tangible™ HYDRA-PEG

Tangible™ Hydra-PEG: A Novel Custom Contact Lens Coating Technology Designed to Improve Patient Comfort and Satisfaction

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The most frustrating aspect of contact lens practice is not the determination of fit or the power, but rather dealing with a non-wetting lens. Inadequate wettability decreases comfort, diminishes visual clarity, and affects a patient's overall lens wearing experience. The Tear Film and Ocular Surface Society (TFOS) executive summary on contact lens discomfort stated that "contact lens discomfort is a frequently experienced problem, with most estimates suggesting that up to half of contact lens wearers experience this problem with some frequency or magnitude."[1] It has also been reported that contact lens discomfort is the primary reason for contact lens dropout.[2]

Silicone-based materials are inherently hydrophobic, so any exposed silicone in a lens has the potential to be non-wetting. Additionally, in some patients, excessive lipids in the tear film may deposit onto the lens to create a foggy, hydrophobic surface. This issue can be reduced by dispensing low-silicone-content or hydrogel contact lenses; however, such lenses also impede oxygen transmission, increasing the chance for neovascularization, endothelial dysfunction or edema. Other solutions include switching lid hygiene regimens and the most common method, treating the lens with plasma. However, nonwetting continues to plague both patient and practitioner, proving these options are insufficient.

This article explores the potential of Tangible Hydra-PEG (developed by Tangible Science LLC, Menlo Park, CA, USA) a novel coating technology designed to enhance CL comfort and satisfaction by virtue of its ability to improve lens wettability, lubricity, deposit resistance and tear film breakup.

The Tangible Hydra-PEG Coating

Polyethylene glycol (PEG) has been used in ocular lubricants for decades and is known to improve lens surface wettability, which improves tear breakup time, increases lubricity and reduces protein and lipid deposition.[3,4] Tangible Hydra-PEG is a 90% water PEG-based polymer mixture that is covalently (permanently) bonded to the surface of the contact lens, effectively creating a wetting surface on the underlying lens material and separating it from the ocular surface and tear film. The optically-clear coating encapsulates the core contact lens with a mucin-like hydrophilic shell. Tangible Hydra-PEG can be applied to all contact lens materials including hydrogel, silicone hydrogel, gas permeable (GP) materials and hybrid lenses.

