The invention relates to an intraocular lens (1) designed to be implanted in the posterior chamber of an aphakic eye and to be sutured to the peripheral iris, the intraocular lens being foldable. The intraocular lens is monobloc, made of hydrophobic acrylic with UV blockage and has plate haptics (2). The optic (1) is an aspheric biconvex lens. The angle (3) at the optic-haptic junction is 10 to 20 degrees. The haptics have a length of 1.25 to 2.25 mm having a hole (4) at the mid-point for the passage of a needle and sutures.
IRIS FIXATED INTRAOCULAR LENS

Technical Field

Current Invention; is related to the intraocular lenses that are placed to posterior chamber and fixed to the iris in the aphakic eyes with no posterior capsule support.

Invention; includes a foldable intraocular lens that is fixed to the iris periphery from two reciprocal points via a special technique for the rehabilitation of aphakic eyes.

Explanation of the Known Status of the Technique

Currently used lenses and techniques to the rehabilitate the aphakic eyes with no capsule support can be evaluated in 5 groups.

1. Angle supported lenses
2. Anterior chamber iris claw lenses
3. Posterior chamber iris claw lenses
4. Scleral fixated lenses
5. Iris-sutured classical posterior chamber lenses

I. Angle Supported Lenses.

- They are hard lenses. Therefore; these lenses require corneal incision as much as their diameter that is at least 6.0 mm wide and suturing to close this much opening. Period for the surgical procedure and healing is longer and causes high astigmatism.

- Causes endothelial loss. Cornea become edematous and later or soon decompensation can occur. That may require keratoplasty, another surgery.

- Causes synechia at the angle. Damage occurs at angle structure. This may cause glaucoma. In case of need to remove the lens, the anterior synechia between angle and lens may cause problems as bleeding, iris damage, vitreous loss and consequently development of retinal detachment.

- Causes posterior synechia and this may lead to acute glaucoma crises through pupillary block. To avoid this, anterior iridectomy can be performed during surgery. If had not been performed, laser iridectomy is required.
Serious inflammation may occur short-(acute) and long-(chronic) after the surgery. This may cause pain, photophobia, visual loss and chronic glaucoma.

2. Anterior Chamber Iris Claw Lenses
- The surgical procedure is highly difficult. Special equipment are necessary to perform implantation.
- If removal is required, the procedure is not easy. During the procedure, endothelial loss, serious iris damage and dispersion of the iris pigment may occur. These causes corneal edema, hemorrhage at the angle, inflammation and increase of intraocular pressure.
- There is a sort of restriction in both miosis and mydriasis. These effect the visual acuity during dark and illuminated environment.
- Because of being an anterior chamber lens, there is a general probability of endothelial loss, corneal edema and decompensation as in cases with angle-supported lenses.

3. Posterior Chamber Iris Claw Lenses
- Surgical procedure is highly difficult that only exclusive surgeons can perform.
- In the necessity of their removal, the procedure is much more challenging.
- The possibility of lens drop into the vitreous is always present during both implantation and removal of these lenses.
- The iris to the lens touch, dispersion of the pigment and consequent development of glaucoma are likelihood. Endothelial loss is another risk.
- There is a sort of restriction in both miosis and mydriasis. These effect the visual acuity during dark and illuminated environment.

4. Scleral-fixated Lenses
- Surgery takes long. Scleral procedures (opening of the flaps or tunneling to bury the sutures) are necessary.
- There is always a risk of serious hemorrhage due to blindly insertion of the needle of the lens supporting suture through the sclera and root of the iris.
- When the needle passed out of the sclera, most of the time exiting point is not the exact desired point. Therefore, the needle must be pulled and reentered.
5 - Burring of the suture ends are challenging, too. Non-absorbable prolene suture irritates, perforates the above tissues (Tenon and conjunctiva), provides easy access to the bacterial invasion and causes inflammation and infection.

- Decentralization and lens tilt are common results those effect the visual acuity and visual quality, cause decrease in the visual acuity and double vision may occur. Complain like photophobia, halo, glare may happen.

