Neuromuscular Controller Embedded in a Powered Ankle Exoskeleton: Effects on Gait, Clinical Features and Subjective Perspective of Incomplete Spinal Cord Injured Subjects

F. Tamburella, N. L. Tagliamonte, I. Pisotta, M. Masciullo, M. Arquilla, E. H. F. van Asseldonk, H. van der Kooij, A. R. Wu, F. Dzeladini, A. J. Ijspeert, and M. Molinari

Abstract—Powered exoskeletons are among the emerging technologies claiming to assist functional ambulation. The potential to adapt robotic assistance based on specific motor abilities of incomplete spinal cord injury (iSCI) subjects, is crucial to optimize Human-Robot Interaction (HRI). Achilles, an autonomous wearable robot able to assist ankle during walking, was developed for iSCI subjects and utilizes a NeuroMuscular Controller (NMC). NMC can be used to adapt robotic assistance based on specific residual functional abilities of subjects. The main aim of this pilot study was to analyze the effects of the NMC-controlled Achilles, used as an assistive device, on chronic iSCI participants’ performance, by assessing gait speed during 10-session training of robot-aided walking. Secondary aims were to assess training impact on participants’ motion, clinical and functional features and to evaluate subjective perspective in terms of attitude towards technology, workload, usability and satisfaction. Results showed that 5 training sessions were necessary to significantly improve robot-aided gait speed on short paths and consequently to optimize HRI. Moreover, the training allowed participants who initially were not able to walk for 6 minutes, to improve gait endurance during Achilles-aided walking and to reduce perceived fatigue. Improvements were obtained also in gait speed during free walking, thus suggesting a potential rehabilitative impact, even if Achilles-aided walking was not faster than free walking. Participants’ subjective evaluations indicated a positive experience.

Index Terms—SCI, Achilles, ankle exoskeleton, assistance as needed, robot-aided walking.

I. INTRODUCTION

SPINAL Cord Injury (SCI) results in paralysis of the lower limbs and trunk and is known to restrict daily activity, to diminish levels of fitness and of work capacity [1]. More than half of people sustaining spinal cord damage present incomplete motor lesions (iSCI) [2], leaving spared neural pathways capable of limited somatic sensormotor functions. Prognosis for walking recovery depends mainly on the level and the completeness of the injury. The more incomplete the injury, the more favorable the potential for ambulation recovery [3]–[5]. Many other factors are known to influence recovery. Among these, muscular strength, balance, spasticity, and age are the major determinants for walking recovery [3]. Given the potential recovery for iSCI subjects, in the last decades a great emphasis was given on research activities focused on the restoration of walking.

Powered exoskeletons (EXOs) are among the emerging rehabilitation technologies claiming to assist functional ambulation, reduce medical complications related to SCI, and stimulate plasticity of motor pathways after iSCI [6]. EXOs support locomotion by partially or completely assisting leg movements of the user, offering the opportunity to walk at hospitals but also at home or in the community [2]. For people with iSCI, the focus is generally on rehabilitation [7], [8] and gait restoration [9], [10]. EXOs have emerged as an advantageous rehabilitation tool [11] and are progressively accepted by clinicians, researchers, and patients [12], [13].
Compared to previous walking training paradigms, EXOs may offer a great deal of independence as well as improve the level of physical activity [12], bone density, cardiorespiratory and gastrointestinal functions, sitting balance, and decrease pain and spasticity [14]. Interaction control, shared between device and human, is critical to increase EXOs effectiveness in supporting gait, to promote adaptation and increase acceptability [15]. Different types of Human-Robot Interaction (HRI) modalities have been developed, such as strategies based on impedance control helping the subject only when away from a reference kinematic pattern or myoelectric control, where the control output is based on the magnitude of surface electromyography signals [16]. For individuals with impaired motor functions who need to be aided by an EXO, an ideal controller should provide “assistance as needed” tailored ad hoc for each subject according to the residual functional abilities, in order to promote shared user-machine control. This aim can be conveniently achieved through controllers making the EXOs intuitive to operate, responsive to the user’s intentions, and adaptable to different walking speeds [17]. By using the robotic gait trainer LOPES, Wu et al. demonstrated a potentially useful SCI subject-machine interaction stemmed from assisting the subject’s impaired function with dynamical virtual muscles and reflex loops [17]. The Authors found a remarkable versatility in generating gait patterns tuned to the SCI subjects’ dynamics and producing near-physiological gait at near-normative speeds when using a novel NeuroMuscular Controller (NMC). This NMC is based on a musculoskeletal model with virtual Hill-type muscles activated by stance and swing reflexes [18]. The model has not fixed patterns of movement and generates walking from the interaction of body dynamics, reflex loops, and virtual muscles with the environment. Not only can the controller recreate human behavior (joint kinematics, kinetic measures, and muscle activations), but it can allow walking at a variety of speeds, selected by the user in real-time and without dedicated commands.

In the framework of assistive EXOs, the possibility of adapting robotic support based on specific residual functional and motor abilities of iSCI subjects is crucial to optimize HRI. Moreover, specific training of the users in exploiting robotic assistance might have a significant impact on the resulting walking capabilities. The Achilles ankle exoskeleton, an autonomous wearable robot able to assist ankle plantar/dorsiflexion during walking, was developed for people with iSCI [19]. Achilles can generate positive plantar flexion with a lower mass and an higher power density than that of existing autonomous EXOs, with the potential to also reduce metabolic cost of walking [20]. Preliminary data collected with healthy subjects suggested that the NMC-controlled Achilles does not disturb walking dynamics in both slow and normal walking, with the potentiality of augmenting or replacing normal walking functions [16]. This was also achieved in the case of iSCI with NMC-controlled LOPES [17].

