SWalker: a robotic platform for hip fracture rehabilitation

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Research

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Abstract

Background

Hip fracture is one of the most common traumatisms associated with falls in the elderly, severely affecting the patient's mobility and independence. The treatment involves hospitalization and prolonged rehabilitation periods with high costs which are associated with an increased mortality rate due to health complications. In recent years, the use of robotic applications has proven to be effective in gait rehabilitation, especially for neurological disorders. However, there is a lack of research in robotic rehabilitation focused on hip fracture of elderly people. This paper presents the design and validation of a novel robotic platform for hip rehabilitation called SWalker aimed at improving the rehabilitation of this condition.

Methods

The performance of the SWalker platform was assessed at Albertia Servicios Sociosanitarios S.A. nursing homes. Preliminary functional validation of the SWalker platform was carried out with five healthy elderly subjects and two physiotherapists. Clinical validation was conducted with 34 hip fracture patients. The control group (n = 24, age = 86.38 ± 6.16, 75% female) followed conventional therapy, while the intervention group (n = 10, age = 86.80 ± 6.32, 90% female) was rehabilitated using SWalker. Physiological parameters, and functional assessment scales such as FAC and Tinetti were collected at the beginning and at the end of the intervention. Gait recovery and rehabilitation process indicators were also gathered.

Results

SWalker had a good acceptability in the functional validation (final scores > 85), as measured by the System Usability Scale. In the clinical validation, the control group required 68.09 ± 27.38 rehabilitation sessions compared to 22.60 ± 16.75 in the intervention group ($p < 0.001$). Patients in the control group needed 120.33 ± 53.64 days to reach ambulation, while patients rehabilitated with SWalker achieved that stage in 67.11 ± 51.07 days ($p = 0.021$). FAC and Tinetti indexes presented a larger improvement in the intervention group when compared with the control group ($p = 0.007$ and $p = 0.01$, respectively).

Conclusions

The SWalker platform can be considered an effective tool to enhance autonomous gait and shorten rehabilitation therapy in elderly hip fracture patients. This result encourages further research on robotic rehabilitation platforms for hip fracture.

Trial registration

This study was performed under the protocol “SWALKERS17”, approved on January 15, 2019 by the Local Ethical Committee of Fundación Jiménez Díaz. Public trial registration ISRCTN28049001 on February, 25 – Retrospectively registered, https://www.isrctn.com/ISRCTN28049001.

Background

Falls and subsequent injuries are among the leading health problems of the elderly population. About 35–40% of people over 65 years old suffer a fall every year, and the percentage is even higher in people above 75 years old [1–3]. Among the potential traumatism resulting from a fall, hip fractures (HF), which consists of a breakage in the upper portion of the femur, stand out because of their frequency, their impairment in the quality of life, and their associated mortality [4]. HF is likely to occur in advanced ages due to osteoporosis affecting the skeletal system and has a higher prevalence in women [5]. Studies combining men and women in different countries of the world showed that North America, Europe and Australia have the highest risk of HF, with an annual average incidence between 150–250 fractures, and exceeding 250 cases per 1000,000 inhabitants in some countries [6]. Just in the United States, about 300,000 subjects are hospitalized every year due to HF [7].

The need for hospitalization after HF involves high associated costs; it is estimated that HF associated treatment costs are almost triple compared with an equivalent group of subjects hospitalized for other reasons [8]. Some studies that examined the incidence of this pathology on women calculated that the associated costs from surgery, laboratory and radiological investigations, length of hospitalization, and rehabilitation might even exceed the expenditure for breast and gynecological cancers combined [9, 10]. These costs arise due to the high number of complications associated with HP hospitalization, such as stress, depression, anemia, or cardiovascular disease [7]. One of the most harmful effects of HF is the disability that the patient experiences [11]. Confinement to bed and reduced mobility in hospitalized patients leads to the loss of muscle mass and muscle function (sarcopenia). Indeed, the prevalence of sarcopenia in elderly patients admitted with fractures ranges between 17% and 59% [12].

Approximately 40% of elderly people who have suffered a HF do not recover their previous health functional status and autonomy, becoming dependent on other people or institutions [13]. This loss of function involves negative psychological and physical consequences for the patient, leading to an increased mortality rate. The most significant mortality risk has been demonstrated to be within the first six months after the fracture [14] and may persist during the next years [15]. It is estimated that in-hospital mortality rates can reach between 25% and 30% within one year after admission [16].

Physical rehabilitation aims to recover functional mobility (walking and other daily activities), pursuing independent ambulation. Recovery patterns vary in HF patients, reaching maximum recovery between four months and one year following the HF. Balance and gait can take up to nine months to recover [17, 18]. Training exercises where early mobilization prevails, encourage the recovery of function and the subject's autonomy [19]. However, due to the postoperative pain and unawareness of the postoperative limitations, sometimes patients find the rehabilitation exercises complicated and scary. Thus, the therapy turns into a limited intervention and a failure in the self-motion goal [20].

It has often been hypothesized that the success of recovery depends on the timeliness and adequacy of the treatment [21]. Therapies that entail an accurate patient's follow-up, enhance the patient's motivation and lead to an increase in the adherence to treatment. However, these treatments involve high costs due

to the need for a large number of specialized staff, and appropriate planning and scheduling [22, 23]. Recently, the usage of robotic devices in rehabilitation is spreading as a solution to the high cost problem [24]. Robotic rehabilitation can provide a cost-effective integrative therapy involving different muscle groups in a precise way while performing functional tasks. Robotic solutions frequently integrate biofeedback techniques using motion or physiological sensors that measure the patient's progress. All these advances contribute to design motivational rehabilitation scenarios that favors adherence to the treatment [25].

