Correlation of real-world digital biomarkers with clinical standards, findings from the MS-DETECT study

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Ad Scientiam

Background

- **Standardized** clinical tools and technologies, like the **EDSS** and **MSFC**, assess and monitor **Multiple Sclerosis (MS)** symptoms but lack the sensitivity to capture subtle disease progression [1-5].

- Inspired by the revised 4-component MSFC, **MSCopilot® is a clinically validated software-as-a-medical-device** measuring four functional parameters notably **walking** capacity, **cognitive** function, **dexterity** and low-contrast **visual acuity** [5-7].

1. Balcer LJ et al, J Neuro-Ophthalmol, 2001. **2.** Dini M et al, Front. Immunol, 2025. **3.** Kurtzke JF, Neurology, 1983. **4.** Cutter GR et al, Brain, 1999. **5.** Balcer LJ et al, Neurology, 2003. **6.** Maillart E et al, Eur J Neurol, 2020. **7.** Tanoh I et al, Mult Scler Relat Disord, 2021.

MSCopilot® digital tests measures MS functions

MSCopilot® digital biomarkers	Digital test description	MSFC-4 equivalent
Mobile Walking Perimeter Test 	30-min or 1 km walk	T25-FW
Mobile Cognitive Test 	Cognitive Processing Speed Test	SDMT
Mobile Dexterity Test 	Upper-limb fine dexterity	9HPT
Mobile Vision Test 	Low-contrast visual acuity	SLCLAT

T25-FW: Timed 25-Foot Walk **SDMT:** Symbol Digit Modalities Test **9HPT:** Nine Hole Peg Test **SLCLAT:** Sloan Low Contrast Letter Acuity Test

Monitoring disability worsening

- Previous studies demonstrated **significant correlations** between **MSCopilot® digital biomarkers**' composite scores and both **EDSS** and **MSFC-4** scores[5,6].

- The ongoing, prospective, longitudinal **MS-DETECT** study (NCT05816122) aims to determine MSCopilot®'s ability to **monitor disability worsening**.

1. Balcer LJ et al, J Neuro-Ophthalmol, 2001. **2.** Dini M et al, Front. Immunol, 2025. **3.** Kurtzke JF, Neurology, 1983. **4.** Cutter GR et al, Brain, 1999. **5.** Balcer LJ et al, Neurology, 2003. **6.** Maillart E et al, Eur J Neurol, 2020. **7.** Tanoh I et al, Mult Scler Relat Disord, 2021.

Comparing tests performed in - clinic or at home

Objective

- To compare individual **MSFC- 4 scores** with **MSCopilot® digital biomarkers** measured in-clinic or at home.

