

CONSTRUCT VALIDITY OF FUNCTIONAL STATUS SCORES OF PATIENTS WITH LYMPHEDEMA

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ABSTRACT

During treatment of lymphedema, routine use of patient-reported outcomes measures (PROMs) is recommended to monitor patient progress; however, the validity functional status (FS) PROMs in these patients is unknown. Our aims were to examine construct validity of the shoulder computerized adaptive testing (CAT) and the foot-and-ankle CAT, as a measure of FS for patients selecting the shoulder or the foot-and-ankle as their main body part affected by their lymphedema. We assessed the ability of the FS scores to distinguish between patient groups in clinically expected ways at admission and discharge from physical therapy. At admission (n=1600), patients who were younger and had more acute symptoms, less severe lymphedema, less co-morbidities, no relevant surgical history, did not use medications for chronic conditions, and exercised regularly, had higher FS. At discharge (n=611), patients who were younger and had less advanced lymphedema, fewer co-morbidities, no relevant surgical history, did not use medications for chronic conditions, exercised regularly, and had more acute symptoms had higher FS change, after controlling for their baseline FS score. Low participation rates in FS outcomes data collection could have biased results. Overall, the CAT-based FS PROMs used in this study discriminated between patient groups in

clinically logical ways both at intake and at discharge from lymphedema treatment.

Keywords: Lymphedema, known-groups construct validity, function status, patient-reported outcomes measures, physical therapy rehabilitation

Lymphedema is a progressive chronic disease that affects quality of life (1-3). Patients with lymphedema often experience deficits in daily tasks, work, sport, and leisure (4-6). Few studies have examined physical functional status (FS) as a patient reported outcome measure (PROM); rather, most use volume measures as the main outcome (7). Among those which assessed function, the Medical Outcomes Study Short Form-12 (SF-12) Health Survey (6); the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30 (EORTC QLQ-C30) (8); or the Disabilities of the Arm, Shoulder and Hand (DASH) (9) were used.

Validity of a questionnaire addresses the degree to which it measures what it claims to measure. There are different aspects of validity, including construct validity (10). Construct validity of a measurement instrument is used when no 'gold standard' exists for comparison. Construct validity uses hypotheses to assess whether the results are consistent with theory. One aspect is the known-groups construct va-

lidity which examines whether the measured scores discriminate between different patient groups in known or clinically-logical ways (11). For example, older patients or patients with a more severe condition(s) are expected to have lower FS than younger and healthier patients (10). Known-groups construct validity for assessing FS in lymphedema has been examined previously using several measures. Launois et al examined construct validity of an upper limb lymphedema (ULL27) questionnaire and found significant and logical trends between four grades of lymphedema severity for the physical dimension (12). Lymphedema functioning, disability, and health were examined using the Lymph-ICF questionnaire among women with and without lymphedema related to breast cancer; patients with lymphedema had lower function than those who had no lymphedema (13).

A few known trends have been found to be associated with FS related to lymphedema at admission to therapy. Severe lymphedema was associated with lower function (3,12-14). However, in other studies, severity was not found to be associated with level of function (15-17). Higher pain levels were associated with lower function (3,15-17). Other factors associated with lower function in lymphedema were: no exercise history (14), cellulitis within the last 30 days (14), substance use (14), and more co-morbidities (3,17).

We did not identify studies on factors associated with FS change in patients with lymphedema. Factors associated with a greater change in FS among patients with musculoskeletal disorders were: early age, acute conditions, less surgeries related to the condition being treated, higher exercise history, and less co-morbidities (11,18-20). Lower severity of lymphedema, defined as the difference (in percent) between a healthy limb and a limb with lymphedema, was associated with greater change in limb volume during treatment (21); younger age was associated with failure to maintain the results of volume change (22). No data were found to support these trends for FS outcomes of patients with lymphedema.

Similar trends, or other trends that seem clinically logical, observed at both admission and discharge from lymphedema physical therapy, would support the construct validity of the FS scores at these time points.

In physical therapy clinics in Maccabi Healthcare Services (Maccabi), a public healthcare organization in Israel, FS is examined during routine practice for all patients with musculoskeletal impairments using the patient-inquiry software developed by Focus on Therapeutic Outcomes (FOTO) (23,24). Data are collected via computerized adaptive testing (CAT) (25), wherein patient's response of perceived ability to perform a functional task are transformed into a continuous score (0-100; low to high function) (18,19,26,27) using an item response theory model (28,29).

