Fusion 1-day: Improving long-term CL comfort

Nick Atkins reviews a new daily disposable contact lens with a unique approach to addressing contact lens induced dry eye

Dry eye is one of the most common conditions we face in clinical practice. Estimates suggest that clinical dry eye affects as many as 21.6 per cent of the patient population between 43 to 86 years of age.[1] Dry eye symptoms are far more prevalent among contact lens wearers than the rest of the population – reported to affect more than 50 per cent[2] of the contact lens wearing population. Furthermore, studies have shown that the number one reason for discontinuation of contact lens wear is 'poor comfort' which has been reported by 72 per cent of patients as a reason for their discontinuation,[3] with dryness as the most common symptom.[4,5] When the dryness sensations are associated purely with the wearing of contact lenses (the patient normally being asymptomatic), this is termed 'contact lens induced dry eye' or CLIDE.

This article reviews a new daily disposable contact lens, the Fusion 1-day now available in the UK from No7 Contact Lenses, which takes a unique approach to tackling the problem of CLIDE.

The tear film in CL wear

For the patient who wishes to wear contact lenses, dry eye can be a major hindrance and in some cases significant enough to be considered a contraindication for prescribing contact lenses. One study showed that the primary reason for such a high percentage of contact lens-wearing patients experiencing dry eye, might be because there is an increase in evaporation over the contact lenses themselves.[6]

Figure 1 Fusion 1-day contact lens

Contact lens wear changes the structure of the pre-corneal tear film, creating two layers known as the pre-lens tear film (PLTF) and the post-lens tear film (PoLTF). The PLTF is much thinner than a normal pre-corneal tear film and there will only be a thin lipid layer on top of hydrogel lenses.[7,8] During contact lens wear the PLTF needs to act like the pre-corneal film, to protect the lens surface from deposition and drying.[9] The PoLTF acts like a cushion to help lubricate the rear contact lens surface. The thickness of the PoLTF has been reported as being between 4.5 microns using OCT10 and 12-microns using pachymetry11 and decreases rapidly to as little as 1 micron after 30mins of eye closure.[12] Some circulation of the tears is essential to prevent the accumulation of tear film debris and metabolic by-products. However, compared to the PLTF there is little research evaluating the PoLTF and its influence upon lens comfort or how successful different lens design and material combinations are at PoLTF exchange.

In recent years there have been many advancements in the technology of contact lens materials, particularly combining wetting and lubricating agents designed to improve their comfort and delaying the onset of CLIDE. Table 1 shows the relative performance of a range of active ingredients for a number of physical characteristics. Intuitively we might expect that those solutions or contact lens materials containing aqueous binding molecules to benefit the PLTF, while those containing molecules with claimed muco-mimetic properties, might also support the PoTLF.

Introducing Fusion 1-day

Fusion 1-day (Figure 1) contact lenses are made from a unique, patented material technology based upon the synergistic actions of tamarind seed polysaccharide and high molecular weight hyaluronic acid obtained by biotechnological synthesis. The Fusion 1-day material is composed of two polymers and can be seen in Figure 2; the synthesised polymer (Filcon 1B), constitutes the solid structure of the lens while the watery part is enriched with the natural bi-polymer of hyaluronic acid and tamarind seed polysaccharide as well as other minerals. The HA-TSP bi-polymer is claimed to support longer lens hydration as well as the continuous lubrication and stabilisation of the pre-corneal tear film, thus improving subjective comfort while wearing the lens. Table 2 shows the parameters of Fusion 1-day.

