Search Strategy

Search

((Robot*[TI] OR ELECTROMECHANIC*[TIAB] OR EXOSKELETON*[TI]) AND (STROKE*[TI] OR SPINAL CORD[TI]) AND RANDOM*[TIAB]) OR

("driven-gait orthosis" [TIAB] OR (Lokomat OR Lokomat-Pro)[TIAB] OR WALKBOT[TIAB] OR "stride management assist"[TIAB] OR ERIGO[TIAB] OR AutoAmbulator[TIAB] OR anklebot[tiab] OR "gait trainer"[tiab] OR "MBZ-CPM1" OR "gait assistance robot"[tiab] OR "bionic leg"[tiab])
$N = 172$

Table S1 Inclusion and exclusion criteria

Study component	Inclusion	Exclusion
Population	• Patient with SCI with gait disorder • Age >18, <75 y	• Neurologic conditions other than SCI or stroke • No neurologic gait disorder • Age <18, >75 y
Intervention	Assistance or rehabilitation with a wearable exoskeleton of the lower extremity	Powered gait orthosis Upper extremity
Comparators	Conservative physiotherapy Powered gait orthosis	
Outcomes	Primary outcomes • Gait outcomes (walking speed, 6-min walking test, TUG, 10MWT) • Functional improvement (LEMS, FIM, SCIM, AMI, Fugl-Meyer-L) Secondary outcomes • Neurologic improvement • Motor strength • Bladder and bowl function • Spasticity • Requirement of walking aid Safety • Fracture • Pain • Cardiopulmonary episodes	Physiologic or metabolic outcomes
Study design	RCTs	

Abbreviations: 10MWT, 10-meter walking test; AMI, Ambulatory Motor Index; FIM, Functional Independence Measure ; LEMS, lower extremity motor score; RCT, randomized controlled trial; SCI, spinal cord injury; SCIM, Spinal Cord Independence Measure; TUG, Timed-Up-and-Go.

Table S2 Summary of main outcome measures

Outcome measure	Assessed by	Components	Score range	Interpretation	MCID
10MWT[1]	Clinician-reported	Gait speed (m/s) calculated by measuring the total time required to walk 10 m	0 to any positive integer	Assesses walking speed in meters per second over a short duration (<5 min)	SCI: 0.06 m/s
6MWT[2]	Clinician-reported	Total distance (m) walked in 6 min	0 to any positive integer	Assesses distance walked over 6 min as a submaximal test of aerobic capacity/endurance	SCI Overall MCID: 0.10 m/s Slow speed MCID: 0.11 m/s Fast speed MCID: NR
WISCI/WISCI II[3]	Clinician-reported	Amount of assistance: • Two persons, defined as moderate to maximum assist	WISCI: 1–20 (best) WISCI II: 0–20 (best)*	Rank orders the ability of a person to walk 10 m after SCI from most to least severe impairment	NR

Table S2 (*Continued*)

Outcome measure	Assessed by	Components	Score range	Interpretation	MCID
		• One person, defined as minimal assist • No assist • Assistive device (parallel bars, walker, etc.) Braces: • One or two, short or long			
FIM-L	Clinician-reported	FIM-L subscore is comprised of the two mobility items: • Walking/wheel-chair locomotion • Stairs Each item scored on a scale of 1–7	2–14 (best)	The higher the score, the better level of function	NR
LEMS	Clinician-reported	LEMS is a motor subscore of the ASIA impairment scale	0–50 (best)	The higher the score, the greater the motor function in the lower extremity	NR
SCIM[4]	Clinician- or patient-reported	3 domains • Self-care (0–20) ◦ Feeding ◦ Bathing ◦ Dressing ◦ Grooming • Respiration and sphincter management (0–40) ◦ Respiration ◦ Bladder management ◦ Bowel management ◦ Use of toilet • Mobility (0–40) ◦ Tasks in the room and toilet ◦ Tasks indoors and outdoors	0–100 (best)	The higher the score, the greater the independence	NR
Defecation time	Clinician-reported	NR	0 to any positive integer	NR	NR
Enema volume	Clinician-reported	NR	0 to any positive integer	NR	NR

