention provide a lens having a posterior surface with support surfaces and with supported surfaces supported by the support surfaces to reduce and/or avoid mechanical contact between an ocular surface and supported surfaces in use.

One aspect of the present invention provides a method of generating data for use in fabricating a contact lens for an eye, the method comprising:

- generating posterior lens data defining a posterior lens surface for the lens to contact the eye, wherein the posterior lens data is generated dependent on ocular surface data generated by a scanner;

- generating anterior lens data defining an anterior surface for the lens to define optical properties for the lens, the anterior lens data generated dependent on the posterior surface data.

The surface data may be generated by scanning a mold or an ocular surface of the eye.

The posterior surface data may be generated dependent on the surface data and dependent on visual axis data associated with the ocular surface data and/or the mold. The axis data may be defined by the DICOM convention, amended to provide notation for two eyes and the polar conventions of the scan axes and the sphero-cylinder corrections for astigmatism.

The posterior surface data may be generated dependent on the surface data and dependent on rotation data associated with the surface data and/or the mold impression.

The visual axis data and/or rotation data may be suitable to enable scanned data taken from a mold impression of an ocular surface to be used with the visual axis data to generate posterior lens data oriented with respect to the ocular surface.

The posterior lens data may also be generated dependent on operator data and/or operator parameters input at an operator terminal to allow adjustment of the posterior surface defined for the lens.

The posterior lens data may conform to ocular surface data such that the posterior lens surface is operable in use to co-operate with the ocular surface. This co-operation may be mechanical cooperation.

The posterior lens surface may match the shape of the ocular surface.

The posterior lens surface may have support surfaces which contact the eye in use and supported surfaces formed in relief in the posterior lens surface and which are supported by the support surfaces.

The posterior-lens data may define a posterior surface with conduits formed in use between the lens and the eye to allow tear fluid to flow across the eye when the lens is in use.

The posterior-lens data may define areas in the posterior surface to support the lens on the eye, and/or restrain it from rotation, and/or support elevated areas use to allow the passage of tears and/or to minimise or avoid pressure on sensitive tissue.

The mold impression may be made by applying a molding material to an ocular surface.

The molding material may be polysiloxane.

The anterior optic zone surface data may be generated using ray tracing algorithms.

In another aspect the invention provides a method of fabricating a contact lens including the steps of:

- generating anterior lens data defining an anterior surface for the lens and posterior data defining a posterior surface for the lens, wherein one or more of the anterior and posterior data are generated dependent on surface data collected from the anterior surface of an eye; and

- controlling a machine using data and/or code generated dependent on the anterior and posterior lens data to form a lens.

In another aspect the invention provides a method of fabricating a contact lens for an eye, the method including generating posterior data defining a posterior surface for the lens;

- generating anterior lens data defining an anterior surface for the lens, wherein the anterior lens data is generated dependent on the posterior lens data.

The method as defined in one of the paragraphs above may include fabricating a lens having anterior and posterior surfaces defined by the anterior-surface data and the posterior surface data respectively.

In another aspect the invention provides a method of fabricating a contact lens for an eye, the method including generating posterior surface data defining a posterior surface for the lens;

- generating anterior lens data defining an anterior surface for the lens, wherein the anterior lens data is generated dependent on the posterior lens data and data and/or parameters defined at an operator interface to define one or more visual corrections to be made by the lens in use. The anterior lens data may be generated using ray tracing.

In another aspect the invention provides a method of fabricating a contact lens for an eye, the method comprising generating posterior surface data defining a posterior surface for the lens;

- generating anterior lens data defining an anterior surface for the contact lens, wherein the anterior lens data is generated dependent on the posterior lens data

and data and/or parameters defining location of the distribution of mass of the lens in relation to parts of the eye in use.

The anterior and/or posterior data may be generated in an STL format.

The data generated may be associated with visual axis data and/or parameters to adjust the position of the anterior and/or posterior surfaces whereby the surfaces may be oriented with respect to the ocular surface.

Other aspects of the invention provide a method of generating lens data suitable for controlling a machine to fabricate a contact lens, wherein the data is generated as defined in one of the paragraphs above.

Other embodiments comprise a method of fabricating a contact lens, the method comprising reading data generated as defined by one of the paragraphs above and controlling a fabrication machine dependent on the data read.

The machine may be a milling machine controlled using point-by-point data generated to represent a solid shape and generated dependent on the anterior surface data and the posterior surface data.

The data read may be in an STL format.

The data read may define points on a surface.

The data read may define a surface mesh.

In another aspect the invention may provide a system for generating data defining surfaces of a contact lens for an eye, the system comprising:

a scanned-data input for reading scanned data defining a corneal surface;

a design input for reading lens characteristic data defining one or more characteristics for the lens;

- a data generator operable to generate data defining the shape of the lens dependent on the scanned data and the lens characteristic data.

The lens characteristic data may define mass distribution characteristics for the lens.

The lens characteristic data may define visual correction characteristics for the lens.

The visual correction characteristics may include a lens power.

The anterior surface defined for the lens may include an optic zone and characteristics for the optic zone are defined in separate steps and/or independently to the rest of the anterior surface wherein optical characteristics may be defined for the optic zone and characteristics defining mass distribution and/or contact with the eye may be defined for the rest of the anterior surface.

Another aspect of the invention provides a method of generating data defining the shape of a contact lens to be fabricated, the method comprising receiving scanned-data collected by scanning a contact lens to define a base curvature. The method may include coating the lens with a material having optical properties suitable for scanning.

Another aspect of the present invention provides a contact lens fabricated using a machine controlled with data generated using data generated using a scanning apparatus and a mold impression of an ocular surface of an eye.

Another aspect of the present invention provides a contact lens fabricated by a machine controlled with data defining a shape having an anterior surface defined by data generated to define optical properties for the contact lens, the anterior surface data generated dependent on posterior data defining a posterior surface for the lens.

Aspects of the present invention provide a contact lens having one or more features formed in surface at the mid periphery of the lens to provide the basis for an opto-mechanical orientation tool to orient the lens for insertion.

Another aspect of the invention provides a method of generating ocular surface data, the method including:

- taking a mold impression of an ocular surface of the eye;

- scanning the mold impression to generate the ocular surface data.

Taking a mold may include taking visual axis measurements of the molding apparatus while positioned on the eye to calculate position adjustments for the ocular surface generated.

The method may include using a molding apparatus having an inner sleeve and an outer sleeve with an 'O' ring sealing the annulus between them.

The measurements may be made using a VAxis camera system.

The position adjustments may be defined using the amended DICOM axis convention.

In another aspect the invention provides a method of preparing a mold for use in fabricating a contact lens, the method including the steps of:

- taking a mold of an ocular surface of an eye, storing the mold in a cassette, storing in the cassette a medium carrying data defining visual axis data associated with the mold.

The method of preparing a mold may include forming a feature in the mold for use in orienting the mold rotationally, and storing the mold in the cassette so as to be aligned in the cassette by the feature.

The method may include storing the mold in a cassette having a window operable to allow the mold to be scanned while in the cassette.

Another aspect of the present invention provides an apparatus suitable for making a mold of an ocular surface of an eye, the apparatus including an inner sleeve and an outer sleeve and an evacuation conduit, the inner and outer sleeves operable to cooperate to seal against the ocular surface when a volume between the inner and outer sleeves is evacuated, the inner sleeve arranged to contain a molding material placed on the ocular surface.

Another aspect of the present invention provides speculum arranged to provide a working field with a dam projecting up to the upper orbital margin to hold

the lid-fold out of the way. The speculum may be plastic. The working field may be completely round.

Other aspects of the present invention comprise combinations of the features of the paragraphs above.

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**Brief Description of the Drawings**

**Figure 1** illustrates a **DICOM** axis convention and orientation, modified to provide for two eyes in one human body.

**Figure 2** illustrates an **Eyelid Speculum** for restraining the eyelids clear of the
10 operating field.

**Figure 3** illustrates a **V.Axis,** being the medical device for gathering parametric information relating to the positioning of the impression on the eye.

**Figure 4** illustrates the **V.Axis Controller,** the electrics and electronics driving and controlling the V.Axis.

15 **Figure 5** illustrates the **Impression Mold** for containing the impression of the eye.

**Figure 6** illustrates the **Impression Mold Gauge** for adjusting the fit of the mold on the eye.

**Figure 7** illustrates the evacuating **Hypodermic Syringe.**

20 **Figure 8** illustrates the **Sighting Device** for determining the relative position of the **Impression mold.**

**Figure 9** illustrates the **Sighting Device** positioned on the **Mold.**

**Figure 10** illustrates the **Camera view** of the **Sighting Device** positioned on the **Mold** and contained within the **Speculum.**

25 **Figure 11** illustrates the basic geometry for calculating the axes of the **Mold** relative to the **Visual Axis** of the eye.

**Figure 12** illustrates the **Dispensing Apparatus** for the Polysiloxane.

**Figure 13** illustrates the **Impression Cup** that contains the **Mold.**

**Figure 14** illustrates the order of assembly of the **Weight, Impression Cup, Mold & Speculum.**

**Figure 15** illustrates the **Cassette** that binds together the material relating to and data logged about the patient.

**Figure 16** illustrates a process for fabrication of a contact lens according to an embodiment of the present invention.

**Figure 17** illustrate various pathological conditions with which a contact lens according to an embodiment of the resent invention may be used;

**Figure 18** illustrates a cornea scarred through trauma with which a contact lens according to an embodiment of the recent invention may be used;

**Figure 19** illustrates a corneal graft with which a contact lens according to an embodiment of the recent invention may be used;

**Figure 20** illustrates a very thin graft with which a contact lens according to an embodiment of the recent invention may be used;

**Figure 21** illustrates the creation of a back optic zone according to an embodiment of the present invention;

**Figure 22** illustrates a graphical representation of separation of the posterior surface of the lens from the cornea;

**Figure 23** illustrates a simulated Fluorescein pattern of tears behind a lens;

**Figure 24** illustrates support areas of a contact lens according to an embodiment of the present invention;

**Figure 25** illustrates a surface image model of a contact lens according to an embodiment of the present invention with support areas and tear conduits formed between the lens and an eye;

**Figure 26** illustrates a colour representation of the posterior surface of a contact lens according to an embodiment of the present invention;

**Figure 27** illustrates a view through a contact lens according to an embodiment of the present invention;

**Figure 28** illustrates a system used to generate data for use in fabricating a lens according to an embodiment of the present invention.

**Figure 29** illustrates the V.Axis data that might be collected according to an embodiment of the present invention.

**Detailed Description**

An embodiment of the resent invention involving a system and process for the design and manufacture of therapeutic contact lenses will now be described. A scan is made of a polysiloxane impression of the ocular surface of an eye to generate an accurate surface model of the anterior of the eye. This surface, such model relating to the patient specific parametric data, is the foundation from which a posterior surface of the contact lens can be created. An anterior surface model can be structured subsequently to correct the vision, to optimise the mass distribution, or centroid position, of the lens and for wearer comfort.

Conventional cosmetic contact lenses fitted to regular, healthy eyes are manufactured to conform to surfaces that are regularly spherical, aspherical, and frequently associated with regular toricity to correct the visual error of astigmatism.

These regular corneal surfaces are almost universally fitted with hydrophilic – soft – lenses that are so flexible that they conform to every corneal irregularity. We are concerned with corneal irregularity because that affects the optical properties. Beyond the cornea, that is at the limbus, the lens may buckle. That may not alter the visual performance, providing the edges of the lens are not too tight, whereupon an 'oilcanning effect' occurs. Or the lens may be too, flat allowing the lens to slide around on the eye, distorting the an optic zone of the lens.

Therapeutic contact lenses are prescribed and fitted to eyes, not for cosmetic reasons, rather they correct the vision when the optics of the cornea is so corrupted that geometrical optics do not apply.

A therapeutic contact lens bridges the surface distortions of the cornea, sustaining the physiology by pooling the tears behind it. By positioning an optic zone in the centre of the lens over the visual axis of the eye, a new 'window to the world' is created.

A tear pool has a similar refractive index to the cornea and largely neutralises the corneal irregularities. There is enough difference however to cause higher aberrations that may be corrected with appropriate profiling of the front surface of a lens. For this reason it is undesirable for the lens to rotate or translate on the corneal surface, restrained by the bearing pads resting on the limbus. The other reason the lens should not move excessively is to avoid bumping on the edges of a graft and perhaps leading to rejection of the graft tissue.

Embodiments of the present invention supersedes conventional geometrical optics. Therefore, lens power cannot be measured with therapeutic lenses designed and manufactured in accordance with this embodiment of the invention.

Rather than stipulating dioptric lens power, the focus is determined by ray tracing to a point of convergence at the retina. It is desirable that at least a first order estimation is made of the vergence, regardless of the difficulty of assessing it subjectively when the eye is effectively blind. If this is not done, the first iteration of the lens could significantly deviate from the correct focus.

To calculate the focal convergence of the optic zone it is necessary to account for the refractive state of the eye, a function of the curve structures of the optic zone of the lens, the dimensions of the tear lens, the internal structures of the eye, including the lens and the axial length.

In a further embodiment a-scan ultrasound biometry may be a useful adjunct measurement as it defines the position of the retina, relative to the cornea.

A number of alternative strategies are available with the invention to provide an objective assessment of the refractive state in such an eye.

Some historical data may be available, knowing the parameters of a previously unsuccessful contact lens fitting, or the characteristics of the opposite eye providing by symmetry, an indication of the expected power range for use in designing a contact lens using ray tracing, for example.

In a further embodiment, even an ill-fitting, but stable trial contact lens may be placed on the anaesthetised, horizontal cornea and a portable auto-refractor or retinoscope used to obtain a result. Knowing the parameters of the trial lens, it is a simple translation from its parameters to imply the vergence of the therapeutic lens to be fabricated.

In a another embodiment, final 'tuning' of the lens focus will almost certainly be required and while fitting the initial manufactured lens to the patient, over refraction may be obtained and higher order aberrations determined by Wavefront Analysis. This information may be incorporated into the data for the front surface to define a revised matrix for ray tracing and a further lens fabricated to incorporate the modified vergences.

The structures of eyes requiring a therapeutic correction are frequently compromised by chronic disease such as atopia, graft rejection processes, corneal vascularisation, faulty tear constitution, accumulations of scar tissue, etc.

According to another embodiment of the present invention a therapeutic lens a lens has a posterior surface which includes support surfaces to support the lens beyond the corneal margin, on the sclera, and to support the lens with reduced, minimal or no contact with given parts of the eye. This allows the lens to avoid contact, or significant contact, with sensitive structures that might become inflamed, infected or further traumatised. To achieve a satisfactory outcome for the design, accurate representation of the surface is required, to a diameter of at least 16mm.

The prior art for measuring corneal surfaces is keratometry and more recently, topography. Keratometry measures only a small central area of the cornea.

Topography measures only exposed corneal surfaces, exposed in the sense that irregularities under the lids are not revealed unless they are retracted and hence no useful information is available for fitting the lens in those areas.

Topographical information is generally confined to a zone of approximately 10mm in diameter, so no information is available for the regions beyond the cornea. Information is usually lost from abrupt changes in contour, such as a setup in the margin of a graft, an area where it most needed for determining the fitting parameters. Finally topography is a graphical representation of the surface, not an absolute measure.

Embodiments of the present invention provide a system to generate an accurate surface model of the anterior eye, (such model relating to the patient specific parametric data) more properly described as Topometry with an order of accuracy of +/- 5mμ over an area of 16mm diameter more or less.

In one embodiment of the present inventions, a topometrical model or characterisation of the eye is achieved by optically scanning an impression made of the ocular surface molded from medical grade polysiloxane or any other biologically compatible material.

In one embodiment, the present invention provides a method for obtaining the polysiloxane impression of the ocular surface with the following steps. First, placing the patient in a supine position on a suitable portable bed with an adjustable head support. This position assists in relaxing the patient if they are anxious about the procedure and is very accessible for the practitioner. They also have to be very still for short periods for alignment and to allow the polysiloxane to cure. This material is a very viscous fluid with a suitable rheology for filling a slightly tilted mold, but it is helpful to maintain a near horizontal position during the process.

Next, reducing the sensitivity of the anterior eye with a local anaesthetic and retracting the lids to expose a circular working field of 20mm or less.

