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

(19) **World Intellectual Property Organization**
International Bureau

(43) **International Publication Date**
23 December 2009 (23.12.2009)

PCT

(10) **International Publication Number**
WO 2009/154455 A1

(51) **International Patent Classification**:
A61F 2/16 (2006.01)

(21) **International Application Number**:
PCT/NL2009/050355

(22) **International Filing Date**:
18 June 2009 (18.06.2009)

(25) **Filing Language**: English

(26) **Publication Language**: English

(30) **Priority Data**:
2001701 19 June 2008 (19.06.2008) NL

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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, 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, IS, JP, KE, KG, KM, 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, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

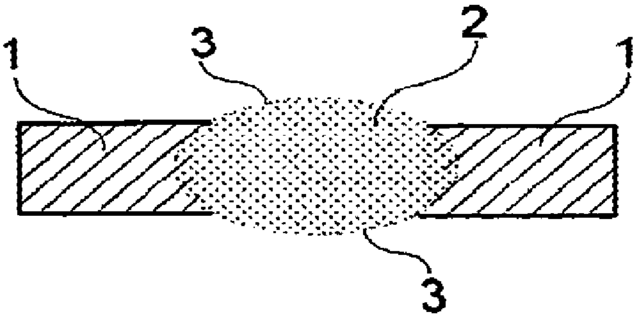
(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE,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

Published:

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

(54) **Title**: ACCOMMODATING INTRAOCULAR LENS

Fig. 1



(57) **Abstract**: The invention concerns an intraocular lens construction comprising optics (2) and positioning means (1) connected with the optics for positioning the optics within the eye, wherein the intraocular lens construction is made of a single material having spatially-distributed different elasto-mechanical properties, and the elasto-mechanical properties of the positioning means differ from the elasto-mechanical properties of the optics. This document describes a novel concept comprising AIOLs of which the positioning means and the optics are from the same polymer material meaning the same molecular constituency. Preferably the optical power of the lens construction changes along with changes in the shape of positioning means and Intraocular lens construction according to any of the preceding claims and the positioning means have such a shape that compression along the circumference of the positioning means results in an increase in optical strength of the optics.

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Accommodating intraocular lens

The invention concerns an accommodating intraocular lens.

Intraocular lenses (“IOLs”) are generally known to correct refraction of the eye after removal of the natural lens of the eye as the so called IOLs for the aphakic eye, with lens removal mostly for treatment of cataracts and, to a lesser extent, for treatment of myopia as the so called phakic IOLs which are in general implanted in the anterior chamber of the eye. Standard aphakic monofocal IOLs generally have a fixed optical power and a combination of such lens and progressive spectacles will allow sharp vision at a distance and close-up, for example reading-distance.

Accommodating intraocular lenses (“AIOLs”) allow the eye to focus itself by the natural driving mechanism which also drives the natural lens of the eye. Numerous designs for such accommodating have been proposed, including single optics moving along the optical axis (for example: WO03/015668), multiple optics moving along the optical axis (for example: WO2005104995), multiple optics including cubic surfaces (for example: WO2005/084587 and WO 2006/118452; NL1025622). In addition designs which include flexible optics which change shape which in turn changes the optical properties of the lens, including designs which press pliable material onto a small hole which amplifies the diopter change of the resulting lens (for example: WO2006/040759; WO2006/103674; WO2005/104994).

In “capsular bag refilling designs” (for example: US2001/0049532) the polymer material is supposed to change its shape to vary its optical power due to mechanical forces exerted on the capsular bag of the eye by the natural driving accommodative system. Such capsular bag refilling method does not constitute an IOL/AIOL in the meaning of such IOL/AIOL described in this and other documents since it constitutes a method, and not a device in itself. The capsular bag refilling material in itself is a flexible polymer liquid, does not have haptics/positioning means and the undefined shape and form as a liquid has when not in a moulding container, for example the capsular bag, which shape also defines the shape of the flexible liquid.

