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Short report

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RESEARCH

Actuation system of the ankle exoskeleton T-FLEX: first use experimental validation in people with stroke

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Abstract

Background: Robotic devices can provide physical assistance to people who have suffered neurological impairments such as stroke. Neurological disorders related to this condition induce abnormal gait patterns, which harm the independence to execute different Activities of Daily Living (ADL). From the fundamental role of the ankle in walking, Active Ankle-Foot Orthoses (AAFOs) have been developed to enhance the users' gait patterns, and hence, their quality of life.

Methods: Ten patients who suffered stroke used the actuation system of the T-FLEX orthosis triggered by an inertial sensor on the foot tip. The VICON motion capture system recorded the users' kinematics for unassisted and assisted gait modalities. Biomechanical analysis and usability assessment measured the performance of the system actuation for the participants in overground walking.

Results: The biomechanical assessment exhibited changes in the range of motion of the lower joints for 70% of the subjects. Moreover, the ankle kinematics showed a correlation with the variation of other movements analyzed. This variation had positive effects on 70% of the participants in at least one joint. The Gait Deviation Index (GDI) presented significant changes for 30% of the paretic limbs, where one volunteer increased this index in 14%. The spatiotemporal parameters did not show significant variations between modalities, although users' cadence had a decrease. Lastly, the satisfaction with the device was positive, being the comfort the most users-selected aspect.

Conclusions: This article presented the assessment of the T-FLEX actuation system in people who suffered stroke. Biomechanical results showed improvement in the ankle kinematic and variation in the other joints. In general terms, GDI did not exhibit significant changes, and Movement Analysis Profile (MAP) registered the main movements altered by the device. Future works should focus on assessing the full T-FLEX orthosis in a larger sample of patients that includes a stage of training.

Trial registration: This study was registered as *Preliminary Biomechanical and Usability Study of an Active Ankle-Foot Orthosis for Stroke Survivors* on 30 January 2020 in Clinical Trials with the identifier No NCT04249349 (available at <https://clinicaltrials.gov/ct2/show/NCT04249349>).

Keywords: Active Ankle-Foot Orthosis (AAFO); Overground gait; Exoskeleton; Biomechanical Analysis; Gait Deviation Index (GDI); Movement Analysis Profile (MAP); Gait Profile Score (GPS)

Background

Stroke is the main cause of disability and the second leading cause of death worldwide [1]. People with a stroke can be affected by after-effects such as hemiparesis, hemiplegia, communication disorders, cognitive deficits, or visual loss (i.e., partial or complete) [2]. Specifically, hemiparesis, which consists of weakness in one side of the body, is one of the most common neurological conditions. Another frequent consequence is spasticity, which causes increased muscle tone on account of the imbalance signals of the central nervous system [3].

Those neurological disorders induce abnormal gait patterns and high metabolic costs because people who suffered stroke perform additional movements to compensate for the limitations [4, 5]. Additionally, those affectations interfere in the execution of different Activities of Daily Living (ADL) (i.e., sit-to-stand, walking, go upstairs, or downstairs) and hence in the reduction of the patient's quality of life [6].

On the other hand, taking into account the fundamental role of the ankle in human gait [4], the foot drop is a relevant condition after the stroke episode that affects this joint. Foot drop is a neuromuscular disorder that impairs the ability of patients to move the foot along the sagittal plane [7]. Therefore, people with this condition present dysfunctions such as low speed in walking, altered gait pattern, and an increased risk of falling. Moreover, the foot drop could also affect the locomotor system [8].

To overcome the dysfunctions aforementioned, the conventional physical therapy in a rehabilitation scenario has been widely used. Mainly, this process helps to improve the patient's motor and neurological recovery [9]. For that, the rehabilitation includes the training in both task-specific and context-specific, particularly in the early stages after injury [2]. Those tasks intend to promote the patients' capacities for completing multiple activities such as bed mobility, body motions to execute ADL, and patient-environment interaction using a wheelchair [10].

According to the importance of walking and its influence on people's quality of life, rehabilitation programs are also focused on the recovery of this capability, although it is one of the most delayed to regain. For this reason, rehabilitation scenarios implement several intervention methods (e.g., classical gait rehabilitation techniques, functional electrical stimulation, gait support orthoses, robotic devices, and brain-computer interfaces) [11]. In terms of ankle rehabilitation, which is one of the most challenging joints to recover, the methods look to enhance patient parameters such as, balance, motor control, foot clearance, among others [12].

Considering the techniques aforementioned, the passive Ankle-Foot Orthoses (AFOs) are the most common solution for patients with ankle impairments. This device is a mechanical structure used to correct ankle-foot deformities, lock the ankle for improving stability, and provide a certain degree of independence for walking [13]. Nevertheless, passive AFOs do not contribute to the recovery of the user. Therefore, both the abnormal gait pattern and the risk of permanent damages on the locomotor system remain in the patient [14].

In this context, and based on promising results in the inclusion of robotic devices in therapy [15, 16, 17], rehabilitation programs are motivating the development of Active Ankle-Foot Orthoses (AAFOs) [18]. Currently, novel control strategies and

different actuation principles are applied in robotic orthoses [19, 18], which are looking for improving the human-robot interaction, and thus the user gait patterns.

T-FLEX [20] is a wearable and portable AAFO for rehabilitation and assistance, which can be manually adjustable and suitable for both limbs. This device has two servo motors located on the anterior and posterior parts of the shank. The orthosis integrates an inertial sensor with a statistical algorithm to estimate the user gait phase in real-time [21]. Hence, it assists in dorsi-plantarflexion movements during the gait phase transitions and reduces the resultant torque on the ankle during the stance phase.

This AAFO is part of a small group of exoskeletons with compliant actuators and soft structures referred to as fully compliant exoskeletons [18]. T-FLEX has a high potential for applications in portable scenarios in contrast to the other devices classified in the same group, which integrate pneumatic actuation and require heavyweight air supplies. Likewise, in the rehabilitation context, T-FLEX reports promising results for a stationary therapy, registering a recovery of the motor capabilities of patients with stroke who present spasticity [22].

From the encouraging results in therapy and the potential application in the gait assistance, this work presents the assessment for the first use of the T-FLEX actuation system in overground gait. The main goal is aimed to measure the changes in kinematic and spatio-temporal parameters between the two conditions proposed (i.e., unassisted and assisted modalities). Additionally, it also intends to determine the level of satisfaction of the user with the device, in aspects such as dimensions, weight, safety, and comfort.

