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Patient Reported Outcomes in Microbial Keratitis

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Abstract

Purpose: The aim of this investigation is to study patient reported outcomes of patients with microbial keratitis (MK) using the 9-item National Eye Institute Visual Function Questionnaire (NEI VFQ-9).

Methods: Using the Sight Outcomes Research Collaborative (SOURCE) ophthalmology electronic health record repository, patients with MK and control patients who completed the NEI VFQ-9 within 7 days of their appointment were identified. The questionnaire is scored as a mean of the 9 items on a scale from 0 to 100, with higher scores indicating better functioning. Composite and individual item scores were compared between groups using analysis of variance (ANOVA).

Results: 916 questionnaires were completed from patients with acute MK (n=83), non-acute MK (n=30), MK with a corneal transplant (n=22), from controls seen in a satellite comprehensive ophthalmology clinic (n=528), and controls seen at a sub-specialty ophthalmology clinic (n=253). The mean NEI VFQ-9 composite score per group was 66.2 (standard deviation, SD = 26.8), 78.1 (SD = 17.1), 60.3 (SD=22.4), 88.0 (SD = 10.2), and 83.5 (SD = 13.0), respectively (p<0.0001). Both acute MK patients and MK patients requiring transplant reported significantly worse function than non-acute MK, comprehensive, and specialty patients. Non-acute MK patients reported significantly worse function than comprehensive control patients (all Tukey-adjusted p<0.05).

Discussion: Patients who had or eventually require corneal transplant for management of their MK report worse visual function than patients with non-acute MK. This may be important in helping physicians counsel their patients.

Keywords

Microbial keratitis; Patient Reported Outcomes; Corneal Transplant

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Microbial keratitis (MK) is a corneal infectious disease with varied pathologies, presentations, and severities.¹ The prevalence of MK and the inciting pathogen are influenced by a combination of climate, hygiene, ocular, and systemic risk factors.¹⁻⁶ In 2010, MK resulted in 930,000 clinic visits and 58,000 emergency department visits in the United States (US).⁷ In 2012, an estimated one out of five patients who had been hospitalized in the US for MK required a corneal transplant⁸ and a 2018 estimate of the global disease burden of MK exceeded two million cases annually.⁹

Patient reported outcomes (PROs) are “any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else.”¹⁰ PROs can be obtained electronically or from a paper survey.^{10,11} Of course, objective clinical measures (e.g., visual acuity, infiltrate size) are critical for health assessment, but PROs are increasingly being used as a measure of symptoms and function in clinical trials, such as monitoring surgical and medical retina disease outcomes.^{12,13}

The National Eye Institute-Visual Function Questionnaire (NEI VFQ-25) is a tool designed to measure patients’ perception of visual function and quality of life.^{14,15} The 25-item NEI VFQ has been used in a randomized control trial of fungal MK to investigate outcomes after different antifungal treatments.¹⁶ In a prospective study, the Chinese version was used to look at vision-related quality of life in infectious keratitis and its correlation to visual acuity and duration of disease.¹⁷

Kodjebacheva et al. published a validated shortened version of this survey, the NEI VFQ-9.¹⁸ This 9-item version covers the following functional domains: general vision, near vision, distance vision, driving, peripheral vision, role limitation, and mental health.¹⁸ The purpose of this investigation was to evaluate PROs from the NEI VFQ-9 in a cohort of patients with MK compared to a control sample.

Methods

Starting in September 2017, all ophthalmology patients seen at the University of Michigan, Kellogg Eye Center were assigned the NEI VFQ-9 at least annually. The 9 items ask about visual function on a Likert scale, where each response is scored from 0 (worse visual function) to 100 (better visual function). The overall composite score is calculated as the mean of the item scores. Questionnaires are self-administered and completed electronically before an appointment through the patient portal or during the appointment using a tablet.

