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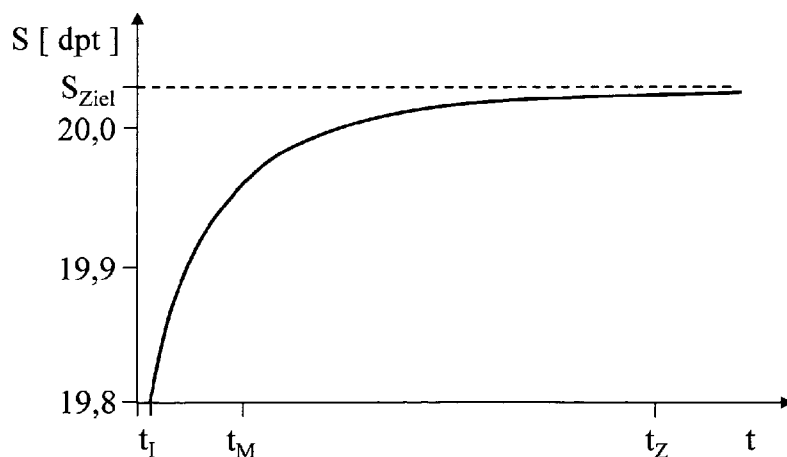
Declarations under Rule 4.17:

— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

— with international search report (Art. 21(3))

(54) Title: METHOD FOR DETERMINING AT LEAST ONE OPTICAL PROPERTY OF A PATIENT EYE WITH AN INTRAOCULAR LENS

FIG. 2

lens (1).

(57) Abstract: A method for determining at least one optical property (S, C) of a patient eye with an intraocular lens (1), comprising the following steps: determining at least one measured value of the optical property (S, C) of the system comprising patient eye and intraocular lens (1) at least one measurement time (t_M) after injecting the intraocular lens (1) into the patient eye; comparing the at least one measured value and the associated measurement time (t_M) to a known time profile of the values of the optical property (S, C) for the intraocular lens (1), wherein the known time profile since unfolding the intraocular lens (1) has been determined experimentally before the intraocular lens (1) is injected and is made available in the form of measurement series or data, formulae or tables derived therefrom; and determining a value for the optical property (S, C) of the system comprising patient eye and intraocular lens (1) at a different time than the measurement time (t_M), according to the known time profile of the values of the optical property (S, C) for the intraocular

**Method for determining at least one optical property of
a patient eye with an intraocular lens**

Intraocular lenses are usually injected into the
5 aphakic eye in a folded state and there they unfold
within a matter of seconds. In some cases, anterior
chamber intraocular lenses are also injected into the
phakic eye. The optical properties of the patient eye
are usually measured before and after the operation.
10 Thus, the medical practitioner obtains no information
during the operation in respect of whether the inserted
lens can also in actual fact enable the desired visual
performance of the patient eye.

15 Hence, it would be desirable to determine the optical
properties of the patient eye with the intraocular lens
during surgery. However, such a measurement proves
impossible using conventional methods because a number
of interfering factors occur during this, and these
20 falsify the measurement result. One source of error
during the measurement lies in the fact that the
optical properties of the intraocular lens change over
a period of time of at least 15 minutes after the
injection into the patient eye, during which the
25 intraocular lens completely unfolds. An intraoperative
measurement performed within a few minutes after the
injection would be falsified as a result of this. Since
conventional cataract surgery only takes approximately
5 to 10 minutes, it however proves not to be possible
30 to wait in the case of the intraoperative measurement
of an implanted intraocular lens until the optical
properties have reached their final value.

DE 10 2007 017 599 A9 describes a method for measuring
35 geometric parameters of an eye in order to be able to
determine a fitting intraocular lens, for example also
for an eye which, as a result of preceding refractive
corneal surgery, has modified relationships between the

front side of the cornea and the back side of the cornea.

5 EP 1 732 471 B1 describes a method for predicting changes in the patient eye caused by the operation. Here, changes of the eye, e.g. a deformation of the cornea as a result of the incisions performed during the operation, are used in the calculation of the optical properties of the intraocular lens.

