Title: CORNEAL DEPTH MEASURING SYSTEM AND METHOD

Abstract: A system and method for determining the depth of a pocket formed in corneal tissue is disclosed. The system generally comprises a reference base component (40) for inserting into the pocket and a measurement component (50) for contacting the anterior surface of the cornea such that the distance between the two components represents the depth of the corneal pocket. The measurement component comprises a sensing coil (SC) and a reference coil (RC) which may be arranged in a bridge circuit and driven by oppositely-phased alternating currents. The sensing coil interacts with the reference base component to vary the reluctance of the sensing coil depending upon the position of the reference base component relative to the sensing coil. The reference coil is arranged relative to the sensing coil in such a way that its interaction with the reference base is different from that of the sensing coil, so that the two signals can be compared to determine the position of the reference base component. The reference base component may comprise a conductive or a magnetically permeable material adapted to interact with the sensing coil. The depth gauge further provides wiring electrically coupling the reference and sensing coils to an electrical circuit to analyse an electrical output of the reference and sensing coils. The electrical circuit may include a temperature gradient compensating circuit to compensate for the effect of temperature on the sensing coil. The reference base component and the measurement component may be separate components or integrated into a single-piece depth measurement gauge.
CORNEAL DEPTH MEASURING SYSTEM AND METHOD

BACKGROUND OF THE INVENTION

Field of Invention

The present invention relates generally to the field of eye surgery and more particularly to a method and apparatus for measuring the depth of an incision or pocket in a patient’s cornea.

Description of the Related Art

Certain surgical procedures such as for the correction of visual disorders require incisions in the patient’s cornea. For example, U.S. Patent No. 4,452,235, incorporated by reference in its entirety herein, describes a method and apparatus for corneal curvature adjustment. The method comprises insertion of one end of a split-end intrastromal corneal ring into an incision formed in the patient’s cornea and movement of the ring in a circular path until the ends of the ring meet. The corneal ring’s thickness relates to the degree of corneal flattening which can be obtained to provide for correction of varying degrees of myopia or other visual disorders. Such corneal rings are discussed in U.S. Patent No. 5,318,047, which is incorporated by reference in its entirety herein. In addition, U.S. Patent No. 5,090,955, incorporated by reference in its entirety herein, describes the adjustment of corneal curvature through the injection of a polymeric gel into an incision made in a patient’s cornea.

These corrective procedures require precise measurement of the depth of the pocket into which the intrastromal corneal ring or gel is to be inserted. These procedures require an initial measurement of the corneal thickness, typically utilizing an ultrasonic pachymeter. An adjustable-depth diamond knife then makes a peripheral incision to a depth that corresponds to a predetermined fraction of the pachymetry measurement at the incision site. For example, to insert an intrastromal corneal ring, the incision depth may correspond to approximately 68% of the pachymetry measurement.
After the initial incision is made, at least one lamellar pocket is formed for insertion of the intrastromal corneal ring or gel therein. Using conventional methodology, the depth of the pocket can be estimated using a set of mechanical corneal thickness gauges, such as those made by KeraVision, Inc., the assignee of the present invention. These gauges feature gaps of different widths for measuring corneal tissue thickness and thus pocket depth. If the measurement indicates that the pocket is not deep enough into the corneal stroma, the diamond knife is used to make a slightly deeper incision to create a second pocket at a deeper level. This procedure is repeated until a corneal pocket of a desired depth is created. After the pocket at the desired depth is formed, the pocket is further formed into an annular shape for insertion of an intrastromal corneal ring injection or injection of a gel therein.

U.S. Serial No. 08/476,462, filed on June 7, 1995 (Attorney Docket No. 251692001700), assigned to KeraVision, Inc., the entirety of which is incorporated by reference herein, discloses depth measuring apparatus suitable for measuring the depth of corneal tissue. An apparatus comprising a reflective energy depth measuring gauge which uses a reflective element inserted into the corneal pocket below the anterior surface and directs radiant energy toward the reflective element is disclosed. A detector determines the depth of the reflective element below the anterior surface based upon the energy reflected by the reflective element.

Many conventional ophthalmic thickness measuring gauges do not provide the capability of measuring partial corneal depths. In addition, many of these gauges are not sufficiently temperature robust to allow the apparatus to be autoclaved or steam sterilized.