The main aim of this pilot study was to analyze the effects of the NMC-controlled Achilles, used as an assistive device, on chronic iSCI participants’ performance, by assessing gait speed during a 10-session training of robot-aided walking. Secondary aims were to assess the impact of the training on motion, clinical and functional features of iSCI participants and to evaluate the subjective perspective in using the robot in terms of attitude towards technology, workload, usability, acceptability and satisfaction.

II. MATERIALS AND METHODS
A. Achilles Exoskeleton and NeuroMuscular Controller

Achilles is an exoskeleton capable of assisting ankle plantarflexion and dorsiflexion during walking. The system, as described in [19], is composed by a compliant linear actuator (motor + spindle drive + leaf spring) for accurate force control (Fig. 1). The measurements from the two encoders together with the knowledge of the spring stiffness and of the kinematic structure allows the estimation of the delivered torque to be used as a feedback in a torque control loop. On top of the low-level torque controller, a high-level NMC is implemented as explained below. The force control of compliant actuators, as the one employed in our low-level control layer, might be sensitive to the human and environment dynamics [21]. For example, motor inertia and series elasticity might reduce actuator control bandwidth thus negatively influencing force tracking performance. Nonetheless, Achilles actuators were tested in a previous work of the Authors to guarantee a force control performance suitable for walking applications. In [19] bench tests evaluated the performance of the actuator and human experiments evaluated the working of the complete system. The actuator can track force reference signals with amplitudes of 1 to 100 N with a bandwidth between 8.1 Hz and 20.6 Hz. The Achilles is connected to the user lower leg through a carbon fiber shank shell and to the foot through a carbon fiber foot shell that is inserted within a standard gym shoe. A sensorized insole lying in the foot shell is used to detect foot contact with the ground and hence gait phases.

The NMC [16] is based on a reflex-based neuro-mechanical simulation of walking developed by Geyer and Herr [18]. The sagittal plane controller consists of seven Hill-type muscle units per leg: hip flexor, gluteus, hamstring, vastus, gastrocnemius, tibialis anterior, and soleus. The controller uses joint angles and ground contact sensors as inputs and produces as output joint torques to be delivered by the exoskeleton.
Joint angles yield virtual muscle length, velocity and force sensory information, which are used to activate the virtual muscles through reflex loops. The forces generated by these muscles are then combined to produce lower limb joint torques. Different reflex loops are used depending on whether the foot is in swing or stance. The stance reflexes support body weight, while the swing reflexes allow for leg swing. The nominal torque provided by the controller is for a simulated human of 80 kg in mass and 1.8 m in height walking at 1.3 m/s. We have previously shown that the controller can produce human-like joint kinematics and joint torques, for both healthy and SCI subjects [16], [17], without the need for tuning its biomechanical or reflex parameters.

One advantage of the NMC model structure is its modularity. The full lower limb NMC, which includes the ankle, knee, and hip, can be decomposed into separate control modules to be applied to different assistive devices. For Achilles, the ankle module was used, and thus only the soleus and tibialis anterior muscles were included. During the stance phase, the soleus muscle is driven by positive force feedback to increase tension while negative force feedback decreases the tension on the tibialis anterior. During swing and throughout the gait cycle, a positive length feedback on the tibialis anterior prevents overextension. The biarticular gastrocnemius was excluded to avoid a control issue, as torques would have been created at both the ankle and nonexistent knee. Further details can be found in [16], including results of tests with Achilles and healthy subjects. As mentioned above, the nominal torque output of the ankle controller corresponds to the contribution of the tibialis anterior and soleus muscles required for the model to walk at 1.3 m/s in computer simulation. A gain (between 0 and 1) multiplying the nominal torque was used to reduce the level of assistance starting from 100% of the nominal torque. Setting the gain to zero put Achilles in zero-torque mode, a condition in which the robot only follows the user’s motion without providing any assistance.

B. Experimental Protocol

The study was conducted at Fondazione Santa Lucia in Rome (FSL). The protocol was written according to the Helsinki declaration and approved by Independent FSL Ethical Committee (Prot. CE/PROG. 509) and written informed consent was obtained from all participants according to the FSL ethical procedures.

1) Overview of the Study: The study was structured to address the following outcomes:

Primary outcome measure: gait speed assessed by 10-Meter Walking Test (10MWT), collected before and after each 40-min training session in both Achilles-aided and free walking conditions. This will be referred to as Performance assessment. Participants were asked to walk for a total of 20 meters to exclude acceleration/deceleration and consider only steady-state condition [22].

Secondary outcomes measures: i) Motion assessment: ankle kinematic pattern, Achilles delivered torque, both measured by Achilles sensors, Spatio-Temporal (ST) parameters and Ground Reaction Forces (GRFs), assessed by force plates. All these measures were collected during Achilles-aided walking; ii) Clinical assessment: clinical data (muscle force, spasticity, spasticity related symptoms, dynamic balance, 6 minutes gait), were collected before and after Achilles-aided sessions; iii) Experience assessment: participants’ subjective perception in using the robot (attitude toward technology, acceptability, usability and satisfaction), collected by means of validated questionnaires before and after Achilles-aided walking.

Based on a previous experience with robot training [23], a 10-session Achilles-aided gait training was performed. Before the beginning of the training (T0), after 5 sessions (T1) and after the end of the training (T2), motion and clinical assessments were carried out. Performance and experience assessments were performed at each training session (S1 to S10). The gait training process was preceded by a participant-specific customization of the NMC controller to tailor the assistance level to the peculiar residual functional abilities of each iSCI participant. The overview of the study is reported in Fig. 2.