Methods

Active ankle-foot orthosis

T-FLEX is a portable and wearable Active Ankle-Foot Orthosis (AAFO) designed to assist and rehabilitate people with ankle dysfunctions [20]. This device incorporates concepts of bioinspiration in the actuation and control systems. T-FLEX is composed of two servomotors MX106 (Dynamixel, Korea) placed on the anterior and posterior part of the user's shank. The actuators emulate the functionality of the muscles to provide the flexion and extension movements on the ankle. Furthermore, the orthosis integrates an inertial sensor BNO055 (Bosch, Germany) with a sample rate of 100Hz on the foot tip. Therewith, a statistical algorithm based on machine learning estimates the user's gait phases in real-time [21].

The control strategy intends to assist the dorsi-plantarflexion on the ankle according to the gait phase detected by the algorithm. The motors operate in opposite directions to provide both torque propulsion on the heel strike and foot clearance during the swing. For the stance phase, the actuators turn in the same direction to provide stability and balance to the user. The control system and the gait phase detector are running under a ROS (Robot Operating System) architecture in a Raspberry Pi 3.

Taking into account the purpose of this study, a passive orthotic structure (Hanover, China) integrated the actuation and control systems of T-FLEX. This system allows one degree of freedom (DOF) on the sagittal plane. Likewise, the structure is composed of an insole adapted with velcro strips that has a mechanism

to limit the passive DOF. Moreover, it has an adjustable system to increase the distance between the motors and the insole. On the other hand, this protocol also included an opposite insole to compensate for wearing the device. Figure 1 shows the adapted structure and the opposite insole used in this experimental validation. On the whole, this study solely assessed the actuation system of T-FLEX, hence the passive structure described was included to ensure the fixation of the actuators to the user and guarantee a proper force transmission during the gait assistance.

Participants

This study enrolled 10 participants (58 ± 4.5 years old) diagnosed with hemiparesis due to a cerebrovascular accident (i.e., eight males and two females). They were active patients who performed therapy processes in a rehabilitation center. Table 1 summarizes the clinical information of the patients who accomplished this study. On the other hand, the volunteers were selected according to the inclusion and exclusion criteria described below:

A Inclusion criteria: People who suffered stroke before six months of being executed this protocol are eligible. The volunteers must present hemiparesis in one side of the body with some ankle dysfunction. Moreover, they must have partial independence for walking without external devices and the ability to follow instructions.

B Exclusion criteria: Candidates with skin alterations in the lower limbs, high level of spasticity (i.e., level 4 of Ashworth scale), and pain of the musculoskeletal system that impede the use of the device was not taken into account in this study. Likewise, patients who suffer from weakening diseases, for instance, cancer. Moreover, people with a previous history or suspected of seizures were also not selected.

Experimental setup

The participants used the actuation system of T-FLEX adapted to the mechanical orthotic structure in their paretic side, as Figure 1 shows. Likewise, the detection of the gait phases employed an inertial sensor placed on the foot tip of the same limb. The actuators operated to the maximum velocity (55 rpm for no-load state) to assist the ankle movements (i.e., dorsiflexion and plantarflexion) along a 6-meter test (6MT). For the other foot, the volunteers also used a similar insole to balance the effect due to the device's height.

On the other hand, each participant was instrumented with 25 markers to perform a lower limb kinematic analysis using an optoelectronic motion capture system. Figure 2 shows the distribution of the markers over a volunteer of this study.

Biomechanical Analysis

The user kinematic was acquired using ten-cameras VICON (Oxford Metrics, Oxford, UK). Nexus software (Oxford Metrics, Oxford, UK) performed the tracking of data. Besides, Polygon software (Oxford Metrics, Oxford, UK) carried out the kinematic analysis of each user. For this purpose, a biomechanical model *Plug-in Gait* [23] was used, which allows estimating the spatio-temporal parameters and range of motion of the participants' joints.

On the other hand, the Gait Deviation Index (GDI), which synthesizes all the variables of the kinematic examination in a single general result, was estimated for each participant's leg [24]. The obtained value represents a percentage of global normality, in comparison with a kinematic reference of people without pathology or mobility alterations. Therefore, values greater than 90% indicates a no pathological gait pattern in the limb. This index allows identifying changes in joint kinematics (i.e., variations above 10%) for several scenarios [25].

Other measures used to detail the kinematic performance were the Movement Analysis Profile (MAP) and the Gait Profile Score (GPS) [26]. The MAP describes the magnitude of the deviation on the lower limb joints across the gait cycle. The GPS compiles and averages the scores of those joints.

This evaluation was executed by members from the Movement Analysis Laboratory of the Rehabilitation Corporation Club de Leones Cruz del Sur (Punta Arenas, Chile).

Experimental procedure

To validate the effect of the device system actuation, each participant accomplished two modalities: (1) unassisted and (2) assisted gait. Both scenarios were composed of multiples 6MT tests overground performed in the same session. The first modality consisted of walking without wearing the device. In this way, the kinematic analysis used the trial data as a baseline. In the second modality, the device assisted the volunteer gait according to the control scheme aforementioned. Each scenario was composed of ten trials executed continuously, where the trajectories were analyzed and compared to identify the curves with the highest intra-test consistency. Thus, the biomechanical analysis used the data of those selected curves.

Usability assessment

Ergonomics and comfort are some of the most relevant aspects of user-machine interaction [27]. For this study, the user perception assessed this interaction employing a QUEST test. The original survey is composed of 27 questions related to participants' satisfaction concerning the robotic device [28]. This study included 13 of those questions adapted to a Spanish version, which were selected for their suitability in this protocol.

Statistical Analysis

This study analyzes the effect on the biomechanical and spatio-temporal parameters of the device during its first use on patients with stroke. For the purpose, initially, a Shapiro-Wilk test verified the normal distribution of data. This way, for each subject, the data segmented by gait phases (i.e., stance phase and swing phase) were averaged. Subsequently, the Student's t-test assessed the statistical significance of changes ($p < 0.05$) between the baseline and assisted gait with the T-FLEX system actuation, for both gait phases. To analyze the first use effects, this part included both inter-subject and intra-subject analyses. Thus, it allowed measuring aspects such as user performance, adaptability to the device, and the influence of actuating the ankle joint. On the other hand, the analysis of spatio-temporal parameters was also performed by the Student's t-test between the two conditions for an intra-subject analysis. The software used for the tests was MS Excel with statistical analysis tools.

Results

Kinematics

In this study, the kinematic results of the users were divided into two main groups: (1) behavior of the ankle kinematics and (2) range of motion (ROM) of the lower limb joints. As an initial approach, ankle kinematics showed no significant changes ($p > 0.05$) for the two groups (i.e., unassisted and assisted), including the complete sample of participants through a Student's t-test. Nevertheless, diverse aspects stated in the following section could explain those results. Therefore, this part presented the results individually for each participant.