Measuring the depth of the corneal pocket is important for intrastromal corneal ring (or ring segment) implantation and other corneal surgery procedures. The depth at which the ring is implanted may affect the resulting refractive change. Therefore, it is desirable to provide an accurate and dependable way of measuring the depth of corneal pockets, which are used for refractive correction and other ocular surgery procedures. It is also desirable to provide a system and method of measuring partial corneal depths. It is further desirable to provide a corneal depth measuring system which allow for the autoclaving and/or can be easily sterilized.
SUMMARY OF THE INVENTION

The present invention involves apparatus and methods for measuring the depth of a pocket made in tissue. Such a pocket may be made by making an incision (e.g., a controlled-depth incision) into the tissue of a patient and delaminating the tissue at the bottom of the incision to create a tissue pocket. The tissue has an anterior surface. It may be the corneal tissue of an eye with the anterior surface of the corneal tissue being the anterior surface of the cornea. According to one aspect of the invention, a reference base component of a depth measuring apparatus is inserted into a tissue pocket. A movable measurement component is placed in contact with the anterior surface of the tissue (e.g., the anterior surface of a cornea) such that the distance between the reference base component and the movable measurement component represents the depth of the pocket (e.g., a corneal pocket).

In one embodiment, the reference base component and the movable measurement component are integrated into a single-piece depth measurement gauge. The single-piece depth measurement gauge generally comprises a housing having a base configured for insertion into corneal tissue, a member coupled and movable relative to the housing, configured to rest on an anterior surface of the corneal tissue and including an interacting member. The gauge further includes a sensing coil and a noise reduction circuit. The base may be configured to be positioned in the corneal pocket approximately parallel to the anterior corneal surface. The sensing coil is disposed within the housing and electrically coupled to an electrical energy source (e.g., a voltage or current source). The sensing coil is adapted to interact with the interacting member of the movable member to vary a measurable parameter, such as reluctance, of the sensing coil, depending upon the position of the interacting member relative to the sensing coil. The circuit is adapted to reduce a portion of the variation of the measurable parameter. The circuit may comprise a reference coil also disposed within the housing and electrically coupled to a second electrical energy source (e.g., a voltage or current source) and preferably the same type, voltage or current as the first source. The reference coil is located near the sensing coil and arranged so that conditions that might affect the reluctance of either coil and that are independent of the position of the interacting member (such as temperature) are the same for both coils, but the effect of the position of the
interacting member is different for each coil. (Generally, the portion of the variation of the measurable parameter of the sensing coil, upon which the noise reduction circuit acts, is independent of the position of the interacting member.) By comparing the reluctance of each coil, the effects which are independent of the position of the interacting member can be corrected for. The interacting member may comprise a conductive or a magnetically permeable material. Where the interacting member comprises a conductive material, the coil(s) is preferably driven with an alternating current or voltage in order to induce eddy currents in the conductive material which, in turn, interact with the magnetic field of the sensing coil(s) to vary its (their) reluctance. The interacting member, for example, may be a ring movable over the sensing coil or a core movable within the sensing coil.

The housing may provide an opening to provide access to a surface of the movable member. The depth gauge may further comprise wiring electrically coupled to the reference and sensing coils and an electrical circuit electrically coupled to the wiring to analyze an electrical output of the reference and sensing coils. The noise reduction circuit may include a temperature gradient compensating circuit to remove the effects of a temperature gradient between the sensing and reference coils.

In another embodiment, the reference base component and the movable measurement component are two separate pieces of the depth gauge. The two-piece depth measurement gauge generally comprises a member having a target configured for insertion into corneal tissue, a housing including a tip portion positionable on an anterior surface of the corneal tissue generally adjacent the incision and a noise reduction circuit, which may comprise a reference coil. The target is adapted to be positioned in the corneal pocket approximately parallel to the anterior corneal surface.

The tip portion comprises a sensing coil. The sensing coil is disposed within the tip portion and is electrically coupled to a first and a second electrical source, respectively. The sensing coil is adapted to interact with the target to vary a measurable parameter, such as reluctance, of the sensing coil depending upon the position of the target relative to the sensing coil. The noise reduction circuit adapted to reduce a portion of the variation of the measurable parameter of the sensing coil. When the circuit comprises a reference coil, the reference coil is disposed distal of
the sensing coil relative to the target such that the reluctance of the reference coil is
independent of the position of the target. Generally, the portion of the variation of
the measurable parameter of the sensing coil, upon which the noise reduction circuit
acts, is independent of the position of the target.

The target may include a magnetically permeable material or a conductive
material. Where the target comprises a conductive material, the coil(s) preferably is
driven with an alternating current or voltage to induce eddy currents in the
conductive material. The eddy currents interact with the magnetic field of the
sensing coil to vary the reluctance of the sensing coil. Again, the depth gauge may
include wiring electrically coupled to the reference and sensing coils. The wiring is
in turn electrically coupled to an electrical circuit for analyzing the electrical output
of the reference sensing coils. The electrical circuit may also include a temperature
gradient compensating circuit.

