FOTO PATIENT OUTCOMES

FOTO outcome measures: Efficiency, Reliability, and Clinical Interpretation

Table of Contents

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Risk-Adjusted Predicted Change (RAPC)

- The FOTO RAPC score is a predicted change estimate that accounts for patient's medical severity as well as many other important patient characteristics known to influence patient outcomes.
- RAPC is the first choice for consideration because it is scientifically robust and pertains to the functional status outcome at discharge.
- On the individual patient level, RAPC is an important guide in that it represents what happens ON AVERAGE with other similar patients. E.g., if a patient has the potential to exceed the RAPC, care should not be stopped once the patient achieves the predicted change score.

Reliability: The Standard Error of Measurement (SEM), Minimal Detectable Improvement (MDI), or Minimal Detectable Change (MDC)

- The random score fluctuations expected from unchanged patients can be viewed as the measurement error, or the ***standard error of measurement (SEM).***
- The SEM of a measure is used to compute the MDI or MDC at different levels of confidence.
- Note that under item response theory, the SEM may vary by level of physical function scores. Therefore, patients with different scores at intake may have different magnitudes of standard errors. *Consequently, MDIs and MDCs may vary by score range.* Typically, extreme scores are more likely to have larger SEMs, and thus need more change to exceed measurement error.
- That said, since FOTO measures are administered using computerized adaptive testing (CAT), the typical SEM for most FOTO measures is approximately 4-5 points for most of the score range because the CAT is set to stop once this level of SEM is reached. That is, functional questions will continue to be administered to the patient until the desired SEM is achieved.
- MDI or MDC are reliability estimates of change scores over time defined as the minimal improvement or change needed to exceed measurement error at a specific level of confidence.
- For example, if the MDI_{90} (an MDI at a 90% confidence level) of a measure is 5 points, 90% of truly unimproved patients would be expected to have Improvement scores below 5 points.
- In other words, 5 or more improvement points are needed to exceed random score fluctuations that are expected from truly unchanged patients, at a 90% confidence level.

Table 1 below describes these reliability estimates by measure and administration mode, including the full item bank, CAT, and short forms (SF).

Table 1: Reliability of point estimates and change scores

PROM	№ of Items			Reliability			Scaled SEM			MDI_{90}/MDC_{80}		
	Full	CAT[f]	SF	Full	CAT	SF	Full	CAT	SF	Full	CAT	SF
Low-Back[a]	28	6.5/6/4-19	10	.98	.92	.94	1.9	3.9	3.3	3.4	7.1	6.0
LEPF[b]	18	4.9/4/4-12	10	.96	.92	.94	3.5	4.9	4.2	6.3	8.9	7.7
Neck[c]	28	5.6/5/3-19	10	.96	.91	.95	2.7	3.7	2.8	4.8	6.8	5.2
Shoulder[d]	53	5.4/5/4-19	10	.99	.94	.97	1.2	3.8	2.8	2.2	6.8	5.0
EWH[e]	42	5.8/5/4-18	10	.99	.94	.97	1.4	3.8	3.0	2.5	6.8	5.4
UQE	25	5.6/5/5-12	10	.96	.93	.93	3.6	4.7	4.9	6.5	8.5	8.8
LQE	20	6.1/5/5-12	10	.96	.92	.92	3.4	4.7	4.8	6.2	8.5	8.8
SUE	28	6.0/5/5-12	10	.97	.96	.93	3.6	4.2	5.5	6.4	7.7	10.0
SLE	24	5.6/5/5-12	10	.97	.95	.93	3.0	4.1	4.6	5.5	7.4	8.3
JFSS	13	5.6/5/4-8	6	.88	.91	.76	3.5	2.9	4.9	6.3	5.3	8.9
BC	16	4.7/4/4-10	6	.98	.96	.95	1.4	1.9	2.2	2.6	3.4	4.0
DPS	4	-	-	.72	-	-	5.3	-	-	9.6	-	-
DFS	13	8.0/8/5-10	7	.92	.91	.89	2.8	3.0	3.4	5.1	5.5	6.1

