

INTRAOCULAR LENS CONFIGURED TO BE INSERTED INTO AN EYE AND METHOD
FOR MANUFACTURE THEREOF

5 The invention relates to an intraocular lens (IOL) to be inserted into an eye. Such a lens is usually inserted into the eye via an incision and secured there using haptic elements. Such intraocular lenses are applied inter alia to replace the natural lens, for instance in the case of cataract surgery, or are placed as addition to the natural lens, for instance in the case of presbyopia.

10 Conventional intraocular lenses are inserted using an incision. Manufacturing the lens from a flexible material makes it foldable and enables an incision of limited dimensions. The lenses are provided with an optical element, and one or more haptic elements whereby the lens can be secured in or to the eye.

15 Diverse lenses are known in practice, these usually having a monofocal design. Such monofocal lenses can be readily manufactured in practice and usually provide good vision, particularly for distance vision, i.e. a distance of more than 2.0 metres. In order to improve intermediate vision as well, adapted lens power profiles for the lens power have been developed. This improves intermediate vision, i.e. from about 66 cm from the eye to about 2.0 metres. A problem is here that this is detrimental to distance vision. This is undesirable. Such adapted profiles can also have an adverse effect on prevention of disruptive effects in respect of for instance halos and glare. In practice, this reduces user comfort of the lens. Diverse types of multifocal lenses are here known in practice. These are usually bifocal or trifocal lenses which are provided with respectively two and three different zones having their own lens power profile with their own progression. It has been found that (said) disruptive effects can occur here.

20 The present invention has for its object to obviate or at least reduce the above stated problems and to provide a lens usable in practice whereby intermediate vision is also improved in addition to distance vision, and adverse effects are counteracted/compensated for.

25 This object is achieved with an intraocular lens according to the invention which is configured to be inserted into an eye, the lens comprising:

- 30 - an optical element of a flexible optical material; and
- at least one haptic element which is connected to the optical element and which is provided with a connecting part configured to connect the lens to an eye part,

 wherein the optical element is provided with a lens power profile, preferably a continuous lens power profile, wherein the profile is provided outside the centre of the lens, as seen in radial direction of the lens, with at least one increasing profile over a first radial distance and at least one decreasing profile over a second radial distance.

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The intraocular lens (IOL) according to the invention is provided with an optical element of a flexible optical material. Using a flexible material makes the lens foldable, such that it can be inserted into the eye in an effective manner using an incision. The lens is further provided with at least one haptic element with a connecting part configured to be connected to an eye part. Such haptic elements can have different designs, depending inter alia on the specific application.

The optical element is provided with a lens power profile, which is also referred to as an optical power profile or dioptric power profile. Such a lens power profile relates to the progression of the dioptr (lens power) over the surface of the lens in radial direction. If the lens power profile is equal as seen in all directions from the centre of the lens, reference is also made to a radial lens power profile, the dioptr of which can if desired also vary in every direction so that an additional toric profile is created. According to the invention, the profile is provided outside the centre of the lens, as seen in the radial direction of the lens, with at least one increasing profile over a first radial distance and at least one decreasing profile over a second radial distance. In a currently preferred embodiment such a profile is substantially equal in all radial directions, so that in this preferred embodiment reference can be made to a radial lens power profile provided with at least one increasing and at least one decreasing profile, as seen in radial direction. Alternatively, it is also possible to provide such profiles in one or several directions, as seen from the centre of the lens.

The lens power profile of the intraocular lens according to the invention preferably has a continuous progression. Abrupt transitions in the lens power profile are avoided hereby, so that disruptions at the position of the transition(s) are counteracted. This continuous progression of the lens power profile results in a monofocal lens in which no multifocal parts or sections are present, and aberrations are optimized smoothly and autonomously in this monofocal lens without compensating for the aberrations of the cornea here.

The lens power profile of the intraocular lens according to the invention is further provided with a profile which is preferably configured in or close to the centre of the lens for distance vision, aimed at a distance of more than 2.0 metres from the eye, wherein the part of the lens lying between the centre and the edge is aimed at least partially at improving intermediate vision, which relates to the distance from about 66 cm to 2.0 m from the eye.

According to the invention, a first radial distance is provided in this range between the centre and the edge of the lens, wherein the power of the lens increases as seen in the radial direction from the centre of the lens, and a second radial distance is provided in which the power decreases.