In either the single or two-piece depth gauge, the currents applied to the
sensing and reference coils are preferably oppositely phased alternating current.

Further, the noise reduction circuit in any embodiment may comprise a
reference coil, a temperature gradient compensation circuit, or both.

**BRIEF DESCRIPTION OF THE DRAWINGS**

FIG. 1 is a side plane view of a single-piece depth measuring gauge of the
present invention;

FIG. 2 is a top plane view of the depth measuring gauge of FIG. 1;
FIG. 3 is a cross-sectional view along line 3-3 of FIG. 1;
FIG. 4 is a cross-sectional view along line 4-4 of FIG. 2;
FIG. 5 is a side plane view of a reference base component of the single-piece
depth measuring gauge of FIG. 1;
FIG. 6 is a top plane view of the reference base component of FIG. 5;
FIG. 7 is a side plane view of a movable measurement component of the
depth measuring gauge of FIG. 1;
FIG. 8 is a top plane view of the movable measurement component of FIG. 7;
FIG. 9 is a side plane view of an alternative single-piece depth measuring
gauge of the present invention;
FIG. 10 is a top plane view of the alternative single-piece depth measuring
gauge of FIG. 9;
FIG. 11 is a side plane view of a measurement component and the target of a
two-piece depth measuring gauge of the present invention;
FIG. 12 is a top plane view of the measurement component of the two-piece
depth measuring gauge of FIG. 11;
FIG. 13 is a block diagram of the depth measuring gauge of the present
invention;
FIG. 14 is a block diagram of the temperature gradient compensating circuit
for use with the depth measuring gauge of the present invention;
FIG. 15 is a schematic perspective view of a probe for measuring thickness of
a cornea;
FIG. 16 is schematic cross-sectional view of an incision formed in the cornea;
FIG. 17 is a partial cross-sectional view showing the formation of an incision
in the cornea; and
FIG. 18 is a schematic cross-sectional view of a tool for separating the
lamella at the base of the incision and forming a pocket in accordance with the
present invention.

DETAILLED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention relates to a method and apparatus for determining the
depth of an incision or pocket in tissue, such as corneal tissue, utilizing a differential
variable reluctance transducer (DVRT). Descriptions of specific applications are
provided only as examples. Various modifications to the preferred embodiment will
be readily apparent to those skilled in the art, and the general principles defined
herein may be applied to other embodiments and applications without departing from
the spirit and scope of the invention. Thus, the present invention is not intended to
be limited to the embodiments shown, but is to be accorded the widest scope
consistent with the principles and features disclosed herein.

One-Piece Depth Measurement Gauge

FIGS. 1 and 2 show, respectively, a side and top plane view of a single-piece
depth measuring gauge 30 of the present invention. FIGS. 3 and 4 show, respectively, a cross-sectional view along line 3-3 of FIG. 1 and along line 4-4 of FIG. 2.

The single-piece depth measuring gauge 30 generally comprises a housing 32 which houses a reference base component 40 and a movable measurement component 50. The movable measurement component 50 is movable relative to both the housing 32 and the reference base component 40 while the reference base component 40 is stationary relative to the housing 32. Housing 32 is preferably a stainless steel tube into which at least a portion of the movable measurement component 50 can retract.

The side and top plane views of FIGS. 5-8 show in more detail the reference base component 40 and the movable measurement component 50.

The reference base component 40 is stationary relative to the housing 32 and comprises a stationary body 42 disposed within the housing 32, an elongate extension 44 extending from the body 42 exterior to the housing 32 and a base 46 extending generally transversely from the elongate extension 44. The elongate extension 44 preferably is tapered and defines an indentation 48 to facilitate depth or partial thickness measurement of the cornea, as will be described in more detail below. The stationary body 42 may be secured to the housing 32 by any suitable mechanism such as by adhesives, welding, set screw, press fit pin, and/or by defining threads 49 at an end thereof engageable with threads 34 defined by an interior surface of the housing 32.

The movable measurement component 50 comprises a tubular body 52 and an elongate member 54 extending from the tubular body 52 exterior to the housing 32. The tubular body 52 defines a space configured to receive the stationary body 42 of the reference base 40 therein such that the tubular body 52 is slidable within the annular space defined between the housing 32 and the stationary body 42 of the reference base 40. In addition, the elongate member 54 of the movable component 50 is generally in contact with and movable relative to the extension 44 of the reference base 40.

The housing may define one or more openings 36 to provide access to the movable component 50 so as to facilitate manipulation thereof by a user, such as a
surgeon. The exposed surfaces 56 of the tubular body 52 of the movable component 50 may be knurled to provide enhanced frictional contact between the movable component 50 and the user. Similarly, a region 38 of the housing 32 may provide grooves or threads to enhance frictional contact between the housing 32 and the user.

