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A Health-Related Quality of Life Measure for Patients Who Undergo Minimally Invasive Glaucoma Surgery

RON D. HAYS, MICHELLE E. TARVER, MALVINA EYDELMAN, GEORGE L. SPAETH, DAVID W. PARKE II, AND KULDEV SINGH, ON BEHALF OF THE GLAUCOMA OUTCOMES SURVEY COLLABORATIVE STUDY GROUP

• PURPOSE: To develop a patient-reported outcome measure to assess the impact of glaucoma and treatment, including minimally invasive glaucoma surgery (MIGS).
• DESIGN: Observational study before and after concomitant cataract and Food and Drug Administration-approved implantable MIGS device surgery.
• SETTING: Survey administration was on a computer, iPad, or similar device.
• PATIENT POPULATION: 184 adults completed the baseline survey, 124 a survey 3 months after surgery, and 106 the 1-month test-retest reliability survey. The age range was 37 to 89 (average age = 72). Most were female (57%), non-Hispanic White (81%), and had a college degree (56%).
• MAIN OUTCOME MEASURES: The Glaucoma Outcomes Survey (GOS) assesses functional limitations (27 items), vision-related symptoms (7 items), psychosocial issues (7 items), and satisfaction with microinvasive glaucoma surgery (1 item). These multiple-item scales were scored on a 0 to 100 range, with a higher score indicating worse health.
• RESULTS: Internal consistency reliability estimates ranged from 0.75 to 0.93, and 1-month test-retest intraclass correlations ranged from 0.83 to 0.92 for the GOS scales. Product-moment correlations among the scales ranged from 0.56 to 0.60. Improvement in *visual acuity* in the study eye from baseline to the 3-month follow-up was significantly related to improvements in GOS functional limitations ($r = 0.18$, $P = .0485$), vision-related symptoms ($r = 0.19$, $P = .0386$), and psychosocial concerns ($r = 0.18$, $P = .0503$). Responders to treatment ranged from 17% for vision-related symptoms to 48% for functional limitations.
• CONCLUSIONS: This study supports using the GOS for ophthalmic procedures such as MIGS. Further evaluation of the GOS in different patient subgroups and clinical settings is needed. (Am J Ophthalmol 2024;000: 1–8.

INTRODUCTION

Glaucoma is the leading cause of blindness worldwide. It is characterized by progressive optic nerve abnormality with corresponding visual field defects secondary to retinal ganglion cell loss and ensuing optic neuropathy.[1] Traditional glaucoma surgical procedures, including trabeculectomy and glaucoma drainage implants, are associated with potentially vision-threatening complications. Minimally invasive glaucoma surgery (MIGS) is an evolving subset of new ophthalmic procedures for implanting a device designed to increase aqueous outflow using various techniques with limited conjunctival and scleral disruption.[2] In 2012, the US Food and Drug Administration approved the first MIGS implantable device for treating mild to moderate open-angle glaucoma.[3] Positive effects of MIGS, such as shorter recovery time, improved safety profile, and fewer vision-threatening complications relative to traditional incisional glaucoma surgical procedures, such as trabeculectomy and drainage tube implantation, have been postulated,[2] but the long-term efficacy and safety of MIGS procedures remains to be determined.

Given the myriad of MIGS devices in development and/or for which Food and Drug Administration approval is being sought, determining the appropriate glaucoma procedures to suit the needs of individual patients with glaucoma is critical. As with any surgical procedure that can impact

