Special Issue

The TFOS International Workshop on Contact Lens Discomfort: Introduction

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See the tables for the members of the TFOS International Workshop on Contact Lens Discomfort.

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For many years, the contact lens field had focused on safety associated with contact lens wear—and for good reason, given the lack of understanding of the risk factors and etiology of serious complications such as microbial keratitis. However, as knowledge came to light on these complications through the 1980s and 1990s, it allowed for practitioners to become more comfortable managing these complications, along with the introduction of products that helped reduce or prevent some of these problems. It was during this time, beginning in the mid-1980s, that the field itself became cognizant of the issues associated with comfort, or discomfort, during contact lens wear.

Since that time, we have witnessed the field (and industry) shift its attention toward understanding the issue of contact lens discomfort (CLD). Contact lens discomfort is a substantial and burdensome problem experienced frequently by contact lens wearers. It is well established that most contact lens wearers experience CLD, at least occasionally, although many experience CLD to such a severity that they feel compelled to alter their wearing habits. Common, although palliative at best, treatments include the periodic use of rewetting drops, contact lens removal, contact lens refitting (using different lens designs or materials or replacement schedules), and changes in the contact lens care solutions or regimens, in addition to other less commonly used approaches including topical or systemic medications, alterations in diet, and punctal plugs. Ultimately, CLD is the primary factor associated with permanent discontinuation from contact lens wear.

Given the importance of the issue of CLD to both patients and practitioners alike, the time was right to move the field forward by taking steps to bring global consensus to our current understanding of this condition.

Purpose and Objectives

In recognition of this need, and after discussions with international experts (i.e., Jennifer Craig, Gary Foulks, Lyndon Jones, Eric Papas, Jason Nichols, Kelly Nichols, Fiona Stapleton, and Mark Willcox) in January 2012, David Sullivan, president of the Tear Film & Ocular Surface Society (TFOS), recommended to the TFOS governing board that TFOS sponsor a workshop on CLD. The goal would be to build a global consensus concerning CLD using an evidence-based approach. The TFOS governing board agreed. TFOS raised funds from industry to support this initiative, invited individuals to serve on a steering committee, and asked this committee to establish detailed objectives, project a timeline, and select additional workshop participants. TFOS also selected *Investigative Ophthalmology and Visual Science* (*IOVS*) to publish the CLD Workshop report after consultation with members of the governing board and steering committee.

Process

Organization

A steering committee was formed in February 2012 and met in June 2012 in San Diego, California. The membership of the steering committee can be found in Table 1.

The steering committee was charged with several tasks, and the CLD Workshop was modeled after two prior workshops, both sponsored by TFOS: the Dry Eye Workshop (DEWS; provided in the public domain by TFOS at http://www.tearfilm.org/tearfilm-reports-dews-report.php) and the Meibomian Gland Dysfunction (MGD; provided in the public domain by TFOS at http://www.tearfilm.org/tearfilm-reports-mgdreport.

Table 1. TFOS CLD Workshop Steering Committee Organization

Chair: Jason J. Nichols (United States)
Vice chair: Mark Willcox (Australia)
Organizer: David A. Sullivan (United States)
Members: Joseph Ciolino (United States), Jennifer Craig (New Zealand), Gary Foulks (United States), Lyndon Jones (Canada), Kelly K. Nichols (United States), Christine Purslow (United Kingdom), Fiona Stapleton (Australia)
Consultants: Anthony Bron (United Kingdom), Carlos Belmonte (Spain), Murat Dogru (Japan), James F. Saviola (United States), Debra A. Schaumberg (United States)
Operations manager: Rose M. Sullivan (United States)

php) Workshop. The first charge of the steering committee was to develop the CLD Workshop's mission, including a series of critical content areas and aims and objectives for workshop focus. These were developed by the steering committee as they were seen as key areas that would serve as the thematic foundation for the workshop in terms of their importance in characterizing CLD. The mission of the CLD Workshop was as follows:

1. Conduct an evidence-based evaluation of CLD in health and disease;
2. Develop a contemporary understanding of the definition, classification, epidemiology, and neurobiology of CLD;
3. Examine the role of lens materials, design, and care in the etiology of CLD;
4. Assess the biocompatibility of contact lenses with the tear film and ocular surface;
5. Develop appropriate norms of trial design, including outcome measures for CLD;
6. Develop recommendations for the management and therapy of CLD; and
7. Develop recommendations for future innovative research in CLD.