Among robotic devices for gait recovery are robotic walkers and orthoses or exoskeletons. Their goal is to enhance the patient's abilities in standing, balance, and walking when there is a partial loss of function [26]. Some of the most remarkable exoskeletons are Lokomat [27], Gait Trainer [28], or the wearable exoskeletons designed by Ekso Bionics [29, 30]. They are used mainly in neurological disorders, such as cerebral palsy, spinal cord injury, or stroke, and they have proven to be effective [31, 32]. However, they are not suitable for elderly people as the patient must support the weight and volume of the equipment, which is particularly disadvantageous due to the lower limb weakness experienced by the elderly after HF [33]. Robotic walkers such as the EXPOS exoskeleton overcomes these disadvantages by including a platform that carries the heavy mechanical parts, thus minimizing the weight of the wearable exoskeleton. Simultaneously, this structure provides the user with firm support to hold the body [34].

In the case of patients affected by HF, the primary rehabilitation targets of physical therapy are to promote safe walking, increase lower limb strength, and improve autonomy from an early stage. To meet the requirements of a robotic rehabilitation platform addressed to elderly people, walkers seem to have more advantages than exoskeletons, since the weight of the elements of the device does not rest on the patient. However, the vast majority of walkers found in the literature are intended to aid the user in the navigation, rather than providing physical support [30], as it is needed in HF patients. Moreover, the availability of an adaptable weight support mechanism to enable a gradual discharge of the patient’s weight is of particular interest in HF rehabilitation [35], and it is not usually present in these walkers. This feature promotes walking in the early rehabilitation stages when the patient's lower limbs are still weak. Furthermore, the monitoring of the support provided might be an indicator of the evolution of the patient's muscular strength [36, 37].

We have not found robotic rehabilitation platforms explicitly designed for HF rehabilitation. Some of the general purpose robotic platforms have been tested in HF patients for balance control exercises and monitoring [38]. However, given that they are not designed specifically for HF rehabilitation, they are not optimized for gait speeds or sway adequate for these patients, nor they provide weight support for early post-operative mobilization [39]. Other devices, such as Hipbot, are aimed to exercise abduction/adduction and flexion/extension in the case of HF through biofeedback techniques based on a graphical user interface [40]. These are static devices intended to rehabilitate the joint Range Of Motion (ROM) through repetitive exercises that the user can execute by himself under a rehabilitation program. This type of therapy is not focused on the target population of this work, where it is necessary to prioritize

user motivation and ambulation. Besides, due to the elderly patient's cognitive level and other complications, they require continuous monitoring by a therapist.

Concerning the review of the scientific literature on comparable devices in which the required characteristics are present, the CPWalker robotic platform was identified to be of great interest [41, 42]. It is a walker focused on the rehabilitation of children with cerebral palsy who have undergone multilevel surgery. This walker incorporates a lower limb exoskeleton with a system for partial weight support, traction support, and a set of human-machine interfaces [43]. CPWalker was designed considering the needs of for children with cerebral palsy, not the ones of elderly HF patients, however these structural modules served as the basis for the design of the SWalker prototype.

This paper describes the conceptual design, technical development and functional and clinical validation of a robotic platform called SWalker. SWalker is intended for HF rehabilitation and it is aimed to facilitate early mobilization and ambulation to increase the patient’s autonomy and confidence. It has a safety structure that incorporates traction and Partial Body Weight Support (PBWS). It also incorporates a set of sensors integrated into its control architecture to deliver feedback of the weight supported, gait speed and hip ROM. SWalker has been designed to meet the functional requirements that permit starting the rehabilitation of HF in the elderly patients as soon as possible, and it includes considerations relative to the patient's motivation and adherence to treatment. The platform was evaluated in the Albertia Servicios Sociosanitarios S.A. nursing home (Madrid, Spain).

First, a preliminary functional validation was carried out with five healthy residents, followed by a clinical validation involving a total of thirty-four patients affected of HF.

Methods

SWalker conceptual design

An iterative process of definition of the user’s needs and technical requirements, supported by a scientific literature review, was conducted to achieve the final SWalker’s design. Both engineers and a clinical team from Albertia Servicios Sociosanitarios S.A. nursing homes were responsible for such a process. The clinical staff was composed of a medical director, occupational therapists, and physiotherapists in charge of HF rehabilitation.

Based on the literature review, and after some iterative meetings between the engineers and the clinical staff, detailed specifications were created. These specifications drove the design of SWalker and defined objective verification points to be assessed during the functional evaluation of the platform (see Table 1). These criteria were grouped into four main groups: mechanical structure, support for the functional activities, user’s safety, and usability and comfort.

Table 1. Analysis of user’s needs and technical requirements of the system

Needs criteria	Requirements
Mechanical structure	
· Structure to support the weight and height of an adult user	· Weight: 45 kg - 90 kg · Height: 150 cm -180 cm
Functional activites support	
· Gait assistance and monitoring biomechanical parameters	· Motor drive system with motor speed sensors. Hip ROM sensors.
· Partial-body weight support for early mobilization	· Gradual weight support structure and weight support sensor
· Robot-therapist interface	· Graphical user interface (GUI) for operating the robot, customizable therapies and visualizing data
User safety	
· Upper body stabilization and support elements	· Integration of parallel bars and trunk harness
· Rigid and stable structure	· Selection of appropriate materials and joints that will withstand the stresses during operation
· Protect the user from mechanical and electrical contact or failures	· Accessible platform and insulation of electrical connections
	· Integration of electromechanical elements for emergency stops and electronic system status indicators
Usability and user comfort	
· Protection of the user's skin in direct contact with the structure	· Use of padded coatted materials for specific parts
· Structure adaptable to the user's anthropometric characteristics	· Mechanical parts adjustable to the contour of the user's body
	· Mechanical elements easy to handle, dismantle and adjust by the therapists
	· Adjustable parts
· The therapist must be able to operate the software interface autonomously	· Interactive and intuitive communication interface

Robotic platform design

At a structural level, SWalker consists of a mechanical structure with a T-shaped frame supported on four wheels and two adjustable parallel grab bars like those used during conventional rehabilitation therapies.

