

Performance of PROMIS Global-10 to Legacy Instruments for Lateral Epicondylitis

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INTRODUCTION

- Patient reported outcomes (PRO) are designed to self-assess patient function, including lifestyle, emotional health, work, and measure response to interventions. Some general health PROs can be used to calculate quality-adjusted life years (QALYs) for economic analysis. Traditional PROs have many questions, and require completion of all questions for grading. Large numbers of questions may reduce patient compliance.
- In 2004 the National Institute of Health began creation of a new series of publicly available, more efficient PROs designed to cover multiple health domains and allow assessment of various diseases and chronic conditions. The goal was to lower patient test burden and improve PRO measurement precision. Item response theory was utilized to assess the relation of questions to each other within health domains.
- Some of the PROMIS PROs that have been used in orthopedics are the PROMIS physical function computer adaptive test (PF-CAT), as well as the PROMIS upper extremity (UE) short form and computer adaptive test (CAT). These have been validated for meniscal injury, shoulder instability, glenohumeral arthritis, and rotator cuff disease.
- The PROMIS Global-10 is a general health PRO designed to replace the EQ-5D and SF-12. It consists of ten questions. Respondents receive a raw physical health score and mental health score. They also receive a normalized physical and mental "T-score" where 50 represents the US population average and the standard deviation is 10. An estimated EQ-5D score can be calculated.
- The PROMIS Global-10 has not been previously validated for specific orthopedic pathologies. As a general wellness PRO, it could potentially be used across orthopedic subspecialties and other medical specialties.

GOAL

Validate the PROMIS Global-10 for lateral epicondylitis to legacy PROs

We hypothesize that (1) there is moderate to high correlation between the PROMIS Global-10 and gold-standard PROs (ASES, EQ-5D, MEPS, QD), (2) PROMIS Global-10 will not show ceiling effects, and (3) estimated EQ-5D scores will show good correlation and low variance with actual EQ-5D scores