The eye is free to rotate under the retracted lids and it is necessary to locate the centre of the cornea as closely as possible to the centre of the working field to utilise the maximum area for the impression. The head should be tilted back, with neck extended, to maintain the gaze as vertical as possible. However for many aging patients full extension is not possible, because of loss of flexibility in the cervical spine.

The head should be comfortably positioned and to facilitate the alignment process the second aspect of the invention is to direct the patient towards an overhead camera device known as the V.axis that is fitted with fixation lights.

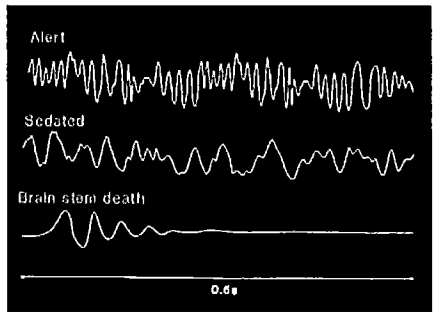
In one embodiment the motorised V.axis assembly travels in a 1m arc more or less, centred on the treated eye, with the patient following the fixation lights and the live-view of the camera monitored on the screen of the laptop controlling the apparatus.

When the eye appears centred within the working field of the Speculum, the V.axis is positioned correctly on the arc. However the camera may be adjusted to centre the image of the treated eye in the middle of the screen, with the alternate eye off to one side, by rotating it on gimbals under the control of a joystick, or in a further embodiment, using machine vision to automate the process.

Note, a camera viewfinder image is transmitted by software to the Laptop computer screen, enabling the operator to monitor the consequences of their control actions.

A picture is taken of the Purkinje images of the fixation lights in the cornea of both eyes. They represent the entry of the visual axes into the eyes with the fixation lights defining the other end of the axes. The line joining the Purkinje images on each eye is the base line, the X axis and the Visual Axes represent $Y_1$ & $Y_2$ of the DICOM convention. See Figure 1

Apart from the voluntary and reflexive movement of the eyes, a low amplitude,



oscillatory physiological movement is always present under the control of the extra-ocular muscles as illustrated in the diagram.

This movement confounds the absolute measurement of the surface contours unless the mold can follow the movement. For this reason the mold is positioned on the surface and centred within the working field of the speculum and held in position against the eye with a vacuum.

According to an embodiment of the present invention, the Impression mold is prepared by the following steps.

The appropriate sized mold is selected for an infant or adult eye and to accommodate the extent of the retraction of the lids.

The mold has an inner and outer sleeve with an 'O' ring sealing the annulus between them. The mold must be heat sterilised before use on the eye.

The annulus area on the lower face and in contact with the eye must be adjusted to follow the contour of the globe. Because the tissue, the conjunctiva, covering the eye is soft and loose, the choice of three positions of the sleeve are generally sufficient to seal on any eye.

In one embodiment, the sleeves are pressed against a flat sterilised surface to level the sleeves. The mold is then transferred to generally the middle of three sterilised domes to accommodate the average eye and the outer sleeve is slid down until it reaches resistance. The inner and outer sleeves will then be in a position that will seal against the eye.

A further drop of local anaesthetic is applied to the cornea with a drop of wetting solution as the cornea exposed by the Speculum is drying.

The mold is carefully centred within the working field of the Speculum and the annulus is evacuated by a spring loaded hypodermic syringe that is connected to it by a small bore silicone tube.

A further picture is taken of the position of the mold relative to the cornea diameter to register any offset using the VAxis.

The mold may be tilted on the eye and displaced in any axis by inaccurate positioning or traumatised anatomy. To register the tilt that will be translated into the impression, a further aspect of the present invention is the Sighting Gauge.

In one embodiment the geometry of the Sighting Gauge is known and when mounted on the mold, it tilts in sympathy with it. A flash illuminated picture is taken of the mold/sighting-gauge assembly. The Sighting Gauge is then removed from the mold.

The picture of the assembly is imported into a graphics programme and the centre of the top ring of the Gauge located and marked. The bottom of the Gauge is defined by four pointed pins, of which only three may be visible through the top ring because of the tilt. However the lines joining the pins provides a geometrical centre for the bottom ring and knowing the distance between the two rings and the position of the centres, the tilt angles can be calculated.

The next stage of the process is to obtain the impression. Dental impressions are routinely taken with polysiloxane of different rheologies and viscosities. For the purposes of the embodiments, the lowest viscosity is used as the mold is horizontal and contains the material. It is also important to ensure that the impression is bubble free and laying the material into the mold takes some practice by the practitioner. The polysiloxane is a two pot mixture and the product and its curing agent is mixed only at the last minute as it has a temperature dependant curing time of less than two minutes.

Impressions with polysiloxane have been determined to be accurate within one micron resolution. Subsequent scanning will generally be resolved to a lower order, but always more than adequate for the process of the lens design is described by the invention.

The preparation and application of the polysiloxane mixture according to an embodiment of the invention will now be described.

The cartridge of the material is loaded into a dispenser gun and a small quantity is injected into the mixer syringe. The plunger is inserted into the mixer, and the mixer is fitted into a Dispenser, described below. The Dispenser is not actuated however until the practitioner is ready to begin injecting the mixture into the mold.

Dispensing the mixture directly from the mixer into the mold is difficult.

The hand is under tension while depressing the plunger which limits dexterity.

The mold is circular and the overhang of the walls requires a $360^0$ approach to lay the material into the corner of the mold and the globe to ensure that no air is trapped at the edge, while taking care not to traumatise the eye with the delivery end of the mixer.

The position of the patient on the bed and the medical devices surrounding them prevents approach to the eye from all directions.

The inner sleeve contains the molding material poured onto the ocular surface of the eye.

The mold is a cylinder and as the mixture is viscous, has a high rheology, and does not flow easily into the angle formed at the base of the cylinder. The loose conjunctival tissue tends to well-up, further closing the angle trapping air bubbles, These can be minimised carefully pushing the immersed nozzle against the material, while trying to avoid traumatising the eye by pushing too deep. It is very difficult to judge the depth , as the nozzle is out of view and only about 1mm from the eye.

A silicone extension tube is connected to the mixer syringe and a switch on the face of the nozzle allows the practitioner control the flow of material, while flowing it around the mold reaching into the corners.

The mixer is fitted into mechanical geared motor Dispenser switched from the tip of the outlet nozzle and under the control of the practitioner to deliver metered quantities of the mixed product to be laid progressively into the mold cavity.

In a further embodiment, and following the introduction of Polysiloxane into the mold, an impression cup is gently pressed into the surface causing the material to flow into relief channels. A small weight is placed over the stem of the Cup to gently depress it into the mold. The weight is removed and a small dab of the mixture applied to a nearby surface is monitored for curing.

While the mixture is curing, a further picture is taken by the V.axis camera of the rear surface of the impression cup to record the position of an indentation in the rim. This will be noted as an angle to the X axis of the DICOM convention to and subsequently the correction will be applied to either the $P_2\beta$ or $P_1\alpha$ angles.

When the material is firm, the hypodermic syringe is actuated to release the vacuum and the mold gently removed from the surface.

A drop of artificial tears is applied to the corneal surface.

The Speculum is removed from the lids.

Conventional lid speculae usually fail to hold the fold of tissue from the upper lid from intruding into the working field. In a further embodiment the present invention features a unique plastic speculum providing a completely circular working field with a dam projecting up to the upper orbital margin to hold the lid-fold out of the way.

Corneal trauma may be associated with internal trauma of the eye. The iris may be torn and the eye aphakic, after removal of a traumatic cataract. For the successful fitting of a traumatised eye it is important to consider all of the optical, machining, and physical parameters of the eye. The pupil maybe displaced away from the optical axis, the cornea tilted and some areas of the eye may not support the pressure of the lens. The Bureau must take all of these factors into account in the design, seeking advice from the practitioner and utilising all of the dimensional data provided.

For patients with comorbidity issues, the practitioner may direct the Bureau to avoid supporting the lens on specific areas of the eye. However if there are a

number of therapeutic options for the fitting, the Bureau may consult with the practitioner to decide how to proceed and agree which design should be forwarded to the laboratory for manufacture. By using bearing areas, an attempt is made to control the pressure distribution and support the lens away from critical areas at the same time as restricting the tendency of the lens to rotate. If it does rotate, ray traces are misaligned.

This mass of data should be retained by the patient as well as by their practitioner in the event that they are travelling and require subsequent treatment or a replacement lens.

According to this embodiment of the invention all of data is retained in association with the impression by the use of a Cassette.

The impression cup is carefully withdrawn from the mold and immediately inserted into the receptacle of the cassette ensuring that the registration indentation on the rim is located on the pin of the holder.

The Cassette is physically marked with a patient ID on the outside for quick reference.

In another embodiment in the base of the Cassette there is inserted a USB – MicroSD adapter with the USB plug projecting from the side. This allows all of the data from the controlling laptop computer, plus pictures to be loaded onto the MicroSD.

The practitioner's current role is completed at this point and the Cassette is forwarded to the Bureau to analyse the data, relating it to the surface model derived from a scan of the impression.

The Bureau processes the data on the Cassette and scans the impression to characterise the ocular surface of the eye, or to get a topometrical model of the ocular surface of the eye. This model may also be referred to as a surface model.

The surface model derived from scanning of the impression becomes the foundation for the expert Bureau practitioner to generate the posterior surface

of the contact lens incorporating features for bearing the pressure, promoting tear circulation and providing a refractive interface in the optic zone.

In a further embodiment an anterior surface model is subsequently structured to correct the vision, to optimise the mass distribution, or centroid position of the lens and to ensure wearer comfort with a satisfactory edge design.

All of these developments are calculated to create the solid model of the lens design using ray tracing algorithms as will be known to the skilled reader. In the case of the present embodiment, the ray tracing algorithms assume a posterior surface of the contact lens defined by the surface model of the eye. In this particular embodiment the posterior surface of the lens used for ray tracing is adjusted for elevation or support of the optic zone away from the eye as supported by support surfaces formed on the posterior surface of the lens.

In a further embodiment the traditional methods of manufacture utilising combinations of spherical, aspherical, and conic surfaces are abandoned; instead the present invention provides a point by point manufacturing process capable of contouring almost any corneal surface irregularity or suspending or locating the lens above or away from given irregularities or sensitive areas.

An exception is the back surface optic zone of the lens. In this embodiment of the present invention a regular geometrical surface is retained using either a spherical or toroidal contour to simplify the calculation of the vergence.

However by relaxing the constraints of the prior art that uses elliptical geometry, the present invention provides increased flexibility by applying any toroidal surface including sections from ellipses, oblate or prolate spheroids and toruses, as well as tilting and rotating them if necessary for optimum tear film clearance.

In this embodiment, the lens solid model surfaces must be converted into Lathe type specific machine code and/or data for manufacture and integrated with laboratory intelligence regarding the materials being used, the design of the diamond cutting tools, etc.

Data such as the surface model of the ocular surface, captured by scanning the mold, V.axis data and other data which may be added by the practitioner are logged into MicroSD in the cassette and emailed to the manufacturing laboratory with the lens order.

A process according to an embodiment of the present invention by which the lens is custom designed will now be described.

A first step is optimisation of the posterior and anterior optical zones of the lens for fit and optical properties, regardless of the degree or form of tissue distortion.

The next step is seamless linking of the optical to the peripheral zones of the lens enabling the posterior surface of the lens at every point to be adjusted for clearance from, or weight bearing on the eye surface. This involved the expert defining surfaces to contact with the eye and support the contact lens and other surfaces which are generally recessed and which are supported by the supporting surfaces. This allows clearance and optimisation of the weight distribution as well as allowing the recessed or supported surfaces to define conduits for movement of tear fluid across the eye.

The next step is optimising the anterior surface contours for lens thickness to minimise lid resistance and to position the centroid either at the geometric centre or to provide prism ballast. This custom design concept departs from the traditional methodology, of fitting from a trial lens set of a proprietary design lenses, providing a limited range of fitting options.

In a further aspect the Laboratory must manufacture the lenses introducing the files prepared by the Bureau for point by point control of the manufacturing process.

In one embodiment, the lathe tooling must be setup with a specially designed diamond with clearance rakes to cope with angles of attack required for sloping surfaces similar to the surfaces observed in the surface models for the ocular surface or the posterior surface of the lens.

These tools must be very sharp to finely finish the irregular surfaces so they require minimal supplementary polishing. With the lack of support to the cutting edge, they become blunt more quickly than with a normal tool and need to be more frequently replaced.

The manufacturing files, including the lathe settings, batch numbers for the lens blanks, are loaded by the laboratory onto the cassette.

The completed lens along with the cassette is returned to the Bureau for verification of quality.

In one embodiment, the lens is received at the Bureau and sprayed with a Titanium Oxide suspension that is reflective to the scanner. The file generated by the scan is compared to the original surface files to ensure that the lens is within acceptable manufacturing standards.

The lens is forwarded to the Practitioner to be trialled or dispensed to the Patient.

In one embodiment the fitting of the lens is assessed after a settling period, by standard optometric practice, including the:

- response of the patient to the comfort of the lens,
- stability of the lens on the surface in all directions of gaze,
- slit-lamp microscope observation for ingress of air under the edge, compression of tissue,
- installation of Sodium Fluorescein excited by cobalt blue or UV illumination, to observe the tear flow and pressure distribution;
- vision constancy with eye or associated lens movement;
- conventional optical over refraction that can be expressed in vergence terms and summated with the original focus to provide a new retinal plane reference
- wavefront analysis if indicated because of the presence of significant higher order aberrations.

In a further embodiment this process may be repeated more than once to refine the lens design, with the additional information loaded into the Cassette and forwarded to the Bureau for re-working into a revised lens design.

In a further aspect the Patient is instructed in the care and handling of the lens. Given that they are visually impaired before the lens is inserted and assistance may not be available to assist them, a technology solution is a component of the present invention.

In one embodiment the lens is placed convex side up on a small battery powered turntable of a device known as a L.axis.

At the touch of a switch the turntable rotates the lens until a beam of light emitted by either a laser of LED passes through either one or two lenslets machined into the front surface.

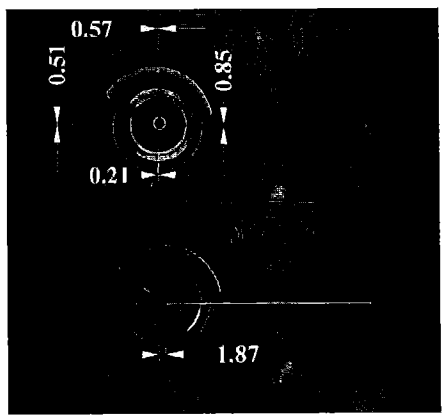
The effect of the lenslet is to focus the image onto a sensor that responds and switches off the rotation, stopping the lens at the correct position for the lens to be lifted forward and onto the eye.

At the time the sensor is activated, one of two pitches of sound will heard that will indicate whether the lens is a L or a R.

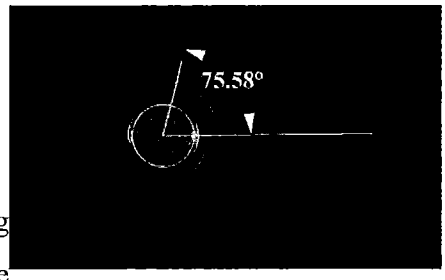
In a further embodiment, the light emission source is moved aside and a suction holder on an hinged arm is swung forward and down onto the convex surface of the lens. The arm is retracted to an angle of more or less $45^0$ whereupon the patient reaches forward and gripping the base of the suction holder between the forefinger and thumb, extracts it from the mount and taking care not to rotate it, places it on the cornea.

To ensure that the geometry of the lens is correctly positioned on the cornea and as far as possible centering the optical zone with the Visual Axis [VAX], the invention enables an accurate assessment of the VAX of the eye in relation to the DICOM convention.

The following diagrams illustrate measurements that are derived from photographs taken with the V.axis camera.



From these data the coordinates for the modified DICOM convention can be determined.




The DICOM convention is feasible with a variety of strategies, even if patient is unable to assist in the process by virtue of the fact that they are technically blind. In association with the process of determining the VAX, the geometrical parameters of the eye are also defined to provide the constraints for the manufacturing process.

