

**OPHTHALMIC IMPLANTS FOR CORRECTING VISION WITH A TUNABLE OPTIC,
AND METHODS OF MANUFACTURE AND USE**

CROSS REFERENCE TO RELATED APPLICATIONS

5 [0001] This application claims priority to U.S. Provisional Application 63/262,073, filed October 4, 2021, the entire disclosure of which is incorporated by reference herein for all purposes.

[0002] The following references are incorporated by reference herein in their entireties for all purposes: U.S. Pat. No. 10,485,655; PCT Pub. No. WO/2017/156077; and U.S. Pub. No. 2019/0076242.

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INCORPORATION BY REFERENCE

[0003] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

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BACKGROUND

[0004] There may be benefits for a peripheral portion (e.g., haptic) of an intraocular lens (e.g., an Intraocular Collamer Lens (ICL)) to be adapted to prevent or minimize visual disturbances caused by the interaction between incident light and one or more surfaces of the lens. Additionally, or alternatively, there may be benefits to providing more customization or tuning options in the design of the optic, such as, without limitation, for one or more dimensions of the optic (e.g., optic diameter, optic central thickness, or optic peripheral thickness). The disclosure herein includes lenses and methods of manufacture that are adapted to provide one or more of these benefits.

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SUMMARY OF THE DISCLOSURE

30 [0005] One aspect of the disclosure is an ophthalmic implant, comprising: a transparent optic portion; and a peripheral non-optic portion coupled to the optic portion and extending peripherally therefrom, the peripheral portion sized and configured to engage a sulcus of an eye, the transparent optic portion made of a transparent optic material adapted to allow visible light to

pass therethrough, and the peripheral non-optic portion made of a light absorbing material adapted to absorb visible light. This aspect may also include any suitably combinable feature from any implant or lens herein, including in any of the claims as filed.

[0006] One aspect of this disclosure is a monofocal ophthalmic implant, comprising: a
5 transparent optic portion with a diameter from 4 mm to 7 mm; and a peripheral non-optic portion coupled to the optic portion and extending peripherally therefrom, the peripheral portion sized and configured to engage a sulcus of an eye, the transparent optic portion made of a transparent optic material adapted to allow visible light to pass therethrough, and the peripheral non-optic portion made of a light absorbing material adapted to absorb visible light. This aspect may also
10 include any suitably combinable feature from any implant or lens herein, including in any of the claims as filed.

[0007] One aspect of this disclosure is an ophthalmic implant for treating presbyopia, comprising: a transparent optic portion configured as an extended depth of field optic to treat presbyopia; and a peripheral non-optic portion coupled to the optic portion and extending
15 peripherally therefrom, the peripheral portion sized and configured to engage a sulcus of an eye, the transparent optic portion made of a transparent optic material adapted to allow visible light to pass therethrough, and the peripheral non-optic portion made of a light absorbing material adapted to absorb visible light. This aspect may also include any suitably combinable feature from any implant or lens herein, including in any of the claims as filed.

[0008] One aspect of this disclosure is a phakic intraocular lens, comprising: a transparent optic made of a transparent optic material, the optic having a power from -15 D to -30 D or from +5 D to +15 D, a diameter from 2 mm to 5 mm, and a difference between a central thickness and an edge thickness less than 500 microns; and an opaque peripheral non-optic portion made of a visible light absorbing material coupled to the optic and extending peripherally therefrom, the
20 opaque peripheral portion sized and configured to engage a sulcus of an eye. This aspect may also include any suitably combinable feature from any implant or lens herein, including in any of the claims as filed.

[0009] One aspect of this disclosure is an intraocular lens, comprising: a transparent optic made of a transparent optic material, the optic having a diameter from 1 mm to 3 mm; and an opaque
30 peripheral non-optic portion coupled to the optic and extending peripherally therefrom, the peripheral portion sized and configured to engage a sulcus of an eye and secure the lens in an eye. This aspect may also include any suitably combinable feature from any implant or lens herein, including in any of the claims as filed.

[0010] One aspect of this disclosure is a method of correcting vision, comprising: positioning a
35 lens into a posterior chamber of an eye, the lens including, a transparent optic made of a

transparent optic material, and an opaque peripheral non-optic portion coupled to the optic and extending peripherally therefrom, the peripheral non-optic portion made of a light absorbing material adapted to absorb visible light, and sized and configured to engage a sulcus of an eye and secure the lens in an eye, wherein positioning the lens into the posterior chamber comprises
5 interfacing the peripheral portion with the sulcus of the eye to secure the lens in the eye, and causing the opaque peripheral non-optic portion to absorb visible light that is incident upon the opaque peripheral non-optic portion. This aspect may also include any suitably combinable feature from any method herein, including in any of the claims as filed.

[0011] One aspect of this disclosure is a method of implanting a monofocal lens, comprising:
10 positioning a monofocal lens into a posterior chamber of an eye, the lens including a transparent optic portion made of a transparent optic material adapted to allow visible light to pass therethrough, the optic portion having a diameter from 4 mm to 7 mm, and an opaque peripheral non-optic portion made of a light absorbing material adapted to absorb visible light, the peripheral non-optic portion coupled to the optic portion and extending peripherally therefrom,
15 wherein positioning the monofocal lens into the posterior chamber comprises interfacing the peripheral portion with the sulcus of the eye to secure the lens in the eye, and causing the peripheral portion to absorb visible light that is incident upon the peripheral portion. This aspect may also include any suitably combinable feature from any method herein, including in any of the claims as filed.