CAT tailors the test content to the individual patient based on the difficulty of the items, (28,30,31), improving efficiency of PROM administration (25). For each patient, the CAT begins with an item that represents a functional task at a medium level of difficulty. Based on the patient's response, the CAT algorithm obtains a provisional functional status estimate for the patient, as well as the standard error of measurement (SEM) associated with that estimate (32). The CAT next selects the item from the item bank that is best targeted for people with the derived provisional estimate of functional status; that is, the item administered next is the one that best discriminates among people whose functional status is close to the provisional estimate. After the patient responds to this second item, the provisional estimate is updated. This continues until stopping rules (which are criteria to stop the process, such as a change of the last 3 items of <1 out of 100) are satisfied) or until all items from the item bank have been administered in this way. Each patient receives a FS score according to his/her response in an efficient way with little loss of precision (33). Since 2009, lymphedema therapists in Maccabi have started to administer FS CATs to patients with lymphedema. Two body-part-specific CATs used most often were

the foot-and-ankle CAT (20) and the shoulder CAT (19), which measure perceived functional status of functions related to these impairments. The foot-and-ankle CAT was based on the Lower Extremity Functional Scale (LEFS) questionnaire (34) and was found to discriminate between known groups for patients with musculoskeletal impairments in clinically-logical ways. Patients who had more chronic symptoms, were older, exercised less, had more co-morbidities, and underwent more surgical procedures reported less FS change (less improvement) at discharge (20). The shoulder CAT was developed from the validated Flex-ilevel Scale of Shoulder Function (FLEX-SF) questionnaire (35). It was found to have good known groups construct validity for patients with musculoskeletal shoulder impairments, discriminating between groups by age, ethnicity, gender, limb dominance, and those who had had operations in clinically-logical patterns (36). To our knowledge, no published study has yet reported CAT-based FS scores for patients with lymphedema.

Before physical therapists started using FS-based PROMs for patients with lymphedema, a content-validity examination was performed by a group of physical therapists trained in lymphedema therapy who compared the items from the foot-and-ankle and shoulder CATs with other questionnaires used in lymphedema studies (12,37,38). They concluded that the items were appropriate for patients with lymphedema as they represented relevant levels of functional difficulties.

Therefore, our aims were to examine construct validity of the shoulder CAT and the foot-and-ankle CAT, as measures of FS for patients selecting the shoulder or the foot-and-ankle as their main body part affected by their lymphedema. We assessed the ability of the FS scores to distinguish between patient groups in clinically-expected ways at admission and discharge from physical therapy. Our hypotheses were that patients who were older and had more advanced lymphedema stage and severity, more co-morbidities, more chronic symptoms, purchased more medication for

chronic conditions, surgical procedures related to their lymphedema, and exercised less will have lower FS scores at admission and lower FS change at discharge.

METHODS

Design

This was a retrospective secondary analysis of longitudinal observational cohort data collected during 2009-2017 at Maccabi.

Sample

Data were captured from the integrated electronic medical records and electronic outcomes system (33) from 51 clinics, including 75 physical therapists treating patients for lymphedema, during 2009-2017. Patient data were extracted if they received therapy for lymphatic disorders and were above 18 years of age. The baseline cohort was identified as having received treatment for lymphedema of the foot-and-ankle or the shoulder using the electronic medical records database. To increase generalizability of our results to patients with lymphedema, we assessed for the potential for a systematic patient selection bias. A common concern with observational data is that a systematic patient selection bias might exist if providers tend to collect admission and discharge outcomes data more from patients perceived to have a better outcome. In such a case, external validity may be jeopardized. Therefore, assessing for differences between patients with or without complete outcomes data is common (11,39-41). First, we examined the percent of patients who had FS scores at admission from the baseline cohort (33). (We analyzed each episode separately; therefore, we refer in the text to episodes of care for patients.) Second, we compared patient characteristics between those with or without FS scores at admission. To assess whether we could generalize the results at discharge, we calculated the percent of patients who had FS scores at both admission and

discharge (complete), compared to those that had only taken the FS CAT at admission (incomplete) (33) and compared characteristics of patients with complete or incomplete FS outcomes to assess the potential for a systematic patient selection bias at discharge.

