Biocompatibility, SiH lenses and the impact of hydration on comfort

Anne Austin recently facilitated a series of online interviews with **Professors Nathan Efron**, **Desmond Fonn** and **James Wolffsohn** to examine conventional and current thinking on water content and lens surface dynamics and their impact on silicone hydrogel biocompatibility and comfort. Here the highlights of the interviews are presented as a 'virtual' roundtable discussion

Silicone hydrogel (SiH) contact lenses have been available for over a decade. During that time, these highly innovative materials and designs have continually improved and now represent a major percentage of fits within the global contact lens market.[1] Their high oxygen transmissibility has drastically reduced the incidence of hypoxia-related conditions such as corneal edema, limbal hyperaemia, and corneal vascularisation.[2,3] However, there remain significant challenges in the quest for the ideal contact lens.

The silicone material used in SiH contact lenses is inherently more hydrophobic than the non-silicone hydrogel materials. SiH lens manufacturers must find ways to overcome lens surface hydrophobicity since it can create issues in terms of lens wettability and surface deposition. Achieving ideal lens water content presents yet another challenge since increasing water content in a silicone hydrogel lens can reduce oxygen transmissibility. This is because increasing water content results in decreased silicone content in the lens and silicone is a better transmitter of oxygen than water.

To address these challenges, SiH manufacturers have employed various techniques to improve wettability and comfort and reduce surface deposits. Plasma surface treatments can be highly effective in improving wetting properties and deposit resistance. Wetting agents added to the lens matrix and/or packaging solutions have helped to varying degrees. Yet manufacturers are still seeking the ultimate goal – for wearers to feel like they're wearing no lens at all, even after hours of wear.

The role of lens hydration

● What is the conventional thinking about how high water and low water content HEMA contact lenses affect dehydration and lens wearing comfort?

James Wolffsohn: Conventional thinking on high water content (with HEMA materials) is that yes, you get more oxygen but you also get more contact lens-related dryness and lens desiccation problems.

Nathan Efron: I've done a lot of research on dehydration and the impact of dehydration on comfort, the environmental impact on dehydration – whether lenses dehydrate more in humid versus dry environments – and so on. We find that with HEMA lenses the higher the water content of the lens, the more propensity it has to dehydrate.[4]

If you're working from the assumption that dehydration of a lens is a 'bad' thing, vis-à-vis comfort – if that is true – and it's debatable, then a lower water content lens is going to be more comfortable than a higher water content lens, because it's got less water to lose. That's the conventional thinking, perhaps.

Desmond Fonn: We published a few papers on lens dehydration years ago, studying medium and low water lenses, and never found it to correlate with dryness symptoms – which as you know is the plague of contact lens wear.[5,6] As the lens dehydrates during the day, most of that dehydration takes place in the first hour or two of lens wear. Yet the dryness symptoms and discomfort that patients experience start slowly and they gradually increase as the hours of wear increase.[7]

● Has the advent of silicone hydrogel lenses changed the water content/ dehydration story?

Efron: Oh, absolutely it has, and Phil Morgan and I published a paper on this. I think it's the only paper showing that dehydration of silicone hydrogel lenses is a lot lower than hydrogels. Suffice it to say whatever dehydration does occur, it's very small – less than a typical

Professor Nathan Efron

hydrogel lens of 58 per cent water content.[8,9,10] Paradoxically, dehydration in a silicone hydrogel lens is a good thing in terms of oxygen performance, because there'll be less water and more silicone proportionately, so essentially if a SiH lens dehydrates, it will theoretically have a higher oxygen performance than a non-dehydrated SiH lens.

Fonn: Most SiH lenses have lower water content than hydrogels yet SiH lenses still create the same kind of response by patients, namely decreased comfort later in the day.[11] In those who are symptomatic from lens wear, generally you'll find a fairly substantial change from morning to evening, the same kind of dryness and decreasing comfort profiles as we published years ago with hydrogel lenses. However, indirect comparisons suggest that the effect may be less with SiH lenses and that might be because they are less prone to dehydration.[5] Whether or not the water loss is from bulk or from the surface is still not established.

