Validation of the FeetMe® System versus GAITRite® to Assess Gait Characteristics in Patients with Multiple Sclerosis: Subpopulation analysis

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Disclosures

Dr. Durán has received speaking and/or advisory board honoraria from: Sanofi, Novartis, AbbVie and Bial.

Dr. Navarro has received speaking and/or advisory board honoraria from: Biogen, Novartis, Merck, Teva, Sanofi, and Roche.

Dr. Izquierdo has received speaking and/or advisory board honoraria from: Bayer, Biogen-Idec, Novartis, Sanofi, Merck-Serono, Almirall, Roche, Actelion, Celgene, and Teva.

Dr. Romero, and **Dr. Moreno** have received personal compensation for activities with Novartis Farmacéutica S.A. as employees.

Dr. Granja, Dr. Hochsprung, Dr. Palao, Dr. Páramo, Dr. Alemán and **Dr. Venegas** have nothing to disclose.

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Background and objective

- **GAITRite®** is considered as **the reference system** device to measure different spatiotemporal gait parameters in multiple sclerosis (MS) patients.[1] However, its usage is limited due to high price, time constraint, material problems, required space, and human resources.
- **FeetMe®** is a **shoe insole device** with integrated motion and pressure sensors that collect quantitative and qualitative parameters to assess the gait disorder.

Objective

- **Primary objective**: To determine statistical agreement and precision of gait velocity in MS patients, measured by FeetMe® compared with the reference system (GAITRite®), in the 25-foot walk test (25FWT)
- **Secondary objectives**: To determine the following parameters in MS patients using FeetMe® and GAITRite®:
  - Ambulation time
  - Gait cadence
  - Stride length

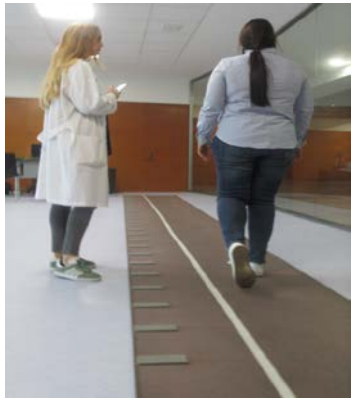
1. Sosnoff J, et al. Gait Posture. 2015;41:860-2.

Methods: Study design, patients and primary endpoint

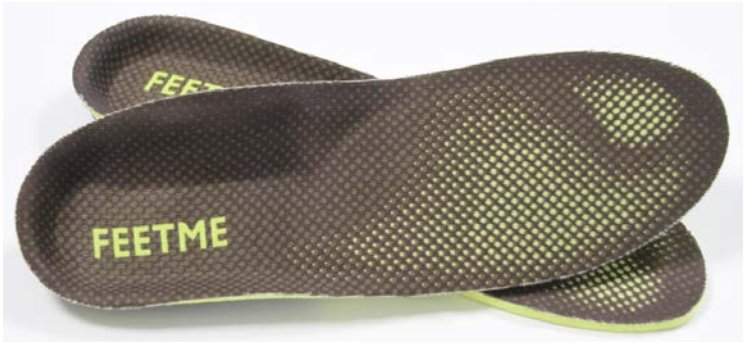
- This was an observational, cross-sectional, single-centre study of consecutively recruited MS patients at the participating site from September-2018 to April-2019. Patients were prospectively recruited, diagnosed with MS according to McDonald 2010 criteria[1], with EDSS scores of 0–6.5 and relapse-free within 30 days from the recovery prior to the study initiation.
- **Primary endpoint**: Gait velocity (cm/second) in the 25FWT with FeetMe® compared to GAITRite®, including Velocity 1 (i.e. distance/ambulation time) and Velocity 2 (i.e. 100 × mean [velocity]).
- Results of the ***25FWT-both devices patient group with valid data (25PG+VD) analysis*** are presented
- This **subpopulation** included all the patients who performed 25FWT test with both devices, registered **exactly the same** number of total **steps** with each device, and with **velocity data within plausible range**.