10

WO 2007/0065670 A2 describes a device for measuring a sample, more particularly an eye, by interferometry.

15 DE 11 2008 002 446 T5 describes an instrument for laser eye surgery, wherein the surgical laser beam is focused as accurately as possible onto the target tissue.

Hence it is an object of the present invention to provide a method for determining at least one optical property of a patient eye with an intraocular lens during surgery, with it being possible to determine the optical property with great accuracy.

25 In order to solve this object, the present invention provides a method according to claim 1. Provision is furthermore made for a computer program product according to claim 7 and a device according to claim 8.

30 A method for determining at least one optical property of a patient eye with an intraocular lens comprises the steps of:

- 35 - determining at least one measured value of the optical property of the system comprising patient eye and intraocular lens at at least one measurement time after injecting the intraocular lens into the patient eye;
- comparing the at least one measured value and the associated measurement time to a known time

profile of the values of the optical property for the intraocular lens, wherein the known time profile since unfolding the intraocular lens has been determined experimentally before the intraocular lens is injected and is made available in the form of measurement series or data, formulae or tables derived therefrom; and

5 - determining a value for the optical property of the system comprising patient eye and intraocular lens at a different time than the measurement time, according to the known time profile of the values of the optical property for the intraocular lens.

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15 Here, the known time profile of the values of the optical property was determined in advance for the utilized intraocular lens. To this end, an intraocular lens manufacturer can, for example, carry out test series in order to establish the time profile of the optical properties for a specific model or for a specific batch of intraocular lenses after the lens unfolds. The results of these test series, or data, formulae or tables derived therefrom are then used during the method according to the invention as known

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25 time profile.

Thus, the method according to the invention can be used to establish a final value of the optical property with great accuracy already at a measurement time at which

30 the change in the at least one optical property of the intraocular lens after the injection has not yet been completed. The known time profile makes it possible to convert a measured value, which was determined shortly after the intraocular lens was injected into the patient eye, into a target value for the optical property which will be present after the intraocular lens has completely unfolded and relaxed in the patient eye. Thus, it is already possible to make a precise

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prediction of the optical property of the patient eye with the injected intraocular lens during the operation. As a result, it is possible to perform possible adjustments of the eye or the intraocular lens in order to enable an improved visual performance.

In this case, the intraocular lens can be injected into the patient eye in a folded state and unfold in the patient eye from the time of the injection. Alternatively, other implantation methods for the intraocular lens are also feasible, in which the intraocular lens is injected into the patient eye in e.g. a rolled or otherwise deformed state.

The at least one measured value can be determined by means of a wavefront measurement. Such a measurement method is known for pre- and postoperative determination of the optical properties of the patient eye and makes it possible to determine the measured value with great accuracy. However, in principle, the present invention is not restricted to a specific measurement method and how the measured values of the patient eye with the intraocular lens and the time profile of the values for the intraocular lens were measured is irrelevant to determining the value of the optical property that will be present after the intraocular lens has completely unfolded.

The at least one optical property can comprise values for the spherical correction, the cylindrical correction and/or a Strehl ratio of the system comprising patient eye and intraocular lens. Here, the most important parameters for the sight of the patient can be determined during the operation with aid of the spherical correction and the cylindrical correction, and so corrections can still be undertaken if required in order to improve the sight of the patient present after the operation.

The Strehl ratio specifies the optical quality of the system comprising intraocular lens and patient eye, and so the method according to the invention can be used to
5 identify defects of the intraocular lens, which impair the optical quality (e.g. as a result of dispersion on a damaged surface of the lens), already during the operation.

10 The at least one measured value can be determined within a time interval of less than 5 minutes, more particularly within a time interval of less than 1 minute, after the injection of the intraocular lens. As a result of measuring the at least one optical property
15 as quickly as possible, a longer period of time remains for the medical practitioner to perform corrections in respect of the optical properties of the patient eye, given a predetermined maximum duration of the cataract operation. By way of example, such a correction can
20 comprise a replacement of the intraocular lens, or corrections that influence the optical properties of the cornea can be performed on the cornea.