The eight patient variables of interest tested for known groups constructs validity were: age groups (18-44, 45-65 or >65), lymphedema stage classifications (0, 1, 2 and 3, with 3 being the most advanced stage) (42); lymphedema severity classification (mild is defined as a difference of up to 20% from the healthy limb; moderate 20-40% difference; and severe is defined as higher than 40% difference than the healthy limb); number of co-morbidities as the number of condition-specific health registries (0/1 registry, 2 or more registries) (43); acuity of symptoms as days from the onset of the lymphedema (up to 21 days; 22-90 days; 91 days and more); number of chronic condition medications purchased (none; 1 or more); number of surgical procedures related to the lymphedema (none; 1 or more); and exercise history (at least 3 times a week; once or twice a week; seldom or never). Most patient characteristics reflect the current status at admission, e.g., purchase of chronic medications and co-morbidities, acuity, and lymphedema severity and stage. Surgical history reflects any past surgery relevant to the current physical therapy episode of care. Exercise history reflects status prior to the onset of the condition being treated.

Data Analysis

Descriptive analyses were used to report frequencies of categorical and nominal variables and means (standard deviation) for continuous variables. Comparisons were done using t-test for continuous variables and Chi-square analysis for nominal and categorical variables. To examine the known groups construct validity, an analysis of covariance (ANCOVA) was used for each variable of interest, one at a time. The dependent variable for the known-groups analyses at admission

was FS at intake, with age as a covariate for the assessment of variables other than age. The dependent variable for the known-groups analyses at discharge was FS change score, with FS score at intake as covariate. Analyses were performed using the Statistical Package for Social Sciences (SPSS version 24.0, SPSS Inc., Chicago, IL, 2012). Approval for this study was granted by the ethics committee of Maccabi.

RESULTS

Descriptive Data

Figure 1 illustrates a sampling diagram of patients for the known-group construct validity study. After exclusions, out of 5545 patients, 1600 participated in the FS survey at admission. A comparison of patients who participated or did not participate in FS outcomes at admission by body region (lower and upper extremities) is presented in Table 1. Participation

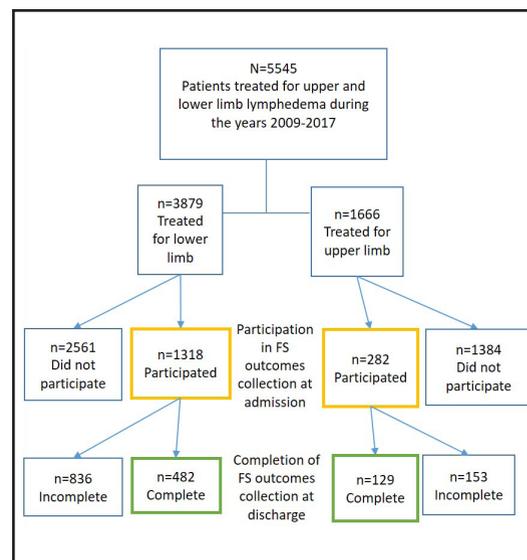


Fig. 1: Patient selection diagram by participation and completion of functional status (FS) outcomes collection. Participation refers to having or not having completed FS surveys at admission. Completion refers to having completed or not completed FS surveys at discharge.

TABLE 1
Comparison of Patient Characteristics by Body Regions Who Participated or Did Not Participate in Functional Status Outcomes Collection at Admission (N=5545)