Abbreviations: 6MWT, 6-minute walk test; 10MWT, 10-meter walk test; ASIA, American Spinal Injury Association; FIM-L, Functional Independence Measure–Leg; LEMS, lower extremity motor score; MCID, minimum clinical important difference; N/A, not available; NR, not reported; SCI, spinal cord injury; SCIM, Spinal Cord Independence Measure; WISCI, Walking Index for Spinal Cord Injury I; WISCI II, Walking Index for Spinal Cord Injury II.

Table S3 Risk of bias and class of evidence for included studies

First author (year)	Random sequence generation	Statement of concealment	Intention to treat	Blind assessment	Cointerventions applied equally	Complete F/U of ≥80%	<10% difference in F/U between groups	Controlling for confounding	Risk of bias
Alcobendas-Maestro (2012)	Yes	Yes	Yes	Yes	Yes	Yes (93.8%)	Yes (92.5% versus 95%)	Yes	Low
Benito-Penalva (2012)	Unclear[a]	Unclear	Yes	Unclear	Yes	Yes (80.8%)	Yes (84.8% versus 78.6%)	Yes	Moderately high
Duffell (2015)	Unclear	Unclear	Yes	Unclear	Yes	Yes (92.77% or 86.7%)[b]	Yes (96% versus 86% versus 96% *or* 89% versus 79% versus 93%)[c]	Yes	Moderately high
Field-Fote (2011)	Yes	Unclear	No[d]	Yes	Yes	Yes (86%)	Yes (93% versus 89% versus 82% versus 83%)	Yes	Moderately high
Hornby (2005)	Unclear	Unclear	No	No	Yes	No (77.4%)	Unclear	Yes	Moderately high
Huang (2015)	Unclear	Unclear	Unclear	Unclear	Yes	Unclear	Unclear	Yes	Moderately high
Shin (2014)	Unclear	Unclear	Yes	Unclear	Yes	Yes (88%)	Yes (90% versus 87%)	Yes	Moderately high
Niu (2014)	Yes	Yes	Unclear	No	Yes	Unclear	Unclear	Yes	Moderately high
Esclarín-Ruz (2014)	Yes	Yes	Yes	Yes	Yes	Yes (overall: 94%, UMN: 95%, LMN: 93%)	Yes (UMN: 95% versus 95%; LMN: 91% versus 95%)	Yes	Low

[a]"Unclear" indicates no information was provided unless otherwise noted below.
[b]Varies by outcome measure; 10-meter walk test 92.7% (77/83), 6-minute walk test 86.7% (72/83).
[c]Varies by outcome measure: 10-meter walk test (Lokomat versus control versus tizanidine), 96% (26/27) versus 86% (25/29) versus 96% (26/27); 6-minute walk test (Lokomat versus control versus tizanidine), 89% (24/27) versus 79% (23/29) versus 93% (25/27).
[d]Analysis was performed on protocol rather than intention to treat.

Table S4 Risk of bias for included crossover studies

First author (year)	Appropriate crossover design	Randomized treatment order	Carryover effect	Unbiased data	Allocation concealment	Blinding	Incomplete outcome data	Selective outcome reporting	Other bias
Gorman (2016)	High	Unclear[a]	Unclear	Unclear	Unclear	Low	High	Low	High
Labruyère (2014)	High	Low	Low	Unclear	Unclear	Low	Low	Low	Low

[a]"Unclear" indicates no information was provided unless otherwise noted below.

