Sensitivity to Change of Patient-reported and Performance Measures for Custom AFO Users

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Introduction

- Patient-reported outcome measures (PROMs) are not used widely to evaluate the benefits of lower-limb orthoses, in part, because there is no consensus on what to measure and little psychometric evidence for PROMs in orthoses users.
- This study builds on our efforts to assess patient and clinician perspectives on quality-of-care topics that are important to measure for custom AFO users, identify instruments to assess care quality for individuals using custom AFOs, and assess orthotists' and physical therapists' perspectives on quality-of-care indicators.
- Aims of this study were to assess sensitivity to change of instruments measuring quality-of-care indicators valued by patients and clinicians.

Methods

Subjects: A convenience sample of adults receiving a new or a major new component of a custom AFO from 2 VAs and a rehabilitation hospital's orthotic clinics.

Instruments: EQ-5D; PROMIS Pain Interference, Physical Function, Participation in Social Roles and Activities, and Satisfaction with Social Roles and Activities short forms; Rivermead Mobility Index; and OPUS Quality-of-Life and Lower Extremity functional status.

Procedures: Staff recruited participants and administered survey instruments and recorded PROMs before device delivery, about 1 month after device delivery, and 1 month later.

Data Analysis: Descriptive statistics and generalized linear mixed models to test if measures changed over time.

PROM Changes Over Time

Measure	Pre-Delivery	Post-Delivery	Follow-Up	p
EQ 5D Total	0.54 (0.04)	0.65 (0.05)	0.70 (0.05)	**.008**
EQ 5D Visual Analog Scale	66.2 (3.0)	64.3 (3.4)	72.1 (3.6)	.098
PROMIS Pain	55.5 (1.7)	53.0 (1.8)	51.6 (1.9)	.176
PROMIS Participation in Social Roles & Activities	42.6 (1.7)	45.5 (1.8)	47.1 (1.9)	.057
PROMIS Satisfaction with Social Roles & Activities	42.0 (1.7)	44.5 (1.8)	46.0 (1.9)	.176
PROMIS Physical Function	36.1 (1.1)	38.3 (1.2)	38.7 (1.3)	**.036**
Rivermead Mobility Index	10.3 (0.4)	11.4 (0.5)	11.7 (0.5)	**.016**
OPUS Quality of Life	53.8 (1.6)	56.7 (1.7)	57.7 (1.7)	**.021**
OPUS Lower Extremity Function	46.9 (2.2)	48.2 (2.2)	52.2 (2.2)	.062

Correlations between PROMs and Performance Instruments

Measure	Timed Up and Go Test	10MWT, Usual Pace	10MWT, Fast Pace	Six Minute Walk Test, Distance
OPUS Lower Extremity Functional Status	***-0.491***	***-0.554***	***-0.493***	***0.554***
Rivermead Mobility Index	***-0.493***	***-0.601***	***-0.480***	***0.560***
PROMIS Physical Function (T)	***-0.493***	***-0.577***	***-0.491***	***0.572***
EQ-5D-5L Visual Analog Scale	***-0.314***	***-0.346***	***-0.308***	***0.273***
PROMIS Satisfaction with Social Roles and Activities (T)	***-0.251***	***-0.432***	***-0.316***	***0.354***
OPUS Health-Related Quality of Life	***-0.307***	***-0.344***	***-0.302***	***0.266***
PROMIS Participation in Social Roles and Activities (T)	***-0.300***	***-0.326***	-0.201	***0.236***
EQ-5D-5L Total	-0.190	***-0.264***	-0.107	***0.215***
OPUS Device Satisfaction	0.006	-0.113	-0.071	0.179
OPUS Service Satisfaction	-0.138	-0.166	-0.077	0.169
PROMIS Pain Interference (T)	0.083	0.059	0.021	-0.042

Spearman correlations

Known Groups Validity Evidence

Measure	Time Up and Go Test (sec)	10MWT, Self-Selected Pace (sec)	10MWT, Fast Pace (sec)	Six Minute Walk Test (meters)
Age < 60 (n=47)	26.8 ± 42.5	16.8 ± 32.0	8.7 ± 12.0	291 ± 158
Age >=60 (n=59)	17.3 ± 10.5	8.9 ± 5.8	6.8 ± 4.5	281 ± 122
Effect size	**0.29**	**0.31**	**0.19**	**0.07**
BMI < 25 (n=33)	24.0 ± 46.6	14.0 ± 30.7	6.2 ± 4.0	298 ± 142
BMI >=25 (n=72)	20.2 ± 17.6	11.7 ± 17.0	8.1 ± 9.9	282 ± 135
Effect size	**0.16**	**0.10**	**0.22**	**0.11**
Neurologic (n=57)	21.3 ± 19.2	12.6 ± 18.9	9.0 ± 11.0	268 ± 127
Trauma (n=36)	22.5 ± 44.2	12.9 ± 29.2	6.3 ± 4.1	313 ± 163
Effect size	**0.04**	**0.01**	**0.31**	**0.32**

Discussion

- Results provide evidence of sensitivity to change in 4 of the 9 measures.
  - EQ-5D total score, OPUS HR-QOL, PROMIS Physical Function, and Rivermead Mobility Index
- OPUS LEFS and Rivermead Mobility Index correlate moderately with all performance instruments.
  - EQ-5D-5L and PROMIS had low correlations with performance instruments.
- Known groups validity supported by age and etiology differences.
  - Older adults are at greater fall risk and walk slower at a usual pace than younger adults.
  - Over-weight adults' fast pace is slower than desirable-weight adults.
  - People with neurological impairments have lower endurance than people with traumatic impairments.
- Clinicians may consider these PROMs for evaluating patients' experiences with orthotic services.
- Limitation: Findings are specific to custom AFO users

Conclusions

- Findings fill a knowledge gap regarding the sensitivity to change and validity of PROMs that are suitable for use with custom AFOs users.
- Orthotists and physical therapists may consider using select PROMs that demonstrate sensitivity to change to document patient experiences with custom AFOs.
- Future studies should evaluate measurement properties in other orthotic and prosthetic populations.

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Thank You

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