WANDERCRAFT

Assessment of the use of the Atalante exoskeleton in patients with hemiplegia following a stroke

Introduction

Stroke (CVA) is the second leading cause of death in the adult population, affecting approximately 12 to 15 million people per year (Feigin et al., 2021; Saposnik et al., 2016).

Approximately two thirds of stroke survivors have motor deficits such as walking and balance disorders and also exhibit compensatory mechanisms impacting activities of daily living and quality of life (Nolan et al., 2021; Saposnik et al., 2016). Recently, the use of robotic devices such as exoskeletons has emerged as a promising walking rehabilitation tool, allowing for a high number of repetitive steps and goal-based rehabilitation work (Hobbs & Artemiadis, 2020).

The INSPIRE study aimed to demonstrate that the Atalante robotic walking exoskeleton can be used safely in stroke patients. An assessment of the clinical effects on walking and balance was also performed.

Methods

At least 30 patients with hemiplegia of at least two weeks' post stroke and lacking the ability to walk independently, as assessed by the Functional Ambulation Category score (from 0 to 3), were eligible for inclusion. Patients with contraindications to the use of the exoskeleton (non-compatible anthropometric measurements, osteoporotic fractures, pressure sores in the areas of contact with the exoskeleton, severe spasticity of the lower limb muscles that limited range of motion), or with significant cognitive impairment, could not be included in the study.

The patients underwent **5 rehabilitation sessions** with the exoskeleton spread over **3 weeks**, with **an evaluation before (S0) and after the sessions with the exoskeleton (S6)**. Six rehabilitation centers participated in this interventional, prospective, and open study, with each patient being their own control: Centre Mutualiste de Kerpape, Fondation Hopale in Berck sur Mer, Centre de Médecine Physique et de Réadaptation (CMPR APAJH) in Pionsat, Fondation Renaissance Sanitaire in Saint-Sébastien de Morsent, France; Cliniques universitaires Saint-Luc in Brussels, Belgium; and Rehazenter in Luxembourg.

The exoskeleton operators were trained to use the Atalante for: installation of the patient; sit to stand; passive and active walking. The operators were also trained in EarlyGait (small step length) and RealGait (large step length) mode, with the option of using the ActiveGait mode (modular assistance, aimed at exploiting the patient's remaining capacities by adapting the level of assistance provided by the exoskeleton). The training also included the Active balance mode, performing side or backward steps and 180 degree turns. The modes used were noted for each session.

The primary objective of this study was to demonstrate that the Atalante exoskeleton can be used safely in a population of stroke patients with limited walking ability. The main assessment criterion was patient safety, as measured by the **number of adverse events (AE)** observed in the study. AEs were characterized in terms of severity (non-serious or serious [SAE]), which could be related to the procedure and/or device or leading to new exploratory facts. An independent Clinical Evaluation Committee (CEC), consisting of three experts, assessed all events for severity, intensity, and whether they were related to the device and/or procedure, and decided whether to continue the study or not, with or without recommendations.

The study contained **secondary objectives** with assessment of:

Rehabilitation session data:

- Performance during walking with the exoskeleton (duration of session and standing, and number of steps)
- The data and notes of the sessions reported by the Atalante exoskeleton operators
- The patients also performed a test of the exoskeleton remote control during the 5th and last rehabilitation session with the Atalante, and answered a satisfaction questionnaire at the end of the rehabilitation sessions

Clinical data, assessments performed without the Atalante exoskeleton:

- Walking speed with the 10-meter walking test (10MWT)
- Endurance with the 6-minute walking test (6MWT)
- Walking ability with the Functional Ambulation Category test
- Balance with the Berg Balance Scale (BBS)
- Depression and anxiety with the Hamilton scale
- Spasticity by the modified Ashworth scale

Pain and skin condition were monitored continuously.

Results

40 patients (mean ± standard deviation: 10.2 ± 12.1 months after stroke) with an average age of 62 ± 10 years and a FAC baseline score of 1.05 ± 1.1 were included in this study. Of these 40 patients, 31 completed the study: 5 study exits were due to the participant's decision, 1 to a medical decision, and 3 to AEs, one of which was serious.

