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ORIGINAL RESEARCH

The Prospective Health Assessment of Cataract Patients' Ocular Surface (PHACO) study: the effect of dry eye

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Purpose: To determine the incidence and severity of dry eye as determined by the International Task Force (ITF) scale in patients being screened for cataract surgery.

Patients and methods: This was a prospective, multi-center, observational study of 136 patients, at least 55 years of age, who were scheduled to undergo cataract surgery. The primary outcome measure was the incidence of dry eye as evaluated by grade on the ITF scale and secondary outcome measures include tear break-up time (TBUT), ocular surface disease index score, corneal staining with fluorescein, conjunctival staining with lissamine green, and a patient questionnaire to evaluate symptoms of dry eye.

Results: Mean patient age was 70.7 years. A total of 73.5% of patients were Caucasian and 50% were female. Almost 60% had never complained of a foreign body sensation; only 13% complained of a foreign body sensation half or most of the time. The majority of patients (62.9%) had a TBUT ≤5 seconds, 77% of eyes had positive corneal staining and 50% of the eyes had positive central corneal staining. Eighteen percent had Schirmer's score with anesthesia ≤5 mm.

Conclusion: The incidence of dry eye in patients scheduled to undergo cataract surgery in a real-world setting is higher than anticipated.

Keywords: cataract surgery screening, dry eye, International Task Force scale, observational study

Introduction

Despite the generally positive outcomes of cataract surgery, some patients are dissatisfied with their postoperative result due to a suboptimal refractive outcome that may be the result of unresolved issues on the ocular surface.[1–3] Ongoing and increasing awareness of these issues has led to anterior segment surgeons commonly performing an array of preoperative evaluations and prescribing treatments to optimize the ocular surface and ensure the health of the cornea and retina before patients undergo cataract surgery.[4] Even with the ocular surface evaluation performed preoperatively, the incidence of dry eye after phacoemulsification has been reported to be 9.8%.[5] Additionally, Cho and Kim found the type of wound created during cataract surgery could exacerbate patient-reported symptoms in those previously thought to be disease-free.[1]

The diagnosis of dry eye can be challenging, as some studies have found that nearly 50% of dry eye patients may show no corneal staining, despite other evidence of dry eye disease (increased tear osmolarity, reduced Schirmer's scores, or presence of dry eye symptoms).[6] Earlier studies showed that dry eye symptoms, such as blurred vision, are sometimes erroneously attributed to the cataract, which may contribute to the higher postoperative incidence.[7]

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Cataract surgery has been reported in the literature to induce dry eye and to exacerbate pre-existing dry eye.[1,2,5,8–14] Treatments for postoperative dry eye have been extensively reported in the literature and include nonsteroidal anti-inflammatory drugs, topical corticosteroids, artificial tears, topical cyclosporine 0.05%, lifitegrast, 3.0% diquafosol, 1% carboxymethylcellulose sodium, oral lactoferrin, oral doxycycline, punctal plugs, and autologous serum, among others.[3,8,10,15–24] Yet, little has been reported in the literature on the preoperative incidence of dry eye in a cataract population.

We hypothesized that the incidence of pre-existing dry eye disease in patients who are scheduled to undergo cataract surgery is higher than previously thought based on the published literature. The Prospective Health Assessment of Cataract Patients' Ocular Surface (PHACO) study sought to determine the incidence of dry eye and its severity (as determined by the International Task Force [ITF] scale)[25] in patients undergoing cataract surgery and to assess the signs and symptoms of dry eye in this patient population.

Patients and methods

This was a prospective, multicenter, observational study of 143 consecutive patients at least 55 years of age scheduled to undergo standard phacoemulsification cataract surgery in one or two eyes at one of nine clinical sites in the US and Canada. Exclusion criteria included any previous intraocular surgery in the previous 3 months before enrollment; subjects without visually significant cataract, corneal laser vision correction surgery in either eye in the previous year; previous lid surgery within 3 months; and use of topical antibiotics, topical nonsteroidal anti-inflammatory drugs, or topical steroid in either eye. Those subjects who had recently initiated topical cyclosporine 0.05% use for dry eye were excluded from study testing, but were asked to complete a questionnaire about medication use and any additional dry eye treatments (ie, warm compresses). Although lifitegrast is currently approved for the treatment of both signs and symptoms of dry eye, that pharmacologic treatment was not approved in the US at the time of this study.