Note the terms ‘pliable’, ‘elastical’, ‘flexible’ and ‘elastical/flexible’ and their derivatives are used interchangeably in this document, as is the term different ‘elasto-mechanical properties’. All of these terms refer to he Poisson’s ratio of the material. For example, a high elasticity means highly elastic and corresponds to a high Poisson’s ratio. Expressed otherwise, a high Posisson’s ratio indicates that a contraction as caused by pressure or tension in a first direction of a piece of material leads to a expansion in a direction perpendicular thereto just as the opposite.

This invention concerns an intraocular artificial lens with variable optical power and comprising optics with variable optical power and positioning means connected with the optics wherein the elasto-mechanical properties of the positioning means differs from the elasto-mechanical properties of the optics. Such deformable optics for the eye are known as prior art and virtually all made of multiple materials (for example: US2007/0021831; US2005/0085906; 5,489,302), generally a rigid material for the haptics and a softer, pliable material for the optics, or even rigid haptics and a, near liquid, material in a enclosing container with a lens-type shape for the optics. This document describes a novel concept comprising AIOLs of which the positioning means and the optics are from the same polymer material meaning the same molecular constituency. It will be clear that the material should be transparent to be able to function as an optical element or lens. The haptics themselves do not need to be transparent although they often will be as they are made of the same material as the optical element.

Note that spatially-distributed different elasto-mechanical properties within the same piece of material can be produced at the material producer source, for example included in a so called ‘button’, being a small standard piece of material which is the starting point for the IOL producer, ready for ultra-high precision lathing. Alternatively, the optics and haptics can be manufactured from separate buttons of the same material and different elasto-mechanical properties and the semi-final products subsequently joined by a re-polymerization process including monomers of, again, the same material (see also WO2006/118452). So, also with re-polymerization the characteristics of the material will not change and the connection can be regarded as being of the same material as the other components of the IOL/AIOL.

Changing the elasto-mechanical properties of a polymer can be achieved by, inter alia, changing its water content. For example, well-known hydrophilic acrylate materials, often used for intraocular applications become more elastic by increasing their water contents, from nearly no water (hard/inflexible) to up to 40% water (nearly liquid), and intermediate water contents in a gliding scale of increasing water content and increasing pliability.

Alternatively, such changes in elasticity can also be achieved by varying the degree of polymerization, varying the degree of molecular cross-linking, or varying the degree molecular side-chains. The above methods to vary the degree of elasticity are some examples, and others can likely be applied.

Clearly, multiple areas with different degrees of flexibility/elasticity can be included in the haptics as well as the optics of an intraocular lens construction, and such elasticities can even made to vary gradually over, for example, an axis of the optics. So, for example, the changing shapes of the optics can be precisely designed and defined as well, and optics with increasing asphericity with increasing optical power can be designed.

The haptics can be in one piece, for example including the complete rim of the optics, and the design of the AIOL can be such that a change in shape of the haptics will result in a change in the shape of the optics resulting, in turn, in a change in the dioptre power of the optics.

Alternatively, the haptics can be constructed of multiple separate pieces and design of the AIOL can be such that a change in shape of the haptics or change in position of the separate pieces relatively to each other or a combination of both effects will result in a change in the shape of the optics resulting, in turn, in a change in the dioptre power of the optics.

In all cases the parts of the haptics adapted to be in contact with the movable part of the natural eye controlling the optical strength of the natural eye are preferably the rigid to be able to transfer the movement to the natural eye to the optical element.

Generally, a circumferential compression of the intraocular lens construction should preferably result in an increase in optical diopter power of the optics because such movement is the driving force which also changes the dioptre power of the natural lens of the eye. Namely, The ciliary body of the eye of which the ciliary muscle fonus a part is positioned just behind the iris and in front of the vitreous body of the eye. In the resting position the ciliary muscle has a relative large diameter and when contracting it contracts to a muscle with a smaller diameter. This muscle drives the accommodative function. The capsular bag is positioned within the ciliary muscle and the natural flexible lens of the eye is positioned in the capsular bag. The capsular bag is connected to the ciliary muscle by zonulea extending substantially radially. The natural accommodation of the eye with a natural lens occurs as follows. During distant viewing the ciliary muscle is relaxed and has a relatively large diameter. Thus a pulling force is applied on the zonulae stretching the capsular bag resulting in a relatively flat lens. The natural state of the ciliary muscle results in distant viewing. The ciliary muscle contracts at distant viewing resulting in a smaller diameter. The zonulae relax and the natural lens resumes its natural more concave shape.

