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Bailey et al.

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(54) **CONTACT LENS COMPRISING A SUPERIOR LENTICULAR ASPECT**

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See application file for complete search history.

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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G02C 7/04 (2006.01)

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(58) **Field of Classification Search**
CPC G02C 7/043; G02C 7/048; G02C 7/049

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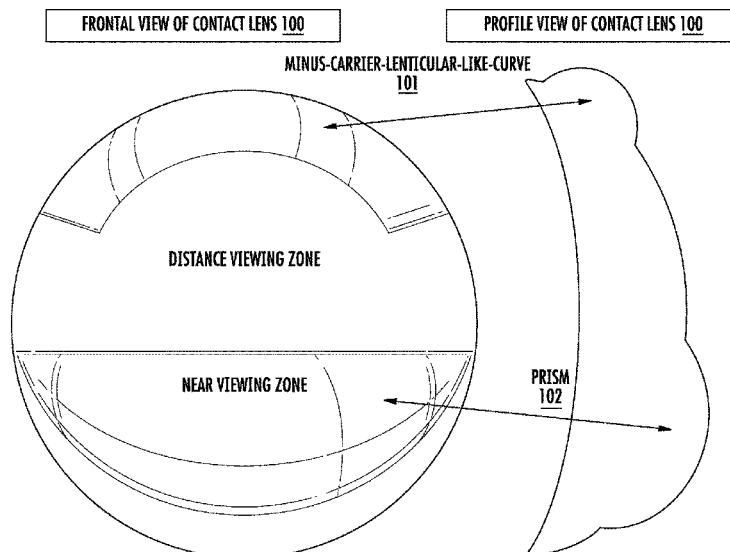
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(57) **ABSTRACT**

Disclosed herein is a contact lens comprising a rounded, minus-carrier, lenticular-like curve over a central, upper portion of the lens that allows the contact lens to translate upwards in downgaze.

20 Claims, 3 Drawing Sheets



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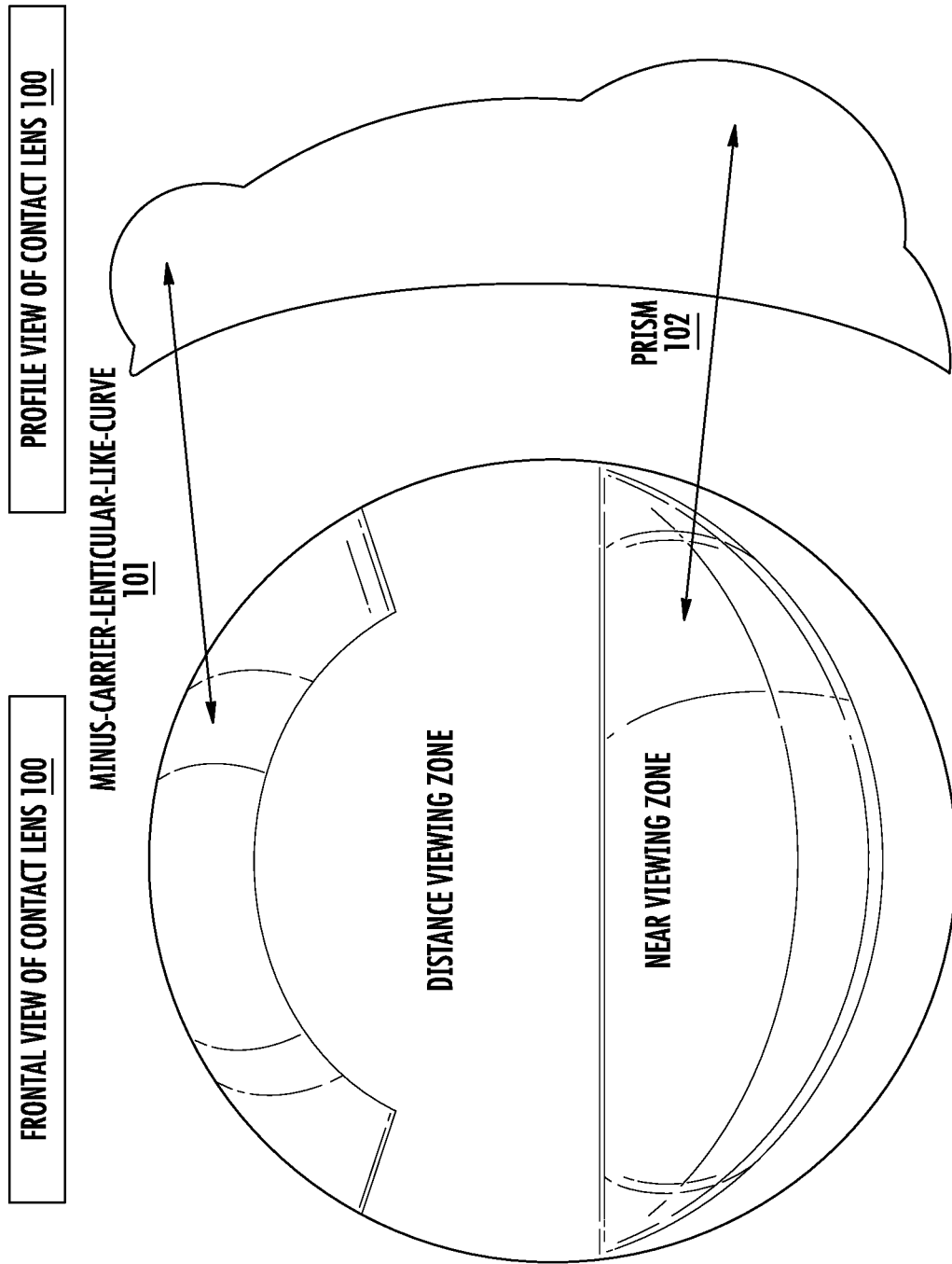