20 **[0012]** One aspect of this disclosure is a method of treating presbyopia, comprising: positioning a lens into a posterior chamber of an eye, the lens including a transparent optic portion configured as an extended depth of field optic to treat presbyopia, the optic portion made of a transparent optic material and having a diameter from 3 mm to 5 mm, and an opaque peripheral non-optic portion made of a light absorbing material adapted to absorb visible light, and the
25 peripheral portion coupled to the optic portion and extending peripherally therefrom, wherein positioning the lens into the posterior chamber comprises interfacing the peripheral portion with the sulcus of the eye to secure the lens in the eye, and causing the peripheral portion to absorb visible light that is incident upon the peripheral portion. This aspect may also include any suitably combinable feature from any method herein, including in any of the claims as filed.

30 **[0013]** One aspect of this disclosure is a method of implanting a phakic lens, comprising: positioning a phakic lens into a posterior chamber of an eye, the phakic lens including a transparent optic portion made of a transparent optic material, the optic portion having a power from -15 D to -30 D or from +5 D to +15 D, a diameter from 2 mm to 5 mm, and a difference between a central thickness and an edge thickness less than 500 microns, and an opaque
35 peripheral non-optic portion made of a visible light absorbing material and coupled to the optic

portion and extending peripherally therefrom, wherein positioning the phakic lens into the posterior chamber comprises interfacing the peripheral portion with the sulcus of the eye to secure the lens in the eye, and causing the peripheral portion to absorb visible light that is incident upon the peripheral portion. This aspect may also include any suitably combinable feature from any method herein, including in any of the claims as filed.

[0014] One aspect of this disclosure is a method of providing vision correction to a patient, comprising: in a patient in which an eye is aberrated, positioning a lens into a posterior chamber of an eye, the lens including a transparent optic portion made of a transparent optic material, the optic portion having a diameter from 1 mm to 3 mm, and an opaque peripheral non-optic portion made of a visible light absorbing material and coupled to the optic portion and extending peripherally therefrom, wherein positioning the phakic lens into the posterior chamber comprises interfacing the peripheral portion with the sulcus of the eye to secure the lens in the eye, and causing the peripheral portion to absorb visible light that is incident upon the peripheral portion. This aspect may also include any suitably combinable feature from any method herein, including in any of the claims as filed.

[0015] One aspect of this disclosure is a method of manufacturing an ophthalmic lens, comprising: creating an optic rod of transparent optic material; creating a peripheral portion rod made of visible light absorbing material adapted to absorb light; forming a cylindrical channel in the peripheral portion rod; positioning the optic rod into the cylindrical channel; and adhering the optic rod to the peripheral portion rod to form an adhered rod with a central transparent region and a peripheral visible light absorbing region. This aspect may also include any suitably combinable feature from any method herein, including in any of the claims as filed.

[0016] One aspect of this disclosure is a method of manufacturing an ophthalmic lens, the method comprising: positioning an optic rod into a cylindrical channel that extends through a peripheral non-optic portion rod, the optic rod made of transparent optic material and the peripheral portion rod made of a visible light absorbing material; and adhering the optic rod to the peripheral portion rod to form a composite rod with a central transparent region and a peripheral visible light absorbing region. This aspect may also include any suitably combinable feature from any method herein, including in any of the claims as filed.

[0017] One aspect of this disclosure is an intraocular lens, comprising: a transparent optic portion and a non-optic peripheral portion comprising a visible light absorbing material, wherein the optic portion has an axis that is offset from and parallel to a peripheral portion axis. This aspect may also include any suitably combinable feature from any lens herein, including in any of the claims as filed.

[0018] One aspect of this disclosure is an intraocular lens, comprising: a transparent optic portion and a non-optic peripheral portion comprising a visible light absorbing material, the non-optic peripheral portion comprising one or more apertures therethrough adjacent the optic, the one or more apertures angled towards the periphery of the lens. This aspect may also include any
5 suitably combinable feature from any lens herein, including in any of the claims as filed.

[0019] One aspect of this disclosure is an intraocular lens, comprising: a transparent optic portion and a non-optic peripheral portion comprising a visible light absorbing material, the non-optic peripheral portion comprising one or more apertures therethrough and adjacent the optic, the one or more apertures each having an axis that is not parallel with an optic portion axis. This
10 aspect may also include any suitably combinable feature from any lens herein, including in any of the claims as filed.

BRIEF DESCRIPTION OF THE DRAWINGS

15 [0020] Figures 1A and 1B are top (anterior) and side views, respectively, of an exemplary lens with a transparent optic made of a transparent material adapted to allow visible light to pass therethrough, and the peripheral non-optic portion also made of a transparent material adapted to allow visible light to pass therethrough.

[0021] Figures 2A and 2B illustrate a top (anterior) view of an exemplary lens with a transparent
20 optic made of a transparent material adapted to allow visible light to pass therethrough, and a peripheral non-optic portion made of a light absorbing material adapted to absorb visible light.

[0022] Figures 3A and 3B illustrate an exemplary lens with a transparent optic made of a transparent material adapted to allow visible light to pass therethrough, and a peripheral non-optic portion made of a light absorbing material adapted to absorb visible light.

25 [0023] Figures 4A and 4B illustrate an exemplary lens with a transparent optic made of a transparent material adapted to allow visible light to pass therethrough, and a peripheral non-optic portion made of a light absorbing material adapted to absorb visible light.

[0024] Figures 5A and 5B illustrate an exemplary lens with a transparent optic made of a transparent material adapted to allow visible light to pass therethrough, and a peripheral non-
30 optic portion made of a light absorbing material adapted to absorb visible light.

[0025] Figures 6A, 6B, 6C and 6D illustrate exemplary lenses each with a transparent optic made of a transparent material adapted to allow visible light to pass therethrough, and a peripheral non-optic portion made of a light absorbing material adapted to absorb visible light.

[0026] Figure 7A illustrates an exemplary lens with a relatively small diameter optic, and
35 peripheral portion apertures.

[0027] Figure 7B illustrates a side view of a portion of an exemplary lens from figure 7A, including one of the peripheral apertures.