Tests have shown that this improves particularly intermediate vision significantly. The lens power profile of the intraocular lens according to the present invention particularly improves intermediate vision, without any substantial loss of distance vision. An additional effect of such a lens power profile is that spherical aberration is avoided or is at least optimized. This makes the lens highly suitable for being utilized in diverse applications in practice, particularly for cataracts

and ophthalmic applications for replacing spectacles. In such applications the natural lens is completely removed and replaced by the intraocular lens according to the invention. In an alternative application use can also be made of the lens according to the invention, for instance in the case of presbyopia.

5 It has further been found that the lens according to the invention suffers less from so-called halo or glare effects, and results here in better neuro-adaptation for the user. This improves the convenience of use/comfort for the user of the intraocular lens according to the invention further.

The (continuous) lens power profile of the intraocular lens according to the invention preferably has a smooth progression. The above stated disruptions and adverse effects are
10 counteracted or even wholly prevented by this smooth progression, i.e. without abrupt transitions in the lens power profile. This obviates the need for (segmented) corneal compensation in the lens according to the present invention, and use of spherical deformation of the surface of the (monofocal) lens conversely results in a continuous, smoothly shifting focal point (smooth dioptric change).

15 In a currently preferred embodiment according to the invention the smooth progression of the (continuous) lens power profile is brought about by a continuous progression of the first derivative of the lens power profile. Because the first derivative of the lens power profile has a continuous progression over the lens, abrupt transitions are avoided. If desired, this effect can be further enhanced by giving higher derivatives, such as a second and/or third derivative, of the lens power
20 profile a continuous progression as well.

In an advantageous embodiment according to the invention the first radial distance and the second radial distance lie in the range of 0.5 to 2.5 mm from the centre of the lens.

Providing the first and second radial distances in said range achieves that the centre of the lens can be used for distance vision, and undesirable effects close to the outer edge of the lens are
25 avoided.

In a currently preferred embodiment according to the invention the first radial distance, in which the power (dioptric) of the lens increases, for instance to a value above 1.0 D, is positioned first as seen from the centre of the lens, after which the first radial distance transitions into the second radial distance in which the power of the lens decreases to for instance 0 D, and preferably
30 decreases further to a negative value of for instance -0.5 D.

Transitions between the first and second radial distance, and between the remaining changes in lens power, are preferably implemented gradually so that, as already indicated above, abrupt transitions are avoided. Such abrupt transitions are visible in the lens power profile as a bend point. By realizing a gradual change of lens power in the currently preferred embodiments bend points
35 and any adverse effects associated therewith are avoided. This increases the user comfort of the intraocular lens in such an embodiment according to the invention.

The first and second radial distance preferably lie in the range of 1.0 to 2.0 mm, as seen from the centre of the lens. The above stated advantages are further enhanced in this preferred embodiment in that any occurring adverse effects, including for instance spherical aberration, are particularly optimized further. This counteracting of such adverse effects can be enhanced still
5 further by avoiding the above stated “bending” in the lens power profile as far as possible.

In a currently preferred embodiment the lens power profile has an increasing strength over a first radial distance in the range of 0.5 to 1.5 mm, more preferably in the range of 1.0 to 1.5 mm as seen from the centre of the lens.

By having the first radial distance start from 0.5 or preferably even from 1.0 mm from the
10 centre of the lens, the lens power profile does not affect distance vision, which is substantially determined with the lens according to the invention by the centre of the lens and the immediate vicinity thereof.

The second radial distance is preferably provided at a greater radial distance than the first radial distance relative to the centre, and preferably lies in the range of 1.5 to 2.5 mm from the
15 centre of the lens, and more preferably in the range of 1.5 to 2.0 mm from the centre of the lens. This prevents peripheral effects in the outer periphery of the lens.

In a currently preferred embodiment according to the invention the lens power at or close to the edge of the intraocular lens is at least equal to the lens power in or close to the centre of the lens.

By making the lens power at or close to the edge equal to or even greater than the lens power
20 in or close to the centre of the lens use can be made of the natural aberrations of the eye without compensating for the cornea. Hereby, the effect on the contrast remains unaffected and energy of the light inside the bandwidth of the so-called circle of confusion in the eye is redistributed during moments of pupil dilation. With the lens in a currently preferred embodiment according to the
25 invention the supply of the energy of light in the projection is intensified directly in front of and behind the macula, whereby users experience a greater depth of field, which is in fact utilized by the visual cortex.

In an advantageous embodiment according to the invention the lens power profile is provided with a peak outside the centre of the lens, preferably lying at a distance of about 1.5 mm from the
30 centre of the lens at the transition from the first to the second radial distance. The peak preferably has a value in the range of 1.0 to 1.5 D. The peak still more preferably has a value of about 1.2 D. It will be apparent that the absolute values for the lens power depend on the circumstances for application of the lens and the further characteristics of the lens, including dimensions and materials.