FIG. 1A

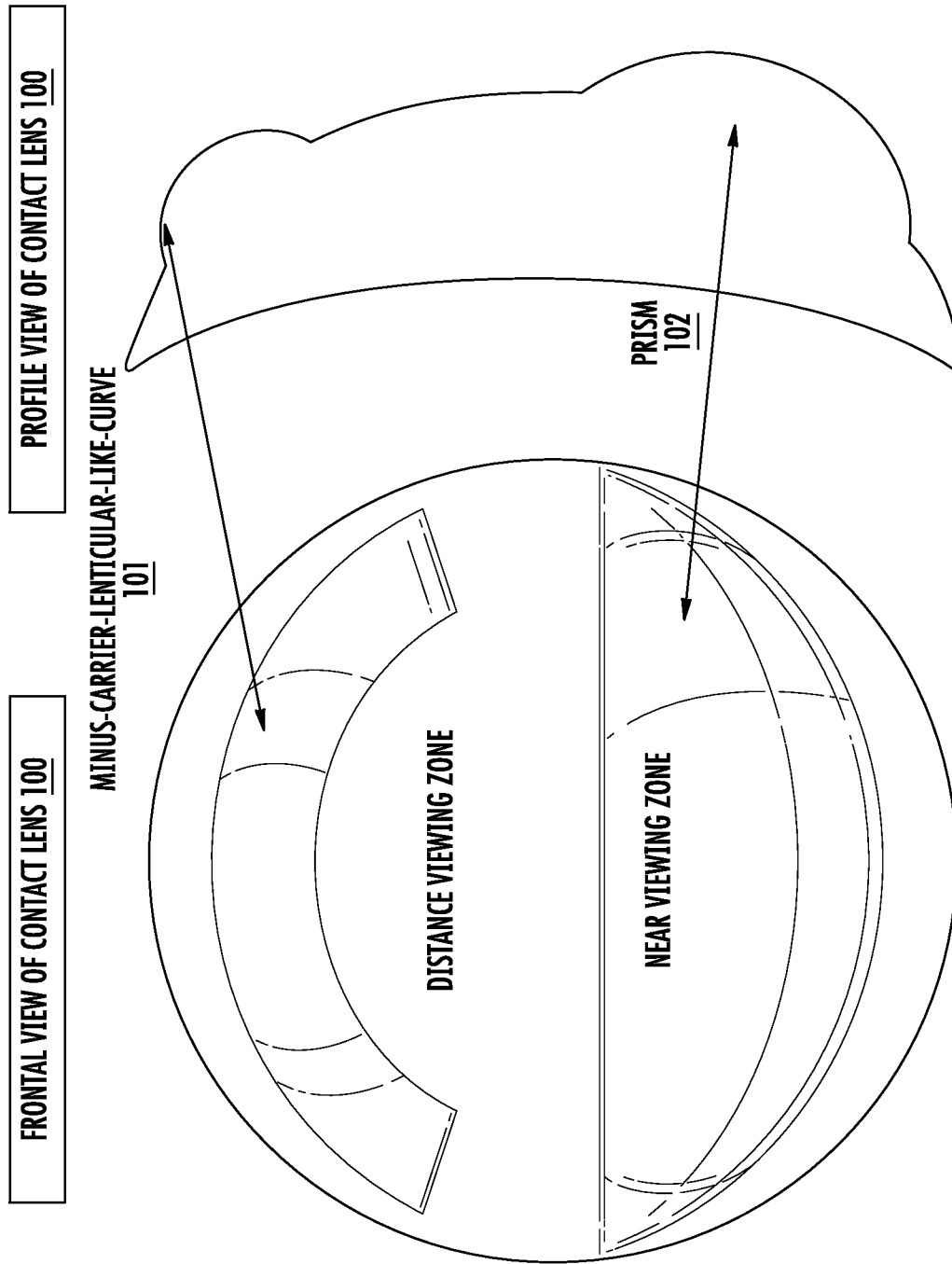


FIG. 1B

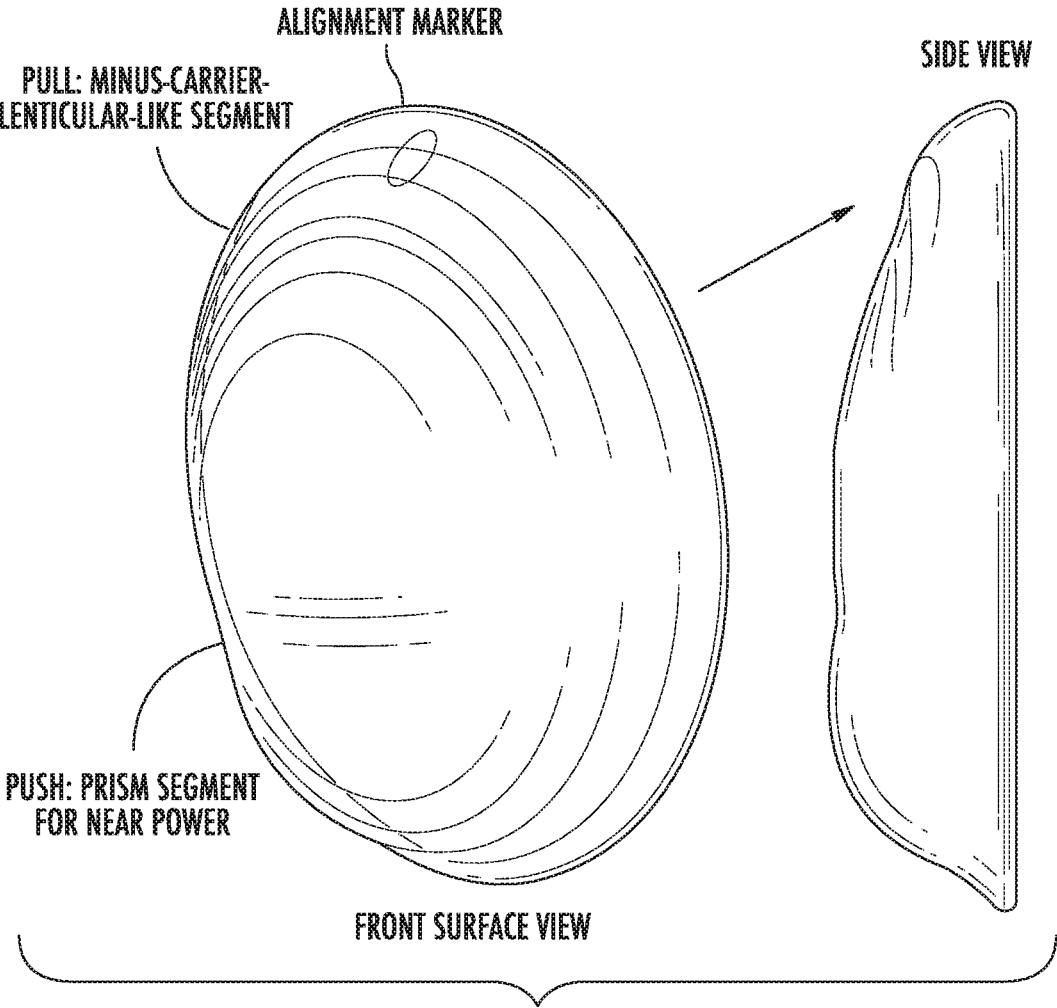


FIG. 2

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**CONTACT LENS COMPRISING A SUPERIOR
LENTICULAR ASPECT****CROSS-REFERENCE TO RELATED
APPLICATIONS**

This application is a continuation application of U.S. application Ser. No. 15/274,159 filed Sep. 23, 2016, which claims priority to and benefit of U.S. Provisional Application No. 62/222,376, filed Sep. 23, 2015, both of which are hereby incorporated by reference in their entirety.

BACKGROUND

The current state-of-the art in rotational stabilization includes back surface toricity (effective for rigid gas-permeable contact lenses), base-down and peri-ballast prism, or Dynamic Stabilization which is a modification of base-down prism. There are patients for whom one or none of the existing designs are sufficient to provide rotational stabilization for a contact lens. What is needed in the art are contact lenses that are alternating vision, meaning that