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a patient's functioning and well-being, evaluating that impact is paramount. Health-related quality of life (HRQoL) measures reflect risks and benefits associated with a procedure in terms of what matters to patients.[4,5] Ophthalmologists routinely use clinical measures, such as intraocular pressure (IOP), central corneal thickness, optic nerve assessment, and visual field testing, to make treatment decisions for glaucoma, but HRQoL measures provide complementary information.[6,7] Existing vision-targeted HRQoL measures include the National Eye Institute 25-Item Visual Function Questionnaire that assesses physical, mental, and social well-being in those with glaucoma and other chronic eye conditions.[8] Other vision-targeted HRQoL instruments assess impacts of specific ocular pathologies and include the National Eye Institute Refractive Error QoL Instrument,[9] the Visual Function Index assessment of functional impairment related to cataracts,[10] the Impact of Dry Eye on Everyday Life instrument,[11] the Quality of Vision questionnaire,[12] the Graves' Ophthalmopathy Quality of Life questionnaire,[13] and the Glaucoma Symptoms Scale.[14] But none of these previously developed measures were designed to evaluate the impact of MIGS on HRQoL.

In response to the need for an HRQoL instrument sensitive to the impact of glaucoma and glaucoma treatment on patients who are eligible for MIGS,[15] the Glaucoma Outcomes Survey (GOS) was developed to assess HRQoL among adults with glaucoma who undergo MIGS. Questions were drafted after a review of the literature and focus group input from physicians and patients. Draft items were revised based on cognitive interviews. This article provides initial information about the psychometric properties of GOS based on administration to a sample of adults who completed the survey before and after MIGS.

METHODS

• **SURVEY:** Study participants were asked to complete the Patient-Reported Outcomes Measurement Information System (PROMIS) general health survey[16] and the GOS before or at scheduled clinic visits at baseline, before combined cataract and MIGS, and 3 months postsurgery. To assess test-retest reliability, a subset of the participants was asked to complete the GOS a second time within 4 weeks of the baseline survey before undergoing the MIGS procedure. Data was collected using an electronic patient-reported outcomes application on a computer, iPad, or similar device. Participants were asked to self-complete the instrument, but due to visual impairments, 52% had the questions read to them and entered by study personnel.

Global Health

The PROMIS global health scale (PROMIS-10) is an outcome measure endorsed by the International Consortium for Health Outcomes Measurement. The 10 PROMIS global health items can be administered in 2 minutes or less. Four items are used in scoring the global physical health scale, and four other items are used for the global mental health scale. The two other items assess general health and general activity.

The 4 PROMIS items used in scoring the global physical health scale are: (1) "In general, how would you rate your physical health?"; (2) "To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?"; (3) "How would you rate your pain on average?"; and (4) "How would you rate your fatigue on average?". Three of these 4 PROMIS items are administered with 5 response options and the pain item is administered with a 0 (no pain) to 10 (worst pain imaginable) response scale. Based on the Sheehan Disability Scale and the Flushing Symptom Questionnaire, the latter item is recorded into 5 categories (5 = no pain; 4 = 1-3; 3 = 4-6; 2 = 7-9; 1 = worst pain imaginable) before scoring the global physical health scale. All 4 items are coded so a higher score represents better global physical health.

The 4 PROMIS global mental health items are: (1) "In general, would you say your quality of life is?"; (2) "In general, how would you rate your mental health, including your mood and your ability to think?"; (3) "In general, how would you rate your satisfaction with your social activities and relationships?"; and (4) "How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?". All 4 of these PROMIS items are administered with five response options and coded so a higher score represents better global mental health. The global physical and mental health scale scores are estimated using an item-response theory graded response model and transformed to have a mean of 50 and SD of 10 in the US general population, with higher scores representing better health.

Glaucoma Outcomes Survey

The development of the GOS was previously summarized.[15] The field test of the GOS included 42 questions that were developed to assess functional limitations (27 items), vision-related symptoms (7 items), psychosocial issues (7 items), and satisfaction with microinvasive glaucoma surgery (1 item). The three multiple-item scales were scored using a 0 to 100 possible range, with a higher score indicating worse health. Two retrospective change items assessing QOL and daily tasks were included in the 3-month postoperative survey: (1) "Compared to 3 months ago, how is your quality of life related to your glaucoma now?" and (2) "Compared to 3 months ago, how well can you perform your daily tasks now?". These items were administered using five response options: *Much better, A little better, About*

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the same, *A little worse*, or *Much worse*. We scored these change items so that a higher score represented more positive health changes.