[0028] Figure 8 and 9 illustrate renderings of exemplary manufactured lenses with transparent optics made of a transparent material adapted to allow visible light to pass therethrough, and
5 peripheral non-optic portions made of a light absorbing material adapted to absorb visible light.

[0029] Figures 10A-10F illustrate an exemplary method of manufacturing a lens.

DETAILED DESCRIPTION

10 [0030] The disclosure is related to ophthalmic implants, such as lenses that are configured for placement into an eye. By way of example only, some lenses herein may be configured to be placed in a posterior chamber of an eye, between an iris and a capsular bag. Lenses herein may optionally be configured as extended depth of field lenses. Concepts herein may also be applicable to lenses implanted in other parts of an eye, and may be applicable to lenses
15 configured for a variety of types of vision correction (e.g., presbyopia, myopia, astigmatism, corneal damage or disease, lenticular damage or disease etc.).

[0031] One aspect of this disclosure is related to implantable lenses configured for correcting vision, wherein the optic is tunable, or adaptable as needed for a particular therapeutic application. Lenses herein may include a peripheral, non-optic portion coupled to a transparent
20 optic. The peripheral portions herein may generally be referred to herein as haptic portions, and they may comprise one or more haptics. The peripheral portions generally provide structural support to the ophthalmic implant, and are generally sized and disposed relative to the optic to engage tissue (e.g., the sulcus) and centrally locate the optic.

[0032] The lenses described herein also include a transparent optic that comprises a transparent
25 optic material adapted to allow light to pass therethrough and to the retina. The transparent material may comprise, for example, silicone, acrylics, or hydrogels. The transparent material may comprise hydrophobic or hydrophilic material. The transparent material may comprise Collamer®.

[0033] The lenses herein may include a peripheral non-optic portion that is made of a visible
30 light absorbing material adapted to absorb visible light. The visible light absorbing material of the peripheral portions may include one or more constituent components or agents that impart visible light absorbing properties to the light absorbing material, such as one or more of titanium, obsidian, gold, titanium dioxide, silicon carbide, carbon, charcoal or soot or organic chromophores that absorb light across the visible part of the electromagnetic spectrum.

[0034] In some mere examples, the peripheral non-optic portions may include one or more of the same components or agents as the optic portion, while also including the one or more visible light absorbing components or agents. For example only, peripheral portions herein may comprise silicone, acrylics, or hydrogels, as well as one or more of titanium, obsidian, gold, titanium dioxide, silicon carbide, carbon, charcoal or soot or organic chromophores. In some examples only, the optic and peripheral material may comprise the same or substantially the same components, except that the peripheral portion material may include the one or more visible light absorbing components or agents. For example only, an optic may comprise Collamer®, while the peripheral portion may comprise Collamer® as well as one or more visible light absorbing components or agents.

[0035] In some examples only, the optic material and the peripheral material may comprise the same or substantially the same components, except that the peripheral portion (which includes the one or more visible light absorbing components or agents) may not include an ultraviolet blocking chromophore that is included in the optic portion material. Since the peripheral portion includes one or more visible light absorbing components or agents, the peripheral portion may not need to include an ultraviolet radiation blocking chromophore, for example. For example only, an optic portion may comprise Collamer® while the peripheral portion may comprise Collamer® without an ultraviolet radiation blocking chromophore (as well as the one or more visible light absorbing components or agents). In some embodiments, however, it may be advantageous that the visible light blocking chromophore in the peripheral non-optic portion also blocks ultraviolet radiation. For example only, for some vision correction applications, the peripheral non-optic portion of lens may extend within the pupil (e.g., figure 5), and it may be advantageous that the peripheral non-optic portion also blocks ultraviolet radiation, preventing it from reaching the retina. In other embodiments, there may be little or no advantage that the visible light blocking chromophore in the peripheral non-optic portion also blocks ultraviolet radiation.

[0036] In some examples only, the organic or inorganic chromophores that provide the visible light blocking in the peripheral portion may be crosslinked with the base polymer of the peripheral portion.

[0037] The peripheral non-optic portions herein generally provide structural support to the ophthalmic implant, and are generally sized, configured and disposed relative to the optic to engage tissue (e.g., the sulcus) and centrally locate the optic (in some, embodiments below, however, the optic may not be centrally located). The peripheral portions herein may thus also be referred to as structural support portions. In some applications, it may be desired that the peripheral structural support portions of the lens have different mechanical properties than the

optic portion of the lens. For example, the optic portion and the peripheral structural support portion may be made from two different materials that have different optical properties as well as different mechanical properties. For example only, it may be desired to provide peripheral portions that are stiffer than the optic portion, or it may be desired for the peripheral portions to be less stiff than the optic portion. The material for the optic and peripheral portions may thus be selected to impart the desired optical and mechanical properties for the different portions of the lens. For example only, the peripheral portion material may be substantially different than the material for the optic portion, and the peripheral portion can also include the one or more light absorbing materials.

10 **[0038]** Figures 1A and 1B illustrate an exemplary lens 100 that includes transparent optic portion 110, which includes central hole 140 that is sized and positioned to provide for flow of aqueous humor through the lens. Lens 100 also includes peripheral non-optic portion 120 coupled to the optic portion, extending radially therefrom, and which may optionally (but not necessarily) be made of a light absorbing material that absorbs light, as is described herein. Lens 15 100 also includes transition zone 150 that connects or couples the optic portion 110 to the peripheral non-optic portion 120. The transition zones herein may be considered part of the lens that acts as a transition between the optic portion and the peripheral non-optic portion. The transition zones herein may optionally be considered part of the non-optic portion of the lens in that they are not specifically configured as part of the optic. Figures 1A and 2B illustrate an exemplary peripheral portion 120 that includes plate or plate-like haptics that include exemplary and optional footplates as shown, but the lenses herein may have other peripheral portion configurations.

