D2.6 Results of technical validation on slow walkers and description of experimental protocol for WP4 [confidential]

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Summary

The objective of WP2 is to provide a "device-algorithm" pair that allows the valid and reliable assessment of digital mobility outcomes (DMOs, D2.1), such as walking speed (WS). A combination of state-of-the-art algorithms that work robustly for diverse patient populations in free-living environments have been selected, implemented and combined in an analytical pipeline for valid estimation of DMOs based on raw data from a single sensor (SS).

This deliverable describes the process followed to validate the DMOs quantified by the "device-algorithm" pair and compared to a reference system (RS, D2.2).

The deliverable includes:

1) An overview of the technical validation study (TVS) Statistical Analysis Plan (SAP) for the validation of the identified DMOs (Technical Validation Study, D2.3)
2) Identification of selected algorithms that form the analytical pipeline (walking bout assembly, D2.5)
3) Presentation the primary (walking speed) and secondary DMOs TVS results detailed by cohort including supplementary analysis (i.e. effect of WB length, contextual information and disease severity on results).

Results:

Identification of selected algorithms that form the analytical pipeline: the algorithm ranking showed good to excellent performances for the top algorithms selected for each block (gait sequence detection, step detection, cadence, turning detection) both in the laboratory and real-world 2.5-hour assessments. As expected, slightly lower but acceptable performances were found for stride length estimation algorithms. This was expected as spatial parameters are more difficult to quantify than temporal ones using a single sensor, and also given that the use of biomechanical models and acceleration integration techniques, which turned out to be superior to other approaches like machine learning, are implicitly challenged when processing non rectilinear walking.

Validation analysis results for primary (walking speed) and secondary DMOs: very good results (relative error <15%) were found across all cohorts and assessment type (i.e. in-lab and in real-world conditions) for Walking Speed across all cohorts, with slightly higher errors (~20%) resulted for the most impaired and slower groups (Proximal Femoral Fracture (PFF) and Congestive Heart Failure (CHF)).
Identification of walking bout, steps and turns showed high sensitivity, accuracy and specificity (>0.75) and excellent agreement was found for the evaluation of walking duration (ICC>0.96) in both in-lab and real-world assessments across all cohorts.
Temporal DMOs estimations (e.g. step duration, cadence, turning) from the single sensor resulted excellent across all cohorts (relative errors<6%) and type of assessment.
As expected, spatial DMO (stride length) showed higher relative errors (~18%) and slightly lower agreement when results from the single sensor were compared to the reference system, this was particularly apparent for the most impaired cohort (PFF). The poor results obtained for stance and swing duration highlighted the unsuitability of these secondary outcomes.

In general, for all DMOs performance metrics were lower for cohorts with significant gait impairments, using walking aids and with a lower walking speed (e.g. CHF, PFF). **Results across all DMOs improved when very short walking bouts (≤10 seconds in duration) were excluded from the analysis**, preliminary analysis on walking bout duration whped that results also improved when

excluding walking bouts with turns. For walking speed estimation, results also **improved when considering outdoor walking** bouts compared to indoor ones, although the former represented a smaller number of all identified walking bouts. **Disease severity appeared to have an effect on walking speed estimation**, this was more apparent for participant with slow walking speed (<~0.7m/s) and especially for people with Parkinson's disease, with Chronic Obstructive Pulmonary Disease and CHF.

We demonstrated that the selected algorithms included in the analytical pipeline provide robust, accurate and acceptable results for walking speed and other secondary DMOs.

Our recommendation to WP4 is to utilise a selective approach for the inclusion of DMOs for the Clinical Validation Study 7-day assessment data:

1. **we recommend using** walking bout, step and turn identification results **(number of WBs and turns) and** all **temporal DMOs (walking bout duration, step duration, cadence, turn duration) evaluated across all walking bouts**;
2. **we recommend** using information about turning and potentially **exclude WB with turns** and, if possible, separate rectilinear from curvilinear walking;
3. **we recommend using of walking speed and stride length estimations that are derived only for walking bouts >10seconds**;
4. We **don't recommend** using derived secondary outcomes (**stance and swing phase duration**)**.**