Using ICD-9 and ICD-10 codes (Appendix 1), patient encounters with an associated diagnosis of MK were identified in the Sight Outcomes Research Collaborative (SOURCE) ophthalmology electronic health record (EHR) repository from September 2017 to May 2019. The encounters were included if an NEI VFQ-9 had been completed within 7 days of that appointment. For patients with >1 encounter with an NEI VFQ-9 and a diagnosis of MK, the first encounter was selected. MK patients were categorized as follows: (1) acute MK infection (NEI VFQ-9 was completed within 30 days of initial MK diagnosis), (2) non-acute MK infection (NEI VFQ-9 was completed >30 days from initial MK diagnosis), and

(3) MK patient who also underwent a corneal transplant (penetrating keratoplasty, PKP, or deep anterior lamellar keratoplasty, DALK; Appendix 1). A control group of patients who completed the NEI VFQ-9 within 7 days of an appointment were identified from a satellite comprehensive ophthalmology clinic. For control patients with >1 visit with an NEI VFQ-9, the first visit was selected. Control patients were subdivided based on whether they saw a comprehensive ophthalmologist or a specialist (cornea or glaucoma). Any patient in the control sample with a history of MK was excluded to maintain independent groups.

Statistical Methods:

Patient demographics and NEI VFQ-9 scores were summarized with descriptive statistics (mean, standard deviation [SD], frequency, percentage) separately for the MK and control patient cohorts. Stacked bar charts and boxplots were used to display the distribution of NEI VFQ-9 responses at the item level and the overall composite score, respectively. Group differences were tested with Chi-square tests, Fisher's exact tests, Kruskal-Wallis tests, and analysis of variance (ANOVA). Significant Kruskal-Wallis or ANOVA results were followed by post-hoc pairwise comparisons with Tukey adjustment. Univariate and multivariable linear regression models were used to assess factors associated with NEI VFQ-9 composite scores. Variables investigated included age, sex, race, and insurance type. SAS version 9.4 was used for all statistical analysis (SAS institute; Cary, NC).

Results

A total of 12,250 ophthalmology patients completed at least 1 NEI VFQ-9 over the 21-month period, of which 99% (12,165 of 12,220) had completed one survey within 7 days of an appointment (Figure 1). Patients include those with acute MK (n=84), non-acute MK (n=30), MK with cornea transplant (n=21), comprehensive patients (n=528), and comprehensive patients who saw a specialist (n=253). Patients with an NEI VFQ-9 but not selected for inclusion in this study (n=11,249) were subjects with a diagnosis other than MK and who were seen in a specialty ophthalmology clinic. Because questionnaires were not necessarily filled out at initial MK diagnosis, rather simply a visit with an MK diagnosis, the timing of the questionnaire could be before or after a transplant (range: 0.6 years [223 days] before to 4.3 years after a graft, in the 21 MK patient with transplant). No significant differences between the study groups were found with respect to gender (p=0.48) or ethnicity (p=0.51; Table 1). However, patients seen in the comprehensive clinic by a specialist were significantly older (mean=63.3, SD=15.5) than all other patient groups (acute MK: mean=55.0, SD=18.6; non-acute MK: mean=53.4, SD=15.6; MK with cornea transplant: mean=51.6, SD=15.8; comprehensive patients: mean=52.9, SD=18.9; p<0.0001). A smaller percentage of patients with MK were Black or other minority races (11.0% acute MK, 10.0% non-acute MK, 14.3% MK with corneal transplant) compared to control patients (25.6% comprehensive, 18.9% specialist; p=0.0055). MK patients who had corneal transplant showed a smaller percentage having commercial insurance compared to non-acute MK patients, comprehensive control patients, and specialty satellite clinic patients (52.4% versus 86.7%, 76.8%, and 69.4%, respectively; p=0.0015).

The distribution of NEI VFQ-9 item and composite scores are displayed in Figures 2 and 3. A smaller percentage of MK patients who also had corneal transplants endorsed better visual function responses on all 9 items of the NEI VFQ-9 compared to all other MK patient groups and controls. For example, when asked how much difficulty they had noticing objects off to the side while walking along, only 4.8% of MK patients who had corneal transplants endorsed “no difficulty at all”. In comparison, 45.1% of acute MK patients, 72.4% of non-acute MK patients, 86.8% of general comprehensive patients, and 75.3% of specialty satellite clinic patients endorsed “no difficulty at all.” Alternatively, a larger percentage of the general comprehensive patients reported better visual functioning responses on all 9 items of the NEI VFQ, compared to the other patient cohorts. In addition, a larger percentage of non-acute MK patients reported better visual functioning responses on 7 of 9 items of the NEI VFQ-9 than acute MK patients.