• **SAMPLE:** A total of 196 patients were enrolled in the study. The number of surveys completed during each administration visit was as follows:

- 191 baseline surveys were partially completed; 184 had at least 50% of the questions answered.
- 106 completed at least 50% of the 1-month (test-retest) surveys.
- 156 3-month surveys were partially completed; 124 had at least 50% of the questions answered.

As shown in Table 1, the baseline sample was 57% female, 81% non-Hispanic White, and had an average age of 72 years (37-89 years). Educational attainment was a high school degree or less for 20%, some college for 24%, a 4-year college degree for 20%, and more than a 4-year degree for 36%. Forty-four percent of the sample self-reported having glaucoma for 5 years or less, and 72% that their glaucoma was mild or moderate. The most common medical conditions were hypertension (55%), arthritis (33%), diabetes (23%), and cancer (22%).

• **ANALYSIS PLAN:** We evaluate the extent to which the data were consistent with the hypothesized three underlying domains using categorical confirmatory factor analysis with the robust weighted least squares estimation procedure, the weighted least squares mean, and variance-adjusted estimation. We evaluate model fit using the comparative fit index (CFI) and root mean squared error of approximation (RMSEA). CFI values of about 0.95 or above and RMSEA values of about 0.05 or less are considered a close fit to the data.[17] Next, we provide descriptive statistics, internal consistency reliability[18], and 1-month test-retest intraclass correlations for the three GOS multiitem scales at baseline. In addition, we estimate product-moment correlations among the GOS scales and correlations with the PROMIS global physical health and mental health scales, age, diabetes, and the number of comorbid conditions. We report changes in the GOS scales from baseline to 3 months postoperatively. Then, we estimate associations of GOS scales with IOP, mean deviation, and visual acuity. We hypothesized that worse GOS scale scores would be correlated with older age, diabetes, number of comorbid conditions, and worse visual acuity. We also calculated mean changes on GOS scales by retrospective ratings of change reported at the 3-month postoperative follow-up. Finally, we identify significant individual change using the coefficient of repeatability.[19]

Analyses were conducted using SAS 9.4[20] software and Mplus Version 7.[21]

TABLE 1. Characteristics of Sample at Baseline ($n = 184$)

Characteristic	*n* (%)
Gender	
Female	105 (57%)
Male	78 (43%)
Race and ethnicity	
Hispanic	5 (3%)
Non-Hispanic White	147 (81%)
Non-Hispanic Black	21 (12%)
Non-Hispanic Asian	6 (3%)
Non-Hispanic Other	3 (2%)
Age (mean, range)	72 (37-89)
Education	
Less than high school	3%
High school graduate	17%
Some college and above	80%
Time with glaucoma at baseline	
5 years or less	81 (44%)
6-10 years	36 (20%)
11-20 years	25 (14%)
21-40 years	14 (8%)
41 years+	2 (1%)
Do not know	25 (14%)
Self-reported severity of glaucoma at baseline	
Mild glaucoma	67 (36%)
Moderate glaucoma	67 (36%)
Severe glaucoma	13 (7%)
Do not know severity of my glaucoma	37 (20%)
Medical condition	
Hypertension	108 (55%)
Arthritis	65 (33%)
Diabetes	45 (23%)
Cancer	42 (22%)
Coronary artery disease	29 (15%)
Depression	18 (9%)
Anxiety	16 (8%)
Age-related macular degeneration	15 (8%)
Sciatica	12 (6%)
Chronic kidney disease	10 (5%)
Stroke	9 (5%)
Congestive heart failure	10 (5%)
Chronic obstructive pulmonary disease	8 (4%)
Inflammatory bowel disease	5 (3%)
Lupus	1 (1%)
Dementia	0 (0%)

N's may not sum to 184 due to missing data.