The value established from the at least one measured
25 value and the time profile of the optical property can specify a final value of the optical property, which is approached by the time profile. The enables a prediction of the final sight of the patient eye on the basis of the measured value determined shortly after
30 the intraocular lens was injected.

The time profile of the optical property can be described by an exponential function of the form:

$$S(t) = a_1 - b_1 \exp(-c_1 t)$$

35 or

$$C(t) = a_2 + b_2 \exp(-c_2 t),$$

with S being a spherical correction and C being a cylindrical correction of the system comprising patient

eye and intraocular lens, and with a_1 , a_2 , b_1 , b_2 , c_1 and c_2 specifying constants which were determined by a curve fit to experimentally determined data of the optical property of the intraocular lens as a function of the time t elapsed since unfolding. In addition to the time profile of the spherical correction and the cylindrical correction, it is also possible to approximate the time profile of further optical properties of the intraocular lens by means of suitable functions.

Furthermore, provision is made for a computer program product which contains program code which, when executed by a processor of a computer, carries out the method described above.

A device for determining at least one optical property of a patient eye with an intraocular lens comprises:

- means for determining at least one measured value of the optical property of the system comprising patient eye and intraocular lens at at least one measurement time after injecting the intraocular lens into the patient eye;
- means for comparing the at least one measured value and the associated measurement time to a known time profile of the values of the optical property for the intraocular lens, wherein the known time profile since unfolding the intraocular lens has been determined experimentally before the intraocular lens is injected and is made available in the form of measurement series or data, formulae or tables derived therefrom; and
- means for determining a value for the optical property of the system comprising patient eye and intraocular lens at a different time than the measurement time, according to the known time profile of the values of the optical property for the intraocular lens.

The device thus enables intraoperative determination of the optical property of the intraocular lens with high accuracy because interference factors that can be
5 traced back to the temporal change of the optical property after the intraocular lens unfolds can be eliminated.

The present invention furthermore provides a surgical
10 microscope which comprises a device as described above. Here, the surgical microscope can furthermore comprise a device for establishing the at least one optical property by means of a wavefront measurement.

15 In the following text, an embodiment of the present invention will be explained on the basis of the attached Figures in an exemplary fashion.

In detail:

20

Figure 1 shows a schematic illustration of an intraocular lens in an injection device;

25

Figure 2 shows a typical time profile of a spherical correction of the intraocular lens after injection into a patient eye;

30

Figure 3 shows a typical time profile of a cylindrical correction of the intraocular lens after injection into a patient eye;

35

Figure 4 shows a typical time profile of a Strehl ratio of the intraocular lens after injection into a patient eye; and

Figure 5 shows a typical time profile of the alignment angle of the cylindrical axis of the

intraocular lens after injection into a patient eye.

As illustrated schematically in Figure 1, an intraocular lens 1 is accommodated in an injection device 2 by means of which the intraocular lens 1 can be injected into a patient eye. The intraocular lens 1 is folded or rolled up in the injection device 2, i.e. elastically deformed.

10

In order to avoid a plastic deformation of the intraocular lens 1, the intraocular lens is usually stored in an unfolded state and only introduced into the injection device 2 shortly before the injection and folded in the process. In the illustrated example, the intraocular lens 1 is a toric lens, but the method according to the invention can also be applied to different types of intraocular lens.

20 After leaving the injection device 2, the intraocular lens 1 unfolds in the patient eye. While the intraocular lens 1 in the process substantially reassumes its original shape within a few seconds, the optical properties of the intraocular lens relax significantly more slowly.

In the present embodiment, the optical properties of the patient eye or the intraocular lens 1 are measured during surgery by means of a wavefront measurement method. The respective time profile of the optical properties of the intraocular lens is also determined by means of a wavefront measurement in the present embodiment.

35 Figure 2 shows an example for the time profile for the spherical correction S of the intraocular lens 1 in diopters from the time t_i of the injection into the patient eye.

It can be identified in Figure 2 that the spherical correction S of the intraocular lens asymptotically approaches a final value S_{Ziel} with increasing time. The
5 period of time elapsed until a substantially constant value is reached is at least 15 minutes.