Table 2 presents summary scores for the NEI VFQ-9 by patient cohort. The mean NEI VFQ-9 composite score was 66.6 (SD=26.8) for acute MK patients, 78.1 (SD=17.1) for non-acute MK patients, 58.6 (SD=21.6) for MK patients with corneal transplant, 88.0 (SD=10.2) for general comprehensive patients, and 83.5 (SD=13.0) for specialty satellite clinic patients (ANOVA $p<0.0001$). Post-hoc pairwise comparisons showed acute MK patients reported significantly worse visual function than non-acute MK patients, comprehensive patients and specialty clinic patients (all Tukey-adjusted $p<0.05$) but reported similar visual function to MK patients who also had corneal transplants. MK patients requiring corneal transplant reported significantly worse visual function than non-acute MK patients, and comprehensive and specialty clinic patients (all Tukey-adjusted $p<0.05$). Non-acute MK patients reported significantly worse visual function than both types of control patients (all Tukey-adjusted $p<0.05$). Individual items of the NEI VFQ-9 showed significantly worse visual function in acute MK patients compared to both control samples (comprehensive ophthalmology and specialist ophthalmology patients; all Tukey-adjusted $p<0.05$).

Univariable and multivariable linear regression models of the composite NEI VFQ-9 score are presented in Table 3. Univariate models found older age ($p<0.0001$), Medicare insurance (versus commercial insurance, $p<0.0001$), and female sex ($p=0.02$) were all associated with reporting worse visual function. Patients of Other race reported significantly better visual function ($p=0.02$) compare to those who were White. Patients with acute MK, non-acute MK, MK with corneal transplant, and those who saw a specialist in the satellite clinic, all reported significantly worse visual functioning compared to comprehensive ophthalmology patients, by 21.4, 9.9, 29.3, and 4.5 points, respectively (all $p<0.05$). After adjusting for age, insurance type, and sex, similar findings in reported visual function were observed between patient groups (multivariable model, Table 3; all $p<0.05$). Specifically, patients with acute MK, non-acute MK, MK with corneal transplant, and those who saw a specialist in the satellite clinic, all reported significantly worse visual functioning compared to comprehensive ophthalmology patients, by 21.6, 9.8, 28.6, and 2.8 points, respectively (all $p<0.05$, after adjustment for age, sex, and insurance type).

Discussion:

MK is an acute vision-threatening infection of the cornea. As such, the impact on patients' function and quality of life must be considered. Published literature regarding PROs in patients who experience MK is limited. This study demonstrates the self-reported visual function loss associated with MK for patients followed at an academic center.

Patients in this cohort with acute MK reported significantly worse visual function as compared to 3 of the remaining 4 patient groups studied. This included control groups of patients with and without specialist care, and patients with non-acute MK—which likely includes both chronic and inactive infections. Previous studies have found a relationship between disease duration of MK and NEI VFQ scores.¹⁷ This study looked at the interval between diagnosis of MK and NEI VFQ score rather than disease duration. Patients with acute MK had significantly worse NEI-VFQ scores, perhaps because they had experienced a recent decrease in visual function and higher severity of symptoms as compared to those with non-acute MK in which patients may have recovered visual function or have had time to adapt their lives to their new level of visual function. This decrease in PRO score is not necessarily reflective of the expected disease duration rather that these patients are at the early stage of their disease course.

Another important finding is that patients with a history of both corneal transplant and MK have significantly lower self-reported visual function than patients with non-acute MK. This is consistent with a prior study that found that generally, corneal transplant recipients had decreased vision-related quality of life.¹⁹ Our study likely captures both the impaired vision-related quality of life caused by both MK and corneal transplant. This is likely confounded by the fact that the corneal transplant patients likely had more severe disease at baseline (necessitating the corneal transplant) or may have ongoing issues with their transplant; however, it highlights nonetheless that patients with histories of MK and a corneal transplant have significantly worse quality of life.

These results show that MK has significant effects on vision-related quality of life across the course of disease. Both acute and non-acute MK patients showed significantly reduced NEI VFQ-9 composite scores compared to general comprehensive patients. While a prior study also examined NEI VFQ-25 scores in MK patients, these patients were enrolled in a clinical trial in which the NEI VFQ was captured at prespecified time points.¹⁶ Our study captures NEI VFQ-9 responses at a spectrum of time points in the clinical course showing that patients have a diminished quality of life across many stages of MK. This reduced quality of life is likely in large part due to the pain and vision loss related to the MK. There is also a significant treatment burden associated with MK due to the high quantity of drops prescribed and cost of treatment.²⁰ MK patients may also have psychological burden from their disease. A lower PRO score has been found to be associated with worse psychological attitudes of patients towards their own health,²¹ as well as depression independent of vision, mental status, and general health.²²