Additionally, the user's stability is achieved by an adjustable trunk harness (Fig. 1). The whole mechanism provides the user with a rigid and stable support while walking. Moreover, the familiar appearance of these components contributes to the patient's acceptance, increasing safety perception. The back of the structure houses the electronic control unit. This unit enables communication with the sensors integrated into the mechanical structure that control traction (speed and direction), body weight support, and range of movement.

The robotic platform integrates three major ensembles comprising its structural design: the *drive system*, the *user's body weight support system* and the *hip coupling mechanism*.

The *drive system* can move the robotic platform in all directions (forward, back, right, and left) and at different speeds. These were indicated by the therapists and graded into minimum (0.058 m/s), medium (0.225 m/s) and maximum (0.4 m/s), according to the average speeds that patients could reach in different phases of the rehabilitation. Two DC gear motors equipped with encoders control the motorized traction into the back wheels.

The *User's body weight support system* is composed of a hydraulic pump that activates two cylinder-piston actuators guided by a rail system to lift the structure to which the user is fastened. The height to which the subject is lifted is directly related to the weight discharge that the patient needs, configured by the physiotherapist using the GUI. Thus, it can be ranged from 0% (fully suspended) to 100% (user entirely on the floor). The weight discharge is measured by a load cell (Fig. 2).

The *Hip coupling mechanism* is a structure intended to attach the trunk harness and integrates two potentiometers, one on each side of the hip, to measure the patient's hip ROM in the sagittal plane. The evolution of the hip flexion and extension angles is an indicator of rehabilitative progress, as they are related to an effective gait pattern [44,45]. The final design comprises a width-adjustable steel structure surrounding the subject's pelvis with two aluminum bars coupled to both thighs with straps that follow the hip flexo/extension movement while walking.

Control architecture

The electronic system is housed inside a metal casing at the rear of the robot. This structural module contains the on/off switch, the battery and fuse status indicators, an emergency stop button, and the weight support system's manual activation as a safety mechanism. The central control unit is governed by a PC104, an embedded computer responsible for executing the control algorithms and the communication with the different modules of the robot. The main controllers and the communication protocols were developed using the Matlab & Simulink environment. Each sensor integrated into the mechanical structure has an electronic board to acquire signals and send them via the CAN (Controller Area Network) protocol with the PC104. The UDP (User Datagram Protocol) is used between the PC104 and a Wifi router that enables information transmission between the control unit and the GUI designed for the physiotherapists (Fig. 3).

Graphical user interface

A software application specifically developed for this purpose enables the clinicians to control the robotic platform and monitor sensor data reflecting both therapy settings, such as the walker speed and percentage of body weight support, or patient's performance, such as hip ROM. The application that runs on a conventional Windows 10 tablet.

The software is divided into three main functional modules that allow the physiotherapist to (1) register a new patient, (2) personalize and carry out a therapy, or (3) visualize the results of a given session. The personalization of the therapy consists of the selection of the driving speed and weight discharge for each patient. Once these two parameters are set, the physiotherapist starts driving the robot (forward/backward/right/left buttons) during the execution of the patient's therapy. He can also start and stop the data recording, which will enable the latter visualization of time-dependent hip ROM graphics.

Preliminary functional and usability validation

The functional and usability validation aimed to evaluate the extent to which the system's requirements in the conceptual design phase were met (see Table 1). While the functional validation assessed the system's technical performance and the patient's satisfaction, the usability validation tested the suitability of the platform to be used in a rehabilitation setting from the therapist's point of view.

The functional test was carried out with five healthy elderly subjects (age=87.6±6.2) from the Albertia Valle de la Oliva-Majadahonda nursing home. These were healthy users that usually practice physical exercises with conventional equipment such as pedaling machines or walking with parallel bars. They did not present intellectual disability and had not used any robotic rehabilitation devices previously. The patients were informed of the goal of the test, so they could provide ideas to improve the system. Each session consisted of 30 minutes of walking along a 25 meters corridor. The number of times they repeated this distance depended on the users' gait speed. An engineer and two physiotherapists supervised all sessions.

Before starting these trials, the physiotherapists were trained in the operation of the robotic platform, the software application, the structural adjustments in the platform, and the process of transferring patients, usually from a conventional wheelchair or walker, to the robotic platform. In this way the physiotherapists were able to operate on the system simulating a typical HF rehabilitation session. Both therapists were needed to set the required adjustments in the robotic platform and transfer the subject.

After the test, users and physiotherapists reported their performance perception evaluating several verification points. These aspects, listed in a template with a total of 28 points, included all the technical requirements that were specified for the robot during the design stage, and they also included other technical details that the engineering team felt should be evaluated.

Usability was assessed by the collaboration of the two physiotherapists who participated in the functional validation. They answered a 10-item usability questionnaire based on the "System Usability

Scale (SUS)" [46,47]. All questions were evaluated from 0 to 5 points, meaning 0 "Strongly disagree" and 5 "Strongly agree". For items 1,3,5,7 and 9, the score contribution was the scale position minus 1. For items 2,4,6,8 and 10, the contribution was 5 minus the scale position. Then, the sum of the scores was multiplied by 2.5 to obtain the overall SUS value, ranging from 0 to 100 [48].

Clinical validation

Patients and procedure

The clinical trial lasted 15 months, starting on January 2019, and was carried out with 34 residents of two centers of Albertia Servicios Sociosanitarios nursing homes. The study admitted all those subjects who voluntarily participated in the research and met the inclusion criteria. The key feature of the target population was patients who, after recently having undergone a hip fracture surgery, needed subsequent rehabilitation to restore autonomous ambulation. All of them started from a state of dependency in which a wheelchair was required. None of them had yet received any other type of HF rehabilitation therapy. The centers participating in the study were Albertia Valle de la Oliva-Majadahonda and Albertia Moratalaz, both located in the province of Madrid, Spain. Both centers accommodate physically and cognitively impaired patients, as well as non-dependent people under temporary or permanent stays. The subjects had an average age of 86.5±6.12 years. The experiment was conducted with a control group in which patients were treated with the conventional rehabilitation therapy (n=24, BMI=25.82±4.98, age=86.38±6.16, 75% female) and an intervention group that was rehabilitated using the robotic platform (n=10, BMI=25.43±5.53, age=86.80±6.32, 90% female).

