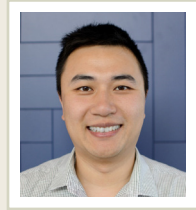


Contact Lens Update

CLINICAL INSIGHTS BASED IN CURRENT RESEARCH

Management of ocular allergy itch with an antihistamine-releasing contact lens

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Pall et al. Management of ocular allergy itch with an antihistamine-releasing contact lens. Cornea. 2019;38(6):713-717.

Introduction

There has been growing interest in contact lens applications beyond simple refractive correction, with their potential to deliver drugs to the eye being a focus of research interest for some time. Understandably, most of this work has been confined to the laboratory or in animal models, however the feature article by Pall et al presents results from two parallel human clinical trials investigating a new ketotifen-loaded contact lens. The studies were relatively large, enrolling a total of 244 participants, who wore control and test lenses at multiple sites, and represent one of the first large scale trials of drug-releasing contact lenses.

Ketotifen is a drug that possesses both antihistamine and mast-cell stabilising properties, and when loaded into a contact lens, is designed to help alleviate the signs and symptoms of allergic conjunctivitis. Those symptoms include itching, which often results in eye-rubbing by the patient and subsequent further exacerbation of symptoms. The authors mention how contact lens wearers may revert to spectacles during allergy season to avoid these issues.

The incorporation of a pharmaceutical agent into the lens itself to reduce these symptoms would thus be worthwhile, improving quality of life for these patients, helping to maintain their contact lens wear and also preventing the need for use of additional pharmaceutical drops during lens wear.

Study Design

The study was a randomized, placebo-controlled design. Participants were required to be regular contact lens wearers with a positive history of allergy symptoms, while also showing positive allergic responses on skin tests. Subjects as young as 8 years of age were eligible to be enrolled, with the youngest actual participant being 12 years of age. To test the efficacy of the drug-releasing lenses, the conjunctival allergen challenge (CAC) was utilized. The CAC involves instillation of a known amount of allergen to produce a reliable and repeated allergic response on the eye. This allows for the effects of treatments such as anti-allergy agents to be quantified when the CAC is repeated. The CAC is a validated method that is utilized by the US Food and Drug Administration to evaluate and approve ophthalmic anti-allergy medications. The study randomized participants into wearing control or treatment lenses in both eyes, or into a third group which had one eye with the test lens and the other with the control. On two separate visits the CAC was administered while wearing their assigned lenses, with the only difference being the time the CAC occurred after lens insertion. One time point was after 15 minutes to establish

the onset of how quickly the drug-lens system was able to suppress itch symptoms, with the other, on a separate visit, was after 12 hours of lens wear to see if the anti-allergy effect was prolonged.

Results

The primary method used to evaluate drug-lens system effectiveness was participant reported itch symptoms on a 0-4 scale. For the CAC, a difference of 1 in itch scores is considered clinically significant, a threshold which was met at all time points after the CAC was administered, when the control and test lenses were compared. Questioning of the patient's itch scores 3, 5 and 7 minutes after allergen exposure demonstrated a clear difference in itch symptoms reported in eyes wearing control versus test lenses, reaching statistical significance and demonstrating test lens efficacy. The paper also reported the onset and longevity of the anti-allergic effect, with differences in itch symptoms post the CAC evident after only 15 minutes of wear, and persisting even after 12 hours of wear. The paper also reported several secondary endpoints, which included gradings of conjunctival, ciliary and episcleral redness. While they reported that there were statistically significant differences in these measurements in the expected direction, they did not reach their defined threshold for clinical relevance.

Clinical Implications

This is the first reported large-scale clinical trial in humans utilizing a drug-releasing contact lens. The ability of the ketotifen-contact lens combination in preventing allergy symptoms in the face of an allergen challenge was evident from the data, demonstrating the feasibility of using a drug-lens system to control symptoms of allergy for a prolonged period. Importantly, the study also did not report any major adverse events when these lenses were used and suggested that these drug releasing lenses were well tolerated when worn. This study has provided evidence of the feasibility of contact lens drug delivery. Importantly it employed the same standard CAC test utilized to test ocular anti-allergy pharmaceuticals, suggesting that it has cleared similar hurdles to therapeutic eye drops being considered for regulatory approval. This study will provide avenues for the field of drug-releasing contact lenses to be furthered. Follow up studies comparing these lenses versus the use of eye drops will allow for demonstration of the differences in drug delivery method on patient signs, symptoms, management and compliance.