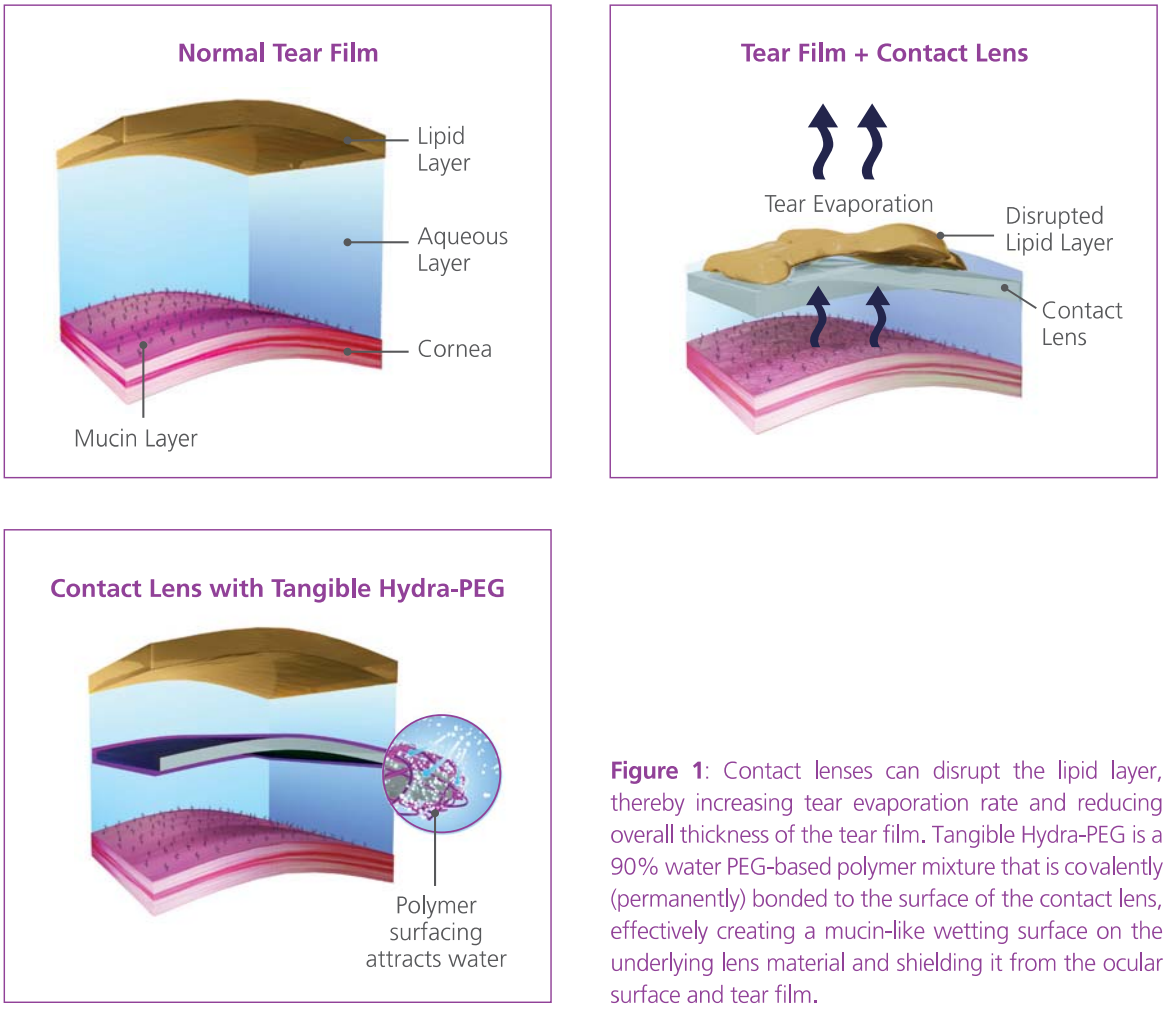


Figure 1: Contact lenses can disrupt the lipid layer, thereby increasing tear evaporation rate and reducing overall thickness of the tear film. Tangible Hydra-PEG is a 90% water PEG-based polymer mixture that is covalently (permanently) bonded to the surface of the contact lens, effectively creating a mucin-like wetting surface on the underlying lens material and shielding it from the ocular surface and tear film.

The Tangible Hydra-PEG Process

The Tangible Hydra-PEG process was designed specifically to integrate seamlessly into existing contact lens manufacturing processes. Once a lens has been lathe-cut or molded it then goes through the Tangible Hydra-PEG application process. The first part of the process is to activate the lens surface so that it will covalently bond to the Hydra-PEG polymers. For cast molded lenses, this is achieved by adding a functional chemical activator to the lens monomer mix prior to molding. For lathe-cut lenses, this is achieved by exposing the lenses to a short plasma cycle which cleans and activates the lens surface.

During application, the first step of lens surface preparation is either the addition of a functional activator to the monomer mix or a short plasma surface treatment. Once active, the lenses are then soaked in the Tangible Hydra-PEG polymers during the extraction/hydration step, or the Tangible Hydra-PEG polymers are added to the blister pack during the autoclave process. In either case, once the active lens is placed in the Tangible Hydra-PEG polymers, the Tangible Hydra-PEG permanently bonds to the lens surface. The resulting lens is completely encapsulated with the Hydra-PEG polymers resulting in a surface with optimal wettability, lubricity, tear film stability and resistance to deposits.

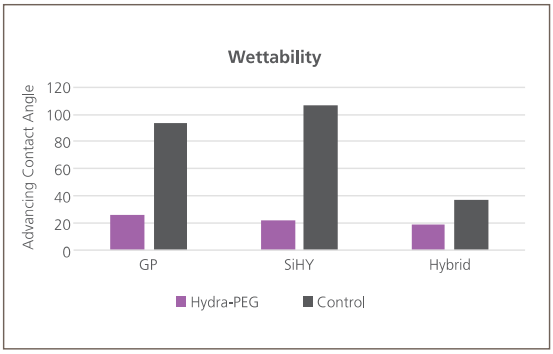
Comparison with Plasma Lens Treatment

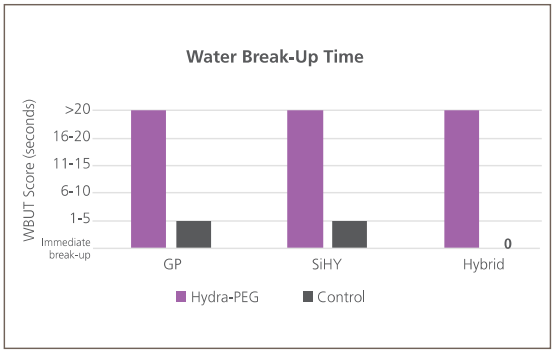
Plasma—ionized gas with an approximately equal number of positively and negatively charged particles—is neither completely a gas nor a liquid but has properties similar to both. It is created by forming a vacuum in a reaction chamber, then refilling with a low-pressure gas, such as oxygen. During contact lens treatment, high-energy oxygen plasma bombards the lens surface, transferring energy from the plasma to it. This also cleans and oxidizes the surface by creating reactive species (i.e., free radicals, ions, electrons, short-wavelength photons and unstable oxygen species) that react with water, altering the lens surface to a hydrophilic state.

