Disclosures

- Flora Lum, Scott P. Kelly, and Danielle Fujino are employees of the American Academy of Ophthalmology
- Ipek Özer Stillman, Corey Joseph, and Csaba Siffel are employees of and owns stock/stock options in Shire
- Reza Dana is a consultant for Aldeyra, Dompé, Kala, and Shire; and has received research support from Allergan and the National Eye Institute
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Patients With Dry Eye Disease (DED) in an Eye-Care Specialized Clinical Registry: Data From AAO's IRIS® Registry

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Background

Dry Eye Disease (DED)

 DED is a chronic, progressive ocular surface disorder that impairs visual functioning and incurs negative social impact for those affected¹⁻³

AAO IRIS® Registry (Intelligent Research in Sight)

 The IRIS Registry is the first comprehensive eye disease clinical registry developed for the profession's shared goal of continual improvement in eye care delivery

Study Objective

 Study objective: to assess clinical and demographic characteristics of patients with DED, stratified by DED-specific treatments and comorbid conditions.

Methods – Patient Population (IRIS Registry)

American Academy of Ophthalmology IRIS Registry (Intelligent Research in Sight)

 A comprehensive clinical ophthalmic database with >37 million unique patients and 148 million patient visits in the United States

Study Period

- Study data covered January 1, 2013 through December 31, 2017
- We report on data from patients with ≥1 eye care visit in 2017

Methods – DED Rule-Based Diagnoses

Diagnosis of DED

- International Classification of Disease (ICD)-9 or ICD-10, Current Procedural Technology codes, and medication codes were used to identify clinical indicators of DED.
- Specifically, either:
 - 2 instances of a DED driving indicator within 12 months, or
 - 1 DED driving indicator and 1 DED nondriving indicator within 12 months

Driving Indicators	Nondriving Indicators
Keratoconjunctivitis sicca	Superficial keratoconjunctivitis
Conjunctival xerosis	Punctate keratitis
Tear film insufficiency unspecified	Exposure keratoconjunctivitis
Sicca syndrome, Sjögren's	Rheumatoid arthritis
Closure of the lacrimal punctum by thermocauterization, ligation, or laser surgery	Lupus – DLE, SLE, DLE of eyelid
Punctal plugs	Conjunctivochalasis
Obliteration of lacrimal punctum	MGD
Prescription for cyclosporine ophthalmic emulsion 0.05%	_
Prescription for lifitegrast ophthalmic solution 5%	_

Methods – Stratification by **DED Severity and DED Comorbidity**

- DED severity was defined by expert opinion and based on the Tear and Film Surface Society Dry Eye Workshop II (TFOS **DEWS II) staged** management algorithm¹
- **DED** comorbidity groupings were defined by diagnosis and/or treatment code claims

Treatment Intensity Level	1	2		3
Hypothesized Disease Severity	Mild	N	/loderate	Severe
Treatments	Treatment naive	Tacrolimus		Tetracyclines
Captured	Topical and systemic omega-3 fatty acids	 Lifitegrast ophthalmic solution 5% Cyclosporine ophthalmic emulsion 0.05% Topical corticosteroids (and corticosteroid combinations) Nonthermal or collagen punctal plugs occlusion 		 Systemic cholinergic agonist (pilocarpine or cevimeline) Systemic anti-inflammatory agents (excluding topical and systemic omega-3 fatty acids) Mucolytic agents (acetylcysteine eye drops) Punctal occlusion by thermocauterization, ligation, or laser surgery Tarsorrhaphy
			, ,	
Cataract (ICD and	Cataract (ICD and CPT codes)		Sjögren's syndrome	
MGD		Lid abnormalities		

Cataract (ICD and CPT codes)	Sjögren's syndrome	
MGD	Lid abnormalities	
Glaucoma	_	

^{1.} Jones L, et al. Ocul Surf. 2017;15(3):575-628. DED, dry eye disease; ICD, International Classification of Disease; CPT, Current Procedural Technology; MGD, meibomian gland dysfunction.