MK has similar effects on visual function and perceived quality of life as chronic ophthalmologic conditions. Our study found that patients report an average NEI VFQ-9

composite score of 66 for acute MK, and 78 for non-acute MK. Patients with dry eye reported an average NEI VFQ-25 scores of 88, displaying better functioning than those with MK.²³ Other ophthalmic diseases have similar impairment in visual function to MK such as diabetic macular edema (composite score of 78),²⁴ chronic cataract (73),²⁵ and retinitis pigmentosa (63).²⁶ Comparing NEI VFQ-25 scores to NEI VFQ-9 scores is not perfect but reasonable due to the same scale and mean scoring, but the comparison should be interpreted with caution.

This study has limitations. First, the NEI VFQ-9 was given automatically through the electronic health record without targeting a specific population. MK severity undoubtedly has an effect on patient's visual function. The lack of a published definition of MK severity meant we had to use surgical indications and time since diagnosis as a method to stratify patients on their disease severity. Lastly, the non-acute MK group in this study includes a wide variety of MK patients, ranging from inactive disease to chronic MK. The heterogeneity of this group with respect to disease severity and stages of healing limits the conclusions we can make about this group specifically, but still allows for valid comparisons between groups.

MK has a direct impact on patients' perceived quality of life. Although MK is an acute eye condition, it can have short-term and long-term effects on patients' quality of life, visual function, and independence. Capturing quality of life metrics allows clinicians to individualize care by understanding a patient's health from their perspective. This could help providers tailor management and treatments to respond to patient's reported functional limitations.

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Acronyms:

MK	Microbial Keratitis
EHR	Electronic Health Record
PROs	Patient Reported Outcomes
NEI VFQ	National Eye Institute Visual Function Questionnaire
PKP	Penetrating Keratoplasty
DALK	Deep Anterior Lamellar Keratoplasty

Appendix 1

Diagnosis codes used to identify microbial keratitis in the electronic health record:

ICD-9: 370.00, 370.03, 370.03, 370.04, 370.04, 370.04, 370.04, 370.05, 370.05, 370.05

ICD-10: H16.009, H16.009, H16.002, H16.001, H16.002, H16.001, 370.00, H16.003, H16.001, H16.002, H16.009, H16.009, H16.009, 370.03, H16.012, H16.031, H16.032, H16.039, H16.039, H16.069, H16.061, H16.069, H16.012, H16.032

Current procedural terminology (CPT) codes used to identify penetrating keratoplasty (PKP) or deep anterior lamellar keratoplasty (DALK) in the electronic health record:

PKP: 65730, 65750, 65755

DALK: 65710

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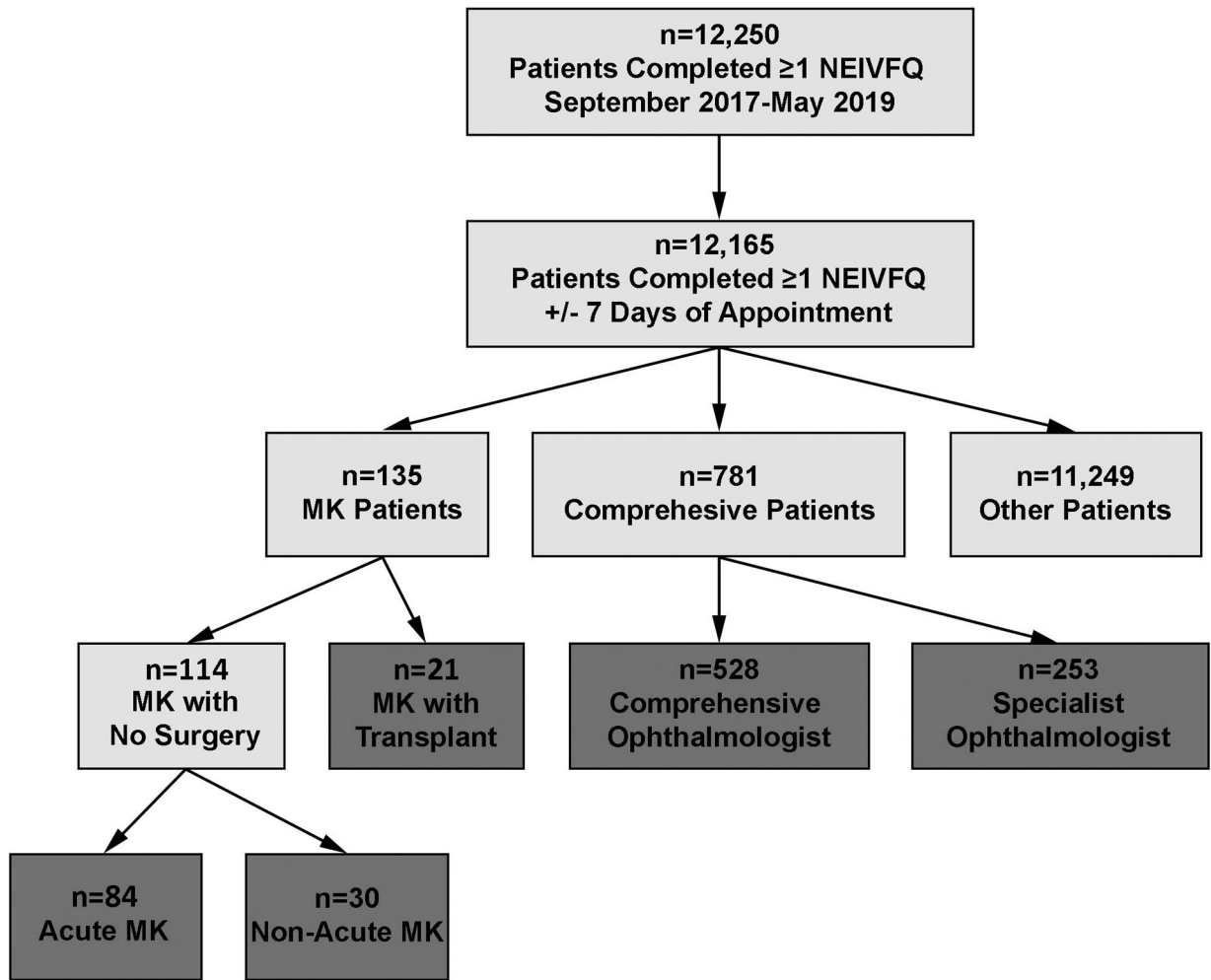


Figure 1.
Flow chart for selection of patient cohorts
MK, Microbial Keratitis; NEI VFQ, National Eye Institute Visual Function Questionnaire