Full=full item bank
NA=Not available
[a] Full item bank reliability from the Low Back Brief Report. [8]
[b] FOTO Lower Extremity Physical Function (LEPF) is the primary outcome measure for orthopedic hip, knee, ankle/foot, lower leg w/o knee. Scaled scores approximate 0-100.[1]
[c] Full item bank reliability from the Neck development manuscript.[2]
[d] Full item bank reliability from the Shoulder Brief Report.[3]
[e] Full item bank reliability calculated from SF reliability using the Spearman–Brown prediction formula.
[f] CAT Number of items are (mean/median/range)
CAT=computerized adaptive testing
SF=short form
SEM=Median standard error of measurement: Described using the scaled metric (same unites used for the measure)
MDI_{90}=minimal detectable improvement at 90% confidence level, which is equivalent to the MDC_{80} (minimal detectable change at 80% confidence level).
UQE= FOTO Upper Quadrant Edema, scaled scores approximate 0-100.[4]
LQE= FOTO Lower Quadrant Edema, scaled scores approximate 0-100.
SUE= FOTO Stroke Upper Extremity, scaled scores approximate 0-100.
SLE= FOTO Stroke Lower Extremity, scaled scores approximate 0-100.
JFSS= FOTO Jaw Functional Status Scale; scores are on the T-score metric.
BC=Balance Confidence scores are on the T-score metric.
DPS= Dizziness Positional Status; scores are on the T-score metric.
DFS= Dizziness Functional Status; scores are on the T-score metric.

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Minimum Clinically Important Improvement (MCII)

- MCII represents the amount of score improvement that is likely to be meaningful to the patient.
- MCII values were determined using patient ratings of 3 or greater on a 15-point Global Rating of Change (GROC) from -7 to +7 where +3 was defined as "Somewhat Better."
- While MCII can be a useful interpretation guide, it has limitations such as:
- MCII values are calculated using anchor-based methods, and anchor-based methods have a number of weaknesses:
- There are no perfect anchors for classifying individuals as improved or not improved by an important amount.
- Patients may find it challenging to recall their initial level of functional abilities when assessing change (recall bias).
- MCII does not represent the end point goal of care as it is designed to identify a minimal change.
- MCII is typically not risk-adjusted.
- FOTO measures provide MCII values in 2 ways:
- By intake FS range because patients at different functional levels at intake tend to differ in the amount of FS improvement needed to be perceived as meaningful.
- Overall estimate representing the average MCII for the full patient population.
- At present, 4 FOTO measures have MCII values developed, as detailed in Table 2 below:

Table 2: Minimal Clinically Important Improvement (MCII) by Intake Score Range

Values are: MCII (score range)	Quartiles of intake scores				
	Q 1	**Q 2**	**Q 3**	**Q 4**	**Overall**
Low-Back	9 (min-43)	5 (>43-51)	3 (>51-58)	5 (>58-max)	5 (min-max)
LEPF	19 (min-38)	12 (39-50)	11 (51-62)	8 (63-max)	11.5 (min-max)
Neck	15.2 (min-43.8)	10.2 (>43.8-51.9)	7.1 (>51.9-59.3)	3.7 (>59.3-max)	8.1 (min-max)
Shoulder	23 (min-43)	10 (>43-52)	5 (>52-60)	2 (>60-max)	8 (min-max)

Functional Staging

- Functional Staging models provide clinicians with yet another tool for clinical interpretation of an individual patient's functional status score.
- Functional Staging provides a visual display of a clinically logical classification system based on Item Response Theory methods.
- Each model is presented below, with a staging model operational definitions and a functional staging chart.
- Staging model operational definitions provide a simple guideline to interpret the functional stage levels, and the functional staging chart illustrates the expected response to a given item at each functional stage.
- At present, four FOTO measures have functional staging models developed, which are presented below.

