Contact Lens Update
CLINICAL INSIGHTS BASED IN CURRENT RESEARCH

Summary: Report of the Clinical Trial Design and Outcomes Subcommittee

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Foulks G, Chalmers R, Keir N, Woods CA, Simpson T, Lippman R, Gleason W, Schaumbert DA, Willcox MDP, Jalbert I. The TFOS International Workshop on Contact Lens Discomfort: Report of the Subcommittee on Clinical Trial Design and Outcomes Investigative Ophthalmology and Vision Science 2013 54:TFOS157-TFOS182.

A review of the peer-reviewed literature found that most clinical trials on the subject of "contact lens discomfort" (31 total) were designed to compare study products and not tailored to investigate the nature and etiology of contact lens discomfort. A further review of the literature was performed to identify potential outcomes measures to describe contact lens discomfort, including staining, hyperemia, tear film changes, vision ocular sensitivity and contact lens surfaces. The objective of the subcommittee on clinical trial design and outcomes was to propose appropriate clinical trial designs and suitable outcome measures for clinical research.

Guidelines for future research

The committee reported that clinical trials should be designed with the following criteria as guidelines:

- **The study should be prospective, randomized and double-masked, and may have other specifications (e.g. contra-lateral or cross-over design) depending on the research question(s).**
- **The study should have a fixed design (e.g. fixed sample size) rather than an adaptive design (e.g. sample size may be modified as study progresses).**
- **Appropriate entry criteria and adequate sample size are crucial.**
- **Although not always possible, masking of investigator and participants is critical and should always be attempted, even if it means assigning different researchers for contact lens assessment and ocular physiology.**
- **The research team should identify and avoid potential sources of bias in study design and data collection.**

Questionnaires

The committee was unable to recommend a specific questionnaire for measuring contact lens discomfort, acknowledging that the CLDEQ-8 is the best option currently available, but not ideal. More work is required to develop distinct questionnaires geared toward different types of contact lenses.

The most suitable outcome measures to describe differences in contact lens discomfort or between groups are

yet to be determined. The ideal outcome measure should be objective, valid, standardized and measurable with minimal bias.

The committee also recommended the use of technology (e.g. smartphones) for recording of data, because it is easy to use and allows for accurate tracking of time and therefore timely collection of data.

Overall, a better understanding of the prevalence and incidence of contact lens discomfort is required before any interventional studies should be performed. The committee recommended conducting basic clinical trials in order to get a better understanding of the outcome measures related to contact lens discomfort and the levels of clinically meaningful change for these measures.

For further details, please refer to The TFOS International Workshop on Contact Lens Discomfort: Report of the Clinical Trial Design and Outcomes Subcommittee.