Development of an Objective Assessment of Conjunctival Hyperemia Elicited via Conjunctival Allergen Provocation Testing (CAPT) and Environmental Exposure Chamber (EEC) Testing

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ABSTRACT

INTRODUCTION

Conjunctival hyperemia is an important endpoint in ophthalmic clinical research. Most methods for assessing hyperemia are highly subjective and variable across sites. This study describes an imaging method and software system that objectively and automatically quantify conjunctival hyperemia elicited by ocular allergen exposure.

METHODS

A historic list of conjunctival hyperemia was exposed to ragweed allergen via conjunctival allergen provocation testing (CAPT) and environmental exposure chamber (EEC) testing. Itching was assessed on a scale of 0 (none) to 4 (extreme severity). Slit-lamp images of conjunctival were captured. The Imaging System for Ocular Surface (ISOS; Novartis) was developed as a software suite for automatic image analysis of conjunctival blood vessel morphology and redness.

RESULTS

This study describes an imaging method and software system developed to objectively and automatically quantify conjunctival hyperemia elicited by ocular allergen exposure in two different allergen provocation models.

METHODS AND MATERIALS

• Thirteen allergic-atopic subjects
• The study population consisted of 7 male and 6 female subjects, between the ages of 28-55 years.
• Environmental Exposure Chamber (EEC) model: ragweed exposure was airborne and continual (3500 particles/m^3 for 3 hours)
• Conjunctival Allergen Provocation Testing (CAPT): drop allergen was instilled per eye at subject-specific concentrations

• On scales from 0 (none) to 4 (extreme severity) in 0.5 unit increments, subjects assessed itching and clinicians assessed hyperemia.
• Slit-lamp images of conjunctiva were captured.
• Imaging System for Ocular Surface (ISOS; Novartis) was developed as a software suite for automatic image analysis of conjunctival hyperemia.
• ISOS images (detection mode) in Figure 1 show grades of hyperemia. On scales from 0 (none) to 4 (extreme severity), grades 1 through 4 were assigned for hyperemia.

RESULTS

• With CAPT, hyperemia transiently rose with a peak at 30 minutes post-exposure, whereas, in the EEC, hyperemia increased gradually, with a maximum at the last time point (180 minutes) (Figure 1).
• Likewise, the itching curves with CAPT depict a peak at 30 minutes post-exposure; whereas, with EEC, itching increased gradually with the maximum at the last time point (180 minutes) (Figure 2).
• Automated image measurements by ISOS provided a variety of vessel morphological measures that were not evident to a clinical observer.
• Vessel density closely correlated with manual grading captured by clinicians assessed hyperemia.

CONCLUSIONS

• Both models elicited robust allergic responses, each with a unique kinetic profile.
• Automated image measurements by ISOS provided a variety of vessel morphological measures that were not evident to a clinical observer.
• Results from this pilot study indicated that the ISOS imaging method and image analysis suite may objectively measure parameters of conjunctival hyperemia resulting from either CAPT or EEC testing.

REFERENCES

DISCLOSURES

Figure 1. Examples of images analyzed with ISOS, showing vessel detection in hyperemia grades 0 to 4.