Complete Summary

GUIDELINE TITLE

Dry eye syndrome.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Ophthalmology Cornea/External Disease Panel, Preferred Practice Patterns Committee. Dry eye syndrome. San Francisco (CA): American Academy of Ophthalmology (AAO); 2003. 21 p. [75 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Ophthalmology (AAO), Preferred Practice Patterns Committee, Cornea/External Disease. Dry eye syndrome. San Francisco (CA): American Academy of Ophthalmology (AAO); 1998. 18 p.

All Preferred Practice Patterns are reviewed by their parent panel annually or earlier if developments warrant.

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SCOPE

DISEASE/CONDITION(S)

Dry eye syndrome

GUIDELINE CATEGORY

Diagnosis Management Treatment

CLINICAL SPECIALTY

Ophthalmology

INTENDED USERS

Health Plans Physicians

GUIDELINE OBJECTIVE(S)

To preserve and/or improve vision, prevent or minimize structural damage to the ocular surface, and improve patient comfort, by addressing the following goals:

- Establish the diagnosis of dry eye, differentiating it from other causes of irritation and redness
- Identify the causes of dry eye
- Establish appropriate therapy
- Relieve discomfort
- Prevent complications, such as loss of visual function, infection, and structural damage
- Educate and involve the patient in the management of this disease

TARGET POPULATION

Individuals of all ages who present with symptoms and signs suggestive of dry eye, such as irritation or redness

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

- 1. Comprehensive adult medical eye evaluation, including complete patient history
- 2. Physical examination, including visual acuity measurement, an external examination, and slit-lamp biomicroscopy
- 3. Diagnostic tests including, tear break-up time test, ocular surface dye staining pattern (rose bengal, fluorescein, or lissamine green), and the Schirmer test

Treatment

Medical

- 1. Elimination of exacerbating medications where feasible
- 2. Ocular environmental interventions
- 3. Computer work site interventions
- 4. Aqueous tear enhancement with topical agents or external means

5. Medications

Surgical

- 1. Correction of the lid abnormality
- 2. Punctal occlusion or tarsorrhaphy for severe cases

Management

- 1. Follow-up
- 2. Counseling and referral, when applicable
- 3. Patient education

MAJOR OUTCOMES CONSIDERED

- Reducing or alleviating signs and symptoms of dry eye
- Maintaining visual function
- Reducing or preventing structural damage

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A detailed literature search of articles in the English language was conducted in July 2002 on the subject of dry eyes for the years 1997 to 2002.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Ratings of strength of evidence

- I. Level I includes evidence obtained from at least one properly conducted, well-designed randomized, controlled trial. It could include meta-analyses of randomized controlled trials.
- II. Level II includes evidence obtained from the following:
 - Well-designed controlled trials without randomization
 - Well-designed cohort or case-control analytic studies, preferably from more than one center

- Multiple-time series with or without the intervention
- III. Level III includes evidence obtained from one of the following:
 - Descriptive studies
 - Case reports
 - Reports of expert committees/organization
 - Expert opinion (e.g., Preferred Practice Pattern panel consensus)

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The results of a literature search on the subject of dry eye were reviewed by the Cornea/External Disease Panel and used to prepare the recommendations, which they rated in two ways. The panel first rated each recommendation according to its importance to the care process. This "importance to the care process" rating represents care that the panel thought would improve the quality of the patient's care in a meaningful way. The panel also rated each recommendation on the strength of the evidence in the available literature to support the recommendation made.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Ratings of importance to care process

Level A, most important Level B, moderately important Level C, relevant but not critical

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These guidelines were reviewed by Council and approved by the Board of Trustees of the American Academy of Ophthalmology (September 2003). All *Preferred Practice Patterns* are reviewed by their parent panel annually or earlier if developments warrant and updated accordingly.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The ratings of importance to the care process (A, B, C) and the ratings of strength of evidence (I, II, III) are defined at the end of the "Major Recommendations" field.