Grade and Strength of Evidence

The strength of the overall body of evidence with respect to each primary outcome was determined based on precepts outlined by the Grades of Recommendation Assessment, Development and Evaluation (GRADE) Working Group.[5,6]

The initial strength of the overall body of evidence was considered high if the majority of the studies were randomized controlled trials and low if the majority of the studies were observational studies. Criteria for downgrading published evidence one or two levels included: (1) serious risk of bias, (2) inconsistency of results, (3) indirectness of evidence, (4) imprecision of the effect estimates (e.g., wide confidence intervals), or (5) non–a priori statement of subgroup analyses. Alternatively, the body of evidence could be upgraded one or two levels based on the following factors: (1) large magnitude of effect or (2) dose–response gradient. The final overall strength of the body of literature expresses our confidence that the effect size lies close to the true effect and the extent to which it is believed to be stable based on the adequacy of or the deficiencies in the body of evidence. An overall strength of high means that we are very confident that the true effect lies close to that of the estimated effect. A moderate rating means that we are moderately confident in the effect estimate; the true effect is likely to be close to the estimated effect, but there is a possibility that it is substantially different. An overall strength of low means that our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate. Finally, a rating of very low means that we have very little confidence in the effect estimate; the true effect is likely to be substantially different than the estimated effect. In addition, this rating may be used if there is no evidence or it is not possible to estimate an effect.

Table S5 Excluded articles

Reference	Reason for exclusion
Arazpour M, et al. The physiological cost index of walking with mechanical and powered gait orthosis in patients with spinal cord injury. Spinal Cord 2013;51(5):356–359	Not a randomized controlled trial
Kressler J, et al. Metabolic responses to 4 different body weight-supported locomotor training approaches in persons with incomplete spinal cord injury. Arch Phys Med Rehabil 2013;94(8):1436–1442	Duplicate to Field-Fote et al (2011)
Raithatha R, et al. Non-invasive brain stimulation and robot-assisted gait training after incomplete spinal cord injury: a randomized pilot study. NeuroRehabilitation 2016;38(1):15–25	Robot-assisted gait training present in both treatment groups; trial does not evaluate effectiveness of robot-assisted gait training
Swinnen E, et al. Effectiveness of robot-assisted gait training in persons with spinal cord injury: a systematic review. J Rehabil Med 2010;42(6): 520–526	Not a randomized controlled trial
Varoqui D, et al. Ankle voluntary movement enhancement following robotic-assisted locomotor training in spinal cord injury. J Neuroeng Rehabil 2014;11:46	Duplicate to Duffell et al (2015) and Niu et al (2014)
Wirz M, et al. Effectiveness of automated locomotor training in patients with acute incomplete spinal cord injury: a randomized controlled multicenter trial. BMC Neurol 2011;11:60	Not a randomized controlled trial; only a protocol
Wu M, et al. A cable-driven locomotor training system for restoration of gait in human SCI. Gait Posture 2011;33(2):256–260	Not a randomized controlled trial
Wu M, et al. Robotic resistance treadmill training improves locomotor function in human spinal cord injury: a pilot study. Arch Phys Med Rehabil 2012;93(5):782–789	Robot-assisted gait training present in both treatment groups; trial does not evaluate effectiveness of robot-assisted gait training
Yoshimoto T, et al. Feasibility and efficacy of high-speed gait training with a voluntary driven exoskeleton robot for gait and balance dysfunction in patients with chronic stroke: nonrandomized pilot study with concurrent control. Int J Rehabil Res 2015;38(4):338–343	Not a randomized controlled trial

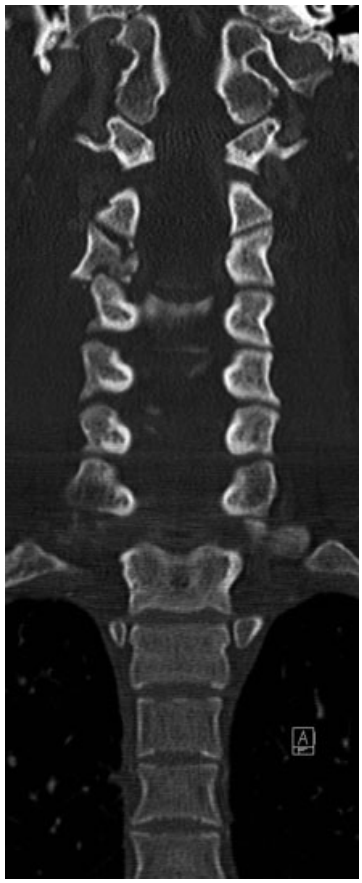

Fig. S1 Preoperative coronal computed tomography demonstrating C3–C4 fracture.