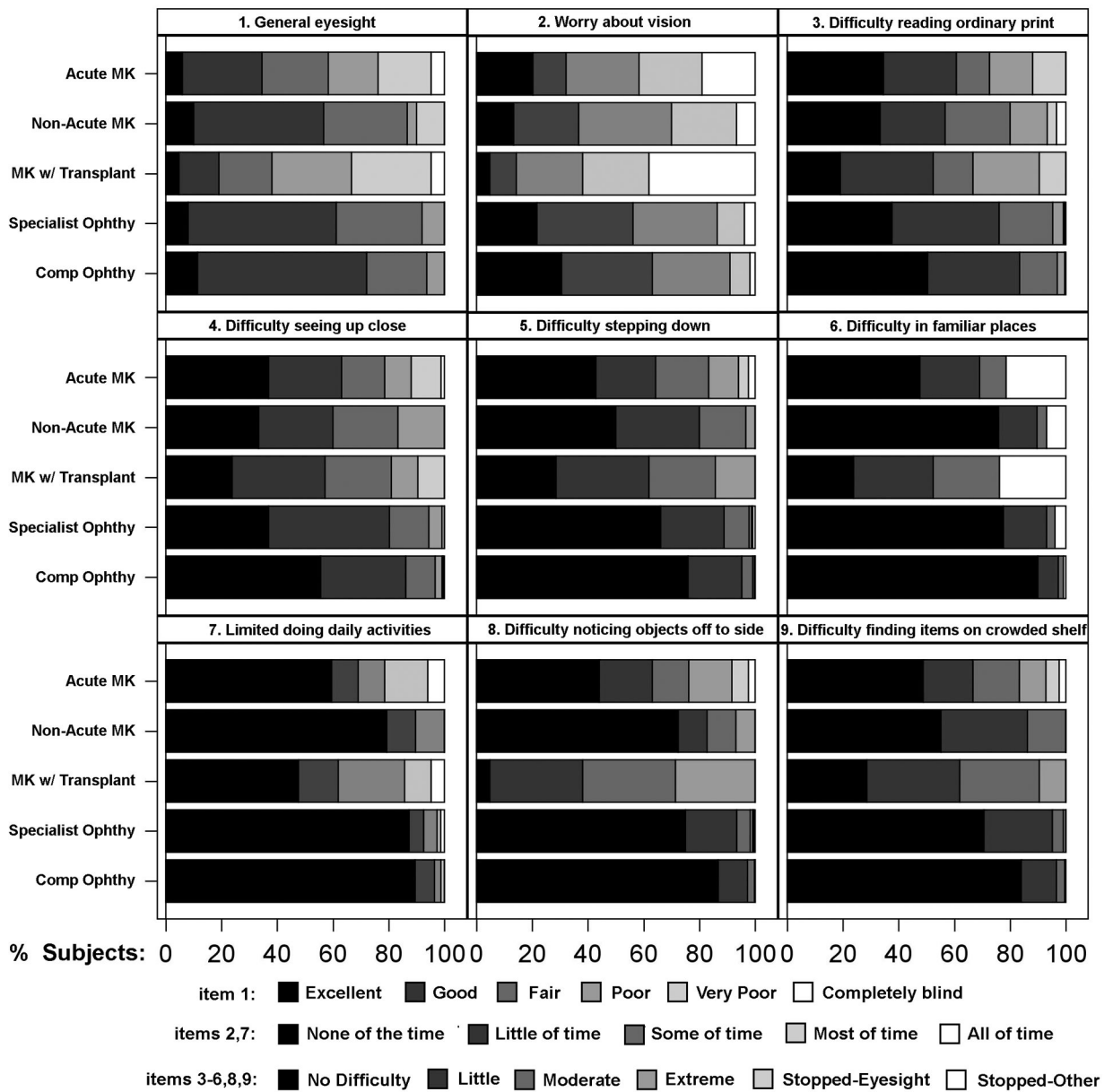


Figure 2.
Stacked bar charts showing the distribution of responses to each item of the 9-item National Eye Institute Visual Function Questionnaire (NEI VFQ-9), stratified by patient cohort