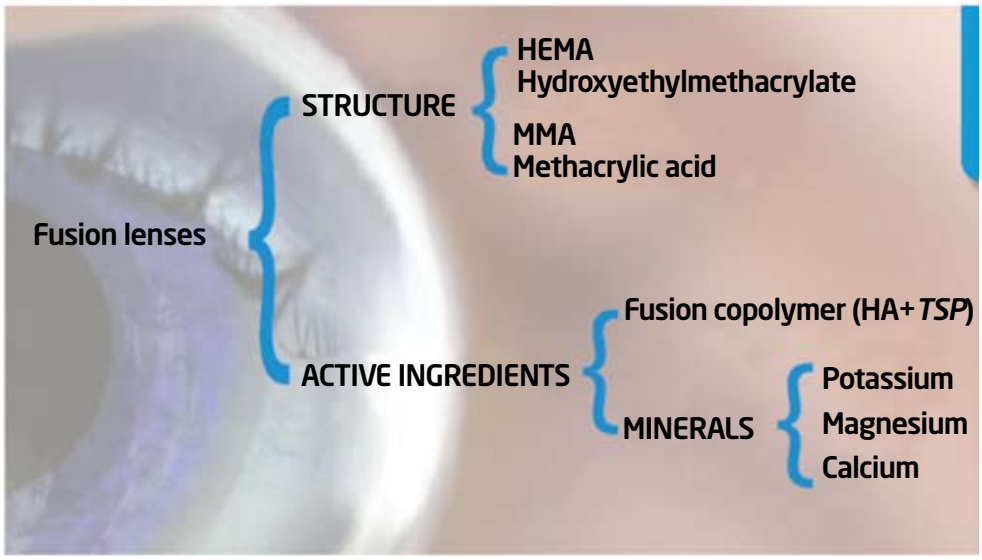

Figure 2 Fusion 1-day material is composed of two polymers

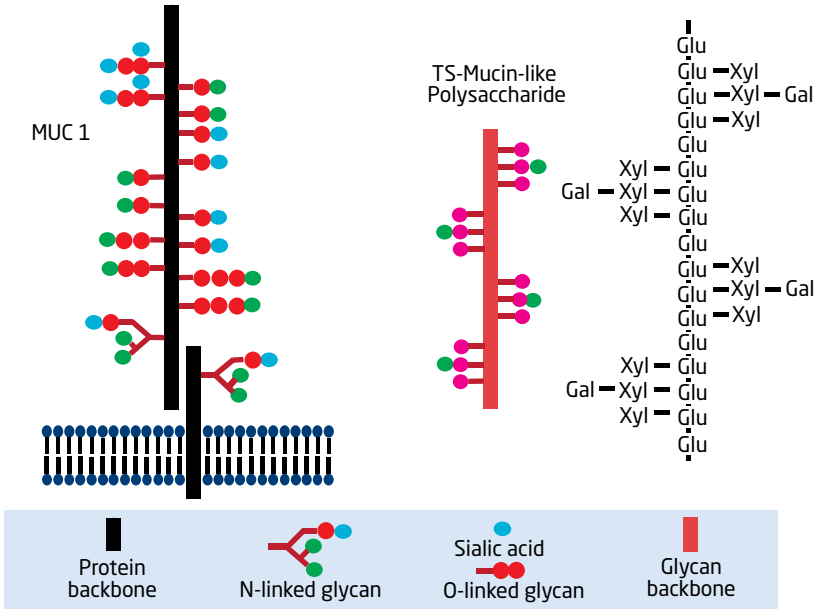

Figure 3 The branched chain structure of TSP

TABLE 1

Relative performance of tear substitutes

	Natural		Semi-synthetic		Synthetic	
	HA	TSP	HPMC	CMC	PVA	PVP
Hydration	****	****	**	****	****	*
Lubrication	****	****	**	***	***	***
Muco-adhesive	****	****	*	****	*	*
Muco-mimetic	****	****	*	*	*	*
Viscoelastic	****	*****	*	***	*	*
Wound healing	***	***	*	**	*	*

Ref: Current medical research and opinion (2006)

TABLE 2

Specifications

Material	Filcon IV Incorporating a bi-polymer of HA-TSP
Water content	60%
Refractive Index	1.42
Dk/t at 35°C	40 (centre of -3.00)
Colour	Light blue
UV protection	Yes
Base curve	8.60mm
Front curve	Aspheric
Diameter	14.10mm
Centre thickness	0.08mm (-3.00)
Power range	-0.50 to -6.00 (0.25 steps) -6.50 to -12.00 (0.50 steps) +0.50 to +4.00 (0.25 steps) +4.50 to +7.00 (0.50 steps)
Replacement	Daily
Pack size	30 lenses

Hyaluronic acid (HA)

HA is a naturally occurring linear-structured polysaccharide that is found in the aqueous and vitreous humour, the synovial fluid of joints, in heart valves and the skin. It is a viscoelastic, biological polymer, which is pharmacologically inert, making it non-toxic. In ophthalmic surgery, HA is used to protect the cornea from cell loss by forming a protective fluid layer to maintain size and shape of the anterior chamber and to support positioning of the ocular tissues. Cataract surgery is the main field of application of viscoelastic compounds such as HA, where it replaces intraocular fluid in the anterior eye. HA was once produced by extraction from rooster combs, but with the possible risk of allergic reactions to avian protein, it is now biotechnologically produced by fermentation using streptococcal cultures.[13]

HA has been shown to increase tear break-up time.[14,15] The all-important sensations of 'burning' and 'grittiness' commonly reported in dry eye are significantly relieved when HA is used in place of hypromellose.[16] HA has previously been incorporated into a patented contact lens called the Safegel 1-Day, with the release of HA throughout the day, improving trialists' mean maximum wearing time from 11 to 13 hours.[17]

Tamarind seed polysaccharide (TSP)

