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A Novel Patient-Reported Outcome Instrument For Meibomian Gland Dysfunction Disease Impact

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OBJECTIVE

To report the results of the Meibomian Gland Dysfunction Impact Questionnaire (MGD IQ), developed using FDA guidance in a prospective, exploratory study.

CONCLUSIONS

MGD has a significant impact on ocular symptoms and vision related activities.

The MGD IQ demonstrated that patients are impacted by vision related activities, which increased with severity.

This novel MGD IQ instrument can help characterize severity and amplify the patient's voice on burden of disease.

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INTRODUCTION

- Meibomian Gland Dysfunction (MGD) is a chronic disease that affects tear film instability leading to ocular irritation and dry eye.
- There is a need to characterize the severity of signs and symptoms of MGD using clinical and patient-reported outcomes.
- We report the results of the MGD Impact Questionnaire (MGD IQ), developed using FDA guidance and utilized to characterize the severity of disease impact on vision related activities.

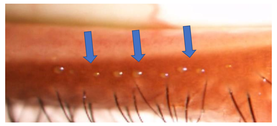


Figure 1: Non-MGD; clear excreta of the central meibomian glands

Figure 2: Mild/Moderate MGD; glands demonstrate opaque excreta with increased viscosity (gel-like)

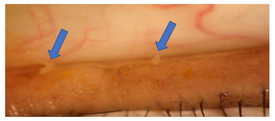


Figure 3: Severe MGD; glands demonstrate waxy excreta with few expressible glands

METHODS

- Prospective, multicenter, non-interventional study with three cohorts based on standard criteria (no MGD, mild/moderate MGD, severe MGD).
- The MGD IQ included 10 items on a Likert scale measuring the difficulty of vision related activities due to MGD and DED.
- Pairwise comparisons between levels of MGD severity were performed using the Cochran Mantel-Haenszel method, and the weighted Kappa statistics was used for agreement.
- Given the variability in the signs and symptoms in subjects with DED, 2 subject visits (Day 1 and 22) were included in the study to assess the degree of concordance between the two sets of outcome measurements.

Table 1: Criteria For Study Group Assignments

Group	MMQS[a]	Schirmer Test Without Anesthesia[a]	Sum Of Worst Two Symptom Scores On The SOSQ
Non-MGD	0 or 1[b]	≥ 7 mm/5 min	0 to 4 with neither symptom scored as > 2
Mild-To-Moderate MGD	2[b]	≥ 7 mm/5 min	0 to 4 with neither symptom scored as > 2
Severe MGD	3	≥ 7 mm/5 min	≥ 4

[a]MMQS and Schirmer test criteria must be met in the same eye
[b]No gland among the 6 central glands being graded may have a meibum quality score greater than the MMQS specified in the cohort designation
MGD = meibomian gland dysfunction; MMQS = maximum meibum quality score among the 6 central glands in the lower lids being graded by the investigator (higher scores indicate lower quality of the secretion); SOSQ = subject ocular symptom questionnaire; min = minute

RESULTS

Table 2: Subject Demographic Characteristics

	Non-MGD (N = 25)	Mild/Moderate MGD (N = 25)	Severe MGD (N = 25)
Mean (SD) Age:	52.0 (8.34)	52.8 (6.26)	58.8 (11.86)
< 45	4 (16.0%)	4 (16.0%)	3 (12.0%)
45-65	19 (76.0%)	21 (84.0%)	17 (68.0%)
> 65	2 (8.0%)	0	5 (20.0%)
Sex:			
Male	9 (36.0%)	9 (36.0%)	7 (28.0%)
Female	16 (64.0%)	16 (64.0%)	18 (72.0%)
Race:			
Caucasian	13 (52.0%)	6 (24.0%)	4 (16.0%)
Black	7 (28.0%)	15 (60.0%)	11 (44.0%)
Asian	1 (4.0%)	1 (4.0%)	2 (8.0%)
Hispanic	1 (4.0%)	2 (8.0%)	8 (32.0%)
Other	3 (12.0%)	1 (4.0%)	0

MGD = meibomian gland dysfunction; SD = standard deviation

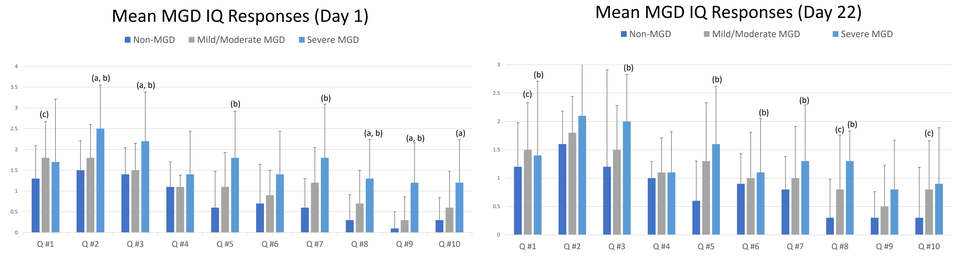
MGD IQ Questions:

In the past 7 days . . .

(1). . . how much difficulty did you have working on the computer…
(2). . . how much difficulty did you have reading . . .
(3). . . how much difficulty did you have doing leisure activities (e.g., watching TV) . . .
(4). . . how much difficulty did you have participating in social activities . . .
(5) . . .how much difficulty did you have driving . . .
(6) . . .how much difficulty did you have doing outdoor activities (e.g., swimming) . . .
(7). . . how often did you have difficulty doing outdoor activities . . .
(8). . . how much time did you spent taking care of your eyes . . .
(9). . . how bothered were you by the amount of time spent taking care of your eyes . . .
(10). . .how bothered were you by the appearance of your eyes . . .

. . . because of your MGD?

Figure 4: Mean (SD) of Responses To MGD IQ



MGD IQ = meibomian gland dysfunction impact questionnaire; SD = standard deviation; CMH = Cochran-Mantel-Haenszel; MGD = meibomian gland dysfunction, bars represent positive standard deviation

[a]p < 0.05, severe MGD cohort vs mild/moderate MGD cohort
[b]p < 0.05, severe MGD cohort vs non-MGD cohort
[c]p < 0.05, mild/moderate MGD cohort vs non-MD cohort

SUMMARY

- Incremental increases in scores were observed with increasing MGD severity at both visits with 8/10 questions in the MGD IQ.
- Comparisons of responses showed significantly higher scores (p = <0.001 to 0.044) at Days 1 and 22 for 4 questions between the severe and non-MGD cohorts.
- Additionally, responses showed significantly higher scores (p = 0.005 to 0.045) at Day 1 for the severe MGD cohort compared to the mild/moderate MGD cohort for 5 questions.
- Agreement between visits for MGD IQ responses ranged from 0.33 to 0.58, indicating fair to moderate agreement.

Figure 5: Normal Meibomian Glands

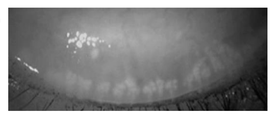


Figure 6: Meibomian Gland Dysfunction