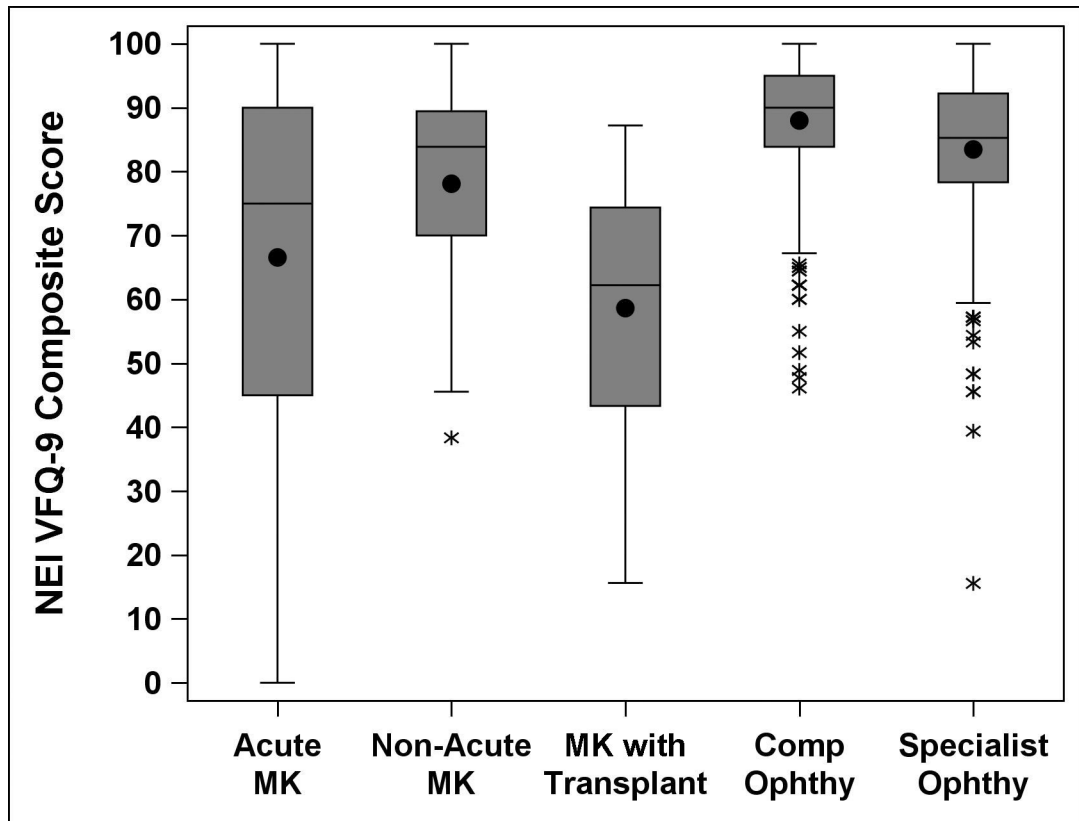


Figure 3. Side-by-side boxplots displaying the distribution of NE IVFQ-9 composite scores by patient cohorts. Boxplots display means (black dot inside box), medians (horizontal line within box), interquartile range (IQR, bottom of box to top of box), outliers (asterisks, observations outside 1.5 times the IQR). NEI VFQ, National Eye Institute Visual Function Questionnaire; MK, Microbial Keratitis; Comp; Comprehensive; Ophthy, Ophthalmology

Table 1.

Descriptive statistics of patient demographics stratified by patient cohorts

Categorical Variable	Acute MK (n=84)		Non-Acute MK (n=30)		MK with Transplant (n=21)		Comprehensive/No Specialist (n=528)		Comprehensive/Specialist (n=253)		P-value*
	#	%	#	%	#	%	#	%	#	%	
Gender											
Female	53	63.1	20	66.7	10	47.6	308	58.3	140	55.3	0.4765
Male	31	36.9	10	33.3	11	52.4	220	41.7	113	44.7	
Race											
White	73	89.0	27	90.0	18	85.7	384	74.4	198	81.2	0.0055
Black or Other	9	11.0	3	10.0	3	14.3	132	25.6	46	18.8	
Ethnicity											
Hispanic	2	2.4	2	7.1	0	0.0	14	2.8	5	2.1	0.5142
Non-Hispanic	82	97.6	26	92.9	20	100.0	482	97.2	237	97.9	
Insurance											
CAID	3	3.9	0	0.0	1	4.8	3	0.6	0	0.0	0.0015
CARE	17	22.1	4	13.3	9	42.9	116	22.6	77	30.6	
COMM	57	74.0	26	86.7	11	52.4	394	76.8	175	69.4	
Continuous Variable	Mean (SD)	Min, Max	Mean (SD)	Min, Max	Mean (SD)	Min, Max	Mean (SD)	Min, Max	Mean (SD)	Min, Max	p-value**
Age (years)	55.0 (18.6)	18.3, 93.7	53.4 (15.6)	22.7, 88.9	51.6 (15.8)	22.2, 78.5	52.9 (18.9)	18.1, 90.8	63.3 (15.5)	18.4, 95.8	<0.0001***

MK, Microbial Keratitis; CAID, Medicaid; CARE, Medicare; COMM, Commercial; SD, Standard Deviation; Min, Minimum; Max, Maximum;

* Chi-square test or Fisher's Exact test (when cell counts <5).

** ANOVA;

*** post-hoc pairwise comparisons with Tukey adjustment show average age of patients seeing a specialist at the comprehensive clinic are significantly older than all other groups (all p<0.05)

Table 2.

Descriptive statistics of 9-item National Eye Institute Visual Function Questionnaire responses and composite score, stratified by patient cohorts