TSP is a natural, water-soluble, branched-chain polysaccharide. Polysaccharide-based biomaterials are an emerging class in several biomedical fields such as tissue regeneration, particularly for cartilage, drug delivery devices and gel entrapment systems for the immobilsation of cells. Important properties of polysaccharides include controllable biological activity, biodegradability, and their ability to form hydrogels. Most of the polysaccharides used are derived from natural sources and TSP is sourced from the nut of the Tamarind tree widely found across Asia. TSP has been found to have numerous properties that make it ideal for use as a tear film supplement. Figure 3 shows the branched chain structure of TSP that consists of a cellulose-like backbone (repeating glucose units) with xylose and galactoxylose substituents, providing a branched chain structure, which is similar to that of natural mucins,

in particular MUC1. Consequently, TSP demonstrates muco-mimetic and muco-adhesive properties, which, as has been shown of HA,[18] may help increase tear film stability by mimicking the epithelial glycocalyx in aqueous deficient dry eyes.[19]

Rolando[20] has reported that TSP 0.5 per cent and 1 per cent offer at least equivalent relief to HA 0.2 per cent for dry eye syndrome. TSP demonstrated optimal tolerability and suitability for frequent use in the therapy of dry eye. TSP 1 per cent produced promising results in terms of improvements in certain patient symptoms and suggests benefits of the TSP formulation.

Synergistic action of HA and TSP

Relative to HA, TSP is new in its use in ophthalmology. Researchers evaluating the development of formulations containing both HA and TSP found a synergistic effect with the resulting bi-polymer demonstrating a higher capacity to encompass water when compared to each individual polymer. Results from NMR spectroscopic investigations have shown that this synergistic effect involves HA acetyl groups as well as TSP glucose (Glc) and galactose (Gal) units (Figure 4).[21] This characteristic is crucial to its properties of bio-adhesion, biocompatibility and moisturising capacity.

Like its individual components, the bi-polymer displays rheological, non-Newtonian behaviour. Figure 5 shows how as a force is applied to a non-Newtonian liquid, viscosity decreases. In this case the bi-polymer mimics the natural tear film in becoming more elastic during the blink, increasing spreading and improving aqueous lubrication of the anterior ocular surface epithelial tissues.

The HA-TSP bi-polymer is currently available for the management of dry eye in a drop format.[22] Following two-month treatment with the newly formulated copolymer in this format (Xiloial Farmigea, Pisa) in symptomatic disposable contact lens wearers, the drop showed high tolerability, reduction in subjective symptoms, reduction in ocular surface epithelial damage and an increase in tear break-up time value.[23] Another after-market, in-practice study also showed a mean improvement in ocular comfort scores with the use of the same drop with general dry eye sufferers. Here there was a mean improvement in ocular comfort score of 2.8 with the mean comfort score at dispensing being 5.4, improving to 8.2 (out of 10) following use of the drop.

The use of HA-TSP with contact lenses was evaluated in a UK in-practice study,[24] where merit was shown for getting patients to put the bi-polymer containing drop into the 'bowl' of the inside surface of a soft contact lens, prior to applying the lens to the eye. This study showed that the prescriptive daily use of this solution formulation on the inside of the lens could lengthen both the comfortable, as well as the actual wearing time. There was a mean improvement in contact lens comfort score (CLCS) of 1.2, with the mean comfort score at dispensing being 6.9, improving to 8.1 (out of 10) at follow-up.

