The TFOS International Workshop on Contact Lens Discomfort: Report of the Definition and Classification Subcommittee

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

Submitted: August 16, 2013
Accepted: August 23, 2013
Keywords: contact lens, dry eye, discomfort, definition, classification

INTRODUCTION AND GOALS OF THE DEFINITION AND CLASSIFICATION SUBCOMMITTEE

Current scientific understanding of contact lens discomfort (CLD) has been limited by a lack of consensus regarding terminology, as well as gaps in knowledge of the steps with which discomfort leads to discontinuation of lens wear. The goals of this subcommittee were to develop a comprehensive definition and an evidence-based classification scheme of CLD, as well as to clarify associated terminology.

In the clinical context, end of day discomfort is an important factor and one of the most common complaints associated with contact lens wear discontinuation.1–8 The condition of CLD can occur with any lens material type or design, and wearing modality; however, it is reported most often in conjunction with soft contact lenses (conventional and silicone hydrogel), as they make up the bulk of the contact lens market. While descriptions of CLD have been used widely in the literature, no uniform definition of CLD has been agreed upon or reported previously to our knowledge. Previously, the term CLD has been used to generally describe symptoms, while failing to delineate underlying mechanisms or outcomes.

Discomfort is considered “a mental or bodily distress, or something that disturbs one’s comfort,” and comfort is considered “a condition or feeling of pleasurable ease, well-being, and contentment.” When contact lens wearers are queried, comfort often is equated with the feeling of “non-lens wear” or what the lens feels like soon after insertion, which often is considered clinically as comfortable lens wear. Attributes of comfortable lens wear include the ability to wear the lens without sensation (lack of lens awareness), to maintain visual clarity, and to have complete tolerance, including the ability to wear lenses as long as desired without problem. When assessing contact lenses, clinicians and scientists sometimes use contact lens comfort or discomfort to determine if the lens is compatible with the eye. It is expected that successful wear can be achieved when a patient has normal ocular surface and lid function, and when the contact lens is compatible with the lids and ocular surface, and minimally disrupts the tear film.10

In developing a definition, this subcommittee addressed the following four questions: (1) What is CLD? (2) How is CLD characterized? (3) What factors are associated or causative with CLD to classify it? (4) What are the resultant outcomes of CLD? Existing terminology also was reviewed to augment the definition and describe the clinical condition further.

DEFINITION OF CLD

Contact lens discomfort is a condition characterized by episodic or persistent adverse ocular sensations related to lens wear, either with or without visual disturbance, resulting from reduced compatibility between the contact lens and the ocular environment, which can lead to decreased wearing time and discontinuation of contact lens wear.
**Terminology Related to the New Definition and Other Considerations**

Previously, CLD was considered to be a definable clinical condition. The term condition, considered as “a defective state of health”13 or “a state of health,”14 accurately describes the collection of abnormal signs and symptoms associated with the discomfort experienced by contact lens wearers as a result of the impact of lens wear on the ocular environment. An additional definition of the term condition is “a certain response elicited by a specifiable stimulus,” which also is appropriate for describing CLD.15

Many chronic conditions are experienced as episodic events in the early or emerging stages. Episodic is defined as having symptom-free periods that alternate with the presence of symptoms.14 Conditions that are persistent are those existing or continuing for a long time; those that continue to exist despite treatment.15 There is no question that CLD can be episodic and persistent.

Adverse ocular sensations are the increased perception, awareness, and feeling of the contact lens on the ocular surface, which can include symptoms of dryness and irritation, among others.

Visual disturbance is the perception, after initial contact lens adaptation, of transient visual symptoms and/or measurable visual disruption related to the wearing of the contact lens. In the case of CLD, visual disturbance can be a primary or secondary complaint, or it may not be present.

Compatibility of a contact lens with the eye, and its associated anterior structures and glands is a fundamental goal in the development of contact lenses. The ultimate contact lens would not elicit undesirable local/systemic effects. Compatibility is defined as the ability to exist in harmony;10 therefore, contact lens compatibility can be defined as a state of the lens being able to exist in harmony with the ocular environment.