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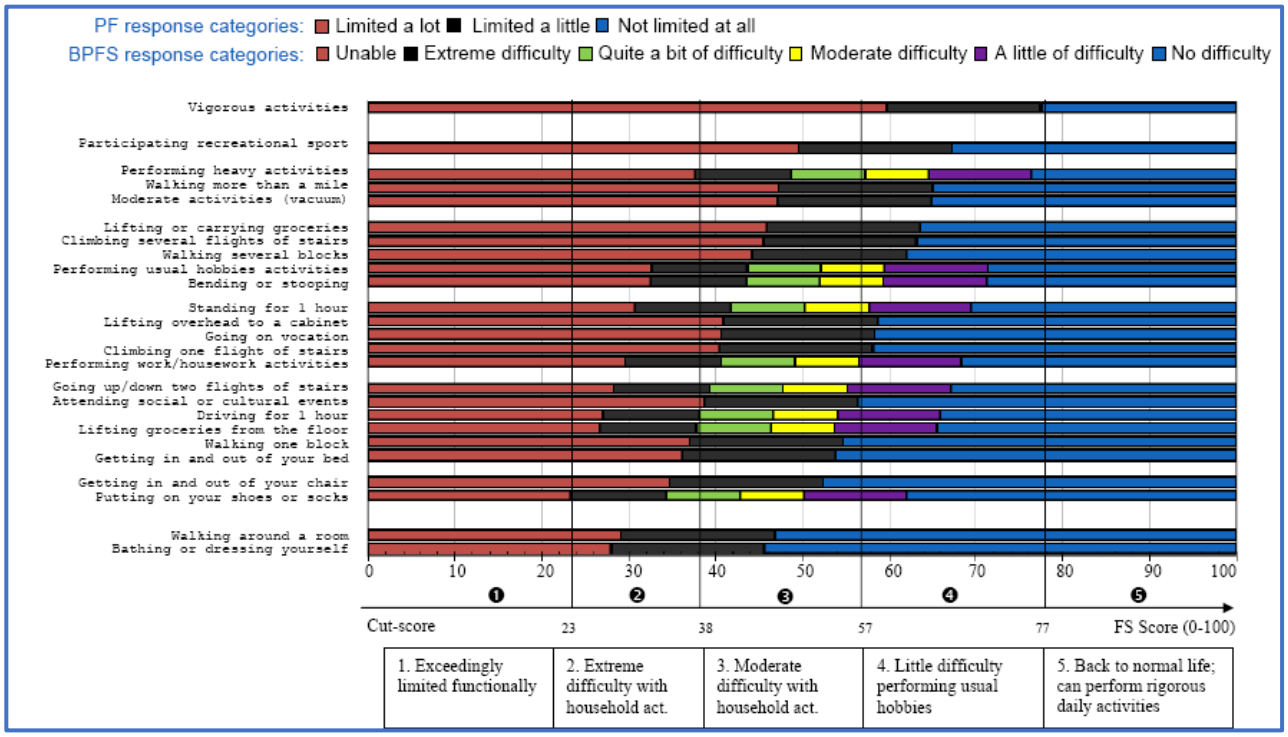
Low-Back functional staging operational definitions:[5]

Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
Score 0-23	**24-38**	**39-57**	**58-77**	**78-100**
Exceedingly limited with routine functions	Exhibits extreme difficulty performing usual work or household activities	Exhibits moderate difficulty performing usual work or household activities	Exhibits little difficulty performing usual work or household activities and hobbies	Back to normal life performing rigorous daily activities
unable to perform or is limited a lot in performing activities such as donning shoes or socks, bathing or dressing, getting into or out of a chair or bed, and walking around a room	has regained limited routine functioning but still has extreme difficulty performing activities such as work or household activities, driving a car for an hour, lifting groceries from the floor, and walking 1 block	has moderate difficulty performing daily activities around the home such as work or household activities, bending or stooping, climbing one flight of stairs, lifting overhead, and standing for an hour	can perform with a little bit of difficulty indoors and outdoors activities such as usual hobbies, bending or stooping, standing for an hour, work or household tasks, and driving for an hour.	has no difficulty walking more than 1 mile or any limitation in performing activities requiring vigorous work, sports, or lifting tasks.

Low Back functional staging chart:[5]