RESULTS

As summarized in Table 2, a categorical confirmatory three-factor model fit the data reasonably well (CFI = 0.930; RMSEA = 0.058). The functional limitations factor correlated 0.704 with the vision-related symptoms factor and 0.710 with the psychosocial issues factor; the vision-related symp-

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TABLE 2. Categorical Confirmatory Factor Analysis at Baseline

	Chi-Square	df	*P*	CFI	RMSEA
Functional limitations	1078.74	324	.0000	0.872	0.113
Functional limitations, plus FL10, FL11 corr.	756.80	323	.0000	0.926	0.085
Symptoms	37.41	14	.0006	0.957	0.095
Psychosocial	29.74	14	.0083	0.974	0.078
3-factors	1487.97	776	.0000	0.897	0.071
3-factors plus FL10, FL11 corr.	1259.97	775	.0000	0.930	0.058
1 overall factor	1643.23	779	.0000	0.875	0.078

CFI = comparative fit index; df = degrees of freedom; *P* = probability; RMSEA = root mean square error of approximation; FL10, FL11 corr = residual correlation of difficulty seeing people who approach from the side (F10) and seeing things off to the side of vision (F11).

TABLE 3. Baseline Median, Mean, Percent Floor and Ceiling, and Reliability Estimates for PROMIS Global Health and Glaucoma Outcomes Survey (GOS) Multiitem Scales

Scale	Median/Mean (SD)	% Floor/Ceiling	Coefficient Alpha	Test-Retest Intraclass[a] (Product-Moment) Correlation
PROMIS physical health (4items)	51/49 (9)	1/4	0.79	0.73 (0.75)
PROMIS mental health (4 items)	52/52 (8)	1/7	0.78	0.65 (0.66)
GOS functional limitations (27 items: 1-26, 39)	26/27 (15)	1/1	0.93	0.92 (0.93)
GOS vision-related symptoms (7 items: 27-33)	24/28 (19)	7/1	0.75	0.83 (0.87)
GOS psychosocial issues (7 items: 34-38, 40-41)	22/26 (20)	10/1	0.80	0.85 (0.89)

[a]3-month endpoint used for PROMIS-10 retest, 1-month endpoint used for GOS measures retest.

toms and psychosocial concerns factors correlated 0.697. One residual correlation was estimated at 0.564 ("difficulty seeing people who approach from the side," with "seeing things off to the side of vision"). Single-factor categorical factor analytic models also fit the data well: functional limitations (CFI = 0.926, RMSEA = 0.085), vision-related symptoms (CFI = 0.957, CFI = 0.095), and psychosocial issues (CFI = 0.974, RMSEA = 0.078).

Table 3 provides medians, means, floor and ceiling rates, and reliability estimates for the PROMIS global health and the GOS scales at baseline. The PROMIS global health scale means/medians indicate that the sample's general health was similar to that of the US general population. Internal consistency reliability estimates ranged from 0.75 (vision-related symptoms) to 0.93 (functional limitations), and 1-month test-retest intraclass correlations ranged from 0.65 (PROMIS global mental health) to 0.92 (functional limitations). Mean scores for the GOS scales were 26 to 27 on the 0 to 100 possible range. Floor and ceiling effects were generally low; the largest was 10% of the sample scoring at the floor on the GOS psychosocial issues scale (floor for this scale denotes no negative issues were reported).

Product-moment correlations among the GOS scales at baseline ranged from 0.56 to 0.60 (Table 4). Correlations of the GOS scale scores with global physical health ranged from –0.30 to –0.33 and with global mental health from –0.13 to –0.30 (Table 4). The global physical and mental health scales correlated significantly with record-based notations of *depression* ($r = –0.15$ and –0.25, respectively) and *anxiety* ($r = –0.22$ and –0.30, respectively). But the GOS scales were not significantly correlated with depression or anxiety.