For the first group, Figure 3 shows the ankle kinematics during a gait cycle for both the healthy pattern and the results of each volunteer, where letters from a to j represent the participant from 1 to 10, respectively. This cycle comprises phases between each heel-strike event for both modalities assessed (i.e., baseline and assisted) and the healthy ankle pattern. Moreover, the vertical line included in the figure highlights the toe-off phase for each case.

Concerning to the toe-off phase (TO), 40% of the participants showed differences of more than 5% in the time of occurrence of this event during the gait cycle (see Figure 3), when they used the T-FLEX actuation system. Likewise, 30% of the subjects brought this event to the estimated percentage in a healthy pattern. The other volunteers did not show changes in this aspect. On the other hand, the ankle angle shape had variations due to the effect of using the device. Specifically, subject 5 registered an increase of 15 degrees in the dorsiflexion movement during the swing phase. However, participants 1 and 9 reduced this movement at 10 degrees, although this reduction was within the healthy range.

For the other group, Table 2 summarizes the range of motion (ROM) for the ankle dorsi-plantarflexion (A-F), knee flexo-extension (K-F), hip flexo-extension (H-F), and hip ab-adduction (H-A) in both modalities. The second part of the table shows the percental variation of the joints when the participant used the T-FLEX orthosis. Positive values in this variation indicate an increase in the ROM of the joint, and by contrast, negative values represent a decrease in this parameter. For this part, the highlighted values represent increases greater than 10% on the joint concerning the baseline state.

From the variation table, 70% of the volunteers exhibited significant changes in the paretic (P) ankle ROM using the device, whether increases or decreases. Likewise, the changes in the ROM for the paretic ankle also tend to variate for the non-paretic (N-P) joint. On the other hand, the number of altered joints was directly proportional to the change presented on the ankle, where values of paretic ankle ROM with variation above 50% registered changes in at least half of the analyzed joints. In general, the changes did not show a common tendency in terms of increases or decreases. Furthermore, the larger values corresponded to alterations on the A-F, although subjects 4, 5, and 7 showed the H-A value as the maximum variation.

According to the variations on the ROM of the lower limb joints (see Table 2), it is essential to determine whether this change represents a positive or negative effect in the joint of the participant (see Fig. 4). For that, the ROM obtained was compared with the mean value in a healthy gait [29]. In this context, 60% of the volunteers showed improvement in the A-F using the device. Among this, subjects 2, 5, and 7

achieved values whose errors, regarding the ROM in healthy people, were less than 2%. This way, positive changes in the paretic ankle joint improved the ranges for the non-paretic joints, especially in the ankle joint. For 30% of the participants, the variations in the A-F did not represent significant improvements, and additionally, one volunteer exhibited a negative effect in this ROM related to a reduction of 33% in its value.

Thus, Figure 4 summarizes the consequences of using the T-FLEX system actuation on the analyzed joints for each participant. The positive effects indicate improvement in the ROM of the corresponding joint, approaching this value to healthy ranges. Negative impacts indicate a pattern disruption, and hence a distancing of the movement with a healthy pattern. Undetermined conditions grouped changes where, although the variation is significant (i.e., above 10%), this value does not improve or impair the ROM. Lastly, the no-changes group integrates the differences between both scenarios of less than 10%.

Bearing in mind the classification of variations for each subject (see Figure 4), 70% of the volunteers showed a positive effect on at least one joint, where the paretic ankle was the more prevalent. The exhibited negative impacts were mainly related to a reduction in the ROM, so only two joints reflected increases that did not represent a risk for the participant.

On the other part, Table 3 contains the values of the Gait Deviation Index (GDI) for each participant. The GDI showed a significant difference for 30% of the paretic limbs of the participants, wherein 20% manifested a reduction below 14%, and one volunteer registered an increase of 14%. For the non-paretic, 40% of the participants exhibited decreases by less than 30% for this index. Reduction in GDI is related to a higher difference between the participant kinematics and a healthy pattern. In contrast, an improvement in the gait kinematics depends on an increase in this index. The mean value of GDI for the participants (see Table 5) did not present a significant difference between the scenarios, and both limbs remained the no healthy condition as the GDI percentage was less than 90%.

Lastly, Figure 5 illustrates the Movement Analysis Profile (MAP) for the paretic (Fig. 5a) and non-paretic (Fig. 5b) limbs between baseline and assisted gait. The most affected joints in the scenarios were the ankle, the knee, and the hip (i.e., ankle rotation, hip rotation, and knee flexo-extension). The ankle dorsi-plantarflexion did not show significant changes in both the paretic and non-paretic. The Gait Profile Score (GPS) significantly increased its value between unassisted and assisted conditions of the non-paretic limb, although this change moved away from the value of healthy people. Nevertheless, this value did not exhibit significant changes for the paretic side.

Spatio-temporal parameters

Considering the variation in ROM presented above, the second part of this study analyzes the changes in spatio-temporal values. For this purpose, Table 4 shows the percentages of variation for the parameters in each participant. The parameters include mean values for the paretic (P) and non-paretic limbs (N-P) in aspects such as the percentage of duration for the stance phase (SP) on the gait cycle, as well as the step length (SL) and the step width (SW). Likewise, walking speed (S), stride length (ST), and cadence (C) also are part of this table.

In general terms, the spatio-temporal parameters did not show significant changes using the T-FLEX actuation system to either of the participants' limbs. Nevertheless, the cadence exhibited a reduction in 70% of the volunteers. This parameter registered decreases below 24% of the baseline state, although, subject 8 presented an increase in the cadence of 20% for the assisted gait.

On the other hand, Table 5 contains the mean values for the participants' parameters. This table summarizes the results aforementioned, showing a decrease of cadence in 14% (i.e., from 99 to 85 steps per minute). Additionally, this table also exhibits other Spatio-temporal values without significant changes.

Usability assessment

This part describes the device performance in terms of user-machine interaction and the perception of the participants with assistive technology. Firstly, no patient exhibited issues (i.e., affectations in the locomotor system, pressure points, skin injuries or falls) during and after wearing the device.

For the users' perception, Figure 6 shows the relevant aspects selected by the participants through the QUEST survey. The most selected parameter was the device's comfort with 70% of recurrence. Other important aspects for the users were safety, weight, and dimensions. Finally, the level of satisfaction of the user was between satisfied and very satisfied in 60% and 40% of the users, respectively.

Statistical analysis

To understand the participants' effects on the gait cycle, statistical analysis aimed to identify differences between assisted and baseline conditions. In terms of the ankle kinematics, the results revealed statistically significant changes for 70% of the subjects in at least one gait phase for the angle. Specifically, this joint showed statistical differences in the stance and swing phase for 60% and 70% of the participants, respectively (see Table 6). Moreover, 40% of them exhibited variations in the entire gait cycle.