Main assessment criteria result

Safety, as measured by the number of adverse events observed in the study, is summarized in Figure 1. The estimate of non-serious AEs per session that could be related to the device or procedure was 2.5 ± 1.4%.

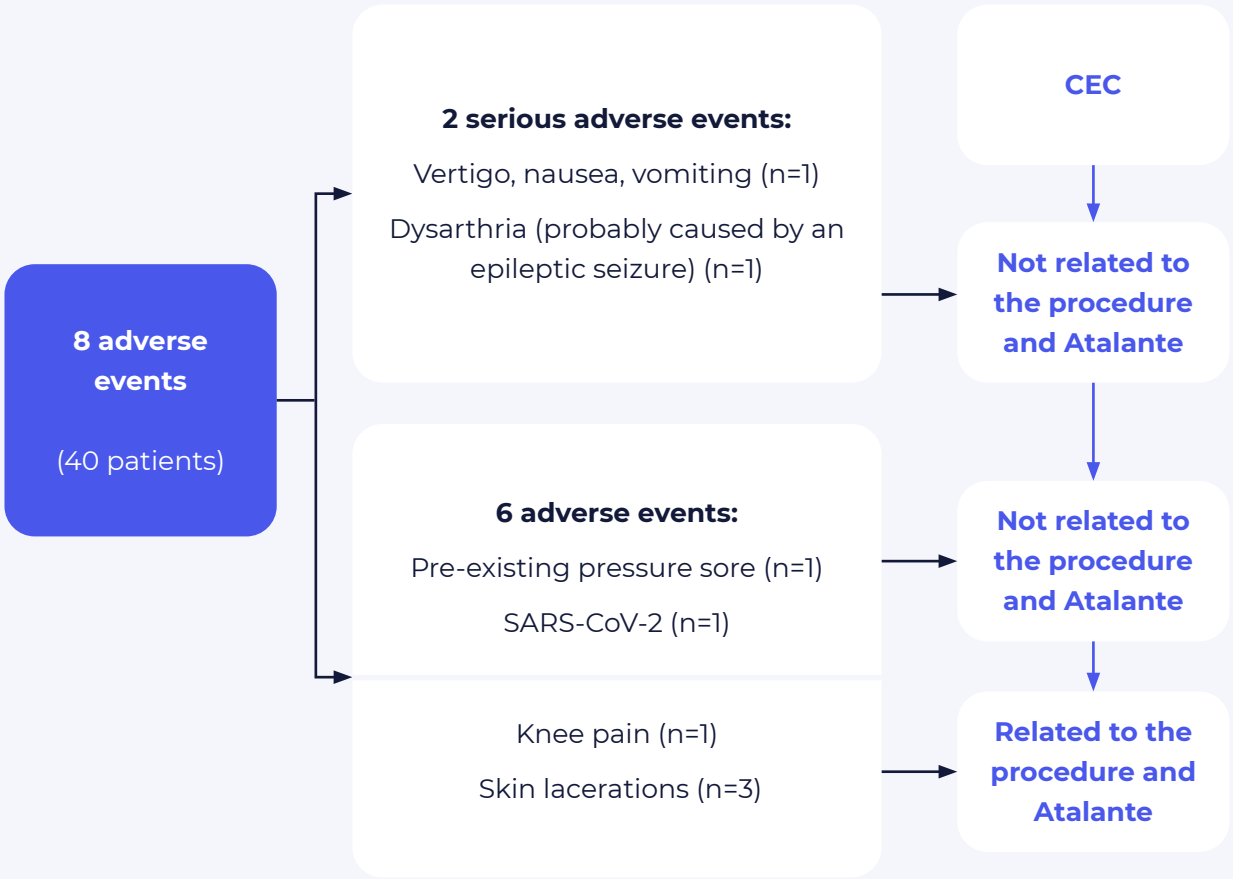

Figure 1 :
Safety of using the Atalante robotic walking exoskeleton in stroke patients

Secondary assessment criteria result

Rehabilitation sessions

The proportion of use of EarlyGait, RealGait, ActiveGait, backward and side steps, and exercise mode per session is available in Figure 2. Overall, EarlyGait mode was used in 80 ± 5.9% of sessions, RealGait in 36 ± 7.2%, ActiveGait mode in 29.5 ± 7.6%, backward steps in 55 ± 5.8%, and exercise mode in 59 ± 11.8% of sessions.