The number of missing items on the baseline GOS survey and whether the survey was self-administered or questions were read and recorded by the study personnel was not significantly correlated with the GOS or PROMIS global health scales at baseline. Older *age* was significantly associated with better PROMIS global mental health ($r = 0.21$, $P = .0044$), GOS functional limitations ($r = –0.18$, $P = .0165$), vision-related symptoms ($r = –0.25$, $P = .0006$) and psychosocial concerns ($r = –0.27$, $P = .0002$) at baseline. *Having diabetes* was associated with worse PROMIS global physical health and mental health (–0.23, $P = .0016$), GOS functional limitations ($r = 0.18$, $P = .0165$), and GOS psychosocial concerns ($r = 0.17$, $P = .0227$) at baseline. The *number of comorbid conditions* at baseline was significantly correlated with the GOS functional limitations scale ($r = 0.21$, $P = .0047$), global physical health ($r = –0.38$, $P < .0001$), and global mental health ($r = –0.22$, $P = .0029$).

Table 5 provides self-rated health scores at baseline and follow-up. Notably, the Hydrus device was used in 70% of study subjects, with the iStent Inject and iStent Model GTS100 used in 26% and 4% of subjects, respectively. The

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TABLE 4. Product-Moment Correlations Among GOS and PROMIS Scales at Baseline

	GOS Functional Limitations	GOS Vision-Related Symptoms	GOS Psychosocial	PROMIS Global Physical
GOS functional limitations				
GOS vision-related symptoms	0.60			
GOS psychosocial	0.58	0.56		
PROMIS global physical	–0.33	–0.30	–0.32	
PROMIS global mental	–0.20	–0.13	–0.30	0.62

TABLE 5. Glaucoma Outcomes Survey (GOS) and PROMIS Global Health Scores at Baseline and 3-Month Follow-Up

	Scores				
	Baseline	1 Month	3 Months	Δ1	Δ3
GOS					
Functional limitations					
N	184	106	133	105	133
Mean (SD)	27 (15)	27 (14)	13 (12)	0 (5)	12 (14)
Median	26	25	10	0	10
Range (min, max)	(2, 72)	(4.69)	(0, 62)	(–21.19)	(–23.61)
Vision-related symptoms					
N	184	106	133	105	133
Mean (SD)	28 (19)	28 (19)	18 (17)	1 (10)	8 (19)
Median	24	27	14	0	6
Range (min, max)	(0.81)	(0.77)	(0.81)	(–36, 36)	(–75, 63)
Psychosocial issues					
N	184	106	133	105	133
Mean (SD)	26 (20)	26 (22)	11 (14)	1 (10)	13 (17)
Median	22	19	6	0	10
Range (min, max)	(0.90)	(0.90)	(0.72)	(–28, 33)	(–22, 72)
PROMIS global health					
Physical health					
N	180	x	132	x	131
Mean (SD)	49 (9)	x (x)	51 (9)	x (x)	–1 (6)
Median	51	x	54	x	–1
Range (min, max)	(27.68)	(x, x)	(23, 68)	(x, x)	(–17, 16)
Mental health					
N	180	x	132	x	131
Mean (SD)	52 (8)	x (x)	53 (8)	x (x)	–1 (6)
Median	52	x	54	x	0
Range (min, max)	(27, 68)	(x, x)	(33, 68)	(x, x)	(–22, 21)

Δ^3 indicates change from baseline at the 3-month follow-up visit; Δ^1 indicates change from baseline at the 1-month follow-up visit.
SD = standard deviation; x = unavailable.

PROMS global health scores changed very little from baseline to the 3-month postoperative survey. In contrast, the GOS scale scores improved significantly: functional limitations by 12 points (effect size = 0.86), vision-related symptoms by 8 points (effect size = 0.42), and psychosocial issues by 13 points (effect size = 0.76).