Methods

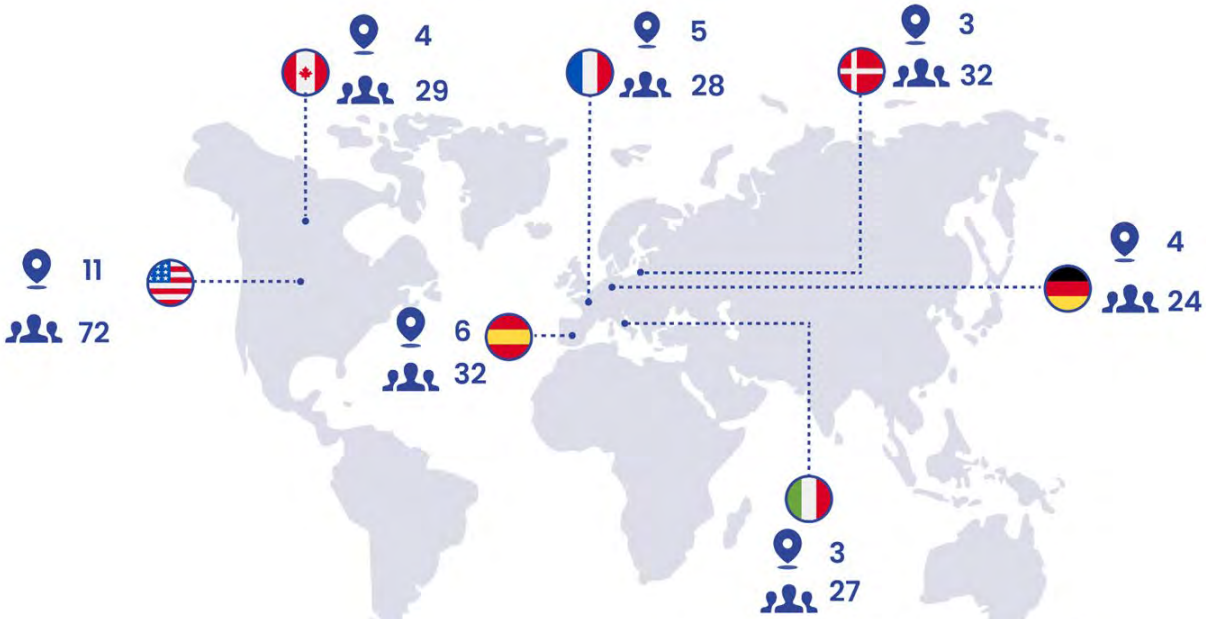
- MSFC-4 scores assessed **in-clinic** during inclusion visit.
- MSCopilot®tests performed **with** and **without supervision** in-clinic and at home, respectively.
- Association between the digital scores and their clinical counterparts was assessed using Pearson correlation coefficients.

MS-DETECT is an international multicenter study

244 Patients

36 Number of sites

7 Principal Investigators



Target enrolment = 336 patients

Baseline socio-demographics characteristics

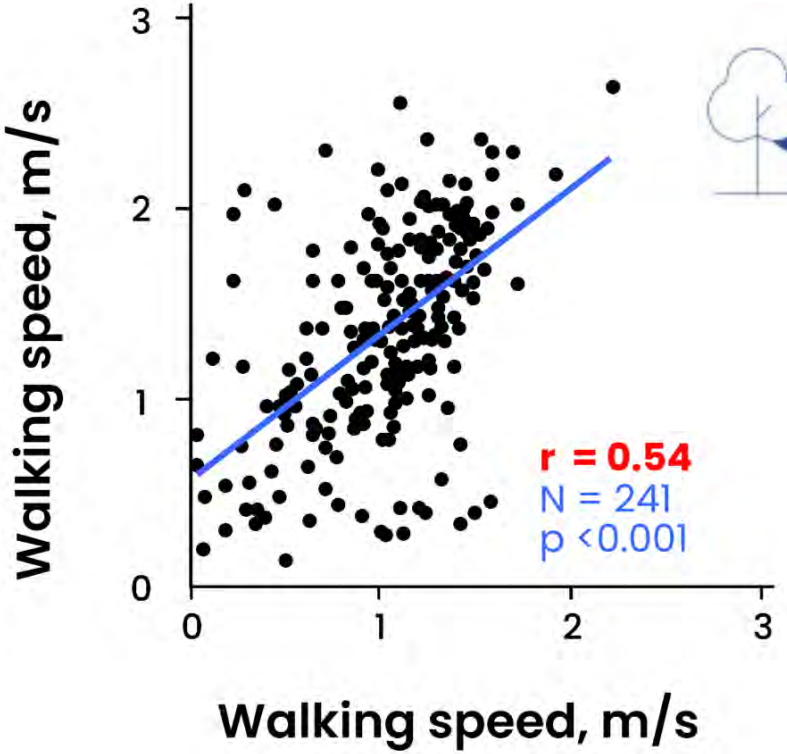
Patients	N = 244
Female, *n (%)*	167 (68.4)
Age, *mean (SD)*	49.2 (8.7)
Age at disease onset, *mean (SD)*	31.6 (9.0)
Disease duration, *mean (SD)*	17.6 (8.0)
EDSS score, *mean (min-max)*	3.8 (2.5-6.5))
MS phenotypes	
RRMS, *n (%)*	205 (84.0)
Non-active SPMS, *n (%)*	32 (13.1)
Active SPMS, *n (%)*	7 (2.9)