2) Enrolled Participants: iSCI participants were recruited from January 2017 until April 2017 at the Spinal Cord Unit of FSL, after a preliminary assessment performed by a medical doctor and a physical therapist (PT). Inclusion criteria were: 18–75 years old; traumatic/non-traumatic iSCI, sub-acute or chronic phase (at least 3 months after injury) incomplete motor lesion (AIS C or D at enrollment) at cervical, thoracic or lumbar level; ability to ambulate over ground if necessary with aids; evidence of preserved cognitive functions (Mini-Mental State Examination score > 26). Exclusion criteria were: presence of transmissible diseases such as (but not limited to) hepatitis or immunodeficiency virus; any clinical condition contraindicating gait; untreated chronic pain; severe spasticity (Ashworth scale score > 3); severe reduction in lower limb joint Range Of Motion (ROM) higher than 20 deg; any skin problem inhibiting robot usage, major depression or psychosis. All the evaluations were performed by the same operator at the same time of the day. Participants’ neurological status was measured at the enrollment by means of the American Spinal Injury Association (ASIA) scale and of the ASIA Impairment Scale (AIS) [24]. Mean time between SCI and enrollment was 18.3 ± 13.52 months.
TABLE I
Epidemiological, Clinical and Neurological Data of Participants

|     | P1   | P2   | P3   | P4   |
|-----|------|------|------|------|
| Age | 58   | 69   | 47   | 42   |
| Gender | M | M | M | M |
| AIS level | D | D | D | D |
| SCI level | C7 | T10 | L4 | T11 |
| Aetiology | Traumatic | Traumatic | Ischemic | Traumatic |
| WISCI level | 20 | 16 | 16 | 16 |

assessed by means of the Walking Index for Spinal Cord Injury (WISCI) [25]. Epidemiological, clinical and neurological data are reported in Table I. Furthermore, participants were screened by means of the Centre for Epidemiologic Studies Depression Scale (CES-D) [26].

3) Achilles Customization: Customization process was devoted to adjust the NMC settings based on the clinical features and functional residual abilities of each participant. For each setting to be tested, participants were asked to walk four times on a 10-meter path according to their personal WISCI level (see Table I) while wearing the Achilles. By modifying the gain multiplier of the nominal NMC torque, different assistance levels were tested systematically in a randomized order: i) 50% assistance for both ankles; ii) 100% assistance for both ankles; iii) 100% assistance for the left ankle and 50% assistance for the right ankle; iv) 50% assistance for the left ankle and 100% assistance for the right ankle. The specific setting for each participant was selected by considering a performance index based on the walking speed (assessed with the 10MWT) and on the participant’s personal perception (scored through questionnaires). This user-driven regulation approach resulted in personalized and self-selected settings for each participant. In particular, for P1 the selected assistance was 100% for the left ankle and 50% for the right one, while for P2, P3 and P4 the assistance was 50% for the left ankle and 100% for the right one. Details about the procedure will be the subject of a separate publication describing a user-centered method for the customization of robotic assistance.

4) Gait Training: Achilles training was performed for a total of ten 40-minute sessions, three times per week. The main goal of the training was to improve the comfortable speed during Achilles-aided walking. The first 10 minutes of each training session were devoted to bilaterally wearing the Achilles and to become familiar with the device. While in a sitting position, participants were asked to perform some ankle movements (dorsal/plantar flexion) or knee movements (flexion/extension). After this preliminary phase, participants were asked to stand up and to start with specific balance training propaedeutic for stance/swing phase while Achilles was in zero-torque mode. The exercises were devoted to properly distribute the body weight on the lower limbs. This initial balance training was expected to have a positive effects on subsequent gait performance of SCI participants, as demonstrated in [27]. PT asked the participants to transfer the body weight in medio-lateral and in antero-posterior direction while maintaining the heels in contact with the ground. To increase the difficulty of the exercises the PT asked the participants to alternatively lift the heel from the ground while doing the medio-lateral transfer of the body weight to reproduce the stance/swing phase of the gait. All these exercises were performed with the eyes open and closed, to properly train the somato-sensory system. The last part of the session was devoted to train Achilles-aided walking: participants were asked to walk according to the body weight transfer scheme learned previously, for instance by shifting in a physiological way the body from one side to the other. PT asked participants to progressively increase gait speed. Subjects walked over flat surfaces during most of the time, but with the progression of the training, also sloped paths were proposed.

C. Assessment Methods

1) Performance Assessment: Gait performance was assessed by means of the 10MWT, at self-selected WISCI level according to [28], with NMC-Achilles and without it (free walking).

2) Motion Assessment: Ankle joint angle and delivered torque were recorded from Achilles sensors. ST parameters were recorded by using four BTS Bioengineering P6000 force plates. Specifically, GRF vector, step length and width, stance phase duration, and also, gait speed were recorded. The three components of the GRF vector, Antero Posterior (AP), Medio Lateral (ML), Vertical (V), were extracted and normalized with respect to the participants’ body weight. During the post-processing phase, raw data were low-pass filtered by using a zero-lag second order Butterworth filter with a cut-off frequency of 5 Hz. Heel strike events were identified based on insoles information. Ankle angle, torque and GRFs were time-normalized and segmented into Gait Cycles (GC), by considering, for each leg, a heel strike for the beginning of the cycle and the subsequent heel strike for its end. Data of 5 GCs were extracted and averaged for each assessment time (T0, T1 and T2).

3) Clinical Assessment: The 6 Minutes Walking Test (6MinWT) [29] was used to evaluate walking endurance for both conditions (Achilles-aided and free walking). Specifically, test was explained per the [30] as follows “The object of this test is to walk as far as possible for 6 minutes, but don’t run or jog. Six minutes is a long time to walk, so you will be exerting yourself. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able”. 6MinWT was performed on a rectangular indoor track of 50 m. Borg Scale [31] was also administered associated to 6MinWT for assessing fatigue perception.