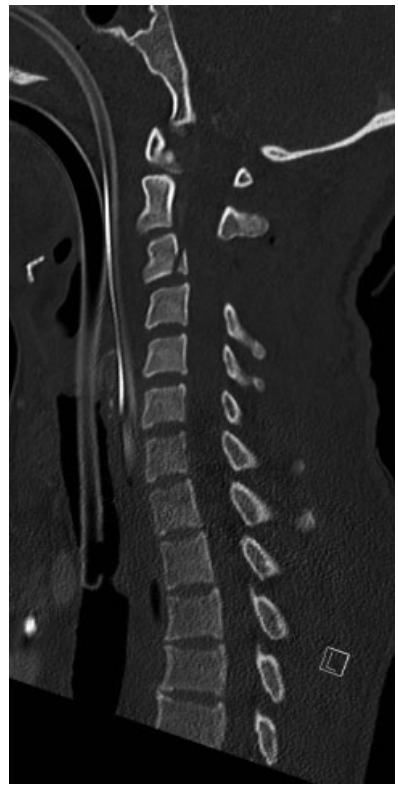

Fig. S2 Preoperative sagittal computed tomography demonstrating C3–C4 fracture.

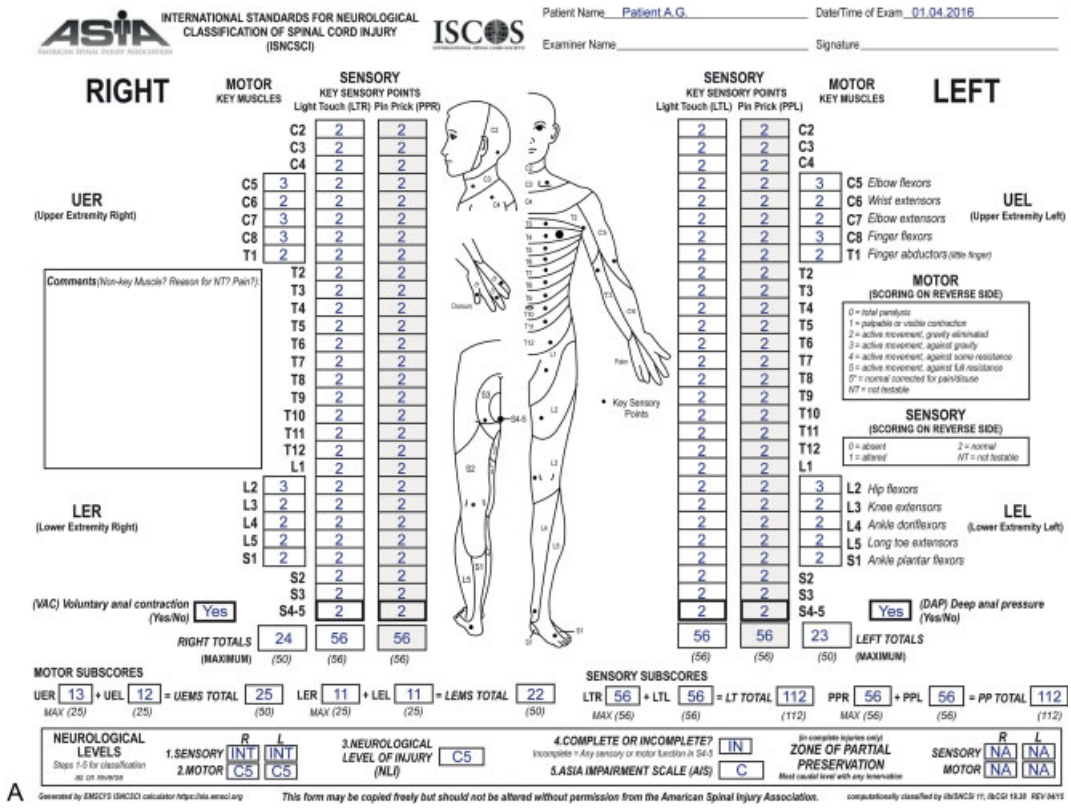

Fig. S3 (A, B) Neurologic status according to the American Spinal Injury Association (ASIA) at the time of study enrollment.