Preoperatively, all eligible subjects underwent ocular surface testing in both eyes that included tear break-up time (TBUT), corneal and conjunctival staining (with fluorescein and lissamine green, respectively) according to the National Eye Institute (NEI) grid,[26] Schirmer's score evaluation with anesthesia,[27] Ocular Surface Disease Index (index range from 0–100),[28,29] and a patient questionnaire to assess dry eye symptoms (if any). For the purposes of this study, a TBUT >10 seconds was considered abnormal, with TBUT >5 seconds considered highly likely of dry eye symptoms.

In this study, corneal staining was evaluated under cobalt blue illumination 2.5–3 minutes after fluorescein instillation and conjunctival staining was performed 2.5–3 minutes after 10 µL of a 1% sodium lissamine green dye was instilled. Both of these followed the NEI scale.[26]

Written consent to publish their data was obtained from all patients prior to being enrolled in the study. This research was approved by the Institutional Review Board Company, Inc. (Buena Park, CA, USA). As this was an observational study, it was not powered to determine statistical significance. Similarly, there was no control arm as all subjects were predetermined to have visually significant cataract. All analyses were descriptive in nature and used StatView Software (SAS Institute, Cary, NC, USA).

Results

Patient demographics

There were 143 patients (286 eyes) scheduled to undergo routine cataract surgery who met the initial inclusion criteria. The mean age of the patients was 70.7±7.8 years (range: 54.5–87.9 years). Seven patients (4.9%) were using topical cyclosporine 0.05% at the time of presentation and were excluded from this analysis. Among the remaining 136 patients (272 eyes) included in this analysis, there were 100 Caucasian patients (73.5%), 15 Hispanic patients (11.0%), 11 Asian patients (8.1%), five black patients (3.7%), and five who identified their race as "other" (3.7%).

Thirty patients (22.1%) had received a prior diagnosis of dry eye but were not on prescription or over-the-counter treatments; 68 patients (50%) were male. If the previously excluded seven patients who were using topical cyclosporine 0.05% had been included in this analysis, the percentage of patients with a previous diagnosis of dry eye would increase to 25.9%.

The incidence of dry eye as evaluated by the ITF[25] level included 34 patients (25%) at level 0 and 39 patients (28.7%) at level 3 (Table 1).

Using the NEI scale to assess corneal staining,[7] 61 patients (44.9%) had a corneal staining score of ≥1. These same

Table 1 Incidence of dry eye as evaluated by ITF

ITF level	Number of patients	Percentage of cohort
0	34	25
1	27	19.9
2	36	26.5
3	39	28.7
4	0	0

Abbreviation: ITF, International Task Force.

patients had a cumulative score of ≤1 (on a scale of 1–4) in burning/stinging, foreign body sensation, dryness, and pain/soreness.

Similarly, the mean (± standard deviation) TBUT score was 4.95±2.5 seconds (range 0–15 seconds); 171 eyes (62.9%) had TBUT scores of ≤5 seconds; 58 eyes (21.3%) had Schirmer's scores of ≤5 mm (mean 12.4±7.3 mm; range 0–35 mm); and 209 eyes (76.8%) had positive fluorescein corneal staining scores (mean 4.3±3.5; range 0–15), with 136 eyes (50%) also showing positive central staining. The mean lissamine staining score was 0.92±0.61, with a range of 0–2.8 (Table 2).

Subjective analyses

All patients (N=136) completed a dry eye signs and symptoms questionnaire (Table S1). Patients were allowed to provide more than one response to each question. The majority (94/136; 69.1%) reported no stinging and burning. Eighty-six patients (63.2%) were never affected by the symptom of dryness; 80 patients (58.8%) reported no foreign body sensation; 73 patients (53.7%) reported no itching; 53 patients (39%) reported no sensitivity to light; 107 patients (78.7%) reported no pain/soreness; 46 patients (33.8%) reported no blurred vision; 50 patients (36.8%) reported blurred vision "some of the time"; and 65 patients (47.8%) reported their eyes never felt tired or fatigued.

When patients were asked about their employment and productivity on a daily basis, most reported missing 0–2 hours of work weekly due to health problems and the majority reported their health problems did not affect work productivity or daily activities.

