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Ocular Surface Homeostasis & Contact Lens Design

Bausch + Lomb ULTRA® ONE DAY silicone hydrogel contact lenses combine two breakthrough technologies that work together to help maintain a stable and healthy ocular environment—to deliver outstanding comfort for a full 16 hours of wear.[1]

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Background

Homeostasis is a state of dynamic equilibrium for all body systems, and the ocular surface is no exception. Immediately upon insertion, contact lenses modify the balance of the ocular surface environment by dividing the tear film and inducing biophysical changes.[2-4] Environmental and patient-specific factors, such as blink rate, completeness of blink, and tear quality, can also alter the natural balance of the ocular surface during contact lens wear.[5] These changes to ocular surface homeostasis may manifest as symptoms of contact lens discomfort and poor visual clarity.[2,6]

Material Properties & Ocular Surface Homeostasis

The material properties of a contact lens play an important role in determining the extent of the impact of contact lens wear on ocular surface homeostasis.[2-4] Advances in contact lens material technology have been aimed at lightening the load on the ocular surface—increasing water content and wettability while maintaining high oxygen permeability. In addition, a daily replacement frequency may contribute to balance in contact lens wear by eliminating variables associated with cleaning solutions and facilitating better patient adherence to the replacement schedule.[7]

A key factor through which contact lenses affect ocular surface homeostasis is through lens oxygen permeability. The avascular cornea requires ambient oxygen for proper cellular metabolism. Insufficient oxygen permeability can lead to contact lens-induced hypoxia and, eventually, corneal edema.[4,8] To help maintain ocular surface homeostasis and for the open eye to remain healthy and white, a contact lens material must allow for sufficient oxygen permeability.

Another important way in which a lens affects ocular surface homeostasis is through its modulus. Modulus describes how a material resists deformation and responds under stress and strain. In contact lens materials, a high modulus may be associated with greater shear stresses upon blinking.[3] The high modulus of early generation silicone hydrogel lens materials has been associated with conditions such as papillary conjunctivitis and mucin balls. Conversely, low-modulus materials may help to reduce the impact on the ocular surface and contribute to wearer comfort.[3,9]

A lens material can also affect ocular surface homeostasis through water content and dehydration resistance. While the primary function of a contact lens is to provide refractive correction, the lens material must be able to resist dehydration in order to maintain optical clarity. When considering the optics of a lens, it is also important to consider the stability of the tear film. A stable, balanced tear film forms a smooth surface for light to pass into the eye and maintains hydration for the ocular surface tissues. Disruption of the tear film can lead to blurry vision and discomfort.[2,6] Soft lenses with a smooth, wettable surface that preserves hydration throughout the wearing day should provide both a clear initial refracting surface and a comfortable wearing experience. To enhance lens surface wettability, in addition to lens material modifications, surfactants may be incorporated into contact lens solutions.[9]

Contact lenses can also impact the balance of factors within the tear film itself. For example, the dynamics of protein interactions with the interface of the contact lens can be complex. In their native state, tear proteins such as lysozyme have beneficial properties that can help maintain the balance of ocular surface homeostasis. This is evidenced by research of the structural changes of lysozyme relative to stabilizing the tear film[10,11] and to its lubricating properties.[12] Stabilizing tear proteins in their native, non-denatured state can have a positive impact on ocular surface homeostasis thus playing a role in successful contact lens wear.

The Tear Film and Ocular Surface Society's (TFOS) Dry Eye Workshop (DEWS) II report highlighted the importance of tear film electrolyte and osmolarity balance for ocular surface

homeostasis.[6,13] Electrolytes perform critical roles in ocular surface homeostasis by helping to maintain cell volume and fluid balance, and osmoprotectants are a group of compatible solutes that protect cells under osmotic stress.[6,13] The TFOS DEWS II report also discussed the components of aqueous supplementation as they relate to the maintenance of ocular surface homeostasis.[6,13] When added to a contact lens solution, moisturizers can lower surface tension and promote the wettability of the contact lens surface.[13]

Bausch + Lomb ULTRA® ONE DAY Silicone Hydrogel Contact Lenses

Taking these properties into account in the design process, Bausch + Lomb ULTRA® ONE DAY contact lenses combine breakthrough moisture and comfort technologies aimed at supporting a stable and healthy ocular surface environment to deliver outstanding comfort for a full 16 hours of wear.[1,14]

ADVANCED MOISTURESEAL® TECHNOLOGY

Created using a proprietary two-phase polymerization process, the Bausch + Lomb ULTRA® ONE DAY silicone hydrogel contact lens material balances moisture, modulus, and oxygen transmissibility for excellent ocular health and a comfortable wearing experience. The Advanced MoistureSeal® Technology behind the Bausch + Lomb ULTRA® ONE DAY lens was developed using advanced computer modeling and material chemistry, with the aim of incorporating additional hydrophilic components. In the first phase of polymerization, a unique combination of long- and short-chain silicone polymers create a flexible matrix. Additional wetting agents are incorporated into the silicone backbone of the lens, helping to boost water content to 55%. The long-chain silicone provides a low modulus while the short-chain silicones provide the majority of oxygen transport capability and structural integrity for excellent handling.