IOP and *mean deviation* were not significantly associated with any of the PROMIS or GOS scales at baseline. But the PROMIS global physical and mental health scales were associated with better Snellen *visual acuity* in the fellow eye (physical health: $r = –0.14$, $P = .0673$; mental health: $r = –0.17$, $P = .0233$). We examined correlations of change in IOP, visual acuity, and mean deviation with change in the PROMIS global health and GOS scales. Improvement in *visual acuity* in the study eye from baseline to the 3-month follow-up was significantly related to improvements in GOS functional limitations ($r = 0.18$, $P = .0485$), vision-related symptoms ($r = 0.19$, $P = .0386$), and psychosocial concerns ($r = 0.18$, $P = .0503$). Improvement in *visual acuity* in the fellow eye from baseline to the 3-month follow-

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TABLE 6. Mean Change (SD) in GOS Scales: Baseline to 3 Months Later by Retrospective Ratings of Change

Quality of Life-Related to Glaucoma Now Compared To 3 Months Ago	Functional Limitations	Symptoms	Psychosocial
Much better ($n = 55$)	17[a] (14)	12[a] (19)	19[a] (19)
A little better ($n = 33$)	10[a,b] (12)	8[a] SD (17)	9[b] (14)
About the same ($n = 39$)	8[b] (12)	4[a] (20)	9[b] (13)
A little worse ($n = 17$)	5[a,b] (17)	−2[a] (14)	−5[b] (18)
Much worse ($n = 1$)	−10[a,b] (0)	−33[a] (0)	−17[a] (0)
How well can you perform daily tasks now compared to 3 months ago	Functional limitations	Symptoms	Psychosocial
Much better ($n = 41$)	19[a] (16)	15[a] (20)	21[a] (20)
A little better ($n = 28$)	13[a,b] (13)	8[a] (14)	10[a,b] (15)
About the same ($n = 58$)	9[b,c] (9)	4[a] (19)	10[b] (13)
A little worse ($n = 4$)	−7[c] (7)	−5[a] (13)	−12[b] (10)
Much worse ($n = 2$)	−1[a,b,c,d] (1)	−17[a] (23)	−11[a,b] (39)

Mean changes on the three GOS scales are shown for the five response levels of the two retrospective ratings of change items. Within each of the six subsets of the GOS scale by retrospective rating item, mean changes that do not share at least one superscripted letter differ significantly ($p < .05$) according to the Tukey-Kramer adjustment for multiple comparisons.

TABLE 7. Significance of Individual Change on PROMIS Global Health and Glaucoma Outcomes Survey (GOS) Scales from Baseline to 3-Month Follow-Up

Scale	Got Better (%)	Stayed the Same (%)	Got Worse (%)
Global physical health	5	93	2
Global mental health	7	92	2
GOS functional limitations	48	48	4
GOS vision-related symptoms	17	82	2
GOS psychosocial issues	21	78	0

up was significantly related to improvements in PROMIS global physical health ($r = –0.21$, $P = .0228$), GOS functional limitations ($r = 0.25$, $P = .0052$), and vision-related symptoms ($r = 0.18$, $P = .0417$), and approached significance for psychosocial concerns ($r = 0.15$, $P = .0902$). Unexpectedly, increases in IOP were significantly associated with improvements in global mental health ($r = 0.21$, $P = .0214$).

Only one of the Spearman rank-order correlations between changes on the GOS scales from baseline to 3 months postsurgery and retrospective ratings of change items met the 0.37 threshold suggested for estimating group-level minimally important differences.[22] The correlations with the retrospective ratings of change in QOL and daily tasks, respectively, were as follows: functional limitations (0.30, 0.38), vision-related symptoms (0.20, 0.31), and psychosocial issues (0.29, 0.29). Table 6 shows that mean changes on the GOS scales by the retrospective change ratings were generally monotonic, but the analysis was limited by small cell sizes. Very few changes between retrospective change subgroups differ significantly at $P < .05$ when applying the Tukey-Kramer adjustments for multiple comparisons.