Manual Muscle Test (MMT) of the Medical Research Council [32] was employed to evaluate muscle force of hip, knee and ankle joints. MMT score ranges from 0 (no movement) to 5 (ability to complete whole range of motion against maximum resistance). The 5-points Modified Ashworth Scale (MAS) [28] was used to evaluate ankle spasticity, with 0 indicating no muscle tone increase and 5 indicating a rigid joint. Penn modified Spasm Frequency Scale (PSFS) [28] was used
Fig. 3. 10MWT speed during Achilles-aided walking and free walking for each training session (from S1 to S10). Pre and post training session measurements are reported. The Delta (difference between the Achilles-aided walking and free walking) is reported on the second row.

for spasms and Spinal Cord Assessment Tool for Spastic Reflexes (SCATS) [28] for clonus assessments. PSFS score ranges from 0 (no spasm) to 4 (spasms occurring more than 10 times per hour), while SCATS is split into 3 subscales, for clonus, flexor and extensor spasms assessment. For each subscale, spasm is triggered and then rated with a score ranging from 0 (no spasm) to 3 (severe spasm). Visual Analogue Scale [33] was employed for pain (VAS_Pain) based on a 10 cm line, with 0 representing “no pain” and 10 representing “the worst pain you can imagine”. Berg Balance Scale (BBS) [28], a 56-point scale that evaluates 14 tasks, was used to evaluate balance impairments.

4) Experience Assessment: To evaluate the dedication and engagement of the participants toward the task, motivation and mood were assessed before each training session, while training satisfaction and perceived workload immediately after. Motivation was evaluated by using an adapted version of the Questionnaire for Current Motivation (QCM) [31] based on 4 factors: i) Mastery Confidence, ii) Incompetence/Fear-To-Fail, iii) Challenge, iv) Interest [34], together with a VAS motivation (VAS_Mot) and mood (VAS_Mood) to test the positive/negative participants’ attitude towards the training and the Achilles. VAS was also used for the assessment of the satisfaction (VAS_Sat) (defined as “freedom from discomfort and satisfaction with the training” [33]). The perceived workload was assessed by using The National Aeronautics and Space Administration Task Load Index (NASA-TLX) [35] composed by 6 subscales: Mental Demand, Physical Demand, Time Pressure, Perceived Performance, Frustration and Effort. At the end of the training (T2), the participants were also administered a modified version of the Quebec User Evaluation of Satisfaction with assistive Technology 2.0 (QUEST 2.0) [36], that is used for gaining an overview of how much useful and acceptable the technology is perceived in various settings: we used selected items.

D. Statistical Analysis

Before statistical comparison, normal distribution of data was confirmed by Kolmogorov-Smirnov test. 10MWT comparisons among 10 training sessions, for both Achilles-aided and free walking conditions, were performed with repeated measures ANOVA. When ANOVA results reached significance, Bonferroni post-hoc test was performed. For other parametric variables recorded from force plates (step length, step width, stance phase duration and gait speed) ANOVA with Bonferroni post-hoc tests were used to assess statistical significance in the comparison among T0, T1 and T2. For non-parametric clinical variables (6MinWT, Borg Scale, MMT, MAS, PSFS, SCATS, VAS_Pain, BBS). Kruskal-Wallis analysis was used to compare T0, T1 and T2 data. Also for Experience assessment, Kruskal-Wallis method was used to compare data among 10 training sessions.

Statistical analysis was considered at $p < 0.05$. The statistical tests were performed by using the software Statistical Package for the Social Science - SPSS (Chicago, IL).

III. RESULTS

No one withdrew from the study and the outcome measures were obtained for all iSCI participants. A video of S1 walking with/without Achilles, at T0 and T2, is available.

A. Performance Assessment

10MWT Achilles-aided or free walking was performed after each training session according to their WISCI level for each participant. Results are reported in Fig. 3. All participants,
both in Achilles-aided and in free walking condition, progressively presented increased speed.

In particular, it appears that speed increased mostly during the first half of the 10-session training, thereafter no substantial variations were observed. This trend is similar for 10MWT Achilles-aided walking and for 10MWT free walking.

ANOVA and Bonferroni post-hoc statistical analysis pointed out that, only for 10MWT Achilles-aided walking, execution time was significantly reduced in comparison to S1 data, at S5 (\(p = 0.025\)), S6 (\(p = 0.011\)), S7 (\(p = 0.009\)), S8 (\(p = 0.008\)), S9 (\(p = 0.002\)) and S10 (\(p = 0.003\)). These results suggest that the training allows to significantly modify 10MWT after 5 training sessions only for the Achilles-aided assessment. No statistically significant results were obtained for 10MWT in free walking assessments. Comparison between Achilles-aided and free walking 10MWT indicates that participants are always faster during free walking (Fig. 3). This difference progressively reduces over the training, even if without statistical significance. Comparisons at T0 indicate that Achilles-aided 10MWT takes 4.61 ± 1.40 s more than free walking one. This delta is progressively reduced at subsequent assessments: T1 (2.28 ± 2.90 s) and T2 (1.00 ± 1.55 s).

B. Motion Assessment

1) Spatio-Temporal Data: Gait speed improvement after the training based on the 10MWT is confirmed by instrumental analysis, i.e. by the measures from force plates. As shown in Fig. 4, for all the participants, gait speed significantly increased between T0 and T2 (\(p = 0.037\)). No statistical difference were pointed out for the other ST parameters. Step length trend suggests a not significant increase for all the participants. Step width remains substantially unchanged during the training. Furthermore, Achilles usage did not appear to affect stance phase percentage: in all the participants only minor variations were observed comparing the three assessments (Fig. 4).

2) Kinematic and Kinetic Data: Data on ankle angle, torque delivered by the Achilles and GRFs are reported in Fig. 5 for each participant. Also free walking data collected in [37] for healthy adults (age: 43.1 ± 15.4) are included for comparison (H). Among different walking speeds analyzed in [37] we considered the slowest one (0.84 m/s), which was compatible with the one of our iSCI participants. The most relevant data are the angle and the torque since only minor changes were observed in the GRF patterns.

