

## **Characterization of the gait in patients with RRMS and SPMS measured by FeetMe®: Results of the MS Feet PRO study**

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**Introduction:** Gait disorder causes disability in patients with multiple sclerosis (MS). FeetMe<sup>®</sup> was the first validated medical device allowing a portable monitoring of the gait of MS patients which objectively assesses and monitors gait disorder. The aim of the present study was to characterize gait pattern of relapsing-remitting MS (RRMS) and secondary-progressive MS (SPMS) patients.

**Methods:** MS Feet PRO is an observational, cross-sectional, non-interventional and multicenter study. Patients 18-65 years (inclusive), with MS (McDonald 2010/2017 criteria), EDSS 2.5-6.5 and relapse free within 30 days from recovery prior to the study initiation were consecutively recruited. Tests performed with FeetMe<sup>®</sup>: 2-minute walk (2MWT) (primary endpoint), 6-minute walk (6MWT) and timed 25-foot walk (T25FW). Gait parameters: velocity, cadence, ambulation time, stride length, stride time and double support.

**Results:** 449 patients (305 RRMS, 144 SPMS) were included (intention-to-treat population) (Table 1). Mean (SD) distance (2MWT): 123.4 (35.5) meters for RRMS patients and 90.0 (35.3) for SPMS patients ( $p < 0.0001$ ) (Figure 1a). Mean (SD) 6MWT score: 356.7 (103.1) meters for RRMS patients and 255.8 (106.0) for SPMS patients ( $p < 0.0001$ ) (Figure 1b). Mean (SD) time to complete T25FW: 7.0 (3.7) seconds for RRMS patients and 12.4 (24.1) for SPMS patients ( $p = 0.0002$ ) (Figure 1c). Gait parameters (2MWT) for RRMS and SPMS patients are shown in Table 2.

**Conclusion:** FeetMe<sup>®</sup> is a medical device able to objectively characterize in real time the gait of RRMS and SPMS patients. This characterization could detect punctual and progressive worsening in the gait pattern, and even indirectly detect progression in real time.

**Table 1. Sociodemographic and clinical characteristics of patients included in the analysis (ITT population)**

| <b>Variable</b>                              | <b>RRMS<br/>(n=305)</b> | <b>SPMS<br/>(n=144)</b> | <b>Total<br/>(n=449)</b> |
|--|-------------------------|-------------------------|--------------------------|
| Age, mean (SD)                               | 46.5 (8.7)              | 52.2 (7.4)              | 48.3 (8.7)               |
| Female, n (%)                                | 205 (67.2%)             | 82 (56.9%)              | 287 (63.9%)              |
| <b>Educational level</b>                     |                         |                         |                          |
| Basic education, n (%)                       | 1 (0.3%)                | 0 (0.0%)                | 1 (0.2%)                 |
| Primary education, n (%)                     | 45 (14.9%)              | 32 (22.5%)              | 77 (17.3%)               |
| Secondary education, n (%)                   | 106 (35.0%)             | 50 (35.2%)              | 156 (35.1%)              |
| Tertiary education, n (%)                    | 151 (49.8%)             | 60 (42.3%)              | 211 (47.4%)              |
| <b>Employment status</b>                     |                         |                         |                          |
| Active worker, n (%)                         | 136 (44.6%)             | 29 (20.3%)              | 165 (36.8%)              |
| Non-active worker, n (%)                     | 169 (55.4%)             | 114 (79.7%)             | 283 (63.2%)              |
| <b>EDSS</b>                                  |                         |                         |                          |
| Mean (SD)                                    | 3.6 (1.1)               | 5.3 (1.1)               | 4.2 (1.3)                |
| Median                                       | 3.5                     | 5.5                     | 4.0                      |
| Years since first symptoms, mean (SD)        | 15.8 (8.8)              | 20.4 (8.5)              | 17.3 (8.9)               |
| Years since diagnosis, mean (SD)             | 13.4 (8.4)              | 18.0 (8.3)              | 14.9 (8.6)               |
| Years since MS progression, mean (SD)        | -                       | 4.5 (4.6)               | 4.5 (4.6)                |
| Presence of relapses in the last year, n (%) | 53 (17.4%)              | 5 (3.5%)                | 58 (12.9%)               |

EDSS, Expanded Disability Status Scale; ITT, intention to treat; MS, multiple sclerosis; n, number of patients; RRMS, relapsing-remitting multiple sclerosis; SD, standard deviation; SPMS, secondary-progressive multiple sclerosis.