the eye is focused by the contact lens for distance when looking far away and then focused by the contact lens for near when looking at an object that is nearby.

SUMMARY

The present disclosure relates to translating contact lenses that work when the cornea is spherical or toric. For rotational stabilization, the contact lenses disclosed herein have an advantage over base-down prism, peri-ballasting, and Dynamic Stabilization in that it uses the interaction between the lenticular aspect described below and the upper eyelid tarsal plate to stabilize the contact lens and may also use the interaction between the base of the prism and the lower eyelid. Interactions between the lens and one or both eyelids provides better stabilization in the lens design disclosed herein. This same contact lens design will also allow for the contact lens to have a translational movement when the patient looks from straight ahead gaze into downgaze. Instead of pushing the base of the prism in the contact lens upwards with the lower eyelid, as much of the prior art attempts to do, this design pulls the contact lens upwards with the superior lenticular aspect. This is because the lenticular aspect allows the contact lens to use a "lid-attached" fit, wherein the lens stays with the upper lid as the patient looks downwards.

The description below sets forth details of one or more embodiments of the present disclosure. Other features, objects, and advantages will be apparent from the description and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying figures, which are incorporated in and constitute a part of this specification, illustrate several aspects described below.

FIGS. 1A and 1B are schematic diagrams providing frontal and profile view of a contact lens according to lens designs disclosed herein. FIG. 1A shows the minus-carrier lenticular-like curve **101** located on the edge of the contact lens **100**, while FIG. 1B shows the minus-carrier lenticular-like curve **101** located further from the edge of the contact lens **100**.