Before starting the study, all patients and families were informed beforehand and signed a consent to participate. For the patients in the control group, the established rehabilitation program was adapted to each subject's characteristics. According to the medical records of other centers' patients who have already undergone rehabilitation, the average duration of conventional rehabilitation is 1-3 months. A re-evaluation six months after the fracture is done systematically. The therapy was always carried out under the help and supervision of a physiotherapist, five days a week in 30-45 minute sessions (depending on the patient's tolerance). Muscle strengthening and balance exercises, standing and walking with parallel bars are techniques used.

Regarding the patients who used SWalker, the therapy was carried out during the same number of weekly sessions, and for the same duration as in conventional rehabilitation. A rehabilitation program with predefined parameters for all the patients was not applied, but rather these were modified as the therapy moved forward. The therapy aimed to increase the weight the patient could bear on his lower limb and the walking speed. Treatment was started with the robot supporting close to 70-80% the patient's body weight and the minimum walking speed (0.058 m/s). In each new session the therapist relied on his observation and an interview of the patient's perception physical condition to define the new level of weight discharge and speed. If this screening resulted in a progress in terms of a positive evolution of his/her lower limb support tolerance, fatigue, pain and feeling of safety, the percentage of load supported by the walker was reduce and the speed was increased. This process was repeated until the end of the treatment. At the end

of the rehabilitation all patients who recover ambulation were able to bear 100% of their body weight and the medium speed (0.225 m/s). In no case the maximum speed was reached.

Metrics collected

After being admitted to the study, each patient was asked for his name, surname, sex and age. Additionally, data regarding the injury, such as type and date of fracture, type of surgery and complications, were registered.

Patient's physiological metrics such as height, weight and body mass index (BMI) were taken at the time of admission (basal characteristics) and repeated at the end of rehabilitation treatment. The nutritional, functional and cognitive patients' status were also evaluated in the two stages with the following screening tools:

- Barthel index [49], which has the purpose of evaluating or assessing a person's level of independence when performing basic daily activities.
- Mini Nutritional Assessment (MNA) [50], that is a tool to identify elderly people who are malnourished or at risk of malnutrition.
- Functional Ambulation Category (FAC) [51], is a functional walking test that evaluates ambulation ability by determining how much human support the patient requires when walking, regardless of whether or not they use a personal assistive device.
- Tinetti scale [52] assesses a person's balance and walking ability to determine their risk of falling.
- Mini Examen Cognoscitivo (MEC) [53], the Spanish version of Folstein's Mini-Mental State Examination (MMSE) [54], that with 35 assessment points checks for suspected symptoms compatible with cognitive impairment or dementia.

Performance indicators of the rehabilitation process, such as the number of physiotherapy sessions, time (days) elapsed between surgery and the start of ambulation, whether or not the subject recovers independent ambulation, or the technical assistance needed after the therapy, were also collected. It was considered that a patient recovered ambulation if he could walk, even requiring assistance from a person and technical help (conventional walker, cane, wheelchair for long-distance). A patient was considered to recover independent ambulation if he consistently established independent walking, without the need for another person's assistance. Technical aid may be partially or fully required in this situation.

Statistical analysis

Statistical analysis was carried out using the Statistical Package IBM® SPSS, version 25. A descriptive analysis of the parameters that characterize the patients and the lesion's clinical history was made at admission. Quantitative variables were expressed as mean ± standard deviation (for normally distributed variables), and categorical variables were defined as the number of subjects (percentage).

The control and intervention groups were compared for each of the variables collected to check whether there were significant differences between them. Comparisons included the BMI, age, Barthel, MEC and MNA index of the patients at the time of admission to check if there were any differences between both groups (control and intervention) before the rehabilitation. The normality of the variables was assessed by the Shapiro-Wilk test ($p<0.05$). A t-test was applied in normally distributed continuous quantitative variables. Mann Whitney test was used for ordinal variables and those continuous variables that were non normally distributed. Unlike the normal continuous variables, these were characterized by their median and interquartile range. In the case of the qualitative variables, the Chi-square test was used. The significance level considered throughout the analysis was $\alpha=0.05$.

Results

The results of the functional test, assessing the 28 verification points that had been specified during the definition of system requirements, are shown in Table 2. Each one of the verification points has an identifier associated; *P* (Performance) in case it refers to an item that evaluates the behavior in the execution of a function, or *U&S* (Usability and Safety) if the item evaluates the comfort and safety of the system for the user. Each point could be judged as *unacceptable*, *approved* or *to be improved*. The choice between these three levels of satisfaction was established gradually depending on whether the test users reported problems or the physiotherapists observed a lack of safety (*unacceptable*); the users and the physiotherapists considered that the verification point has no issues (*approved*); or any of the users or therapists suggested some functional improvements (*to be improved*). All checkpoints resulted either *approved* or *to be improved*. The points to be improved were not considered as limiting for further clinical validation. However, they were collected for evolved designs of the prototype and they are discussed in the last section of this paper.