In an advantageous embodiment according to the invention the lens power profile is provided with a third radial distance, wherein the third radial distance has an increasing power as seen in radial direction from the centre of the lens.

5 Providing a third radial distance with increasing lens power, preferably connecting directly to the second radial distance with a decreasing power, enables the spherical aberration to be optimized further, while intermediate vision is improved. In such a preferred embodiment the profile is provided with a valley in respect of the lens power which lies outside the centre of the lens. Such a valley preferably lies in the transition from the second to the third radial distance, preferably in the range of 1.5 to 2.0 mm from the centre of the lens. This valley preferably
10 corresponds with the minimum lens power of the lens and in a currently preferred embodiment is lower than -0.3 D, and preferably lies in the range of -0.3 to -1.0 D. The lens power more preferably has a valley in the range of -0.3 to -0.55 D, and amounts to for instance -0.4 D. The increase of the lens power in the third radial distance preferably runs from the valley to the “base” lens power, which is preferably substantially equal to the lens power in the centre of the lens. It
15 will be apparent that other lens powers and other profiles can also be envisaged according to the invention.

Tests have shown that undesirable effects, including the spherical aberration particularly during periods of dusk or night, are further counteracted/compensated for thereby. It has particularly been found that the positive aberration (dioptré) in the lens, which produces a positive
20 addition, is compensated with the negative aberration (dioptré), so that the lens can perform better with a variable (large and small) aperture of the iris without causing double vision, as occurs with multifocal lenses (bifocal and trifocal lenses).

In a further advantageous embodiment according to the invention the connecting part of the haptic element is configured to connect the lens to an eye part in order to replace the natural lens.
25 Configuring the haptic element for connection of the lens to an eye, particularly an eye part thereof, provides the option of replacing a natural lens. This can for instance take place during so-called cataract surgery.

The present invention also relates to a method for manufacturing an intraocular lens, wherein the method comprises the steps of:

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- providing an optical element of a flexible optical material;
 - providing at least one haptic element which is provided with a connecting part for connecting the haptic element to the optical element;
 - arranging a lens power profile, wherein the profile is provided in radial direction of the lens with at least one increasing profile over a first radial distance and at least one
35 decreasing profile over a second radial distance.

Such a method provides similar advantages and effects as described for the lens. The lens is preferably provided in one of the embodiments according to the invention. It will also be apparent that, if desired, the method can comprise different steps for arranging a profile as described above in relation to the intraocular lens. It is preferred to arrange a profile which shows an increase of the lens power as seen from the centre of the lens in radial direction toward the outer periphery of the lens over a first radial distance, is followed after reaching the peak by a second radial distance resulting in a negative lens power and, after reaching such a valley, shows over a third radial distance an increasing lens power up to the "base" lens power which is preferably substantially equal to the lens power in the centre of the lens. It will be apparent that other lens powers and other profiles can also be envisaged according to the invention.

Further advantages, features and details of the invention are elucidated on the basis of preferred embodiments thereof, wherein reference is made to the accompanying figures, in which:

- Figure 1 shows a view of an intraocular lens according to the invention;
- Figure 2A shows a 3D view of a conventional lens power profile;
- Figure 2B shows a 3D view of a lens power profile in an embodiment according to the invention;
- Figure 3A shows a conventional lens power profile as shown in figure 2A;
- Figure 3B shows a lens power profile in an embodiment according to the invention as shown in figure 2B;
- Figure 3C shows a further lens power profile in an embodiment of the lens according to the invention;
- Figure 4 shows results with a lens power profile according to figure 3B; and
- Figures 5A-C show test results with an intraocular lens according to the invention.

Intraocular lens 2 (figure 1) is provided with optics 4 with lens centre 8, peripheral edge 6 and haptic elements 10. In the shown embodiment of lens 2 haptic elements 10 take a curved form. It will be apparent that it is also possible according to the invention to apply haptic elements 10 of a different form. It is further possible to vary the number of haptic elements 10, for instance by making use of a single haptic element.

The material of lens 2, particularly of optics 4 thereof, is preferably a hydrophobic or hydrophilic material, for instance a silicone material and/or hydrophilic or hydrophobic acrylate. Haptic element 10 can be provided from the same material or from a different, preferably more rigid or stiffer material, for instance (compression moulded) PMMA (polymethyl methacrylate) or PES (polyethersulfone), or other suitable materials.

Conventional lens 12 (figure 2A) is provided with optics 14, outer edge 16, centre 18 and haptic elements 20. 3D lens power profile 11 consists of a peak 11a in centre 18, followed by a decreasing lens power toward outer edge 16 (figure 3A). In the shown embodiment profile 11 has a

continuously decreasing lens power, wherein a number of additional bend points 11b are also arranged in lens power profile 11.