The analysis of the spatial information enables the complex calculations required for machining what might be an highly irregular contact lens design that requires specific location on the eye for a satisfactory visual outcome.

In order that the invention may be more readily understood and so that further features thereof will be appreciated, a preferred embodiment of the process and system will now be described, by way of example only, with reference to the accompanying drawings.

**Figure 1** The Axis Convention and DICOM – Orientation Compliant

A modified DICOM axis system, has been adopted. It is widely used by the medical fraternity, particularly with radiological recording, however as two eyes are involved and the DICOM system applies to one human body, the convention has been adapted by linking the eyes by a common X axis.

Overlaying the convention are two further axes originating from the node of the Cartesian co-ordinates. These axes use ophthalmic polar conventions to describe the optical properties of the lens system and the parameters of the optical zone.

Figure 1 illustrates the relationship of the invention to the human body in terms of spatial co-ordinates. The axes are as follows:

X axis joins the Optical Axes.

Y1 is Left Optical Axis

Y2 is Right Optical Axis

Z1 & Z2 are normal to the Optical Axes

P1 & P2 are the Polar (Machining) axes and are unlikely to be in the same plane for each eye. They pass through the Cartesian node, but are defined by specific altitude angle ($P_1\alpha$ & $P_2\alpha$) to the $Y_1$ & $Y_2$ axes.

The P1 & P2 Polar (Machining) axes are described in the Y – Z plane at an azimuth angle to the X axis from 0 to 360 deg with the origin (Zero) on R side. ($P_1\beta$ & $P_2\beta$ )

Astigmatism axis is defined by Ophthalmic convention from 0 to 180 deg with the origin (zero) on the R side.

**Figure 2** Speculum

With reference to Figure 2, the Aperture 1 in the centre of the Speculum provides a view of the anterior eye, while a Dam 2 restrains folds of upper eyelid tissue from encroaching on the Aperture 1.

The projecting Skirt 3 is entrapped by the upper lid, while the lower lid covers the lessor projection of the Skirt 4. Both the upper and lower lids contract into the Groove 5, firmly holding the Speculum in place.

**Figure 3** V.Axis

With reference to Figure 3[1] &[2], the V.Axis camera assembly is supported by an Arm 6 anchored above the bed. The V.Axis camera assembly follows a Rail 8 with an arc of 1M more or less, centred on either the R or the L eye. Driven by a Geared Motor 10 engaging on a Pinion Rack 11, a Carriage 9

follows the Rail 8 to direct the Camera 12 through a range of angles of presentation to the eye.

With the Patient fixating on Lights surrounding the objective of the Camera 12, the V.axis carriage 9 must be positioned optimally on the Rail 8, followed by rotation of the Gimbal 13, driven by a Stepper Motor 14 and Gimbal 15 driven by a Stepper Motor 16 to locate the image of the working field of the Speculum as close as possible to the centre of the Camera field.

With the image of the eye as near as possible to the centre of the Speculum, the magnification setting of the Zoom lens must be adjusted to present the image of the alternate eye near the periphery of the screen.

In one embodiment the Gimbal assembly 13 & !5 may be anchored to a motor driven Slew Drive 19 to align the position of the eyes as close as possible to the X axis of the DICOM convention - Figure 1.

Supporting the Gimbals are Stays 17 anchored to the Translation Beam 18 that transfers the assembly to direct it over the R or the L eye. The Translation Beam 18 may either be manually manipulated or in a further embodiment, driven along its axis by a geared reduction motor.

**Figure 4.** V.Axis Controller

All drive motors and the fixation lights are under the control of the V.Axis Controller.

The Camera Controller 20 is a joystick with three degrees of freedom. It can be moved horizontally to control the Gimbal Y axis 21 and vertically to control the Gimbal X axis 22. Rotating the Joystick slews the Camera 12.

Pressing the three position self centering Camera Switch 24 away from the operator towards the Out Position 25 drives the V.axis carriage drive motor 10 further around the arc towards the patient's feet.

Operating Camera switch 24 towards the In Position 26 drives the V.axis Carriage Drive motor 10 towards the patient's head.

Operating the three position self centering Eye Selector switch 27 translates the assembly along the Beam Fig 3 [18] for the R Eye 28, or the L eye 29.

The Fixation Lights 13 are switched on or off by operating the Control 30.

**Figure 5.** Impression Mold

Impression Molds are manufactured in a range of sizes to treat eyes of babies through to adult dimensions.

The Mold comprises two principle components, the Outer Sleeve 31 and the Inner Sleeve 32.

The Outer Sleeve 31 has a Spigot 33 sealed into the shoulder that communicates through a Port 34 to the inner surface of the Outer Sleeve 31.

The outer surface of the Inner Sleeve 32 is sealed onto the inner surface of the Outer Sleeve 31, by an 'O' ring 35 allowing the two sleeves to slide one within the other and creating on the lower face an annulus 36 between them to seal onto the eye.

To follow the contour of the eye the Inner Sleeve 32 must be retracted a suitable amount to provide more or less contact pressure on the edges of the Mold. The loose conjunctival tissue on which the annulus rests allows the assembly to bed in and vacuum seal the Impression Mold 37 onto the eye.

**Figure 6** Impression Mold Gauge

To adjust the Annulus 36 depth by retracting of the Inner Sleeve 32 against the Outer Sleeve 31 of the Impression Mold 37, it is pressed against the appropriate Dome for a Small 38, Medium 39, or Large 40 eye. Although the Impression Mold 37 is sterilised by heat, to prevent transfer or organisms

between patients, safety is not compromised if the domes are asepticised with Isopropyl Alcohol wipes, since in fact the human eye and ocular adnexa is not sterile throughout the procedure.

**Figure 7** Vacuum Syringe

To evacuate the Annulus 36, a Hypodermic Syringe is fitted with a Spring 41 under the Plunger Grip 42. When the Plunger Grip 42 is depressed, air is expressed out of the Barrel 43 through the Silicone Tube 44 that is connected to the Impression Mold 37.

When the Impression Mold 37 is placed on the eye and the Spring 41 loaded Plunger 42 released, a vacuum is created in the Barrel 43 and the air drawn through the Silicone Tube 44, evacuating the Annulus 36 and anchoring the Impression Mold 37 to the eye.

A photograph is taken by the V.axis focussed on the cornea and the Purkinje image representing the origin of the Visual Axis.

**Figure 8** Sighting Gauge

The Sighting Gauge is manufactured from Titanium for lightness when resting on the apparatus anchored to the eye.

The location of the eye within the field exposed in the Aperture 1 of the Speculum Fig 2 is discussed in the paragraph Fig 3. above describing the V.Axis and the location of the Camera 12. When the Impression Mold 37 is placed on the eye it must be centred as far as possible in the middle of the Aperture 1 of the Speculum Fig 2, to allow a little 'float' for minor eye movement.

When in position, the axis of the Impression Mold 37 is unlikely to be co-axial with the Visual Axis of the eye, and the deviation between them must be determined to provide a reference for the co-ordinates of the Impression.

The Sighting Gauge provides a magnified reference to the position of the Impression Mold 37 relative to the Visible Iris Diameter of the eye and the location of the Purkinje image.

The view of the V.axis camera, more or less down the axis of the Sighting Gauge, focuses on an Upper Ring 45 and through its aperture and at a known distance below it, also images at least three Reference Points 46 to the centre of the Bottom Ring 47 of the Gauge.

Whereas the tilt and axis of the Sighting Gauge could be determined if the complete Bottom Ring 47 could be observed, part of it is usually hidden and the only three of the Reference Points 46 need to be observed to find the centre of the ring.

**Figure 9** Sighting Gauge on Impression Mold

The Turned Shoulder 48 closely fits inside the Inner Sleeve 32 of the Impression Mold 37 and rests on top of it, assuming the same axis.

**Figure 10** Camera view of the Sighting Gauge on the Mold

The Upper Ring 45 is seen from the Camera 12 perspective and through the aperture, the Reference Points 46 locate the centre of the Bottom Ring 47 of the Gauge. The whole assembly is located within the Speculum 48. Through the gap between the Reference Points 46, the Purkinje image can be seen in the cornea and a flash photograph of the assembly provides all of the information for the subsequent analysis.

**Figure 11** Model of Geometry for Axis Determination

Geometric calculations are undertaken with an understanding of the relationships between the components.

**Figure 12 Dispensing Apparatus for the Polysiloxane.**

Medical grade Polysiloxane is loaded into a dispenser, then injected into the Mixer Syringe 49. The Plunger 50, driven by a geared reduction motor 50A, driving a lead screw 50B forces the two active ingredients through a Mixer Tube 51 and into a silicone Delivery tube 52. The motor driven lead screw is actuated by a fingertip control 52A at the nozzle.

The Practitioner must lay the polysiloxane into the Impression Mold 37 until the dispenser is empty. Care must be taken not to traumatise the eye with the nozzle, or entrap bubbles of air under the mixture resulting in a loss of data.

**Figure 13** The Impression Cup

To provide a permanent receptacle for the impression, an Impression Cup 53 is gently pressed down into the mixture until the shoulder reaches the limit of travel against the top of the Impression Mold 37.

As the pressure on the Impression Cup 53 increases the Intra Ocular Pressure [IOP] within the eye possibly distorting the corneal surface, care must be taken to proceed cautiously and slowly by placing a small Weight Fig14:58 on the Stem 54. When the Impression Cup 53 reaches the limit of its travel, the Weight Fig14:58 is carefully removed. This allows equilibrium to be restored between the IOP and the external forces before curing is completed.

Excess Polysiloxane wells up through the Relief Passages 55, but they also provide an anchor for the material that molds the cornea within the Hollow 56 in the front of the Impression Cup 53.

The reaction time between the active ingredients is dependent upon it's temperature, but generally it will cure in under 2 mins.

The Indentation 57 in the rim of the Impression Cup 53 provides a polar reference co-ordinate relative to the X axis of the DICOM axes Figure 1.

While waiting for curing to occur, a photograph is taken of the rear of the Impression Cup 53 and the image of the Indentation 57 is overlaid on the images processed to determine the DICOM coordinates. The angle of rotation of the Impression Cup 53 is then allowed for when processing the surface model obtained from the Impression. See diagram below:

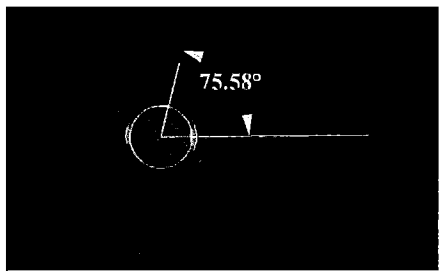



**Figure 14** Order of Assembly of Components.

The order of assembly of the components is illustrated with the Weight 58 placed over the Stem 54 of the Impression Cup 53 that has been lowered into the Impression Mold 37, held in place by vacuum within the Speculum 48.

When curing is complete and the vacuum released, the Impression Mold 37, retaining the Impression Cup 53 is lifted clear of the eye and the Speculum 48 removed from the eyelids.

**Figure 15** Cassette

To ensure that the historical and current data relating to the patient is linked immediately to an impression cup that has no identification, it is inserted into a Cassette.

The Cassette comprises plastic layers and components that clip together to encapsulate all of the data including the Impression Cup 53.

The Base 61 retains a USB – MicroSD Adapter 62 that is cemented within. While transferring data, the projecting USB Connector 62 is connected to the

Laptop controlling the Examination equipment, including the V.axis and Camera 12.

A MicroSD memory device is plugged into the USB Connector 62 and has sufficient capacity to accumulate the data produced by the analysis of the surfaces, files generated in the lens design process, and the manufacturing files. These data are retained by the patient to enable future lenses to be produced as replacements due to loss or change in fitting or vision.

A Retention Shell 64 encloses the USB Connector 62 and provides the base for Impression Cup 53, now loaded with the Polysiloxane Impression. A pin on the Shell locates the Indentation 57 on the Impression Cup 53 and aligns it with the rear face of the Cassette.

While scanning the Impression in the Cup retained within the Cassette, the clamp in the scanner aligns with the Rear Face of the Cassette to prevent any ambiguity about the polar co-ordinate of the impression.

To retain the Impression Cup 53 in the Retention Shell 64, a rotationally located Cover 65 encases the barrel allowing the impression to project through. This projection is protected by a Guard Ring 66.

Finally a Cover 67 encases the top of the Cassette protecting the top of the impression and locking the assembly together.

The patient's unique identifier is labelled on the outside panel.

For optical scanning of the impression and to obtain a surface model, the Cover 67 is removed and the whole Cassette is clamped into the Scanner.

**Figure 16** Process Flow Diagram

An overview of the process of fabricating a contact lens will now be described with reference to Figure 16.

At step 16-1 the patient is placed in a supine position.

At step 16-2 the Lids of the patient are separated with a speculum.

At step 16-3 the molding apparatus is rested on the sclera of the patient's eye centred in the space exposed by the speculum and the annulus between inner and outer sleeves of the mold is evacuated using a syringe.

At step 16-4 V axis device is centred above the eye and a photograph taken to determine the visual axis of the eye relative to the position of the molding apparatus.

At step 16-5 with the Sighting Gauge positioned on the face of the mold, a further photograph is taken through the Sighting Gauge to reference any displacement of the mold from the axis of the eye.

At step 16-6 a corneal trial lens is positioned to determine ammetropia.

At step 16-7 polysiloxane is injected into the mold.

At step 16-8 an impression cup is lowered into the polysiloxane molding apparatus.

At step 16-9 the V axis device photographs the polar axis of the impression cup.

At step 16-10 the vacuum is released and the molding apparatus is withdrawn from the aperture formed by the speculum.

At step 16-11 the speculum is removed from the eyelids.

At step 16-12 the impression cup is removed from the molding apparatus and the impression or mold is attached to the data cassette, which also contains the Vaxis data collected in steps 16-4, 16-5 and 16-9 and is stored in the storage medium associated with the cassette.

At step 16-13 the practitioner checks that all relevant patient history and management information is stored in the storage medium associated with the cassette.

At step 16-14 the practitioner forwards the cassette to the Bureau

At step 16-15 the cover is removed from the casette at the bureau and it is clamped in the Scanner holder.

At step 16-16 the impression is scanned and the data is stitched and compiled into a &*.stl file.

At step 16-17 the *.stl file is loaded into a surface modelling program and a model of the cornea or surface of the eye is generated resulting in scan data defining a surface matching the ocular surface of the eye.

At step 16-18 posterior surface data defining a posterior surface for the lens is generated and anterior surface data defining an anterior surface is generated to provide optical properties for the visual correction and the mass of the lens.

At step 16-19 a solid model of the lens is generated from the surface data and the centroid of the lens is located at the geometrical centre or just below the geometrical centre if 'prism' ballast is required to bias any rotation of the lens towards a particular axis. The location of the centroid is achieved by an iterative process of modification of the front surface to modify the distribution of mass

At step 16-20 the surface data is converted into machine code and/or data to drive or control a CNC machine, such as a lathe or mill.

At step 16-21 the CNC code is stored in the storage medium associated with the cassette.

At step 16-22 the laboratory sets up data for the CNC machine and material parameters of the lens.

At step 16-23 the lens is fabricated, manufactured, machined and returned to the Bureau.

At step 16-24 the finished lens is scanned for quality control, compared at step 16-21 to the model of the lens passed or failed, with fail information being stored on the medium associated with the cassette.

At step 16-25 if the lens meets the quality control standard it is returned to the practitioner,

At step 16-26 it is fitted to the patient. It is determined whether the fit is satisfactory and if not, what modifications will be necessary. This information is stored on the medium associated with the cassette.

At step 16-27 an over refraction is made of the settled lens on the patient's eye. This information is stored on the medium associated with the cassette.

At step 16-28 if any amendments to the design or refraction of the lens are required the Cassette containing the requisite information stored on the medium associated with it, is passed to the bureau for redevelopment of the surface data at another iteration of step 16-16.

At step 16-29 if it is determined that there is remaining over refraction or a fitting intolerance step 16-16 is reiterated. Otherwise the lens is dispensed to the patient.

Embodiments of the invention and design considerations for the optic zone of the contact lens, will now be described with reference to Figures 17 to 31.

An eye may be defocused from $2^{nd}$ order optical conditions – Spherical; myopia, hyperopia or aphakia & astigmatic – regular or irregular; lenticular or corneal.