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FIG. 2 is a schematic diagram of the Buck-Eye Contact Lens, showing the "push" and "pull" mechanism associated therewith.

DETAILED DESCRIPTION

The present disclosure now will be described more fully hereinafter with reference to specific exemplary embodiments. Indeed, the present disclosure can be embodied in many different forms and should not be construed as limited to the embodiments set forth herein.

Disclosed herein is a contact lens comprising a rounded, minus-carrier, lenticular-like curve over a central, upper portion of the lens. This contact lens is referred to throughout this disclosure as a "Buck-Eye Contact Lens."

The Buck-Eye Contact Lens disclosed herein couples two primary features in a design that creates: (1) rotational stability of the contact lens in all gazes, (2) upwards translation, or movement, of the contact lens when the eye is in downward gaze, and (3) a general, centered placement of the contact lens over the cornea and the pupil as needed as the person's gaze changes. By "upwards translation of the contact lens when the eye is in downward gaze" means that the contact lens is held in an upwards position when the patient looks down.

Referring to FIGS. 1A and 1B, a schematic diagram of frontal and profile view of a contact lens **100** according to lens designs disclosed herein is illustrated. The first feature of the design is the placement of a rounded, minus-carrier-lenticular-like-curve **101** over the upper, central portion of the contact lens only. The second feature of the design is the possible use of prism **102** in the lower portion of the contact lens. The combined features of the contact lens disclosed herein provide rotational stabilization, translation, and/or centration. The Buck-Eye Contact Lens disclosed herein could be a rigid gas permeable or soft contact lens design, or a hybrid design, such that the contact lens has a rigid center with soft surround. The lens can be made of a material that can sense light activity or molecules in the ocular environment and that contains elements that modulate light or the surrounding ocular environment, i.e., liquid crystal displays, filters, photochromatic materials, compartments containing other materials, or sensors.

The minus-carrier-lenticular-like-curve **101** can be seen at the top of the contact lens **100**. The minus-carrier-lenticular-like-curve **101** can be placed at the upper edge of the contact lens **100**, as seen in FIG. 3A, or can be located some distance from the edge of the contact **100**, as can be seen in FIG. 3B. For example, it can be located in the central, upper portion of the contact lens **100**. The minus-carrier-lenticular-like-curve **101** can be 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, or 5.0 millimeters, or more, less, or any amount in-between, away from the outer edge of the contact lens **100**. A prism **102** can be located in the lower half of the contact lens **100**. The use of prisms is discussed in more detail herein.

The current state-of-the-art in translating contact lenses is a rigid gas permeable contact lens. There are currently no successful soft contact lenses that achieve translating vision. All of the prior art in translating soft contact lenses moves in the opposite direction of this design, i.e., all other designs attempt to thin the upper portion of the contact lens as much as possible, rather than making it thicker and attached to the upper lid. The contact lens disclosed herein provides a translating soft contact lens that is more comfortable and requires less adaptation time than a rigid gas permeable lens. Generally speaking, patients are more willing and able to

wear a soft contact lens than a rigid gas permeable contact lens, and a soft contact lens requires less expertise to fit. The current state-of-the-art in bifocal or multifocal soft contact lenses is simultaneous vision. In these lenses, both the rays focusing the distance vision and the rays focusing the near vision are within the pupil at the same time. Thus, the patient must be able to ignore the rays that are not in focus. This leads to some degradation vision. The translating soft contact lens disclosed herein allow only light from one distance to be in focus at a time, providing clearer vision at each distance.

