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## 2.1 Impact of Dry Eye Disease

Dry eye disease (DED) is a common and chronic condition, which is considered a major health concern internationally. It causes eye discomfort and pain; it limits vision and reduces quality of life (Reddy et al. 2004). Those with dry eye are two to three times more likely to report problems with everyday activities such as reading, performing professional work, computer use, watching television, and daytime or nighttime driving (Schaumberg et al. 2003, 2009; Miljanovic et al. 2007). Dry eye disease also impacts socially, as those with dry eye and refractive errors are unsuitable for refractive surgery and are limited in their ability to wear contact lenses or use cosmetics (Reddy et al. 2004; Miljanovic et al. 2007).

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Dry eye may also compromise outcomes of cataract surgery.

Those with dry eye are two to three times more likely to report problems with everyday activities such as reading, performing professional work, computer use, watching television, and daytime or nighttime driving.

Dry eye disease is a significant problem for up to 35 % of the population, and two-thirds of sufferers are women, with a higher risk in postmenopausal women (Chia et al. 2003). More severe dry eye affects 8 % of women and 4 % of men over 50 years of age (Schaumberg et al. 2003, 2009). Dry eye is the most commonly reported reason for seeking medical eye care, and thus dry eye has a significant cost due to direct and indirect healthcare costs and through reduced productivity at work (Moss et al. 2000). The economic burden of dry eye is substantial: in the United States, the average cost of dry eye management was estimated to be US\$ 11,302 per sufferer and US\$ 55 billion overall (Yu et al. 2011). The annual cost to treat dry eye including direct costs, such as oral and topical medication, punctal plugs, practitioner visits, and nutritional supplements and indirect costs, was \$783 (range \$757–\$809) or \$3.84 billion (Yu et al. 2011). Utility assessment studies suggest that severe dry eye disease impacts life to a similar extent as moderate to severe angina, and

in the most severe cases, the utility was poorer than for a hip fracture (Schiffman et al. 2003; Bushholz et al. 2006). Dry eye disease comprises approximately 20 % of presentations to hospital outpatient clinics (Hikichi et al. 1995; Onwubiko et al. 2014) and 11–20 % of presentations to optometric practice (Doughty et al. 1997; Albiez 2000).

- Dry eye is the most common reason for seeking eye care.
- Dry eye is more common in women, and women are more likely than men to suffer from severe dry eye.

Dry eye is poorly controlled with current therapy; hence, those with severe disease suffer chronically with symptoms for over 200 days each year and exhaust on average 50 % of their annual sick leave due to dry eye (Schiffman et al. 2003). Less severe (non-Sjögrens) disease interferes with work for 191 days per year and resulted in 2 days of absenteeism per year (Nelson et al. 2000). There have been limited studies to evaluate the impact of therapies on long-term patient-reported outcomes or their economic impact. With increased life expectancy and an aging population, the economic and social impacts of this condition would be expected to grow substantially.

- Current treatment for dry eye is inadequate resulting in ongoing symptoms and repeat eye-care visits.
- An aging population will only increase the economic burden of dry eye.

There have been significant advances in our understanding of the epidemiology of DED over the past 10 years largely due to a better understanding of the underlying causes of the condition, namely, tear osmolarity and ocular surface inflammation. The 2007 International Dry Eye Workshop of the Tear Film and Ocular Surface

Society defined DED 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” (2007).

Dry eye disease occurs when the tear film is compromised by reduced aqueous tear production and/or excessive tear evaporation, and the disease can be broadly classified as either aqueous deficient or evaporative, although practically subjects with dry eye disease frequently manifest with signs consistent with both classifications, and the subtypes are not exclusive. Evaporative dry eye due to meibomian gland dysfunction appears to represent the most common DED subtype in both population and outpatient clinic cohorts (Tong et al. 2010; Lemp et al. 2012; Viso et al. 2012), where 45–65 % of those with dry eye symptoms have MGD, although many with MGD lack dry eye symptoms. This chapter will summarize the frequency of disease and relevant risk factors for both classes of dry eye disease where possible.