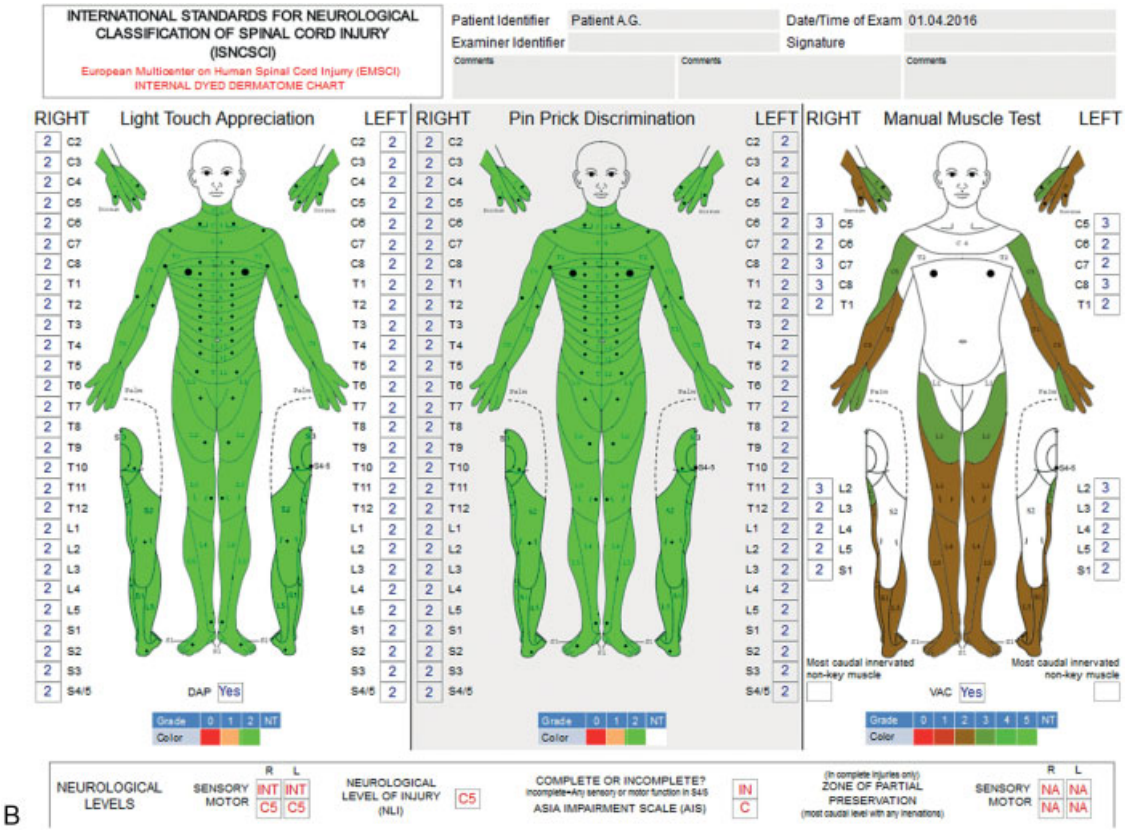

Fig. S3 (*Continued*)