The other current state-of-the-art option for fitting presbyopic patients in soft contact lenses is called monovision. In this case, one eye is powered for distance vision (usually the dominant eye) and one eye is powered for near vision (usually the non-dominant eye). Some patients are unable to adapt to this type of lens, again, especially when the patient requires a greater reading add power. The difference between the two eyes becomes too uncomfortable. Also, it is well established that monovision correction in contact lenses or laser vision correction leads to a loss of depth perception. The translating soft contact lens disclosed herein allows for the use of higher reading add powers without degradation of the quality of distance vision. Because both eyes are fully and equally corrected at distance and near in the disclosed design, there is no induced loss of depth perception. The translating soft contact lens disclosed herein can also have an optical segment that provides a gradient of power change between the distance and near segments.

The contact lens disclosed herein are designed to suit many practical purposes. For example, in both rigid and soft contact lenses, the lens designs disclosed herein provide rotational stabilization in all gazes for toric contact lens designs, contact lenses designed to correct for various types of ocular aberration beyond a spherical correction, for electronically-generated and/or virtual optically displayed images, and/or bifocal or multifocal contact lenses. Additionally, the lens designs disclosed herein create upwards translation of a bifocal/multifocal contact lens in downward gaze. Furthermore, the lens designs disclosed herein achieve a "lid attached" fit similar to rigid gas permeable contact lens, i.e., keep the contact lens attached under the upper lid before, during, and after a blink.

In one embodiment, the upper portion of the contact lens interacts with an upper lid of the wearer. The upper portion of the contact lens that interacts with the upper lid can comprise 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, or 75% of the area between the upper edge of the contact lens and the geometric center of the contact lens. For example, the area of the upper portion of the contact lens (meaning the "top half" of the contact lens, or the area between the upper edge and geometric center of the contact lens) that interacts with the upper lid can comprise 10 to 50% of the upper area of the lens.

Traditionally, the minus carrier lenticular is used in rigid gas permeable contact lenses in order to create a lid attached fit in a plus-shaped contact lens. In the Buck-Eye Contact Lens design disclosed herein, a rounded, minus-carrier-lenticular-like-curve is placed in the central, upper portion of the lens only, rather than over a larger portion of the lens circumference. The lens designs disclosed herein have a smaller area where a relatively thick edge is present to interact with the upper eyelid margin, and the minimal presence of the lenticular improves comfort over a more traditional minus carrier lenticular that would ordinarily be placed over the entire lens circumference. There is enough surface area and thickness of the lenticular present in the

contact lens disclosed herein, however, to interact with the upper tarsal plate to assist with centration and rotational stability.

The upper eyelid can also interact with the prism in the lower portion of the contact lens according to the lens designs disclosed herein. The edge of the upper eyelid squeezes the thicker, base of the prism of the Buck-Eye Contact Lens downwards with each blink. The base of the prism also interacts with the lower eyelid with each blink; therefore, the base of the prism is placed above the lower contact lens margin, high enough to remain above the lower eyelid when the eye is open. Just as multiple base curve options are available for fitting different corneal curvatures, multiple heights of the prism base are optionally used to account for differences in aperture size and position of the eyelids. In addition, multiple overall diameters of the contact lens can also be used. In other words, the prism portion can provide a change in power from the central optic zone of the contact lens. The base of the prism may not slide more than 1, 1.5, 2, 2.5, or 3 millimeters (mm) behind the lower lid, when in the patient is looking straight ahead and/or downwards when the eye is open and during the blink.

As disclosed above, the contact lens comprises a relatively thick area compared to the remaining portion of the contact lens. This area of thickness can be 1.5, 2, 3, 4, 5, 6, 7, 8, 9, or 10 times thicker than the remaining "non-thick" portion of the contact lens. For example, the relatively thick area can comprise a thickest portion, which is 2 to 5 times thicker than the remaining portion of the contact lens.

The Buck-Eye Contact Lens disclosed herein can be used in the correction of ametropia (myopia, hyperopia, astigmatism, and/or higher order aberrations) in patients with or without presbyopia, i.e., a reading add that moves upwards through translation, in patients with other accommodative disorders, and/or patients with a binocular vision disorder can also be provided in the lens designs disclosed herein. Presbyopia affects 100% of the population who live long enough (-45 years of age) to develop the condition. The Buck-Eye Contact Lens can also treat other accommodative disorders, or binocular vision disorder. The Buck-Eye Contact Lens can also be used to display an electronically-generated and/or other virtual optically-displayed image.