Meibomian gland dysfunction (MGD) is the most common subtype of dry eye disease.

## 2.2 Prevalence of Dry Eye Disease

Early reports of the prevalence of DED showed markedly variable results partly due to the different disease definitions used in these studies and the lack of a single validated test or combination of tests to confirm a diagnosis. The Epidemiology Subcommittee of the 2007 DEWS reviewed major epidemiological studies of dry eye and demonstrated that the prevalence of dry eye ranged from 5 to 30 % of individuals aged over 50 (2007). Their consensus was that the prevalence of severe disease was likely to be at the low end of this range and that the true prevalence of mild or episodic disease was closer to the upper

end of this range. Higher rates are generally observed with questionnaire-based studies and in clinic-based studies, with lower rates amongst intention to treat or treatment studies.

- Prevalence estimates of dry eye disease range from 5 to 30 % of people over the age of 50.
- Prevalence estimates vary because of nonstandardized definitions.
- A large proportion of individuals with dry eye disease are asymptomatic.

Prevalence estimates of DED both from key population-based and records analyses are shown in Table 2.1. The recent findings are broadly consistent with those reported in the DEWS report from 2007, with higher rates associated with age and gender. Compared with recent studies in Caucasian populations (USA Beaver Dam Study, Beaver Dam Offspring Study, Physicians Health Study, Veterans Affairs Database Audit), those in Asian populations (Korea, China – Beijing Eye Study and Japan) showed a consistently higher prevalence, following adjustment for age and gender. Based on the body of evidence, it would be appropriate to consider race as a confirmed risk factor for DED.

Prevalence estimates of MGD have been similarly confounded by the lack of a standardized definition and standardized method for grading MGD (Schaumberg et al. 2011). There are also no standardized questionnaires available for MGD; symptoms frequently overlap with those reported in dry eye disease and/or anterior blepharitis, and the disease is frequently asymptomatic (Viso et al. 2012). Estimates of prevalence from population-based studies have varied widely from 3.5 to 68.3 % (Schein et al. 1997; Jie et al. 2008; Siak et al. 2012).

Table 2.2 summarizes the key population studies and their disease definitions. Key features are firstly that lower prevalence rates have been published in studies where symptoms were not included as part of the disease definition. The clinical signs used as part of the diagnostic criteria have also varied widely, with some studies focusing on secondary outcomes such as measures of

tear quality or tear stability and others on specific but varied lid signs. The relatively high prevalence rate of 68 % from the Beijing Eye Study, for example, is consistent with a definition that included clinical signs of lid disease and symptoms of dry eye. Secondly, the prevalence data appears to be consistently higher in studies of Asian populations compared with reports where the majority of participants are Caucasian for broadly similar disease definitions and sampling techniques (Schein et al. 1997; Lin et al. 2003; Uchino et al. 2011; Siak et al. 2012; Viso et al. 2012).

- Meibomian gland dysfunction appears to be more common in Asian populations.
- The prevalence of meibomian gland dysfunction is likely to increase with age and to be higher in the female population.

There have been few age-specific prevalence studies on MGD. There is limited consensus on the impact of age on MGD with Asian studies showing no impact of age. These generally confirm that MGD is the more common subtype and demonstrate a 2.5× higher rate of asymptomatic MGD compared to a Caucasian population.

However, it would be logical if dry eye disease prevalence increases with age, that MGD as the most common subtype of dry eye disease would most likely increase in prevalence with age. One Spanish study (Viso et al. 2012) looked at both asymptomatic and symptomatic MGD in over a thousand patients over 40. This study found that both asymptomatic and symptomatic MGD prevalence increased with age. The same study found that asymptomatic but not symptomatic MGD was more common in males than females. Again like age, very few gender-specific prevalence studies have been done on MGD. Overall most studies seem to point that dry eye disease is more common in women and that women are more at risk of severe dry eye disease. Again logically, since MGD is the most common subtype of dry eye disease, it could be expected that prevalence and severity of MGD should be higher in women.