Efron: In terms of comfort, no one has actually studied whether SiH lens dehydration leads to discomfort – no one really knows the answer to that.

Wolffsohn: I don't think that silicone is making a major effect upon comfort at the moment. Which is not to say that it can't with the right combinations. Hydrogels of course are far more developed in terms of other comfort technology – with silicone I don't think we're quite there yet.

Lens/eye interface

● What are the most important aspects about the interface between the cornea, the tear film, and the contact lens?

Efron: All three components need to be healthy and in good working order. A healthy cornea, a good healthy tear film, and a good biocompatible lens surface are important. We could talk at length about all those things but maybe it's best to focus on the lens properties.

Anne Austin: Once the lens is introduced into that ecosystem, there's a different dynamic – so from the perspective of this discussion, what has the biggest impact on the biocompatibility of the lens?

Efron: One might well be the intrinsic water content, the actual water content of the lens. Theoretically it might be that a higher water content lens is going to be more comfortable than a lower water content lens. Also, the lubricity of the surface is going to be important, how slippery or smooth the surface is. It does appear that lenses with more lubricious surfaces are going to be more comfortable. Also related is the concept of the wettability of the lens – a more wettable surface is theoretically going to be more comfortable. However, current thinking is that wettability measurement is technique-dependent and correct interpretation of results can be extremely difficult.

The role of the tear film

● What aspects of the post- and pre-lens tear film have an important impact on contact lens comfort and overall biocompatibility?

Fonn: I think this is one of the most important questions that has gone unanswered – and I don't think it's a single answer. There's a lot of speculation whether it's the friction between the tarsal conjunctiva and lens surface or the loss of lubricity on the anterior surface and water loss of lenses, or whether the ocular reaction to lens wear is a type of low-grade inflammatory response. Korb and others have spoken about the palpebral

Professor James Wolffsohn

Professor Desmond Fonn

tissue reacting with the lens – so there are many different reasons that could potentially be the cause.

What we do know is that if you measure tear break-up time on the corneal surface, it averages 15 seconds and when you measure tear break-up time with a contact lens on the eye it's significantly reduced.[12] Therefore, the more fluid there is on the anterior lens surface, logically the more comfortable the lens would be, because you're creating more of a cushion and you would imagine there would be less friction.

To date, no one has really addressed what happens with respect to dehydration of the posterior lens surface and the fact that the post-lens tear film thins over time (daytime wear).

Wolffsohn: When a contact lens is on the eye, there are two major issues that I think people may forget. One is the sheer physical size of the contact lens – which is about 10 times the thickness of the tear film. We tend to visualise the tear film with its three layers (which may or may not be correct) and the contact lens sort of slotting in the middle somewhere. But actually you've got to imagine that you've chopped the tear film in half, and separated those halves by an object that is 10 times larger in scale, which is quite amazing when you think about it.

The second issue is we know that things like lipid bind to the contact lens[13,14] and people can think of that as a negative or a positive, but of course it's got to get that lipid from somewhere, and it's taking that lipid away from your tear film. We've been taught that the lipid layer is a really good thing, sitting on top of the tear film, preventing evaporation. So this huge contact lens sitting in the tear film gets coated with that lipid, and that doesn't exactly leave much lipid in terms of the tear film and evaporation in order to maintain a healthy pre-lens tear film. Those are two big issues we need to come to terms with if we're going successfully and comfortably wear a contact lens.

Fonn: As you know, there are different hypotheses about the structure of the tear film and the old traditional one was mucin first, then aqueous, then lipid. That makes sense, because lipid prevents evaporation of the aqueous, and mucin is there so that aqueous can bind to the glycocalyx of the epithelium. Whereas, on the contact lens, the mucin doesn't apparently stick to the lens – but lipid does.[13,14]

If the mucin layer is absent or significantly reduced, you would expect the break-up to decrease as the aqueous can't adhere to the lens.