IOLs are of the phakic type (implanted in an eye in which the natural lens remains) or of the aphakic type (implanted as a replacement of the natural lens). The AIOL described in this document can be of a phakic (generally implanted in the anterior chamber of the eye) or an aphakic type.

Most aphakic IOLs/AIOLs are designed to fit the capsular bag of the eye from which the natural lens is removed by the eye surgeon. AIOLs as described in this document can be designed to fit the capsular bag and be driven by the ciliary muscle indirectly, and through the action of the zonulae. However, the capsular bag is prone to shrinkage and hardening which affects the functioning of any AIOL.

Therefore, alternatively, AIOLs as described in this document can be designed to fit the sulcus of the eye which positions them in front, but outside, the capsular bag. In this position the AIOL will be driven by the ciliary muscle directly, and, in part, by the sulcus itself.

Subsequently the present invention will be elucidated with the help of the accompanying drawings wherein show:

Fig. 1: a cross section of a first embodiment of the invention in the first relaxed position;

Fig. 2: a cross section of the embodiment depicted in figure 1 in a second active position;

Fig. 3: a frontal view of the first embodiment in the situation depicted in figure 1;

Fig. 4: a frontal view of the first embodiment in the situation depicted in figure 2;

Fig. 5: a cross section of a second embodiment of the invention in a first, relaxed position;

Fig. 6: a cross section of the second embodiment in a second, active position;

Fig. 7: a cross section of a third embodiment in the situation depicted in figure 5;

Fig. 8: a cross section of the third embodiment in the situation depicted in figure 6;

Fig. 9: a cross section of a fourth embodiment of the invention in the first relaxed position; and

Fig. 10:a cross section of the fourth embodiment 5 in a second, active position.

The first embodiment depicted in the figures 1-4 of the drawings disclose an intraocular lens construction comprising an optical element 2 and a haptic 1 comprising two parts 1a, 1b located at either side of the optical element 1. The haptic 1 is adapted to locate the intraocular lens construction in the human or animal eye. It is feasible that the haptics comprise more parts than 2, like 3, 4, 5 of 6 elements, in dependence of the location in the eye wherein the intraocular lens construction is to fixed. Note that in this and all other figures low elasto-mechanical properties are ‘striped’ and high elasto-mechanical properties are ‘dotted’ in the figures.

The haptic 1 is made of relatively rigid material, while the optical element is made of relatively soft, pliable, or flexible material, which is at least softer than the material of which the optical element is made. The optical element has a large radius 3 at both sides. This implies that when the optical element is compressed, this compressing will be mainly absorbed by the optical element 2, leading to a a change of the shape of the optical element and hence to a change in the optical power of the optical element.

A cross section of the optical structure depicted in figure 1 in a compressed situation is depicted in figure 2. Clearly it appears form this figure that the optical part ha a smaller radius 4 so that its optical power is enlarged.

This also appears form figure 4 showing the compressed element depicted in figure 2, wherein the distance between the parts 1a, 1b of the haptic 1 is reduced relative to that in figure 3. In principle it is feasible to make use of a single part haptic, but this would require that some parts of the haptic would relative rigid, while other parts would be relatively flexible, to allow deformation of the optical part.
Figure 5 shows a second embodiment mainly in accordance with figure 1, but wherein both haptic parts 1a, 1b comprise a funnel shaped cavity 5 into which the flexible material of the optical part protrudes. The effect thereof is that the radius of the compressed optical part is smaller than that in the first embodiment as clearly shown from figure 6, leading to an amplification of the lens power

Figure 7 shows a third embodiment which forms a small variation of the second embodiment, to which a constricting body 6 is added to the haptics 1a, 1b. The shape of the optical element is amended accordingly. The presence of the constricting body further amplifies the effect of the funnel shape so that a an even larger variation of the optical power is achieved as appears from figure 8.

A fourth embodiment is shown in figures 9 and 10. In this fourth embodiment forms again a variation of the first embodiment, but wherein the haptics extend at a mutually slightly angled or slanted position to prevent undesired des-accommodation. Indeed this configurations leads to a slight movement of the optical element in the axial direction so which may be used to correct the possibility of the lack of focus due to the change of the optical properties, that is the optical strength of the optical element.