The experimentally determined time profile, illustrated in Figure 2, can in this case be stored as a table of
10 measured values, or it is possible, for example, to fit an exponential function of the form

$$S(t) = a_1 - b_1 * \exp(-c_1 * t)$$

to the measured values, with a_1 , b_1 and c_1 being constants.

15

Such a time profile of the spherical correction and other optical properties can be determined experimentally for each model and/or for each individual batch of intraocular lenses 1. By way of
20 example, the manufacturer of the intraocular lenses performs this determination. The time profile of the values after the intraocular lens unfolds can then be offered by the manufacturer together with the corresponding intraocular lens, and so a medical
25 practitioner can, during the intraoperative measurement of the system comprising patient eye and intraocular lens, refer to the data in respect of the time profile provided by the manufacturer.

30 If a measured value for the spherical correction S of the system comprising patient eye and intraocular lens is determined at a measurement time t_M after the injection in the case of an intraocular lens 1 for which the time profile of the spherical correction S
35 was already determined, a value for any desired target time t_z can thus be established for the spherical correction S of the system comprising patient eye and intraocular lens from the known time profile of the

values for the intraocular lens and the measured value at the time t_M .

5 In particular, this enables the final value of the spherical correction S to be determined already a few seconds after injecting the intraocular lens 1 into the patient eye, which final value will be present after complete unfolding and relaxation of the optical properties of the intraocular lens 1.

10

Figure 3 shows an example for a time profile for the cylindrical correction C in diopters from a time t_I of the injection of the intraocular lens 1 into the patient eye.

15

As described above in the context of the time profile of the spherical correction S of the intraocular lens 1, the value of the cylindrical correction C of the intraocular lens 1 also relaxes to a substantially constant final value C_{Ziel} over a period of time of at least 15 minutes.

20

It is also possible in this case for the time profile of the cylindrical correction C , determined experimentally in advance by the manufacturer, to be stored as a table of measured values, or it is possible for example to fit an exponential function of the form

25

$$C(t) = a_2 + b_2 * \exp(-c_2 * t)$$

to the measured values, with a_2 , b_2 and c_2 being constants.

30

Thus it is also possible to determine a measured value at a measurement time t_M for the cylindrical correction C of the system comprising patient eye and intraocular lens already a few seconds after the time t_I of the injection, from which measured value the target value of the cylindrical correction C for the patient eye with intraocular lens can then be calculated with the

35

aid of the known time profile of the values for the intraocular lens.

Figure 4 shows the time profile of a Strehl ratio of the intraocular lens 1 from a time t_1 of the injection into the patient eye. The Strehl ratio describes the ratio between the part of the light energy which an optical system actually unifies in the Airy disk and the light energy which an error-free system would unify there. Hence, measuring the Strehl ratio makes it possible to check the optical quality of the injected intraocular lens 1.

As described above in the context of the spherical correction, the known time profile for the Strehl ratio can also for example be approximated by an exponential function. A measured value of the Strehl ratio of the system comprising patient eye and intraocular lens determined at a measurement time t_M can then be converted into a final value, which will be present at a time t_Z , with the aid of the known time profile.

Hence problems in respect of the quality of the intraocular lens 1 can already be reliably detected a few seconds after the injection if the calculated, final value of the Strehl ratio lies under the expected value for this model or this batch of intraocular lenses. As a result, the medical practitioner still has sufficient time during the operation to replace a defective intraocular lens 1 if necessary.

Figure 5 shows that in the case of the intraocular lens 1 considered in an exemplary fashion, the alignment of the cylinder axis remains substantially constant during the unfolding and the relaxation of the remaining optical properties.

Hence the alignment of the cylinder axis of the system comprising patient eye and intraocular lens can be measured at any time after the injection for this intraocular lens 1 and it is unnecessary for the shown
5 intraocular lens 1 also to correct this measured value using a known time profile. However, it is feasible that the alignment of the cylinder axis could also change over time in the case of other intraocular lenses 1 such that the method described above can then
10 also be applied for this optical property.