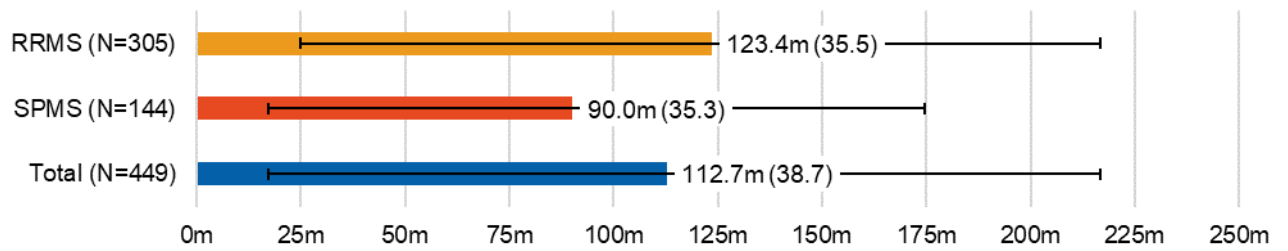
**Table 2. Gait parameters comparison between RRMS and SPMS patients in the 2MWT (ITT population)**

| <b>Variable</b>                                  | <b>RRMS<br/>(n=305)</b> | <b>SPMS<br/>(n=144)</b> | <b>Total<br/>(n=449)</b> | <b>P-value</b> |
|--|-------------------------|-------------------------|--------------------------|----------------|
| <b>Step count</b> , mean (SD)                    | 206.9 (38.0)            | 178.2 (42.5)            | 197.7 (41.7)             | <0.0001        |
| <b>Velocity (cm/sec)</b> , mean (SD)             | 104.5 (27.4)            | 75.7 (28.4)             | 95.2 (30.8)              | <0.0001        |
| <b>Cadence (steps/min)</b> , mean (SD)           | 105.0 (15.2)            | 90.1 (19.3)             | 100.2 (18.0)             | <0.0001        |
| <b>Ambulation time (sec)</b> , mean (SD)         | 121.4 (2.5)             | 121.5 (1.6)             | 121.4 (2.3)              | 0.8597         |
| <b>Stride length (cm)</b> , mean (SD)            | 117.4 (19.4)            | 98.2 (24.3)             | 111.2 (22.9)             | <0.0001        |
| <b>Stride time (sec)</b> , mean (SD)             | 1.2 (0.2)               | 1.4 (0.4)               | 1.3 (0.3)                | <0.0001        |
| <b>Double support (% gait cycle)</b> , mean (SD) | 32.8 (4.0)              | 34.1 (5.9)              | 33.2 (4.7)               | 0.0045         |

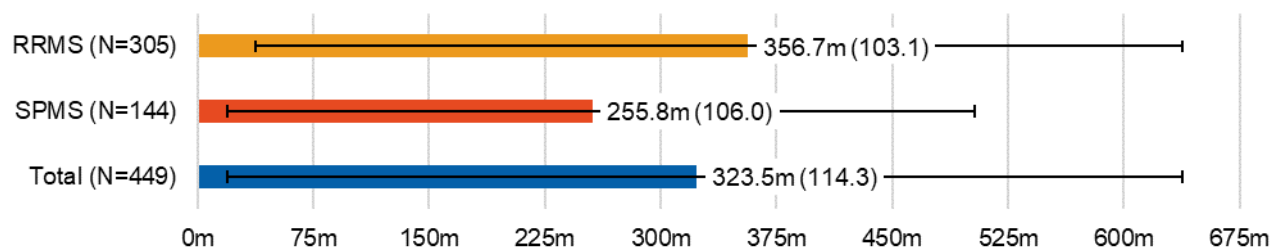
cm, centimeter; ITT, intention to treat; min, minute; MS, multiple sclerosis; n, number of patients; RRMS, relapsing-remitting multiple sclerosis; SD, standard deviation; sec, second; SPMS, secondary-progressive multiple sclerosis.

**Figura 1. Performance in 2MWT, 6MWT and T25FW collected with FeetMe®**

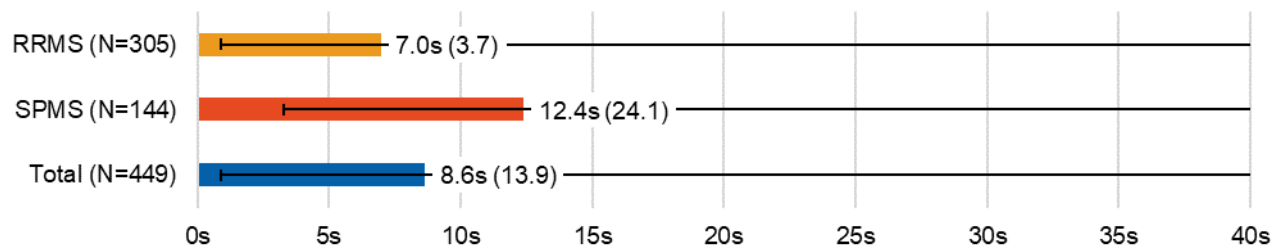
**a) Performance (distance in meters) on the 2MWT for RRMS and SPMS patients**



**b) Performance (distance in meters) on the 6MWT for RRMS and SPMS patients**



**c) Performance (time in seconds) on the T25FW for RRMS and SPMS patients**



The coloured bars represent the mean distance walked in meters for 2MWT and 6MWT, and the the mean time to complete the test in seconds for T25FW. Standard deviation shown inside brackets. The thinner black bars represent the minimum and maximum distance walked in meters for 2MWT and 6MWT, and the minimum and maximum time to complete the test in seconds for T25FW. RRMS, relapsing-remitting multiple sclerosis; SPMS, secondary progressive multiple sclerosis.