Note that the extension of the pliable material can be of a funnel shape protruding in the direction of the optical axis which amplifies the degree of change in shape which in turn amplifies the change in diopter value of the resulting lens. A constriction ring can be added to such funnel design to even more amplify the effects, although the total area of the variable lens will decrease.

In the above mentioned embodiments the shape of the lens perpendicular to the optical axis in the compressed situation is substantially circular. As the compression takes place in only a single direction, this implies that the shape of the lens in the relaxed position is not a circle, but rather an ellips. Care must be taken to allow sufficient cross section of the optical part so that the full area of retina can be reached by the light. Note that a preferred construction has optics which are slightly at an angle to the haptics. This is to prevent a possible backward movement of the optics which would result in undesired des-accommodation.

In the above mentioned embodiments the haptics are made of rigid material, while the optical element is made of more flexible material. It will be clear that numerous variations may be made to this configuration. It is possible that the extension of the pliable material extends radially from the center of the construction in at least one sector.

It is also possible to use a more gradual change in rigidity but this may lead to complicated production methods. It seems more logical to use a discrete border between the volumes with different rigidities. Nevertheless it may be feasible to use more than two different rigidities so that a gradual change of rigidity can be approached more closely.

The embodiments described above al relate to a lens construction with the single optical element, of which the strength changes due to deformation of the optical element. It is however also possible to make use of two optical elements cooperating, and wherein the optical power of the elements changes with their mutual position. This can be a movement in the direction of the optical axis or a movement perpendicular to the optical axis. In both cases the optical elements should be rigid and the flexibility is present in the haptics or positioning elements. It will however be clear that the positioning elements will also contain parts with more rigid properties.

Note that an AIOL of the same material as described in this document offers advantages to

- the material producer as only a single material, albeit in different configurations is used;

- the AIOL manufacturer as no combination of different materials is required, just as there is no need for assembly or repolymerization;
- the doctors and patients, as the single material will be chosen for inter alia its biocompitability, and there is no need to prove the biocompatabiliy of combinations of materials and the simple functioning of the device, required only a single element to be implanted into the eye, possibly in the sulcus.

Claims

1. Intraocular lens construction comprising optics and positioning means connected with the optics for positioning the optics within the eye, **characterized in that**
    - the intraocular lens construction is made of a single material having spatially-distributed different elasto-mechanical properties, and that
    - the elasto-mechanical properties of the positioning means differ from the elasto-mechanical properties of the optics.

2. Intraocular lens construction according to claim 1 **characterized in that** the elasto-mechanical properties are specified by water content of the same material.

3. Intraocular lens construction according to claim 1 **characterized in that** the elasto-mechanical properties are specified by the rate of polymerization of the same material.

4. Intraocular lens construction according to claim 1 **characterized in that** the elasto-mechanical properties are specified by the rate of molecular cross-linking of the same material.

5. Intraocular lens construction according to claim 1 **characterized in that** the elasto-mechanical properties are specified by molecular side-chains of the same material.

6. Intraocular lens construction according to one of the preceding claims, **characterized in that** the positioning means comprises at least two areas having mutually different elasto-mechanical properties.

7. Intraocular lens construction according to any of the preceding claims, **characterized in that** the optics comprise at least two areas having mutually different elasto-mechanical properties.

8. Intraocular lens construction according to claim 7, **characterized in that** the optics have a gradual change in elasto-mechanical properties along the radius.

9. Intraocular lens construction according to any of the preceding claims, **characterized in that** the optical power changes along with changes in the shape of positioning means.

10. Intraocular lens construction according to any of the preceding claims, **characterized in that** the optics comprise at least two optical elements and that the optical strength of the optics changes with the mutual position of at least two optical elements.

11. Intraocular lens construction according to any of the preceding claims, **characterized in that** the positioning means have such a shape that compression along the circumference of the positioning means results in an increase in optical strength of the optics.

12. Intraocular lens construction according to any of the preceding claims, **characterized in that** the construction is adapted for implantation in the anterior chamber of the eye.