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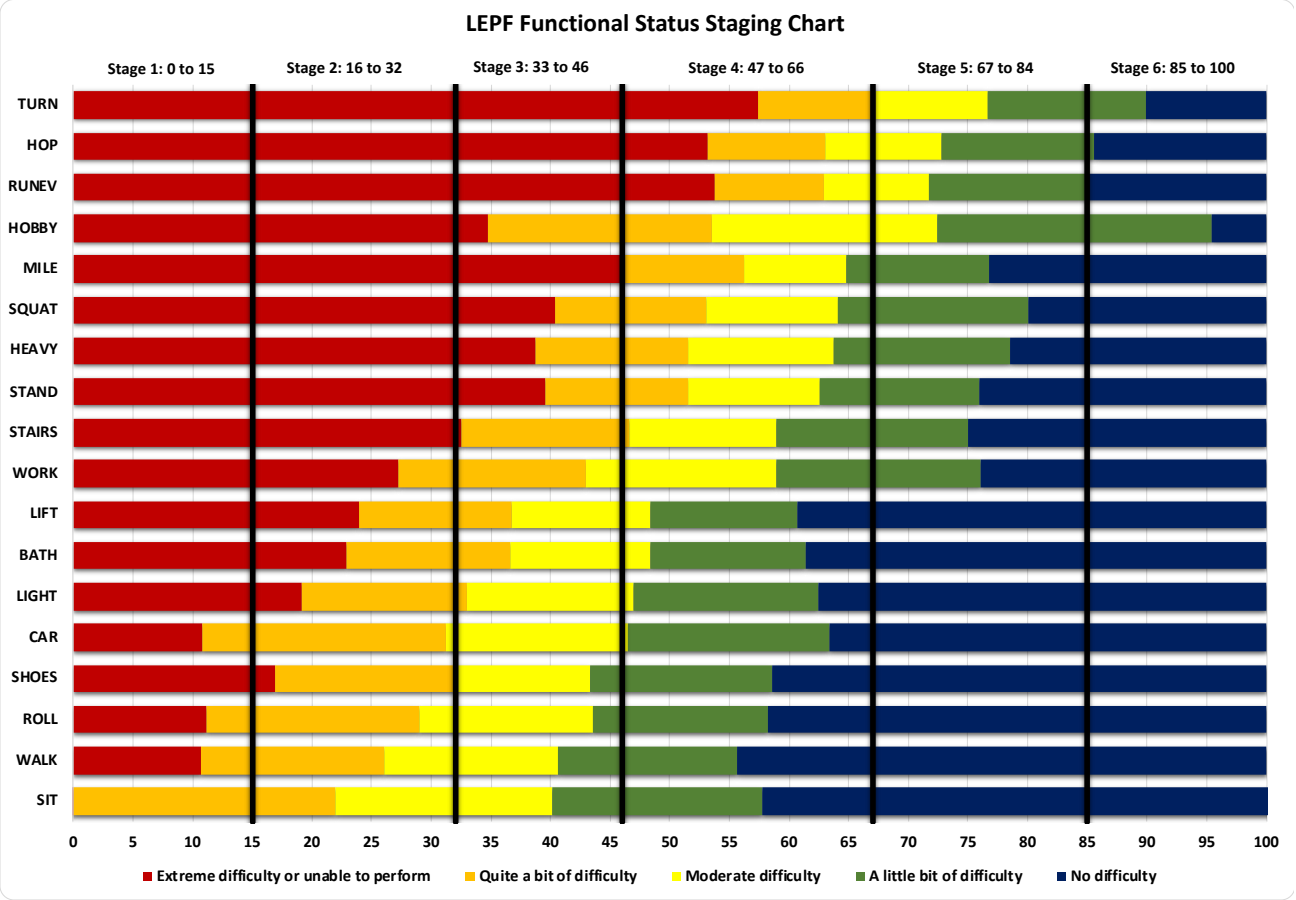
LEPF functional staging operational definitions:

Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 6
Score 0-15	**Score 16-32**	**Score 33-46**	**Score 47-67**	**Score 68-84**	**Score 85-100**
Highly Restricted Ambulation	Household ambulator	Limited community ambulator	Independent community ambulator	Advanced Ambulation	Athletic Ability
Unable/extreme difficulty walking between rooms or light activities around the home	Quite a bit of difficulty with light activities around the home and unable/extreme difficulty going up or down 10 stairs.	Quite a bit of difficulty with going up or down 10 stairs and unable/extreme difficulty walking a mile	Moderate difficulty walking a mile and quite a bit of difficulty with running on even ground	No difficulty with light activities around the home and a little bit of difficulty with running on even ground	No difficulty with running on even ground

LEPF functional staging chart:



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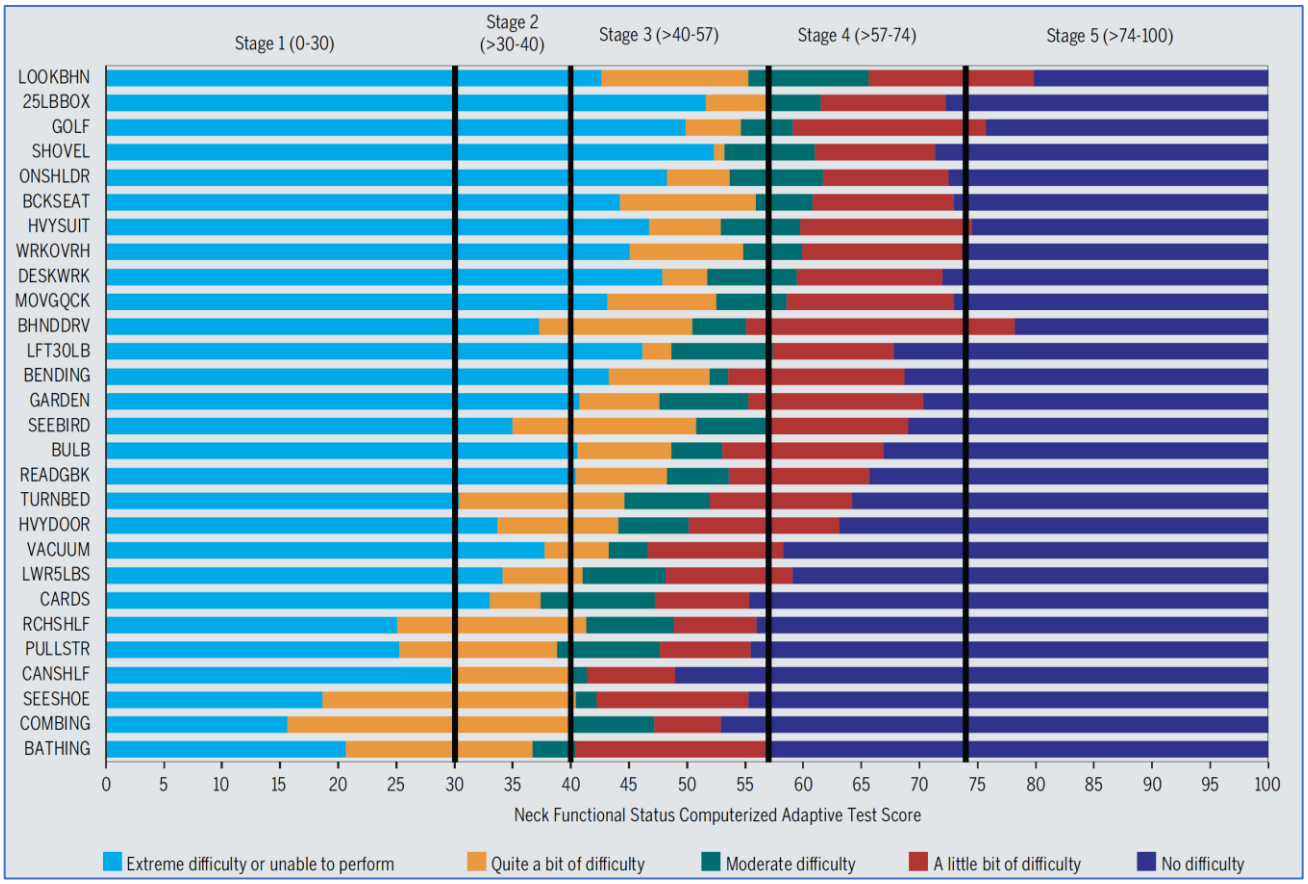
Neck functional staging operational definitions:[6]

Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
Score 0-30	**Score 31-40**	**Score 41-57**	**Score 58-74**	**Score 75-100**
Limited self-care	Light activity	Moderate activity	High activity	Vigorous activity
Exceedingly limited in neck motion, basic self-care tasks, or reaching	Able to perform neck motion, basic self-care tasks, or reaching with difficulty	Able to move light- to medium-weight objects, perform neck motions, or move in bed with minimal to moderate difficulty. Able to perform basic self-care tasks with minimal to no difficulty	Able to perform high-level activities with minimal to moderate difficulty or neck motions with minimal to no difficulty	Able to perform vigorous work/occupation tasks, sports, recreational activities, and heavy household tasks/yard work and able to handle heavy objects overhead with minimal to no difficulty

Neck functional staging chart:[6]



