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Biomarkers from clinic deployable, multiplex, diagnostic test stratifies ocular surface disease and sub-clinical inflammation in patients.

Abstract

Purpose : The pathology of most ocular conditions is driven by a number of known molecular pathways. However, targeted management requires tear-based, rapid, multiplexed diagnostic systems in the clinical setting. We deployed such a system that measures 8 soluble factors in the cornea clinic to stratify patients based on correlations between clinical indices and biomarker levels

Methods :

We tested tear samples collected from 621 eyes categorised clinically into controls(n=214), dry eye disease(DED; n=107), Keratoconus(KC; n=125) based on slit lamp examination, ocular surface disease index(OSDI) scoring, dry eye evaluation and ocular surface staining. Tear fluid collected using Schirmer's strips were evaluated for soluble factors on a customised multiplex ELISA platform (Bio-M Pathfinder). Another group of clinically healthy subjects were further stratified into – sub-clinical inflammation (SCI) groups 1(n=95) and 2(n=80) based on the level of biomarkers and correlation to clinical indices.

Results :

Patients with DED showed significantly higher OSDI scores, MMP9, IL6, TNFα, IL1β, IL17A and sICAM1 levels with reduced Schirmer's test and TBUT values. KC eyes showed significantly higher MMP9 levels. IL10 and VEGF levels remained unchanged across the conditions. SCI-1 and SCI-2 groups had significantly higher inflammatory markers, significantly reduced Schirmer's and TBUT levels which were not low enough to be clinically classified as DED. Inflammatory biomarker detection was successful in all cases with good reproducibility, high sensitivity and specificity.

Conclusions :

Clinical usage of a rapid, biomarker platform is feasible and useful to identify subjects with sub-clinical inflammation, helping stratify subjects for customised treatments and surgery.

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