Contact Lens Update
CLINICAL INSIGHTS BASED IN CURRENT RESEARCH

Barriers to drug delivery via contact lenses: A report from the 2012

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As Alex Hui explains in this issue's editorial, contact lenses able to deliver drugs via the eye will revolutionize both optometric and medical care, addressing the limitations of eye drop use–which include loss of liquid during instillation, pulsatile concentration profiles in the tear fluid and over-reliance on patient compliance. Silicone hydrogel materials in particular can be beneficial for long term extended wear due to their high oxygen permeability, allowing devices made from these materials to continually deliver therapeutic agents to the eye. While we can certainly look forward to seeing these products on the market in the near future, delays in their development are complex and far-reaching. With so many potential clinical applications for this new technology, what is taking so long for it the reach the market? Noel Brennan explained, at the 2012 meeting of the British Contact Lens Association:

Regulatory agencies are still determining how best to manage the use of this new technology

In 2002, the United States Federal Drug Administration (FDA) classified these devices as "combination products" (both medical device and pharmaceutical solution). It has been a challenge to determine the best regulatory path for this type of product. And that's just in the United States: Contact lenses designed for drug delivery are classified and administered differently by regulatory agencies worldwide, including the ways in which these devices are evaluated clinically and the vigilance and transparency with which they are monitored.

Industry hasn't committed yet

These "combination products" also pose difficulties for industry, which has traditionally separated contact lens and pharmaceutical research. Manufacturers need to determine if these products are worth the effort that will be required to reorganize research and funding pathways.

Competing health priorities

With growing concern about macular degeneration and macular edema related to diabetes, funding priorities have focused on the development of treatments for the back of the eye—an area not addressed particularly well by contact lens drug delivery.

What happens next? The work that comes after regulatory approval

Once these developmental hurdles have been addressed, a cascade of new challenges will crop up: How will these combination products be dispensed? Who is best suited to teach patients how to use these devices? What is the best way to fit these contact lenses in a way that ensures that the effects of drug release are taken into account?

Miles to go but worth the wait

Current research continues to push the boundaries of our understanding of materials and technology, opening the field of eye care to possibilities that weren't even conceivable decades ago—and yet we still have a long way to go. Brennan outlined a few the questions that remain unanswered:

- Researchers are currently focused on developing a means of achieving "continuous release" of medication into the eye, but are we sure that this what we should be aiming for?
- The eye has a complex system of pathways designed to keep intruders out, which means that any drug must be of a consistency that can easily penetrate those pathways. What consistency would enable a drug to reach the back of the eye?
- How soluble are these drugs within the lens polymers? What are their release kinetics?
- What is the minimum dose required to maximize therapeutic benefits? What would constitute a toxic dose?

Just as Otto Wichterle speculated in his 1963 patent, it appears that soft hydrogel contact lenses are in fact "capable of absorbing considerable amounts of water-soluble medicinal compounds … and to release them to an eye on which [the] hydrogel lens is placed" to treat ophthalmic diseases. In the meantime, research continues to investigate nanotechnology and molecular imprinting in exploring different methods of achieving high-loading and extended release times, both of which have been a challenge in the development of successful drug-delivery devices. The future of this technology is promising, but will unfortunately take some patience.