Table 2
Functional test results

Major System	Id	Verification point	Status
Electronic control unit	*P*	On/off status	*Approved*
	P	Battery load	*Approved*
	P	Isolated conductors	*To be improved*
	P	Fuse indicators	*Approved*
	P	Emergencies stop button	*Approved*
Drive	*P*	Control of trajectory direction	*Approved*
	P	Speed control	*Approved*
	U&S	Suitable speed ranges	*Approved*
User's body weight support	*P*	Activation and % discharge	*Approved*
	U&S	Electromechanical obstacles	*To be improved*
Hip structure	*P*	Motion capture sensors	*Approved*
	P	Withstand bending stress	*Approved*
	U&S	Mechanical adjustments	*To be improved*
	U&S	Proper harness and straps	*Approved*
	U&S	Prevention of skin harmful points	*Approved*
T-shape structure	*U&S*	Safety and easy user access	*To be improved*
	U&S	Mechanical obstacle	*To be improved*
Parallel bars	*U&S*	Height adjustment	*Approved*
	U&S	Prevention of skin harmful points	*Approved*
Software app.	*P*	Transmission of data	*Approved*
	P	Editable patients' database	*Approved*
	P	% weight discharge	*Approved*
	P	Metric visualization module	*Approved*
	P	Adapted speed ranges	*Approved*
	P	Data saving option	*Approved*
	U&S	Intuitive	*Approved*
	U&S	User-friendly	*Approved*

Major System	Id	Verification point	Status
	U&S	User manual and protocol	*To be improved*

Table 3 shows the scores given by the physiotherapists for each of the usability items, the total points obtained, and the equivalence according to the System Usability Scale (SUS).

Table 3
System usability items

Item	Description	Scores Therapist 1	Scores Therapist 2
1	I think that I would like to use this system frequently	4	4
2	I found the system unnecessarily complex	1	1
3	I thought the system was easy to use	5	4
4	I think that I would need the support of a technical person to be able to use this system	1	1
5	I found the functions in this system were well integrated	5	5
6	I thought there was too much inconsistency in this system	1	1
7	I would imagine that most people would learn to use this system very quickly	4	4
8	I found the system very cumbersome to use	1	1
9	I felt very confident using the system	5	4
10	I needed to learn a lot of things before I could get going with this system	1	2
TOTAL		38	35
SUS Score		95	87.5

Regarding the results of the clinical validation, Table 4 shows the baseline characteristics of the patients in the form of mean and standard deviation and those associated with the lesion in the form of a percentage. All these parameters were collected at the time of admission. All were older patients (86,5 ± 6,12 years old) affected by different types of hip fractures and had undergone different types of surgery depending on the clinical history and diagnosis. For both groups, the number of days between the injury and the operation was similar on average (2.64 ± 2.42 days).

Table 4
Descriptive analysis of characteristics at admission

Variables	Patients (n = 34)	Control group C (n = 24)	Intervention Group (n = 10)
Age (years)	86.5 ± 6.12	86.38 ± 6.16	86.80 ± 6.32
Males	82.71 ± 8.04	82.17 ± 8.65	86 ± 0
Females	87.48 ± 5.26	87.78 ± 4.58	86.89 ± 6.70
Males (%)	7 (20.6%)	6 (25%)	1 (10%)
Females (%)	27 (79.4%)	18 (75%)	9 (90%)
Type of fracture			
Basicervical	4 (11.8%)	4 (16.7%)	0
Intracapsular	1 (2.9%)	0	1 (10%)
Pertrochanteric	19 (55.9%)	12 (50%)	7 (70%)
Subcapital	10 (29.4%)	8 (33%)	2 (20%)
Type of surgery			
Intra-medullary nails	3 (8.8%)	3 (12.5%)	0
Osteosynthesis gamma nails	17 (50%)	11 (45,8%)	6 (60%)
Osteosysthesis cannulated screws	2 (5.9%)	1 (4.2%)	1 (10%)
Periprosthetic	10 (29.4%)	7 (29.2%)	3 (30%)
No surgery. Immobilization	2 (5.9%)	2 (8.3%)	0
Time from injury to surgery (days)	2.64 ± 2.42	2.91 ± 2.61	2 ± 1.88

Table 5 presents the hypothesis test results that compared the subjects' anthropometric characteristics, degree of independency (Barthel), and mental (MEC) and nutritional status (MNA) of the control and intervention groups at the beginning of the experiment. The basal values of all the variables but age (which is given in Table 4) can be viewed in Table 6. No statistically significant differences were detected ($p > 0.05$) except for the Barthel index ($p = 0.034$). It should be noted that the control group is the one with the highest level of independence (highest value of the Barthel index), as shown in Table 6.

Table 5
Hypothesis test on basal characteristics of the control and intervention groups

Variable	p-value
BMI	0.956
Age	0.859
Barthel	0.042
MEC	0.723
MNA	0.511

Table 6 presents both the descriptive analysis and the hypothesis test results for the metrics of both groups at the time of admission and discharge. The study aimed to evaluate the improvement between those two moments. At the time of admission, each patient may enter the study from a different initial health state. For instance, the control group presented a greater degree of independence, as measured by the Barthel scale (see Table 6), being this difference statistically significant (see Table 5). Therefore, the comparison of both groups was made over the improvement (the subtraction) between admission and discharge values. In the absence of a piece of data due to human error or inconsistency, that subject was not considered in the analysis of the affected variable.

The Barthel index showed an improvement in case of the control group changing from 37.5 (10–85) to 42.5 (10–90), while the intervention group started with 30 (15–40) points and ended with 37.5 (30–70) at the end of treatment. However, its p-value did not indicate a statistically significant difference between the improvements of each group. The gait capacity and the balance improvement, assessed with the Tinetti index, was more noticeable for the intervention group, with a median value increasing by more than 11 points, from 5.5 (1–13) to 17 (1–24); while in the control group this index changed 3.5 points ($p = 0.01$).

The FAC index for both groups presented an improvement, being higher for SWalker users ($p = 0.007$): half of SWalker users reached a level 3 in the FAC index at the end of the treatment, while half of the patients subjected to conventional rehabilitation achieved level 2. MEC and MNA indexes, which asses the mental and nutritional status of the patient, respectively, did not undergo substantial changes.