	Lower limb (N=3879)		Upper limb (N=1666)			
	Participated (n=1318)	Did not participate (n=2561)	P-value	Participated (n=282)	Did not participate (n=1384)	P
	%(n)	%		%	%	
Age, Mean (SD)*	61.5 (14.9)	62.8 (14.8)	0.011	54.5 (12.4)	57.7 (12.8)	0.000
Age groups %			0.275			0.005
18 to <45	14.1(186)	12.8 (329)		22.3 (63)	16.8 (233)	
45 to <65	39.2 (516)	37.9 (970)		55.0 (155)	51.7 (715)	
65 to highest	46.7 (616)	49.3 (1262)		22.7 (64)	31.5 (436)	
Women %	68.1 (897)	68.4 (1752)	0.823	97.2 (274)	95.6 (1323)	0.228
Stage, %**			0.248			0.008
Stages 0 & 1	26.1 (203)	24.3 (293)		71.3 (129)	60.3 (502)	
Stage 2	58.3 (453)	57.3 (691)		28.2 (51)	36.6 (305)	
Stage 3	15.6 (121)	18.3 (221)		0.6 (1)	3.1 (26)	
Severity, %**			0.109			0.005
Mild	71.5 (313)	65.1 (433)		82.5 (94)	67.1 (349)	
Moderate	21.5 (94)	26.1 (171)		12.3 (14)	21.0 (109)	
Severe	7.1 (31)	8.7 (58)		5.3 (6)	11.9 (62)	
Co-morbidities count, %			<0.000			0.038
0-1 co-morbidities	25.5 (336)	18.9 (485)		21.3 (60)	16.2 (224)	
2 or more co-morbidities	74.5 (982)	81.1 (2076)		78.7 (222)	83.8 (1160)	
Purchase of chronic medication count, %			0.150			0.253
No purchase of medications for chronic conditions	18.7 (247)	20.7 (530)		11.0 (31)	13.5 (187)	
Purchase of medications for chronic conditions	81.3 (1071)	79.3 (2031)		89.0 (251)	86.5 (1197)	

Note: *Independent t-test, otherwise Chi-square analysis. **Stage Foot-&-ankle (n=1982); Shoulder (n=1014); Severity: Foot-&-ankle (n=1100); Shoulder (n=634)

rate for the lower limb was 34% (1318/3879), with no significant differences found on all variables except for co-morbidities and age. Patients who had FS scores at admission had fewer co-morbidities (0-1) and were younger compared to those without FS scores at admission. Participation rate for the upper limb was 17% (282/1666), with no significant differences found on gender and purchase of medications for chronic conditions between patients with and without FS at admission. However, patients with FS scores were younger, had less

advanced and mild lymphedema, and had fewer co-morbidities (0-1), compared to those without FS scores at admission.

Completion rate was 37% (482/1318) for the foot-and-ankle CAT and 46% (129/282) for the shoulder CAT. The comparison of characteristics of patients with complete or incomplete outcomes data are presented in *Table 2*. No significant differences were identified between those with complete or incomplete outcomes data for all variables tested and for both body regions.

TABLE 2
Comparison of Patient Characteristics by Body Regions Who Completed or Did Not Complete Functional Status Outcomes Collection at Discharge (N=1600)

	The Foot & Ankle CAT (N=1318)			The Shoulder CAT (N=282)		
	Complete (n=482)	Did not complete (n=836)	P	Complete (n=129)	Did not complete (n=153)	P
	% (n)	% (n)		% (n)	% (n)	
Intake	48.4 (17.9)	49.2 (17.2)	0.34	55.1 (12.8)	54.0 (11.9)	0.485
Age, Mean \pm SD*	59.9 (15.2)	60.9 (14.1)	0.177	53.0 (11.7)	53.3 (13.5)	0.845
Age groups %			0.490			0.255
18 to <45	12.7 (61)	15.0 (125)		21.7 (28)	22.9 (35)	
45 to <65	39.0 (188)	39.2 (328)		51.2 (66)	58.2 (89)	
65 to highest	48.3 (233)	45.8 (383)		27.1 (35)	19.0 (29)	
Women %	66.3 (319)	69.1 (578)	0.290	96.9 (125)	97.4 (149)	0.806
Stage, %**			0.394			0.223
Stages 0 & 1	23.4 (68)	27.7 (135)		66.7 (58)	75.5 (71)	
Stage 2	61.0 (177)	56.7 (276)		33.3 (29)	23.4 (22)	
Stage 3	15.5 (45)	15.6 (76)		0.0 (0)	1.1 (1)	
Severity, %**			0.153			0.882
Mild	72.8 (123)	70.6 (190)		81.0 (47)	83.9 (47)	
Moderate	23.1 (39)	20.4 (55)		13.8 (8)	10.7 (6)	
Severe	4.1 (7)	8.9 (24)		5.2 (3)	5.4 (3)	
Co-morbidities count, %			0.979			0.405
0-1 co-morbidities	24.7 (119)	26.0 (217)		9.3 (12)	12.4 (19)	
2 or more co-morbidities	75.3 (363)	74.0 (619)		90.7 (117)	87.6 (134)	
Acuity			0.596			0.399
Onset up to 21 days	3.30 (16)	4.4 (37)		11.6 (15)	17 (26)	
Onset between 22-90 days	18.0 (87)	17.3 (145)		35.7 (46)	35.9 (55)	
Onset more than 91 days	78.6 (379)	78.2 (654)		52.7 (68)	47.1 (72)	
Purchase of chronic medication count, %			0.246			0.246
No use of medications for chronic conditions	17.0 (82)	19.7 (165)		17.0 (82)	19.7 (165)	
Use of medications for chronic conditions	83.0 (400)	80.3 (671)		83.0 (400)	80.3 (671)	
Number of surgeries			0.144			0.94
No surgeries at intake	74.5 (359)	78.1 (653)		22.9 (35)	23.3 (30)	
1 or more	25.5 (123)	21.9 (183)		77.1 (118)	76.7 (99)	
Exercise History			0.330			0.769
At least three (3) times a week	23.2 (112)	24.3 (203)		31.0 (40)	28.1 (43)	
Once or twice a week	32.2 (155)	28.3 (237)		35.7 (46)	34.6 (53)	
Seldom or never	44.6 (215)	47.4 (396)		33.3 (43)	37.3 (57)	