Lens 2 according to an embodiment according to the invention has a lens power profile 21 (figure 2B and figure 3B) which is provided close to centre 8 with base lens power level 22, which
5 in the shown embodiment remains constant in radial direction r over a distance of slightly more than 1 mm, after which the lens power increases to peak 26 over first radial distance 24. In the shown embodiment peak 26 is about 1.2 D. From peak 26, the lens power decreases over a distance 28 to valley 30. In the shown embodiment valley 30 lies at about -0.6 D. The lens power subsequently increases over third radial distance 32 until base level 22 is reached again. In this
10 shown embodiment this takes place at about 2.0 mm from centre 8 of lens 2.

In the shown embodiment for lens 2 base level 22 is particularly relevant for distance vision, i.e. particularly a distance greater than 2.0 m. Base level 22 runs from centre 8 of lens 2 to the start of the first radial distance 24 at about 1.2 mm from centre 8. In the first radial distance 24 the lens power rises to peak 26 at about 1.35 mm from centre 8. This particularly improves intermediate
15 vision, i.e. particularly the distance from 66 cm to 2.0 m from the eye. Third radial distance 32, which ends at about 2.0 mm from the centre 8 of lens 2, starts from valley 30 at about 1.6 mm from the centre.

In the shown embodiment the radial distances 24, 28, 32 are provided following directly on from each other. This makes a gradual transition between individual parts relatively simple. It will
20 be apparent that alternative embodiments, for instance with application of something resembling platforms at the position of peak 26, valley 30 and/or intermediate parts, are also possible. The gradual transition(s) in shown profile 21 counteract/compensate for adverse effects as far as possible. Realizing the second radial distance and the decreasing lens power which ends in valley 30 at a negative lens power followed by third radial distance 32 whereby the lens power is
25 preferably returned to base level 22 optimizes adverse effects such as spherical aberration still further.

In an alternative lens power profile 41 (figure 3C) there is, as seen from the centre toward the edge, a flat, increasing, decreasing, increasing and once again flat profile wherein there are no abrupt transitions or bend points. At least the first derivative of profile 41 is continuous. In area A
30 to B profile 41 has increased and improved intermediate vision and slightly reduced (long) distance vision. Area B to C restores the reduced (long) distance vision caused by area A-B wholly or at least for the most part. In the shown embodiment of profile 41 the lens powers in area A-B-C are wholly or at least largely dependent on each other, and complement each other. This characteristic successive shape and positioning of at least one sinusoidal period in the lens has resulted in a
35 unique link independent of the pupil. The shared characteristics of the entire shape of lens power profile 21, 41 in area A-B-C thereby optimizes the image quality at varying pupil aperture. In the

shown embodiment the lens power at the edge is at least equal to the lens power in the centre. If desired, the lens power at the edge can be higher/greater than the lens power in the centre.

Lens 2 was tested in various experiments. In these experiments the so-called modulation transfer function (MTF), among other things, was examined. This through-focus MTF is usually used when testing intraocular lenses. In a number of these experiments lens 21 was compared to a conventional monofocal lens. Both lenses were preheated here to 35°C on a hot plate within a margin of ± 2 °C. The lenses were measured with a Nimo VISU with IOL Mentor. In the results of one of these experiments discussed here the (pupil) aperture is 4 mm and the aberration is $+0.28$ μm . For data analysis use was made of MATLAB, wherein shown results (figure 4) are such that the peaks for infinite distance are set to 0.0 D defocus. The shown MTF value is the average MTF value for the frequencies from 10 to 15 lp/mm.

In the results (figure 4) a characteristic difference in the defocus results is designated with an EdoF arrow (extended depth of focus). This difference runs from about -0.85 D to 1.75 D. These results show an improved EdoF for lens 2, this resulting in better vision, particularly intermediate vision. Use of lens 2 therefore produces improved intermediate vision without any relevant loss of (long) distance vision. Adverse effects such as spherical aberration are also counteracted/optimized. This also results in improved comfort for the user of lens 2.

