Long-term self-balanced exoskeleton rehabilitation to treat lower limb weakness and/or impairments in adult population: a feasibility study

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INTRODUCTION

In 2019, approximately 2.4 billion people worldwide required rehabilitation for various health pathologies, a 63% increase since 1990 (Cieza et al., 2020). Patients with lower limb weaknesses, resulting from various conditions (for example stroke, traumatic brain injury, spinal cord injury and others) require long-term management and motivation for engagement, which are crucial for functional outcomes (Cieza et al., 2020; Kamenov et al., 2019). This highlights the **need for sustainable gait and balance rehabilitation**.

New technologies like exoskeletons have shown promising results in short-term inpatient programs, improving gait, balance, and quality of life, however, long-term follow-up data are still needed (Jayaraman et al., 2020).

Objective

To investigate the effects of long-term rehabilitation with hands-free **Atalante X exoskeleton** in participants with lower limb weakness and/or impairments, regardless of etiology.

METHODS

Study design

Interventional, national, prospective, open study, with before-after trial design, each participant serving as their own control.

Participants

100 adults over 18 years old, diagnosed with lower limb weakness and/or impairment will be included. Exclusion criteria encompass severe spasticity, osteoporotic fractures, pressure ulcers, and device-specific morphological contraindications.

Intervention

During the **one-year intervention period**, participants will complete at least one exoskeleton session per week (≥36 sessions) with the Atalante X. The additional voluntary year follows the same design. During the exoskeleton sessions, patients will engage in ambulatory exercises using the device. Intensity will increase over successive sessions, with the percentage of assistance provided by the device reduced when appropriate.

Outcome measures

Primary outcome was measured using the Function in Sitting Test (FIST), assessing seated postural control..

Secondary outcomes included, among other:

- Rehabilitation session characteristics (number of sessions, verticalization duration, steps performed, and level of assistance),
- Safety (adverse events occurrence (AEs), and
- Functional capacities assessment (6-minute walk/wheeled test).
- Personal goals during rehabilitation (Goal Attainment Scale [GAS])

The study flow-chart is available in Figure 1.

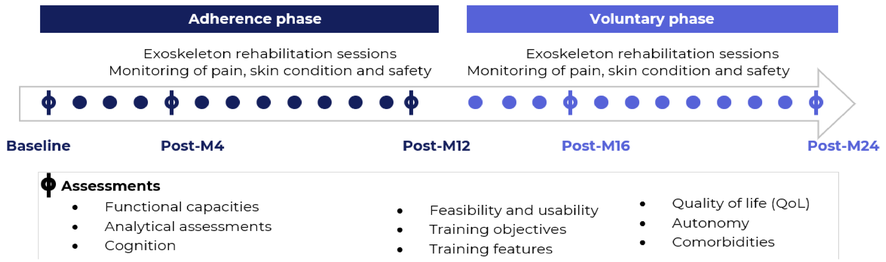

Figure 1. The study flow-chart

RESULTS

Figure 2. Illustration of the hands-free Atalante X exoskeleton in use

Fourteen participants (47.8 ± 13 years old) with various impairments, including paraparesis (n=5), complete paraplegia (n=4), tetraparesis (n=4), and hemiparesis (n=1), were included. The duration of their conditions* averaged 11 ± 8.3 years.

After 4 months and 12 months of rehabilitation, participants completed an average of **9.4 ± 3.4** and **28.6 ± 8.6 exoskeleton rehabilitation sessions** (Figure 2), respectively. Session characteristics are available in Table 1.

Table 1. Characteristics of rehabilitation sessions for sessions completed after 4 (Post-M4) and 12 months (Post-M12) of Atalante X exoskeleton rehabilitation. Data are presented as mean ± standard deviation.

	Post-M4	Post-M12
Verticality duration (min)	40 ± 10.6	39 ± 10.1
Number of steps/session	744 ± 263	806 ± 329
Device assistance (%)	33 ± 27	29 ± 25

Adverse events analysis

Between baseline and the 12-month post-assessment, 15 adverse events occurred, including two related to the device (elbow pinching, n=2); all resolved without sequelae.

*diagnosed with: (in)complete spinal cord injury (T9- to-L1 level, n=6), multiple sclerosis (n=4), myelitis (n=1) post-radiation radiculoplexopathy (n=1), congenital teratoma (n=1) and stroke (n=1)

Clinical outcomes analysis

- FIST score increased by 7.2 ± 4.4 and 8.6 ± 4.1 points, after 4 and 12 months of exoskeleton rehabilitation, respectively (Wilcoxon test, p<0.05) (Figure 3.A)
- Wheeled/walked distance increased by 32.4 ± 46.7 and 37.4 ± 58 meters, after 4 and 12 months of exoskeleton rehabilitation, respectively (Wilcoxon test , p<0.05) (Figure 3.B)

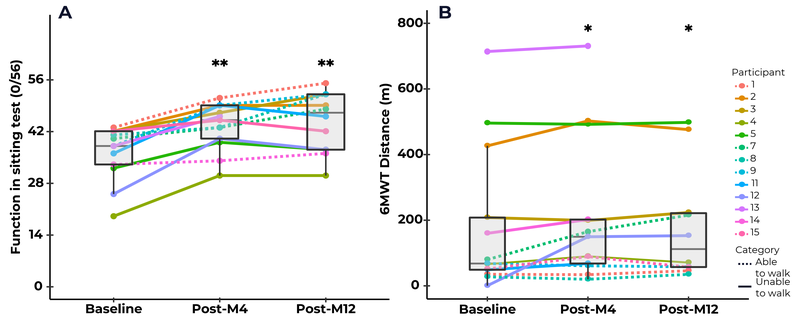

Figure 3. A. Effects of the Atalante X exoskeleton rehabilitation on seated postural control (Figure 3. A), and on walked/wheeled distance (Figure 3. B). Each graph represents the boxplots, with lines representing each assessed participant, lines being differentiated according to initial ability to walk. Results were obtained at baseline, and after 4 months (Post-M4) and 12 months (Post-M12) of exoskeleton rehabilitation. * p < 0.05 as compared to the Baseline assessment.

- When describing **GAS,** participants aimed to improve their gait, balance, muscle strength, and mobility. At 4 months post-treatment, 38% remained at the initial level, 28% partially improved, and 34% were better than expected; at 12 months, these percentages were 33%, 41%, and 26%, respectively.

DISCUSSION/CONCLUSION

- Preliminary findings indicate that rehabilitation with hands-free Atalante X is **safe** and shows **promising results** in improving seated postural control, walked/wheeled distance, and goals attainment in rehabilitation, among adults with lower limb weakness and/or impairments, aligning with short-term exoskeleton rehabilitation literature.
- Further investigation is needed to determine its clinical effectiveness.

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