To measure the depth of a pocket, flap, graft or incision using the single-piece depth measuring gauge 30 of the present invention, the surgeon retracts the movable component 50 further into the housing 32, creating a gap or space between the base 46 of the reference base 40 and a free end of the elongate member 54 of the movable component 50. The surgeon then inserts the reference base 40 between lamellar layers of the tissue via the incision and allows the movable component 50 to rest on an anterior surface of the tissue. As is evident, the indentation 48 facilitates both insertion and placement of the base 46 into the pocket or incision. Base 46 preferably is positioned to be generally tangential to the lamellae.

The depth gauge 30 is configured to place a light, constant pressure on the anterior surface of the cornea so as to minimize variations due to compression of tissue. The light constant pressure may be exerted by merely the weight of the movable component 50 resting on the anterior surface of the cornea and/or a force provided by a spring coupled between the housing 32 and the movable component 50.

The gap between the base 46 and the free end of the movable elongate member 54 represents the depth of the pocket or incision. Thus, the depth measuring gauge 30 measures the position of the measurement component 50 relative to the base component 40, i.e. the gap or space between the base 46 of the reference base 40 and the free end of the movable elongate member 54 and delivers an electrical output to be analyzed via wiring 60, as will be described in more detail below.

Although not shown, the wiring 60 may be protected by a strain relief which provides flexibility but prevents sharp bending of wiring 60 at the wiring 60 and housing 32 interface. The strain relief may be a standard off-the-shelf part such as a polyurethane tubing or winding which may be threaded into or otherwise attached to an end of the housing 42. In addition, the interior surface of the housing 32 may be coated with a thin continuous layer of insulation to provide enhanced electrical and/or thermal isolation of the internal electronics from the housing 32 as well as the
external environment. Further, the electrical connections within the housing 32 are preferably potted in epoxy, resulting in enhanced moisture resistance.

FIGS. 9 and 10 show, respectively, a side and a top plane view of an alternative single-piece depth measuring gauge 130 of the present invention. The depth gauge 130 similarly comprises a housing 132, a reference base component 140 and a movable measurement component 150. The movable measurement component 150 comprises a tubular body 152 exterior to the housing 132 and is slidable over the body 142 of the reference base 140. Such an embodiment facilitates movement of the movable component 150, but requires the user to hold the housing 132 and manipulate the movable component 150 simultaneously.

Two-Piece Depth Measurement Gauge

FIGS. 11 and 12 show, respectively, a side and a top plane view of a two-piece depth measuring gauge 230 of the present invention. The two-piece depth measuring gauge 230 generally comprises a target 240 and a measurement tip 250. Similar to the single-piece depth measuring gauges described above, the gap between the target 240 and the free end of the measurement tip 250 represents the depth of the pocket or incision being measured. Thus, the depth measuring gauge 230 measures the position of the measurement tip 250 relative to the target 240 and delivers an electrical output to be analyzed via wiring 260, as will be described in more detail below.

In either the single-piece depth measurement gauge or the multiple- or two-piece depth measurement gauge, the gauge is contained such that it is sufficiently temperature robust to withstand steam sterilization or autoclaving.

The base of the single-piece depth gauge and the target of the two-piece depth gauge comprise a biocompatible material or, at the minimum, an exterior biocompatible layer, such as a biocompatible polymer or other biocompatible material(s). For example, the base or target may comprise gold-coated stainless steel or other ferrous material such as iron. The base or target is preferably sterilizable and sufficiently rigid to be placed in the cornea.

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Function and Operation of the Depth Measurement Gauge

Each of the depth measurement gauges of the present invention utilizes a differential variable reluctance transducer ("DVRT") to deliver the electrical output to be analyzed via wiring. Examples of DVRTs are disclosed in U.S. Patent Nos. 5,497,147 and 5,777,467, which are incorporated by reference in their entireties herein. The function of the DVRT during operation of the single-piece depth measurement gauge embodiment and the two-piece depth measurement gauge embodiment will each be described in turn.

Function and Operation of the Single-Piece Depth Measurement Gauge

For the single-piece depth measurement gauge, the DVRT is described below in terms of the depth gauge 30 shown in FIGS. 1-8, although similar function and concepts are applicable to other variations of the single-piece depth measurement gauge, such as that shown in FIGS. 9-10.