Following the creation of the CLD Workshop's mission, a second charge of the steering committee was the formation of nine specific subcommittees, including their membership. In total, 79 international experts were assembled to develop and achieve consensus on CLD using an evidence-based approach. The steering committee also appointed subcommittee chairs and steering committee liaisons to each subcommittee. The subcommittees and their membership can be found in Table 2.

Workshop Process

The CLD Workshop spanned an approximate 18-month period from beginning to end, and included a series of meetings and open presentations of the various subcommittees on the approach and content. Once each subcommittee was formed and members accepted their invitation for involvement, each of the eight subcommittees (Table 2) met for a one- to one- and a half-day in-person meeting in September and October 2012 in various locations across the world in order to develop draft subcommittee report outlines. The subcommittee outlines were intended to document the scope and aims of each subcommittee and were to be developed in draft form by each subcommittee. Following the subcommittee meetings, each subcommittee submitted a draft outline to the entire workshop for review and content by mid-October 2012. Following an open period of comment, the steering committee reviewed and edited each outline, followed by approval of each outline and return of a final outline to the various subcommittees. The steering committee was charged with oversight of all

Table 2. Subcommittees and Membership

Subcommittee Name	Membership
Definition and Classification	Kelly K. Nichols, chair and subcommittee (SC) liaison (United States) Desmond Fonn (Canada) Lance Forstot (United States) Brien Holden (Australia) Jing-Feng Huang (United States) Jean Jacob (United States) J. Daniel Nelson (United States) Rachel Redfern (United States)
Epidemiology	Kathy Dumbleton, chair (Canada) Christine Purslow, SC liaison (United Kingdom) Murat Dogru, consultant (Japan) Barbara Caffery (Canada) Sheila Hickson-Curran (United States) Jami Kern (United States) Takashi Kojima (Japan) Philip Morgan (United Kingdom) Danielle Robertson (United States)
Contact Lens Materials, Design & Care	Lyndon Jones, chair and SC liaison (Canada) Noel Brennan (United States) Jose Manuel Gonzalez-Meijome (Portugal) John Lally (United States) Carole Moldonada-Codina (United Kingdom) Tannin Schmidt (Canada) Lakshman Subbaraman (Canada) Graeme Young (United Kingdom)
Neurobiology of Discomfort and Pain	Fiona Stapleton, co-chair and SC liaison (Australia) Mark Rosenblatt, co-chair (United States) Carlos Belmonte, consultant (Spain) Carolyn Begley (United States) David Bereiter (United States) Darlene Dartt (United States) Juana Gallar (Spain) Blanka Golebiowski (Australia) Pedram Hamrah (United States) Carl Marfurt (United States)
Contact Lens Interactions with the Ocular Surface & Adnexa	Nathan Efron, chair (Australia) Jason J. Nichols, co-SC liaison (United States) Mark Willcox, co-SC liaison (Australia) Anthony Bron, consultant (United Kingdom) Reiko Arita (Japan) Stefano Barabino (Italy) Erich Knop (Germany) Maria Markoulli (Australia) Alison McDermott (United States) Edoardo Villani (Italy)
Contact Lens Interactions with the Tear Film	Jennifer Craig, chair and SC liaison (New Zealand) Pablo Argüeso (United States) Cecile Maissa (United Kingdom) Ulrike Stahl (Canada) Alan Tomlinson (United Kingdom) Jay Wang (United States) Mark Willcox (Australia) Norihiko Yokoi (Japan)