Figure 1. Devices used in the study: GAITRite® and FeetMe®

A) GAITRite®



B) FeetMe®



1. Polman CH, et al. Ann Neurol. 2011;69(2):292-302.

Baseline characteristics (25PG+VD)

- A total of **207 MS patients** were enrolled in the study. Of them, **205** were considered in 25FWT-both devices patient group **(25PG)**, and of them **127** were considered in 25FWT-both devices patient group with valid data* **(25PG+VD)**.

Table 1. Baseline demographic and clinical characteristics

Characteristic	25PG+VD* (N=127)
Age, years, mean (SD)	40.7 (8.2)
Sex, female, n (%)	86 (67.7%)
BMI, Kg/m^2, mean (SD)	24.9 (4.6)
Leg length (mean of right and left), cm, mean (SD)	85.7 (6.1)
Type of MS	
Relapsing-remitting MS, n (%)	106 (83.5%)
Primary progressive MS, n (%)	11 (8.7%)
Secondary progressive MS, n (%)	10 (7.9%)
Time since first symptoms, years, mean (SD)	11.3 (8.5)
Time since diagnosis, years, mean (SD)	7.9 (7.0)
EDSS score, mean (SD)	2.8 (1.9)
Number of relapses in the last year, mean (SD)	0.4 (0.7)
Time since last relapse, years, mean (SD)	0.4 (0.3)
Number of patients receiving MS treatments, mean (SD)	85 (66.9%)

*Valid data at least for velocity parameter. 25PG+VD populations need to meet selection criteria; BMI, body mass index; EDSS, expanded disability status scale; MS, multiple sclerosis; SD, standard deviation.

High correlation and agreement (25PG+VD)

- The **ICC** obtained for Velocity 1 (0.883) and 2 (0.899) indicates a **very strong agreement between both devices** on the same set of subjects. Also, **Pearson correlations** of 0.888 and 0.908, for Velocity 1 and 2, respectively, for 25PG+VD indicate a **high correlation**.
- **Agreement** between GAITRite® and FeetMe® was **almost perfect** (ICC≥0.8) in ambulation time and cadence.

Table 2. Statistics obtained in the paired analysis (25PG+VD)

Parameter	N	GAITRite®		FeetMe®		Difference		Correlation	ICC	Agreement*
		Mean	SD	Mean	SD	Mean	SD	Pearson		
Velocity 1 (cm/sec)	127	104.5	31.6	107.6	30.3	-3.2	14.7	0.888	0.883	Almost perfect
Velocity 2 (cm/sec)	127	104.5	31.6	108.9	31.0	-4.5	13.4	0.908	0.899	Almost perfect
Ambulation time (sec)	127	8.1	5.0	8.1	5.1	-0.0	0.3	0.998	0.998	Almost perfect
Cadence 1 (steps/min)	127	100.4	17.2	100.7	17.5	-0.3	2.7	0.988	0.988	Almost perfect
Cadence 2 (steps/min)	127	100.4	17.2	102.9	17.9	-2.5	2.7	0.989	0.978	Almost perfect
Stride length (cm)	127	122.6	24.0	125.3	25.6	-2.6	19.8	0.683	0.679	Moderate agreement

*Criteria for agreement (ICC): 0<ICC<0.3: Poor; 0.3<=ICC<0.5: Fair; 0.5<=ICC<0.7: Moderate; 0.7<=ICC<0.8: Strong; ICC>=0.8: Almost perfect.
Velocity 1: distance/ambulation time; Velocity 2: 100 × mean(Velocity); Cadence 1: 60 × number of steps/ambulation time; Cadence 2: mean(Cadence).
cm, centimetre; ICC, intraclass coefficient correlation; min, minute; SD, standard deviation; sec, second.

Association between EDSS and gait parameters (25PG+VD)

- A **strong association** was observed between **EDSS** and **velocity, cadence,** and **stride length**.
- Patients with **high EDSS** (5.0-6.5) had **lower velocity**, (i.e. decrease 62cm/sec) **cadence** and **stride length**; but also **higher ambulation time** (i.e. increase 8.7 sec).