For all participants, joint angle data at T0 of the most affected ankle (i.e. the one with the lowest MMT score at the flexor muscles) presents a pattern of hyper-flexion in comparison to healthy data. This is the case of the left ankle of P1 and of the right ankle of S2, S3 and S4. Over the training, this plantar flexion trend is slightly reduced (Fig. 5). Moreover, the heterogeneity of ankle kinematics among the participants indicated that the NMC-controlled Achilles did not force the ankle joints towards predefined trajectories and did not impose a stereotyped motion. As regarding to torque delivered by Achilles, the capability to cope with participants’ specific force deficit is depicted in Fig. 5. For each participant, the peak torque is always higher on the most affected limb with respect to the healthiest one: 42% for P1, 43% for P2, 9% for P3 and 22% for P4. Hence, the Achilles exoskeleton provided a higher torque to the ankle joint with the lowest MMT score, thus matching with the clinically evaluated deficit (compare Figs. 5 and 6). This aspect is not trivial, since the assistive torque profile is not pre-planned but it emerges from the personal walking style and speed of each participant.

C. Clinical Assessment

1) 6MinWT Gait Endurance: As stated above, the training significantly improves 10MWT results for the Achilles-aided condition. Comparison between Achilles-aided and with free-walking was not possible in terms of 6MinWT since participants were not able to complete the test without Achilles support. At T0, 3 out of 4 participants preferred not to start the 6MinWT after the verbal explanation, while P1 started the test and stopped after 186 s. At T1 and T2 only P1 started 6MinWT but he did not complete it (he walked for 202 s at T1 and for 245 s at T2). On the other hand, 6MWT was easily completed in Achilles-aided condition, without any rest, by all the participants already at T0 (Fig. 6). Path length constantly improved for P1, P3 and P4 throughout assessments, even if not reaching statistical significance. P2 performance at T1 was initially worse than at T0, but at T2 gait speed was higher than at T0.

6MinWT improvement between T2 and T0 was associated with a reduction of the perceived fatigue, as assessed by the Borg scale (Fig. 6). This was particularly evident for P1, P3 and P4. On average, at T0 Borg score was 11.75 ± 3.20, while at T2 it was 8.75 ± 2.50. Besides the effects on gait performance, the training also slightly positively affected balance, as indicated by BBS data (BBS score T0: 34.75 ± 8.61; T2: 38.25 ± 6.49).

2) Force, Spasticity and Spasticity-Related Symptoms: Despite the reduced sample size and the similarities among participants in AIS and WISCI scores, as well as in the overall good functional and clinical status, participants are unique in terms of muscle force, spasticity and spasticity-related symptoms (see Fig. 7). MMT at T0 highlights the force impairment for each participant (Fig. 7). Notably, the user-centered customization process resulted in a robotic level of
assistance that turned out to be consistent with the ankle MMT assessment. Even if no significant modifications were highlighted for any of the mentioned clinical data, some slight differences during the training were found. MMT did not vary at T1. At T2 two participants presented the same MMT scores while other two participants, namely P3 and P4, showed muscle force improvements. P3 knee scores improved of 1 point for flexor muscles at both sides (T2: MMT = 4 left knee and MMT = 4 right knee). P4 ankle scores suggested a force enhancement at the right ankle flexor (T2: MMT = 2) and extensor (T2: MMT = 2). Spasticity and spasticity-related symptoms indicated a general low degree of spasticity, clonus and spasm already at T0. In detail, P1 presented a very low level of spasticity (MAS = 1) at right and left knee, as well as at right ankle. At the left ankle a slight higher level of spasticity was denoted (MAS = 2). In association, mild clonus and mild flexors spasm were present for P1 at left ankle. For P2 spasticity was detected at right (MAS = 1) and particularly left (MAS = 2) ankles. P3 presented a low spasticity level at right knee and ankle (MAS = 1). P4 had low degree of spasticity only at the right ankle, associated with mild clonus and flexor spasms, similarly to P1. No modifications were reported for most of the subsequent evaluations. The only exceptions were the reduced left ankle spasticity at T2 for P1 and P2 (from MAS = 2 to MAS = 1). Pain symptoms were present in all the participants with the exception for P3. Achilles training positively reduced pain symptoms. On average, VAS_Pain score at T0 was 4.25 ± 2.60 and 2.25 ± 2.50 at T2.

D. Experience Assessment

Statistical analysis did not show significant modifications for any of the analyzed variables, with the only exception for the NASA-TLX sub-score of performance (p = 0.007). VAS_Mood, VAS_Sat and VAS_Mot results show very low variability among training sessions and within participants. All participants rated mood and motivation as good and training satisfaction as very high (Fig. 8). The daily evaluation scores of the QCM questionnaire factors of Mastery Confidence, Challenge and Interest were all rated high over
the training by all the participants. On the contrary, the factor Incompetence/Fear-to-Fail was rated low at the beginning of the training and very low at the end of the training. This demonstrates that as long as the participants became more self-confident and proficient in using the Achilles, they showed reduced fear to fail (Fig. 8).

