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Validation of a Hand-held Dynamometer for Assessment of Lower Extremity Muscle Strength in Multiple Sclerosis

> Ted R. Brown, MD, MPH EvergreenHealth MS Center



Disclosures

	Research Grant	Consulting	Honoraria
Acorda	✓	✓	✓
Astellas	✓		
Biogen Idec	✓	✓	✓
Genzyme		✓	✓
Pfizer			✓
Teva	✓	✓	✓
Galen	✓		

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Background

Weakness is an important sign of MS

- Legs affected > arms
- Consequences: loss of mobility, falls, ↓QOL
- Testing strength is important for clinical and research purposes



Strength assessment

- How to measure/what to measure?
 - MMT
 - Isometric or isokinetic
 - Peak strength or muscle fatiguability



- NIH Toolbox recommended testing of Lower extremity (LE) strength
 - A) 5 rep sit to stand
 - B) isometric knee extension w dynamometer



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Reuben, et al. Neurology 2013 80 (March Suppl 3)

Hand-held dynamometer (HHD)

Commercially available Microfet2

Wt: <500gm Wireless, digitial display

Records peak force (kg, lb or Newtons)

Range 1.4kg-140kg Increments 0.1kg

Interchangeable heads for variable anatomy





HHD LE Strength assessment: Key features

- ➤ No bulky equipment
- ➤ Includes several muscle groups with composite measure
- ➤ Average repeated efforts
- >Strict protocol with objective, continuous output

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Objective

Single center, cross-sectional validation study of Lower extremity (LE) strength assessment in MS with hand-held dynamometer (HHD)

Outcomes

Inter-rater and inter-session reliability for 5 muscle groups and composite score



Methods

- Recruited: 21 adult subjects with stable MS,
 - 7 = EDSS 0-3.5
 - 7 = EDSS 4.0-5.5
 - 7 = EDSS 6.0-7.5
- **Exclusions**: Contraindication to strength testing, pregnancy
- Strength testing
 - Testing at EvergreenHealth Rehabilitation Dept.
 - Two examiners at each of two separate visits (4 tests total)
 - Blinded PT examiners.
 - Two visits within 21 days.
 - Bilateral testing: hip abduction, hip flexion, knee extension, knee flexion, ankle dorsiflexion
 - HHD- Average of 3 trials, isometric, "make" technique
 - Manual muscle test, 1 trial (grade 0-5)

Lower Extremities Strength summary score (LESS)

LESS = Sum of peak values for each muscle group

	Left	Right
Hip flexion	20, 19.5, 23	22) 20.5, 17
Hip abduction	17, 18.5, 14	16, 14.5
Knee extension	22) 20.5, 17	20, 19.5, 23
Knee flexion	14,16 15.5	17, 13.5, 15
Ankle plantar flexion	18, 18.5, 19	18.5, 18, 17

LESS = 23+22+18.5+16+22+23+16+17+19+18.5 = 195kg

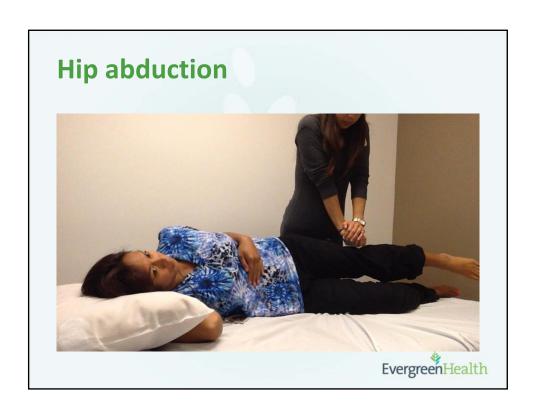
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Hip flexion











Intraclass correlation coefficient (ICC)

ICC is a measure of the reliability of measurements or ratings. The data is centered, using a pooled mean and standard deviation. Values range between 0-1.

ICC > 0.70 = acceptable for clinical purposes

ICC > 0.85 = strong correlation (basis for our p-values)