Currently marketed contact lenses provide very limited options in terms of design parameters such as diameter and curvature. The disclosed lenses achieve translation in a soft contact lens. Soft contact lenses are typically only feasible to manufacture in two base curve options, and very few are offered in multiple diameters. These multiple options in these two parameters in addition to the ability to vary the prism height, size, amount, or axis are optionally considered in the lens designs disclosed herein. Back surface toricity takes advantage of a toric, rather than spherical, corneal shape that occurs in some patients with astigmatism. The lenses disclosed herein still work when the cornea is spherical (not toric). The described lenses also have an advantage over base-down prism, peri-ballasting, and Dynamic Stabilization in that it optionally uses a lenticular aspect described above to use the upper eyelid tarsal plate to stabilize the contact lens in addition to the prismatic interaction of the lower lid. Interactions with both lids provide better stabilization.

Disclosed herein are methods of making the contact lenses disclosed herein. For example, disclosed is a method of making a contact lens, the method comprising manufacturing a contact lens comprising forming a rounded, minus-carrier, lenticular-like curve over a central, upper portion of the lens. The contact lens can further comprise a base down

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prism in the inferior portion of the lens where the minus-carrier, lenticular-like curve. In one example, the base down prism is added to the lens in a second step of a manufacturing process.

Also disclosed is a method of treating an individual in need of vision correction, the method comprising dispensing the contact lens disclosed herein to the individual, thereby treating the individual in need of vision correction. In one example, the individual has been diagnosed with ametropia. In another example, the individual has been diagnosed with presbyopia, another accommodative disorder, and/or a binocular vision disorder.

As used in the specification, and in the appended claims, the singular forms “a,” “an,” “the,” include plural referents unless the context clearly dictates otherwise.

The compositions and methods of the appended claims are not limited in scope by the specific compositions and methods described herein, which are intended as illustrations of a few aspects of the claims and any compositions and methods that are functionally equivalent are intended to fall within the scope of the claims. Various modifications of the compositions and methods in addition to those shown and described herein are intended to fall within the scope of the appended claims. Further, while only certain representative compositions and method steps disclosed herein are specifically described, other combinations of the compositions and method steps also are intended to fall within the scope of the appended claims, even if not specifically recited. Thus, a combination of steps, elements, components, or constituents may be explicitly mentioned herein or less, however, other combinations of steps, elements, components, and constituents are included, even though not explicitly stated. The term “comprising” and variations thereof as used herein is used synonymously with the term “including” and variations thereof and are open, non-limiting terms. Although the terms “comprising” and “including” have been used herein to describe various embodiments, the terms “consisting essentially of” and “consisting of” can be used in place of “comprising” and “including” to provide for more specific embodiments of the invention and are also disclosed. Other than in the examples, or where otherwise noted, all numbers expressing quantities of ingredients, reaction conditions, and so forth used in the specification and claims are to be understood at the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of the claims, to be construed in light of the number of significant digits and ordinary rounding approaches.

What is claimed is:

1. A contact lens comprising a superior lenticular aspect located in a central, upper portion of the lens, wherein the superior lenticular aspect of the lens is shaped to interact with an upper tarsal plate of an upper eyelid of a wearer such that the contact lens translates upward in a downgaze of the wearer to place a viewing zone of the contact lens over a pupil or cornea of the wearer and the superior lenticular aspect provides rotational stabilization to the contact lens, wherein:

a distance from an outer edge of the contact lens to the superior lenticular aspect is from 0.1 mm to 5.0 mm.