RESULTS

Table 1. Patient Demographics

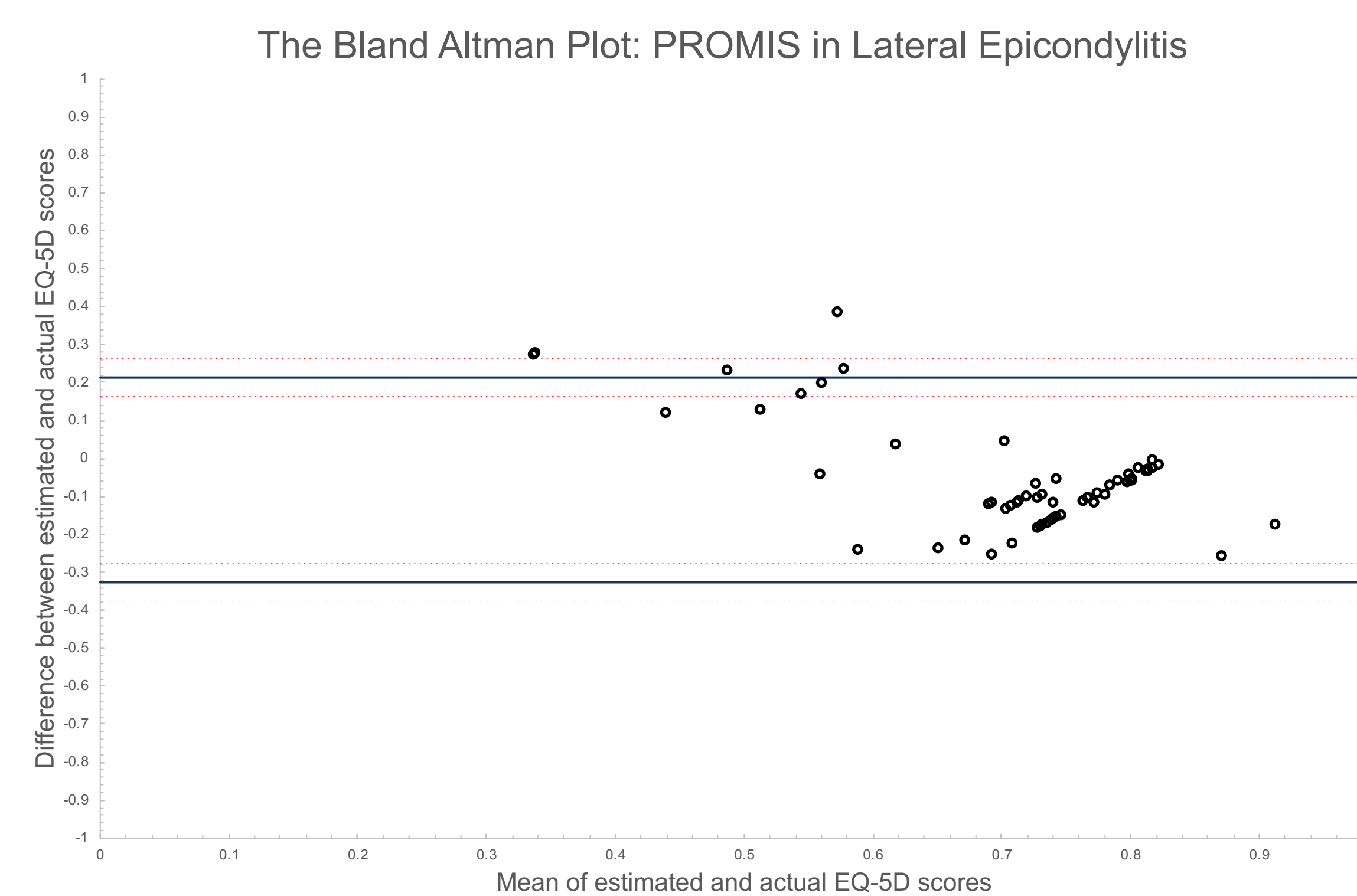
Parameter	Total	Parameter	Total
Age		Activity	
Mean (SD)	47.9 (10.8)	Professional Athlete	1 (1.6%)
Sex		Contact sports	3 (4.9%)
Male	26 (41.95%)	Non-contact sports	17 (27.4%)
Female	36 (58.1%)	Somewhat active	32 (51.6%)
Hand Dominance		Minimally active	9 (14.5%)
Right	58 (90.3%)	Insurance	
Left	4 (6.5%)	Private	50 (80.7%)
Ambidextrous	2 (3.2%)	Medicare	3 (4.8%)
Affected Side		Medicaid	3 (4.8%)
Right	37 (59.7%)	Workers Comp	6 (9.7%)
Left	23 (37.1%)	Smoking Status	
Both	2 (3.2%)	No	55 (88.7%)
Occupation		Yes	7 (11.3%)
Heavy or manual labor	4 (6.4%)	Diabetes	
Moderately strenuous work	14 (22.6%)	No	60 (96.8%)
Mildly strenuous work	16 (25.8%)	Yes	2 (3.2%)
Light or sedentary work	28 (45.2%)		

Table 2. PRO scores summary

	Scale	Mean ± SD	Median (Range)
PROMIS Global-10 Physical Health	4-20	14.0 ± 2.4	14.0 (8.0-19.0)
PROMIS Global-10 Mental Health	4-20	15.6 ± 3.3	16.0 (5.0-20.0)
PROMIS Global-10 Physical T-Score			
	0-100	45.3 ± 6.7	44.9 (29.6-61.9)
PROMIS Global-10 Mental T-Score			
	0-100	53.1 ± 9.0	53.3 (25.1-67.6)
EQ-5D			
	0-1	0.7 ± 0.2	0.8 (0.2-1.0)
PROMIS Estimated EQ-5D			
	0-1	0.7 ± 0.1	0.7 (0.5-0.8)
ASES			
	0-100	55.5 ± 15.7	55.9 (21.2-86.8)
MEPS			
	0-100	50.0 ± 14.9	50.0 (0.0-80.0)
QD			
	0-100	38.8 ± 22.3	38.6 (4.6-91.0)

Table 3. Correlation of PROMIS Global-10 to Gold-Standard PROs

Full Cohort (n=323)	R value	P-Value	Correlation Strength
PROMIS Global-10			
EQ-5D	0.72	<0.0001	Excellent
Global-10 Physical Health			
ASES	0.58	<0.0001	Good
MEPS	0.61	<0.0001	Excellent – Good
QD	0.64	<0.0005	Excellent – Good
Global-10 Mental Health			
ASES	0.26	=0.0492	Poor
MEPS	0.37	=0.0038	Poor
QD	0.50	<0.0001	Good



Plot demonstrating the difference between the actual EQ-5D score and the estimated EQ-5D score from PROMIS (vertical axis) and the average of actual EQ-5D score and the estimated EQ-5D score (horizontal axis). Each dot represents one respondent. The blue lines are the lower and upper 95% limits of agreement, and the red lines are the lower and upper 95% confidence interval for the lower and upper limits.