Table 2 TBUT, Schirmer's score, and staining scores*

Testing method	Number of eyes N=272	Percentage of eyes
TBUT (n=268)		
≤5 seconds	171	62.9
>5 seconds	97	35.6
Missing	4	1.5
Schirmer's scores (n=272)		
≤5 mm	58	21.3
≤10 mm	214	78.7
Corneal staining (fluorescein) (n=271)		
Positive	209	76.8
Negative	62	22.8
Missing	1	0.4
Central staining (fluorescein) (n=271)		
Positive	136	50
Negative	135	49.6
Missing	1	0.4
Conjunctival staining (lissamine) (n=271)		
Mean	0.92	
Standard deviation	0.61	
Minimum	0	
Maximum	2.8	

Note: *Not all patients completed all preoperative corneal testing.
Abbreviation: TBUT, tear break-up time.

Discussion

In our observational study, fewer than 25% of patients had been previously diagnosed with dry eye when they presented for cataract surgery, yet 30% reported at least occasional symptoms (Table S1). Our results add to the literature findings of diagnosed dry eye prevalence rates between 3.5% and 33.7%.[30]

Dry eye is already considered both underdiagnosed and undertreated, and our findings support that belief.[16,31–43] It is now well accepted that people affected by dry eye are often more symptomatic than clinical tests may indicate,[44,45] and in our study, almost 45% had a corneal staining score of at least 1, but a cumulative score of ≤1 in traditionally reported subjective symptoms of dry eye including burning/stinging, foreign body sensation, dryness, and pain/soreness. This suggests that somewhere between 15% and 20% of our study population would have eluded the diagnosis of dry eye suspect/confirmed dry eye had they not presented for cataract surgery evaluation. The visual complications associated with dry eye are well reported, as is the risk of postoperative complications after cataract surgery in known dry eye patients.[9,46–55]

With more than 24 million Americans affected by cataracts,[56] there is an increased need to ensure preoperative evaluations encompass all aspects that may have a deleterious effect on postoperative outcomes. This should include an evaluation of the ocular surface, as suggested by the American Academy of Ophthalmology.[56]

Ten seconds has been the usual cutoff for an abnormal TBUT; some studies indicate 7 seconds will identify more patients with poor ocular surfaces,[57] and a cutoff of 5 seconds is generally accepted as definitive dry eye.[52]

In our study, the mean TBUT was 4.95 seconds and >80% of our patients had a TBUT of ≤7 seconds. Additionally, 76.8% of patients in our study were positive for fluorescein staining, while 50% showed positive central staining as well. A large number of eyes (n=95, 46.6%) had Schirmer's scores of ≤10. Our results suggest that more than one diagnostic test may be necessary to identify those with undiagnosed preoperative dry eye.

This study is not without its limitations. We included only those patients who were already identified with a visually significant cataract and did not include those in whom a cataract had not yet reached a visually significant level. The investigators were not masked to the findings, as all our patients

undergo these evaluations before being cleared for cataract surgery. We also did not include age-matched control subjects, as this study was designed to be observational and not interventional. These decisions may have skewed our results in that our patient population was older and more likely to have dry eye. However, we attempted to compensate for that by eliminating patients who were already diagnosed with dry eye and were on a prescription treatment from our analysis. It is interesting to note, however, that only seven patients were actively being treated, although substantially more (n=30) had been previously diagnosed, adding to our supposition that if dry eye is not being actively screened for in this patient population, it may be overlooked altogether. Although the study had strict exclusion criteria to eliminate other disorders and known treatments that are associated with dry eye or its treatment (such as topical steroid use), we did not exclude patients who used antihistamines, antidepressants, or anticholinergic drugs because the literature has shown that while the latter may have an association with dry eye, different drugs within those classes may alleviate, exacerbate, or have no effect on dry eye.[58–63] It was not the purpose of this study to determine the cause of dry eye, just to ascertain its presence.

The evaluations were conducted at a time when newer diagnostic modalities such as tear osmolarity and methods to detect the presence of inflammatory markers were not available. It is possible that the true incidence of dry eye might have been even higher had those modalities been included in the overall assessment. Finally, as an observational study, it is subject to all the potential biases inherent with these types of evaluations.