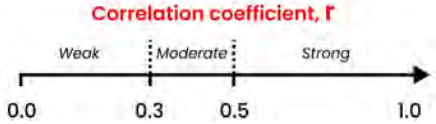
MSCopilot® evaluations in-clinic and at home

MSCopilot® digital biomarkers	Number of in-clinic evaluations , n	Number of home evaluations, n	Percent of analyzable* evaluations, %
Mobile Walking Perimeter Test 	242	218	98.9%
Mobile Cognitive Test 	243	218	100%
Mobile Dexterity Test 	231	211	92.7%
Mobile Vision Test 	209	182	92.8%

*analyzable: percentage of collected data that could be processed

Walking Test correlates with T25-FW

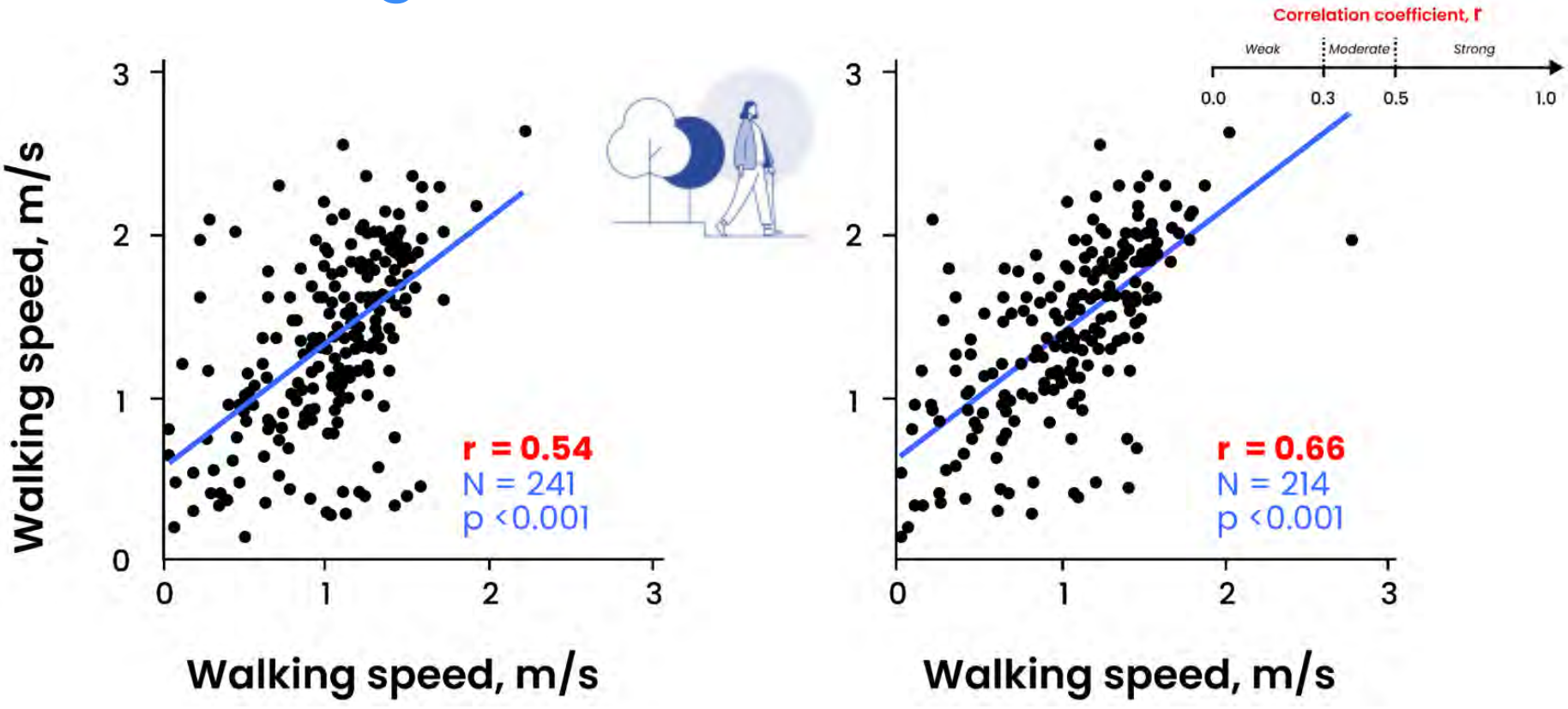




In-clinic

T25-FW: Timed 25-Foot Walk

Walking Test correlates with T25-FW

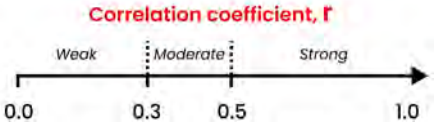


In-clinic

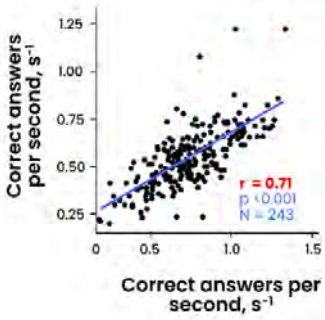
At home

T25-FW: Timed 25-Foot Walk

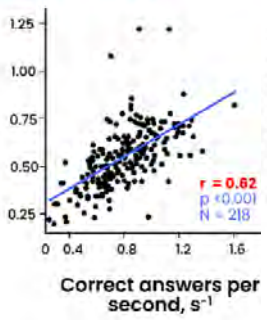
MSCopilot® digital tests correlate with clinical assessments