Also during phase one of polymerization, the hydrophilic component dimethylacrylamide (DMA) is integrated into the silicone backbone, along with a Class II UV blocking agent that provides broad spectrum protection, blocking at least 50% of UVA rays and 95% of UVB rays.† In the second phase of polymerization, the humectant polyvinylpyrrolidone (PVP) is permanently grown around and throughout the silicone backbone to further enhance moisture retention.[15]

The resulting properties of this kalifilcon A lens material support vision, comfort, and health, providing high oxygen permeability, low modulus, high water content, moisture retention, and exceptional optics. With a Dk/t of 134 at the center of a -3.00D lens, the lens offers outstanding breathability for corneal health.[8] It also features a low modulus of 0.5 MPa, and 55% water content that is maintained throughout the wearing day, with 96% of lens moisture remaining after 16 hours of wear.[15-18] The high and sustained moisture content of the lens material works in tandem with High Definition™ aspheric optics, providing exceptional clarity in a wide variety of activities.

COMFORTFEEL TECHNOLOGY

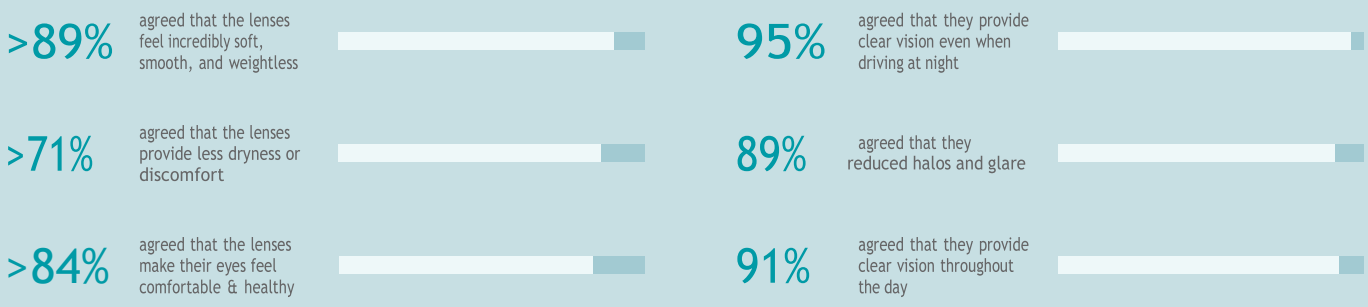
Just as the material properties of the Bausch + Lomb ULTRA® ONE DAY lens were engineered to support ocular health and comfort, the lens is also enhanced with ComfortFeel technology. Inspired by the TFOS DEWS II report, ComfortFeel Technology includes a proprietary blend of ingredients that includes the osmoprotectants glycerin and erythritol, and a balanced combination of key electrolytes, including potassium.[6,13] ComfortFeel Technology also incorporates the moisturizers poloxamine 1107 and poloxamer 181 to help retain lens hydration and wettability. They also help to maintain tear proteins in their healthy, natural state.

> ***Bausch + Lomb ULTRA® ONE DAY contact lenses combine breakthrough moisture and comfort technologies.***

The ingredients in ComfortFeel Technology are released from the lens during wear through the principles of passive diffusion. The rate of diffusion depends on the size, shape, and chemistry of the ingredients, as well as the polymer chemistry of the kalifilcon A material. The size, shape, and chemistry of each of the ingredients in ComfortFeel Technology vary, and therefore, the rate at which they release from the lens varies. Once the difference in concentration of the ingredients inside the lens as compared with the environment outside the lens becomes small, some ingredients remain in the lens.

†**WARNING:** UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear, such as UV-absorbing goggles or sunglasses, because they do not completely cover the eye and surrounding area. The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV light has not been established at this time. You should continue to use UV-absorbing eyewear as directed. NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduces the risk of developing cataracts or other eye disorders.

FIGURE 1. Among wearers of Bausch + Lomb ULTRA® ONE DAY Lenses...[14]



REAL WORLD PATIENT EXPERIENCE

Most importantly, the effects of these breakthrough technologies are not lost on patients. Approximately 9 out of 10 silicone hydrogel daily disposable wearers agreed that Bausch + Lomb ULTRA® ONE DAY contact lenses feel incredibly soft, smooth, and weightless.[14] Even among wearers with contact lens dryness, about 80% agreed that the lenses provided ultra comfort to their eyes, and greater than 82% agreed that the lenses are comfortable even when working long hours at the computer.[19]

Regarding vision, 95% of patients who experienced habitual contact lens dryness agreed that the lenses provide clear vision even when driving at night, and 89% agreed that the lenses reduced halos and glare. Among those who wore lenses for 16 hours or more per day, 99% agreed that they provide clear vision throughout the day.[1]

Bausch + Lomb ULTRA® ONE DAY Lenses – A Complete System

Bausch + Lomb ULTRA® ONE DAY contact lenses offer a complete moisture + comfort system with Advanced MoistureSeal® Technology and ComfortFeel Technology resulting in a complete design of high oxygen permeability, low modulus, UV blocking†, and High Definition™ Optics. The features of Bausch + Lomb ULTRA® ONE DAY contact lenses combine to provide an exceptionally clear and comfortable contact lens wearing experience.

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