Table 2. Continued

Subcommittee Name	Membership
Trial Design & Outcomes	Gary Foulks, chair and SC liaison (United States) James F. Saviola, consultant (United States) Debra A. Schaumberg, consultant (United States) Robin Chalmers (United States) William Gleason (United States) Isabelle Jalbert (Australia) Nancy Keir (Canada) Richard E. Lippman (United States) Trefford Simpson (Canada) Craig Woods (Australia)
Management & Therapy	Eric Papas, chair (Australia) Joseph Ciolino, SC liaison (United States) Deborah Jacobs (United States) William Miller (United States) Heiko Pult (Germany) Afsun Sahin (Turkey) Sruthi Srinivasan (Canada) Joseph Tauber (United States) James Wolffsohn (United Kingdom)
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subcommittee outlines to ensure that the outlines were broad in scope yet not overly redundant with one another.

Following steering committee approval of the final outlines, the subcommittees were charged with developing a draft version of the subcommittee report (based on the content outline). Again, these reports were intended to be evidence based, using the American Academy of Ophthalmology's Preferred Practice Pattern guidelines for levels of evidence. By steering committee directive, the subcommittees were primarily asked to focus on peer-reviewed literature, but could include non–peer-reviewed literature in their reports when needed (e.g., when there was no peer-reviewed literature).

Subcommittee representatives reviewed their progress at a meeting of the Industry Liaison Subcommittee (ILS) in Houston, Texas, in January 2013. The role of the ILS was to provide proactive and reactive comments about the goals of, and draft reports from, all other subcommittees. Toward that end, ILS members forwarded their constructive critiques to specific subcommittees for their consideration. In this way the workshop process was able to benefit from the collective experience and knowledge of all industry sponsors.

Subcommittee draft reports were due to the steering committee by April 1, 2013, in anticipation of a post-Association for Research in Vision and Ophthalmology (ARVO) TFOS CLD Workshop plenary session (May 10–11, 2013, Seattle, WA). All subcommittee report drafts were openly circulated prior to the post-ARVO meeting to the entire CLD Workshop for review.

At the post-ARVO plenary session, the eight subcommittee chairs presented the draft version of their subcommittee reports to all members of the CLD Workshop in attendance (the entire CLD Workshop membership). This was an open period for further comments, suggestions, dialogue, development, and refinement of the draft reports. Each subcommittee was then tasked with refining their draft reports and submitting them to the steering committee by June 1, 2013.

Table 3. TFOS CLD Workshop Harmonization Subcommittee

Chair: Jason J. Nichols (United States)
Vice chair: Mark Willcox (Australia)
Members: Lyndon Jones (Canada), J. Daniel Nelson (United States), Fiona Stapleton (Australia)

Following submission of the draft reports to the steering committee, the reports were assigned to the Harmonization Subcommittee appointed by the steering committee, the membership of which can be found in Table 3. The goals of the Harmonization Subcommittee were to review, edit, and develop the subcommittee draft reports to ensure that all content included was evidence based and that the content was expansive and broad in scope. Further, the Harmonization Subcommittee was tasked by review of all of the eight subcommittee reports to have a global overview of the content of each, also ensuring that each report was focused on its outlines and on removing redundancies.

The subcommittee report harmonization period lasted through September 2013, and once each report was taken through the harmonization process and finalized, the final version was returned to the subcommittee for their review. Lastly, the reports were submitted to *IOVS* prior to the TFOS Seventh International Conference on the Tear Film & Ocular Surface: Basic Science and Clinical Relevance (Taormina, Sicily, September 18–21, 2013). During this conference, the CLD Workshop reports were presented to the public for the very first time.

Future Directions

While the details of the subcommittee reports and findings are found within the pages of this journal, it is important to recognize that it became apparent to many involved in the workshop process that "we just don't know as much as we thought we knew" about CLD. While there are hundreds, even perhaps thousands, of scientific papers that may relate to CLD in some way, it is clear that there are still significant gaps in our knowledge about this condition.

While it is obvious that CLD is a condition associated with the wearing of contact lenses, the condition remains equivocal in many senses. Below are key areas that need further study, delineation, and characterization, broken down by subcommittee.