Here, a method according to an embodiment of the present invention initially comprises the insertion of an intraocular lens 1 into an injection device 2 and
15 the injection of the intraocular lens 1 into a patient eye at an injection time t_I .

A wavefront measurement method is then used at a measurement time t_M , which is a few seconds after the
20 injection time t_I , to determine optical properties such as e.g. the spherical correction S , the cylindrical correction C and/or the Strehl ratio of the patient eye with injected intraocular lens 1.

25 The measured values determined at the measurement time t_M and the known time profiles of the optical properties are used to calculate final values for the optical properties. In this case, "final values" are understood to mean those values which the respective time profile
30 of the optical properties asymptotically approaches for long periods of time after the injection time t_I . In general, the value of the optical property still changes relatively rapidly during the first approximately 10 minutes after the injection, and the
35 rate of change over time reduces from approximately 15 minutes after the injection such that the value of the optical property then gradually approaches its constant target value.

Alternatively, it is also possible to set a fixed target time t_z , for example 30 minutes or 60 minutes after t_1 , and the values of the optical properties can be determined for this target time t_z . This procedure is advantageous, particularly if no function was fitted to the measured values made available by the manufacturer of the intraocular lens 1 and hence it is not readily possible to determine a target value to which the optical property converges.

Here, it is also possible to provide a plurality of measurement times t_m , e.g. 5 measurement times respectively spaced apart by a few seconds, and to determine measured values for the optical properties for each measurement time t_m . As a result of the fact that a temporal sequence of measured values is determined, the measured time profile of the measured values of the optical properties can be compared to the time profile determined in advance. By way of example, this makes it possible to identify damage to the injected intraocular lens in a quick and reliable manner if it turns out that the time profile of the values for the optical properties, determined by the plurality of measured values, strongly differs from the respective time profiles for this model or this batch of intraocular lenses 1 determined in advance.

Finally, the determined values for the optical properties are output, for example by means of a display device, and the medical practitioner can use these displayed values to determine the quality of the injected intraocular lens and the patient eye operated on with great accuracy. Hence, it is already possible to perform corrections on the patient eye at a time during the operation at which the intraocular lens 1 has not yet reached the final values of its optical properties.

The method according to the invention enables the medical practitioner to determine these final values already a few seconds after the injection of the
5 intraocular lens into the patient eye and hence after a few seconds to already obtain precise data in respect of the final visual performance of the patient eye operated on.

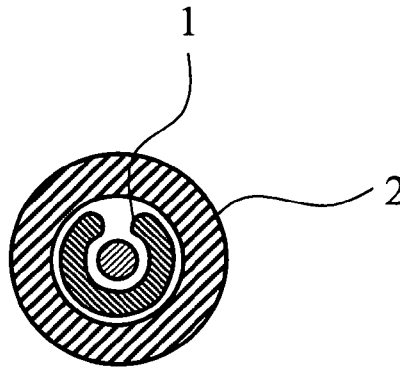
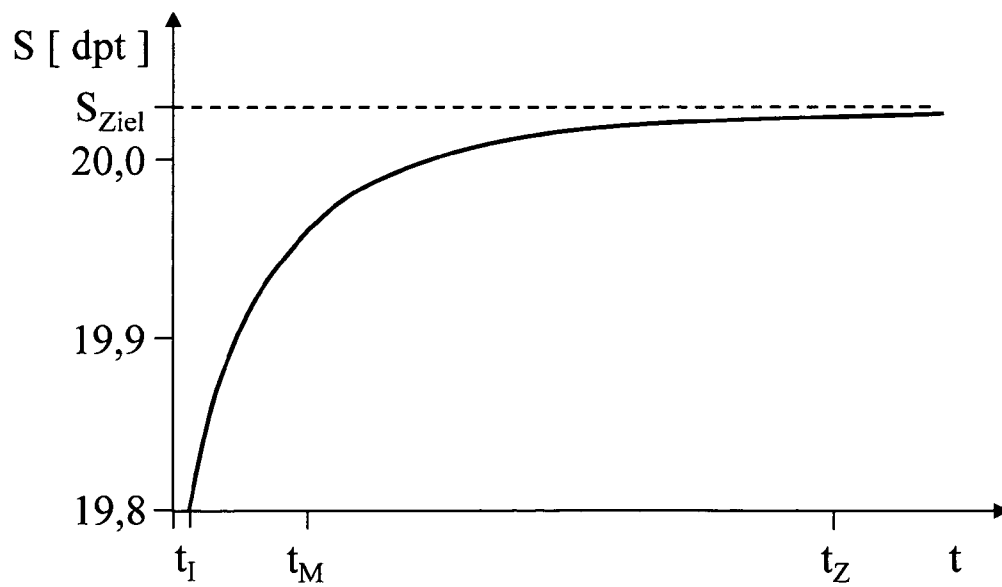
Patent claims

