

TOTAL30® Soft Contact Lenses

Category:

Best Medical Technology

Company Name:

Alcon

Product/Solution Name:

TOTAL30® Soft Contact Lenses

Compound/Tech Name:

TOTAL30® (lehfilcon A)

Trade Name:

TOTAL30® Spherical, TOTAL30® for Astigmatism, TOTAL30® Multifocal

Corporate Name:

Alcon

Date of Approval:

2021-04-12

Indications:

TOTAL30® (lehfilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hypertropia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

TOTAL30® for Astigmatism (lehfilcon A) toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hypertropia) in phakic or aphakic persons with non-diseased eyes with up to approximately 6.00 diopters (D) of astigmatism.

TOTAL30® Multifocal (lehfilcon A) soft contact lenses are indicated for the optical correction of presbyopia with or without refractive ametropia (myopia and hypertropia) in phakic or aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have up to 1.50 diopters (D) of astigmatism

that does not interfere with visual acuity.

The lenses are to be prescribed for daily wear, with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, or disposal, as recommended by the eye care professional. Lenses should be discarded and replaced with a new pair each month, or more often if recommended by the eye care professional.

Therapeutic Areas:

Optical Correction of Refractive Ametropia, Astigmatism, Presbyopia

General Information File Document upload:

[**FDA Letter_TOTAL.pdf**](#)

Background information and need for drug / device:

Contact lenses are one of the most successful applications of biomaterials. The chemical structure of the polymers used in contact lenses plays an important role in determining the function of contact lenses.¹ In addition, controlling the surface properties of contact lenses in direct contact with the cornea tissue through surface polymer modification mimics the surface morphology of corneal tissue while maintaining the essential properties of the contact lens, a significant improvement for long-term use and reuse of contact lenses.¹⁻⁶

TOTAL30® contact lenses are the first and only monthly replacement lenses that include CELLIGENT® Technology, which was inspired by the biology of the ocular surface in order to create a new level of biomimicking properties in a monthly contact lens. The innovative CELLIGENT® Technology allows for lipid and bacterial adhesion resistance, which is important for a monthly replacement contact lens.⁴⁻⁹

The surface of TOTAL30® features a polymer structure very different than its core. The lens surface was created to have a similar structure to the glycocalyx on the cornea. The surface polymers (2-methacryloyloxyethyl phosphorylcholine, MPC) create nanofiber structure on the TOTAL30® lens surface that is like the nanofiber structure of the glycocalyx on the corneal surface (Figure 1).³⁻⁵ Therefore, the structure of the glycocalyx is mimicked by the CELLIGENT® Technology, giving TOTAL30® contact lenses its biomimetic properties. MPC has demonstrated biocompatible properties and benefits within the body. These polymers have been used in several other applications (i.e. grafts, implants) and have shown to help reduce protein, bacteria and cell adhesion.^{1,4} It is these characteristics that were the basis behind the development of CELLIGENT® Technology on TOTAL30® contact lenses.

Alcon has a strong commitment to research and development efforts and prioritizes finding solutions that address the unmet needs of Eye Care Professionals and patients to help people See Brilliantly. The creation of TOTAL30® was a monumental R&D effort as Alcon embarked on the journey to develop the first and only biomimetic monthly replacement contact lens. The TOTAL30® portfolio of lenses includes TOTAL30®

Spherical, TOTAL30® for Astigmatism and TOTAL30® Multifocal.

Background File Document upload:

N/A

History of the development of the solution/product:

Contact lenses are one of the most successful applications of biomaterials. The chemical structure of the polymers used in contact lenses plays an important role in determining the function of contact lenses.¹ In addition, controlling the surface properties of contact lenses in direct contact with the cornea tissue through surface polymer modification mimics the surface morphology of corneal tissue while maintaining the essential properties of the contact lens, a significant improvement for long-term use and reuse of contact lenses.¹⁻⁶

TOTAL30® contact lenses are the first and only monthly replacement lenses that include both Water Gradient Technology and CELLIGENT® Technology. CELLIGENT® Technology was inspired by the biology of the ocular surface in order to create a new level of biomimicking properties in a monthly contact lens. The innovative CELLIGENT® Technology allows for lipid and bacterial adhesion resistance, which is important for a monthly replacement contact lens.⁴⁻⁹

The surface of TOTAL30® features a polymer structure very different than its core. The lens surface was created to have a similar structure to the glycocalyx on the cornea. The surface polymers (2-methacryloyloxyethyl phosphorylcholine, MPC) create nanofiber structure on the TOTAL30® lens surface that is like the nanofiber structure of the glycocalyx on the corneal surface (Figure 1).³⁻⁵ Therefore, the structure of the glycocalyx is mimicked by the CELLIGENT® Technology, giving the TOTAL30® contact lens its biomimetic properties. MPC has demonstrated biocompatible properties and benefits within the body. These polymers have been used in several other applications (i.e. grafts, implants) and have shown to help reduce protein, bacteria and cell adhesion.^{1,4} It is these characteristics that were the basis behind the development of CELLIGENT® Technology on TOTAL30® contact lenses. Alcon took the Water Gradient Technology, first introduced in DAILIES TOTAL1®, and adapted it with CELLIGENT® Technology to form the Water Gradient surface. The innovative CELLIGENT® Technology also allows for lipid and bacterial adhesion resistance, which is important for a monthly replacement contact lens.⁴

Alcon has a strong commitment to research and development efforts and prioritizes finding solutions that address the unmet needs of Eye Care Professionals and patients to help people See Brilliantly. The creation of TOTAL30® was a monumental R&D effort as Alcon embarked on the journey to develop the first and only biomimetic monthly replacement contact lens. The TOTAL30® portfolio of lenses includes TOTAL30® Spherical, TOTAL30® for Astigmatism and TOTAL30® Multifocal.