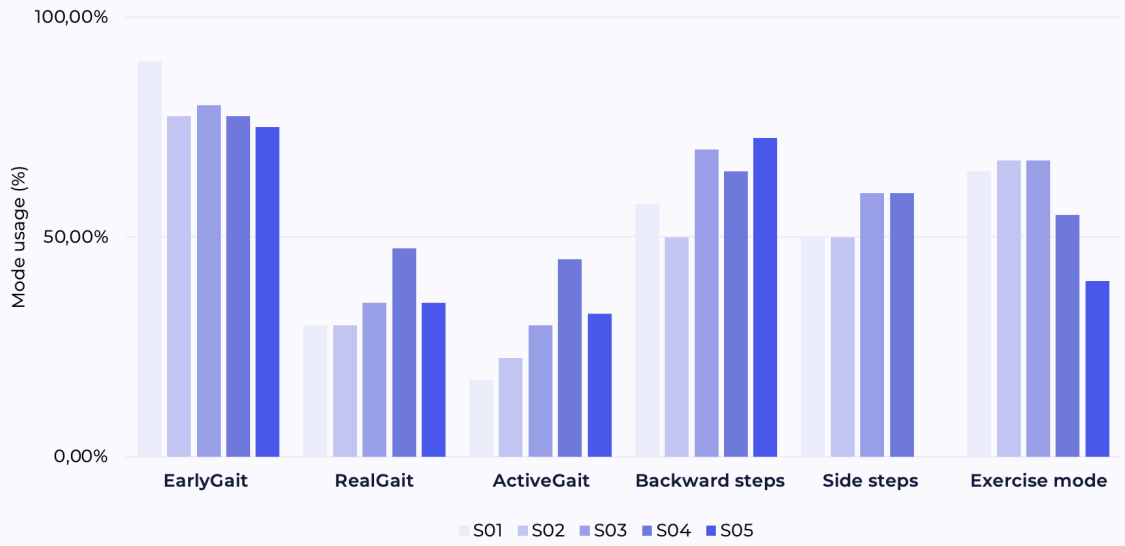

Figure 2 : Rehabilitation sessions: modes selected by the operators. The figure shows the modes used during each session. Data expressed as a percentage of use.

The overall duration of the sessions remained stable over time with an average value of 30.5 ± 12.2 minutes, without significant difference between the rehabilitation sessions (Figure 3. A). Walking performance data during the Atalante exoskeleton sessions showed that **the duration of standing and the number of steps increased between the first and the last session ($p<0.05$)**. Post-hoc analysis revealed an increased in standing time between the 1st and the 3rd and the 1st and the 4th sessions ($p<0.05$) (Figure 3. B), while the number of steps increased between the 1st and 3rd, 4th, and 5th rehabilitation sessions ($p<0.05$) (Figure 3. C).