10 - When applied to the pediatric cases, because of the growth of the eye ball the fixing sutures may rupture from the sclera and the dropping of the lens into the vitreous is very high. In this case, retina and optic nerve may be damaged and require much more serious, complicated surgery.

15 - When these lenses are needed to be removed, again a 6.5mm corneal incision and brutal intraocular manipulations are necessary.

5. Iris-sutured Classical Posterior Chamber Lenses

- It is based on the principle of suturing of the classically used posterior chamber intraocular lenses after the cataract surgery. There are various suture techniques. Most commonly used one is suturing technique of McCannel and Siepser.

- Since this technique requires excessive anterior chamber manipulation, risk of the corneal endothelial loss and corneal edema is highly.

- The suture techniques require expertise. Learning period is a long term.

25 - Since most of the classical lenses have no haptic to optic angle, lens touches to the iris. Then, pigment dispersion and pupillary block may occur.

- Due to absence of any piece to suture knobbing on the haptic of these lenses, suture cannot always be placed on the same point.

30 Explanation of the Advantages of the Invention

The advantages of suturing the newly designed iris-fixating lenses with whole diameter in the range of 7.5 to 10.5 mm according to the "White to White" iris diameter by using a special surgical technique can be summarized as almost being able to handle all of the technical problems and disadvantages of the lenses in use. In the order;

35 - The invented subject is a new type of soft-, foldable-lens. Since it can be inserted into the eye through a small incision (3 mm), it does not require any suture. There is no waste of time and material for purpose of suturing. Healing occurs in the short time and astigmatism will be minimum.
Because of the posterior chamber location, there is no concern about endothelium. There is no manipulation in the anterior chamber during lens implantation. There is no endothelial loss because the lens passes into the posterior chamber in the space filled with viscoelastic material while pulling the outsider sutures.

Because of the absence of any manipulation in the anterior chamber, there is no inflammation, flare, corneal edema, short- or long-term decompensation. As a result there is no possibility of the need of keratoplasty.

Since there is no relationship with the anterior chamber angle, there is neither sinechia, nor damage on the structures. Therefore, there will not be glaucoma. Therefore, there is no need to perform peripheric iridectomy during surgery or laser iridotomy after the surgery in order to prevent those. For any reason, as a result of a mistake, if an adhesion between lens and edge of the pupil that causing obstruction of the passage of aqueous humor from posterior chamber to anterior chamber, the holes happens while perforating the iris by four needle in order to fix the lens on iris function as peripheric iridotomy and the risk of development of glaucoma would be eliminated.

The new type lens, the subject of invention has anterior angulation. Therefore, the only touching points to the iris are the edges of the haptics where it is sutured to the iris. The optic of the lens is away from iris and pupillary edge. Therefore, there is no concern of posterior sinechia and glaucoma crises.

During the surgery, the only trauma is four passages of PC-9 needle through iris and there is no touch between lens optic and iris, the possibility of short- or long-term serious inflammation have been eliminated.

The implantation of new type lens, the subject of invention is easier than both the anterior- and the posterior- chamber iris claw lenses. Any surgeon who can perform scleral fixed lenses and even who can enter through cornea, pass the needle through the peripheric iris, bring the needle to the pupillary space and take the suture from main incision to outside, can perform the procedure. No special equipment is needed for the implantation. The instruments in the simple set of cataract surgery and two non-absorbable suture are enough.

There is no possibility of lens drop into the vitreous space. Because the suture is knotted to the lens haptics after the needle-suture that is previously passed from corneal-side incision and then though the iris is taken out side of the eye ball through main corneal incision. Simply, when the lens is pushed into the globe (posterior chamber), both haptics are sutured and ends of the sutures are outside of the cornea.