To generate an electrical output representative of the gap or space between the base 46 of the reference base 40 and the free end of the movable elongate member 54, the depth measurement gauge 30 comprises a reference coil "RC" and a sensing coil "SC" disposed within a space 43 defined by the body 42 of the reference base component 40. The sensing coil and the reference coil are disposed next to each other along an axis 62 of the depth gauge 30. The coils are also electrically serially connected. Preferably, the coils are windings of fine wire wound about the axis 62. Other suitable methods of forming the coils may also be utilized, such as vacuum deposition of conductive material over a bobbin and subsequent controlled photolithographic or laser micro-machining for selective removal of conductive material leaving a coil behind on a bobbin.

The sensing coil is disposed closer to the movable body 52 so as to interact with the movable body 52 while the reference coil is disposed further away from the movable body 52. Preferably, the coils are potted within housing 42 such as by vacuum pumped epoxy. Potting of the coils ensures that the coils remain stationary relative to the housing and also protects the coils from moisture and other external environment conditions.

The body 52 of the movable component 50 preferably provides a region 58 in
which a ring 59 (shown in phantom) is disposed. Preferably, the ring comprises a magnetically permeable material. The ring 59 may be press fitted, bonded, welded, or otherwise securely disposed in region 58. The position of the ring 59 of the movable component 50 along the axis 62, preferably adjacent to and/or over the sensing coil but not the reference coil, affects the reluctance of the sensing coil while the reluctance of reference coil remains relatively constant to serve as a reference. Reluctance, as is known to a person of ordinary skill in the art, is the inverse of magnetic permeability. The coils are driven by opposite phase alternating currents (AC) and their differential reluctance is measured and converted to depth measurements, as will be described below.

In addition to the displacement of the ring 59 affecting the reluctance of the sensing coil, temperature variations or gradients also affect the reluctance of the coils. However, because the sensing and reference coils in general experience the same temperature variations, i.e. little or no temperature gradient between the two coils, temperature variations generally are compensated and do not affect the output of the depth gauge 30.

Rather than comprising a magnetically permeable material, the ring 59 may alternatively comprise a highly conductive metallic material, such as aluminum or gold. Provision of a conductive ring 59 requires the application of an alternation current or voltage source to the coil(s) such that eddy currents are induced in the ring 59 and interact with the magnetic field around the sensing coil to vary the reluctance of the sensing coil. The inductor may be a single or multiturn inductor or may have other configurations.

Further, although the movable component 50 is shown and described to provide a magnetically permeable or a highly conductive metallic ring displaceable or slidable over the sensing coil, the movable component 50 may alternatively provide a magnetically permeable or a highly conductive metallic core disposable within a central opening of the sensing coil. Such a configuration functions in a similar manner as described above and can be calibrated in the same manner to result in similar depth measurement data.

One advantage of the single-piece depth measurement gauge is that it positions the coils away from the cornea such that the size of the coils is generally
not of much concern and the coils can be relatively large to provide strong signals. Thus, such a device can provide results with very good signal-to-noise ratios.

In the two-piece depth gauge, each coil can be approximately 0.030-0.120 inches in diameter. The tip may be plastic or other nonmagnetic material such as titanium and may be cylindrical with a diameter range of approximately 0.050-0.150 inches and a length of about 0.25-0.75 inches. It should be understood, however, that the tip may have other configurations such as a conical configuration with a taper. Such tapering of the tip allows better targeting for the surgeon and easier machining.

Function and Operation of the Two-Piece Depth Measurement Gauge

The two-piece depth measurement gauge operation is similar to that of the one-piece depth measurement gauge. The DVRT for the two-piece depth measurement gauge is described below in terms of the depth gauge 230 shown in FIGS. 11-12, although similar function and concepts are applicable to other variations of the multi-piece depth measurement gauge.

To generate an electrical output representative of the gap or space between the target 240 and the free end of the measurement tip 250, the depth measurement gauge 230 comprises a sensing coil 264 and a reference coil 266 disposed within the measurement tip 250. The sensing coil 264 and the reference coil 266 are disposed next to each other. The coils are also electrically serially connected. Preferably, the coils are windings of fine wire. Other suitable methods of forming the coils may also be utilized, as described above with respect to the one-piece depth gauge.

The target 240 may be made of a conductive or magnetic material that will affect the magnetic field created by the coils in a measurable way, such as be measuring coil reluctance. Examples of such materials are aluminum (conductive), gold (conductive), or steel, (magnetic). In addition, the target 240 is preferably biocompatible.

As with the single-piece depth gauge, the sensing coil 264 is disposed closer to the target 240 such that the magnetic field around the sensing coil 264 interacts with the eddy currents induced in the target 240 as a result of a current driven therethrough. The interaction of the magnetic field around the sensing coil 264 and the eddy currents results in a variation in the reluctance of the sensing coil 264. In
contrast, the reference coil 266 is disposed further away from the target 240 such that
the magnetic field around the reference coil 266 does not interact with the eddy
current induced in the target 240. Thus, the reluctance of the reference coil 266 is
unaffected by the eddy currents through the target 240.