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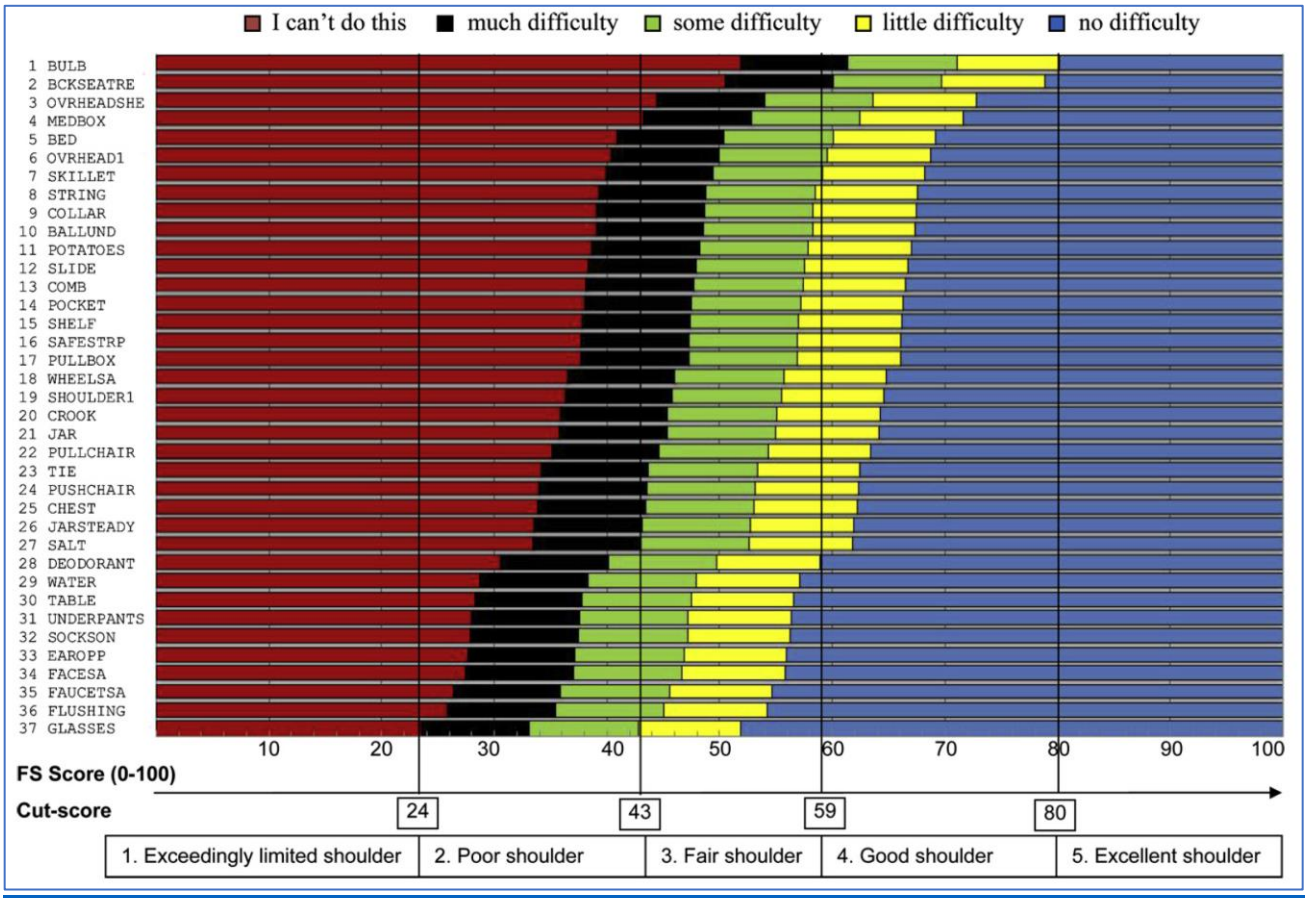
Shoulder functional staging operational definitions:[7]

Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
Score 0-24	**Score 25-43**	**Score 44-59**	**Score 60-80**	**Score 81-100**
Exceedingly limited shoulder	Poor shoulder	Fair shoulder	Good shoulder	Excellent shoulder
Unable to perform or limited a lot performing light routine activities using the affected arm like taking off glasses, flushing the toilet, turning a faucet or washing the face	Regained limited functioning and can perform light daily activities with some difficulty but still has much difficulty performing moderate upper extremity activities such as picking up and drink out of a full water glass, pulling a chair out from a table, and tightening a jar lid	Can perform light daily activities with little difficulty and moderate daily activities with some difficulty but still has much difficulty performing heavy upper extremity activities such as lowering a lightweight object from the top shelf of a closet and reaching an overhead shelf	Can perform routine daily activities using the affected arm with no difficulty but still has a little difficulty performing heavy activities that require a combination of good range of motion, muscle strength, and endurance such as reaching an overhead shelf, working overhead for more than 2 min, or touching an object on the back seat while sitting in the front seat of a car	No difficulty using the affected arm to perform almost any rigorous activity

Shoulder functional staging chart:[7]



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