Diagnosis

The initial evaluation of a patient who presents with symptoms suggestive of dry eye should include those features of the comprehensive adult medical eye evaluation relevant to dry eye. [A:III]

Patient History

- Symptoms and signs [A:III]
- Exacerbating conditions [B:III]
- Duration of symptoms [A:III]
- Topical medications used and their effect on symptoms [A:III]

The ocular history may include details about the following:

- Contact lens wear, schedule, and care [A:III]
- Allergic conjunctivitis [B:III]
- Corneal history [A:III]
- Punctal surgery [A:III]
- Eyelid surgery [A:III]
- Bell's palsy [A:III]
- Chronic ocular surface inflammation [A:III]

The medical history takes into account the following elements:

- Smoking [A:III]
- Dermatological diseases [A:III]
- Atopy [A:III]
- Menopause [A:III]
- Systemic inflammatory diseases [A:III]
- Systemic medications [A:III]
- Trauma [B:III]
- Chronic viral infections [B:III]
- Surgery [B:III]
- Radiation of orbit [B:III]
- Neurological conditions [B:III]
- Dry mouth, dental cavities, oral ulcers [B:III]

Examination

The physical examination includes a visual acuity measurement, [A:III] an external examination, [A:III] and slit-lamp biomicroscopy. [A:III]

The external examination should pay particular attention to the following:

- Skin [A:III]
- Eyelids [A:III]
- Adnexa [A:III]
- Proptosis [B:III]
- Cranial nerve function [A:III]
- Hands [B:III]

The slit-lamp biomicroscopy should focus on the following parts of the eye:

- Tear film [A:III]
- Eyelashes [A:III]
- Anterior and posterior eyelid margins [A:III]
- Puncta [A:III]
- Inferior fornix and tarsal conjunctiva [A:III]
- Cornea [A:III]

Diagnostic Tests

For patients with moderate to severe aqueous tear deficiency, the diagnosis can be made by using one or more of the following tests: tear break-up time test, ocular surface dye staining pattern (rose bengal, fluorescein, or lissamine green), and the Schirmer test. Corneal sensation should be assessed when trigeminal nerve dysfunction is suspected. [A:III] A laboratory and clinical evaluation for autoimmune disorders should be considered for patients with significant dry eyes, other signs and symptoms of an autoimmune disorder (e.g., dry mouth), or a family history of an autoimmune disorder. [A:III]

Treatment

For patients with aqueous tear deficiency, the following measures are appropriate: [A:III]

- Elimination of exacerbating medications where feasible
- Ocular environmental interventions
- Computer work site interventions
- Aqueous tear enhancement with topical agents or external means
- Medications
- Correction of the lid abnormality
- Punctal occlusion or tarsorrhaphy for severe cases

Follow-up

The frequency and extent of the follow-up evaluation will depend on the severity of disease, the therapeutic approach, and response to the therapy. Patients with

sterile corneal ulceration associated with dry eye require careful monitoring, sometimes on a daily basis. [A:III]

Provider and Setting

Because dry eye can be associated with systemic immunological disorders and use of systemic medications, broad medical skills and training are important for appropriate diagnosis and management. Patients with dry eye who are evaluated by non-ophthalmologist health care providers should be referred promptly to the ophthalmologist if any of the following occurs: [A:III]

- Visual loss
- Moderate or severe pain
- Lack of response to the therapy
- Corneal ulceration

Counseling/Referral

The most important aspects of caring for patients with dry eye are to educate them about the chronic nature of the disease process and to provide specific instructions for therapeutic regimens. It is helpful to reassess periodically the patient's compliance and understanding of the disease, the risks for associated structural changes, and to re-inform the patient as necessary.

For patients with irreversible tear deficiency or evaporative increase associated with chronic conditions such as blepharitis, the ophthalmologist should educate the patient about the natural history and chronic nature of dry eye. [A:III] Patients with pre-existing dry eye should be cautioned that laser in situ keratomileusis or photorefractive keratectomy may worsen their dry eye condition. [A:III]

In moderate to severe cases that are unresponsive to treatment or when systemic disease is suspected, timely referral to an ophthalmologist who is knowledgeable and experienced in the management of these entities is recommended. [A:III] Patients with systemic disease such as primary Sjögren syndrome, secondary Sjögren (associated with a connective tissue disease), or connective tissue disease such as rheumatoid arthritis should be managed by an appropriate medical specialist. [A:III]

Definitions:

Ratings of importance to care process

Level A, most important Level B, moderately important Level C, relevant but not critical

