

Walking speed during daily living, a systematic review

C. TYCHON, M. POLEUR, L. SERVAIS



Introduction : why do we need new endpoints ?

- Objective, quantifiable walking speed endpoints are lacking
- Real-life walking speed is a key factor of quality of life

Current walking speed evaluation compared to wearable devices :

	Dedicated labs	6-minute walking test	Wearable
Cost	+++	---	+
Availability	---	+++	+++
Workload	+++	++	---
Hawthorne effect (Patients perform better when observed)	+++	+++	---

Wearable devices offer :

- Cost-effective and available solutions
 - Reduce workload
 - Eliminate biases
- ➔ Endpoints have to be validated by regulatory agencies such as the EMA or FDA before clinical use.

What is the purpose of this poster ?

- ✔ Currently published data
- ✔ Focus on Duchenne Muscular Dystrophy
- ✔ What is missing for global validation ?
- ✔ Insights on clinical application

What has been proposed so far :

Pediatric focus :

Duchenne Muscular Disease (DMD) :

- Only disease with a validated digital endpoint by the EMA
- Uses Sv95c : 95th percentile of walking speed

🔍 These results are displayed in the main circle ^{1,2}

Sv95c have also been used in Facioscapulohumeral dystrophy :

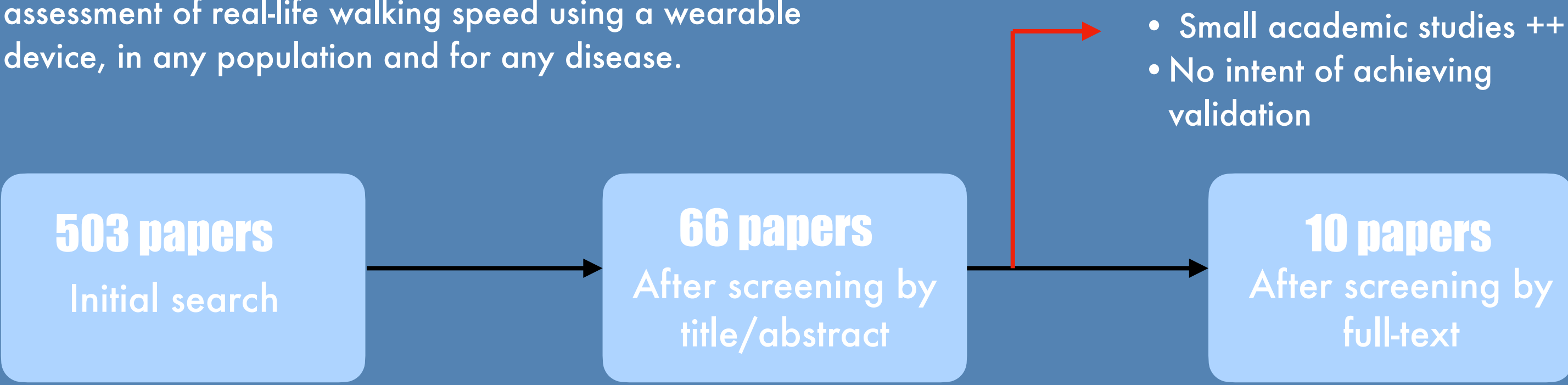
- Validity confirmed : compared to controls
 - Good reliability : intraclass correlation coefficient > 0.9
 - Sensitivity to change : confirmed
- ➔ Insufficient data for official validation

And beyond pediatrics :