Note: *Independent t-test; otherwise, Chi-square analysis, **Stage for Foot-&-ankle CAT (n=777); Shoulder CAT (n=181); Severity: Foot-&-ankle CAT n=438; Shoulder CAT (n=114)

Estimated marginal means of 1600 patients who had FS scores at admission on the foot-and-ankle (n=1318) or shoulder (n=282) CATs are presented in *Tables 3 and 4*, respectively. For the foot-and-ankle CAT, seven of eight expected trends were observed, with

higher FS scores at admission for patients who were younger and had lower lymphedema stages, less severe lymphedema, fewer co-morbidities, did not purchase medications for chronic conditions, had no relevant surgeries to the foot-and-ankle, and exercised

TABLE 3
Estimated Means for Functional Status at Intake of Lower Limb (N=1318)

Independent variable	n	Estimated Marginal Means	Confidence Interval	F value	P value
Age-groups*				56.5	<0.000
18 to <45	186	58.9	56.1-61.7		
45 to <65	516	48.9	47.3-50.4		
65 to highest	616	43.5	42.1-44.8		
Lymphedema Stage**				15.2	<0.000
Stages 0 & 1	203	52.4	49.9-54.8		
Stage 2	453	46.2	44.6-47.8		
Stage 3	121	42.5	39.4-45.7		
Lymphedema Severity***				7.6	0.001
Mild	313	51.3	49.3-53.3		
Moderate	94	49.3	45.6-52.9		
Severe	31	37.7	31.1-44.3		
Co-morbidities count				13.0	<0.000
0-1 co-morbidities	336	51.3	48.7-53.9		
2 or more co-morbidities	982	46.1	44.9-47.3		
Acuity				1.6	0.195
Onset up to 21 days	53	46.6	41.7-51.2		
Onset between 22-90 days	232	49.6	47.2-51.8		
Onset more than 91 days	1033	47.3	46.3-48.4		
Purchase of chronic medication count				16.5	<0.000
No purchase of medications for chronic conditions	247	52.5	49.6-55.3		
Purchase of medications for chronic conditions	1071	46.1	45.1-47.2		
Number of surgeries				45.1	<0.000
No surgeries at intake	1012	49.5	48.4-50.5		
1 or more surgeries	306	41.9	40.0-43.8		
Exercise History				9.2	<0.000
At least three (3) times a week	315	50.1	48.2-52.1		
Once or twice a week	392	49.5	47.7-51.2		
Seldom or never	611	45.6	44.2-47.0		

Note: *ANOVA analysis; all other variables controlled for Age-groups variable; **data available on n=777, *** data available on n=438

regularly prior to admission. The expected trend for the acuity variable was not observed. For the shoulder CAT, five of eight expected trends were observed, with higher FS scores at admission for patients who had fewer co-morbidities, were treated for acute con-

ditions, did not purchase medications for chronic conditions, had no relevant surgical procedures for the shoulder, and had exercised regularly. The expected trends for the variables of age, lymphedema stage and severity were not observed.