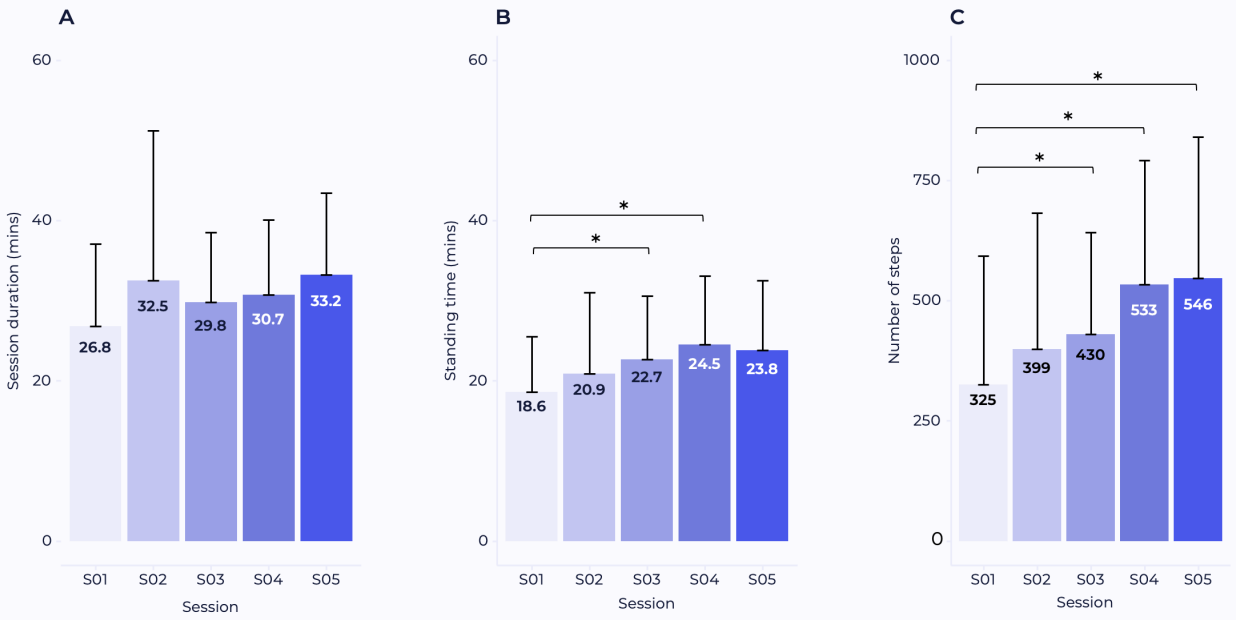

Figure 3 :
Rehabilitation session data on session duration (A), standing time (B) and number of steps (C)

Clinical assessment of walking and balance

Walking speed during the 10MWT test, distance covered during the 6MWT test, functional ambulatory capacity (FAC), and balance measured by the BBS, assessed without the device, improved by 0.05 ± 0.08 m/s, 11.6 ± 18 meters, 0.6 ± 1.0 and 6.2 ± 8.1 points ($p<0.05$), respectively (Figure 4).

Spasticity, depression, and anxiety were unchanged. The incidence of pain and skin lesions while subjects were in the study was low.

82.6% of patients successfully used the remote control of the Atalante exoskeleton and **patients' overall satisfaction with the robotic rehabilitation was high.**