In the spatio-temporal context, the parameters showed a statistically significant decrease in the cadence ($p=0.0002$) and speed ($p=0.03$) concerning the assisted gait. The parameters of long stride, step length, step width, and stance phase did not show statistically significant changes.

Discussion

The results showed in the previous section intend to find the effects on the lower limb joints for the assisted gait with the actuation system of T-FLEX. For that, the kinematics presented the results for the participants individually. This analysis allowed determining aspects such as the participant performance during the trial, adaptability to the device, improvement in the ankle kinematics, and the consequences on the other planes of motion. On the other hand, an inter-subject analysis did not evidence significant changes comparing unassisted and assisted gait. However, those results could be affected by the poor-performance exhibited in some participants. Thus, a modification of the experimental setup that includes the training stage could improve the performance and adaptability of the user to the device.

In this context, the ankle kinematics described the influence of the device in this joint for each user (see Figure 3). From the significant changes found in both phases,

the T-FLEX actuation system positively impacted the dorsiflexion movement, improving the angle on the joint and hence the foot clearance during the swing phase. Therefore, the device reduced the risk of falls and injuries in the participants [30]. For the stance phase, subjects experimented reduction in the ankle's angle due to the actuators, providing stability to the user during this phase. Other changes related to the dorsi-plantarflexion movements can be associated with both the user-device synchronization and the calibration stage carried out manually. However, those changes did not represent a risk for the users' stability. On the other hand, taking into account the first 10% of the gait cycle, 60% of the volunteers exhibited a kinematic behavior similar to the shape of the healthy pattern. Likewise, assisted gait also showed a smoother transition between phases, which ensures a suitable control of the joint to provide stability and safety.

In general terms, the kinematic results during the first use of the T-FLEX actuation system showed improvements in some participants (i.e., increase foot clearance, and early push-off), which are similar to a robust AAFO based on pneumatic actuation [31]. Additionally, these results are comparable to devices controlled by Force Sensitive Resistor (FSR) for gait detection [32, 33] that is the most common detection strategy used in wearable robotic orthoses. Nevertheless, those previous studies enrolled a smaller sample of subjects reducing the probability of poor-performance in the participants. Lastly, the ankle kinematics results also tended to the outcomes of another study that included a training stage [34], unlike this protocol.

Gait performance can be also analyzed through the other joints of both paretic and non-paretic sides [35]. Usually, this assessment includes at least the knee and ankle joints, where the results commonly exhibit kinematics improvement [32]. This study showed proper adjustment of ankle's ROM to avoid foot drop, through the mechanical structure that limits the sagittal plane as well as the T-FLEX actuation system. In the hip context, the H-A movement decreased in 70% of the participants for the non-paretic limb. This reduction is a result of the restriction and actuation on the paretic ankle. In contrast to the non-paretic, the other side presented disruptions in 40% of the subjects related to reductions in the ROM value.

In particular, subject 7 showed high performance in the estimated ROM for both sides. The positive effects were in 75% of the analyzed joints with the best improvement in the A-F for the non-paretic limb. This outcome could not be associated with the user's spasticity level because subjects 2 and 8 have clinical conditions comparable to this participant, but they did not exhibit similar performance. Hence, it could relate to external variables such as correct synchronism of the device and the appropriated actuation performance.

Spatial-temporal parameters allow measuring the device's effects on the user [19, 35]. Mainly, orthotic devices should improve the subjects' parameters to enhance their mobility in the execution of ADLs [36]. The first use of T-FLEX showed a decrease in cadence. This reduction is related to both the training stage (not included in this study) and the restricted structure on the ankle. Therefore, the inclusion of training stages is imperative to improve the obtained results.

On the other hand, Table 3 shows the GDI and the variation according to each scenario. Regarding the baseline, most of the participants decreased the GDI, although only 30% of the limbs registered a reduction above 10%. Several factors can explain

the decrease in this index. The first factor is related to the MAP information (see Figure 3), where the foot rotation represents one of the most significant movements with affectations. This alteration is due to the mechanical structure coupled to the T-FLEX actuation system. The restriction on the ankle triggers a disruption in the other joints pattern, which induces a decline in this index. The second factor comprehends the performance of the actuation system in aspects such as response time to position set-points, processor speed for running the detection algorithm, and the manual calibration stage that recorded the maximum flexo-extension angles of the user. On the other part, multiple studies have presented GDI analysis for children with cerebral palsy using a passive orthotic device [37, 38, 39]. However, in studies that involve patients with stroke using AAFO, this index was not shown.

Finally, in the MAP context (see Figure 5a), assisted gait with T-FLEX affected several movements on the paretic joints (e.g., K-F, A-F, and F-R). Nevertheless, as mentioned previously, the changes could lead to a mechanical restriction on the ankle. This block alters the natural gait pattern and induces compensatory motions on the other joints, although the lack of training could also cause this wrong pattern. For the non-paretic side (see Figure 5b), the main affectations were the H-R and F-R movements related to the device's weight compensation. As GDI, different studies used GPS to analyze the effects on people with cerebral palsy [40, 41]. Although, in protocols that include patients with stroke in assisted gait with AAFO, the score was not reported.

Conclusions

This work presented an assessment of the T-FLEX actuation system during its first use. For that, ten patients who suffered stroke wore the device in overground walking. In the inter-subject analysis context, the biomechanical analysis showed improvements for some patients in dorsiflexion to avoid foot slap and control of the ankle in the phases transition. Moreover, the other joints exhibited positive and negative changes related to the actuation on the paretic ankle with T-FLEX. For the intra-subject analysis, the results showed no significant differences between baseline and assisted gait. This value could be related to the poor-performance evidenced by several participants.

The Spatio-temporal parameters did not present significant changes, although the cadence decreased for the assisted gait. Lastly, the GPS and GDI measured the kinematic behavior for each participant in both modalities. Those parameters did not evidence significant improvements between subjects and a healthy pattern, and they also determined the main joints affected by the device.

Future works should focus on the assessment of full T-FLEX orthosis in a more extensive sample of patients with stroke. Additionally, the device's calibration stage and the performance of actuation should be optimized to improve the presented results. Further studies will also aim to complete gait analysis after a training stage, which will allow measuring the biomechanical and kinetic effects on the users.