TABLE 4
Estimated Marginal Means for Functional Status at Intake of Shoulder (N=282)

Independent variable	n	Estimated Marginal Means	Confidence Interval	F value	P value
Age-groups*				2.10	0.123
18 to <45	63	55.2	52.1-58.2		
45 to <65	155	51.8	49.7-53.9		
65 to highest	64	54.6	51.9-57.4		
Lymphedema Stage**				0.15	0.694
Grades 0 & 1	129	53.9	51.6-56.2		
Grade 2	51	53.6	49.8-57.4		
Grade 3	1	34.4			
Lymphedema Severity***				0.23	0.796
Mild	94	54.9	52.2-57.6		
Moderate	14	56.4	48.3-61.9		
Severe	6	49.5	30.9-68		
Co-morbidities count				0.94	0.334
0-1 co-morbidities	60	54.9	50.8-58.9		
2 or more co-morbidities	222	52.7	51.0-54.5		
Acuity				0.72	0.488
Onset up to 21 days	41	55.2	51.1-59.3		
Onset between 22-90 days	101	53.9	51.3-56.5		
Onset more than 91 days	140	52.5	50.4-54.5		
Purchase of chronic medication count				2.22	0.137
No purchase of medications for chronic conditions	31	56.7	51.8-61.7		
Purchase of medications for chronic conditions	251	52.8	51.2-54.4		
Number of surgeries				0.03	0.861
No surgeries at intake	65	53.4	50.2-56.5		
1 or more	217	53.1	51.3-54.8		
Exercise Adherence				3.894	0.021
At least three (3) times a week	83	55.8	53.1-58.5		
Once or twice a week	99	53.4	50.9-55.8		
Seldom or never	100	50.6	48.1-53.1		

Note: *ANOVA analysis; all other variables controlled for Age-groups; **data available on n=181, ***data available on n=114

Estimated marginal means for the foot-and-ankle CAT and the shoulder CAT are presented in *Tables 5 and 6*, respectively. For patients who answered the foot-and-ankle CAT, seven of eight expected trends were found, with more FS change for patients who were younger and had less advanced lymphedema stage classification, fewer co-morbidities, were treated for acute problems, did not purchase medications for chronic conditions, had no relevant surgery, and exercised reg-

ularly. The expected trend for the severity classification variable was not observed. For patients who answered the shoulder CAT, four of eight expected trends were found, with more FS change for patients who were younger, had fewer co-morbidities, were treated for more acute symptoms, and did not purchase medications for chronic conditions. The expected trends for the variables of stage and severity classifications, and surgical and exercise history were not observed.

TABLE 5					
Estimated Marginal Means for Functional Status at Discharge Controlling for Intake, for Lower Limb (N=482)					
Independent variable	n	Estimated Marginal Means	Confidence Interval	F value	P value
Age-groups				1.198	0.303
18 to <45	61	10.9 (61)	7.0-14.8		
45 to <65	188	7.8 (188)	5.9-9.8		
65 to highest	233	7.6 (233)	5.7-9.4		
Lymphedema stage*				0.912	0.403
Stage 0 & 1	68	11.9	8.3-15.6		
Stage 2	177	9.3	7.1-11.5		
Stage 3	45	8.6	4.2-13.0		
Lymphedema Severity**				0.289	0.75
Mild	123	8.8	6.5-11.2		
Moderate	39	6.9	2.7-11.2		
Severe	7	8.2	-3.5-19.9		
Co-morbidities count				5.06	0.025
0-1 co-morbidities	119	10.9 (119)	8.3-13.6		
2 or more co-morbidities	363	7.5 (363)	6.0-8.9		
Acuity				3.713	0.025
Onset up to 21 days	16	12.5 (16)	5.6-19.4		
Onset between 22-90 days	87	11.4 (87)	8.5-14.3		
Onset more than 91 days	379	7.4 (379)	6.1-8.8		
Purchase of chronic medication count				2.555	0.111
No purchase of medications for chronic conditions	82	10.8 (82)	7.5-14.2		
Purchase of medications for chronic conditions	400	7.8 (400)	6.5-9.3		
Number of surgeries				0.52	0.471
No surgeries at intake	359	8.6 (359)	7.1-10.0		
1 or more	123	7.5 (123)	4.9-10.1		
Exercise History				0.33	0.716
At least three (3) times a week	112	9.2	6.7-11.7		
Once or twice a week	155	7.9	5.8-10.2		
Seldom or never	215	7.9	6.1-9.8		