SDMT vs Cognition Test

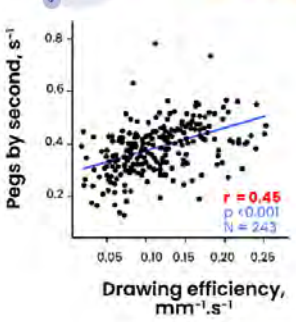


In-clinic

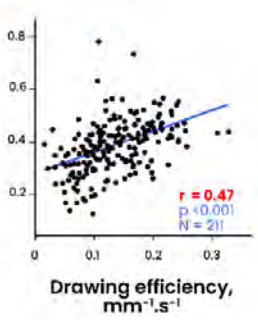


At home

9HPT vs Dexterity Test

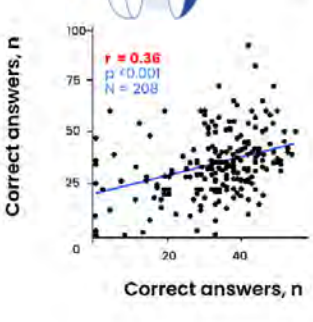


In-clinic

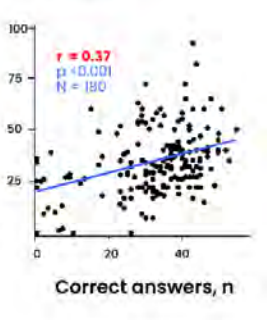


At home