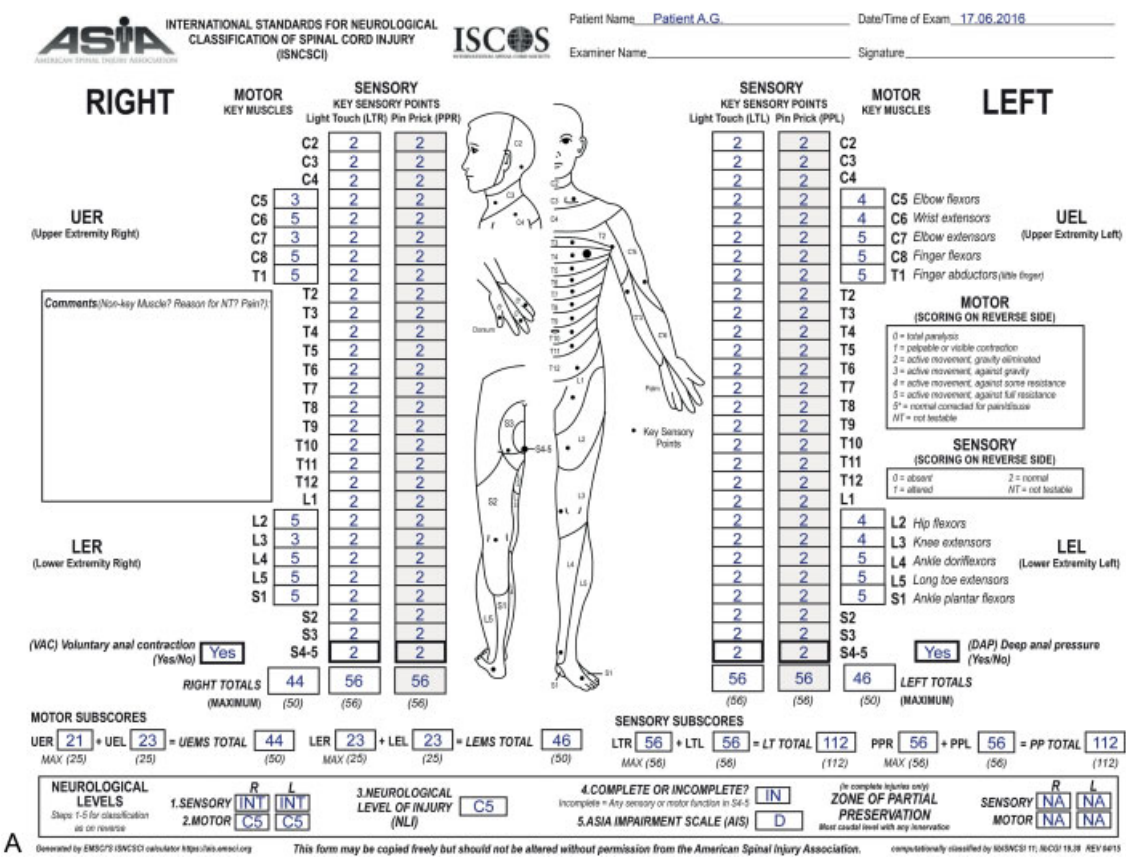

Fig. S4 (A, B) Neurologic status according to the American Spinal Injury Association (ASIA) at the time of admission after 12 weeks of HAL (Hybrid Assistive Limb, Cyberdyne, Tsukuba, Japan) body weight-supported treadmill training.