Tangible Hydra-PEG is unique from plasma in that a distinct bulk layer of polymers encapsulates the lens, while plasma alone only modifies the existing lens material. This effect only occurs to depths of several hundred angstroms to 10μm without any change to the bulk properties of the lens material. In contrast to plasma treatment alone, the Tangible Hydra-PEG coating is designed to be permanent; several studies are underway to quantify the longevity of the coating on various lens materials.

In-Vitro Demonstration of Improved Wettability, Lubricity, and Water Breakup

In benchtop tests, Tangible Hydra-PEG was shown to improve wettability, surface water retention, and lubricity on various lens materials.[5] Wettability was quantified by measuring the advancing contact angle using the captive bubble technique. GP, silicone hydrogel, and hybrid lenses treated with Tangible Hydra-PEG all demonstrated improved wettability compared to untreated controls. Tangible Hydra-PEG increased the water break-up time on GP lenses from less than five seconds to greater than 20 seconds. Lubricity was assessed on a scale of "1" to "6", with "6" being the most lubricious. Tangible Hydra-PEG improved the lubricity of all lens types, with the most pronounced improvements observed on GP lenses. Manual rubbing was used to simulate contact lens wear and cleaning to assess the durability of the Tangible Hydra-PEG treatment.





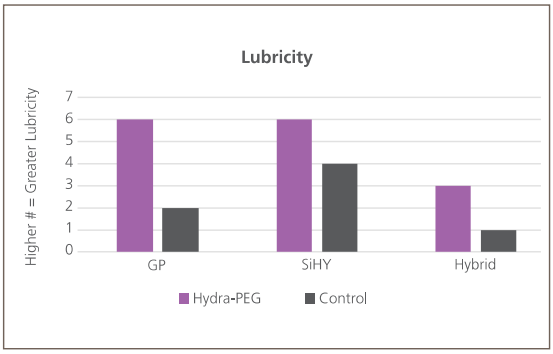


Figure 2: In benchtop tests, GP, silicone hydrogel, and hybrid lenses coated with Tangible Hydra-PEG exhibited improved wettability, lubricity, and water break-up time compared to uncoated lenses

Clinical Experience To-Date

At the 2015 Global Specialty Lens Symposium, the Pacific University College of Optometry presented data describing initial experience with Tangible Hydra-PEG technology.[6] Twenty-four habitual soft lens wearers were selected for their self-reported symptoms of lens dryness and discomfort. The subjects were fitted with two different pairs of the same silicone hydrogel lens (ACUVUE® OASYS®, Johnson & Johnson Vision Care, Inc.) One pair was treated with Tangible Hydra-PEG; while the other was left untreated. The lenses were worn daily for seven consecutive days and disinfected at night with a hydrogen peroxide system. The subjects rated their lens wearing comfort (1 = poor to 10 = excellent) at three time intervals: after morning lens application, midday, and at the end of the day. In this study, the Tangible Hydra-PEG treated lenses showed, on average, a 2.8 differential in end-of-day comfort **(Figure 3)**.

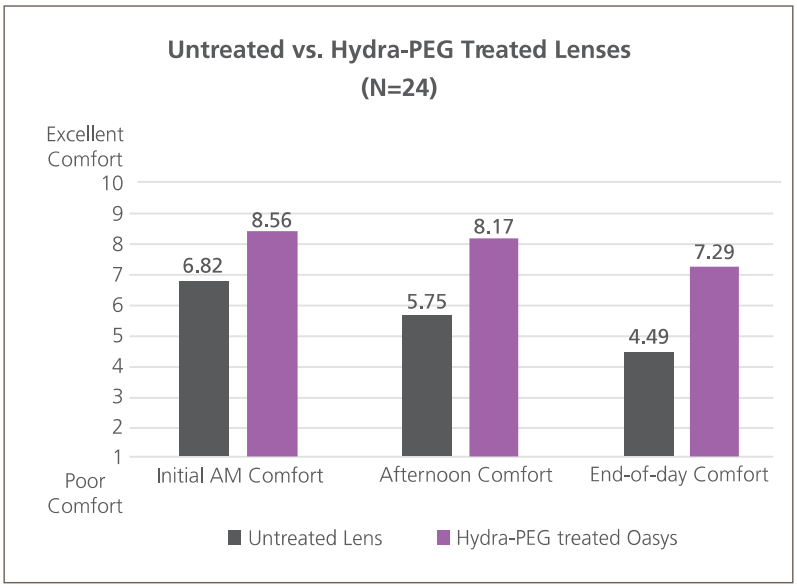


Figure 3: In a recent study, 24 patients fitted with silicone hydrogel lenses treated with Tangible Hydra-PEG indicated clinically significant improvement in comfort compared to the same lenses without the coating.