For the purpose of the definition, the ocular environment includes structures of the eye and adnexa, including the cornea, conjunctiva, eyelids, tear film, and main and accessory lacrimal glands, as well as the meibomian glands.

Wearing time encompasses any aspect of the time that the contact lens is worn, and includes comfortable wearing time, and the total wearing time during the day and/or overnight (during sleep). The total wearing time is the number of contact lens wearing hours with a specific modality; for instance, the total daily wearing time for a daily lens wearer is the overall time the patient reports between contact lens insertion and removal. The comfortable wearing time is the number of wearing hours that the patient characterizes the lens as being comfortable (without adverse ocular sensations) for a specific modality; for instance, the comfortable daily wearing time for a daily lens wearer is the number of comfortable wearing hours between contact lens insertion and removal, usually less than the total wearing time. Comfortable wearing time and total wearing time can be used clinically, as well as in research settings, to characterize successful or unsuccessful wear, as well as to characterize the quality of the wearing period.

The CLD occurs while wearing a contact lens; removal of the contact lens diminishes or eliminates the condition, and, in particular, the adverse ocular sensations. It should be noted that CLD, as defined here, is a condition that occurs after initial adaptation to contact lens wear and generally is not related to insertion of or adaption to a contact lens. Discomfort may be accompanied by physical signs, including but not limited to conjunctival hyperemia, changes to the meibomian glands, or corneal or conjunctival staining (refer to the Tear Film & Ocular Surface Society [TFOS] CLD Workshop Report of the Contact Lens Interactions with the Ocular Surface and Adnexa Subcommittee). The full range of severity can occur with CLD, from mild discomfort to ocular sensations requiring immediate lens removal. Clinically, CLD is reported to impact a patient’s quality of life, although the association with severity and chronicity has yet to be delineated (refer to the TFOS CLD Workshop Report of the Epidemiology Subcommittee for more information on prognostic factors).

**Existing Terminology Related to CLD**

A number of other terms currently are used in the scientific literature that relate to CLD. Contact lens dryness often is used by patients to describe the adverse ocular sensations experienced while wearing contact lenses. However, in reality it likely is not the dryness of the contact lens, as the term implies, but rather adverse ocular sensations reported by patients. Contact lens dryness, therefore, should not be used to describe this condition, except to describe a specific symptom associated with CLD. Terms that describe the symptoms of dry eye experienced by contact lens wearers include contact lens dry eye, contact lens-related dry eye, or contact lens-induced dry eye (CLIDE), but to our knowledge there is no evidence in the literature to define or to provide an associated definitive pathophysiology.

The 2007 TFOS Dry Eye Workshop (DEWS) report lists discomfort as the one of the main symptoms of patients with dry eye, and defines dry eye as “…a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability, with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.”17 This definition suggests an association between discomfort and dry eye, although the direct mechanisms are not delineated. Similar pathophysiological changes that occur in dry eye can be observed in contact lens wearers; alternatively, contact lens wear can be a precipitating factor in dry eye disease and/or meibomian gland dysfunction.18–19 Thus, the terms contact lens dry eye or contact lens-induced dry eye (CLDE) should be used to describe the pathophysiology of preexisting dry eye in a contact lens wearer.

Some features of subclinical dry eye may become clinically apparent once a contact lens is placed on the eye. In this case, the contact lens can amplify a preexisting dry eye state leading to increased symptoms of dryness. The use of the term contact lens dry eye is appropriate to describe the clinical scenario of increased tear film evaporation in patients with preexisting meibomian gland dysfunction20 or other types of dry eye. Contact lens–wear has been associated with increased meibomian gland atrophy measured with meibography, which also can be associated with an increase in tear evaporation.21,22

Throughout the literature, the terms contact lens dry eye, contact lens–related dry eye, and contact lens–induced dry eye often are used to describe a symptomatic condition during lens wear that mimics the symptoms of dry eye. However, when the lenses are removed and symptoms no longer persist, this scenario is not a dry eye condition. Therefore, these terms should not be used interchangeably with CLD.