Preferably, the coils are potted within the tip 250 such as by vacuum pumped
epoxy. Potting of the coils ensures that the coils remain stationary within the tip 250
and protects the coils 264, 266 from moisture and other external environment
conditions. The coils are driven by opposite phase alternating currents (AC) and
their differential reluctance is measured and converted to depth measurements.

Unlike the single-piece depth measurement gauge, the coils of the two-piece
depth measurement gauge must be sufficiently small to allow the gauge to be utilized
on the cornea and to allow the surgeon good visibility of the work area. Because the
coils are relatively small, the coils provide relatively small signals.

Similar to the single-piece depth measurement gauge, the temperature
variations or gradients of the sensing and reference coils also affect the reluctance of
the sensing coils. However, unlike the single-piece depth measurement gauge, there
may be a temperature gradient between the reference and the sensing coils because
the sensing coil is in very close proximity to the anterior surface of the cornea as the
tip 250 is placed directly upon the anterior surface of the cornea. Further, the
accuracy of the output may further be degraded by the small signal output from the
small coils. Thus, a sufficiently large temperature gradient between the sensing and
the reference coils may result to adversely affect the accuracy of the measurement
output.

Analysis of the Output from the One- or Two-Piece Depth Measurement Gauge

As shown in FIG. 13, the sensing coil 276 and the reference coil 278 are
electrically coupled, via the wiring extending from the depth gauge, to oscillators
280, 282, respectively. The oscillators 280, 282 resonate at a frequency dependent
upon the position of the movable component of the depth gauge. A mixing circuit
284 combines those frequencies from the oscillators 280, 282 and outputs the
frequency difference. This frequency difference is sent to a high frequency carrier
oscillator 286 and is used to modulate the high frequency carrier.
The signal from the high frequency carrier oscillator 286 may be sent through an amplifier 288 and enter a phase-locked-loop circuit 290 which clarifies the signals and sends the signals to a microprocessor 292. A software program 294 controls the function of the microprocessor, accesses calibration files (the collected calibration coefficients of the polynomial regression discussed below) for specific DVRTs, and enhances their performance by implementing algorithms for temperature compensation and linearization. After processing the signals, the microprocessor 292 sends the data to display 296 and storage 298, respectively, to display and store the data.

Linearization is accomplished by multiple breakpoint polynomial regression. The data used to develop the multiple breakpoint polynomial regression may be determined by calibrating the DVRT using gauge blocks of known thickness or by incrementally moving the DVRT using a fine micrometer thread. These calibrations are curve fitted using multiple ordered polynomial connected at breakpoint, which are selected by the user in order to achieve a required accuracy.

Many variations may be made to the analysis of the electrical output of the depth gauge described above. For example, electronic output from the depth gauge may be sent via wireless transmission so as to free the depth gauge from wire connections.

*Temperature Gradient Compensation Circuit*

As noted above, temperature variations or gradients may adversely affect the accuracy of the depth measurements, particularly with the two-piece depth gauge utilizing relatively small sized coils. Such a temperature gradient compensation circuit is shown in FIG. 14 and disclosed in copending U.S. Serial No. 09/110,513, filed on July 6, 1998 by Arms and Townsend, which is a continuation-in-part application of U.S. Serial no. 08/590,835, filed on January 24, 1996, now U.S. Patent No. 5,777,467, the entireties of which are incorporated by reference herein.

The wires from the coils of the depth gauge described above are utilized to complete a wheatstone bridge which serves as an inductive or AC bridge 400. The AC bridge 400 is also driven with DC current from a DC power supply 402 to enable the measurement of the effect of temperature gradients independently of the change.
in the reluctance of the coils. The output of the bridge 400 is routed to a low pass filter 404 to remove the AC signal component of the output of the bridge 400. The output of the low pass filter 404 is then fed into an adjustable gain instrumentation amplifier 406. The output of the instrumentation amplifier 406 is a signal which is proportional to the temperature gradient experienced by the coils.

In addition to the DC signal conditioning, the output of the AC bridge 400 is fed to a high pass filter 408 and sent to a synchronous demodulator or other AC signal conditioner 410. This output signal 412 is proportional to the sum of the effects of the temperature gradient and the physical parameter being measured, i.e. the corneal depth.