The results of the NASA-TLX workload global score at S1 was rated as medium for P1 (55) and medium-low for P2 (16) and as very low (16 and 5 respectively) at S10; conversely, P3 and P4 rated the perceived workload as medium at S1 (44 and 50 respectively) and high at S10 (60 and 63 respectively). We decided to consider independently each dimension of the workload (Fig. 9) and results showed that the participants were different in evaluating the Achilles experience: P1 and P4 rated Mental Demand as medium-high or high over the training; Physical Demand and Effort were high for P3 and P4 while for P1 and P2 conversely were medium-high from S1 to S5 and very low from S6 to S10. It is worth to note that the Perceived Performance was rated high, or medium-high, in the first part of the training but in the second part the participants began to perceive it as very low. Kruskall-Wallis Analysis pointed out a significant difference in Perceived Performance scores, in the comparisons of S10 versus S5, S4,
S3, S2 and S1 as well as in the comparison of S6 or S7 or S8 or S9 versus S3 and S4. This data suggests that starting from S6 Performance was significantly perceived as very low by participants, with the lowest significantly perception at S10. We found that Frustration was always rated very low by all the participants. To evaluate the satisfaction with Achilles, specific items were selected from the QUEST 2.0 questionnaire. We evaluated Effectiveness, Comfort, Easy to use, Reliability/Robustness, Easy in adjusting and Dimensions. P1 and P2 were very satisfied about the Achilles for all the investigated aspects, with the only exception for P1 (low satisfaction about Achilles donning/doffing procedures and Reliability/Robustness). P3 and P4 level of satisfaction was high, even if lower than other participants: particularly, P3 and P4 were satisfied by Dimension, Safety and Easiness of use.

IV. Discussion

Exoskeletons are increasingly being employed for both gait therapy and assistance of people with partial or full walking disabilities due to SCI. One of the main challenges in clinical applications is customizing robotic intervention to let the user i) receive physical assistance based on residual functional abilities, ii) not be forced toward unnatural or stereotyped walking patterns, iii) be motivated and stimulated to actively participate in the walking task at the best of their abilities and engagement and iv) be trained to increase their performance. In the present pilot study, we tested the Achilles, a new ankle assistive exoskeleton, designed to be adaptable to the specific needs of walking subjects with iSCI thanks to its NMC [18].

NMC-controlled Achilles has the potentiality to address the abovementioned desired features thanks to its versatility and high compliance to users’ natural walking. These characteristics are achieved through an intrinsic capability of the NMC to mimic muscles and reflexes during locomotion.

Baseline data showed that all iSCI participants, without any specific training for the use of the Achilles, at T0 walked slower with the robot in comparison to free walking (Fig. 3). This result was probably due to the lower limb muscles impairment and to the added weight, inertia and friction introduced by the Achilles to the ankle joint. Hence, some adaptation time and some practice to optimize HRI were expected to be required. Results indicated that to significantly improve robot-aided gait speed, 5 training sessions were necessary, suggesting a progressive mastering of the Achilles use (Fig. 3).

A trend of speed increase in 10MWT (not statistically significant) was found in free walking condition. It must be stressed that iSCI participants were in a chronic stage, in which further recovery seldom occurs (especially more than one year after the lesion) [38]. Overall, results suggest a possible rehabilitation potential for NMC-controlled Achilles that deserves further analysis, e.g. by considering a control group not using the robot. Importantly, even if differences in free walking 10MWT did not reach statistical significance, the independent community ambulation speed (as defined in [13]) could be achieved by all the participants, after the training, in free-walking condition.

Beside the supposed rehabilitation potential, data on gait endurance clearly indicated the usefulness of the NMC-Achilles for iSCI participants. Indeed, all of them were unable to successfully execute 6MinWT in free walking condition at T0 while they were able to complete the test in the Achilles-aided condition since the first assessment. In subsequent assessments, further improvements in 6MinWT were recorded, also associated with a reduction in the perceived fatigue (Fig. 6). This data indicate that Achilles allows participants to reduce walking efforts and to better manage longer distances.

The specific reduction in walking effort when using the Achilles cannot be easily explained but it can be brought back to the adaptability of the assistance level to each single participant. As stated in Sec. II-C.1, assistance was set using either 100% or 50% of the nominal deliverable torque profile (Fig. 5). This setting translated into a torque assistance pattern specific for each participant. In particular, Achilles assistance level was customized based on the participants’ specific features, and maintained unchanged along the training. Results of the customization process turned out to be consistent with the clinical status of each participant, assessed through the MMT (Fig. 7). Indeed, a higher level of assistance was set for the most affected ankle and also a higher torque was delivered by the actuator connected to the weaker joint (Fig. 5).

Heterogeneity of ankle kinematics among the participants (Fig. 5) indicated that the NMC-controlled Achilles properly adapted to each user and did not force the ankle joints towards predefined trajectories. Indeed, it provided assistive torques without imposing a stereotyped motion thus allowing each participant to smoothly manage interaction with the machine based on his personal adaptation strategy and walking style dictated by his individual neuro-physiological features.

Moreover, the variability in the walking speed among participants, and also among sessions, demonstrated the capability of the NMC-controlled Achilles to detect participants’ intended speed and automatically adapt to it without delay and without any prescribed command, trigger or pre-set. During the training with the Achilles, gait speed improvement was combined with a (not statistically significant) trend of step length increase, thus suggesting an improved HRI. Gait speed in most of lower limb assistive EXOs is pre-set by the PT or by the user by regulating joints ROM and/or GC duration [10]. This was not the case for NMC, which adapted automatically to the specific desired speed of the user.

All the participants had a favorable subjective experience during the training and using Achilles, exhibiting a high engagement and a good mastery of the robot. They were highly motivated, supporting the idea that NMC-controlled Achilles was positively accepted with a good compliance/adherence to the training itself. In particular, we observed that the satisfaction was maintained high along training sessions and also participants perceived no frustration (NASA-TLX subscale). Similarly, the trend of the motivational factors showed that participants perceived the Achilles-aided walking experience as doable, challenging and interesting. The sum of these factors could lead to an increase in the personal commitment.
to succeed in the training; maybe it also promoted an increase in self-esteem and therefore in the perception of the personal evaluation of one’s ability to walk. This may be related to the ability to perform robot-aided 6MinWT already at T0, also by the participants who preferred not to perform the test without Achilles. We can cautiously infer that the participants evaluated as high the effectiveness of the Achilles, meaning effectiveness as the accuracy and completeness with which a user achieves specific tasks thanks to a device (ISO 9241-11, 1998, [39]). In addition, positive evaluation was provided by all the participants since S1, and it was maintained during the training, thus excluding possible placebo effects on the perceived performance. More specifically, participants improved their speed and the assessment of their personal perception demonstrated that they were aware of this improvement since the first training session. At S5 a plateau in the 10MWT performance was reached (Fig. 3), thus participants considered S6 as a failure (Fig. 9), even if their performance had not decreased.