Table 6
Physiological parameters and functional assessment scales before and after the treatment, for both control and intervention groups

Variable	Control group (n = 24)		Intervention group (n = 10)		p-value
	Basal	End of treatment	Basal	End of treatment	
Height (cm)	152.97 ± 8,36	152.97 ± 8.36	159.5 ± 10	159.5 ± 10	-
Weight (Kg)	59.91 ± 9.57	59.71 ± 9.76	64.73 ± 14.46	66.04 ± 14.93	0.136
BMI (kg/m^2)	25.82 ± 4.98	25.62 ± 4.69	25.43 ± 5.53	25.95 ± 5.72	0.128
MNA	19.25 (12.50–25.50)	21.25 (8.00-26.50)	19.50 (17.00–24.00)	21.50 (18-24.50)	0.323
FAC	1 (0–2)	2 (0–5)	0.5 (0–2)	3 (0–5)	0.007
Tinetti	8.5 (1–16)	12 (1–26)	5.5 (1–13)	17 (1–24)	0.01
Barthel	37.5 (10–85)	42.5 (10–90)	30 (15–40)	37.5 (30–70)	0.107
MEC	20 (0–34)	16 (0–34)	23 (8–31)	23.5 (8–31)	0.495

Table 7 presents parameters that characterize the duration of the rehabilitation process and the patient's ambulation recovery. The number of physiotherapy sessions in the control group was 68.09 ± 27.38, while for those subjects who used SWalker was 22.60 ± 16.75 ($p < 0.001$). A reduction was also observed in days until ambulation, which was 120.33 ± 53.64 for the control group and 67.11 ± 51.07 for SWalker users ($p = 0.021$).

The recovery rates show that 90% of the subjects who used the robotic platform recovered their walking ability, compared to 75% in the control group. The percentage of patients who recover independent ambulation was 60% in the intervention group and 50% in the control group. Regarding the technical aid that patients required at the end of the rehabilitation period, only 8.3% of patients recovered total independent ambulation, without the need of any technical assistance. 80% of patients rehabilitated with SWalker could use a conventional walker at the end of rehabilitation, compared to 20.8% in the control group. 20% of the SWalker users need a wheelchair after the therapy, compared with 45.8% in the control group.

Table 7
Descriptive analysis and hypothesis test for gait recovery indicators and rehabilitation process length

Variables	Control group (n = 24)	Intervention group (n = 10)	p-value
Nº physiotherapy sessions	68.09 ± 27.38	22.60 ± 16.75	< 0.001
Days until ambulation (from surgery)	120.33 ± 53.64	67.11 ± 51.07	0.021
Recover ambulation			0.644
Yes	18 (75%)	9 (90%)	
No	6 (25%)	1 (10%)	
Recover independent ambulation			0.715
Yes	12 (50%)	6 (60%)	
No	12 (50%)	4 (40%)	
Technical aid			
None	2 (8.3%)	0	
Conventional walker	5 (20.8%)	8 (80%)	
Wheelchair	11 (45.8%)	2 (20%)	
Conventional Walker + wheelchair for long distances	6 (25%)	0	

Discussions and conclusions

SWalker is a robotic platform to rehabilitate HF in the elderly population. Although exoskeletons and smart walkers have been used to rehabilitate lower-limb motor disorders, there is a lack of solutions specifically designed to address the specific requirements for a proper hip fracture rehabilitation. SWalker integrates mechanical and electronic elements into a robotic platform with partial body weight and gait support, providing a safe platform for the patient and an easy operation tool for the physiotherapist. By incorporating a traction system and a reliable weight support system, the patient can be rehabilitated from an early post-surgery stage, starting rehabilitation in a standing position earlier than in a conventional treatment. Equipped with adjustable parts and parameters, the robotic platform enables the therapy's personalization according to the patient's needs and tolerance. The control of the weight support system, driving speed and hip joint ROM offers quantitative monitoring of the therapy.

We have performed a functional and clinical validation of SWalker with patients and physiotherapists. Regarding the functional validation, all the verification points passed the validation (see Table 2). This fact proved the design of SWalker was technically sound and adapted to the target population for real

rehabilitation. Some verification points were graded with the status *to be improved*. One of the most critical issues was the patients' transfer procedure from the wheelchair or conventional walker to the SWalker. A relevant conclusion of this validation is that the system should be more accessible. Even though it has a removable T-shaped structure, a design that eliminates this structural framework altogether without compromising the stability of the system would be desirable in the next target for design improvement. The evaluation of other points, such as the electrical connections and some mechanical adjustments, suggested that there are still improvements to be made. In this regard, the development of plastic casings, mainly in the hip support assembly and the weight support system, would completely isolate the potentiometers and the load cell connections from users' contact, providing them with greater comfort and safety. Furthermore, the use of hand screws on the adjustable parts of the robot and the marking of these areas with numerical scales would make it easier for the physiotherapist to prepare the system.

The usability questionary fulfilled by therapists who were in contact with SWalker yielded very good scores: 95 points from physiotherapist 1 and 87.5 points from physiotherapist 2. According to acceptability ranges reviewed in the scientific literature, these ratings classified SWalker as a product with excellent acceptability [55]. In any case, we plan to include more therapists for a complete evaluation of the device.

Regarding the clinical validation, the most outstanding outcome is the number of physiotherapy sessions and the number of days until the start of ambulation achieved by the intervention group, which were significantly reduced (Table 7). The number of sessions of the control group was 68.09 ± 27.38, compared with 22.60 ± 16.75 in the intervention group ($p < 0.001$). The time to recover autonomous ambulation in the control group was 120.33 ± 53.64, while in the intervention group was 67.11 ± 51.07 ($p = 0.021$). This shortening of the rehabilitation time for patients using the robotic platform is a promising result in the study of hip fracture rehabilitation in older people. The standard duration in conventional rehabilitation, even with early therapeutic intervention, is from 2 to 6 months to achieve good post-fracture mobility [56]. Concerning the distribution of patients recovering from ambulation, SWalker therapy seemed to be more effective since 90% of patients could recover ambulation. In comparison, only 75% of patients in the control group have achieved it. Among the technical aids, the use of a conventional walker prevails over the use of a wheelchair since it implies that the patient can stand up, initiate and maintain a walking pattern with a larger support of his weight, and has acquired good balance. Among those who do need technical aid, in patients who have undergone therapy with SWalker, 80% are supported by a conventional walker, compared with 20,8% in the traditional rehabilitation group; 45,8% of the patients in the latter group required a wheelchair. This means greater autonomy and better motor recovery for the patients in the intervention group.