A number of terms in the literature have been used describe the cessation of lens wear, including discontinuation, dropout, intolerance, abandonment, and lapse, and they often are used synonymously with each other.5,6,25 It is recommended, henceforth, that discontinuation of contact lens wear should describe the process of temporary or permanent cessation of lens wear. Further, contact lens dropout should refer to an individual who has discontinued wear for a sustained period of time. Thus, discontinuation of lens wear has the end-result of contact lens dropout. Time references can be used to clarify...
discontinuation and dropout; for example, discontinuation of lens wear for a sustained period of time (e.g., one year) could be considered permanent dropout.

The word ‘tolerance’ in medicine is a general term that refers to ‘the ability to endure continued exposure with a lack of or low levels of immune response,’ or ‘the capacity to endure pain.’ Intolerance, the ‘quality or state of being intolerant,’ then would be the lack of ability to tolerate a stimulus. Thus, contact lens intolerance is the state of being unable to tolerate contact lenses. The condition of CLD may well be a predisposition to intolerance with lenses and leads to, but is not synonymous with, discontinuation. The community often synonymously applies the terms intolerance and discontinuation, but intolerance should be considered, henceforth, as the physiological process by which a patient moves toward permanent discontinuation, and should not be used to describe an individual who has dropped out of lens wear.

**CLASSIFICATION OF CLD**

As yet to our knowledge, no definitive classification systems for CLD have been reported in the literature, although descriptions of groupings and etiologic approaches have been suggested. A prior attempt to standardize successful contact lens wear included considerations of wearing time, comfort, vision, and ocular physiology. Additional efforts to characterize successful contact lens wear have included contact lens factors, clinical evaluation of the fit and contact lens interactions, and tear film considerations. However, most approaches evaluating CLD discuss the various factors or clinical findings associated with symptoms, such as patient, contact lens, and environmental factors. Additional factors associated with CLD are discussed in detail in the TFOS CLD Workshop Report of the Epidemiology Subcommittee.

The CLD classification scheme in the Figure categorizes discomfort into two major subclasses: the contact lens and the environment. These major subclasses are subdivided further into their potentially contributing elements; the contact lens subclassification is categorized further into material, design, fit and wear, and lens care. The environment subclassification is subdivided further into patient (inherent and modifiable factors) and environment (ocular and external) subcategories.

**Progression of CLD**

Discomfort into two major subclasses: the contact lens and the environment. These major subclasses are subdivided further into their potentially contributing elements; the contact lens subclassification is categorized further into material, design, fit and wear, and lens care. The environment subclassification is subdivided further into patient (inherent and modifiable factors) and environment (ocular and external) subcategories.

**Material, design, and fit and wear, and lens care subcategories may impact CLD, and are discussed in detail in the TFOS CLD Workshop Report of the Contact Lens Materials, Design and Care Subcommittee. The contact lens material subcategory relates to the inherent polymeric composition of the lens material, and may include, but are not limited to, lubricity, water content, and wettability. Lubricity, a promising material characteristic, may have a significant role in reducing wear and tear associated with interacting surfaces (e.g., material and lid). Water content, ionicity, and dehydration have been widely studied relative to the impact on contact lens wear. Dehydration characteristics have been shown to be difficult to measure on-eye as well as in regards to CLD, yet it is presumed that dehydration would be expected to impact the fit of the lens. Material oxygen transmissibility is a requirement for corneal health and the prevention of corneal edema. It does not appear to be substantiated as of yet in terms of its relation to CLD (refer to the TFOS CLD Workshop Report of the Definition and Classification Subcommittee).
Contact lens materials and designs are important for movement and fit of the lens on the cornea and ocular surface. While different, the effects of material, design, and fit are challenging to separate as each impact the other. Design effects, such as the sharpness, thickness, contour, or slope of the lens edge, have been reported to have corneal, conjunctival, and lid effects.\textsuperscript{37–45} The thickness of the lens, and thickness variation across the lens, also can trigger adverse corneal and lid responses.\textsuperscript{36–44} In addition, the pressure exerted by the contact lens, or by regions of the contact lens based on design, can affect the corneal epithelial cells and parasympathetic nerves, in addition to tear exchange.\textsuperscript{55–50} Tear exchange represents the elements of patients actually using their contact lenses following the fitting; for example, wear may represent whether the patient wears lenses on a daily, 2-week, or monthly schedule. Deposition on or within the contact lens material is the result of tear film component interactions with the chemical moieties and/or pores within the material.\textsuperscript{51–56} and is associated with material, and fit and wear, as well as lens care. More in depth discussions on the effects of contact lens care, including solution chemistry and the impact of the care regimen, can be found in the TFOS CLD Workshop Report of the Contact Lens Materials, Design, and Care Subcommittee.