NEIVFQ	Acute MK (n=84)		Non-Acute MK (n=30)		MK with Transplant (n=21)		Comprehensive Ophthy (n=528)		Specialist Ophthy (n=253)		P-value *
	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	
General eyesight	54.0 (27.0)	60.0	68.7 (21.5)	80.0	44.8 (26.0)	40.0	75.4 (14.6)	80.0	72.2 (15.0)	80.0	<0.0001 ^{a,c,d,e,h,i}
Worry about vision	47.9 (34.8)	50.0	53.3 (28.4)	50.0	29.8 (30.2)	25.0	70.7 (25.1)	75.0	65.1 (26.3)	75.0	<0.0001 ^{b,c,d,e,f,h,i}
Difficulty reading ordinary print	64.0 (35.2)	75.0	68.1 (29.8)	75.0	57.1 (32.7)	75.0	82.8 (20.5)	100.0	77.4 (21.8)	75.0	<0.0001 ^{c,d,f,h,i,j}
Difficulty seeing up close	67.5 (33.8)	75.0	69.2 (27.6)	75.0	63.1 (31.2)	75.0	84.8 (20.2)	100.0	77.7 (21.9)	75.0	<0.0001 ^{c,d,f,h,i,j}
Difficulty stepping down	72.9 (29.7)	75.0	81.7 (21.7)	87.5	69.0 (26.1)	75.0	92.5 (14.8)	100.0	88.6 (18.3)	100.0	<0.0001 ^{c,d,f,h,i}
Difficulty in familiar places	87.1 (17.7)	100.0	94.4 (12.7)	100.0	75.0 (20.4)	75.0	97.2 (9.3)	100.0	94.4 (12.2)	100.0	<0.0001 ^{a,b,c,d,e,h,i,j}
Limited doing daily activities	75.3 (34.2)	100.0	92.2 (16.5)	100.0	72.6 (31.5)	75.0	96.2 (12.5)	100.0	94.0 (18.0)	100.0	<0.0001 ^{a,c,d,e,h,i}
Difficulty noticing objects off to side	70.4 (33.1)	75.0	87.1 (23.7)	100.0	53.6 (22.8)	50.0	96.0 (11.2)	100.0	91.9 (16.3)	100.0	<0.0001 ^{a,b,c,d,e,f,h,i,j}
Difficulty finding items on crowded shelf	74.7 (30.8)	87.5	85.3 (18.3)	100.0	70.2 (24.5)	75.0	95.2 (11.9)	100.0	91.2 (15.0)	100.0	<0.0001 ^{a,c,d,e,f,h,i,j}
Composite	66.6 (26.8)	75.0	78.1 (17.1)	83.9	58.6 (21.6)	62.2	88.0 (10.2)	90.0	83.5 (13.0)	85.3	<0.0001 ^{a,c,d,e,f,h,i,j}

MK, Microbial Keratitis; SD, Standard Deviation; Ophthy, Ophthalmology

* ANOVA (Kruskal-Wallis tests also showed all $p < 0.0001$); Post-hoc pairwise comparisons show significant differences after Tukey adjustment for:

^a Acute MK vs. non-acute MK,

^b Acute MK vs. MK with corneal transplant,

^c Acute MK vs. Comprehensive/No Specialist,

^d Acute MK vs. Comprehensive/Specialist,

^e Non-acute MK vs. MK with corneal transplant,

^f Non-acute MK vs. Comprehensive/No Specialist,

^g Non-acute MK vs. Comprehensive/Specialist,

^h MK with corneal transplant vs. Comprehensive/No Specialist,

ⁱMK with corneal transplant vs. Comprehensive/Specialist,

^jComprehensive/No Specialist vs. Comprehensive/Specialist

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Univariate and Multivariable linear regression models for 9-item National Eye Institute Visual Function Questionnaire composite score

Table 3.

Variable	Univariate Models			Multivariable Model		
	Estimate	95% CI	P-value	Estimate	95% CI	P-value
Age (per 10 years)	-1.8	-2.4, -1.3	<0.0001	-1.5	-2.1, -0.1	<0.0001
Race (vs White)						
Black	0.1	-3.7, 4.0	0.9461			
Other	3.8	0.5, 7.0	0.0230			
Insurance (vs Commercial)						
Medicare	-6.5	-9.0, -4.0	<0.0001	-2.9	-5.4, -0.5	0.0188
Sex (vs Male)						
Female	-2.5	-4.7, -0.3	0.0236	-2.9	-4.8, -1.0	0.0024
Group (vs Comprehensive Ophthy)						
Active MK	-21.4	-24.7, -18.1	<0.0001	-21.6	-24.9, -18.3	<0.0001
Inactive MK	-9.9	-15.2, -4.6	0.0003	-9.8	-14.8, -4.7	0.0002
MK with Transplant	-29.3	-35.5, -23.2	<0.0001	-28.6	-34.7, -22.6	<0.0001
Specialty Ophthy	-4.5	-6.7, -2.3	<0.0001	-2.8	-5.0, -0.6	0.0134

CI, Confidence Interval; MK, Microbial Keratitis; Ophthy, Ophthalmology