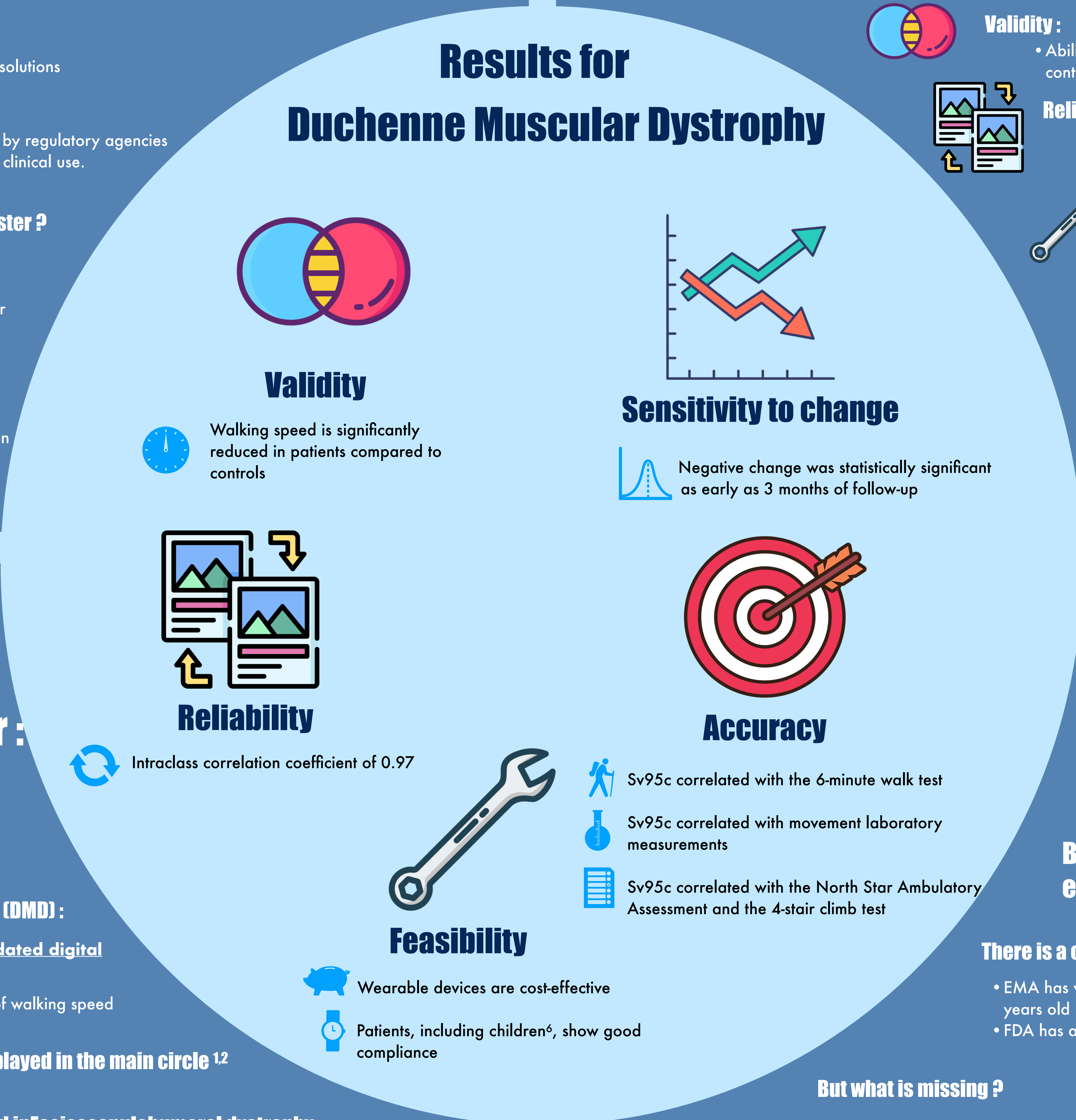
	Validity	Reliability	Feasibility	Accuracy	Sensitivity to change	Letter of intent
Parkinson's ³	YES	?	YES	+/- (medium bouts did not correlate to MDS-UPDRS III)	YES	YES (FDA)
Sarcopenia	?	?	YES	YES (Medium correlation with 6-MWT)	?	YES (FDA)
Multiple sclerosis ^{4,5}	?	?	YES	+/- (Real-walking speed overestimate)	?	YES (FDA)
Huntington disease	?	?	?	?	?	YES (but rejected by FDA)

Methods :

We searched the MEDLINE database for studies on the assessment of real-life walking speed using a wearable device, in any population and for any disease.



Results divided into 5 categories :



Discussion :

Bridging the gap in digital endpoint validation :

There is a clear interest from regulators :

- EMA has validated Sv95c for DMD before 4 years old
- FDA has accepted multiple letters of intent

But what is missing ?

- **Limited large-scale initiatives** : mainly small, academic studies without clear interest or resources for validation. Only MOBILISE-D and Sv95c generate extensive database
- **Costly and long validation process** : even MOBILISE-D, a \$50 million-funded project faced significant challenges that limited its ability to develop and implement a digital mobility assessment solution

How can validation be facilitated ?

- **Streamlined regulatory pathways** : the EMA has fast-tracking pathways for pain medication approval across various diseases - why not digital endpoints ?
- **Improved study framework** : A unified approach would allow data integration across diseases, populations and devices

What does the future hold :

- ✔ **Early detection of decline** through a clinician-friendly app, prompting therapeutic changes
- ✔ **Tracking therapy impact** by the clinician and the patient through the app, enhancing motivation and engagement
- ✔ **Accelerate drug approvals** and improve patient's quality of life

Scan the QR code for references