There were significant differences between the improvements of the two groups in FAC ($p = 0.007$) and Tinetti ($p = 0.01$) indexes (see Table 6). For the intervention group, the values increased considerably between the baseline and the end of treatment. An increase in the Tinetti index meant that the group that performed the therapy with SWalker experienced a larger improvement in gait and balance and, therefore

a lower risk of falling. Regarding the FAC index, the intervention group attained level 3 on its assessment scale for half of the subjects. This means that after rehabilitation with the robotic platform, the patients could walk indoors and outdoors, and they could climb stairs occasionally. Barthel index was improved for both groups. The improvement in these indexes reflects a substantial impact on the subjects' motor capacity and lower limb strength derived from rehabilitation with SWalker when compared to traditional rehabilitation. These results are even more remarkable considering that the initial values of these three indexes were lower for the intervention group than for the control group.

The study results are supported by the homogeneity of the control and intervention groups. As shown in Table 5, several baseline parameters were tested statistically to prove that both groups are equivalent at the beginning of the experiment. All parameters returned p-values > 0.05, but the Barthel functional index ($p = 0.042$). However, it was considered that this value was not significant enough to discard the equivalence between groups, especially considering that the intervention group is the one that started with the lowest values for this index.

The number of women in the study is much higher than the number of men (79.4% compared to 20.6%) (Table 4), and even more pronounced in the case of the intervention group (90% women). This gender distribution was expected since there is a higher prevalence of hip fracture among women from the age of 50 due to their higher level of osteoporosis when compared with men.

Cognitive assessment with the MEC index (see Table 6) showed that half of the patients have some cognitive impairment level in both groups. However, they were able to follow the SWalker therapy without this being a limiting fact. Preliminary conclusions of this circumstance might support that the robotic platform has a structural design that contributes to a quick familiarization in the patient as well as a high degree of safety. Despite these results, a more exhaustive study of the relationship between the degree of cognitive impairment and rehabilitation with SWalker should be carried out.

Regarding the future work, the first step would be the development of a second prototype, which we are already working on, that incorporates the technical points to be improved resulting from the functional validation.

Secondly, even though the display of the data gathered by the ROM sensors, traction speed, and weight sensors have provided the physiotherapist with an objective view of the patient's progress, it is necessary to define accurate therapies with SWalker based on the achievement of specific and measurable goals through such metrics.
Additionally, the integration of other measurement sensors such as electromyography, pressure or ROM for the knee and ankle would provide a more complete patient evolution. Further clinical validation is expected to be carried out increasing the total number of subjects in the study, which allow us to confirm the positive results shown here. That would involve a larger number of nursing homes in a study that could be extended to other regions and, ideally, to other countries.

Figure legends

Figure 1 General view of the SWalker robotic platform. Image of the SWalker robotic platform for hip fracture rehabilitation showing the main modules that comprise the structure.

Figure 2 User's body weight support system detail.

The rail system is assembled parallel to the cylinder-piston actuators to guide them enabling an accurate vertical movement during the patient lifting.
The load cell rests on a partially cantilevered horizontal structure and the hip coupling mechanism is attached to the end of the load cell for detection of the weight supported.

Figure 3 Schematic overview of the communication flow between the user interface and the sensors. The load cell (located in the weight support system), potentiometers (part of the hip coupling mechanism) and motor encoders (located in the drive system) communicate bi-directionally with the PC104 to send and receive data gathering weight, hip ROM and velocity, respectively. The parameters can be read and adjusted on a user interface thanks to the wifi connection.

Tables

Abbreviations

HF: Hip fracture; ROM: Range Of Motion; GUI: graphical user interface; PBWS: Partial Body Weight Support; CAN: Controller Area Network; UDP: User Datagram Protocol; SUS: System Usability Scale; BMI: body mass index; MNA: Mini Nutritional Assessment; FAC: Functional Ambulation Category; MEC: Mini Examen Cognoscitivo; MMSE: Mini-Mental State Examination; P (Performance); U&S (Usability and Safety).

Declarations

Ethics approval and consent to participate

The "Fundación Jiménez Díaz Clinical Research Ethics Committee" gave approval to the study and warranted its accordance with the guidance on Good Clinical Practice, CPMP/ICH/135/95. The study was carried out under the name SWALKERS17. All patients and families were informed beforehand and provided consent to participate.

Consent for publication

Not applicable

Availability of data and materials

The dataset supporting the conclusions of this article is available in the Zenodo repository, DOI: 10.5281/zenodo.4549307, https://zenodo.org/record/4549307#.YC6fPWhKhPZ.

Competing interests

The authors declare that they have no competing interests.

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Authors’ contributions

VC led the design and manufacturing process of the prototype, collaborated in the design of the functional and clinical validation, analyzed the clinical data and drafted the manuscript. OR was involved in the development of the electronic system of the prototype and was the technical support during functional validation. LP led the clinical team collaborating in the conceptual design of the prototype, established guidelines for the clinical protocol, follow-up of the clinical trials and reviewed the manuscript. AV participated in patients’ recruitment, follow-up of functional and clinical validations and reviewed the manuscript. AO contributed to the conceptualization of the study, assisted in the analysis of the clinical data and reviewed the manuscript. ER collaborated in the design and manufacturing process of the prototype and reviewed the manuscript. RR conceptualized the study, participated in its design, supervised all tasks, and reviewed the manuscript.

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Figures

Figure 1

General view of the SWalker robotic platform. Image of the SWalker robotic platform for hip fracture rehabilitation showing the main modules that comprise the structure.