If the astigmatism is regular and corneal, generally the term used is with the rule [horizontal = $180^0$]. As it is a shape factor, the toric surface may be inherited.

If the astigmatism is regular and lenticular, the axis is often against the rule [vertical = $90^0$].

Irregular astigmatism is generally associated with higher order aberrations resulting from pathological conditions, grafts or trauma – see Figure 17 illustrating various ectasic pathologies.

Note the centre of the cone (red) with Keratoconus is decentred approximately 3mm below the pupil. This will cause the lens to drop over the peak of the cone, inducing tilt/residual astigmatism. Spectacles may be worn over the top of the lens to correct the remaining error.

Figure 19 illustrates at a very early post-operative stage, a corneal graft stitched into the host cornea. The stitches holding it in place can be clearly seen. In time scar tissue forms at the junction and after a year or two the stitches are removed.

Graft buttons are frequently:

- not inserted in the centre of the cornea,
- may be tilted or are distorted out of shape by scarring
- puckered around the perimeter from the stitches
- distorted by uneven tension on the stitches
- even more distorted when relaxation occurs following removal of stitches

A graft may be recessed below the host, See Figure 20, or projecting out of the host. Both situations present a challenge of fitting, bubbles can form behind the lens spanning the recessed graft and lenses 'fall off' projecting grafts.

An attempt is always made to refract these distortions but frequently it results in high amounts of astigmatism power and correction with a spectacle correction lens may induce intolerable perceptual problems. Ghost images are common and night vision may be very poor.

A scarred cornea illustrated in Figure 20 may be likened to fitting a mountain range and erosion of the peaks from heavy pressure from the lens may lead to pain and infection.

Attempts to treat these conditions with therapeutic lenses designed and manufactured using the prior art may or may not be successful, usually

because the fitting them is by trial and error.

Embodiments of the present invention provides a repeatable method to construct back surfaces in any format to bridge these distortions and most of these challenges will be readily resolved.

Optical properties of a lens in accordance with an embodiment of the present invention will now be described. If the cornea is distorted, the refractive state of the eye is not able to be determined by refracting through it's surface. The problem for the practitioner is to estimate the starting point for the therapeutic lens refractive power. However there are frequently clues about condition of the eyes.

Many ectasic conditions such as those illustrated in Figure 17 may not be evident until the second or third decade of life, so historical data about their vision may be available.

If the patient has been adventitiously visually impaired from trauma, See Figure 18, historical information also may be available about their spectacle refraction.

If they have previously been a contact lens wearer before a graft, the expected refraction nay be adduced if the base curve optic radius of the lens and if the power in air is known.

If they belong to a particular ethnicity, e.g. Hong Kong Chinese they have very high chance of being myopic to the order of -5D [approx 85%].

A measurement of the refractive state may be determined by resting a contact lens on the eye that has been anaesthetised to supress tears and prevent discomfort from what is likely to be an ill-fitting lens.

An ill-fitting lens may still provide very useful data however as the patient is supine during the procedure, and providing the lens base curve optic radius conforms closely enough to the surface not to allow a bubble to form behind it, it is possible to objectively refract through it.

This may be performed with a portable refractometer or using retinoscopy. It is not practical to carry out a subjective refraction as it is too time consuming and impractical to balance lenses that are unstable in a trial frame cell in the horizontal position.

A further idea to be investigated is to fill the impression mold with saline. The fluid would neutralise all of the corneal imperfections and present a plano surface for refraction. As approximately 47D of normal corneal power would be removed from the refractive equation, some form of relay lens would have to be introduced to bring the refraction back into range.

Topography may provide average radii of curvature in the pupil area of the cornea, from which the power contribution of the cornea may be roughly assumed.

Design of the Optic Zone (OZ) of a lens according to an embodiment of the present invention will now be described.

At the outset of the design process when a 'fit' for the optic zone is being determined using surface modelling, the difference between this geometry and the topographical estimation will noted.

To simplify the starting point for the optical design process, surface models with geometric shapes have been overlaid to generate a toroidal format. These include sections from the equator of the ellipse, spheroids and torus.

They may be tested by a custom surface modelling programme that illustrates the conformation of the surface with the underlying corneal irregularities. See Figure 22. The space between the OZ and the underlying corneal surface is represented by the size of the white dots. They are dimensioned such, that when they are large enough to touch, the sagital depth is 200mμ. It is obvious from the representation in Figure 22 that an increase in toricity is required, sloping $15^0$ to the left for better conformation. Figure 23 illustrates a different representation simulating the more traditional picture of sodium fluorescein introduced in the tears. Where it is black, the sagital depth is in excess of 200mμ and it is likely that bubbles will form behind the lens. Adjustment to

the surface geometry is required.

A profile of the Optic Zone (OZ) suspended over the surface model of the cornea and spaced to allow tear flow is illustrated in Figure 21. The OZ is centred on a machining axis at an angle above the horizontal line to be over the pupil.

There are up to 7 axes used at various stages of the design and manufacturing process and all are derived from the DICOM convention. See Figure 1.

The peripheral design of the lens according to an embodiment of the invention will now be described.

To treat conditions where corneal lenses are unstable, larger diameter lenses from 13.5 to 16mm diameter or even larger are used. These are known as semi scleral or scleral lenses.

These lens designs have the advantage of providing support from the outer margins of the cornea and onto the sclera itself, tissue that is only as sensitive as skin, unlike the cornea that, being a very vulnerable organ, is well protected by pain receptors.

The peripheral design for the lens extends from the OZ tangentially blended along axes that follow the irregular contours of the corneal surface and feature zones for support, with channels between to promote tear flow. The radials are lofted to create a blended continuous surface.

Support Zones may be three or more to stabilise the lens, stopping it from rotating on the eye and preventing contact with sensitive tissue by the lens.

Figure 24:100 illustrates three zones outside the injury to hold the lens away from the peaks of tissue.

Figure 25 is a more conventional design where the four pads 102 support the lens, and are separated by tear channels 100. The OZ is centred over a graft represented by the ring 101.

Figure 26 graphically illustrates the irregularity of the rear surface of the lens surrounding the OZ.

Figure 27 shows a distorted view through the irregular surface generated to follow the irregularities of the corneal surface. Two lenslets 102 cut into the surface provide a disruptive optical pathway for the L.axis device that provides a mechanism for orienting the lens for insertion on axis into the eye and also to indicate whether it is a R [one lenslet] or L [to lenslets].

A further embodiment of the present invention will now be described in reference to Figure 28.

A scanner 201 scans an impression mold 202 from within a cassette 203. The same cassette has a storage medium storing V.axis data associated with the impression mold 202. The cassette receives the impression mold with a unique rotation so the scanner scans the mold as it was oriented rotationally with respect to the eye, as described above.

The medium 204 is read by a reader 205 which sends V.axis data 206 to a posterior surface module 207. The module 207 of this embodiment is a software module running on a computer, not shown.

The scanner 201 sends corresponding scan data 208 to the posterior surface module.

A Graphical User Interface (GUI) 209 receives inputs from an operator, not shown, to adjust the posterior surface of a lens to be fabricated. In this embodiment the Posterior surface adjustments are the size, geometry depth and position of support or bearing surfaces as described above and/or the size, geometry depth and position of conduits which would be formed between the eye and the lens. Posterior adjustment data/parameters are sent to the posterior surface module above.

The posterior surface module generates a posterior surface dependent on the scan data 208 and combinations of the V.axis data 206+ and posterior adjustment data and/or parameters 210. In this example the posterior surface

module generates posterior data 211 defining a surface which matches the anterior surface of the eye with areas defined as supported or elevated away from the eye by pads defined by the operator.

The posterior data is sent to an anterior module 212. The anterior module has a ray tracing module 213 which performs ray tracing algorithms known to the reader. The module 212 also has a mass distribution module 214 which performs algorithms to centre the mass of the lens. A GUI 215 allows an operator to input data or parameters defining visual corrections to be provided by the lens. Patient history data may also be input at the GUI. Anterior surface adjustment data 216 is sent to the anterior surface module which generates an anterior surface for the lens dependent on the posterior data 211 and any anterior adjustment parameters defined in data 216. The anterior surface module performs ray tracing and centre of mass algorithms in generating the data defining the anterior surface. The anterior and posterior surface data are combined into a model of the lens suitable for fabrication by a CNC module 218.

In alternative embodiments the modules described above may be combined or divided to provide equivalent functionality. Embodiments of the invention are implemented using a computer with processor and storage memory and a processor with storage memory storing code which provides the modules described above when executed. Embodiments of the invention implemented using a storage medium or software product defining code which provides the modules above when executed on a computer.

Embodiments of the present invention provide the following advantages.

- Provide therapeutic solutions for visually handicapping conditions caused by corneal insult that previously were untreatable.
- Establish a technological procedure for fabricating contact lenses that supersedes the skilled based prior art. Overcome the problems faced by the Optometric profession of the lack of opportunity and mentoring, to

develop and sustain the skill based prior art when routine treatment has moved away from the foundations of rigid lens fitting to soft lenses.

- Establish a method that provides flexibility for experimentation and research into design, providing novel contact lens options, not previously feasible.
- Concentrate the knowledge base for the technology at a Bureau level to provide constant improvement, while providing the Optometrist with the professional satisfaction of clinical interaction with the patient that will usually have very positive outcomes.
- Provide a novel and highly reliable method of accurately establishing the topometry of highly irregular corneal surfaces from which can be derived a replicated surface model.
- Enable surface modelling to define all points of the surfaces of therapeutic lenses to optimise their comfort, physiological and optical performance.

Embodiments of the present invention overcome the problem of trialling rigid lenses in countries affected by the characteristics of such diseases as Bovine Spongiform Encephalopathy [BSE]. Particularly in the United Kingdom & Eire, practitioners have been instructed to destroy trial cases of fitting lenses because of the risk of contamination by prions, the microbial element that transmits the disease to humans resulting in new variant, Creutzfeldt–Jakob disease.

Fitting without trial lenses presents significant inaccuracy and results in multiple refits, but embodiments of the present invention provides a solution. In countries where trial cases are not contaminated, they continue to be used, however they represent a resource for the creation of fitting libraries of lens design files. Trial case lenses may be rendered reflective by spraying the surface with a suitable removable coating, then scanning them to produce a progressive base curve optic radius selection of files. These may be overlaid on the surface model of the anterior eye, acquired by the invention. Software

analysis of the tear film depth between the two surface models may reveal the suitability of the design, in effect a virtual fitting.

Exemplary features of the invention comprise: the discovery by the ophthalmic practitioner, of the physical, geometric and visual axes for the eye to be treated, describing them as Cartesian and polar co-ordinates; topometrical [1] mapping of the anterior surface of the eye including the cornea and surrounding sclera, enabling the creation of a point cloud or *.stl file representing the surface related to the eye co-ordinates; the use of surface modelling software, overlaying the *.stl file, to generate the posterior and anterior surfaces for optimally designed therapeutic contact lenses; creation of the machine code to control the CNC lathe/mill, generating the therapeutic surfaces, integrating them with the machine manufacturer's programs for edge designs and material parameters, to manufacture the therapeutic lens; a parametric review of the therapeutic lens parameters by scanning the surfaces and comparing them with the original files for quality control; assessment by the ophthalmic practitioner of the vision, physical and physiological outcomes of the therapeutic lens on the eye to optimise it's performance and if necessary revise the original design to produce the ultimate lens.

Among other advantages, an embodiment of the present invention:

- compensates for restricted and/or limited skill base, whereby the practitioner no longer needs to be directly responsible for the design of the therapeutic lens. The practitioner will instead determine physical and physiological information about the patient including measurement of axes and dimensions, obtain an accurate impression of the surface of the eye and determine the refractive status of the patient. These procedures are within the present scope of practice for New Zealand practitioners and are easily trainable. These data, integrated with patient management information will be forwarded to a Bureau, allowing expert development of the therapeutic contact lens.

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1 Topometrical representing absolute measurements.
Topographical representations using algorithms to interpret the data derived from limited areas of the corneal surface by Topographer's.

- scans the polysiloxane impression of the ocular surface to generate an accurate surface model of the anterior eye, to a diameter of 16mm or less for adults, the maximum area conventionally fitted with semi scleral lenses.

- Proportionally smaller lenses may be designed for babies or infants with congenital defects. The specific parametric data for that patient may be formatted either as a 'point cloud' or *.stl file to create a surface model. The corneal surface model will provide the foundation for the development of initally the posterior surface of the contact lens, fundamental for an optimum fitting. Subsequently the anterior surface model will be created to correct the vision, optimise the mass distribution, centroid position, of the lens and for wearing comfort. If it is evident that alternate therapeutic options are feasible the Bureau will discuss these with the practitioner, and the preferred option will proceed.

- Modelling data into machine code for the lathe, manufacturing by point-to-point control instead of the traditional Cartesian geometry, providing complete flexibility for fitting highly irregular surfaces.

- integrates the point-by-point control of the manufacturing with existing lathe operating programs and technology

- comprises diamond tooling with the appropriate clearances of rake angles to enable extreme surfaces to be machined using point-by-point criteria.

- comprises a method for post-production scanning of therapeutic lenses to verify their parameters for quality control.

- fits the manufactured lens to the patient to disclose any malfunction or potential fitting problem, unresolved visual correction, or any other unforeseen therapeutic issue.

- amends the optical surfaces of the initial lens to improve the visual correction or the peripheral surfaces to resolve fitting issues discovered in #7 above.

- remakes the amended lens [step through from #3 above]

- dispatches the final lens design to the practitioner for dispensing to the patient.

In particular, embodiments provide a system and process for the design and manufacture of therapeutic contact lenses wherein a scan is made of the polysiloxane impression of the ocular surface to generate an accurate surface model of the anterior eye (such model relating to the patient specific parametric data).

With reference to this surface model, the posterior surface of the contact lens may be created with optimum clearance for the tear film and for bearing areas. An anterior surface model may be subsequently structured to correct the vision for a given posterior surface, to optimise the mass distribution, centroid position, of the lens and for patient comfort.

Embodiments of the present invention resolve the requirement for mechanical/analogue constraints and the requisite subjectivity of expertise, embracing digital technology at every step in the design, manufacturing and dispensing process.

Embodiments of the present invention established the visual parameters for the physical eye; produces an impression of the anterior eye and integrates scan data of the impression or a model made from the impression with the parametric information. The present invention thus enables processing of data in a 'bureau'; laboratory manufacture; quality control; dispensing and subsequent performance assessment and design review if required.

Embodiments of present invention resolve the requirement for mechanical/analogue constraints and the requisite subjectivity of expertise. Further, embodiments of the present invention comprise digital means for the design, manufacturing and dispensing of therapeutic contact lenses.

Embodiments of the invention provide a system and process for the design and manufacture of therapeutic contact lenses wherein a scan is made of the polysiloxane impression of the ocular surface to generate an accurate surface

model of the anterior eye (such model relating to the patient specific parametric data).

With reference to this surface model, the posterior surface of the contact lens may be created with optimum clearance for the tear film and for bearing areas. An anterior surface model may be subsequently structured to correct the vision, to optimise the mass distribution [centroid position] of the lens and for patient comfort.

Embodiments of the present invention thus resolve the requirement for mechanical/analogue constraints and the requisite subjectivity of expertise, embracing digital technology at every step in the design, manufacturing and dispensing process.

Among the advantages, the present invention establishes the visual parameters for the physical eye; produces an impression of the anterior eye and integrates the impression with the parametric information. The present invention thus enables processing of data in a 'bureau'; laboratory manufacture; quality control; dispensing and subsequent performance assessment and design review if required.

Embodiments of the present invention provide a system and process for the design and manufacture of therapeutic contact lenses wherein a scan is made of the polysiloxane impression of the ocular surface to generate an accurate surface model of the anterior eye (such model relating to the patient specific parametric data).

With reference to this surface model, the posterior surface of the contact lens may be created with optimum clearance for the tear film and for bearing areas. An anterior surface model may be subsequently structured to correct the vision, to optimise the mass distribution, or centroid position, of the lens and for patient comfort.