The present work was aimed at evaluating the capability of the NMC-controlled Achilles of providing motor assistance to iSCI subjects by automatically and intuitively adapting to their intended motion. Hence, the study was not aimed at specifically demonstrating any possible impact on the clinical status of the participants and clinical assessments were planned to safely monitor clinical conditions during the training. Nonetheless, improvements of the status of the participants were surprisingly experienced.

Generally, an assistive device is aimed at supporting an impaired muscle or function [11], [14] and its use often results in a further reduction of muscle force and in a loss of function when the device is not worn. Achilles training indicated just the opposite effect. Despite the short testing time and the chronic condition of the participants, the observed (not significant) changes highlighted some improvements. Beside the already discussed speed increase in free walking, MMT score improved in P3 and P4 and MAS improved in P1 and P2. Also a reduction in the pain perception was reported. Pain is considered a spasticity-related symptom and the spasticity reduction may allow a pain reduction too. In line with this assumption, P1 and P2 showed the highest spasticity and pain reduction (Fig. 7).

Being this work one of the few investigations of the NMC on subjects with SCI, there are several potential future areas of study. We used a 2D reflex-based model, but there exists a 3D version that is robust against uneven terrain in simulation. It would be an interesting area of future work to test how well the controller rejects ground perturbations with SCI subjects [40]. We used our controller on top of a low-level force control. Anyhow, force control could have been used also in combination with other different control approaches, e.g. a higher-level impedance control [21] with a speed-dependent reference trajectory or a sliding-mode control, as proposed in [41]. Further direct comparisons with these other possible controllers would inform whether the NMC would benefit subjects at different levels of impairment. We have shown the benefits of a bio-inspired controller that allows for positive shared control but future work is required to further elucidate critical factors that best facilitate gait or gait recovery.

V. CONCLUSION

For iSCI participants using the NMC-controlled Achilles powered exoskeleton, it is possible to adapt NMC in line with participants’ features. A short training is necessary to allow a positive perception of HRI and consequently to significantly improve Achilles-aided gait speed. This training generates a positive trend in gait performance also during free walking, thus suggesting a potential rehabilitative impact that deserves further future investigations. This rehabilitative potential is also supported by other clinical assessments indicating a tendency toward clinical improvements. Participants’ evaluations of Achilles design and impact suggested positive mental engagement and good acceptance of the device since the first session. Some caveats related to the present results must be stressed. The study was aimed at evaluating gait assistance effects, thus rehabilitation potentials have to be tested in a dedicated study. This should be considered a preliminary study, even if a statistical analysis was performed. To confirm these data, it is necessary to increase the sample size, to perform a follow-up assessment and to consider a control group not using the robot. Present results will be used to properly design an ad hoc study with adequate sample size, to address NMC-Achilles impact as assistance device on gait endurance in iSCI subjects.

ACKNOWLEDGMENT

The authors would like to thank all the participants involved in this study.

REFERENCES

[1] J. A. Haisma, L. H. V. van der Woude, H. J. Stam, M. P. Bergen, T. A. R. Shihs, and J. B. J. Bussmann, “Physical capacity in wheelchair-dependent persons with a spinal cord injury: A critical review of the literature,” Spinal Cord, vol. 44, no. 11, pp. 642–652, Nov. 2006.
[2] A. E. Palermo, J. L. Maher, C. B. Baamsgaard, and M. S. Nash, “Clinician-focused overview of bionic exoskeleton use after spinal cord injury,” Topics Spinal Cord Injury Rehabil., vol. 23, no. 3, pp. 234–244, Jun. 2017.
[3] G. Scivoletto et al., “Clinical factors that affect walking level and performance in chronic spinal cord lesion patients,” Spine, vol. 33, no. 3, pp. 259–264, Feb. 2008.
[4] A. Kozlowski, T. Bryce, and M. Dijkers, “Time and effort required by persons with spinal cord injury to learn to use a powered exoskeleton for assisted walking,” Topics Spinal Cord Injury Rehabil., vol. 21, no. 2, pp. 110–121, Mar. 2015.
[5] G. Stampacchia, A. Rustici, S. Bigazzi, A. Gerini, T. Tombini, and S. Mazzoleni, “Walking with a powered robotic exoskeleton: Subjective experience, spasticity and pain in spinal cord injured persons,” NeuroRehabilitation, vol. 39, no. 2, pp. 277–283, Aug. 2016.
[6] C. Morawietz and F. Moffat, “Effects of locomotor training after incomplete spinal cord injury: A systematic review,” Arch. Phys. Med. Rehabil., vol. 94, no. 11, pp. 2297–2308, Nov. 2013.
[7] M. Aach et al., “Voluntary driven exoskeleton as a new tool for rehabilitation in chronic spinal cord injury: A pilot study,” Spine J., vol. 14, no. 12, pp. 2847–2853, Dec. 2014.
[8] J. F. Veneman, R. Kruidhof, E. E. G. Hekman, R. Eekelenkamp, E. H. F. Van Asseldonk, and H. van der Kooij, “Design and evaluation of the LOPES exoskeleton robot for interactive gait rehabilitation,” IEEE Trans. Neural Syst. Rehabil. Eng., vol. 15, no. 3, pp. 379–386, Sep. 2007.
[9] A. Esquenazi, M. Talaty, A. Packel, and M. Saulino, “The ReWalk powered exoskeleton to restore ambulatory function to individuals with thoracic-level motor-complete spinal cord injury,” Amer. J. Phys. Med. Rehabil., vol. 91, no. 11, pp. 911–921, Nov. 2012.