1. A method for determining at least one optical property (S, C) of a patient eye with an intraocular lens (1), comprising the following steps:
 - determining at least one measured value of the optical property (S, C) of the system comprising patient eye and intraocular lens (1) at at least one measurement time (t_M) after injecting the intraocular lens (1) into the patient eye;
 - comparing the at least one measured value and the associated measurement time (t_M) to a known time profile of the values of the optical property (S, C) for the intraocular lens (1), wherein the known time profile since unfolding the intraocular lens (1) has been determined experimentally before the intraocular lens (1) is injected and is made available in the form of measurement series or data, formulae or tables derived therefrom; and
 - determining a value for the optical property (S, C) of the system comprising patient eye and intraocular lens (1) at a different time than the measurement time (t_M), according to the known time profile of the values of the optical property (S, C) for the intraocular lens (1).
2. The method as claimed in claim 1, characterized in that the intraocular lens (1) is injected into the patient eye in a folded state and unfolds in the patient eye from the time of the injection.
3. The method as claimed in claim 1 or 2, characterized in that the at least one optical property (S, C) comprises a spherical correction (S), a cylindrical correction (C) and/or a Strehl ratio of the intraocular lens (1).

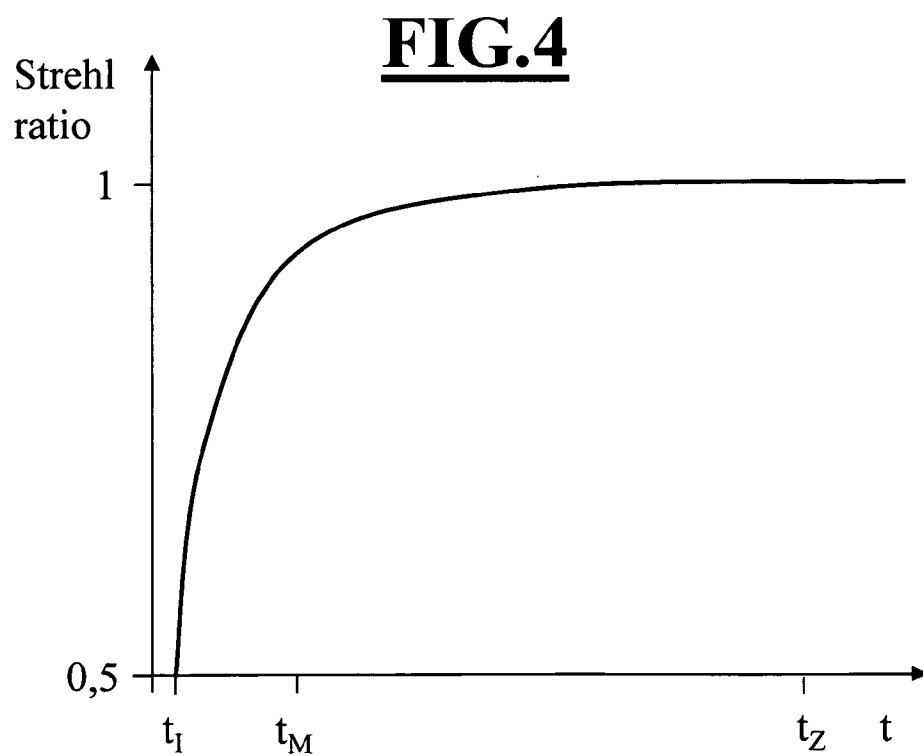
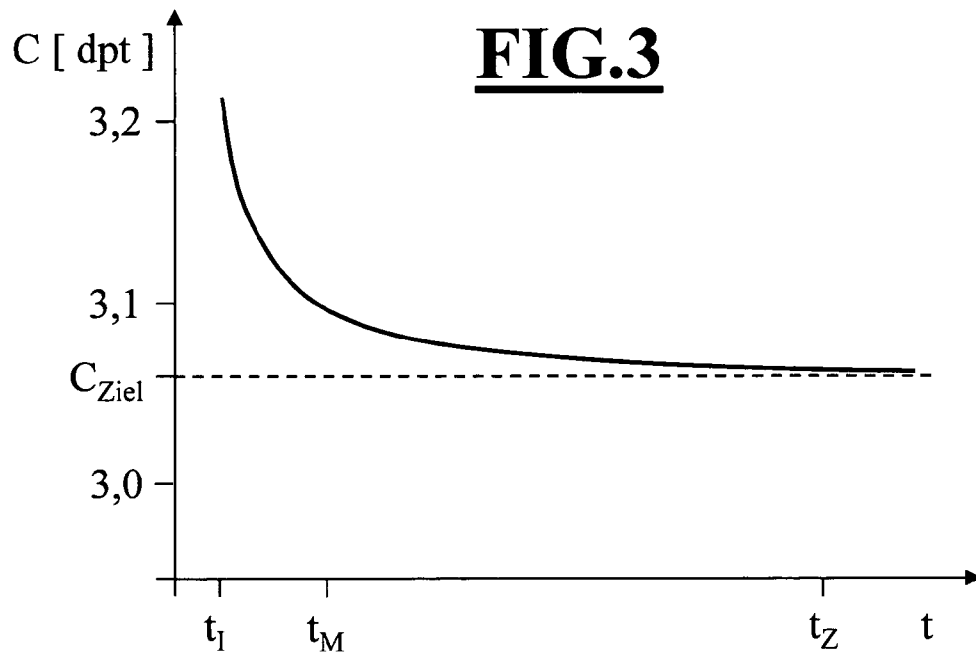
4. The method as claimed in one of claims 1 to 3, characterized in that the at least one measured value is determined within a time interval of less than 5 minutes, more particularly within a time interval of less than 1 minute, after the injection of the intraocular lens (1).
5. The method as claimed in one of claims 1 to 4, characterized in that the value established from the at least one measured value and the time profile of the optical property (S, C) specifies a final value of the optical property (S, C), which is approached by the time profile.