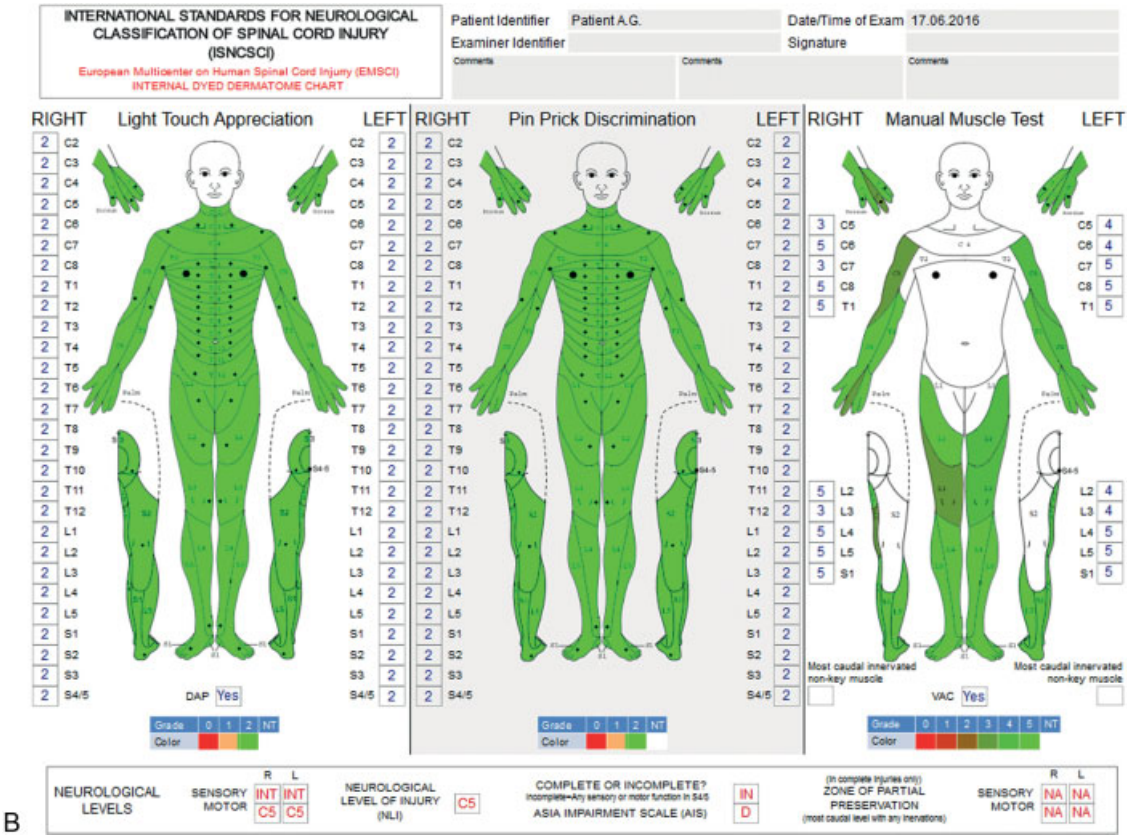

Fig. S4 (*Continued*)

Video 1

Walking performance with HAL (Hybrid Assistive Limb, Cyberdyne, Tsukuba, Japan) body weight-supported treadmill training at baseline and after 12 weeks. (Online content including video sequences viewable at: www.thieme-connect.com/products/ejournals/html/10.1055/s-0036-1593805.)

Video 2

Performance for 10-meter walk test at baseline and after 12 weeks. (Online content including video sequences viewable at: www.thieme-connect.com/products/ejournals/html/10.1055/s-0036-1593805.)

Video 3

Walking performance on stairs after 12 weeks. (Online content including video sequences viewable at: www.thieme-connect.com/products/ejournals/html/10.1055/s-0036-1593805.)

References

1 Rehabilitation Measures Database. Rehab measures: 10 meter walk test. 2014. Available at: http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=901. Accessed June 6, 2016
2 Rehabilitation Measures Database. Rehab measures: 6 minute walk test. 2013. Available at: http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=895. Accessed June 6, 2016
3 Rehabilitation Measures Database. Rehab measures: walking index for spinal cord injury. 2013. Available at: http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=957. Accessed June 6, 2016
4 Rehabilitation Measures Database. Rehab measures: spinal cord independence measure. 2013. Available at: http://www.rehabmeasures.org/Lists/RehabMeasures/PrintView.aspx?ID=967. Accessed June 6, 2016
5 Atkins D, Best D, Briss PA, et al; GRADE Working Group. Grading quality of evidence and strength of recommendations. BMJ 2004; 328(7454):1490
6 Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol 2011;64(4): 401–406