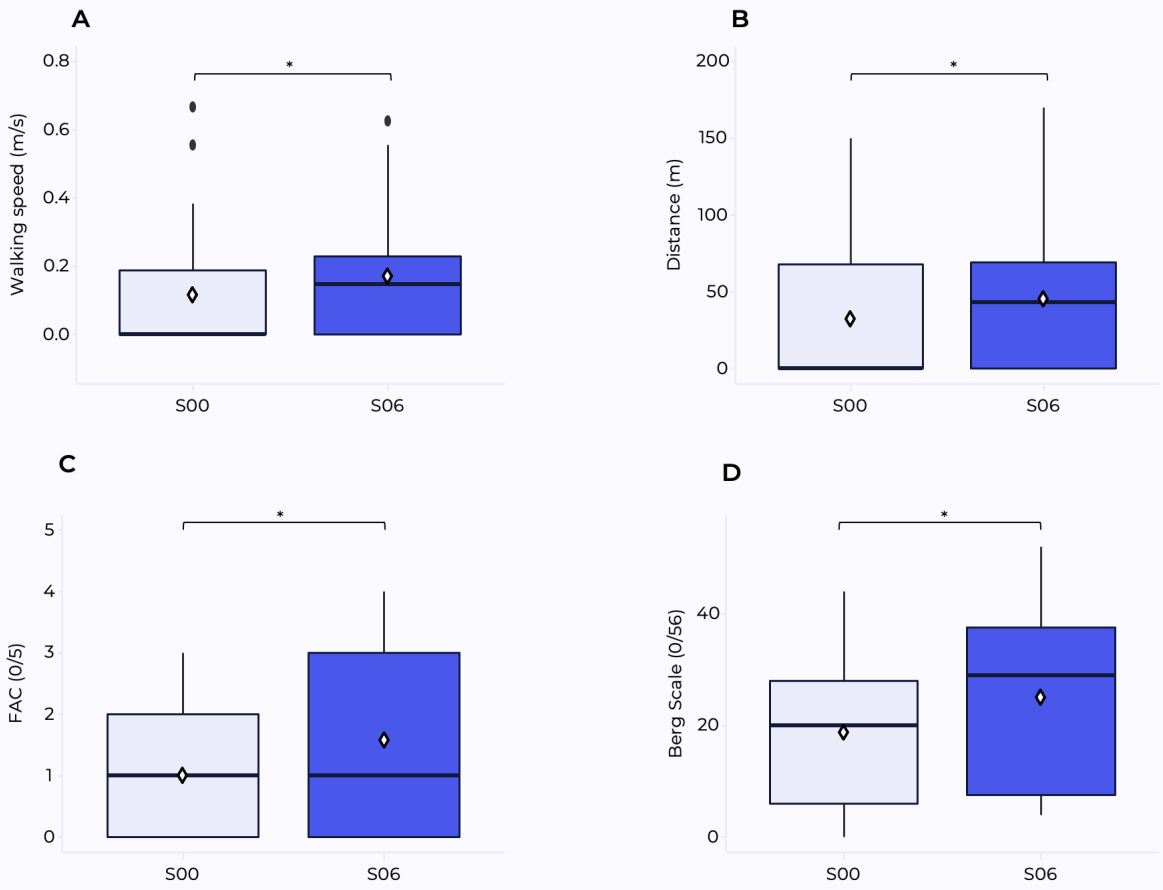

Figure 4 :
Effects of rehabilitation with the Atalante exoskeleton on walking speed (A), distance covered (B), functional ambulatory capacity (C) and balance (D) in post-stroke patients.

Conclusion

This study showed that the **Atalante exoskeleton can be used safely** in the population of patients who have suffered hemiplegia following a stroke. A total of 31 patients who completed the 5 rehabilitation sessions with the exoskeleton **were satisfied** and were able to increase their performance during robotic walking. In addition, the data suggests that robotic walking **may result in clinical improvements in walking speed, ambulatory capacity, endurance, and balance**, as demonstrated by clinical assessment without the Atalante exoskeleton. Further studies are needed to determine clinical efficiency in randomized controlled trials and to determine the neural mechanisms involved in the clinical improvements.

References

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Glossary

Operator: a professional trained to safely and efftively operate the exoskeleton. In this study, the term “operator” is used as a general term to refer to health professionals who conduct the sessions with patients.

Adverse event (AE): any adverse medical event, illness, unintended injury, or adverse clinical indication, including abnormal laboratory findings in subjects, users, or others in the context of a clinical investigation, whether or not related to the medical device.

Serious adverse event related to the device: an adverse event related to the use of an experimental device, resulting in any of the characteristics of a serious adverse event.

Serious adverse event (SAE): any adverse event that results in death or serious deterioration of the subject’s health, resulting in any of the following events: life-threatening illness or injury, permanent impairment of a body structure or function, hospitalization or prolongation of hospitalization of a patient, medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment of a body structure or function, chronic disease, fetal suffering, fetal death, or congenital physical or mental impairment or birth defect.

Unexpected serious adverse effect of the device: an effect that, by its nature, impact, severity, or outcome, has not been identified in the current risk assessment.

New fact: any new data that may lead to a reassessment of the benefits and risks from the research or the product being researched, changes in the use of this product, in the conduct of the research, or in the research documentation, or to the suspension, discontinuation, or change to the research protocol or similar research.

10-meter walking test (10MWT): the measurement of the time required to walk 10 meters at a comfortable speed, allowing walking speed to be reached.

6-minute walking test (6MWT): measures the maximum distance covered during a 6 minute walking period, giving information on the subject’s endurance. The greater the distance, the better the functional capacity to exercise.

Functional Ambulation Category (FAC): assesses mobility status by determining the extent to which the patient requires human assistance to walk, whether or not they use a technical walking aid. Scores range from 0 (non-functional walking) to 5 (independent walking).

Berg Balance Scale (BBS): measures static and dynamic balance with the aim of identifying people at risk of falling, with scores from 0 to 56. The higher the score, the better the balance.

Hamilton Anxiety and Depression Scale (HADS): assesses the severity of symptoms of anxiety and depression, with scores from 0 to 21 for each dimension, with higher scores reflecting symptom severity.