6. The method as claimed in one of claims 1 to 5, characterized in that the time profile of the optical property (S, C) is described by an exponential function of the form:
- $$S(t) = a_1 - b_1 \cdot \exp(-c_1 \cdot t)$$
- or
- $$C(t) = a_2 + b_2 \cdot \exp(-c_2 \cdot t),$$
- with a_1 , a_2 , b_1 , b_2 , c_1 and c_2 specifying constants which were determined by a curve fit to experimentally determined data of the optical property (S, C) of the intraocular lens (1) as a function of the time elapsed since unfolding.
7. A computer program product which contains program code which, when executed by a processor of a computer, carries out the method as claimed in one of claims 1 to 6.
8. A device for determining at least one optical property (S, C) of a patient eye with an intraocular lens (1), comprising:
- means for determining at least one measured value of the optical property (S, C) of the system comprising patient eye and intraocular lens (1) at

- at least one measurement time (t_M) after injecting the intraocular lens (1) into the patient eye;
- means for comparing the at least one measured value and the associated measurement time (t_M) to a known time profile of the values of the optical property (S, C) for the intraocular lens, wherein the known time profile since unfolding the intraocular lens (1) has been determined experimentally before the intraocular lens (1) is injected and is made available in the form of measurement series or data, formulae or tables derived therefrom; and
 - means for determining a value for the optical property (S, C) of the system comprising patient eye and intraocular lens (1) at a different time than the measurement time (t_M), according to the known time profile of the values of the optical property (S, C) for the intraocular lens (1).
9. A surgical microscope, comprising a device as claimed in claim 8.
10. The surgical microscope as claimed in claim 9, furthermore comprising a device for establishing the at least one optical property by means of a wavefront measurement.