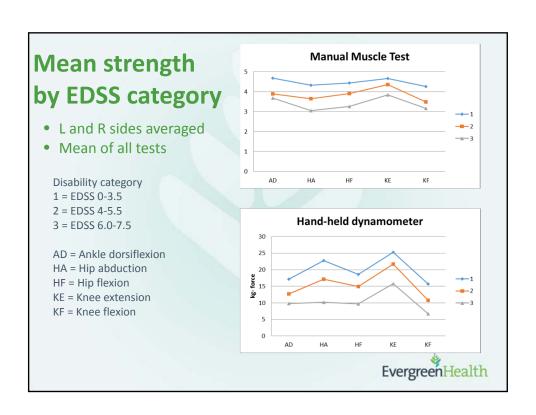


Participant Demographics

Group	Age	Gender	Race	Duration of Disease (years)	MS type	MS drug therapy	EDSS (total score)
One	46.71 avg	Male (3)	Caucasian (7)	7.21 avg	RRMS (7)	Yes (5)	2.10 avg
	6.80 sd	Female (4)		4.12 sd		No (2)	1.02 sd
Two	53.29 avg	Male (4)	Caucasian (6)	14.29 avg	RRMS (4)	Yes (3)	4.10 avg
	9.78 sd	Female (3)	Moroccan (1)	7.45 sd	SPMS (1), PPMS (2)	No (4)	0.24 sd
Three	59.86 avg	Male (1)	Caucasian (6)	19.00 avg	RRMS (3)	Yes (6)	6.0 avg
	12.13 sd	Female (6)	Hispanic (1)	9.52 sd	SPMS (3)	No (1)	0.00 sd







HHD LE Sum Score • for 10 muscle groups (LESS)

- Sum of peak values

	LESS	Standard
EDSS group	mean (kg)	deviation
1	207.2	57.4
2	157	45
3	111.1	29.2

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Inter-rater reliability (L and R sides and 3 EDSS groups combined)

		Visit 1			Visit 2		
	ICC	C.I.	P value	ICC	C.I.	P value	
Hip Flexion	0.94	0.89- 0.97	0.002	0.95	0.9- 0.97	<0.001	
Knee Extension	0.7	0.43- 0.84	NS	0.73	0.2- 0.88	NS	
					0.58-		
Ankle Dorsiflexion	0.81	0.64- 0.90	NS	0.85	0.93	NS	
Hip Abduction	0.73	0.5- 0.85	NS	0.74	0.5- 0.87	NS	
					0.04		
Knee Flexion	0.95	0.9- 0.97	<0.001	0.97	0.94- 0.98	<0.001	
	0.55	0.0 0.07	.0.001	0.57	0.50	3.301	
					0.55-		
LE Sum Score	0.87	0.69- 0.95	NS	0.9	0.97	NS	
Cinnifican on to atte							
Significance testing for ICC > 0.85							

Inter-session reliability

(L and R sides and 3 EDSS groups combined)

		Examiner 1			Examiner 2	
	ICC	C.I.	p value	ICC	C.I.	P value
Hip Flexion	0.94	0.88- 0.97	<0.01	0.94	0.89- 0.97	0.002
Knee Extension	0.89	0.79- 0.94	NS	0.89	0.79- 0.94	NS
Ankle Dorsiflexion	0.94	0.89- 0.96	0.001	0.92	0.8- 0.94	NS
Hip Abduction	0.93	0.87- 0.97	0.008	0.95	0.91- 0.97	<0.001
Knee Flexion	0.95	0.9- 0.97	<0.001	0.99	0.98- 0.99	<0.001
LE Sum Score	0.93	0.84- 0.97	0.04	0.97	0.93- 0.99	<0.001

Significance testing for ICC > 0.85

Inter-rater and Inter-session analyses by EDSS subgroups (data not shown)

- Lower ICC's than for combined data
- Subgroup inter-rater and inter-session reliability similar to findings for all EDSS categories combined
- Reliability of LE Sum Score was lower for EDSS group 3 (highest disability level).



HHD test performance issues

- 2520 tests total. No device issues.
- A few examiner errors during documentation
- Test administration times: HHD = 10 minutes, MMT = 8 minutes
- Very strong subject could overpower the examiner (HF, KE, AD)
- Some variability due to examiner error (applying "break," not "make" technique)
- One test-related adverse event = muscle spasm (1 subject with HHD). No report of fatigue by subject or examiner AE's.

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Discussion

- 1. HHD- and MMT- generated strength declined with disability level for all muscle groups.
- 2. HHD strengths were highest for Knee extension and lowest for Knee flexion in all categories.
- 3. Inter-rater reliability high for weakest muscle groups (Hip flexion, Knee flexion). Reliability was lower for other muscle groups and LE Sum Score.
- 4. Inter-session reliability was high, in general.
- 5. LE Sum Score was less reliable at the highest disability level.

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Study limitations

- 1. Small sample size
- 2. Single center, two experienced PTs
- 3. Excluded very-severely disabled people (EDSS >7.5)
- 4. Only tested LE's, no small muscle groups
- 5. Testing protocol used a specific device (Microfet2)



Conclusions

- 1. HHD myometric testing of LE strength is feasible with a MS population.
- 2. Reliability statistics of HHD assessment:
 - Better for weaker than stronger muscle groups
 - Better for inter-session than inter-rater reliability
- 3. Lower Extremity Strength Sum Score may be used as a combined measure of LE strength



Next Step

Multi-center validation study using same device and revised protocol