List of abbreviations

The following abbreviations are used in this manuscript:

AAFO	Active Ankle-Foot Orthosis
ADL	Activities of Daily Living
AFO	Ankle-Foot Orthosis
A-F	Dorsi-plantarflexion
C	Cadence
DOF	Degree of Freedom
FSR	Force Sensitive Resistor
F-R	Foot Rotation
GDI	Gait Deviation Index
GPS	Gait Profile Score
H-A	Hip Abd-adduction
H-F	Hip Flexo-Extension
K-F	Knee Flexion-Extension
MAP	Movement Analysis Profile
N-P	Non-paretic
P	Paretic
P-A	Pelvis Anterior-posterior
P-R	Pelvic Rotation
P-U	Pelvic Up-down
ROM	Range of Motion
S	Walking Speed
SL	Step Length
SP	Stance Phase
SW	Step Width
ST	Stride Length
TO	Toe-off

Declarations

Ethics approval and consent to participate

The ethics committee of the Club de Leones Cruz del Sur rehabilitation center approved this protocol. At the beginning of each trial, the researchers explained the experimental setup and device's functionality to each volunteer. Besides, all the participants signed an informed consent, which allows the use of their clinical details and results of this study anonymously.

Consent for publication

Not applicable.

Availability of data and materials

The data that support the findings of this study are openly available in figshare at <https://doi.org/10.6084/m9.figshare.12576965.v1>

Competing interests

The authors declare that they have no competing interests.

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Author's contributions

Conceptualization, P.B., M.M. and C.A.C.; methodology, D.G.V., F.B.M., P.B., M.M. and C.A.C.; software, D.G.V.; hardware, D.G.V., F.B.M., R.C. and P.B.; validation, R.A. and P.B.; resources, P.B., J.M.A. and M.M.; data curation, D.G.V., F.B.M., R.A. and P.B.; writing—original draft preparation, D.G.V., F.B.M. and P.B.; writing—review and editing, J.M.A., M.M. and C.A.C.; supervision, P.B., J.M.A., M.M. and C.A.C.; project administration, M.M. and C.A.C.; and funding acquisition, P.B., J.M.A., M.M. and C.A.C.

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Figures

Figure 1 Actuation system of T-FLEX exoskeleton implemented on the passive orthotic structure. The insole of the left part is added in the non-paretic limb to compensate for the effect due to the use of the device.

Figure 2 Biomechanical setup model used in the study for each participant. The red points on the patient represent the markers for the VICON acquisition system.

Figure 3 Volunteers' ankle kinematic during the gait cycle. Letters from a to j represent the participant number in ascending order. The red curve indicates the assisted gait condition. On the other hand, the green curve refers to the natural gait pattern (baseline condition). The gray curve shows a healthy gait pattern of the ankle. Finally, the vertical lines describe the toe-off event for each of these conditions.

Figure 4 Effect of T-FLEX scenario on the joints range of motion. Positive changes (purple bar) refer to variations that approach the value to a healthy pattern. Negative changes (orange bar) comprehend joints where the ROM departs from the normal gait. Undetermined conditions (red bar) integrate magnitudes that exhibit variation, but they do not generate an improvement or an impairment. Lastly, no changes state (blue bar) include percentages of less than 10%.

Figure 5 Movement Analysis Profile. The upper part of the figure refers to the paretic limb. The lower illustrates the part non-paretic side. Each column represents one of the kinematic variables such as P-A (Pelvis Anterior-Posterior), H-F (Hip Flexion-Extension), K-F (Knee Flexion-Extension), A-F (Ankle Dorsi-Plantarflexion), P-U (Pelvic Up-Down), H-A (Hip Abd-Adduction), P-R (Pelvic Rotation), F-R (Foot Rotation), and GPS (Gait Profile Score). The height of the bar indicates the median and IQR RMS value during the trial. Black columns at the bottom denote the mean value for healthy gait pattern. Unassisted and assisted scenarios correspond to red and blue columns, respectively.

Figure 6 Results of the usability assessment through the QUEST test. The percentage of each topic refers to the number of participants who considered that characteristic as relevant.

Tables

Table 1 Subjects anthropometric measurements and clinical information.

Subject	1	2	3	4	5	6	7	8	9	10	$\bar{x} \pm sd$
Gender	Male	Female	Female	Male	-						
Age [years]	54	52	59	54	61	61	66	60	60	53	58 ± 4
Weight [Kg]	80	91	95	87	96	62	67	73	69	84	80 ± 12
Height [cm]	170	165	167	175	168	160	170	166	165	176	168 ± 5
Left leg length [cm]	90	87	88	91	88	83	88	88	85	92	88 ± 3
Right leg length [cm]	90	87	88	91	88	83	88	88	85	93	88 ± 3
Stroke diagnosis	Ischemic	-									
Time from injury [years]	2	7	5	1	7	2	4	4	4	5	-
Paretic side	Right	Right	Right	Left	Left	Right	Right	Left	Left	Left	-
Ashworth scale	1	1	2	1	3	1	2	2	1	3	-

Table 2 Range of motion on the lower limb joints of the participants in the proposed scenarios (i.e., Baseline and T-FLEX). Each one divides the limbs in paretic (P) and non-paretic (N-P), where the analyzed movements comprise the flexo-extension on the ankle, knee, and hip joints (A-F, K-F, and H-F respectively), and the add-abduction on the hip (H-A). Values in parenthesis represent the standard deviation. The second part shows the percentage of variation on the joints using the device concerning the baseline. The positive values refer to increases in this value in contrast with the negative values that indicate decreases. The highlighted values indicate significant changes in the joint greater than 10% for both increases (green) and decreases (red).