Because the therapeutic lens designed according to some embodiments of the invention do not to use geometric optics, no prescriptive dioptric power is measurable. The resolution of the optical correction is by vergence of all rays

passing through each of the surfaces of the lens, the tear film, corrupted cornea and optics of the eye to converge on the retina. In one embodiment this optical correction is used to generate data defining an anterior surface of the lens for a given

For one embodiment the vergence can be closely estimated from the interpreting historical information about correction of the eye with a previous correction and using the focal distance, moderated by other known constants to infer the vergence.

For one embodiment the vergence for the Gullstrand eye provides an approximation.

For one embodiment a trial contact lens can be rested on an anaesthetised supine eye even if the lens is not perfectly fitting, then refracting through it. The summation of the focal components provides the pertinent information. For one embodiment A-scan biometry provides a measurement of the length of an eye, and hence the position of the retina upon which the rays of light must fall.

The vergence of the lens and hence the optical correction of the ammetropia of the eye can only be estimated when constructing the initial therapeutic lens, so improvements to the vergence and hence the focus can only be established by fitting iterative developments of the lens to the eye and refracting through it. The optical properties of the system include the tear film overlaying the cornea and can only be established by considering the interface of the lens surfaces with the tears.

Using ray tracing algorithms, higher aberrations can be corrected. Once a successful fitting has been determined to meet the physical and physiological demands of the eye, raw data from Wavefront Analysis over the lens enables refinement of the front surface to provide the ultimate potential for visual performance.

To exactly centre the Optic Zone over the pupil and independently position the visual axis, requires it's position to be accurately determined whereas with the

prior art, the optical centre for manufacturing constrained it always to be placed in the geometric centre.

As defined in claim 4, 5 & 6 together with the resolution of the optical correction using the lens vergence of ray paths, the lens cannot be allowed to rotate on the cornea. Design features are built into the lens to constrain it. These may include ballasting to place the centroid below the geometric centre or support and bearing areas on the rear of the lens that closely fit the irregular surface to resist rotation off axis. In one embodiment, these features are input as data or parameters or manipulations of a graphical user interface at a computer terminal.

The Optometrist will use medical devices designed specifically to obtain the physical and historical and medical information to enable the therapeutic device to be designed. These will facilitate;

- access to the area of treatment, the anterior eye including the affected cornea,
- the determination of its surface characteristics,
- the location of the reference axes of the ocular features
- the optical, physical and physiological characteristics for the therapeutic lens

The Speculum, manufactured from heat sterilisable or gamma irradiated plastic, by injection molding or stereolithography, claims to encircle the treatment area, comfortably constraining the lids and tissue folds.

The V.axis medical device claims to provide a mechanism to aid the positioning of the eye within the working field in claim10. The V.axis medical device includes a camera with live viewing that claims to provide a digital photographic record for future analysis of the visual axis of the eye, the relative position of the mold on the eye and the polar axis of the impression.

As the eye is never still except in death, the prior art captures information about the corneal surface by analysis of optical information from an area, too restricted to enable semi scleral lenses to be designed with accuracy. To represent the corrupted corneal surface absolutely by molding it in polysiloxane, while the mold is free to oscillate with the eye. It is then scanned optically with high resolution and accuracy to construct a surface model from which to develop a unique lens design.

By departing from the prior art of designing lenses to geometric parameters, embodiments of the present invention provide an opportunity to design surfaces for optical correction, clearance from sensitive tissue, or support of the lens.

Embodiments of the present invention allow the ability to control the position of the centroid by independent manipulation of the front surface and the formation of an irregular lens edge to follow the contours of the globe providing comfortable wear. To ensure that quality standards are maintained, finished lenses in one embodiment may be spray coated with Titanium oxide suspended in a vehicle to provide a temporary surface. The lens can be oriented, then scanned to generate a surface model file that can be compared with the original to establish that it falls within manufacturing tolerance.

As patients are visually handicapped without their lenses, they cannot determine which lens they are attempting to insert. Even if they have correctly chosen, then they must determine the orientation as the lens will only fit the irregular surface if rotated to within a few degrees. To provide a mechanism for both the handedness and the orientation, the front surface is provided with an optical reference in one embodiment as for the right eye one lenslet and for the left two adjacent lenslets.

The lens is placed on battery driven turntable and the lenslets are detected by a light beam passing through the lens. Upon detection of whether one or two lenslets are detected, an audible signal indicates it is a L or a R lens and the turntable stops rotating, presenting the bottom of the lens at the farthest point on the turntable.

A suction holder on a swinging arm may be arced over into contact with the convex surface and upon returning to a mid-position in space before the patient with the concave surface of the lens now presented towards the eye, the fingers may grip the suction holder and without rotating it, the lens may be advanced onto the eye.

In particular, the potential of CNC contact lens lathe manufacturing technology is realised by generating lens surfaces under point by point control to achieve an optimum fitting, rather than approximating the design by utilising the prior art of distorting geometry, originally developed for fitting normal eyes.

Data is generated for transformation into a solid model of the design of a lens. By generating an accurate digitised surface model of the anterior eye, rather than a topographical representation over a limited area, patient specific parametric data is available for the entire contact surface on which the posterior surface of therapeutic lenses may bear. Pressure in critical areas of graft junctions and scars can be avoided and the posterior optic zone may be tilted, rotated and optimised for comfort or safety to any geometric form.

An anterior optic zone surface, or anterior lens surface, is subsequently generated using ray paths to correct the vision, if necessary with aberration control, and the mass distribution of the lens optimised, centroid position, for wearer comfort and visual stability. The anterior surface generated by ray paths provides a lens shape in conjunction with, and dependent on, a posterior lens surface data defining a posterior surface for the lens which has been generated from the scan data taken from the mold and representing the ocular surface of an eye. The posterior surface may match the ocular surface defined by data captured by scanning the mold. Posterior and or anterior lens surface data may be generated dependent on data or parametric inputs from an operator at a bureau to allow the operator to adjust the posterior surface to cooperate with the ocular surface. Inputs from an operator may also adjust anterior and or posterior surfaces for aberration control and/or mass distribution. A terminal is provided at the bureau to allow an expert or other

operator to define characteristic data or parameters for the lens. This may be characteristics of the anterior and posterior surfaces but might also be correcting power or characteristics relating to mass distribution or other characteristics apparent to the reader. Suitable inputs and lens characteristics will be apparent to the skilled reader.

Because every lens design is unique to the abnormal eye and geometric forms have been abandoned, all existing lens modelling parameters are redundant; fitting from trial lenses is superseded. Thus existing lens regulatory standards are mostly irrelevant and lenses cannot be checked with traditional methods for power and surface parameters.

Embodiments of the present invention provide a way to fit therapeutic lenses when conventional instrumentation cannot be used to establish for the fitting and to adjust the designs at regular intervals for growth and changing visual demands. By customising the therapeutic lenses using embodiments of the present invention, the fitting for babies and infants is more stable and comfortable on the eye resulting in negligible awareness by the child who will leave the eye alone, and produce an optimum physiological response for an extended wear period, minimising the drama for the parents and the child when handling the lens.

The prior art relating to the fitting and manufacture of therapeutic contact lenses has evolved from optical and mechanical methods of assessment and manufacture, with incremental gains in material science and from accuracy and efficiency with digital technology. However conventional methods use regular geometric parameters of normal eyes, and can only approximate the fitting of highly irregular corneal surfaces.

In one embodiment, a terminal allows an operator, or expert, at the bureau, for example, to input data and/or parameters which adjust the posterior and/or anterior data defining surfaces of the lens.

To generate data defining a lens, machined code is generated for the lens design, rather than the laboratory directly interpreting the order from

parameters specified by a practitioner. In one embodiment optical features are integrated into the surface at the mid periphery of the lens to provide the basis for an opto-mechanical orientation tool that will unambiguously assist the patient by identifying which lens they are handling and to orient it for insertion.

Embodiments of the invention provide a rigid contact lens which is well-tolerated physically and physiologically by providing a lens which has surfaces shaped for each patient to optimize fluid dynamics to provide the minimum of pressure on sensitive surfaces and minimum resistance to lid and eye movement.

In embodiments of the present invention the optical power of the lens is determined by refracting the eye over a trial lens of a known power and summating the powers.

As the unique lens must exactly conform to the distorted corneal surface it rests upon, an electro-mechanical dispensing device is required to identify the L or R lens and present it at the correct rotation for insertion into the eye.

Some embodiments of the present invention apply modelling to the metrics of topometrically defined surfaces.

Embodiments of the present invention resolve the requirement for mechanical/analogue constraints and the requisite subjectivity of expertise.

Embodiments of the present invention provide digital means in the fitting, manufacturing and dispensing of therapeutic contact lenses.

Embodiments of the present invention provides a revision of the known process from the clinical evaluation of the patient, the design of the therapeutic contact lens, the manufacturing process, the quality control of the device, it's dispensing and subsequent revision.

Scanning the eye to achieve metrics of the surface is confounded by the fact that the eye is never still. Micro rotations are induced by the extraocular muscles seeking to optimise the position of the retina for visual stimulation.

Also the globe is pulsed by the retrobulbar blood supply and of course the position of the eye is subject to voluntary and involuntary control.

Embodiments of the present invention resolve the problems of movement relative to the measuring apparatus, by anchoring the mechanism on the surface of the eye so it oscillates in sympathy, accurately reflecting the underlying metrics .Embodiments of the present invention relate to processes and systems for the assessment of the patient, the design, manufacture and dispensing of therapeutic contact lenses.

In different embodiments of the invention visual axis data may be associated with the mold taken of an ocular surface or associated with the mold itself. It will be apparent to the skilled reader that the visual axis data can be used to relate a posterior surface of the lens, or data generated for use in fabricating the posterior surface, to orient the posterior surface with the ocular surface represented by the mold or scanned data.

Predicating the present invention, all steps in the process systematically derive digital information for transformation into a solid model of the design, wherein initially a 3D scan is made of the polysiloxane impression of the ocular surface. By generating an accurate digitised surface model of the anterior eye, (such model relating to the patient specific parametric data) from which a posterior surface of the contact lens can be created; an anterior optic zone surface is subsequently generated to correct the vision, and the mass distribution of the lens optimised [centroid position] for wearer comfort and visual stability.

Physiological and physical tolerance for a therapeutic lens is essential because the wearer does not have an alternative if the eye becomes traumatised, reactive or infected. By shaping the surfaces to optimise the fluid dynamics to maintain a healthy eye and to minimise pressure on sensitive surfaces while offering minimum resistance to lid and eye movement, the lens will be well tolerated.

Embodiments of the present invention obviate the requirement for mechanical/analogue constraints and the requisite subjectivity of expertise in designing and/or fabricating a contact lens. Further, embodiments of the present invention comprise digital means in the design, and/or fabrication and/or dispensing of therapeutic contact lenses.

Embodiments of present invention thus provide a system and process for the design and manufacture of therapeutic contact lenses wherein a scan is made of the polysiloxane impression of the ocular surface to generate an accurate surface model of the anterior eye, (such model relating to the patient specific parametric data) from which a posterior surface of the contact lens can be created and an anterior surface model subsequently structured to correct the vision, to optimise the mass distribution [centroid position] of the lens and wearer comfort.

Among other advantages, embodiments of the present invention:

- compensate for restricted and/or limited skill base, whereby the practitioner will no longer need to be directly responsible for the design of the therapeutic lens. The practitioner will instead determine physical and physiological information about the patient including measurement of axes and dimensions, obtain an accurate impression of the surface of the eye and determine the refractive status of the patient. These procedures will be within their present scope of practice and easily trainable. These data, integrated with patient management information will be forwarded to a Bureau, allowing expert development of the therapeutic contact lens.

A significant problem for wearers of therapeutic lenses with very poor uncorrected vision, is to identify which lens they are inserting. Colour coding may be used with intra-corneal lenses to indicate which eye the lens has been manufactured for, but this is generally unacceptable for larger lenses that extend onto the sclera showing a ring of colour. Engraved and inked markings on the lens are problematic for a number of reasons as well as being difficult to see.

A further difficulty is to be able to rotationally orient their lenses for insertion, essential with a lens that is specifically designed to match a corneal surface. As every feature of the lens surface is able to be configured there is the opportunity for basic research to define what influences successful design for comfort, stability or visual performance.

Embodiments of the present invention allow fabrication of a therapeutic lens without prescribing lens designs or fitting philosophies. The Practitioner and the Bureau can have complete flexibility when considering the physiological and physical parameters for a successful design.

Embodiments of the present invention are described with reference to a practitioner who works with the patient, a bureau which designs the lens and a manufacturing or fabrication agency. It will be understood by the reader that the functions of these parties as described herein may be divided or combined in alternative arrangements.

In some embodiments a mold impression of an eye may be used to make a physical model of the ocular surface and that model may be scanned. The skilled reader will understand this to be equivalent and not materially different to scanning the mold impression.

Where the foregoing description reference has been made to integers having known equivalents thereof, then those equivalents are herein incorporated as if individually set forth.

The invention has been described by way of exemplary embodiments but having read and understood this description further embodiments and modifications will be apparent to those skilled in the art. All such embodiments and modifications are intended to fall within the scope and spirit of the present invention as defined in the accompanying claims.

**Claims:**

1. A method of generating data for use in fabricating a contact lens for an eye, the method comprising:

   - generating posterior lens data defining a posterior lens surface for the lens to contact the eye, wherein the posterior lens data is generated dependent on ocular surface data generated by a scanner;

   - generating anterior lens data defining an anterior surface for the lens to define optical properties for the lens, the anterior lens data generated dependent on the posterior surface data.

2. The method of claim 1, wherein the ocular surface data is generated by scanning a mold of an ocular surface of the eye.

3. The method of claim 1 or claim 2, wherein the posterior surface data is generated dependent also on visual axis data associated with the ocular surface data and/or the mold.

4. The method of any one of the preceding claims, wherein posterior lens data and/or anterior lens data is generated dependent also on operator data and/or operator parameters input at an operator terminal to allow adjustment of the posterior surface and/or the anterior surface defined for the lens.

5. The method of any one of the preceding claims, wherein posterior lens data conforms to ocular surface data such that the posterior lens surface is operable in use to co-operate with the ocular surface.

6. The method of any one of the preceding claims, wherein the posterior lens surface match the shape of the ocular surface.

7. The method of any one of the preceding claims, wherein the posterior lens surface may have support surfaces which contact the eye in use and supported surfaces formed in relief in the posterior lens surface and which are supported by the support surfaces.

8. The method of any one of the preceding claims, wherein the posterior-lens data may define conduits formed in use between the lens and the eye to allow tear fluid to flow across the eye when the lens is in use.

9. The method of any one of the preceding claims, including scanning a mold made by applying a molding material to an ocular surface.

10. The method of claim 9, wherein the molding material may be polysiloxane.

11. The method of any one of the preceding claims, wherein the anterior surface data is generated using ray tracing algorithms.

12. A method of fabricating a contact lens including forming a lens by controlling a machine dependent on the anterior and posterior lens data.

13. The method of claim12, wherein the machine is oscillating head lathe/mill or an end milling machine controlled using point-by-point data generated to represent a solid shape and generated dependent on the anterior surface data and the posterior surface data.

14. A system for generating data defining surfaces of a contact lens for an eye, the system comprising:

- a scanned-data input for reading scanned data defining a corneal surface;

- a design input for reading lens characteristic data defining one or more characteristics for the lens;

- a data generator operable to generate data defining the shape of the lens dependent on the scanned data and the lens characteristic data.

15. The system of claim 14, wherein the lens characteristic data define mass distribution characteristics for the lens.

16. The system of claim 15, wherein the lens characteristic data may define visual correction characteristics for the lens.

17. The system of claim 16, wherein visual correction characteristic data may include a lens power.

18. A method of generating data defining the shape of a contact lens to be fabricated, the method comprising receiving scanned-data collected by scanning a contact lens to define a base curvature.

19. The method of claim 18, including coating the lens with a material having optical properties suitable for scanning.

20. A contact lens fabricated using a machine controlled with data generated using data scanned from a mold of an ocular surface of an eye.

21. A contact lens fabricated using a machine controlled with data defining a shape having an anterior surface defined by data generated to define optical properties for the contact lens, the anterior surface data generated dependent on posterior data defining a posterior surface for the lens.

22. A method of generating ocular surface data for use in fabricating a contact lens, the method including:

- taking a mold of an ocular surface of the eye;

- scanning the mold to generate the ocular surface data.