**Table 2.1** Prevalence of all dry eyes (large cohort studies or records analyses)

Authors	Study duration	Region/country	Population studied	Age (years)	Definition	Denominator	Prevalence	95 % CI
Schein et al. (1997)	1993–1995	USA	2,420 participants in the Salisbury Eye Study	65 ≤	At least one (of six) symptoms occurring often or always	2,420	14.6 %	13.2–16.0 %
McCarty et al. (1998)		Australia	926 participants in the Melbourne Visual Impairment project. 493 females, 433 males	40 ≤	At least one (of six) symptoms (not attributed to hay fever) rated as severe	926	Symptoms 5.5 % 1.5–16.3 % objective tests	4.0–7.0 %
Moss et al. (2000)	1995–2005	USA	3,722 participants in the 5- and 10- year Beaver Dam Eye Study	63 ± 10 (48–91)	Self-report to questions "For the past 3 months or longer have you had dry eyes?"	2,414 (44 % men)	All subjects 21.6 % 48–59 17.3 % 80 < 28.0 %* Men 17.2 % Women 25.0 %*	19.9–23.3 %
Chia et al. (2003)	1999–2001	Australia	1,174 participants in the Blue Mountains Eye Study	60.8 (50–90)	At least one (of 4) symptoms, regardless of severity or at least 1 symptom rated either moderate or severe	1,075	16.6 % (at least one symptom) 15.3 % (3 or more symptoms)	14.3–18.7 % 13.1–17.5 %
Schaumburg et al. (2003)	1992–1996	USA	38,124 female participants in Women's Health Study	49–89	History of clinically diagnosed DED or severe symptoms constantly or often	36,995	7.8 % (age adjusted prevalence for women over 50)	7.5–8.1 %
Schaumburg et al. (2009)	1997–2004	USA	25,444 men, participants in Physicians Health Studies I or II	64.3 (50–90)	Clinically diagnosed dry eye or severe symptoms (both dryness and irritation constantly or often)	25,444	Men 4.3 % 50–54 3.9 % 80 < 7.7 %*	4.1–4.5 % 3.7–4.1 %
Galor et al. (2011)	2005–2010	USA	Data extracted from the Miami and Broward Veterans Affairs database. Total 16,862	21–90	International Classification of Disease, 9th edition, Clinical Modification (ICD-9-CM) code 375.15	16,862	All subjects 10 % Male 12 % Female 22 %	9.5–10.5 %
Viso et al. (2012)	2005–2006	Spain	1,155 from National Health Service Registry	63.6 ± 14.4 (40–96)	Symptoms and at least one of Schirmer test score ≤ 5 mm, TBUT ≤ 10 s, fluorescein staining score ≥ 1, and rose bengal score ≥ 3	654 (32.7 % males, 411 females 62.8 %)	All subjects 11 %	8.6–13.3 %
Paulsen et al. (2014)	2005–2008	USA	3,275 Beaver Dam Offspring Study (BOSS) participants. 1,789 females (54.9%)	21–84	Self-report of frequency and the intensity of symptoms and use of eyedrops at least once a day	3,275	14.5 % Men 10.5 % Women 17.9 %	13.3–15.7 %