*Data available on n=290, **data available on n=169

TABLE 6
Estimated Marginal Means for Functional Status at Discharge for
Shoulder Controlling for Intake (N=129)

Independent variable	n	Estimated Marginal Means	Confidence Interval	F value	P value
Age groups				0.693	0.500
18 to <45	28	13.4	8.6-18.3		
45 to <65	66	10.3	7.2-13.5		
65 to highest	35	9.9	5.5-14.4		
Lymphedema stage*				0.026	0.872
Stage 0 & 1	58	9.9	6.6-13.3		
Stage 2	29	9.5	4.8-14.2		
Stage 3	-	-			
Lymphedema Severity**				2.471	0.094
Mild	47	8.5	4.8-12.2		
Moderate	8	13.7	4.6-22.7		
Severe	3	-5.6	-20.5-9.2		
Co-morbidities count				3.995	0.021
0-1 co-morbidities	32	16.5	11.9-20.9		
2 or more co-morbidities	97	8.7	6.2-11.3		
Acuity				6.283	0.03
Onset up to 21 days	15	20.6	14.4-26.9		
Onset between 22-90 days	46	10.8	7.2-14.3		
Onset more than 91 days	68	8.3	5.4-11.2		
Purchase of chronic medication count				2.89	0.092
No purchase of medications for chronic conditions	12	16.8	9.4-24.3		
Purchase of medications for chronic conditions	117	8.3	7.7-12.5		
Number of surgeries				0.00	0.949
No surgeries at intake	30	10.5	5.7-15.3		
1 or more	99	10.7	80.1-13.3		
Exercise History				2.042	0.134
At least three (3) times a week	40	10.2	6.2-14.3		
Once or twice a week	46	13.6	9.7-17.4		
Seldom or never	43	7.9	40.1-11.9		

*Data available on n=87, **data available on n=58

DISCUSSION

This study aimed to examine the known-groups construct validity of FS scores derived from the foot-and-ankle and shoulder CATs for patients with lymphedema, and to explore whether known trends from other studies on FS scores at intake and FS change at discharge also exist among patients with lymphedema. Overall, most of our hypotheses were confirmed, with FS scores discriminating

patient groups in clinically logical ways for the majority of variables of interest. Hypotheses not confirmed are discussed below.

The foot-and-ankle CAT scores at admission discriminated between patient groups in known and clinically logical ways for all variables tested, except for the acuity variable. No prior studies have reported construct validity of the foot-and-ankle CAT for patients with lymphedema. Our findings do not support Keeley et al's (2010) report. In their study, the

FS scores on the LYMPHQOL questionnaire (a quality of life questionnaire with different dimensions) did not discriminate between different lymphedema severity stages (37). The researchers thought that other factors such as co-morbidities and neurological problems could be associated with lower function and were not tested in their study; our findings support this notion as patients who had more co-morbidities had lower FS scores at admission. We expected people with more chronic symptoms to have lower FS scores at admission. However, the majority of patients who had lymphedema in our study (96.7%) did not have acute symptoms, which made it unlikely to be able to identify the expected trend for this variable.

The shoulder CAT scores at admission discriminated between patient groups in clinically logical ways for five of eight variables assessed, partially supporting our hypothesis. Discrimination between severity and stages of lymphedema was not supported. However, a validity study on the ULL27 questionnaire examined FS scores and reported on logical discrimination between different grades of lymphedema severity at admission (15). It is clinically logical to expect that women with more advanced stages of lymphedema will have lower FS scores. The fact that our shoulder cohort included very few patients with an advanced stage and severity (one with Stage 3 and six with severe lymphedema) might limit our ability to test the association between these factors and FS scores at admission.