The procedure to remove the lens in case of a need is easy. Cutting the suture knobs at the iris periphery by the 27- Gauge needle tip will release the lens. While one hand easily manipulating this, the other hand must hold the lens. The possibility of lens drop into the vitreous space that is specifically high with the posterior chamber iris claw lenses, is very low with this newly invented lens because one hand does very simple manipulation while the other hand holds the lens.
There is no restriction in miosis or mydriasis. Because the sutures are at the far periphery of the iris and there is only 1 mm wide iris within the holes of the needling. This does not have any effect on the function of 360 degree dilator muscle. Since the sutures are not neighboring with the dilator muscles of iris, mydriasis will not be effected. Therefore, there is no glare caused by excessive light due to lack of miosis and not enough light entrance into the eye due to lack of pupillary dilation during dim light or darkness. Eyes can adapt to the light and dark as normal. Visual acuity and visual quality will not be negatively affected.

- The lens implantation lasts pretty less than scleral-fixed lenses especially the ones require scleral flap preparation. There is no scleral manipulation.

- Since there is no suture external to the globe or on the sclera, there is no problem as irritation, tearing, perforation, need of suture remove. Therefore, it is much more comfortable compare to the scleral-fixating lenses.

- The sutures to hold the lens on its’ place pass in the iris and are buried, there is no serious bleeding problem. Addition to the absence of large caliper blood vessels at this zone, it is possible to needle at the point away from the any vessel since even tinny ones are visible.

- The placement of the lens can be exactly adjusted in the center of the pupillary opening via clearly visible passage of the needles through the iris. There is no possibility of decentralization. Lens tilt is even not a concern. Since the invention subject this new lens is tightened on two reciprocal point on the iris. Therefore, there is no negative effect on vision. Visual acuity does not decrease, double vision, photophobia, halo and glare are not experienced.

- In the pediatric cases, since the invention subject the new lens and sutures holding it are not related to the scleral wall, there will not be a problem due to growing-up.

Legends

Figure 1. Front view of the graphical drawing of the invention.

Figure 2. Side view of the graphical drawing of the invention.

Reference numbers:

1 Optic
2 Haptic
3 Haptic-optic angle
4 Suture holes

Detailed Technical Description of the Invention
The subject of the invention, a new type of lens is monoblock (single piece), with the optic (1) in the range of 5.0 to 7.5 mm size, two haptics in 1.25 to 2.25 mm length (2) in the size of total diameter in the range of 7.5 to 10.5 mm. The material of this intraocular lens is UV blocking hydrophobic acrylic, plate haptic, aspheric, biconvex and foldable.

- There is an angle (3) in the range of 10 to 20 degrees at the haptic-optic junction. This provides single iris touch only at end point of the haptics (edge of haptics) and at the same time keeps optic away from the iris and pupillary plane.

- Haptics (2) are in the plate form with the holes in the middle (4), which are wide enough to passage of 10/0 (specific technical term for the needle and the suture) needle-suture.

- In difference from the all other lenses used in this field, the preferred lens in the range of 7.5 to 10.5 mm total lens size prevents stretch of the pupil in other words an esthetic error so called "cat eye" which causes negative effect on the vision.

- Foldable lenses has a specialty of memory. After insertion in to the body by the body temperature and the lens memory, it receives the normal shape in a short time.
5 Requirements

1. The invention is for visual rehabilitation of the aphakic eyes by using a special technique to implant into the posterior chamber via suturing on the peripheral iris. It is a new type of iris-fixating foldable lens in the size range of 7.5 to 10.5 mm as whole diameter.

2. The lens in the requirement 1 is monoblock (single piece).

3. The lens in the requirement 1 has optic in the size of 5.0 to 7.5 mm.

4. The lens in the requirement 1 has 2 plate haptics.

5. The lens in the requirement 1 is made out of hydrophobic acrylic material with UV-blocking, in the shape of aspheric biconvex and foldable intraocular lens.

6. The lens in the requirement 1 has haptic-optic junction angle in 10 to 20 degrees.

7. The lens in the requirement 1 has the haptics in the length of 1.25 to 2.25 mm.

8. The lens in the requirement 1 has haptics with holes at their center to allow passage of 10/0 needle and suture.

9. The specificity of the handling of lens in the requirement 1 is:

   "After performing a corneal incision in 1 to 2 mm size at 3 o'clock position, a non-absorbable suture is introduced into the eye through this corneal entrance. The suture is passed through the iris, then brought to pupillary opening from posterior chamber and taken out the eye through the main entrance.