In the same study, a topographer was used to visualize the tear breakup over the surface of the coated and uncoated lenses following eight hours of lens wear at zero, five, and ten 10 seconds after a blink. The images illustrate that lenses coated with Tangible Hydra-PEG exhibited a more stable tear film compared to the uncoated lenses **(Figure 4)**.

Clinical Experience to Date (Continued)

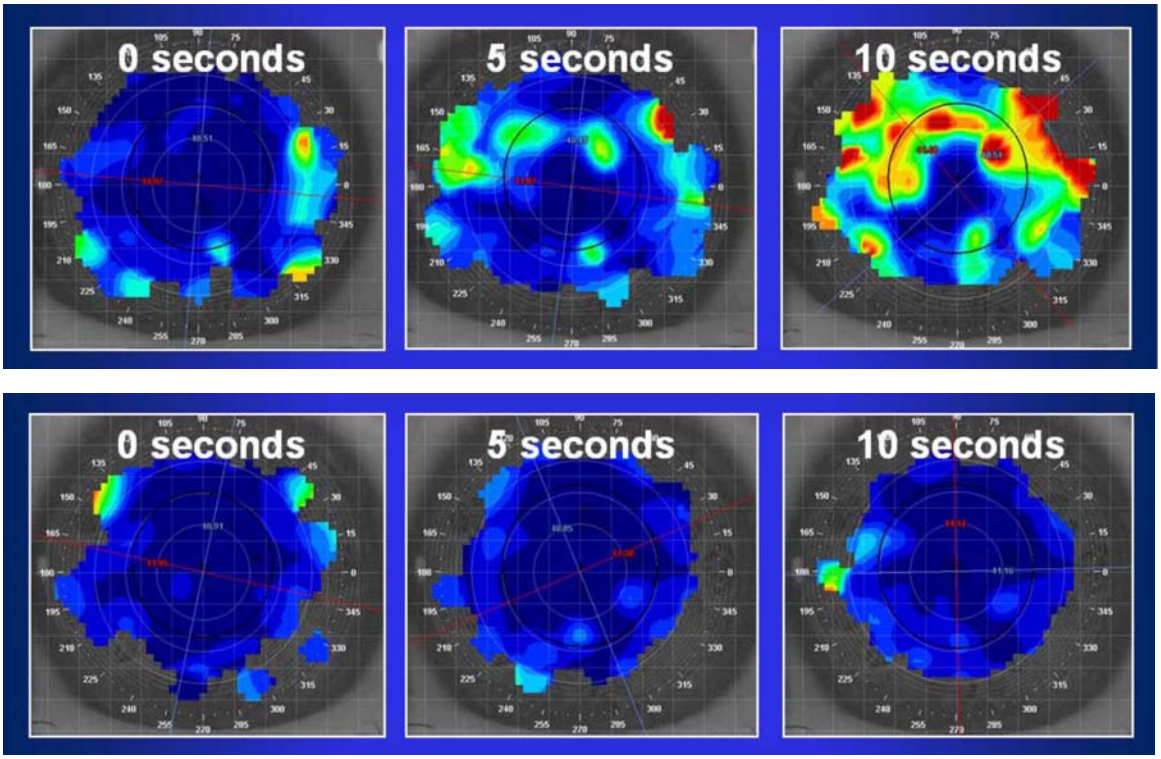


Figure 4: The top images show the surface quality of an untreated silicone hydrogel lens following eight hours of lens wear at 0, 5, and 10 seconds after a blink. The images below show the same patient with a Hydra-PEG treated lens following eight hours of lens wear.

At the 2016 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO), we presented some of our initial experience with the Tangible Hydra-PEG coating at the University of Iowa.[7] Three patients, who were well adapted GP lens wearers with a history of minimal to heavy lens deposits were dispensed a Tangible Hydra-PEG treated lens in one eye and a plasma treatment lens in the other eye, using their habitual lens material. They wore the lenses for four consecutive weeks.