Development File Document upload:

N/A

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

TOTAL30® contact lenses, a groundbreaking medical device, represents a significant advancement in biomaterial technology. TOTAL30® is crafted from lehficon A, a novel biomimetic material engineered to replicate the surface properties of the ocular cornea.¹⁻⁵ The glycocalyx of the cornea is what also helps to hold the tear film onto the ocular surface, reduces frictional forces with the eyelid during each blink and serves as a barrier to microbes. Similarly, the polymer nanofibers on the TOTAL30® lens surface draw water into the lens surface to create and maintain the water gradient, giving it lubricity and softness, and also helps to resist against lipid and bacteria deposition. This innovation addresses critical challenges in contact lens design, including wettability, lubricity, and biocompatibility, ultimately providing outstanding patient comfort and vision quality.³⁻¹³ The TOTAL30® portfolio are the first and only monthly replacement Water Gradient lenses which help deliver outstanding comfort, for a full 30 days.⁸ In in vitro studies, TOTAL30® delivered superior softness and superior lubricity (lower surface modulus^{2,3,12*} and greater surface lubricity^{5,13**}).

Innovation and Implications:

TOTAL30® lens material, lehficon A, represents a paradigm shift in contact lens material advancement, departing from conventional silicone hydrogel materials to introduce a biomimetic design concept.¹

lehficon A is manufactured through a precise process involving the grafting of a poly(2-methacryloyloxyethyl phosphorylcholine) (PMPC) polymeric layer onto a silicone hydrogel base substrate.⁵ This grafting process is crucial for imparting biomimetic surface properties to the contact lens, as it supports tear film stability, reduces friction, and minimizes discomfort during wear.⁶⁻¹¹

PMPC plays a pivotal role in achieving biomimetic surface properties in lehficon A contact lenses by closely resembling the phospholipid molecules found in cell membranes.¹ Its chemical structure enables it to exhibit high hydrophilicity, excellent water retention properties, and unique antifouling properties that inhibit the adsorption of proteins and lipids from the tear film onto the contact lens surface.⁴ This contributes to a more harmonious interaction between the contact lens and the ocular environment, minimizing friction, supporting tear film stability, and providing outstanding overall wearer satisfaction and comfort.²⁻¹¹

Improving Human Condition:

TOTAL30® addresses key challenges associated with traditional contact lens materials, such as poor wettability, protein/lipid deposition, and discomfort during wear.¹

The biomimetic design of lehficon A enhances tear film stability, reducing friction and shear stress on the ocular surface, thereby minimizing discomfort and ocular complications.²⁻⁶

By providing outstanding comfort, TOTAL30® contributes to enhanced quality of life for contact lens wearers.⁶⁻¹¹

Future Research and Impact:

The development of TOTAL30® water innovation contact lenses sets a new standard for contact lens material design, inspiring future research into biomimetic materials and their applications in biomedical devices.

Further research on biomimetic surface treatments and material modifications holds promise for enhancing the performance and biocompatibility of a wide range of medical devices beyond contact lenses. In conclusion, TOTAL30® contact lens material represents a groundbreaking innovation that combines scientific rigor, biomimetic design principles, and clinical relevance to address critical challenges in contact lens technology.^{1,6-11} By providing outstanding patient comfort and vision quality, TOTAL30® exemplifies the transformative potential of biomedical engineering in enhancing the human condition.

Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract, Website):

*Based on surface modulus measured with AFM nanoindentation; vs. ACUVUE OASYS® 2-week, ACUVUE VITA®, Biofinity® and ULTRA® contact lenses.

**Based on in vitro testing of out of pack lenses and ex vivo testing of worn lenses; critical coefficient of friction as measured by nano-tribometer; vs. ACUVUE OASYS® 2-week, ACUVUE VITA® and Biofinity® contact lenses.

1. K Ishihara, X Shi, K Fukazawa, T Yamaoka, G Yao, JY Wu*, "Biomimetic-engineered silicone hydrogel contact lens materials for reusable wearing", ACS Applied Bio Materials, 2023, 6, 3600-3616. <https://doi.org/10.1021/acsabm.3c00296>
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3. X Shi, V Sharma, D Cantu-Crouch, G Yao, K Fukazawa, K Ishihara*, JY Wu*, "Nanoscaled Morphology and Mechanical Properties of a Biomimetic Polymer Surface on a Silicone Hydrogel Contact Lens", Langmuir 2021, 37, 13961–13967. <https://doi.org/10.1021/acs.langmuir.1c02678>
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9. Capote-Puente, R., Sánchez-González, J. M., Sánchez-González, M. C., & Bautista-Llamas, M. J. (2023). Evaluation of Celligent® biomimetic water gradient contact lens effects on ocular surface and subjective symptoms. *Diagnostics*, 13(7), 1258. <https://doi.org/10.3390/diagnostics13071258>
10. Capote-Puente, R., Bautista-Llamas, M. J., & Sánchez-González, J. M. (2023). Tear film dynamics between low and high contact lens dry eye disease questionnaire (CLDEQ-8) score with a Lehfilcon A silicone hydrogel water gradient contact lens: A non-invasive methodology approach. *Diagnostics*, 13(5), 939.
<https://doi.org/10.3390/diagnostics13050939>
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13. Surface lubricity testing of lehfilcon A and commercial lenses using nano-tribometer; Alcon data on file, 2020.

Figure 1. TOTAL30® Contact Lenses Mimic the Surface Morphology and Biology of the Human Eye. Featured on the journal cover of *Langmuir*, November 30, 2021 issue.

See instructions for use for wear, care, precautions, warnings, contraindications and adverse effects.

References File Document upload:

N/A