13. Intraocular lens construction according to any of the preceding claims, **characterized in that** the construction is adapted for implantation in the capsular bag of the eye.

14. Intraocular lens construction according to any of the preceding claims, **characterized in that** the construction is adapted for implation in the sulcus of the eye.

Fig. 1

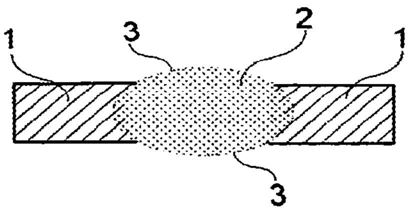


Fig. 2

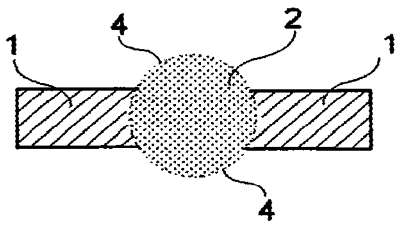


Fig. 3

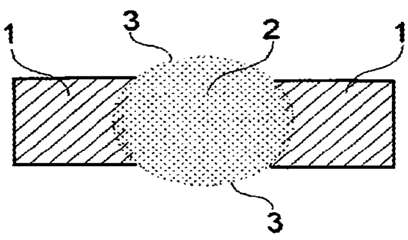


Fig. 4

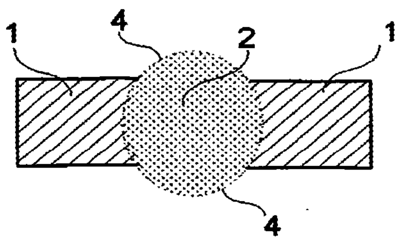


Fig. 5

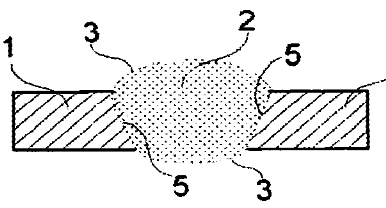


Fig. 6

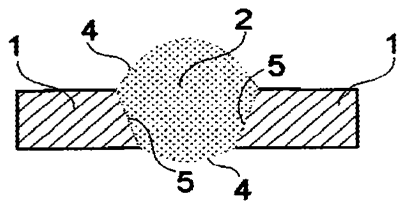


Fig. 7

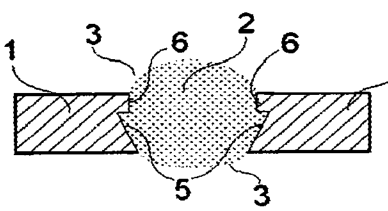


Fig. 8

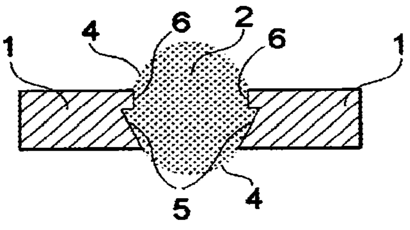


Fig. 9

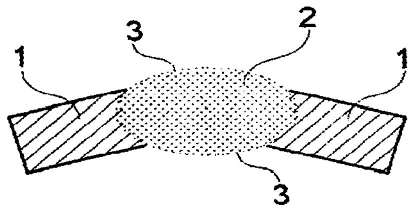
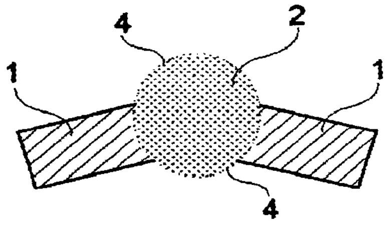


Fig. 10



INTERNATIONAL SEARCH REPORT

International application No
PCT/NL2009/050355

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/16

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)
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 practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	paragraph [0013] paragraph [0027] - paragraph [0029]; figures 1-6	12,14

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Y	DE 10 2005 045540 A1 (HAMPP NORBERT [DE]) 29 March 2007 (2007-03-29) paragraph [0025]	12,14

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☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search 15 September 2009	Date of mailing of the international search report 24/09/2009
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Lega, A

INTERNATIONAL SEARCH REPORT

International application No
PCT/NL2009/050355

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/NL2009/050355

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