[0039] It is noted that figures 2-7 illustrate the peripheral non-optic portions as “black” regions, while figures 1A and 1B are also optional examples of a lens that includes a peripheral non-optic portion with one or more visible light absorbing materials, but instead shows them without the blackened designation. It is understood that the visible light absorbing peripheral portions herein may be illustrated as blackened regions (e.g., figures 2-7, which may more depict how the lens would look after manufacture) or as depicted in figures 1A and 1B.

[0040] Figures 2A and 2B shows an exemplary lens 200 that includes a transparent optic portion 210, which includes central hole 240 that is sized and positioned to provide for flow of aqueous humor through the lens. Lens 200 also includes peripheral non-optic portion 220 coupled to the optic portion, extending radially therefrom, and which may optionally be made of a light absorbing material that absorbs light, as is described herein. Lens 200 also includes transition zone 250 that connects or couples the optic portion 210 to the peripheral non-optic portion 220. Figures 2A and 2B illustrate an exemplary peripheral portion 220 that includes plate or plate-like

haptics that include exemplary and optional footplates as shown, but the lenses herein may have other peripheral portion configurations.

[0041] The lenses herein, including peripheral portions made of visible light absorbing material, may impart one or more advantages or benefits to the lens, as well as creating more options for tuning or adapting the optic design as desired. For example, previous peripheral portions that transmit visible light, for example transition zones, may occasionally cause visual disturbances, such as glare or halos. For example, at night, pupils will dilate to let in more light, and light interacting with the non-optical peripheral portion surfaces of the lens may cause halos or other disturbances, symptoms or dysphotopsias. Peripheral portions described herein that absorb visible light prevent light from passing therethrough and thereby prevent the visual disturbances caused by the interaction between incident light and the non-optical surfaces of the peripheral portion.

[0042] An additional exemplary benefit of incorporating light absorbing peripheral portions into the lenses herein is that it may allow for more customization or tuning in the design of the optic, such as allowing more design options for one or more dimensions of the optic portion of the lens (e.g., diameter, optic central thickness, optic peripheral thickness). In some particular applications, the lenses herein may be placed in the sulcus between the iris and the capsular bag (with the native lens or a replacement IOL in the bag). This may be a region of the eye where there is limited space, and it may be beneficial to have a relatively very thin optic portion (e.g., 200 microns or less) to occupy as little space as possible and apply as little force on the iris as possible, and to avoid contacting the crystalline lens altogether, and for the rest of the lens to also be as thin as possible to occupy as little space as possible and apply as little force on the iris, and avoid contacting the crystalline lens altogether. For example, applying forces on the iris may reduce the angle and thereby reduce the aqueous drainage through Schlemm's canal, increasing intraocular pressure. Additionally contacting the crystalline lens may induce traumatic cataract. Additionally or alternatively, for some lenses (and treatments), it may be beneficial for the optic to have a relatively small optic diameter. With respect to peripheral portions that do not include any visible light absorbing components, decreasing the diameter of the optic inherently increases the radially inward extent of the peripheral portion, which extends the non-optic surfaces of the peripheral portion further radially inward, and thereby increases the likelihood of unwanted light scattering. Incorporating one or more light absorbing components into the peripheral portion, however, as is described herein, creates a peripheral portion that prevents visible light scattering in the peripheral non-optic portion. Peripheral portions that incorporate one or more visible light absorbing components may thus extend further radially inward without causing unwanted visible light scattering. In fact, when the peripheral portion includes visible light absorbing

component(s), the optic portion diameter may be decreased as much as desired without having to worry about visible light scattering off the non-optical surfaces of the peripheral portion.

[0043] As an illustration of the aforementioned design options, while optic portions in a monofocal lens (e.g., as shown in figures 2A and 2B) may have relatively large diameters, it may be desirable to have optic portions for treating presbyopia (for example only) that are generally relatively smaller than those for typical monofocal lenses. For example, for some extended depth of field lenses, such as those described in U.S. Patent Nos. 10485655 and 10881504, which are incorporated by reference herein in their entireties for all purposes, it may be beneficial to have relatively smaller optic diameters to avoid having to manage rays that are radially further from the visual axis ("Axis" shown in the side sectional view of figure 1B) and therefore incident on the cornea and crystalline lens at larger angles to the normal than more central rays. As a further example, for some extended depth of field lenses, such as those described in U.S. Patent Nos. 10485655 and 10881504, which are incorporated by reference herein in their entireties for all purposes, it may be beneficial to have optic diameters that are large enough to provide different optic regions having different optical powers, wherein the regions are large enough to provide enough visible light intensity to provide bright enough images that allow the objects at different distances to be clearly seen. Figures 3A and 3B illustrate exemplary lens 300 that may be configured as an extended depth of field lens to treat presbyopia. Generally, having an optic diameter that can be tuned and optimized for a lens design that refracts light from different distances to focus on the retina simultaneously, even when the crystalline lens has become rigid due to presbyopia, is an advantage in providing good images from objects that lie at a range of distances from the eye, e.g. 40 cm, 67 cm, 80 cm, 2 m and in the far distance.