Wolffsohn: There's a recent paper that shows that patients who get mucin balls – sort of a similar concept – are less likely to get corneal inflammatory events.[15]

Efron: If the pre-lens tear film more closely mimics the pre-corneal tear film, that's got to be a positive thing. The closer we can mimic nature, the closer we're going to be to a natural scenario – and that's potentially a very good thing.

The 'comfort zone'

● What are the most important factors affecting contact lens comfort?

Fonn: I don't think anyone has the answer – we're all of the opinion that building a thick tear layer both on the front and back surface of a lens is the answer. But how to get the eye to produce more fluid while wearing a lens is difficult. How do you 'trick' the eye into assuming that the lens is wetter than it is – that's the key.

Efron: It appears from some work from Eric Papas and other colleagues in

Sydney that the cornea and conjunctival sensitivity thresholds are similar,[16] indicating both the inside of the upper eyelid over the front lens surface and the corneal surface under the lens surface are critical to contact lens comfort. So the conjunctival surface is as important as the corneal surface in terms of lens comfort. And of course the tear film does come into that. But I think it's the anterior lens surface in this regard that is pretty critical.

Wolffsohn: I suppose we need to make the surface of the contact lens like a tear film. The surface quality of the lens makes a huge difference. People's eyes are generally less comfortable in the evenings anyway regardless of whether they are wearing lenses – the lens is just an exacerbating factor. You take any lens and put it in the eye for a long day, there is going to be an element of discomfort.

One thing that I often point out with the latest DEWS model of dry eye is the fact that the contact lens is the only factor to appear on it twice – once in terms of disturbing the normal tear flow but the other of potentially affecting ocular physiology in terms of corneal sensitivity and therefore affects how much tears get onto the ocular surface in the first place.[17] And so having a contact lens that allows a healthy cornea is also very important.

The best of both worlds?

● What if a SiH lens had a gradient of water content across the lens, with lower amounts in the bulk, increasing to high water content at the lens surface?

Efron: My reaction is this would be a very intelligent and ingenious engineering solution to a very considerable problem that we've faced in the contact lens industry. The problem we've faced is trying to make silicone hydrogel lenses more comfortable, which has been difficult because the bulk surface properties of these lenses are not intrinsically wettable or lubricious. Companies in the contact lens field have introduced various engineering solutions, with varying levels of success, to try and make that surface more biocompatible. And of course the primary strategy employed from the very beginning when SiH came on the market was to have some sort of plasma surface coating or plasma treatment – and that was of some assistance. Then there's the use of components in the wetting solution or impregnating lubricious compounds into the surface to make the lens more wettable and theoretically more comfortable.

Wolffsohn: It's a very attractive concept, because that's exactly what you want. You want a material that can have a relatively low percentage of water and other substances that can hold the physical shape of the lens and matrix structure. But you want the front and back surface to be heavily water laden, in which case it can interact with the tears. It's certainly a nice concept.

Fonn: If there's something in the polymer mix that is surface concentrated with water, that's good, assuming that's a primary driver of improving lens comfort. If they've been able to do that, it's nothing short of a miracle. I hope I live long enough to see this done.

Conclusion

Against this background it is worth considering what an ideal contact lens would look like. The properties in the bulk or core of the lens need not be the same as the surface. At the core, high silicone and low water content would deliver high oxygen transmissibility and favourable mechanical properties for lens fit and handling. At the surface, however, low or no silicone and high water content could deliver high wettability and high lubricity. This could help maintain a stable tear film and reduce interaction with ocular tissues, in particular the palpebral conjunctiva.

So far, soft lenses have been manufactured to have one water content throughout the lens, but a water gradient contact lens would deliver the different and desired properties at the core and surface of the lens. Such a lens would herald a new era in contact lens wear, with the potential to improve end of day comfort, patient satisfaction, reduce contact lens drop out and so help practitioners to grow their contact lens business. ●

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