23. The method of claim 22, including taking visual axis measurements of a molding apparatus while positioned on the eye to calculate position adjustments for the ocular surface generated.

24. The method of claim 22 or claim 23, including using a molding apparatus having an inner sleeve and an outer sleeve with an 'O' ring sealing the annulus between them.

25. A method of preparing a mold for use in fabricating a contact lens, the method including the steps of:

– taking a mold of an ocular surface of an eye;

– storing the mold in a cassette,

– storing in the cassette a medium carrying data defining visual axis data associated with the mold.

26. The method of claim 25, including forming a feature in the mold for use in orienting the mold rotationally, and storing the mold in the cassette so as to be aligned in the cassette by the feature.

27. The method of claim 25 or claim 26, including storing the mold in a cassette having a window operable to allow the mold to be scanned while in the cassette.

28. An apparatus suitable for making a mold of an ocular surface of an eye, the apparatus including an inner sleeve and an outer sleeve and an evacuation conduit, the inner and outer sleeves operable to cooperate to seal against the ocular surface when a volume between the inner and outer sleeves is evacuated, the inner sleeve arranged to contain a molding material placed on the ocular surface

.

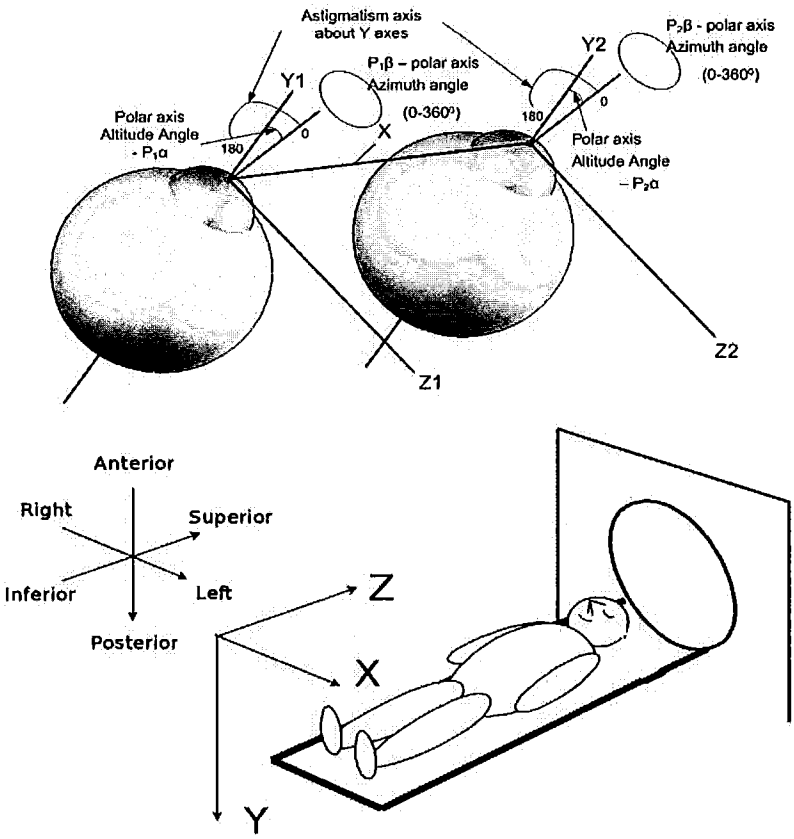
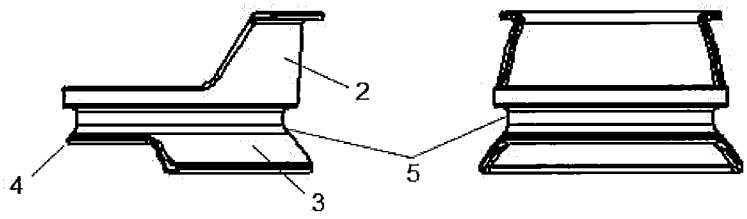



Figure 1



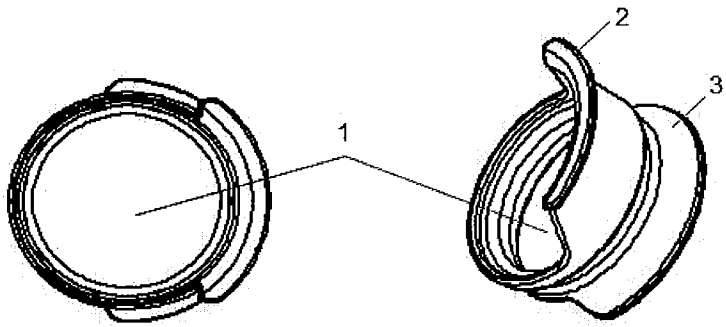




Figure 2 Speculum

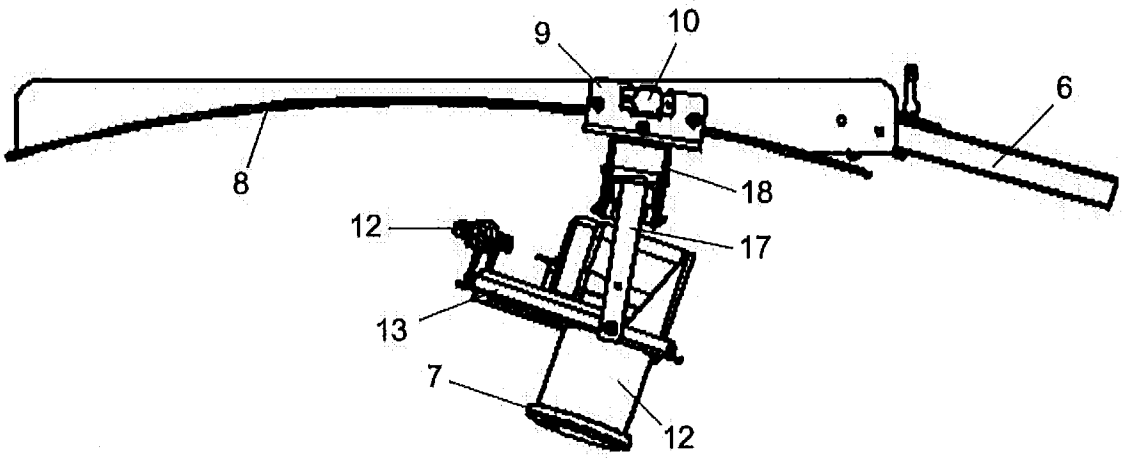



Figure 3 [1]

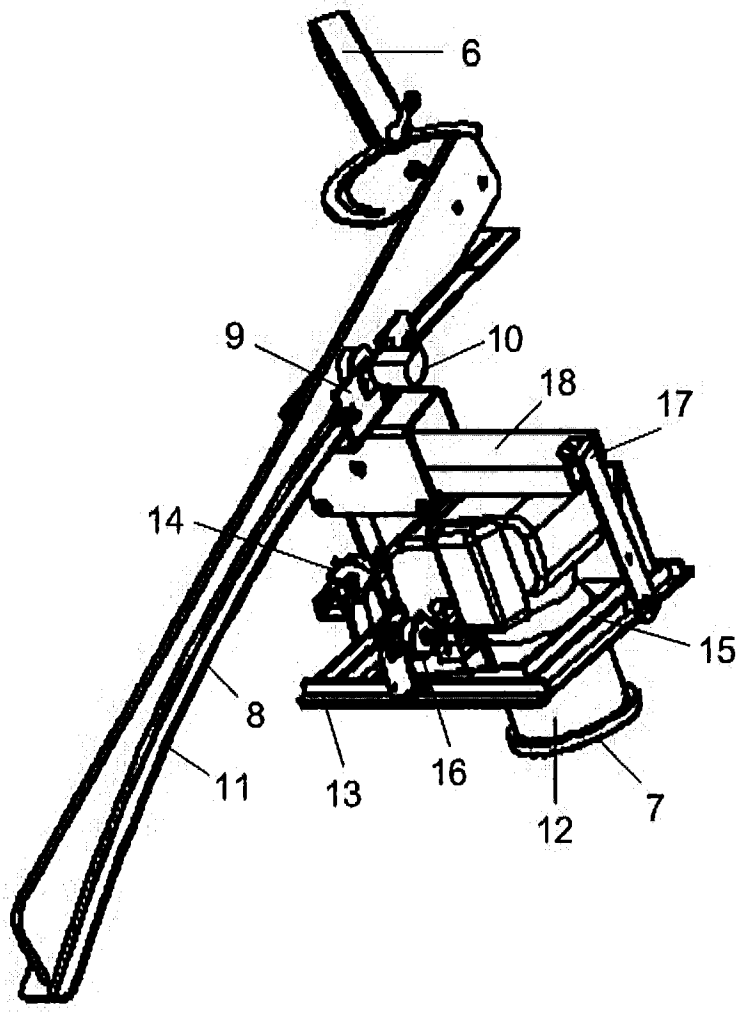



Figure 3 [2]

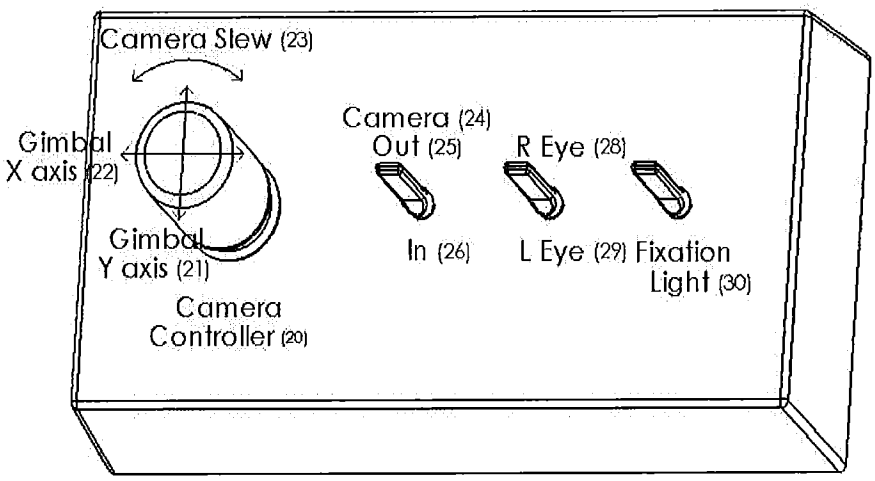
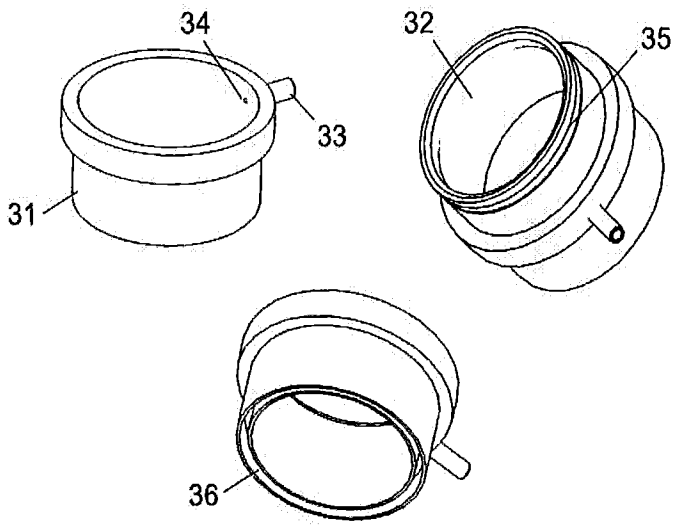



Figure 4

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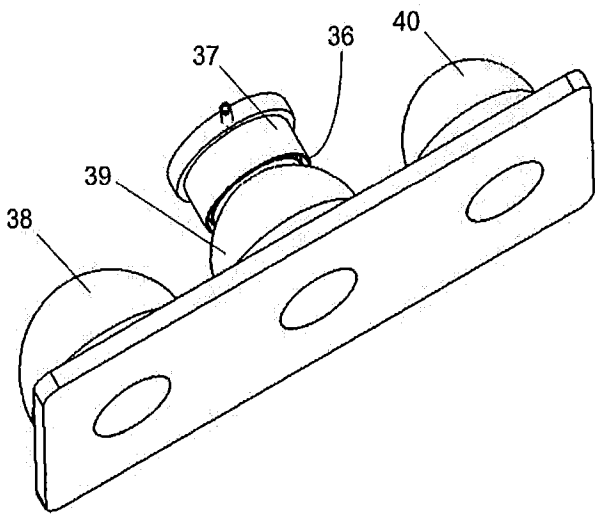



Figure 6

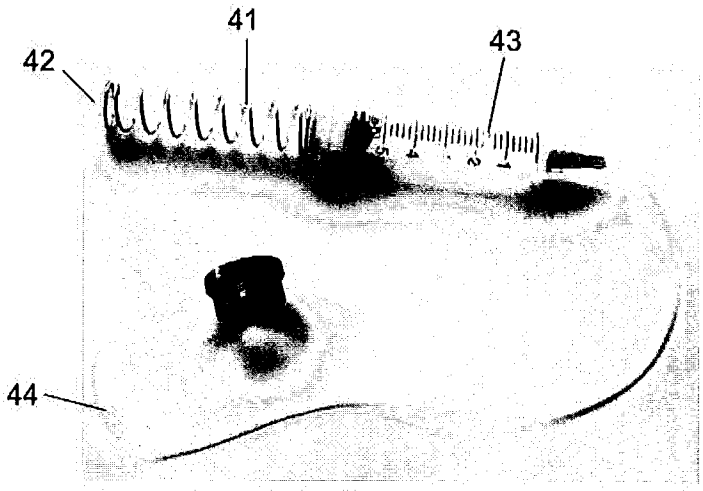



Figure 7

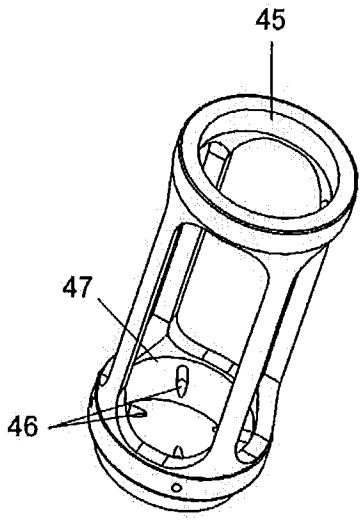
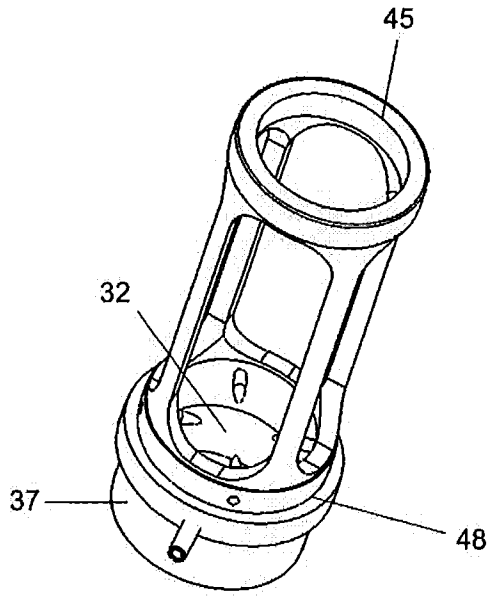



Figure 8

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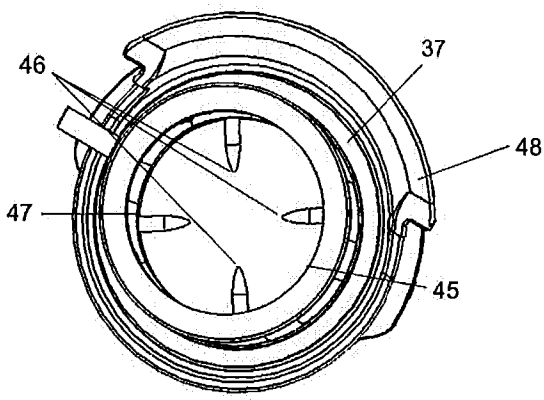