   The second suture is entered to the eye as the first suture but in a distance of 1 mm. Both two of the sutures are sutured to the new type of lens haptic as: after a 9 o'clock second corneal incision the same things are repeated. And the other haptic of the new type of iris fixated lens is sutured.

   After pulling of the sutures, the knots are tied on the iris and the new type of iris fixated lens is fixed at the posterior chamber."
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/16

ADD.

According to International Patent Classification (IPC) into 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 database consulted during the international search (name of database and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>FR 2 998 474 AI (CT HOSPITALIER UNIVERSITAIRE DE ROUEN [FR] ; CRISTALENS IND [FR]) 30 May 2014 (2014-05-30) page 3, line 25 - page 5, line 22 page 6, line 28 - page 10, line 3 page 13, line 18 - page 14, line 7; figures lb-2e</td>
<td>1-8</td>
</tr>
</tbody>
</table>

X Further documents are listed in the continuation of Box C. X 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

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

"L" document which may throw doubts on priority claim(s) one of which is cited to establish the priority 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

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"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

"Y" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"Z" document member of the same patent family

Date of the actual completion of the international search: 25 May 2016

Date of mailing of the international search report: 03/06/2016

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
<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>US 4 504 981 A (WALMAN GERALD B [US] ) 19 March 1985 (1985-03-19) col umn 6 - col umn 7, l i n e 4 col umn 8, l i n e 41 - col umn 9, l i n e 62; f i g u r e s 8-12</td>
<td>3, 6</td>
</tr>
<tr>
<td>A</td>
<td>US 4 664 666 A (BARRETT GRAHAM D [AU] ) 12 May 1987 (1987-05-12) the w h o l e document</td>
<td>1-8</td>
</tr>
</tbody>
</table>
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.: 9 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).

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.
Continuation of Box III.1

Claims Nos.: 9

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery. Claim 9 is specifying a handling of the lens comprising steps (for example "performing a corneal incision in 1 to 2 mm size at 3 o'clock position") which involve a surgical intervention. Pursuant to Art. 17(2)(a)(i) PCT and Rule 39.1(iv) PCT, the subject-matter of claim 40 has not been searched.
<table>
<thead>
<tr>
<th>Patent document cited in search report</th>
<th>Publication date</th>
<th>Patent family member(s)</th>
<th>Publication date</th>
</tr>
</thead>
<tbody>
<tr>
<td>FR 2998474</td>
<td>30-05-2014</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>US 200303011</td>
<td>13-02-2003</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>US 4504981</td>
<td>19-03-1985</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>AU 4998697 A</td>
<td>15-05-1998</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BR 9712375 A</td>
<td>25-01-2000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2267185 A</td>
<td>30-04-1998</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DE 69729573 DI</td>
<td>22-07-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DE 69729573 T2</td>
<td>09-06-2005</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 0934038 A</td>
<td>11-08-1999</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ES 2224223 T3</td>
<td>01-03-2005</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 4023829 B2</td>
<td>19-12-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2001509695 A</td>
<td>24-07-2001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 6015435 A</td>
<td>18-01-2000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 6428574 BL</td>
<td>06-08-2002</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 9817205 A</td>
<td>30-04-1998</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 1237851 A</td>
<td>14-06-1988</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DE 3483738 DI</td>
<td>24-01-1991</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DE 3486263 DI</td>
<td>17-02-1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DE 3486263 T2</td>
<td>28-04-1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DK 191185 A</td>
<td>26-06-1985</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 0136807 A2</td>
<td>10-04-1985</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IE 56822 BL</td>
<td>18-12-1991</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IL 72779 A</td>
<td>06-09-1992</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP S6077765 A</td>
<td>02-05-1985</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP S6664981 B2</td>
<td>14-12-1988</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NZ 209291 A</td>
<td>30-04-1987</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PT 79154 A</td>
<td>01-09-1984</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 4664666 A</td>
<td>12-05-1987</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 4936850 A</td>
<td>26-06-1990</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ZA 8406570 A</td>
<td>25-06-1986</td>
</tr>
</tbody>
</table>