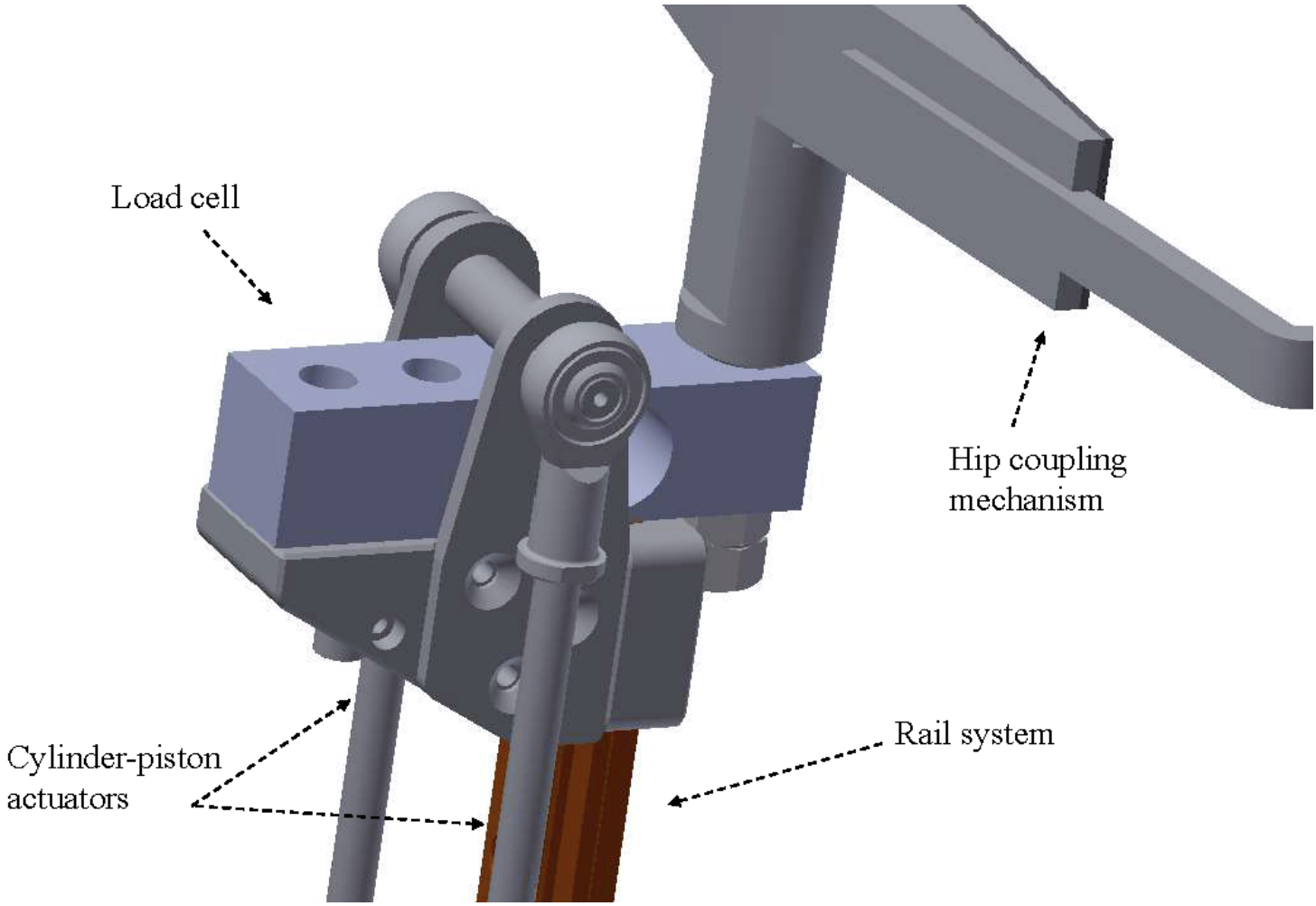

Figure 2

User's body weight support system detail. The rail system is assembled parallel to the cylinder-piston actuators to guide them enabling an accurate vertical movement during the patient lifting. The load cell rests on a partially cantilevered horizontal structure and the hip coupling mechanism is attached to the end of the load cell for detection of the weight supported.

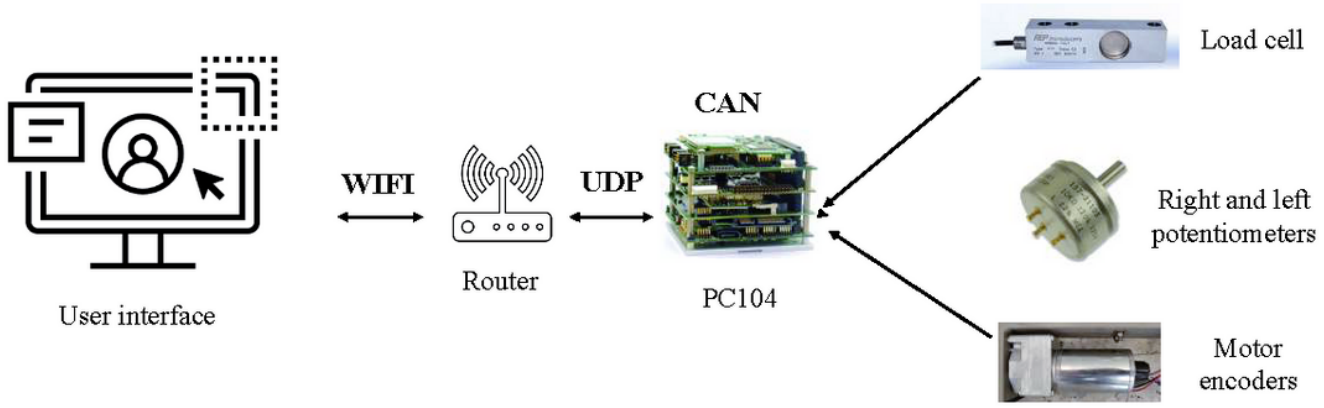

Figure 3

Schematic overview of the communication flow between the user interface and the sensors. The load cell (located in the weight support system), potentiometers (part of the hip coupling mechanism) and motor encoders (located in the drive system) communicate bi-directionally with the PC104 to send and receive data gathering weight, hip ROM and velocity, respectively. The parameters can be read and adjusted on a user interface thanks to the wifi connection.