While there was no change in visual acuity between the habitual lens, baseline and four week visits, the subjects with moderate and heavy deposits reported clearer vision and less haze in the eye fitted with the Tangible Hydra-PEG coated lens. (The subject with minimal deposits had no preference between eyes.) The moderate and heavy depositors had visible deposits on both lenses **(Figure 5)**, with visibly fewer deposits on the Tangible Hydra-PEG coated lens at the end of four weeks. (There was no difference in visible deposits between the eyes of the minimal depositing patient.) There was an increase in subjective comfort and an overall lens preference favoring the lenses coated with Tangible Hydra-PEG.

Clinical Experience to Date (Continued)

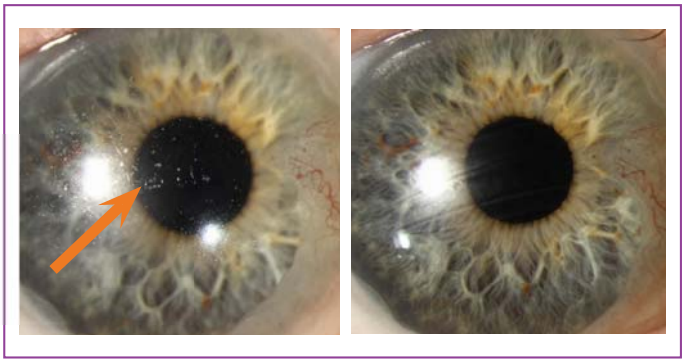


Figure 5: At four weeks, greater deposits are evident on a plasma-treated GP lens (left) compared to the same lens type treated with Tangible Hydra-PEG (right) for moderate and heavy depositor subjects.

Ongoing Clinical Studies

The University of Missouri is currently conducting a study comparing the benchtop and clinical performance of untreated GP lenses, GP lenses with plasma treatment and GP lenses with Tangible Hydra-PEG treatment across several cleaning cycles, including multi-purpose and peroxide systems. Endpoints will include benchtop evaluation of wettability, lubricity and water break-up. Additionally, 10 patients will undergo a single-blinded bilateral study to compare different lenses for visual acuity and on-eye comfort.

Another study is currently underway at the University of Houston comparing visual acuity, subjective lens preference, subjective end of day comfort, midday fogging via optical coherence tomography, tear film quality score (tear break up time) via corneal topography, and lens debris in patients each wearing Tangible Hydra-PEG coated and non-coated scleral lenses.

Clinical Implementation

Tangible Hydra-PEG may be applied to any contact lens and worn by any patient. There are no contraindications for use of Tangible Hydra-PEG. The technology should be of most benefit to patients who currently experience ocular dryness or discomfort associated with contact lens wear, moderate or heavy depositors, and scleral lens wearers who experience fogging.[8,9,10] Tangible Hydra-PEG was designed with the practitioner in mind and requires no changes to the fitting regime. Practitioners and patients should be aware that the Tangible Hydra-PEG surface will result in a more "slippery" lens and may require a brief adjustment period for handling, inserting and removing the lens. Patients familiar with handling contact lenses should experience no difficulty adjusting to their new lenses.

Lenses with Tangible Hydra-PEG should be cleaned and disinfected on a daily basis. Tangible Hydra-PEG is compatible with most multi-purpose and peroxide-based cleaning and disinfecting solutions. Tangible Science recommends using Menicon Unique pH® (Menicon Co. Ltd.) for GP lenses of the CLEAR CARE® family of solutions (Alcon Laboratories, Inc). Alcohol-based or abrasive solutions and tap water should be avoided, as they may damage the surface and reduce the benefits of the coating.

Ordering lenses with Tangible Hydra-PEG is simple and easy. Practitioners contact a custom lens manufacturer certified to apply the Tangible Hydra-PEG coating. The practitioner orders the lenses with the prescription and design desired for their patient, requesting the Tangible Hydra-PEG coating upgrade for the order. The lenses are shipped to the practitioner in the appropriate solution to keep the polymer coating hydrated and the lenses disinfected.

Conclusion

Tangible Hydra-PEG is a promising new coating technology that should serve to significantly improve the custom contact lens experience for both patients and physicians. Benchtop tests and early clinical studies point to improvements in wettability, lubricity, deposit resistance, tear film quality, subjective comfort and overall patient preference. Tangible Hydra-PEG is designed to make the custom contact lens experience less of a hassle for patients by freeing them from rewetting drops and reducing deposits that require mid-day cleanings. The improved lens wettability has the potential to reduce lens return rates and can allow the physician to focus on fitting new patients instead of repeatedly re-fitting the same ones. This much-needed innovation warrants evaluation by all eye-care professionals seeking to improve the satisfaction of their custom lens patients and, by extension, satisfaction with their own contact lens practice.

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