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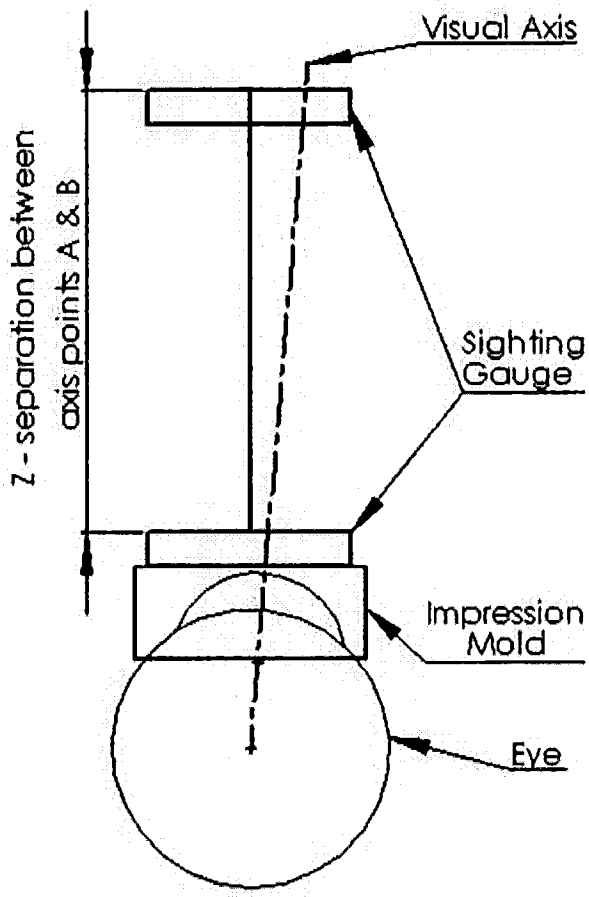



Figure 11

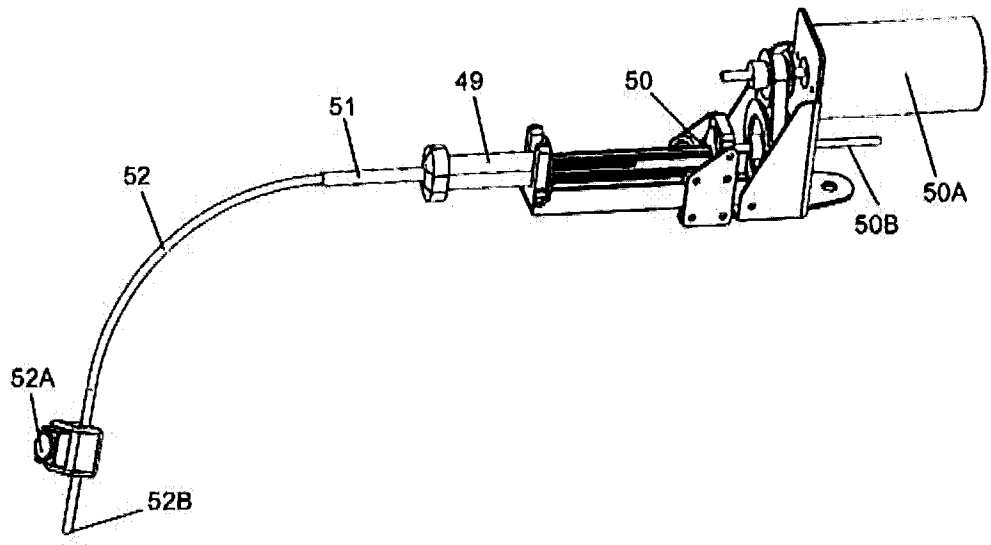
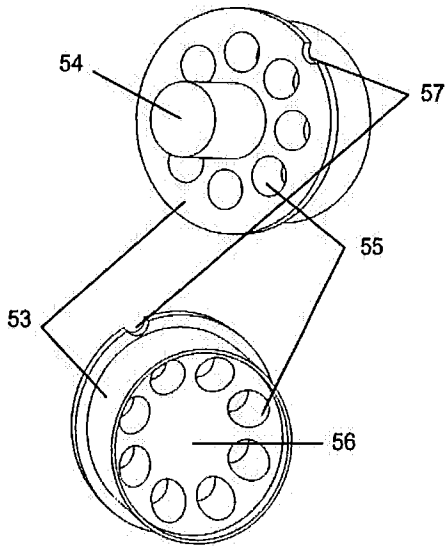



Figure 12

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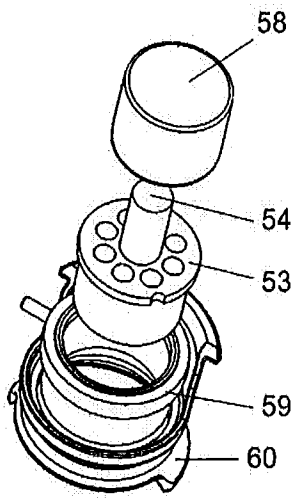



Figure 14

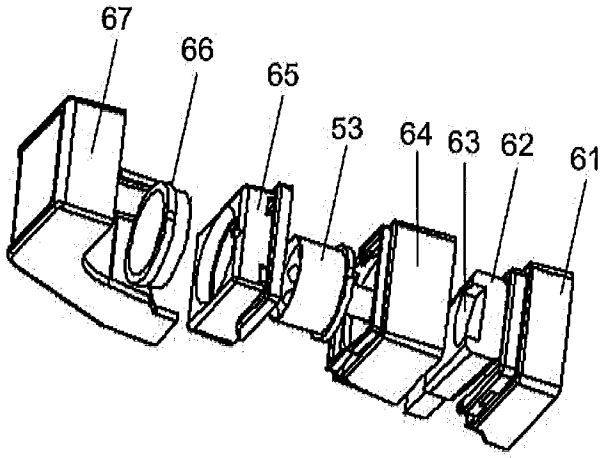
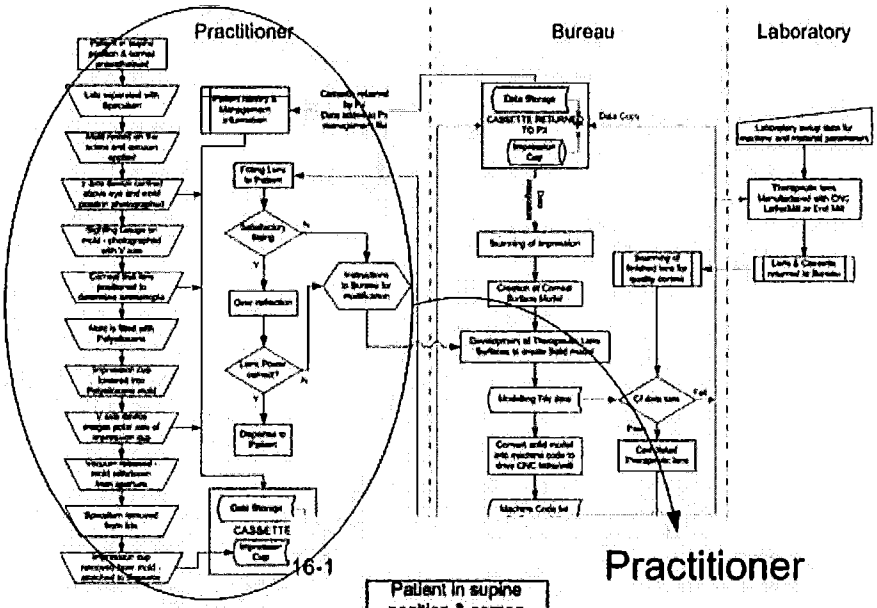



Figure 15


Practitioner
Bureau
Laboratory
16-1

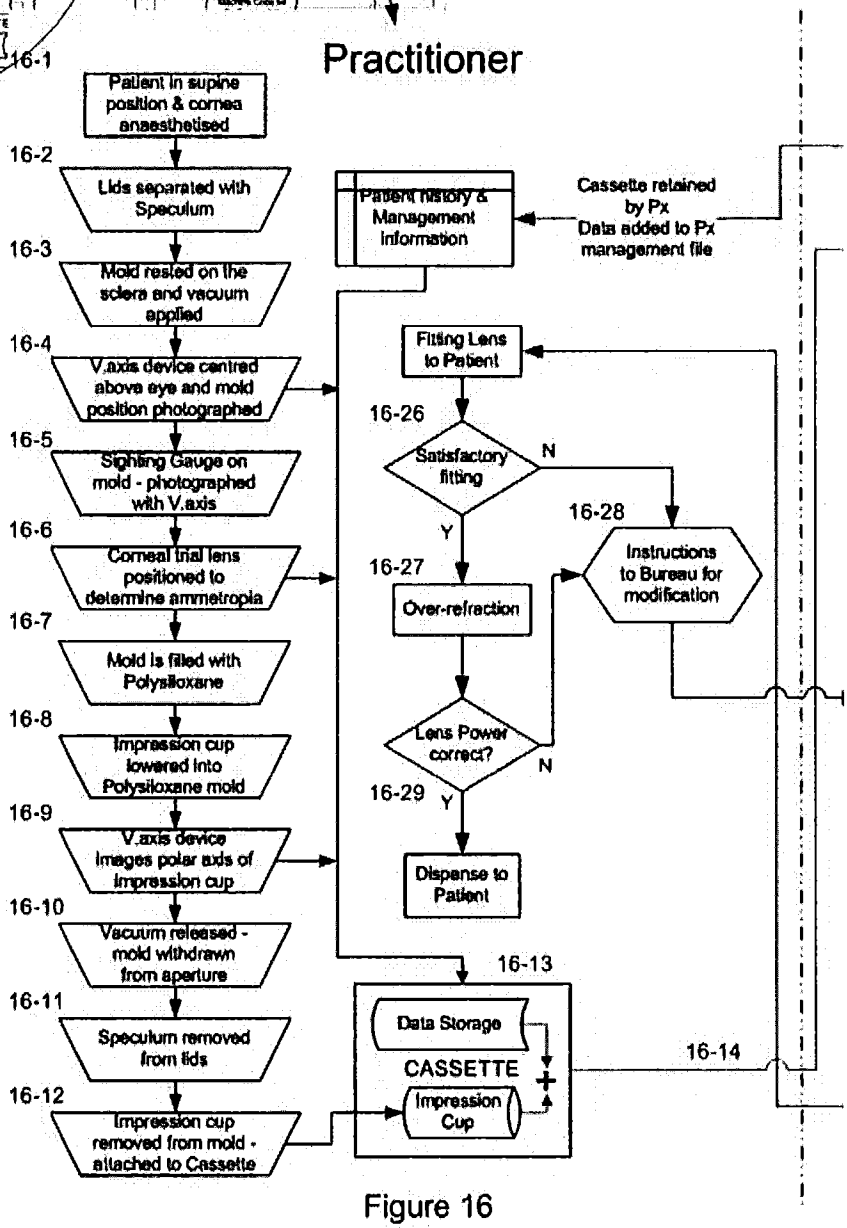

Practitioner
Patient in supine position & cornea anaesthetised
16-2
Lids separated with Speculum
16-3
Mold rested on the sclera and vacuum applied
16-4
V.axis device centred above eye and mold position photographed
16-5
Sighting Gauge on mold - photographed with V.axis
16-6
Corneal trial lens positioned to determine ammetropia
16-7
Mold is filled with Polysiloxane
16-8
Impression cup lowered into Polysiloxane mold
16-9
V.axis device Images polar axis of impression cup
16-10
Vacuum released - mold withdrawn from aperture
16-11
Speculum removed from lids
16-12
Impression cup removed from mold - attached to Cassette
Patient history & Management information
Cassette retained by Px
Data added to Px management file
Fitting Lens to Patient
16-26
Satisfactory fitting
N
Y
16-28
Instructions to Bureau for modification
16-27
Over-refraction
Lens Power correct?
N
16-29
Y
Dispense to Patient
16-13
Data Storage
CASSETTE
Impression Cup
16-14

Figure 16

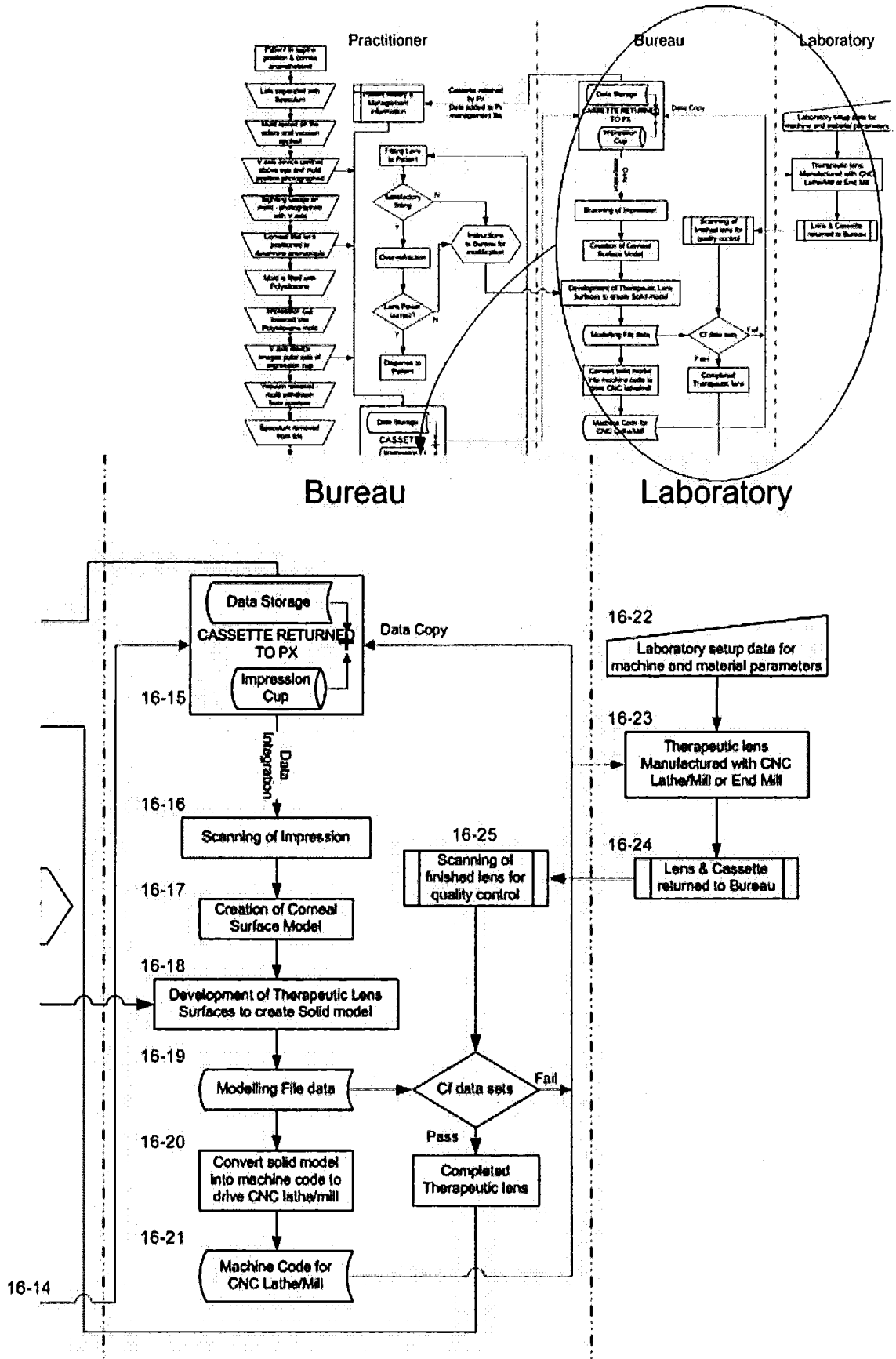
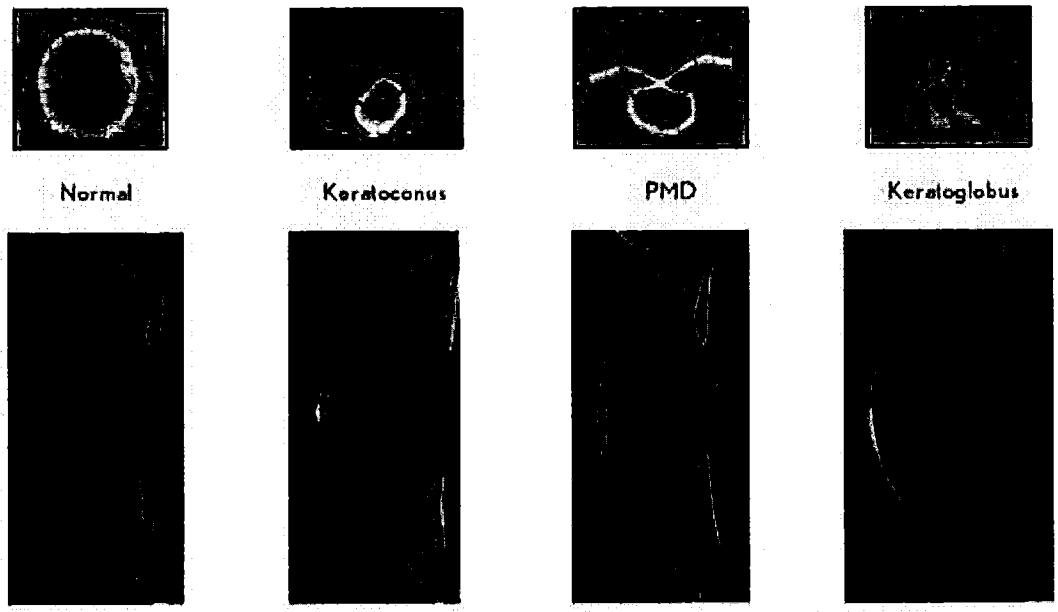
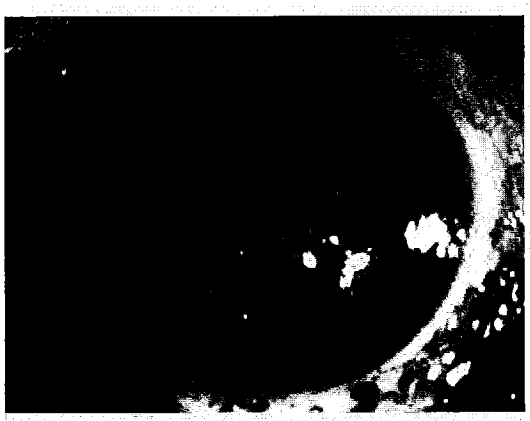