2. A contact lens comprising a superior lenticular aspect located in a central, upper portion of the lens, wherein the superior lenticular aspect of the lens is shaped to interact with an upper tarsal plate of an upper eyelid of a wearer such that the contact lens translates upward in a downgaze of the wearer to place a viewing zone of the contact lens over a

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pupil or cornea of the wearer and the superior lenticular aspect provides rotational stabilization to the contact lens, wherein:

a distance from an outer edge of the contact lens to the superior lenticular aspect is from 0.1 mm to 5.0 mm; and

the superior lenticular aspect comprises from 5% to 75% of an area from the outer edge of the contact lens to a geometric center of the contact lens.

3. A contact lens comprising a superior lenticular aspect located in a central, upper portion of the lens, wherein the superior lenticular aspect of the lens is shaped to interact with an upper tarsal plate of an upper eyelid of a wearer such that the contact lens translates upward in a downgaze of the wearer to place a viewing zone of the contact lens over a pupil or cornea of the wearer and the superior lenticular aspect provides rotational stabilization to the contact lens, wherein:

a distance from an outer edge of the contact lens to the superior lenticular aspect is from 0.1 mm to 5.0 mm; and

the superior lenticular aspect comprises from 5% to 75% of an area from the outer edge of the contact lens to a geometric center of the contact lens; and

a thickness of the superior lenticular aspect is from 1.5 to 10 times thicker than a maximum thickness of a remainder of the contact lens.

4. The contact lens of claim 3, wherein the thickness of the superior lenticular aspect is 1.5 times thicker than the maximum thickness of the remainder of the contact lens.

5. The contact lens of claim 3, wherein the thickness of the superior lenticular aspect is 2 times thicker than the maximum thickness of the remainder of the contact lens.

6. The contact lens of claim 3, wherein the thickness of the superior lenticular aspect is 3 times thicker than the maximum thickness of the remainder of the contact lens.

7. The contact lens of claim 3, wherein the thickness of the superior lenticular aspect is 4 times thicker than the maximum thickness of the remainder of the contact lens.

8. The contact lens of claim 3, wherein the superior lenticular aspect comprises from 10% to 70% of an area from the outer edge of the contact lens to the geometric center of the contact lens.

9. The contact lens of claim 3, wherein the superior lenticular aspect comprises from 15% to 65% of the area from the outer edge of the contact lens to the geometric center of the contact lens.

10. The contact lens of claim 3, wherein the superior lenticular aspect comprises from 20% to 60% of the area from the outer edge of the contact lens to the geometric center of the contact lens.

11. The contact lens of claim 3, wherein the superior lenticular aspect comprises from 25% to 55% of the area from the outer edge of the contact lens to the geometric center of the contact lens.

12. The contact lens of claim 3, wherein the superior lenticular aspect comprises from 25% to 55% of the area from the outer edge of the contact lens to the geometric center of the contact lens.

13. The contact lens of claim 3, wherein the superior lenticular aspect comprises from 5% to 25% of the area from the outer edge of the contact lens to the geometric center of the contact lens.

14. The contact lens of claim 3, wherein the superior lenticular aspect comprises from 10% to 20% of the area from the outer edge of the contact lens to the geometric center of the contact lens.

15. The contact lens of claim 3, wherein the distance from the outer edge of the contact lens to the superior lenticular aspect is from 0.1 mm to 0.5 mm.

16. The contact lens of claim 3, wherein the distance from the outer edge of the contact lens to the superior lenticular aspect is from 0.5 mm to 1.0 mm. 5

17. The contact lens of claim 3, wherein the distance from the outer edge of the contact lens to the superior lenticular aspect is from 1.0 mm to 1.5 mm.

18. The contact lens of claim 3, wherein the distance from the outer edge of the contact lens to the superior lenticular aspect is from 0.5 mm to 1.5 mm. 10

19. The contact lens of claim 3, wherein the distance from the outer edge of the contact lens to the superior lenticular aspect is from 1.5 mm to 2.0 mm. 15

20. The contact lens of claim 3, wherein the contact lens further comprises a prism.

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