Lee et al. (2002)	2001	Indonesia	1,058 selected from 100 households, predominantly rural population	21 ≤	At least one (of six) symptoms often or all of the time	1,058	Age adjusted rate 27.5 %	24.8–30.2 %
Lin et al. (2003)	1999–2000	Taiwan	2,038 participants in the Shihpai Eye Study	65 ≤	At least one (of 6) symptoms often or all of the time	1,361	21–29 19.2 % 60 < 30.0 % 33.7 %	15.0–23.5 % 20.1–39.5 % 32.4–34.9 %
Han et al. (2011)	2008–2009	Korea	657 (317 males (48.2%), 340 female (51.8%)). 346 urban and 311 rural participants	72 (65–95)	One + symptoms of dry eye often or most of the time, and at least one of: TBUT ≤ 10 s, Schirmer score ≤ 5 mm, and corneal staining ≥ grade 1	657	Age, gender, rural adjusted 33.2 %	28.8–37.3 %
Jie et al. (2009)	2001	Beijing, China	4,439 previous participants in the Beijing Eye study 2001	57 (40–84)	One + of the following: TBUT ≤ 10 s; Schirmer ≤ 5 mm; fluorescein staining ≥ 1, lid margin telangiectasia; and/or plugging of the gland orifices. OR TBUT ≤ 4 s or Schirmer ≤ 4 mm, or fluorescein staining ≥ 2	1,957 (1,112 females)	21 %	19.2–22.8 %
Zhang et al. (2012)	2010	Shandong, China	1,902 senior high school students		Either a previous diagnosis of DES or severe symptoms (both dryness and irritation constantly or often) per Schaumberg et al. (2003)	1,885 (958 male, 927 female)	23.7 %	21.8–25.6 %
Guo et al. (2010)	Jun–Sep 2006	Mongolia	2,112 native Mongolians (1,125 male (53.3%))	54.9 ± 11.7 (40–91)	One or more symptoms often or all the time	1,816	50.1 %	47.8–52.4 %
Uchino et al. (2011)	Feb – Mar 2010	Japan	3,294	40–≥ 80	Severe symptoms of DED (both ocular dryness and irritation either constantly or often or clinically diagnosed DED as reported by participants)	2,644 (1,211 men and 1,423 women)	21.6 % women 12.5 % men	19.5–23.9 % 10.7–14.5 %
Uchino et al. (2013)		Japan	561 Japanese young and middle aged office workers using VDTs	22–65	One or more symptoms of dry eye often or most of the time, and at least one of: TBUT ≤ 10 s, Schirmer ≤ 5 mm, and fluorescein staining ≥ grade 1	561 Office (187 women, 374 men)	18.7 % (women) 8.0 % (men)	13.4–25.1 % 5.5–11.3 %

Shaded studies represent those carried out in Asian populations

TBUT\* tear breakup time

\*Statistically significant effect of age or gender

**Table 2.2** Prevalence of evaporative dry eye

Authors	Study duration	Region/country	Population studied	Age range	Definition	Denominator	Prevalence	95 % CI
Viso et al. (2009)	May 2005–Mar 2006	Spain	1,155 from National Health Service Registry,	63.6±14.4 (40–96)	Viscous or waxy secretion or no secretion at all upon digital expression, lid margin telangiectasia, or plugging of the gland orifices	654 (32.7 %) 243 males, 411 females (62.8 %)	30.5 % In those with dry eye 45.8 %	26.9–34.1 % 34.8–57.2 %
Viso et al. (2012)	May 2005 – Mar 2006	Spain	619, 229 males (37 %) and 390 females (63 %)	63.4 (40–96)	One or more of: (1) absent, viscous or waxy white secretion upon digital expression; (2) presence of two or more lid margin telangiectases; and (3) plugging of two or more gland orifices	619	Asymptomatic MGD 21.9 % Symptomatic MGD 8.6 %	18.8–25.3 % 6.7–10.9 %
Siak et al. (2012)		Singapore	3,271 (51.8 % females) in the Singapore Malay eye study (SiMES)	40–79	Either lid margin telangiectasia or gland orifice plugging in at least one eye	3,271	56.3%	53.3–59.4 %
Lin et al. (2003)	1999–2000	Taiwan	2,038 participants in the Shihpai Eye Study	65≤	Telangiectasia at the lid margin or plugging of the gland orifices	1,361	60.8%	59.5–62.1 %
Molinari et al. (2000)	1999	USA	226 (113 active duty forces (ADF), 113 US veterans (USV))	23.2 for ADF 68.1 years for USV	Signs of inability to express; not clear, mildly turbid; mild hyperemia; exclusion cysts over meibomian gland orifices but with no symptoms only with mild irritation	113 ADF; 113 US USV	5.3 % MGD in ADF (all CL wearers) 14.2 % MGD in USV (non CL wearers)	1.7–9.4 % 7.8–20.6 %
Home et al. (1990)		USA	398	10–60≤	Cloudy or absent gland secretion upon repeated expression of the lower lid	398 (200 males, 198 females)	38.9 % 10–19; 18.2 % 20–29; 33.3 % 30–39; 40 % 40–49; 34.9 % 50–59; 51.4 % >60; 67.2 %	34.1–43.7