Subjects		1	2	3	4	5	6	7	8	9	10	
Baseline	P	A-F	27.4 (1.4)	26.1 (1.3)	17.9(1.3)	22.1 (0.9)	40.5 (2.1)	15.5 (2.2)	17.0 (1.1)	16.2 (0.5)	7.2 (0.8)	44.4 (1.2)
		K-F	62.4 (2.3)	51.7 (2.5)	29.6 (1.3)	70.9 (1.1)	46.6 (1.4)	64.2 (1.8)	18.4 (1.5)	49.4 (2.3)	31.1 (2.1)	40.1 (1.8)
		H-F	39.5 (2.6)	44.4 (1.7)	26.8 (2.5)	42.2 (1.3)	27.1 (0.3)	53.7 (3.7)	16.2 (3.6)	41.8 (0.9)	31.0 (2.5)	35.9 (1.4)
		H-A	7.5 (0.7)	13.9 (0.7)	12.1 (1.8)	11.8 (0.7)	8.1 (0.7)	10.2 (1.3)	10.1 (2.1)	8.4 (0.5)	8.6 (1.2)	11.2 (0.7)
	N-P	A-F	16.2 (2.3)	35.0 (2.3)	21.3 (1.3)	20.5 (1.5)	23.3 (2.2)	18.1 (3.2)	19.6 (3.7)	16.8 (0.5)	20.2 (1.6)	38.7 (2.9)
		K-F	60.1 (1.7)	67.1 (2.4)	33.7 (1.6)	71.5 (0.9)	62.0 (0.8)	62.5 (1.8)	51.9 (0.6)	65.0 (0.9)	71.4 (2.0)	68.1 (1.1)
		H-F	39.3 (0.9)	48.2 (1.3)	38.7 (1.0)	46.1 (0.7)	39.3 (1.1)	48.7 (2.0)	39.4 (2.5)	54.9 (1.5)	49.5 (0.9)	52.1 (1.5)
		H-A	9.9 (1.8)	15.3 (1.8)	12.7 (0.5)	12.1 (1.4)	10.1 (1.0)	10.3 (1.4)	4.9 (1.2)	8.3 (1.0)	19.5 (1.4)	14.8 (2.0)
T-FLEX	P	A-F	17.2 (0.8)	29.7 (2.5)	17.0 (3.5)	23.4 (1.4)	29.9 (1.3)	26.3 (2.5)	30.6 (3.8)	17.3 (0.9)	14.3 (2.78)	20.8 (2.0)
		K-F	50.6 (3.4)	61.2 (3.1)	31.7 (2.7)	65.1 (1.7)	41.3 (1.9)	53.1 (1.1)	20.3 (2.6)	51.2 (1.1)	29.3 (1.4)	39.4 (4.4)
		H-F	38.4 (0.6)	47.5 (2.5)	26.9 (1.8)	41.1 (0.9)	30.5 (0.9)	53.1 (3.0)	31.9 (4.8)	37.6 (1.2)	25.2 (2.8)	31.7 (2.5)
		H-A	7.7 (1.5)	14.8 (1.8)	11.7 (0.8)	8.7 (1.6)	14.1 (4.7)	6.5 (1.3)	8.9 (1.2)	7.2 (1.1)	9.8 (0.7)	8.8 (0.9)
	N-P	A-F	16.2 (0.8)	22.5 (2.1)	18.5 (1.6)	20.4 (1.6)	21.3 (1.7)	23.7 (0.6)	27.3 (3.5)	22.0 (0.7)	28.7 (3.2)	25.4 (4.0)
		K-F	51.8 (1.6)	76.2 (2.6)	34.7 (1.5)	52.5 (0.9)	51.9(0.6)	62.8 (1.6)	60.0 (1.5)	55.6 (1.9)	68.9 (1.5)	59.6 (0.8)
		H-F	40.2 (1.5)	47.2 (1.8)	37.9 (3.2)	42.7 (0.6)	39.6 (1.2)	48.9 (2.4)	51.4 (5.0)	58.1 (2.1)	48.3 (3.9)	52.4 (0.7)
		H-A	8.1 (1.0)	15.0 (1.3)	12.1 (1.1)	7.9 (0.3)	9.2 (3.1)	7.2 (1.0)	10.2 (1.4)	5.8 (0.5)	18.6 (1.3)	19.3 (1.6)
Variation	P	A-F	-37.2	13.8	-5.4	5.9	-26.2	69.6	79.6	7.0	97.6	-53.1
		K-F	-19.1	18.4	7.2	-8.2	-11.3	-17.4	10.5	3.1	-5.8	-1.6
		H-F	-2.8	-4.4	0.5	-2.8	1.0	-1.1	96.6	-10.0	-18.8	-11.6
		H-A	2.2	-7.9	-2.9	-26.2	75.1	-35.9	-11.5	-14.3	13.5	-21.3
	N-P	A-F	0.4	-35.8	-13.1	-0.1	-8.7	31.0	38.9	29.7	41.1	-34.2
		K-F	-13.8	13.6	2.9	-26.5	-16.3	0.4	15.6	-14.4	-3.4	-12.5
		H-F	2.3	-2.0	-2.2	-7.3	-2.8	0.4	30.4	5.7	-2.5	0.6
		H-A	-18.7	-1.7	-4.3	-34.5	-7.9	-30.2	107.3	-29.7	-4.7	29.8

Table 3 Gait Deviation Index for each subject in Baseline and T-FLEX scenarios. The first part has the index for the paretic (P) and non-paretic (N-P) limbs. The highlighted values denote variation above 10% for both increases (green) and decreases (red).

Subjects		1	2	3	4	5	6	7	8	9	10
Baseline	P	72.0	75.9	69.1	80.2	78.5	80.5	73.3	76.4	67.7	53.8
	N-P	73.0	74.0	57.4	85.3	84.0	101.4	80.8	91.0	64.7	73.2
T-FLEX	P	64.6	61.9	67.2	84.5	67.2	83.0	68.6	78.4	62.6	68.1
	N-P	65.6	60.7	64.7	83.2	85.7	74.3	68.3	60.7	57.9	71.5
Variation	P	-7.3	-14.0	-1.8	2.2	-11.3	2.5	-4.7	2.0	-5.2	14.3
	N-P	-7.4	-13.3	7.3	-2.1	1.7	-27.1	-12.5	-30.3	-6.7	-1.7

Table 4 Percentage of variation of spatial-temporal parameters. The first part includes values for the paretic (P) and non-paretic (N-P), which are the percentage of the stance phase (SP), the step width (SW), and step length (SL). The second part shows general parameters such as walking speed (S), stride length (ST), and cadence (C). The highlighted values indicate a change above 10% for both increases (green) and decreases (red).

Subject		1	2	3	4	5	6	7	8	9	10
P	SP	7.8	-1.9	1.4	-1.1	3.5	1.1	2.3	-0.8	4.1	-5.9
	SW	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	-0.0	0.0
	SL	0.1	-0.1	0.0	-0.1	-0.1	-0.1	0.1	-0.1	0.1	0.0
N-P	SP	1.6	-5.3	0.0	2.6	-2.1	5.3	-4.1	0.6	-1.4	-1.7
	SW	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	SL	0.0	-0.1	0.0	0.0	0.0	-0.1	0.2	-0.1	0.0	-0.1
S	0.0	-0.1	0.0	-0.3	-0.2	0.0	0.2	-0.3	-0.1	-0.1	
ST	0.0	-0.1	0.0	-0.2	0.0	-0.1	0.4	-0.2	0.0	0.0	
C	-11.0	2.0	-6.1	-15.0	-21.1	-24.0	-11.60	20.0	-17.8	-14.7	

Table 5 Spatial-temporal parameters and Gait Deviation Index of baseline and assisted gait with T-FLEX actuation system. It also divided in paretic (P) and non-paretic (N-P) side. GDI is defined in percentage, as well as the stance phase (SP). Following by the step width [m] (SW), and step length [m] (SL). The second part shows general parameters such as walking speed [m/s] (S), stride length [m] (ST), and cadence [step/min] (C). The highlighted values are parameters with significant changes.