[0044] Monofocal ophthalmic lenses function via refracting light from anterior and posterior curved surfaces. Generally, the anterior and posterior surfaces are curved in different ways to each other that cause the lens thickness to vary across the surface of the optic, generally from thin at the center to thicker at the periphery for negatively powered lenses such as those added to the eye to correct myopia (such as those shown in figures 1A and 1B), and from relatively thick at the center to relatively thin at the periphery for positively powered lenses such as those added to the eye to correct hyperopia or to replace the natural crystalline lens. It may be desirable to implant relatively high power lenses depending on the desired vision correction for the patient. Higher powered lenses (positive or negative), however, require larger variations in thickness across the surface of the optic than lower powered lenses to provide the higher power optic. An exemplary variation in optic thickness between the center and periphery is shown generally in figure 1B, and in one exemplary embodiment a center thickness along axis A may be 150 microns, the thickness at a radius of 1.0 mm may be 193 microns, the thickness at a radius of 1.5

mm may be 216 microns, the thickness at a radius of 2.25 mm may be 382 microns, and the thickness at a radius of 3.0 mm may be 565 microns, for example. In this example, the lens may have a power of -9.5 D. These exemplary thicknesses may also be applied to lens 200 in figures 2A and 2B, for example. As the lens must have a minimum thickness at any given position

5 across the optic to retain mechanical stability, the lenses become thicker as power increases, most strongly in the periphery for negatively powered lenses and at the center for positively powered lenses. If the lens peripheral portion does not include a visible light absorbing component, the peripheral portion cannot extend too far radially inward or unwanted scattering will generally occur as described herein. The optic portion may thus generally have a radial

10 extent (diameter) that prevents unwanted scattering from the peripheral portion. For higher power lenses, however, the relatively larger difference in thickness between the thinner and thicker regions may cause the lens to be so thick that it undesirably interacts with the iris and/or the native lens or native lens capsule. By incorporating one or more light absorbing components into the peripheral portion, however, the problems with light scattering with the peripheral

15 portions herein are avoided. The high power optic can thus be made to have a smaller diameter, and the periphery of the optic and the peripheral portion do not need to be as thick as if the lens did not have a light absorbing peripheral portion, which can prevent or at least minimize the likelihood of the undesired tissue interaction discussed herein. As such, it may be advantageous to have a smaller optic diameter to prevent the lens from becoming so thick that it either rubs on

20 the crystalline lens or pushes up on the iris, or both. Being able to decrease the diameter of the optic by incorporating opaque peripheral portions as described herein can thus allow higher power lenses to be designed and safely implanted within the sulcus. The term "high power" lenses as used herein includes negative high power lenses and positive high power lenses. Negative high power lenses include lenses that are -15 D or -30 D, or from -15 D to -30 D.

25 Positive high power lenses herein include lenses that +5 D or +15 D, or from +5 D and +15 D. It was heretofore challenging to safely implant a high power lens within a sulcus of an average sized eye. Figures 4A and 4B illustrate exemplary lens 400 that may be used as any of the high power lenses herein. In some embodiments, high power lenses herein (e.g., lens 400 in figures 4A and 4B) may have optic diameters from 2 mm to 4 mm, such as from 2.5 mm to 3.5 mm,

30 such as 2.5 mm, 2.6 mm, 2.7 mm, 2.8 mm, 2.9 mm, 3.0 mm, 3.1 mm, 3.2 mm, 3.3 mm, 3.4 mm, or 3.5 mm. In some embodiments, high power lenses herein may have a central thickness from 100 microns to 200 microns, such as 120 microns to 180 microns, such as 130 microns to 170 microns, such as 140 microns to 160 microns, such as 150 microns, and optionally an optic edge thickness from 200 microns to 700 microns, such 300 microns to 700 microns, such as 400

35 microns to 700, microns, such as 500 microns to 700 microns. In some embodiments, high

power lenses (whether negative or positive) herein may have a difference between a central thickness and an edge thickness from 100 microns and 600 microns, such as from 200 microns to 600 microns, such as 300 microns to 600 microns, such as 350 microns to 550 microns.

[0045] An additional aspect of the disclosure is lenses with a transparent optic and opaque peripheral non-optic portions as described herein, wherein the optic has a relatively much smaller optic diameter, such as from 1 mm to 3 mm, such as 1 mm, 1.5 mm, 2 mm, 2.5 mm, or 3 mm, an example of which is shown in lens 500 in figures 5A and 5B. The lenses in this aspect may be implanted in an eye that has poor vision due to an aberration. Such eyes may be the result of keratoconus or previous corneal transplant or physical injury or other reasons. The optic is designed to provide a refractive correction for the central portion of the eye and blocks visible light that is peripheral to the center. The visible light that reaches the retina and is focused thereupon travels only through the central portion of the eye thus blocking rays that enter through a large portion of the pupil. The restriction of the rays that reach the retina to a single portion of the eye that incorporates larger than normal perturbations to its shape allows those rays that do reach the retina to be more similar to each other and thus to create a better image than if all rays incident upon the pupil were allowed to reach the pupil. Such a lens can provide vision that is substantially improved relative to a lens that has no restrictions for eyes that require such therapeutic treatment. Figures 5A and 5B illustrate an exemplary ICL that has a relatively small diameter optic portion (e.g., 1 mm to 2 mm). Figure 5A illustrates an exemplary peripheral portion 520 that is adapted to absorb visible light. Figure 5B illustrates a region of the peripheral portion in dashed lines as a reference, wherein the dashed line region illustrates a part of the lens that could be part of the optic portion of the lens in previous lens designs. Alternatively, the lens can be designed so that the transparent optic portion of the lens is disposed in the lens such that the optic, when implanted, is situated in a non-central region of the pupil, or otherwise not centered in the pupil. This configuration may be desirable when, for example only, the central portion of the optical pathway is more aberrated than more peripheral portions, for instance when the central portion of the cornea has been selectively injured to the extent that it has been aberrated or made more opaque.