However, this study also has numerous strengths. Enrolled patients had already undergone extensive preoperative assessment, both of their cataract and of their overall ocular health, consistent with commonly used cataract assessment parameters. As such, patients with known dry eye or presumed dry eye that may be the result of glaucoma medication use, or disorders such as meibomian gland dysfunction, chronic conjunctivitis, or trichiasis, would have been excluded from our analysis. To our knowledge, this is the first study to evaluate preoperative levels of dry eye in a real-world cataract population, regardless of a previous diagnosis or lack thereof. We encourage further exploration on our findings, especially as they may relate to potential cataract surgery outcomes.

Conclusion

The percentage of prospective cataract patients who have signs or symptoms of dry eye continues to be underreported; increased awareness should lead to careful monitoring of the patient's ocular health both before and after surgery.

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Author contributions

WBT, PAM, EDD, MBM, KGS, and DFG conducted the study; WBT, PAM, EDD, MBM, KGS, and DFG analyzed data and revised the paper; and WBT, PAM, EDD, MBM, KGS, and DFG reviewed and approved the manuscript.

Disclosure

None of the authors have a financial interest in any product mentioned, but all are consultants to Allergan. In addition, EDD, MBM, KGS, and WBT are consultants to Shire. The authors report no other conflicts of interest in this paper.

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Supplementary material

Table S1 Dry eye signs and symptoms

Parameter evaluated	n	%
Stinging and burning		
Frequency		
None of the time	94	69.1
Some of the time	32	23.5
Half of the time	4	2.9
Most of the time	4	2.9
All of the time	2	1.5
How bothered by each symptom? (0=not at all; 4=extremely)		
0	90	69.2
1	19	14.6
2	13	10.0
3	5	3.8
4	3	2.3
Dryness		
Frequency		
None of the time	86	63.2
Some of the time	29	21.3
Half of the time	11	8.1
Most of the time	6	4.4
All of the time	4	2.9
How bothered by each symptom? (0=not at all; 4=extremely)		
0	82	63.6
1	23	17.8
2	13	10.1
3	6	4.7
4	4	3.1
Foreign body sensation		
Frequency		
None of the time	80	59.3
Some of the time	38	28.1
Half of the time	4	3.0
Most of the time	10	7.4
All of the time	3	2.2
How bothered by each symptom? (0=not at all; 4=extremely)		
0	75	58.1
1	34	26.4
2	8	6.2
3	8	6.2
4	4	3.1
Itching		
Frequency		
None of the time	73	54.1
Some of the time	47	34.8
Half of the time	12	8.9
Most of the time	1	0.7
All of the time	2	1.5
How bothered by each symptom? (0=not at all; 4=extremely)		
0	72	55.0
1	33	25.2
2	19	14.5
3	2	1.5
4	5	3.8
Sensitivity to light		
Frequency		
None of the time	53	39.6
Some of the time	40	29.9
Half of the time	11	8.2
Most of the time	13	9.7
All of the time	17	12.7
How bothered by each symptom? (0=not at all; 4=extremely)		
0	50	38.5
1	35	26.9
2	26	20.0
3	8	6.2
4	11	8.5
Painful/sore		
Frequency		
None of the time	107	78.7
Some of the time	21	15.4
Half of the time	5	3.7
Most of the time	1	0.7
All of the time	2	1.5
How bothered by each symptom? (0=not at all; 4=extremely)		
0	103	79.2
1	11	8.5
2	10	7.7
3	3	2.3
4	3	2.3
Blurred vision		
Frequency		
None of the time	46	34.1
Some of the time	50	37.0
Half of the time	11	8.1
Most of the time	14	10.4
All of the time	14	10.4
How bothered by each symptom? (0=not at all; 4=extremely)		
0	44	33.6
1	28	21.4
2	30	22.9
3	14	10.7
4	15	11.5
Tired/fatigued eyes		
Frequency		
None of the time	65	47.8
Some of the time	51	37.5
Half of the time	9	6.6
Most of the time	7	5.1
All of the time	4	2.9
How bothered by each symptom? (0=not at all; 4=extremely)		
0	67	50.8
1	31	23.5
2	21	15.9
3	8	6.1
4	5	3.8

Note: Not all eligible patients (N=136) answered every question.