SLCLAT vs Vision Test



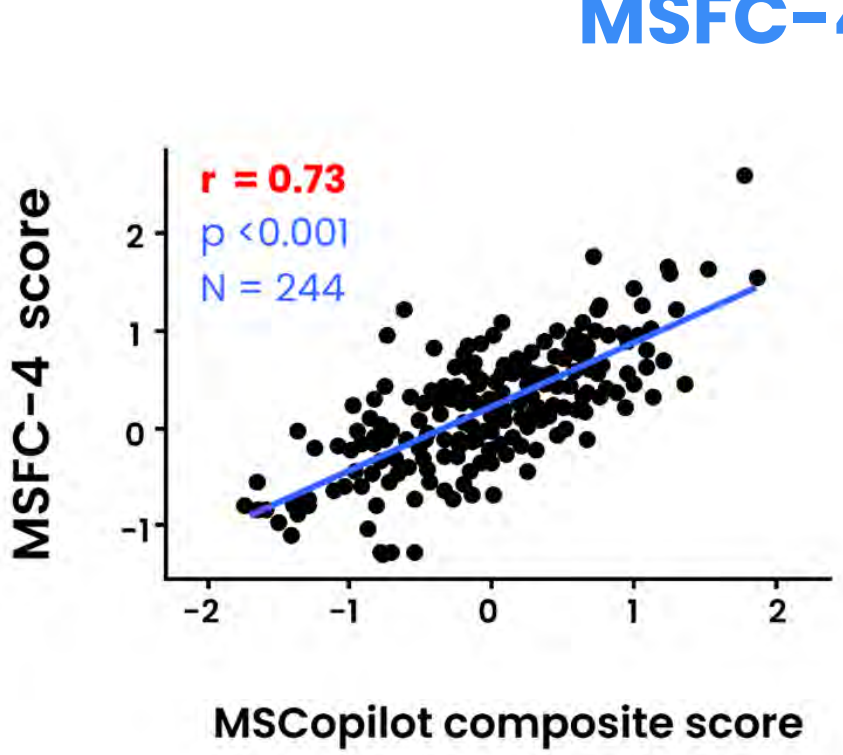
In - clinic



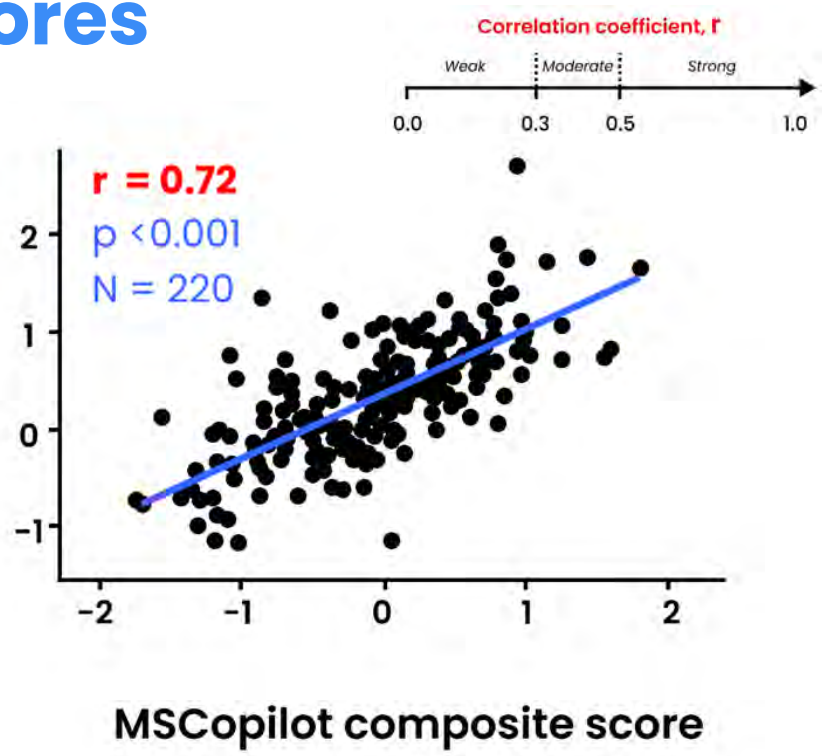
At home

T25-FW: Timed 25-Foot Walk **SDMT:** Symbol Digit Modalities Test **9HPT:** Nine Hole Peg Test **SLCLAT:** Sloan Low Contrast Letter Acuity Test