[0046] Figures 6A-6D illustrate the lenses from 2B, 3B, 4B, and 5B, respectively, to illustrate exemplary differences in optic portion diameter, illustrating the design options for ICL's herein when incorporating a peripheral portion that is adapted to absorb visible light. Figures 6A-6D illustrate how the optic and peripheral portions of lenses herein may be tuned depending on the visual impairment the lens is designed to treat. For example only, the lens in figure 2B and 6A may be designed as a monofocal lens, or monofocal lens that is also shaped to correct astigmatism, and may include an optic with a diameter from 4 mm to 7 mm, such as 4.5 mm to

6.5 mm, such as 6.0 mm, for example. For example only, the lens in figures 3B and 6B may be designed as an ICL adapted to treat presbyopia (such as an extended depth of field lens), or monofocal lens that is also shaped to correct ametropia, or monofocal lens that is also shaped to correct astigmatism, or monofocal lens that is also shaped to correct ametropia or astigmatism, and may include an optic portion with a diameter from 3 mm to 5 mm, such as 3.5 mm to 5 mm, such as 3.5 mm, 3.6 mm, 3.7 mm, 3.8 mm, 3.9 mm, 4.0 mm, 4.1 mm, 4.2 mm, 4.3 mm, 4.4 mm, 4.5 mm, 4.6 mm, 4.7 mm, 4.8 mm, 4.9 mm, or 5.0 mm, for example. For example only, the lens in figures 4B and 6C may be designed as a high-power ICL to correct high levels of ametropia, or high levels of ametropia with astigmatism, and may have an optic portion with a diameter from 2 mm – 4 mm, such as 2.5 mm – 3.5 mm, such as 3.0 mm, for example. For example only, the lens in figures 5B and 6D may be designed as a therapeutic ICL (examples of which are provided herein) that may also correct ametropia or ametropia with stigmatism, and may have an optic portion with a diameter from 1 mm to 3 mm, such as 1.5 mm to 2.5 mm, such as 2.00 mm, for example.

15 **[0047]** The ICL 200 in figures 2A and 2B, which may be adapted as a monofocal ICL, includes a peripheral portion 220 that is opaque, which helps block visible light incident to the transition zone between the optic 110 and the peripheral portion 220.

[0048] The ICL 300 in figures 3A and 3B, which may be adapted to treat presbyopia, includes a peripheral portion 320 that is opaque, the size of which helps block peripheral visible light rays to improve the image on the retina (described above), but it can also help the ICL fit into a relatively small space without damaging tissue, as well as blocking visible light incident upon a transition zone between the optic portion and the peripheral portion.

20 **[0049]** The ICL 400 in figures 4A and 4B, which may be adapted as a high powered lens, includes a peripheral portion 420 that is opaque, the size of which the lens fit into a relatively small space without damaging tissue (described above), as well as blocking light incident upon a transition zone between the optic portion 410 and the peripheral portion 420.

25 **[0050]** The ICL 500 in figures 5A and 5B, which may be adapted as a therapeutic lens, includes a peripheral portion 520 that is opaque, the size of which helps block mid-peripheral and peripheral rays to improve the image on the retina (described above), and which may also help the lens fit into a relatively small space without damaging tissue (described above), as well as blocking visible light incident upon a transition zone between the optic portion 510 and the peripheral portion 520.

30 **[0051]** In some embodiments, the lenses herein with peripheral opaque regions may also be adapted to provide correction of astigmatism through the use of a lens that includes cylindrical power. Such lenses are not radially symmetrical but have an axis about which the lens thickness

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varies. Such lenses can benefit from the innovative concepts described herein in the same way that the spherical lenses benefit.

[0052] The exemplary benefits set forth directly above illustrate the design and tuning options provided by incorporating an opaque peripheral portion to the ICLs herein.

5 **[0053]** As described in more detail below, lenses herein may include a transparent optic and a peripheral non-optic portion made of a visible light absorbing material that is different than the optic portion material. Lenses, when made from hydrophilic materials, when implanted into the aqueous environment of the eye, or when stored in a fluid for transportation, for instance balanced salt solution, will swell to some extent relative to the lens in its unhydrated state. If one
10 of the optic and peripheral non-optic portions swells more than the other, the coupling region between the optic and non-optic portions may be stressed or otherwise compromised after implantation. This may cause the lens, including the optic and/or the peripheral portion, to assume an undesired configuration after implantation, such as due to buckling between the optic and the non-optic portions, which may cause the lens to perform sub-optimally. Additionally,
15 different relative swelling may apply forces to the bond between the optic and periphery, which may cause the optic and peripheral portion to detach from each other. The optic and peripheral portions herein may thus have swell indices that are the same or substantially the same so that when they are manufactured, packaged and/or implanted, they will swell to as close to the same extent as possible. The phrase swell index as used herein may also be referred to as an expansion
20 factor, or other similar phrase. Swell index as used herein generally refers to the extent to which a material swells after being exposed to the natural aqueous humor of the eye, or similar solution such as Balanced Salt Solution (BSS), and may optionally be characterized generally by a change in linear dimensions, or volume, or change in weight, before and after swelling.

[0054] In any of the examples herein, the transparent optic material and the visible light
25 absorbing material may have swell indices that are the same as each other. In any of the examples herein, the transparent optic material and the visible light absorbing material may have linear swell indices that are within about 5% of each other, such as within 5% of each other, or preferably within 1% of each other. As set forth above, the material of the optic portion may be substantially the same as the material of the peripheral portion. As an example, an optic may
30 comprise Collamer®, and the peripheral portion may comprise Collamer® and may or may not include an ultraviolet radiation blocking chromophore. In these examples, the materials may not be exactly the same, but they may have swell indices within about 5% of each other. When the disclosure herein refers to materials that have swell indices that are within a certain percentage of each other, such as within 5% of each other, or preferably within 1% of each other, it is referring
35 to the linear swell index, or how much bigger the material becomes in the linear direction. To

measure a swell index in a particular fluid, for example, a material can be prepared (dry), then exposed to the fluid, and then measured to determine how much larger it has become in the linear direction.

[0055] For example only, a first optic material may have a swell index of 1.21 in BSS. Swell indices within 5% of 1.21 would include from 1.15 - 1.27 in BSS. Swell indices within 1% of 1.21 would include from 1.20 - 1.22. These are merely examples of swell indices that are within 5% and 1% of each other, respectively.