Practitioner
Bureau
Laboratory
Bureau
Laboratory
Data Storage
CASSETTE RETURNED TO PX
Impression Cup
16-15
Data Copy
Data Integration
16-16
Scanning of Impression
16-17
Creation of Corneal Surface Model
16-18
Development of Therapeutic Lens Surfaces to create Solid model
16-19
Modelling File data
CI data sets
Fail
Pass
16-20
Convert solid model into machine code to drive CNC lathe/mill
Completed Therapeutic lens
16-21
Machine Code for CNC Lathe/Mil
16-14
16-22
Laboratory setup data for machine and material parameters
16-23
Therapeutic lens Manufactured with CNC Lathe/Mill or End Mill
16-24
Lens & Cassette returned to Bureau
16-25
Scanning of finished lens for quality control

Figure 16



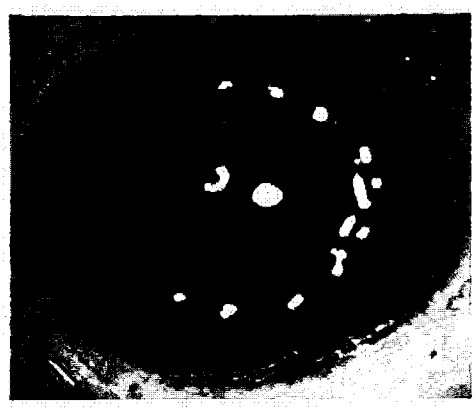

Ectasic – pathological conditions causing gross corneal distortions.

Figure 17



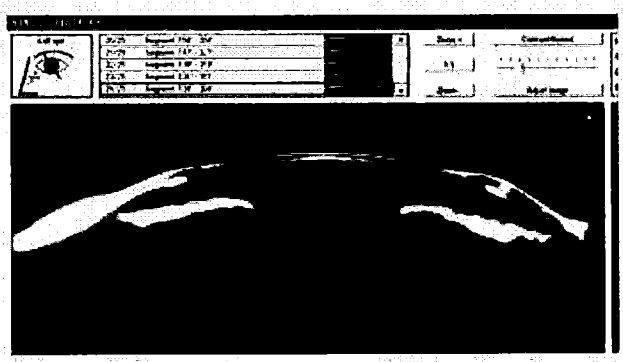
Scarred from Trauma

Figure 18



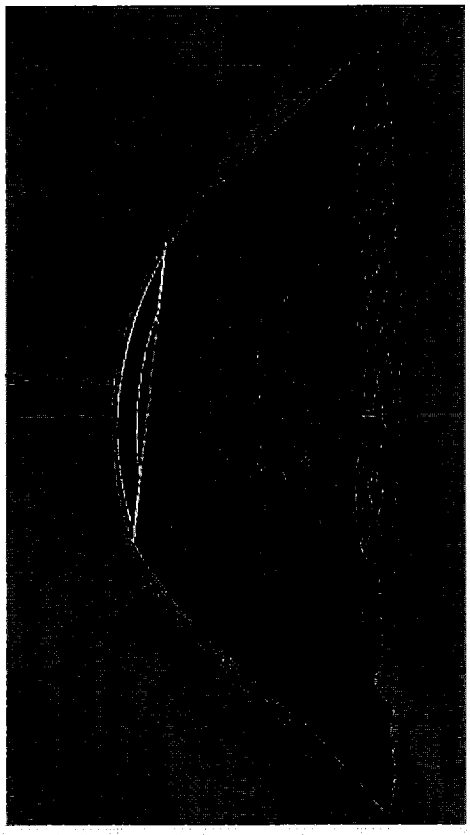
Corneal Graft

Figure 19



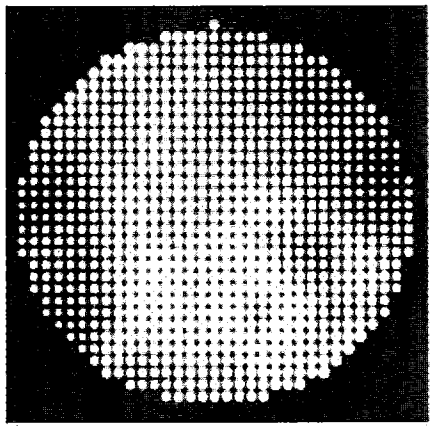
Very thin graft recessed into the host.

Figure 20



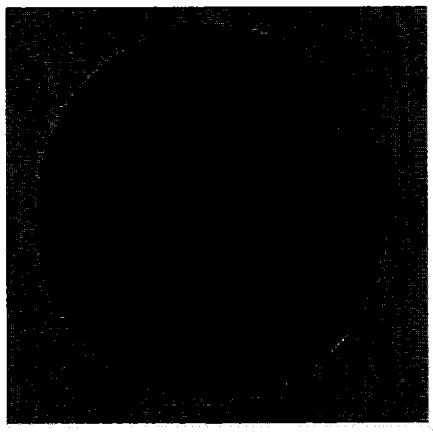
Creating the back optic zone

Figure 21



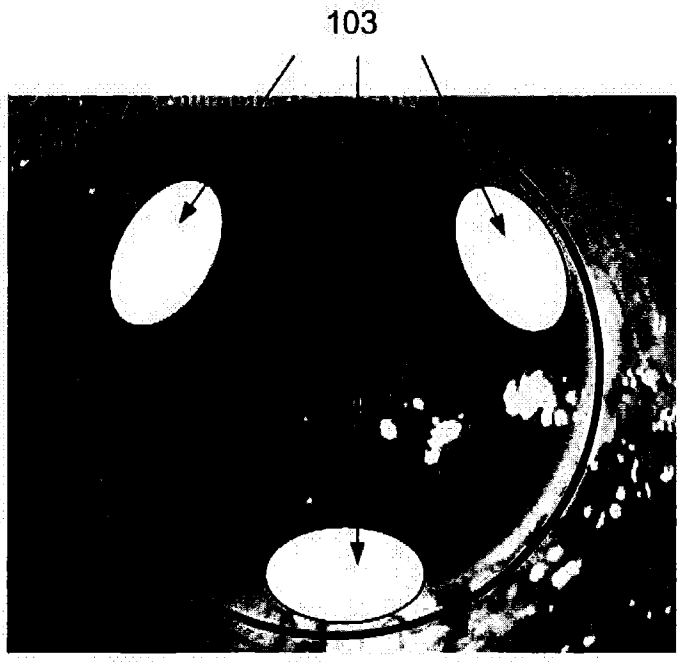
A graphical representation of the separation of the rear surface of the lens from the cornea.

Figure 22



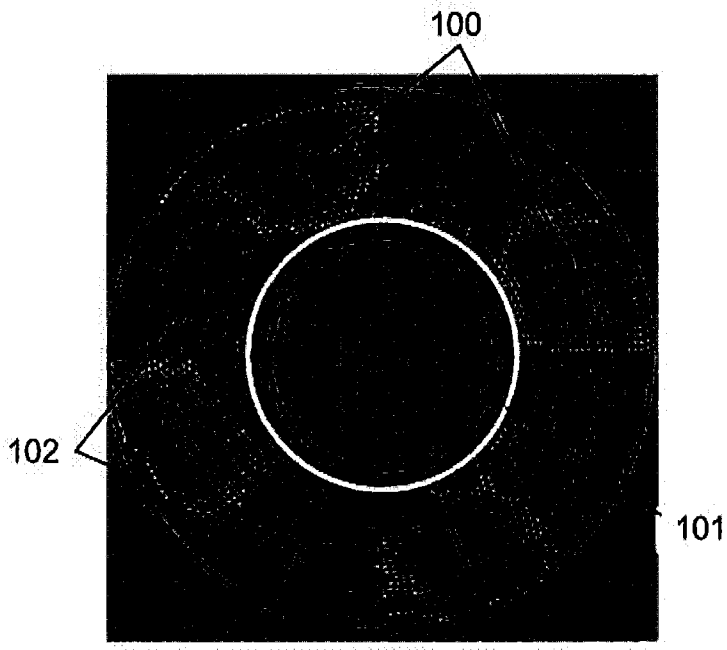
A Simulated Fluorescein pattern of tears behind the lens.

Figure 23



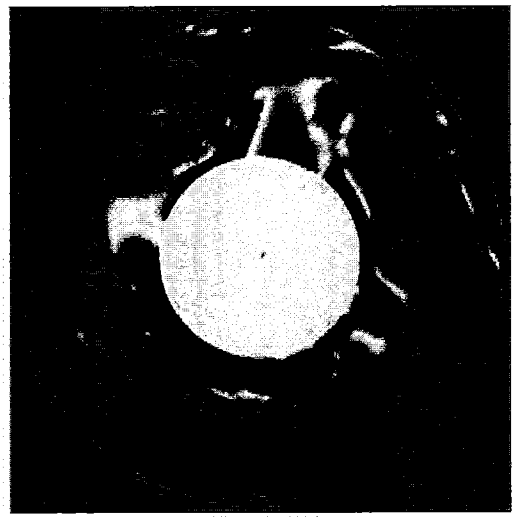

Support beyond the injury

Figure 24



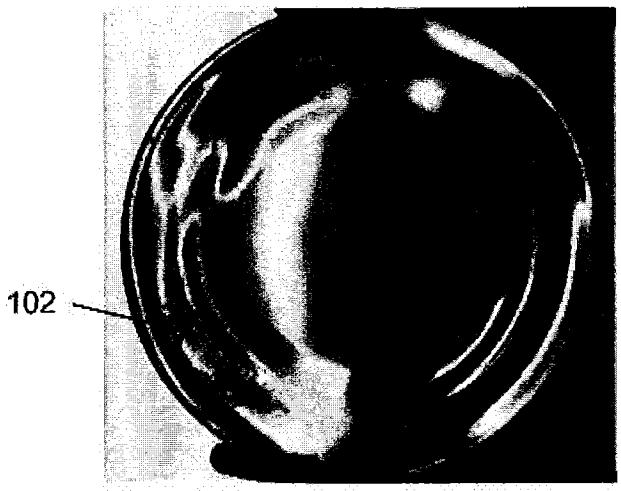

Surface Model Image of Posterior Surface of Lens Design

Figure 25



Colourisation of Irregular Back Surface of a therapeutic lens provided by the embodiments of the invention

Figure 26




View through a therapeutic lens according to the embodiments of the invention

Figure 27

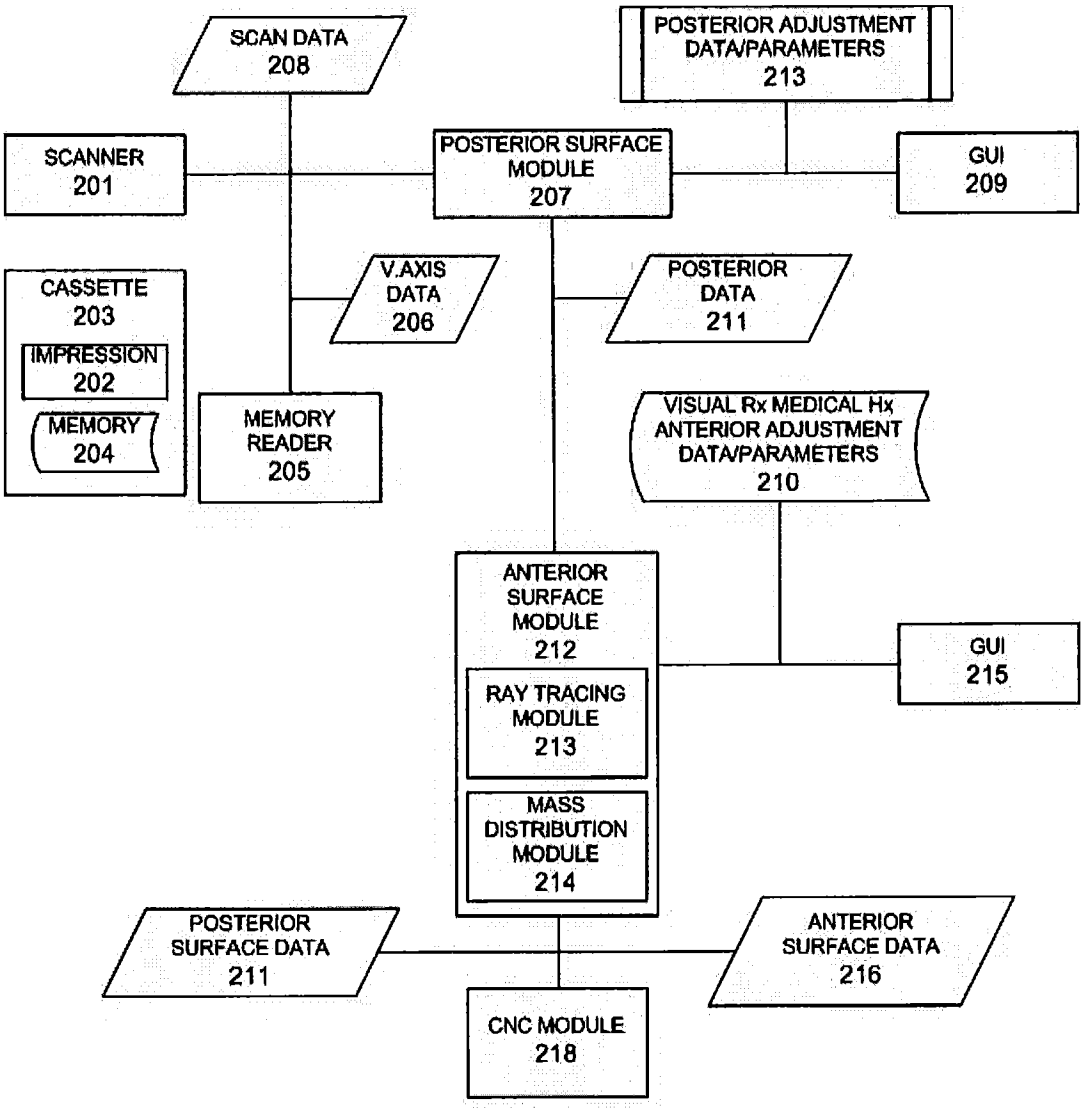



Figure 28

Figure 29