**Table 2.3** Risk factors for dry eye

Level of evidence		
Mostly consistent <sup>a</sup>	Suggestive <sup>b</sup>	Unclear <sup>c</sup>
Older age	Asian race	Cigarette smoking
Female sex	Medications	Hispanic ethnicity
Postmenopausal estrogen therapy	Tricyclic antidepressants	
Omega-3 and omega-6 fatty acids	Selective serotonin reuptake inhibitors	Anticholinergics
Medications	Diuretics	Anxiolytics
Antihistamines	Beta-blockers	Antipsychotics
Connective tissue disease	Diabetes mellitus	Alcohol
LASIK and refractive excimer laser surgery	HIV/HTLV1 infection	Menopause
Radiation therapy	Systemic chemotherapy	Botulinum toxin injection
Hematopoietic stem cell transplantation	Large incision ECCE and penetrating keratoplasty	
	Isotretinoin	Acne
Vitamin A deficiency	Low humidity environments	Gout
Hepatitis C infection	Sarcoidosis	Oral contraceptives
Androgen deficiency	Ovarian dysfunction	Pregnancy

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<sup>a</sup>Mostly consistent evidence implies the existence of at least one adequately powered and otherwise well-conducted study published in a peer-reviewed journal, along with the existence of a plausible biological rationale and corroborating basic research or clinical data

<sup>b</sup>Suggestive evidence implies the existence of either (1) inconclusive information from peer-reviewed publications or (2) inconclusive or limited information to support the association, but either not published or published somewhere other than in a peer-reviewed journal

<sup>c</sup>Unclear evidence implies either directly conflicting information in peer-reviewed publications or inconclusive information but with some basis for biological rationale

## 2.3 Risk Factors for Dry Eye Disease

Higher prevalence rates are consistently reported with:

1. Age
2. Female gender, estrogen therapy in postmenopausal women, and androgen deficiency
 

The meibomian glands are thought to be partially under hormonal influence with androgen/estrogen balance affecting function. A relative lack of androgen or relative excess of estrogen is thought to promote meibomian gland dysfunction.
3. Systemic antihistamines
4. LASIK and refractive surgery

Dry eye is a recognized complication due to refractive surgery. Disruption of the corneal sensory nerves leads to a relative neuro-

trophia and disruption of the normal lacrimal reflex arc.

5. Radiation therapy
6. Vitamin A deficiency
7. Hepatitis C infection
8. Hematopoietic stem cell transplantation

Ocular graft-versus-host disease can occur in patients after bone marrow transplantation.

A range of other risk factors with varying levels of evidence was proposed by this review (Table 2.3). Environmental factors not mentioned in Table 2.1 but frequently associated with dry eye are contact lens wear and computer/visual display terminal use. A significant proportion of contact lens wearers (50–75 %) experience dry eye symptoms, and this is a major reason for discontinuation of contact lens wear. Computer use may cause dry eye symptoms due to prolonged visual attention and an associated reduced blink rate.

## 2.4 Summary

The prevalence of dry eye disease may be as high as 33 % in some populations, with moderate to severe disease affecting 5–10 % of individuals. The frequency of DED varies considerably with diagnostic criteria for DED although there is concordance in the major risk factors identified from well-designed population studies. There are clearly significant societal costs associated with this major public health concern, particularly given the disease chronicity and limited management options, and these costs will escalate in the future with an aging population. Future directions will include the development of rational treatments based on better understanding of the disease pathophysiology and the design of studies to elucidate the impact of therapy on the economic costs of disease. Population-based studies should employ standardized classification criteria and outcome measures including biomarkers to better elucidate the epidemiology and natural history of different subtypes of dry eye.

**Compliance with Ethical Requirements** Fiona Stapleton, Qian Garrett, and Jennifer Craig declare that they have no conflict of interest. No human or animal studies were carried out by the authors for this article.

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