[0056] The central hole 140 (and other lens holes herein, central or otherwise) allows aqueous humor to flow throughout the eye in a manner similar to the flow of aqueous humor in an eye that does not contain a lens as described herein. The central hole is positioned centrally in order to minimize optical disturbances that occur due to visible light scatter from the walls or entry or exit of the hole but its position does not eliminate scatter entirely. In order to allow the flow of aqueous humor, the hole must be positioned within the pupil of the eye during most of the time as the iris changes size. For lenses that have relatively smaller optic regions (for example only, lens 500 in figures 5A and 5B), the one or more holes 740 may advantageously be positioned in the visible light-absorbing region 720 of the lens close to but radially outside of the optic region 710 (as shown in exemplary lens 700 in figures 7A and 7B) such that aqueous humor can flow through the one or more holes 740 for sufficient time to prevent pressure build-up in the eye, but by angling the one or more hole 740 towards the lens peripheral and away from the retina (as shown in the sectional partial view in figure 7B), scattered light will not be bothersome to the lens recipient. The central axis of the hole may be tilted or angled relative to the optical axis of the lens in a direction that is away from the fovea at an angle (e.g., figures 7A and 7B) that is, in some embodiments, between 10 degrees and 45 degrees (e.g., figure 7B). In some embodiments the one or more angled holes may have a diameter from 100 microns to 500 microns, such as from 200 microns to 400 microns, such as from 250 microns to 400 microns (e.g., 300 microns).

[0057] Figure 8 illustrates a rendering of a manufactured exemplary lens 800, which includes optic portion 810 and peripheral portion 820. Figure 8 is an anterior view of the lens. Peripheral portion 820 is made of a visible light absorbing material, as is described herein, and optic portion 810 is made of a transparent material. Any of the disclosure herein related to any aspect of any of the lenses herein may be incorporated by reference into exemplary lens 800. Lens 800 also includes a central aperture 840, and transition zone 850, which is considered part of the non-optic peripheral portion 820. Figure 8 illustrates coupling or bonding location 890, generally referring to the annular region where a periphery of the optic portion 810 is coupled to or bonded to an inner region of the peripheral portion 820 (exemplary methods of manufacture are described herein). Lens 800 may optionally include any other suitably combinable feature of any

of the lenses herein, including any of the dimensions and may also be adapted for any of the vision corrections herein. In this example, the optic axis passes through the central aperture 840.

[0058] Figure 9 illustrates a rendering of a manufactured exemplary lens 900, which may be the same or similar to lens 800 in any regard. Lens 900 includes a transparent optic 910 coupled to opaque peripheral portion 920. Peripheral portion 920 is made of a visible light absorbing material, as is described herein, and optic portion 910 is made of a transparent material. Any of the disclosure herein related to any aspect of any of the lenses herein may be incorporated by reference into exemplary lens 900. Lens 900 includes transition zone 950, which is considered part of the non-optic peripheral portion 920. Lens 900 does not, in this example, include a central aperture. Figure 9 illustrates coupling or bonding location 990, generally referring to the annular region where the optic portion 910 is coupled to or bonded to the peripheral portion 920 (exemplary methods of manufacture are described herein). Lens 900 may optionally include any other suitably combinable feature of any of the lenses herein, including any of the dimensions and may also be adapted for any of the vision corrections herein.

[0059] The disclosure herein also includes methods of manufacturing any of the lenses herein. Figures 10A-10F illustrate an exemplary sequence of manufacturing that may optionally be used to manufacture any of the lenses herein that include an opaque peripheral portion that includes one or more visible light absorbing materials. The methods may include coupling an optic portion material to a peripheral non-optic portion material. In some embodiments the optic portion material is chemically coupled or connected to the peripheral non-optic portion material. An exemplary method of manufacturing may include creating rods of the starting materials for the optic and non-optic portions. The rods may be made of materials that have the same or substantially the same swell index (details of which are described herein), and wherein one of the rods includes a visible light absorbing component or agent. For example, figure 10A illustrates a peripheral portion rod 1050 that is made of a visible light absorbing material, and a starting optic rod 1010 that is made of transparent material. Figure 10B illustrates optic rod 1010' that has been formed by reducing the diameter of the starting rod 1010 to be the desired diameter of the optic of the lens. Both of rods 1010 and 1010' may be considered optic rods as that phrase is used herein, even though rod 1010' in this example is the rod that is sized with the desired diameter of the lens optic. Figure 10C illustrates peripheral portion rod 1050' after a cylindrical hole or channel 1051 has been created longitudinally through rod 1050. Figure 10C also illustrates rod 1010' about to being positioned into the channel 1051, in the direction of the arrow shown. The material of the optic rod 1010' may then be adhered or bonded to the material of the peripheral rod 1050', as shown in figure 10D, which may also be considered as a "composite" rod. Figure 10D may also represent the optic rod after it has been inserted into the

peripheral rod but before bonding. Once the optic material is bonded to the peripheral material, they are considered to be coupled together. Figure 10E illustrates a button 1070 that has been created by cutting a small section from the composite rod shown in figure 10D. Button 1070 includes a central transparent section 1072 and a peripheral section 1071 that is coupled to the central section 1072 at coupling location 1073, which is an annular region. The ophthalmic lens 1073 may then be formed from the button 1070 using a variety of surface forming steps, such as lathing and/or milling the desired optical and non-optical surfaces of the optic and the peripheral portion. The exemplary method shown in figures 10A-10F may be used to manufacture any of the lenses described herein. Additionally, if an optic rod is first created to have a desired diameter, it may not be necessary to reduce the diameter as shown in the transition from figure 10A to figure 10B. It is thus understood that this step may not necessarily be needed in this exemplary method. Additionally, the peripheral portion and the optic portion (of any of the lenses herein) should preferably (but not necessarily) have a common, or the same, axis so that when they are coupled together their axes are aligned.