[10] S. Wang et al., “Design and control of the MINDWALKER exoskeleton,” IEEE Trans. Neural Syst. Rehabil. Eng., vol. 23, no. 2, pp. 277–286, Mar. 2015.

[11] A. S. Gorgey, “Robotic exoskeletons: The current pros and cons,” World J. Orthopedics, vol. 9, no. 9, pp. 112–119, Sep. 2018.

[12] S. Federici, F. Meloni, M. Braccalenti, and M. L. De Filippis, “The effectiveness of powered, active lower limb exoskeletons in neurorehabilitation: A systematic review,” NeuroRehabilitation, vol. 37, no. 3, pp. 321–340, Nov. 2015.

[13] D. R. Louie, J. J. Eng, and T. Lam, “Gait speed using powered robotic exoskeletons after spinal cord injury: A systematic review and correlational study,” J. NeuroEngineering Rehabil., vol. 12, no. 1, p. 82, Dec. 2015.

[14] P. R. Geigle and M. Kallins, “Exoskeleton-assisted walking for people with spinal cord injury,” Arch. Phys. Med. Rehabil., vol. 98, no. 7, pp. 1493–1495, Jul. 2017.

[15] P. M. Rossini and G. D. Forno, “Integrated technology for evaluation of brain function and neural plasticity,” Phys. Med. Rehabil. Clinics North Amer., vol. 15, no. 1, pp. 263–306, Feb. 2004.

[16] F. Dzeladini et al., “Effects of a neuromuscular controller on a powered ankle exoskeleton during human walking,” in Proc. 6th IEEE Int. Conf. Biomed. Robot. Biomechatronics (BioRob), Jun. 2016, pp. 617–622.

[17] A. R. Wu et al., “An adaptive neuromuscular controller for assistive lower-limb exoskeletons: A preliminary study on subjects with spinal cord injury,” Frontiers NeuroRobotics, vol. 11, p. 30, Jun. 2017.

[18] H. Geyer and H. Herr, “A muscle-reflex model that encodes principles of stress during graded arm exercise in persons with spinal cord injuries,” Arch. Phys. Med. Rehabil., vol. 88, no. 9, pp. 1205–1211, Sep. 2007.

[19] W. G. Wright, “Muscle training in the treatment of infantile paralysis,” Boston Med. Surgical J., vol. 167, no. 17, pp. 567–574, 1912.

[20] G. Z. Heller, M. Manuguerra, and R. Chow, “How to analyze the visual analogue scale: Myths, truths and clinical relevance,” Scand. J. Pain, vol. 13, no. 1, pp. 67–75, Oct. 2016.

[21] H. Geyer and H. Herr, “A muscle-reflex model that encodes principles of legged mechanisms produces human walking dynamics and muscle activities,” IEEE Trans. Neural Syst. Rehabil. Eng., vol. 18, no. 3, pp. 263–273, Jun. 2010.

[22] W. van Dijk, C. Meijneke, and H. van der Kooij, “Evaluation of the Achilles ankle exoskeleton,” IEEE Trans. Neural Syst. Rehabil. Eng., vol. 25, no. 2, pp. 151–160, Feb. 2017.

[23] C. Meijneke, W. van Dijk, and H. van der Kooij, “Achilles: An autonomous lightweight ankle exoskeleton to provide push-off power,” in Proc. 5th IEEE RAS/EMBS Int. Conf. Biomed. Robot. Biomechatronics, São Paulo, Brazil, Aug. 2014, pp. 918–923.

[24] A. Calanca, R. Muradore, and P. Fiorini, “A review of algorithms for compliant control of stiff and fixed-compliance robots,” IEEE/ASME Trans. Mechatronics, vol. 21, no. 2, pp. 613–624, Apr. 2016.

[25] S. Fritz and M. Lusardi, “White paper: Walking speed: The sixth vital sign,” J. Geriatric Phys. Therapy, vol. 32, no. 2, pp. 9–46, 2009.

[26] F. Sylos-Labini et al., “EMG patterns during assisted walking in the exoskeleton,” Frontiers Human Neurosci., vol. 8, p. 423, Jun. 2014.

[27] International Standard for Neurological Classification of Spinal Cord Injury (Rev), Amer. Spinal Injury Assoc., Chicago, IL, USA, pp. 1–23, 2000.

[28] P. Dittuno and J. Dittuno, Jr., “Walking index for spinal cord injury (WISCI II): Scale revision,” Spinal Cord, vol. 39, no. 12, pp. 654–656, Dec. 2001.

[29] E. Doozeman, D. J. F. van Schaik, H. W. J. van Marwijk, M. L. Stek, H. E. van der Horst, and A. T. F. Beekman, “The center for epidemiological studies depression scale (CES-D) is an adequate screening instrument for depressive and anxiety disorders in a very old population living in residential homes,” Int. J. Geriatric Psychiatry, vol. 26, no. 3, pp. 239–246, Mar. 2011.

[30] F. Tamburella, G. Scivoletto, and M. Molinari, “Balance training improves static stability and gait in chronic incomplete spinal cord injury subjects: A pilot study,” Eur. J. Phys. Rehabil. Med., vol. 49, no. 3, pp. 353–364, 2013.

[31] P. Poole-Wilson, “The 6-minute walk. A simple test with clinical application,” Eur. Heart J., vol. 21, no. 7, pp. 507–508, Apr. 2000.

[32] S. Song and H. Geyer, “A neural circuitry that emphasizes spinal feedforward generates diverse behaviours of human locomotion,” J. Physiol., vol. 593, no. 16, pp. 3493–3511, Aug. 2015.

[33] A. Calanca, L. Capisani, and P. Fiorini, “Robust force control of series elastic actuators,” Actuators, vol. 3, no. 3, pp. 182–204, 2014.