	Baseline			T-FLEX		
	P	Mean	N-P	P	Mean	N-P
GDI	72.9	-	78.5	70.6	-	69.3
SL	-	0.9	-	-	0.9	-
C	-	99.0	-	-	85.1	-
S	-	0.8	-	-	0.7	-
SP	62.9	-	70.0	63.6	-	69.5
ST	0.5	-	0.5	0.5	-	0.4
SW	0.2	-	0.2	0.2	-	0.2

Table 6 Probability value (p-value) of each subject for stance and swing phases. The highlighted cells indicate a statistical difference.

Subjects	Stance phase	Swing phase
1	1.41e-4	4.38e-11
2	3.10e-3	8.54e-1
3	1.40e-3	2.85e-1
4	1.03e-9	1.18e-10
5	5.27e-2	1.67e-23
6	8.12e-3	3.21e-2
7	8.89e-1	8.26e-2
8	7.47e-1	1.65e-8
9	3.90e-15	1.08e-33
10	8.10e-2	1.14e-12

Figures

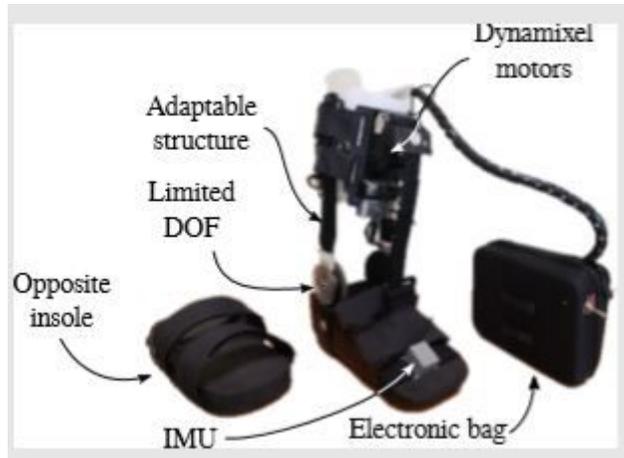


Figure 1

Actuation system of T-FLEX exoskeleton implemented on the passive orthotic structure. The insole of the left part is added in the non-paretic limb to compensate for the effect due to the use of the device.

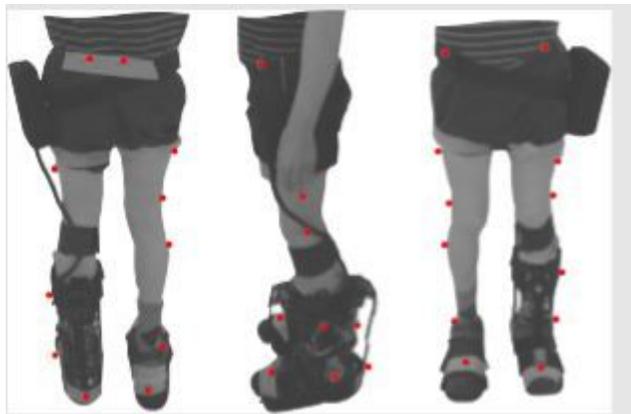


Figure 2

Biomechanical setup model used in the study for each participant. The red points on the patient represent the markers for the VICON acquisition system.

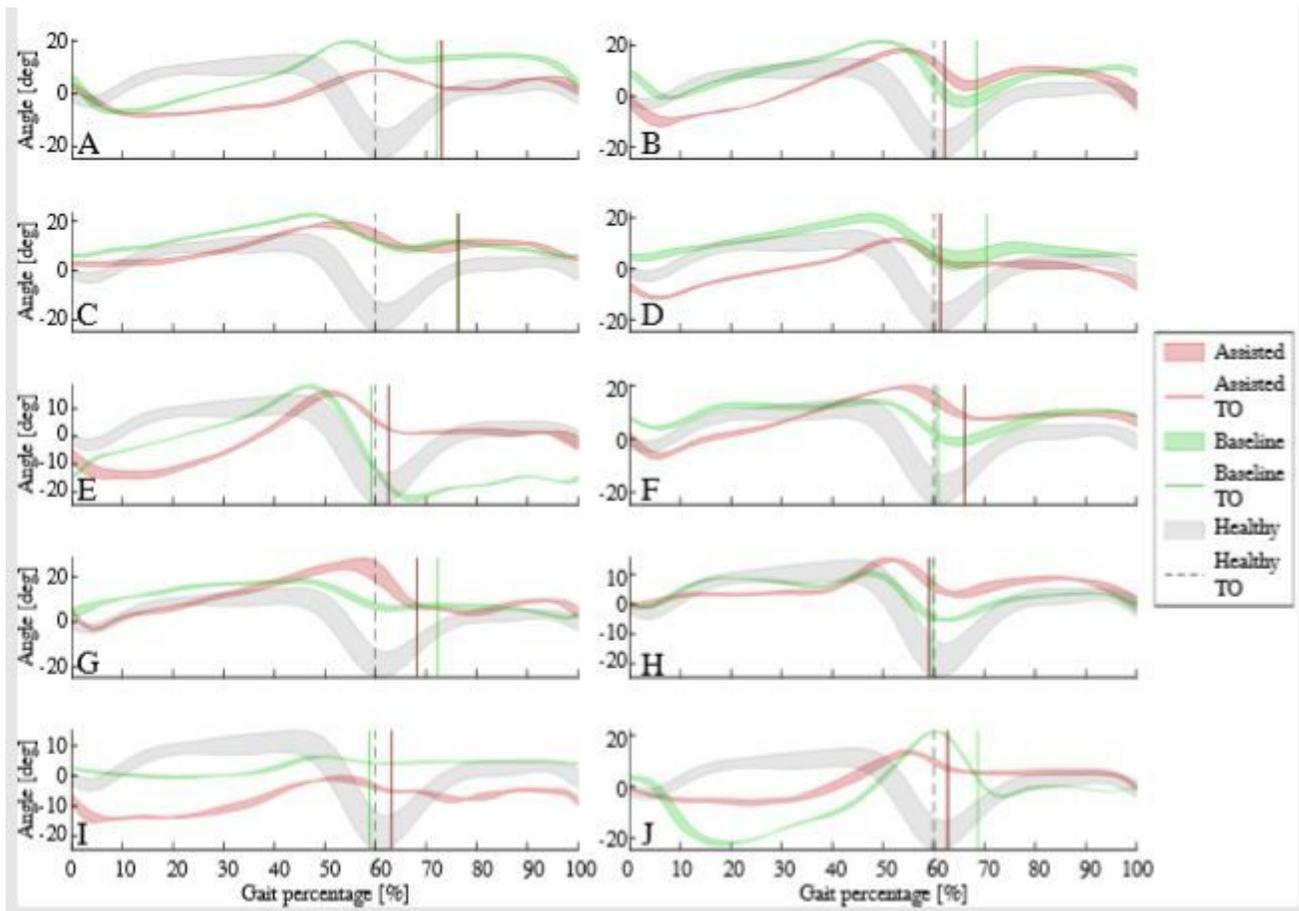


Figure 3

Volunteers' ankle kinematic during the gait cycle. Letters from a to j represent the participant number in ascending order. The red curve indicates the assisted gait condition. On the other hand, the green curve refers to the natural gait pattern (baseline condition). The gray curve shows a healthy gait pattern of the ankle. Finally, the vertical lines describe the toe-off event for each of these conditions.