A difference amplifier 414 subtracts the output from the DC signal conditioner 406 from the output 412 of the AC signal conditioner 410. In other words, difference amplifier 414 removes the temperature gradient effects provided that the gain of the AC system is the same as the gain of the DC system. Thus, the output 416 of the difference amplifier 414 is independent of the effects of temperature. Alternatively, a microprocessor may be utilized to measure the AC and DC outputs, appropriately scale the values and obtain the difference. The output of the DC circuit is proportional to the DC resistance of the winding while the output of the AC circuit is proportional to the sum of the AC resistance at the excitation frequency and the DC resistance of the leadwire. The following equations illustrate the above (\( \alpha \) means "is proportional to" as is conventional).

\[
\begin{align*}
\text{AC}_p \text{ Output} & = 2 \pi F L_{\text{sens}} + R_{\text{dc}} \\
\text{DC Output} & = R_{\text{dc}} \\
\text{Final Output} & = \text{AC}_p \text{ Output} - \text{DC Output} = 2 \pi F L_{\text{sens}}
\end{align*}
\]

where:

\[
\begin{align*}
R_{\text{dc}} & = \text{DC resistance of the sensor} \\
L_{\text{sens}} & = \text{Inductance of the sensor} \\
F & = \text{Frequency of excitation to the inductive sensor}
\end{align*}
\]

Another embodiment of the temperature gradient compensation circuit utilizing an AC signal rather than a DC signal for the secondary bridge drive is also shown in FIG. 14. In this embodiment, rather than the DC drive 402, a secondary
AC (Fs) drive 420 generates signals significantly lower than that generated by the primary AC (Fp) drive 422. The low pass filter 404 would include a cutoff frequency such that the filter 404 would pass the secondary drive signal and filter the primary drive signal such that the output would be the bridge output at the secondary drive frequency. This output is fed to a secondary synchronous demodulator 424.

The output of the synchronous demodulator 424 would be fed to the difference amplifier 414 and subtracted from the output 412 of the primary AC synchronous demodulator 410. In this embodiment, the system may be utilized for other sensors, which require synchronous demodulation, such as capacitive sensors.

The following equations illustrate that the output is proportional to the inductance and is independent of the DC resistance:

\[ \text{AC}_p \text{ Output} = 2 \pi F_p L_{\text{sens}} + R_{dc} \]
\[ \text{AC}_p \text{ Output} = 2 \pi F_s L_{\text{sens}} + R_{dc} \]
\[ \text{Final Output} = \text{AC}_p \text{ Output} - \text{AC}_s \text{ Output} = 2 \pi L_{\text{sens}} (F_p - F_s) \]

where:

- \( F_p \) = Primary frequency of excitation to the inductive sensor
- \( F_s \) = Secondary frequency of excitation to the inductive sensor

The addition of a summing amplifier 426 following the low pass filter 404 allows a direct measure of the temperature, rather than the temperature gradient provided at the output of the DC instrumentation amplifier 424. This provides the option for additional temperature compensation, such as span error compensation. The output of the DC instrumentation amplifier 424 can be input into a microprocessor for span correction or input into a voltage controlled amplifier for span compensation. Although one arrangement is shown in FIG 14, it should be understood that other configurations can be used. The AC drive can be either a voltage or current source for example. In addition, the DC drive can be either a voltage or current source.

**Overview of Corneal Surgery**

FIGS. 15-18 illustrate some of the steps of a corneal surgery procedure,
specifically, preparation of a patient’s cornea for the implantation of an intrastromal corneal ring. Those skilled in the art will recognize that the present invention may be employed to measure tissue pockets in a wide variety of surgical procedures, including automated lamellar keratotomy, suture cataract incisions, or any procedure to implant an inlay into the eye.

Prior to the initial incision, an ultrasonic pachymetry probe 300 is placed against the cornea 302 of the patient’s eyeball 304 as shown in FIG. 15 to measure the thickness of the cornea. As shown in FIGS. 16 and 17, an incision 306 is made in the cornea using a diamond blade knife 308. The depth D is preferably in the range of 0.30-0.45 mm, preferably approximately 68% of the corneal thickness T, and the incision length is preferably between 1-2 mm, although these dimensions may vary depending upon the particular application or procedure.

A tool or glide 310 is inserted into the incision 306 as shown in FIG. 18 to separate the lamella at the base of the incision 306. The glide 310 is moved parallel to the anterior surface of the cornea 302 to form an initial pocket 312 within the cornea at the base of the incision 306.

Prior to the formation of the complete annular track for an intrastromal corneal ring or other corneal implant, it is desirable to determine whether the initial pocket 312 is at the correct depth or within the correct depth range. In contrast, the depth measurement gauge of the present invention provides a method and apparatus for measuring the depth of the pocket 312, flap, or incision made at a partial depth of the cornea.

The depth gauge of the present invention provides an important capability to make partial thickness corneal measurements. Such measurements can be utilized in several surgical procedures such as intrastromal corneal ring implantation, lamellar keratoplasty, and laser assisted in situ keratomileusis (LASIK).