Digital composite scores strongly correlate with MSFC-4 scores



In-clinic

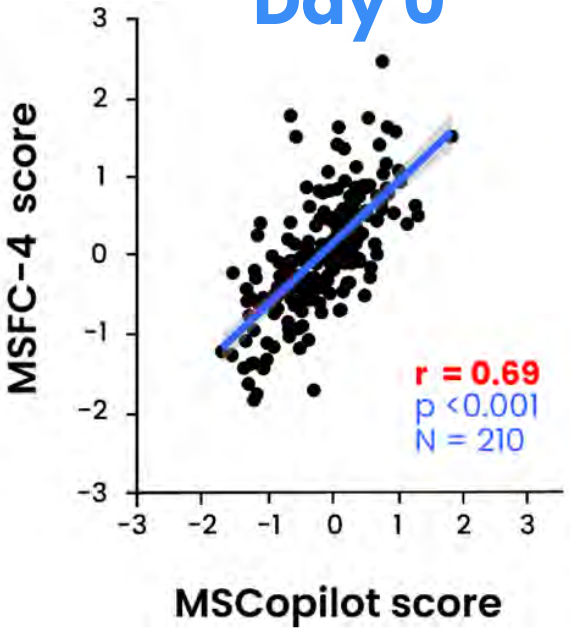


At home

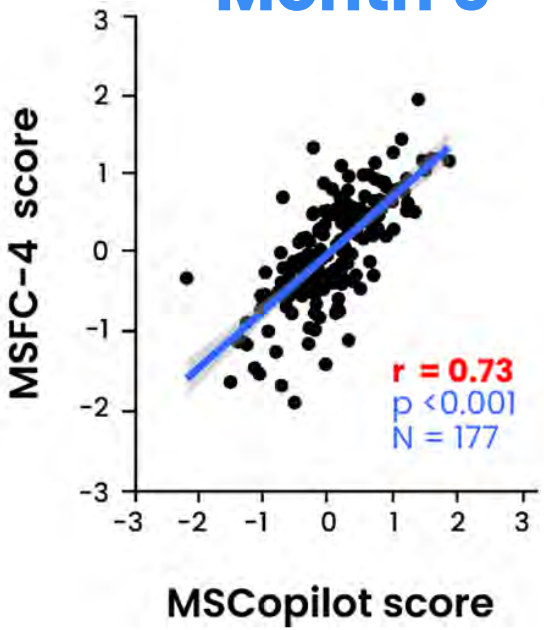
MSFC-4: revised 4-item MS Functional Composite

Correlation with MSFC - 4 is conserved over time

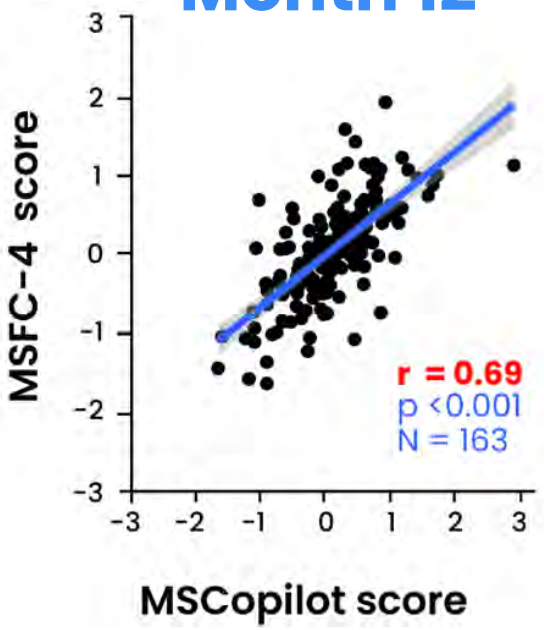
Day 0



Month 6



Month 12



Longitudinal relationship confirmed with a mixed model analyses

Conclusions

- **MSCopilot®** digital biomarkers scores, whether **performed in - clinic or at home**, showed **moderate to strong correlations** with their clinical counterparts
- **Over time**, MSCopilot®**composite scores maintained their strong correlation** with MSFC-4 composite scores.
- These findings highlight MSCopilot®'s potential for **long - term monitoring** of Multiple Sclerosis and for **predicting disability progression**.

THANK YOU

for your attention

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