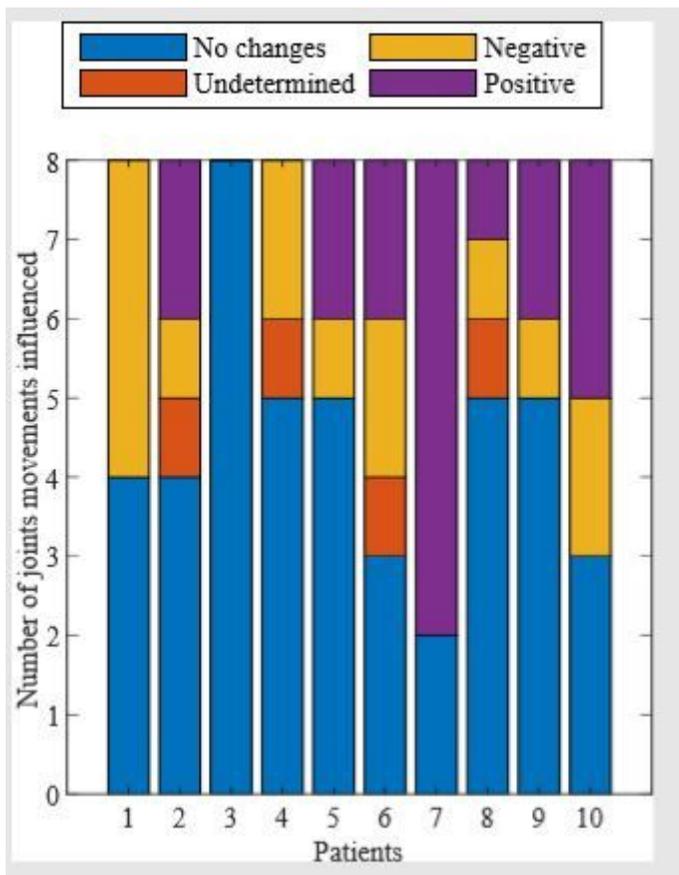


Figure 4

Effect of T-FLEX scenario on the joints range of motion. Positive changes (purple bar) refer to variations that approach the value to a healthy pattern. Negative changes (orange bar) comprehend joints where the ROM departs from the normal gait. Undetermined conditions (red bar) integrate magnitudes that exhibit variation, but they do not generate an improvement or an impairment. Lastly, no changes state (blue bar) include percentages of less than 10%.

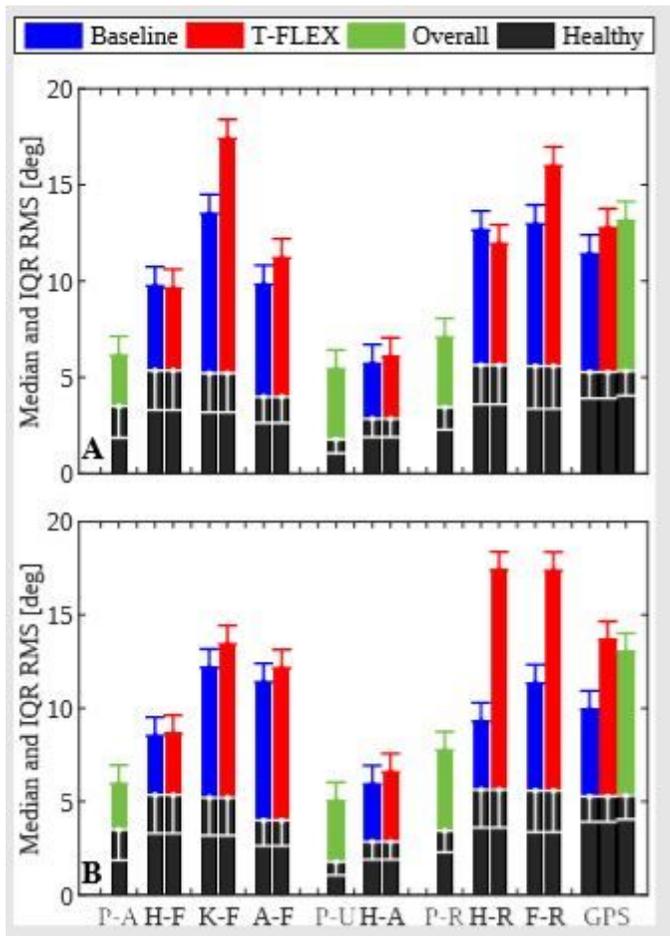


Figure 5

Movement Analysis Profile. The upper part of the figure refers to the paretic limb. The lower illustrates the part non-paretic side. Each column represents one of the kinematic variables such as P-A (Pelvis Anterior-Posterior), H-F (Hip Flexion-Extension), K-F (Knee Flexion-Extension), A-F (Ankle Dorsi-Plantarflexion), P-U (Pelvic Up-Down), H-A (Hip Abd-Adduction), P-R (Pelvic Rotation), F-R (Foot Rotation), and GPS (Gait Profile Score). The height of the bar indicates the median and IQR RMS value during the trial. Black columns at the bottom denote the mean value for healthy gait pattern. Unassisted and assisted scenarios correspond to red and blue columns, respectively.

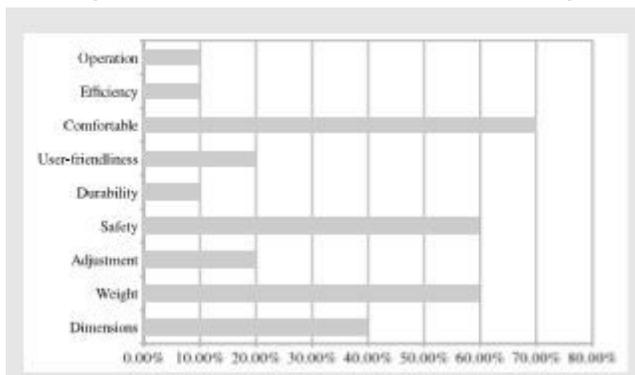


Figure 6

Results of the usability assessment through the QUEST test. The percentage of each topic refers to the number of participants who considered that characteristic as relevant.