

Evaluation of ambulatory function with a wearable sensor in myotonic dystrophy type 1

Margaux Poleur¹, Stéphanie Delstanche¹, Manon Hustinx¹, Guillaume Parinello², Noor Benmhammed¹, Camille Bisson², Charline Dubois¹, Manon Duclos,¹ Thao Nguyen Le Lam², Laurie Médard,¹ Damien Eggenspieler² and Laurent Servais^{3,4}

Affiliations: 1. University department of neurology, CHR Citadelle, Liège, Belgium; 2. SYSSNAV, Vernon, France; 3. Neuromuscular Reference Center, Department of Pediatrics, University Hospital Liege & University of Liege, Belgium; 4. University of Oxford, United Kingdom.

BACKGROUND

- Lack of reliable and sensitive endpoints** to evaluate drug efficacy in clinical trials in myotonic dystrophy type 1 (DM1)
- Wearable digital health technology (wDHT) could help** assess ambulation in daily life and provide sensitive measures to determine treatment response

OBJECTIVES

- Assess stride detection and gait parameter measurement accuracy in a controlled environment study in DM1
- Determine the feasibility of using the DHT in daily living and evaluate the psychometric properties of digital variables

WEARABLE DHT

- Wearable sensors worn on both ankles
- Daily recording in the real-world setting
- Based on inertial technology
- Provides accurate stride-level ambulation data

Figure 1. Syde DHT.

1. CONTROLLED ENVIRONMENT

DESIGN & DEMOGRAPHICS

Figure 2. 8-shaped track.

- Patients were equipped with 2 ankle sensors
- They performed 3 exercises (normal, fast and perturbed walk) in a room equipped with a reference motion capture system (OptiTrack), following a predefined track (Figure 2)

9 Patients with DM1

♀ 55% 5 females

Age (years) min 5 median 42 max 72

ACCURACY OF STRIDE DETECTION AND VELOCITY MEASUREMENT

Figure 3. DHT accuracy to detect strides.

Figure 4. DHT accuracy to measure stride velocity.

- The DHT showed an **average sensitivity and positive prediction value of 99%** (n=5131 strides; Figure 3)
- Mean difference in stride length and velocity (Figure 4) measured by the DHT and reference were 0.6 cm and 0.5 cm/s, respectively

2. STUDY IN DAILY LIVING CONDITIONS

STUDY DESIGNS

- ActiLiège-Next (NCT05982119) and Acti-Adult (NCT07136844) are natural history studies enrolling patients with DM1 (Belgium)
- First subject enrolled in April 2023
- For each patient, one age-matched control from external studies was used

Figure 5. Schedule of assessments and data collection.

RESULTS - KNOWN-GROUP VALIDITY

Figure 6. Known-group validity analysis at BL.

RESULTS - CONVERGENT VALIDITY

Figure 7. Spearman's correlation coefficient between digital variables and timed tests in DM1.

	10MWT	6MWT	4SC	TRF
SV95C	-0.73 * (N=11)	0.89*** (N=13)	-0.79 ** (N=11)	-0.54 (N=7)
Nb strides/h	-0.54 (N=13)	0.3 (N=14)	-0.29 (N=13)	0.64 (N=8)
WD95C	-0.45 (N=11)	0.37 (N=13)	-0.39 (N=11)	0.14 (N=7)
Med stance %	0.55 (N=11)	-0.84*** (N=13)	0.68 * (N=11)	0.32 (N=7)

RESULTS - DATA AVAILABILITY and RELIABILITY

Table 1. Baseline characteristics.

Median [min; max]	DM1 (N=23)
Age (years)	37 [6; 72]
Gender (F / M)	14 / 9
Time since diagnosis (years)	14.4 [0.6; 29.9] (N=21)
6MWT (m)	486 [271; 700] (N=20)

Table 2. Adherence with wDHT wear.

Visit	Number of patients	< 50 h of data	≥ 50 h of data
Baseline (first month)*	N=20	2 (10%)	18 (90%)
Month 6*	N=13	1 (8%)	12 (92%)
Month 12*	N=8	0 (0%)	8 (100%)

Table 3. Intra-class correlation coefficient.

Variable	ICC2k†
SV95C	0.99 (N=14)
Nb strides/h	0.91 (N=15)
WD95C	0.49 (N=14)
Med stance %	0.97 (N=14)

CONCLUSIONS

- Good accuracy** of the DHT to detect strides and measure stride length and velocity
- Good adherence** with sensor wear
- SV95C and median stance percentage exhibited interesting metric properties** (reliability, known-group and convergent validity)

NEXT STEPS

- Continue **collection of longitudinal data** to evaluate sensitivity to detect change
- Explore other digital endpoints**, including ones related to fatigability
- Collect additional data to strengthen the clinical validity of digital measures

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