On discharge, the foot-and-ankle CAT discriminated between patient groups in clinically logical ways on seven of the eight variables assessed. Although not all variables were statistically significant, possibly due to sample size limitations, the trend in each group was clinically logical. No published report on CAT FS at discharge on patients with lower limb lymphedema was found; however, a study in 2008 by Hart et al examined known-group construct validity on the foot-and-ankle CAT in patients who received musculoskeletal

rehabilitation in outpatient clinics and found the same trends on the variables of age, acuity, co-morbidities, surgery history, and exercise history (20), supporting the construct validity of this CAT when answered by patients with lymphedema. Contrary to our expectations, no logical trend was found for the variable of lymphedema severity, possibly due to the low sample size of this group with only seven patients with a severe classification.

On discharge, the shoulder CAT discriminated between patient groups in clinically logical ways on four of the eight variables assessed. Although not all variables were statistically significant, the trend in each group was clinically logical, adding to the previous support of the construct validity of this CAT when answered by patients with lymphedema. The study by Hart et al (19) which examined shoulder CAT among patients who received rehabilitation in outpatient clinics found the FS at discharge to discriminate among groups of age (older people had lower discharge FS scores), gender (women had lower FS scores than men), and ethnicity (Caucasian had higher discharge FS than other ethnic groups). Our findings partially support these findings, as we found FS change at discharge to discriminate between age groups. Furthermore, no logical trend was found in other variables, such as stage and severity classifications of lymphedema, which can be explained as discussed above, by the low sample of severe lymphedema (three patients) with no patient in Stage 3 lymphedema classification. No trends were found on exercise history; however, we can observe that patients who exercise seldom have lower change in FS change scores than those who do exercise. We cannot provide an explanation why no trend was found on the surgical history variable.

Altogether, the findings suggest that shoulder, ankle, and foot function of patients with lymphedema can be measured with the CAT questionnaires in routine practice.

LIMITATIONS

This study did not examine clinical meaningfulness of the FS score differences between the groups assessed. Qualitative or anchor based methods of assessing clinically-important group differences are needed to assess clinical meaningfulness of our findings. The potential for patient selection bias was a major concern in our study, as the overall participation rate was only 29%, possibly reducing generalizability of our results for patients with lymphedema. However, in an attempt to address this issue, we compared characteristics between those who had FS scores at admission and those who did not in patient groups with both lower and upper limb lymphedema. Our findings show that in the group with lower limb lymphedema, people who had no FS score at admission had more co-morbidities. No other differences were found between the groups, reducing the overall concern for a potential patient selection bias at admission. In the upper limb group, patients with no FS scores at admission had no differences on the variables of gender and the use of medication; however, they had more severe lymphedema, more advanced stages of lymphedema, more co-morbidities, and were older. As the number of patients with more severe and advanced lymphedema was small, we may not know if these patients represent the population of people with lymphedema.

An overall low completion rate (38%) was another limitation in our dataset. We did not find any differences between patients with complete or incomplete outcomes data, reducing the concern for a systematic patient selection bias, although selection bias might still exist, as our findings are limited to the variables available to us. Improved participation and completion rates will help reduce concerns for a patient selection bias at admission. In addition to enhanced education and implementation efforts, it is also possible that participation and completion rates may be improved by developing a condition-specific FS-based PROM for patients with lymph-

edema which might better address their most relevant functional limitations. Whether such a tool can help increase therapist and patient interest in the FS scores for clinical decision-making and outcomes monitoring is yet to be studied.

CONCLUSION

Our findings suggest that FS estimated scores from the foot-and-ankle and shoulder CAT can discriminate between groups of patients in clinically logical ways on selected patient characteristics, supporting the known-group construct validity of the CAT FS in patients with lymphedema at admission and at discharge. We recommend further use of the foot-and-ankle and shoulder CAT for assessing perceived physical function for patients with lymphedema to enhance clinician's focus on functional goals in addition to swelling reduction. Improved participation and completion rates of routine use of FS outcomes at admission and discharge are important implementation goals that may increase both clinical and research applications of PROMs, for the benefit of our patients.

CONFLICT OF INTEREST AND DISCLOSURE

Dr. Deutscher acknowledges that he is a consultant for Focus on Therapeutic Outcomes (FOTO), the database management company that provided the patient-reported outcome measures used for this study. All authors declare no other competing financial interests exist.

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