Table 7 summarizes individual changes on the five health scales from baseline to follow-up. Significance was assessed using the coefficient of repeatability at $P < .05$: 2.77 $SD_1 \sqrt{1 - Alpha}$. Only 5% and 7% of the sample had significant improvement in PROMIS global physical and mental health, respectively. The greatest number of responders to treatment was seen for the GOS functional limitations scale (48%), followed by GOS psychosocial issues (21%) and GOS vision-related symptoms (17%).

Only 4% (3%) and 4% (4%) of the sample reported that their quality of life (daily task performance) was better and had significant improvement on the PROMIS global physical and mental health scales, respectively. Thirty-seven percent (33%) of the sample reported that their quality of life (daily task performance) was better and had significant improvement in GOS functional limitations, 12% (11%) in GOS vision-related symptoms, and 17% (14%) in GOS psychosocial issues. Forty-nine percent of the sample reported on the 3-month survey that they were "completely satisfied" with their microinvasive glaucoma surgery (MIGS), 35% were "very satisfied," 9% "somewhat satisfied," 4% "did not know" if they had the surgery, and 3% reported they did not have the surgery.

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DISCUSSION

The results of this study provide strong support for the reliability and validity of the GOS, a patient-reported outcome measure designed to assess HRQoL of patients with glaucoma who undergo MIGS. Internal consistency reliability estimates for the three GOS multiitem scales were 0.75 or higher, and 1-month test-retest reliability intraclass correlations ranged from 0.85 to 0.92. A categorical confirmatory factor analytic model provided support for the three GOS scales. Construct validity of the GOS scales was supported by significant cross-sectional correlations with hypothesized relations with older age, diabetes, number of comorbid conditions, and visual acuity, and significant associations between improvement over 3 months from before to after surgery in visual acuity.

The GOS scales were responsive to change associated with combined cataract removal MIGS. That is, there was a large positive group mean change from baseline to 3 months postoperatively in functional limitations, a medium change in psychosocial issues, and a small change in vision-related symptoms. The percentage of the responders to treatment (ie, reported a statistically significant improvement) ranged from 17% for vision-related symptoms to 48% for functional limitations. The majority (84%) of the sample reported being completely or very satisfied with their MIGS.

The study had some limitations. Most of the sample was non-Hispanic White, but glaucoma is disproportionately more prevalent in Hispanic and Black patients. The finding that an increase in IOP was related to improvement in global mental health may be due to confounding factors. For example, it is possible that mental health decreased due to side effects associated with adhering to medication recommendations or that those who are nonadherent may have a higher IOP but avoid medication side effects. In addition, the study had a relatively small sample with mostly highly educated adults. MIGS is mainly used for patients with less severe glaucoma. Evaluation of the GOS in more diverse study populations is needed to assess the robustness of the psychometric results reported here. Importantly, the study was designed to assess the reliability and construct validity of the GOS, not to estimate the unique effects of MIGS versus cataract removal. Future randomized clinical trials are needed to tease out the specific impact of MIGS on HRQOL.

Despite limitations, the results of this initial study suggest that this patient-reported outcome measure may be useful for evaluating the effect of MIGS and other interventions for persons with glaucoma in clinical trials and observational studies. In addition, given a reliability that was greater than the 0.90 threshold for assessing individuals,[23] the GOS functional limitations scale may be useful for assessing patients in clinical practice.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Ron D. Hays: Conceptualization, Formal analysis, Methodology, Supervision, Writing – original draft, Writing – review & editing. **Michelle E. Tarver:** Conceptualization, Methodology, Resources, Writing – review & editing. **Malvina Eydelman:** Conceptualization, Supervision, Writing – review & editing. **George L. Spaeth:** Conceptualization, Supervision, Writing – review & editing. **David W. Parke II:** Funding acquisition, Project administration, Supervision, Writing – review & editing. **Kuldev Singh:** Conceptualization, Data curation, Methodology, Project administration, Resources, Supervision, Writing – review & editing.

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