The influence of the environment on CLD is based on patient and environment factors. Patient factors can be described as inherent, or existing as a permanent characteristic or attribute,\textsuperscript{57} or patient factors can be modifiable. Inherent patient factors include demographic factors, such as age, sex, and race, as well as ocular and systemic disease. It is possible to modulate, although perhaps not eliminate, a patient’s disease through treatment. Modifiable patient factors include, but are not limited to, medication use and contact lens wear, and/or care compliance. Medications can affect tear film production and precorneal tissue health,\textsuperscript{58} and ocular and systemic diseases have been shown to impact the health and function of the tissues, and nerves of the cornea, conjunctiva, eyelids, and glands associated with tear film production.\textsuperscript{59–64}

External environment factors include climate, allergens/pollutants, and visual demand. The climate the eye is exposed to, in terms of relative humidity, temperature, and air currents, can affect the tear film integrity and the contact lens material hydration, and, therefore, is a potential factor associated with CLD.\textsuperscript{65–70} For example, allergens and pollutants introduced to the ocular surface by the air or touch can produce adverse reactions in the tear film, cornea, conjunctiva, and eyelids that are associated with CLD.\textsuperscript{52–54} Visual demand and use of computers, as well as adverse lighting, can produce ocular strain due to unnatural blink rates.\textsuperscript{75,76} Patient and environment factors are discussed further in the TFOS CLD Workshop Report of the Epidemiology Subcommittee.

By definition, CLD occurs when there is reduced compatibility between the contact lens and the ocular environment. The lids, glands, ocular tissues, tear film, and blinking all may have a role in this process. The lipid layer, and the role of the lipid layer in tear stability and reducing evaporation, are examples of factors related to the ocular environment. Tear film deficiencies in production or exchange can impact the health of the entire ocular surface. The completeness and rate of the eyelid blink also has been shown to be associated with contact lens wear, and possibly CLD.\textsuperscript{79–81} Further detailed discussion of the interaction of the contact lens with the tear film and ocular environment can be found in the TFOS CLD Workshop Report of the Contact Lens Interactions with the Tear Film Subcommittee and the TFOS CLD Workshop Report of the Contact Lens Interactions with the Ocular Surface and Adnexa Subcommittee.

The modes of progression of CLD are presented in the Figure. The five steps show the progression from struggling and lens awareness, to reduced wearing time, to temporary and permanent discontinuation (drop out) of contact lens wear.

**Summary**

The condition of CLD is a major concern for patients and clinicians alike, in that the end result of this condition is permanent contact lens discontinuation, or drop out. Successful contact lens wear can be described best as harmonious coexistence of the contact lens on the eye without any adverse effects. Ultimately, the ideal contact lens has material, design, and care characteristics allowing for optimal fit and wear, vision, and comfort, with minimal patient and environment effects, thereby preventing discontinuation, promoting ocular health, and improving quality of life.

**Acknowledgments**

Supported by the Tear Film & Ocular Surface Society (TFOS; available in the public domain at http://www.tearfilm.org). Individual author support is listed in the Appendix of the Introduction.

Disclosure: Each workshop participant’s disclosure data can be found in the Appendix of the Introduction.

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