Ratings of strength of evidence

- I. Level I includes evidence obtained from at least one properly conducted, well-designed randomized, controlled trial. It could include meta-analyses of randomized controlled trials.
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 - Descriptive studies
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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- In some individuals, exacerbating factors such as systemic medications that decrease tear production or environmental conditions that increase tear evaporation may lead to an acute increase in the severity of symptoms. Elimination of such factors often leads to marked improvement and may even be curative.
- Patients treated with the cholinergic agonist pilocarpine at a dose of 5 mg orally four times a day experienced a significantly greater overall improvement in the ability to focus their eyes during reading and symptoms of blurred vision compared to placebo-treated patients.
- In clinical trials, topical cyclosporine for the treatment of keratoconjunctivitis sicca (KCS) has been reported to increase aqueous tear production and decrease ocular irritation symptoms. This agent has also been reported to heal paracentral sterile corneal ulcers associated with Sjögren syndrome and rheumatoid corneal ulceration.
- Corticosteroids have been reported to decrease ocular irritation symptoms, decrease corneal fluorescein staining, and improve filamentary keratitis. In one study, a 2-week pretreatment of patients with a topical nonpreserved corticosteroid prior to punctal occlusion was reported to reduce ocular irritation symptoms and corneal fluorescein staining.
- Cevimeline is an oral cholinergic agonist that has been found to improve ocular irritation symptoms and aqueous tear production and may have fewer adverse systemic side effects than oral pilocarpine.

 Semipermanent plugs have the advantage of being reversible if the patient develops symptoms of epiphora and may be retained for many years without complications.

POTENTIAL HARMS

- Spectacle side shields, moisture inserts, and moisture chambers are noninvasive therapies that can be used, but they may be poorly tolerated because of the negative cosmetic effect.
- The most common side effect from taking cholinergic agonist pilocarpine was excessive sweating that occurred in over 40% of patients. Two percent of the patients taking oral pilocarpine withdrew from the study because of this and other drug-related side effects.
- Soft contact lenses are effective in preventing recurrence of filamentary keratopathy but are poorly tolerated if the patient has severe dry eyes. If the patient has associated neurotrophic keratopathy, contact lenses should be avoided.
- Displacement of semipermanent plugs into the lacrimal system may result in passage through the system, continued residence with partial blockage of tear flow, or, rarely, blockage with secondary infection. Rarely, surgical removal is necessary.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Preferred Practice Patterns provide guidance for the pattern of practice, not for the care of a particular individual. While they should generally meet the needs of most patients, they cannot possibly best meet the needs of all patients. Adherence to these Preferred Practice Patterns will not ensure a successful outcome in every situation. These practice patterns should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the best results. It may be necessary to approach different patients' needs in different ways. The physician must make the ultimate judgment about the propriety of the care of a particular patient in light of all of the circumstances presented by that patient. The American Academy of Ophthalmology is available to assist members in resolving ethical dilemmas that arise in the course of ophthalmic practice.
- Preferred Practice Patterns are not medical standards to be adhered to in all individual situations. The Academy specifically disclaims any and all liability for injury or other damages of any kind, from negligence or otherwise, for any and all claims that may arise out of the use of any recommendations or other information contained herein.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Sep (revised 2003)

GUIDELINE DEVELOPER(S)

American Academy of Ophthalmology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Ophthalmology

GUIDELINE COMMITTEE

Preferred Practice Patterns Committee, Corneal/External Disease Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Cornea/External Disease Panel Members: Alice Y. Matoba, MD (Chair); David J. Harris, Jr., MD; David M. Meisler, MD; Stephen C. Pflugfelder, MD; Christopher J. Rapuano, MD; Jayne S. Weiss, MD; David C. Musch, PhD, MPH (Methodologist)

Preferred Practice Patterns Committee Members: Joseph Caprioli, MD (Chair); J. Bronwyn Bateman, MD; Emily Y. Chew, MD; Douglas E. Gaasterland, MD; Sid Mandelbaum, MD; Samuel Masket, MD; Alice Y. Matoba, MD; Donald S. Fong, MD, MPH

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The following authors have received compensation within the past 3 years up to and including June 2003 for consulting services regarding the equipment, process, or product presented or competing equipment, process, or product presented:

Jayne S. Weiss, MD: Alcon, Allergan - Reimbursement of travel expenses for presentation at meetings or courses.

Stephen C. Pflugfelder, MD: Allergan - Compensation received within the past three years for consulting services regarding the equipment, process, or product presented. Contribution to research or research funds.

Christopher J. Rapuano, MD: Allergan - Ad hoc consulting fees.

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GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>American Academy of Ophthalmology (AAO)</u> Web site.

Print copies: Available from American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; Phone: (415) 561-8540.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• Summary benchmarks for preferred practice patterns. San Francisco (CA): American Academy of Ophthalmology; 2006 Nov. 21 p.

Available in Portable Document Format (PDF) from the <u>American Academy of Ophthalmology (AAO) Web site</u>.

Print copies: Available from American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; telephone, (415) 561-8540.

PATIENT RESOURCES

The following patient education brochures are available:

- Dry eye. (1995)
- Dry eye (Spanish-Ojo Seco) (2003)

Print copies: Available from the American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; Phone: (415) 561-8540.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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