The mean difference between PROMIS Global-10 estimated EQ-5D scores and actual EQ-5D scores was -0.0564 on a scale of 0 to 1, indicating that the scores were similar overall. However, on a scoring scale of 0 to 1, any individual estimated score could range from -0.33 to 0.21 below or above the actual EQ-5D score, respectively.

PRO	Number of Questions
PROMIS Global-10	10
PROMIS SF-UE	7
PROMIS PF CAT	4-12
MEPS	7
QD	11
ASES	10
EQ-5D	6

METHODS

- Patient cohort: 62 patients with lateral epicondylitis were prospectively enrolled before treatment from January 2015 to October 2017. They were above age 18, English-speaking, and provided informed consent.
- Each patient completed the PROMIS Global-10, EQ-5D, ASES shoulder assessment form, Mayo Elbow Performance Score (MEPS) assessment form, and QuickDash (QD).
- Spearman correlations were calculated between PROs. Bland-Altman Agreement tests were conducted between estimated EQ-5D scores from PROMIS and actual EQ-5D scores.
- Ceiling and floor effects were assessed, defined as ≥15% respondents with highest or lowest possible score

PROMIS Global-10

Please respond to each item by marking <u>one box per row</u>		Excellent	Very good	Good	Fair	Poor
Global 01	In general, would you say your health is:	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global 02	In general, would you say your quality of life is:	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global 03	In general, how would you rate your physical health?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global 04	In general, how would you rate your mental health, including your mood and your ability to think?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global 05	In general, how would you rate your satisfaction with your social activities and relationships?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global 09	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
		Completely	Mostly	Moderately	A Little	Not At All
Global 06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
		Never	Rarely	Sometimes	Often	Always
Global 10	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
		None	Mild	Moderate	Severe	Very Severe
Global 08	How would you rate your fatigue on average?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global 07	How would you rate your pain on average?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
		No Pain				Worst Imaginable Pain

Scoring:

Re-code Global07. The recoded score ranges from 1 to 5. (0 No pain =5; 1, 2, or 3 =4; 4, 5, or 6 =3; 7, 8, or 9 =2; 10 worst pain imaginable =1)

After recoding, the
Global Physical Health score = SUM responses to G03 + G06 + G07 + G08.
Global Mental Health score = SUM G02 + G04 + G05 + Global10.

CONCLUSIONS

- PROMIS Global-10 physical function scores show high correlation with gold-standard PRO instruments for lateral epicondylitis
 - Revicki examined PROMIS Global 10 and found similar limits of agreement of -0.2 to 0.2 between estimated and actual EQ-5D scores.
- No floor or ceiling effects for PROMIS Global-10 in lateral epicondylitis.
- This suggests PROMIS Global-10 is a reliable tool for outcome assessment in lateral epicondylitis.
- PROMIS Global-10 has the potential to be used for pathologies and diseases across multiple treating specialties.
- The large 95% limit of agreement on Bland-Altman analysis suggests estimated EQ-5D scores cannot replace traditional EQ-5D scores.
 - Estimated EQ-5D scores may not be suitable for quality-adjusted life years (QALYs) derived from EQ-5D scores for economic analysis.

REFERENCES

- Kahan, J.B., Nicholson, A. D., Saad, M.A., Kassam, H. F., & Kovacevic, D. (2019). Performance of PROMIS Global-10 Compared With Legacy Instruments for Lateral Epicondylitis. *Arthroscopy*.
- Revicki DA, Kawata AK, Harnam N, Chen W-H, Hays RD, Cella D. Predicting EuroQol (EQ-5D) scores from the patient-reported outcomes measurement information system (PROMIS) global items and domain item banks in a United States sample. *Quality of Life Research*. 2009;18:783-791.