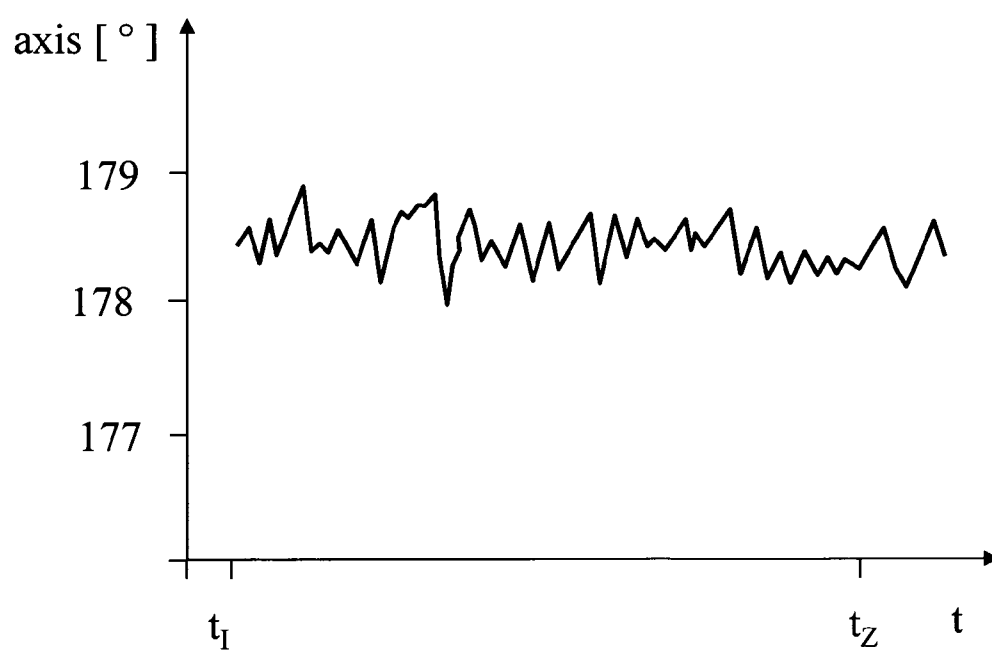
1/3

FIG.1**FIG.2**

2/3



3/3

FIG.5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2012/059179

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

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

1. ☒ Claims Nos.: 1-7
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2012/059179

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B3/10 A61B3/103 A61F9/007
ADD.

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)

A61B A61F

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/71411 A2 (CALIFORNIA INST OF TECHN [US]) 27 September 2001 (2001-09-27)	8
Y	abstract figure 9 page 5, line 26 - page 6, line 28 page 34, line 10 - line 30 -----	9,10
Y	WO 2010/054268 A2 (WAVETEC VISION SYSTEMS INC [US]; PADRICK THOMAS D [US]; HOLLADAY JACK) 14 May 2010 (2010-05-14) paragraphs [0061], [0146], [0147] -----	9,10
A	WO 99/27334 A1 (AUTONOMOUS TECHNOLOGIES CORP [US]) 3 June 1999 (1999-06-03) page 12, line 19 - line 34 -----	8-10
A	US 2009/069794 A1 (KURTZ RONALD M [US]) 12 March 2009 (2009-03-12) paragraph [0112] -----	8-10



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 1-7

The method for determining at least one optical property of a patient eye, including the step of injecting an intraocular lens into the patient eye in a folded state as defined in claims 1-7 is regarded to be a method for surgical treatment of the human or animal body, since it intervenes in the structure of an organism. Said method is therefore excluded from patentability according to Rule 39.1(iv) PCT.