In further tests with lens 2 compared to a conventional monofocal lens the so-called postoperative logMAR visual acuity (VA) is also determined as a measure of the success of the surgery, this in addition to the MTF graph and the through-focus MTF graph. Tests were performed at 3.0 and 4.5 mm (pupil) aperture and a $+0.28$ μm aberration at 5.15 mm. Tests were further performed at a defocus in the range of $+1.0$ to -2 D. In order to determine the size of halos at a 4.5 mm aperture use was made of a so-called polychromatic point spread function (PSF). Results are shown in figures 5A-C. The MTF graph (figure 5A) for the best focus for a 4.5 mm (pupil) aperture shows a great deal of similarity between the two lenses in respect of distance vision. The through-focus MTF graph (figure 5B) at 50 lp/mm has for a 3.0 mm (pupil) aperture a greater through-focus range with a greater peak width for lens 2 compared to the conventional lens, and a secondary peak at about -1.5 D. The logMAR VA graph (figure 5C) shows similar results for long distance for both lenses, with a peak close to -0.1 logMAR. Lens 2 however shows better performance in the defocus range of -0.50 D tot -2.0 D, wherein lens 2 shows a VA improvement of about 0.08 logMAR at around -1.5 D. The study of halo effects has shown that lens 2 is less sensitive thereto than the conventional lens.

For manufacture of lens 2 optics from a suitable base material are selected and provided with desired optics 4. Haptic elements 10 are also arranged. Optics 4 are provided with lens power profile 21. During insertion of lens 2 it is preferably folded and/or rolled prior to being placed,

whereby only a limited length is required for the incision in the eye. After lens 2 has been inserted into the eye through the incision, lens 2 can unfold and be positioned using haptic elements 10.

The present invention is not limited to the above described embodiments thereof. The rights sought are defined by the following claims, within the scope of which many modifications can be envisaged.

CLAIMS

1. Intraocular lens configured to be inserted into an eye, the lens comprising:
 - an optical element of a flexible optical material; and
 - 5 - at least one haptic element which is connected to the optical element and which is provided with a connecting part configured to connect the lens to an eye part,
wherein the optical element is provided with a lens power profile, preferably a continuous lens power profile, wherein the profile is provided outside the centre of the lens, as seen in radial direction of the lens, with at least one increasing profile over a first radial distance and at
10 least one decreasing profile over a second radial distance.
2. Intraocular lens according to claim 1, wherein the lens power profile has a smooth progression.
- 15 3. Intraocular lens according to claim 2, wherein the smooth progression comprises a continuous progression of the derivative of the lens power profile.
4. Intraocular lens according to claim 1, 2 or 3, wherein the first radial distance and the second radial distance lie in the range of 0.5 to 2.5 mm from the centre of the lens.
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5. Intraocular lens according to any one of the foregoing claims, wherein the first radial distance and the second radial distance lie in the range of 1.0 to 2.0 mm from the centre of the lens.
- 25 6. Intraocular lens according to any one of the foregoing claims, wherein the profile has an increasing strength over the first radial distance in the range of 0.5 to 1.5 mm from the centre of the lens, and preferably in the range of 1.0 to 1.5 mm from the centre of the lens.
7. Intraocular lens according to any one of the foregoing claims, wherein the profile has a
30 decreasing strength over the second radial distance in the range of 1.5 to 2.5 mm from the centre of the lens, and preferably in the range of 1.5 to 2.0 mm from the centre of the lens.
8. Intraocular lens according to any one of the foregoing claims, wherein the lens power at or close to the edge of the intraocular lens is at least equal to the lens power in or close to the
35 centre of the lens.

9. Intraocular lens according to any one of the foregoing claims, wherein the profile has a peak outside the centre of the lens.
10. Intraocular lens according to the foregoing claim, wherein the peak has a value in the range of 1.0 to 1.5 D.
11. Intraocular lens according to claim 9 or 10, wherein the peak lies at the transition from the first to the second radial distance.
12. Intraocular lens according to any one of the foregoing claims, wherein the profile is provided with a third radial distance, wherein the third radial distance has an increasing power.
13. Intraocular lens according to any one of the foregoing claims, wherein the profile has a valley outside the centre of the lens.
14. Intraocular lens according to claim 13, wherein the valley has a value of at least -0.3 D, and preferably lies in the range of -0.3 to -1.0 D, and more preferably in the range of -0.3 to -0.55 D.
15. Intraocular lens according to any one of the foregoing claims, wherein the connecting part of the haptic element is configured to connect the lens to an eye part in order to replace a natural lens.
16. Method for manufacturing an intraocular lens, comprising of:
- providing an optical element of a flexible optical material;
 - providing at least one haptic element which is provided with a connecting part for connecting the haptic element to the optical element;
 - arranging a lens power profile, wherein the profile is provided in radial direction of the lens with at least one increasing profile over a first radial distance and at least one decreasing profile over a second radial distance.
17. Method according to claim 16, wherein arranging of the lens power profile further comprises of arranging a profile according to one or more of the claims 1-15.