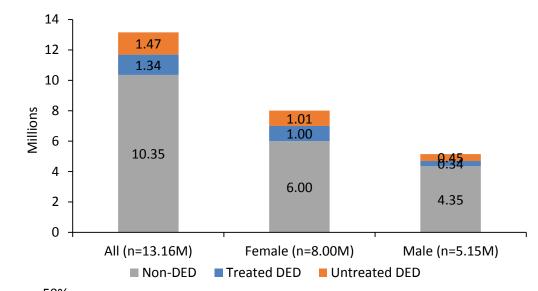
Results – Demographics

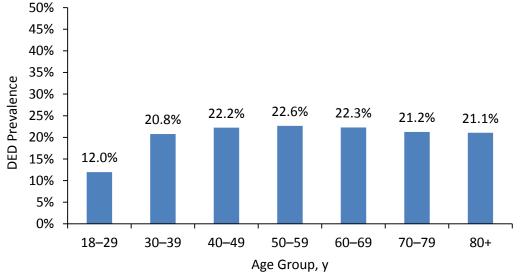
Total 2017 Adult Population

- 13.2 million patients (60.9% female, 39.1% male)
- 2.8 million patients with DED (71.5% female,
 28.5% male)
 - 21.3% DED prevalence (25.0% female, 15.5% male)
- 1.5 million (52.5%) patients with untreated DED (50.4% female, 61.9% male)

DED by Age Group

 Prevalence rises rapidly from the 20's to 30's age groups and affects nearly a quarter of the study population by the 40's and beyond





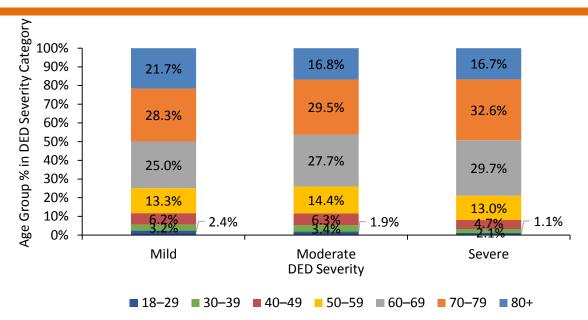
Results – DED Severity and Treatment Patterns

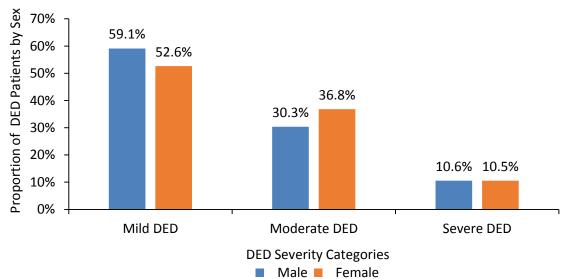
By Age Group

 DED severity and more specific treatment of DED is seen to increase with age

By Sex

 DED severity and DED treatment patterns show sex differences for mild and moderate DED





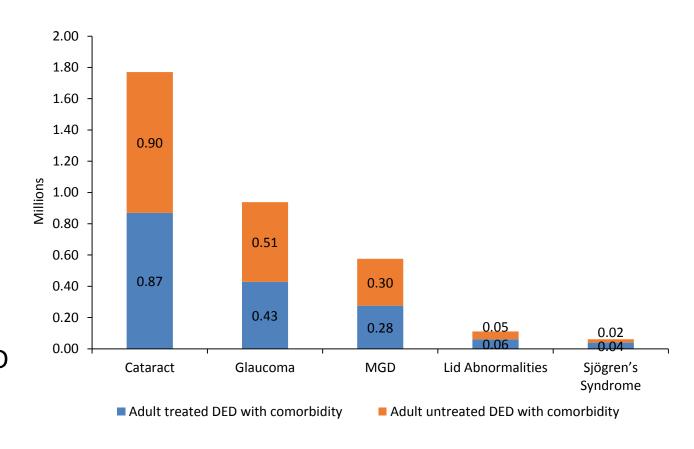
Results – DED Comorbidities and Treatment

DED Comorbidities

- A total of 3.4 million instances of 5 major DED-associated comorbidities
- 1.8 million (61.2%) patients had cataract diagnoses

DED Treatment in Comorbid Patients

 ~50% of all patients with DED comorbidities, excepting Sjögren's syndrome, are untreated for their DED



Conclusions

- Data from the IRIS Registry show that DED affects a substantial proportion of eye care patients, especially women, and that prevalence increases with age from the 20s to 40s
- Age group analysis indicates DED severity may worsen with age
- Among patients with DED, high rates of DED-associated ocular comorbidities and low rates of DED-targeted treatments were found
- The majority of patients identified with DED did not have record of a prescribed treatment and, given the high prevalence of associated ocular conditions, undertreatment is plausible