[0060] It is also understood that methods of manufacturing that are described and claimed herein need not necessarily include all of the steps from figures 10A-10E. For example, methods of manufacturing herein may include positioning an optic rod into a cylindrical channel (e.g., as shown by the arrow in figure 10C), and bonding or adhering the optic rod to the peripheral portion rod to form an adhered or composite rod with a central transparent region and a peripheral visible light absorbing region, an example of which is shown in figure 10D.

[0061] As an alternative to the peripheral portions herein that are made of one or more light absorbing materials, the peripheral portions may optionally have one or more surfaces adapted to scatter light, and adapted such that the scattered light is not incorrectly focused. For example, the scattering surfaces may be adapted to cause incident light to scatter in a generally random manner such that no particular direction is preferred. Peripheral portions with one or more scattering surfaces may optionally be made of the same material as the optic, and the lenses may be manufactured as a one-piece lens. After the lens is manufactured, one or more of the peripheral portion surfaces may then be modified such that it is adapted to scatter light. An exemplary non-limiting manner to create the scattering surfaces is to, generally speaking, roughen the surfaces. One or both of an anterior surface and a posterior surface of the peripheral portion may be adapted for scattering as set forth herein.

CLAIMS

1. An ophthalmic implant, comprising:
a transparent optic portion having a diameter that is tunable; and
5 a peripheral non-optic portion coupled to the optic portion and extending peripherally therefrom, the peripheral portion sized and configured to engage a sulcus of an eye, the transparent optic portion made of a transparent optic material adapted to allow visible light to pass therethrough, and the peripheral non-optic portion made of a light absorbing material adapted to absorb visible light, and
10 wherein the transparent material and the visible light absorbing material have linear swell indices that are within 5% of each other when exposed to one or both of aqueous humor or balanced salt solution ('BSS').
2. The ophthalmic implant of Claim 1, wherein the transparent material and the visible light
15 absorbing material have linear swell indices that are within 1% of each other when exposed to one or both of aqueous humor or balanced salt solution ('BSS').
3. The ophthalmic implant of Claim 1, wherein the transparent optic material is different
20 than the light absorbing material and is bonded to the light absorbing material.
4. The ophthalmic implant of Claim 1, wherein the peripheral portion extends all the way
from a periphery of the optic portion to a radially outermost surface of the ophthalmic implant.
5. The ophthalmic implant of Claim 1, wherein the peripheral portion includes a transition
25 zone adjacent to the optic portion and extending from the optic portion to a supporting structure of the peripheral portion.
6. The ophthalmic implant of Claim 1, wherein the transparent optic material and the
peripheral portion material comprise the same constituent components but for one or more
30 visible light absorbing components being present in the peripheral portion material.
7. The ophthalmic implant of Claim 1, wherein the transparent optic material and the
peripheral portion material comprise the same constituent components except that the peripheral
portion material includes one or more light absorbing components, and the peripheral portion
35 material does not include a UV blocking chromophore.

8. The ophthalmic implant of Claim 1, wherein the tunable transparent optic portion diameter and the peripheral non-optic portion surrounding it are sized based on the visual impairment the ophthalmic lens is designed to treat.
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9. The ophthalmic implant of Claim 8, wherein the optic portion has a diameter from 1 mm to 7 mm.
10. The ophthalmic implant of Claim 9, wherein the ophthalmic implant is a monofocal ophthalmic implant and the optic portion has a diameter from 4 mm to 7 mm.
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11. The ophthalmic implant of Claim 9, wherein the ophthalmic implant is an ophthalmic implant for treating presbyopia, and wherein the optic portion has a diameter from 3 mm to 5 mm.
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12. The ophthalmic implant of Claim 11, wherein the lens is shaped to provide an extended depth of field.
13. The ophthalmic implant of Claim 12, wherein the lens is shaped to provide varying powers, optionally continuously varying, from different portions of the optic.
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14. The ophthalmic implant of Claim 13, wherein the lens is shaped to provide a gradual variation of power whereby the power varies from the center outwards to the outer edge , optionally with radial symmetry.
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15. The ophthalmic implant of Claim 14, wherein the gradual variation of power continuously increases from the center to the outer edge or continuously decreases from the center to the outer edge.
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16. The ophthalmic implant of Claim 9, wherein the ophthalmic implant is a phakic ophthalmic implant for treating high levels of ametropia, and wherein the optic portion has a diameter from 2 mm to 5 mm.
17. The ophthalmic implant of Claim 9, wherein the optic portion has a diameter from 1 mm to 3 mm for treating highly aberrated eyes.
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18. The ophthalmic implant of Claim 1, wherein the lens has a width from 10 mm to 14 mm.
19. The ophthalmic implant of Claim 1, wherein the lens is shaped to correct ametropia.
- 5 20. The ophthalmic implant of Claim 1, wherein the lens is shaped to correct myopia.
21. The ophthalmic implant of Claim 20, wherein the lens is shaped to also correct astigmatism.
- 10 22. The ophthalmic implant of Claim 1, wherein the lens is shaped to correct hyperopia.
23. The ophthalmic implant of Claim 22, wherein the lens is shaped to also correct astigmatism.
- 15 24. The ophthalmic implant of Claim 1, wherein the lens is shaped to correct astigmatism.
25. The ophthalmic implant of Claim 1, wherein a central thickness of the optic portion is from 100 microns to 400 microns, optionally 100 microns to 200 microns.
- 20 26. The ophthalmic implant of Claim 1, wherein a thickness of a peripheral region of the peripheral portion where it engages the sulcus is between 50 and 200 microns.
27. The ophthalmic implant of Claim 1, wherein an edge thickness of the optic is less than 700 microns.

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