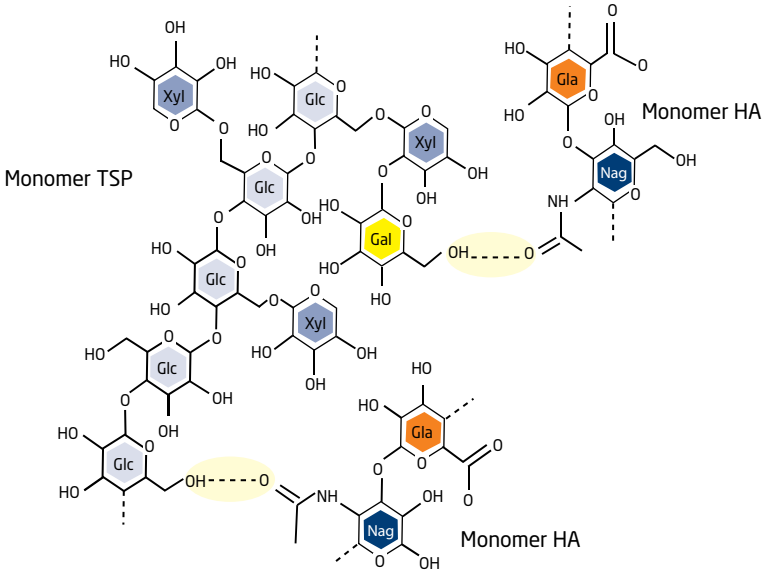

Figure 4 Synergistic bi-polymerisation of TSP and HA monomers

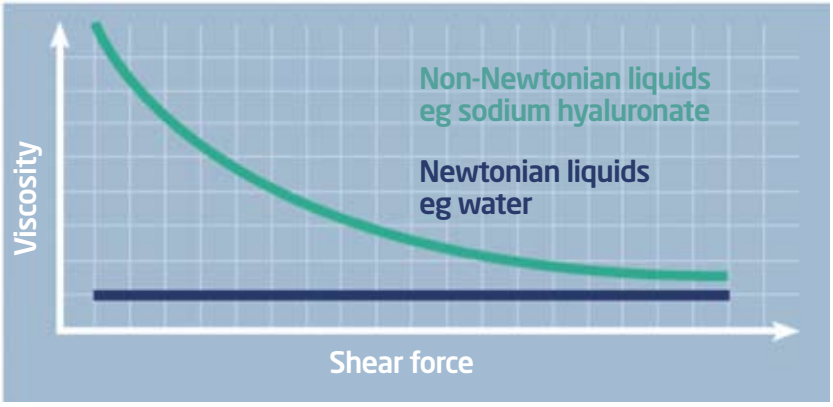

Figure 5 As a force is applied to a non-Newtonian liquid, viscosity decreases

HA-TSP hydrogel combination

The big challenge to researchers was to somehow incorporate the HA-TSP bi-polymer within the soft lens substance to allow its release with wear. This is possible due to the bi-polymer's property of thermo-reversibility. Heating the solution to over 100°C results in the polymer chains becoming disorganised and passing into a more liquid state. In this state it is possible to introduce the polymer evenly within the soft gel matrix and, when it is subsequently cooled, it recovers its organised state within the hydrogel material. Another temperature increase, for example to the 'on eye' temperature of around 36°C, results in some increase in fluidity, so allowing a gradual release of the HA-TSP bi-polymer from the lens into the tears.

Silicone hydrogel vs hydrogel

While the debate in recent years has been about the importance of higher Dk materials in successful contact lens wear – a high Dk is of no benefit if the patient is unable to tolerate the lens for a reasonable wearing time. There is no doubt that SiH lenses have improved the clinical signs associated with hypoxia, but they have also been

associated with lens surface issues.[25] It is interesting to reflect that while some patients need the greater oxygen transmissibility of SiH lenses in daily wear, the whole development of this technology was actually driven in an attempt to find the contact lens 'holy grail' of achieving oxygen levels for safe continuous wear and thus the nirvana of hassle-free, semi-permanent vision correction. It could be argued then that for the many daily wearers the compromises in performance – such as lipid deposition and its influence on the stability of the tear film – created by lenses containing hydrophobic silicone monomers, are unnecessary and undesirable.

Manufacturers heralded the abolition of hypoxic response in patients as the breakthrough to finally crack the static contact lens market. This was supposed to be the final frontier, that once conquered would create healthy, comfortable, happy wearers who would have no need to drop-out a few years down the line. This objective has clearly not been achieved, strongly suggesting that SiH lenses are not the panacea many hoped they'd be. In fact, contact lens practitioners seem to now be starting to question whether SiH should be the automatic first choice for their patients. This is particularly true in the daily disposable category, with reports of poor comfort and lid changes with SiH materials, as highlighted at a recent round table,[26] resulting in dropout or a return to hydrogel materials.

In recent years there have been great advancements in the technology of dry eye and contact lens rewetting drops, designed to improve contact lens comfort and reduce CLIDE. It is possible that the introduction of these new molecules – with better aqueous binding properties and enhanced biomimesis, including muco-mimetic properties, into contact lenses – could assist in prolonging contact lens comfort and delaying the onset of CLIDE. Fusion 1-day's slow release of the highly hydrophilic and bio-mimetic HA-TSP copolymer has the potential to be especially helpful for patients with CLIDE, as well as first-time contact lens wearers.

Conclusion

The debate in recent years has been about the importance of higher Dk materials in successful contact lens wear, but a high Dk is of no benefit if the patient is unable to tolerate the lens for a reasonable wearing time. SiH lenses may have improved the oxygen performance of soft contact lenses, but the trade off can be stiffer lenses with less lubricious, lipid attracting surfaces and for some patients factors other than high Dk will have a greater influence on lens tolerability. A return to a more traditional approach, considering the individual requirements of the patient and in particular selecting the right material for their specific eyes and lifestyle requirements, will ultimately lead to happier patients and market growth. As such the introduction of a unique new lens technology, such as Fusion 1-day, with its patented material, containing the bi-polymer of hyaluronic acid and tamarind seed polysaccharide, is a welcome addition the contact lens fitter's armoury in the ongoing battle to maximise comfortable wearing times and reduce the drop-out of our contact lens patients.

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