Definition and Classification

1. Relative to classifying CLD, is it appropriate to differentiate CLD as distinct from dry eye disease, given the significant overlap of phenotypic characteristics of the two conditions?
2. Are there better ways to classify CLD, rather than focusing on contact lens and patient attributes?

Epidemiology

1. What is the natural history of CLD? What is the average age of onset, and how long do patients live with CLD prior to dropping out of contact lenses?

2. What are the risk factors for CLD?
3. Should CLD be considered distinct from other forms of dry eye disease (e.g., MGD) when the epidemiology of dry eye disease is evaluated?

Materials, Design, and Care

1. What contact lens material attributes have the most influence on CLD?
2. Are there advanced technologies in lens design that could reduce CLD?
3. What specific components in contact lens care systems matter most in improving comfort during CL wear? Are there specific steps in the regimen that matter more than others in terms of comfort?
4. How significant is replacement frequency in improving CLD? Are there substantially meaningful differences between lenses replaced daily, every two weeks, and monthly in preventing patients from reducing or discontinuing contact lens wear?

Neurobiology of Discomfort

1. What models can be used to determine the exact sensory pathways in CLD? Do sensory changes to the conjunctiva occur as a result of neural adaptation due to the continued stimulus of a contact lens, and how do those sensory changes mediate discomfort?
2. Does neural sensitization due to hyperosmolarity or inflammatory mediators in the tears contribute to CLD?
3. What corneal mediators, or neuropeptides, are altered during contact lens wear that interplay with the neurobiological system?
4. Is the key interaction related to CLD the upper lid (lid wiper zone) with the contact lens, and what role does sensing cooling effects have in CLD?

Ocular Surface and Adnexa

1. Is meibomian gland loss or atrophy in contact lens wearers the initial cascade that leads to other tissue changes provoking symptoms of discomfort?
2. How can contact lenses and care solutions be better improved to increase biocompatibility during lens wear?
3. Are changes to the ocular surface, such as corneal and conjunctival staining or changes in goblet cell density, more important in CLD than we presently realize?

Tear Film

1. Relative to the altered lipid layer and increased evaporation during contact lens wear, can the actual class, or species, of lipid that is associated with these changes be determined?
2. Are proteins from the ocular surface released into the tear film that change the stabilization of the tears during contact lens wear, leading to structural alterations of the tear film?
3. What role is there for mucin degradation during contact lens wear in CLD?
4. Is it possible to better elucidate how the "compartments" of the pre- and postlens tear film found during contact lens wear impact on CLD in a relative sense, if at all?

Trial Design and Outcomes

1. How will the definition of CLD as determined in this workshop report be adopted in clinical trial research?
2. Can trial design be better standardized and can validated endpoints be agreed upon?
3. Is it possible to determine specific objective outcomes, or even biomarkers, that predict symptoms reported by patients with CLD?

Management and Therapy

1. It is well recognized that most management strategies and therapies used in managing CLD are not entirely effective. What investments are needed to move the field forward to advance clinical care of these patients?
2. How can future knowledge of the impact of various contact lens materials and care solution attributes be harnessed into improving the care of the patient with CLD?
3. Are pharmaceutical agents or devices alone, or in combination with contact lenses, able to improve CLD in order to prolong safe and comfortable wear of contact lenses?

Conclusions

The TFOS International Workshop on Contact Lens Discomfort was an 18-month process of open communication, dialogue, and transparency among workshop participants that culminated in a series of evidence-based reports. These eight reports are the work and dedication of 79 global experts, and are the consensus-based efforts that define the current state of CLD, a condition characterized by episodic or persistent adverse ocular sensations that can ultimately lead to decreased wearing time or discontinuation of contact lens wear. It is the aspiration of those involved in the CLD Workshop that these reports serve as a blueprint for future research and clinical activity such that CLD can be reduced or eliminated, leading to successful long-term wear of contact lenses for millions of people across the world.

Acknowledgments

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APPENDIX

Disclosures

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