While the preferred embodiments of the present invention are described and shown above, it is to be understood that they are merely illustrative and that no limitations are intended thereby other than as described in the appended claims.
CLAIMS

What is claimed is:

1. A corneal tissue depth measuring gauge, comprising:
   a housing having a base configured for insertion into corneal tissue;
   a member coupled and movable relative to the housing, said member
   having a first end configured to rest on an anterior surface of the corneal tissue and
   comprising an interacting member disposed at a second end of said member;
   a sensing coil disposed within said housing and adapted for electrically
   coupling to an electrical energy source, said sensing coil arranged to interact with
   said interacting member to vary a measurable parameter of said sensing coil
   depending upon the position of said interacting member relative to said sensing coil;
   and
   a circuit adapted to reduce a portion of the variation of the measurable
   parameter of the sensing coil which is independent of the position of said interacting
   member.

2. The corneal depth measuring gauge of claim 1, wherein the circuit
   includes a reference coil disposed within said housing and adapted to be electrically
   coupled to a second electrical energy source.

3. The corneal depth measuring gauge of claim 1, wherein said housing
   base includes a portion adapted to be positioned in a corneal pocket approximately
   parallel to the anterior corneal surface.

4. The corneal depth measuring gauge of claim 3, wherein said first end of
   said movable member is configured to rest on said base of said housing.

5. The corneal depth measuring gauge of claim 1, wherein said housing
   defines an opening providing access to a surface of said member.

6. The corneal depth measuring gauge of claim 1, wherein said measurable
   parameter is reluctance.
7. The corneal depth measuring gauge of claim 1, wherein said interacting member comprises a magnetically permeable material.

8. The corneal depth measuring gauge of claim 1, wherein said interacting member comprises a conductive material.

9. The corneal depth measuring gauge of claim 1, further comprising: wiring electrically coupled to said reference coil and sensing coil; and an electrical circuit electrically coupled to said wire to analyze an electrical output of said reference coil and sensing coil.

10. The corneal depth measuring gauge of claim 9, wherein said electrical circuit includes a temperature gradient compensating circuit.

11. A corneal tissue depth measuring gauge, comprising: a member having a target configured for insertion into corneal tissue; and a housing including a tip portion positionable on an anterior surface of the corneal tissue, said tip portion comprising: a sensing coil disposed within said tip portion and electrically coupled to an electrical energy source, said sensing coil being adapted to interact with said target to vary a measurable parameter of said sensing coil depending upon the position of said target relative to said sensing coil; and a circuit adapted to reduce a portion of the variation of the measurable parameter of said sensing coil, said variation being independent of the position of said target.

12. The corneal depth measuring gauge of claim 11, wherein the circuit includes a reference coil disposed within said tip portion and electrically coupled to a second electrical energy source, said reference coil being distal of said sensing coil
relative to said target.

13. The corneal depth measuring gauge of claim 12, wherein the measurable parameter of said reference coil is independent of the position of said target.

14. The corneal depth measuring gauge of claim 11, wherein said target is adapted to be positioned in a corneal pocket approximately parallel to the anterior corneal surface.

15. The corneal depth measuring gauge of claim 11, wherein said measurable parameter is reluctance.

16. The corneal depth measuring gauge of claim 11, wherein said target comprises a magnetically permeable material.

17. The corneal depth measuring gauge of claim 11, wherein said target comprises a conductive material.

18. The corneal depth measuring gauge of claim 17, wherein said sensing coil is adapted to interact with induced eddy currents of said target.

19. The corneal depth measuring gauge of claim 12, further comprising: wiring electrically coupled to said reference coil and sensing coil;

and

an electrical circuit electrically coupled to said wire to analyze an electrical output of said reference coil and sensing coil.

20. The corneal depth measuring gauge of claim 19, wherein said electrical circuit includes a temperature gradient compensating circuit.
21. A method for determining the depth of a corneal pocket comprising:

inserting a first member into said pocket; placing a second member at a reference location; and comparing the relative positions of the said first and second members to determine said depth by applying electrical energy to a sensing coil disposed within one of said members, and interacting a magnetic field of said sensing coil with an interacting member disposed within the other of said members.
FIG. 13
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC 7 A61F9/013

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

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61B

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

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

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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X Further documents are listed in the continuation of box C. X Patent family members are listed in annex.

**Date of the actual completion of the international search**

17 October 2000

**Date of mailing of the international search report**

27/10/2000

**Name and mailing address of the ISA**

European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rivneuk Tel. (+31-70) 340-2040, Tx. 31 651 epo.nl, Fax: (+31-70) 340-3016

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