Table 3. Multivariate models for each gait variable by GaitRite®

Parameter	EDSS 2.5-4.5 (N=39)	EDSS 5.0-6.5 (N=19)
GaitRite® - Velocity (cm/sec)	-17.90	-62.00
GaitRite® - Ambulation time (sec)	1.65	8.73
GaitRite® - Cadence (steps/min)	-7.80	-35.59
GaitRite® - Stride length (cm)	-14.07	-37.53

Summary of significant values ($p<0.05$) obtained in the multivariate models for each parameter in 25PG+VD population.
cm, centimeter; EDSS, Expanded Disability Status Scale; min, minute; sec, second.

- These data indicate that the **disability of patients with MS**, determined by the EDSS, **is correlated** with the **objective gait parameters** presented.
- However, this analysis shows that **precision of FeetMe®** device could be affected by the **level of disability** of MS patients.

Sensitivity analysis: Good level of agreement

- In the **sensitivity analysis** performed, **most of the parameters** were also found to **improve** their **agreement**.

Table 4. Statistics obtained in the paired analysis (25PG+VD)

Parameter	SA1: 25PG+VD (N=125)		SA2: 25PG+VD (N=15)	
	ICC	Agreement*	ICC	Agreement*
Velocity 1 (cm/sec)	0.962	Almost perfect	0.994	Almost perfect
Velocity 2 (cm/sec)	0.970	Almost perfect	0.996	Almost perfect
Ambulation time (sec)	0.998	Almost perfect	1.000	Almost perfect
Cadence 1 (steps/min)	0.987	Almost perfect	0.999	Almost perfect
Cadence 2 (steps/min)	0.977	Almost perfect	0.993	Almost perfect
Stride length (cm)	0.901	Almost perfect	0.984	Almost perfect

*Criteria for agreement (ICC): 0<ICC<0.3: Poor; 0.3<=ICC<0.5: Fair; 0.5<=ICC<0.7: Moderate; 0.7<=ICC<0.8: Strong; ICC>=0.8: Almost perfect.
SA1: Analysis of parameters excluding patients with out of range values for type A variables (FeetMe® and GaitRite®) 25PG+VD. Type A variables were those with high correlation between devices: Stride Length (m), Width Motion (m), Stride Time (msec), Velocity (m/sec), Cadence (stride/min), Swing Time (msec), Stance Time (msec), Swing Phase (%), Stance Phase (%).
SA2: Analysis of parameters excluding patients with out of range values for type B variables (FeetMe® and GaitRite®) 25PG+VD. Type B variables were those with low correlation between devices: Step Length (m), Single Support Time (msec), Double Support Time (msec), Single Support (%), Double Support (%), Step Time (msec).
Velocity 1: distance/ambulation time; Velocity 2: 100 × mean(Velocity); Cadence 1: 60 × number of steps/ambulation time; Cadence 2: mean(Cadence).
25PG+VD, 25FWT-both devices patient group with valid data; cm, centimetre; ICC, intraclass coefficient correlation; min, minute; SA, sensitivity analysis; SD, standard deviation; sec, second.

Conclusions

- **FeetMe® device** is a transportable and field-usable alternative for the assessment of gait characteristics in research settings as well as during neurologist's visits
- **FeetMe®** and **GAITRite® devices** produce **very similar results in velocity**, regardless of the formula being applied.
- According to our study, **agreement between FeetMe®** and **GAITRite® was almost perfect** (ICC≥0.8) in **velocity, ambulation, cadence,** and **stride length** parameters**.** FeetMe® assesses the gait of MS patients completely and objectively, with results significantly correlating to those with **GAITRite®**.
- The analysis performed on the **25PG+VD subpopulation** shows an even **higher level** of precision and agreement between **FeetMe®** and **GAITRite® devices**.
- To our knowledge, this is the first validated medical device that would allow a **portable monitoring of the gait of MS patients**, being potentially able to reflect upon the disease activity, progression and treatment response.

Thank you