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3 Combined effects of physiotherapy and robotic therapy on gait balance and speed in 4 patients with incomplete spinal cord injury

5 Efeitos combinados da fisioterapia e terapia robótica no equilíbrio e velocidade da 6 marcha em pacientes com lesão medular incompleta 7

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23 ABSTRACT

Restoring the ability to walk, especially independently, is one of the goals in the rehabilitation of 24 25 patients with incomplete spinal cord injury (ISCI). Thus, task-oriented gait training takes into account the fundamental principles of motor learning, involving mechanisms of central 26 neuroplasticity and consequently cortical reorganization. The G-EO System (GS) robotic gait 27 28 training acts as a reinforcer of the repetitive and specific practice of the gait phases. **Objective:** 29 To investigate the combined effects of physiotherapy and robotic therapy on gait functionality in relation to balance and gait speed in patients with ISCI. Methods: Retrospective cohort study 30 31 with 14 patients in the chronic phase of the disease, using the GS as a robotic intervention for 32 gait and stairs, consisting of a 20-session protocol associated with conventional physical therapy. We used the 10-meter Walk Test (10WT) and the Berg Balance Scale (BBS). P values 33 <0.05 were considered statistically significant using the Wilcoxon test at the beginning of 34 conventional physical therapy and before and after intervention. Results: Significant differences 35 between the scales were observed. At the 10WT, the mean initial velocity ranged from 2.60 m/s 36 37 \pm 1.72 at the beginning of conventional physical therapy to 1.57 m/s \pm 0.80 at the end of the 20 38 GS sessions with p = 0.0424. For BBS at the beginning of conventional physical therapy, the average was 31.85 points ± 12.50, and 42.35 ± 14.25 at the end of the 20 GS sessions, with p 39 40 = 0.0096. Conclusions: Robotic gait therapy associated with conventional physiotherapy has 41 been shown to be effective in promoting balance and gait speed improvement in individuals in 42 the chronic phase after involvement of incomplete spinal cord injury.

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44 Keywords: Spinal Cord Injury, Gait, Balance, Physical Medicine and Rehabilitation,
 45 Neurological Rehabilitation, Robotic

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46 RESUMO

47 Restaurar a capacidade de andar é um dos objetivos da reabilitação na lesão medular incompleta (LMI). O treino orientado a tarefa abrange os princípios do aprendizado motor, 48 49 envolvendo mecanismos de neuroplasticidade central e, consequentemente, reorganização 50 cortical. O treinamento da marcha robótica G-EO System (GS) atua como um reforco da prática 51 repetitiva e específica das fases da marcha. Objetivo: Investigar os efeitos combinados da 52 fisioterapia e da terapia robótica na funcionalidade da marcha em relação ao equilíbrio e 53 velocidade da marcha em pacientes com LMI. Métodos: Estudo de coorte retrospectivo com 54 14 pacientes na fase crônica da doença, que realizaram 20 sessões de GS associado à 55 fisioterapia convencional (FC). Utilizamos o Teste de Caminhada de 10 Metros (TC10) e a 56 Escala de Equilíbrio de Berg (EEB). Valores de p <0,05 foram considerados estatisticamente significativos pelo teste de Wilcoxon ao início da fisioterapia convencional e pré e pós 57 58 intervenção. Resultados: Observou-se que no TC10, a velocidade inicial média variou de 2,60 59 m/s \pm 1,72 no início da FC a 1,57 m/s \pm 0,80 no final das 20 sessões de GS com p = 0,0424. 60 Para a EEB no início da FC, a média foi de 31,85 pontos ± 12,50 e 42,35 ± 14,25 ao final da intervenção, com p = 0,0096. Conclusão: A terapia robótica da marcha associada à FC 61 mostrou-se eficaz na promoção do equilíbrio e da melhora da velocidade da marcha em 62 63 indivíduos na fase crônica da LMI.

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65 **Palavras-chave:** Traumatismos da Medula Espinal, Marcha, Equilíbrio, Medicina Física e 66 Reabilitação, Reabilitação Neurológica, Robótica

68 INTRODUCTION

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Restoring and regaining the ability to walk, especially independently, is one of the goals in the 70 rehabilitation of patients with ISCI, due to its great impact on the individual's guality of life, 71 independence and participation in society. Thus, task-oriented gait training¹ takes into account 72 the fundamental principles of motor learning,² involving mechanisms of central neuroplasticity³ 73 and consequently cortical reorganization.^{4,5} From this, robotic gait training allows for repetitive 74 75 practice and specific to the gait phases,^{6,7} knowing that the practice of all phases is necessary for the complete accomplishment of the gait cycle,⁸ we use the GS as reinforcer for the 76 77 occurrence of this process. 78

It is worth remembering that robotic therapy saves the physiotherapist's effort to assist the individual during training, also offering greater security regarding the risk of falls due to gait impairment,⁹ because the GS is seen as a robotic gait rehabilitation device, aimed at for individuals who have a change in lower extremity motor function.¹⁰

Thus, the GS is regarded as a modern robotic gait rehabilitation device¹⁰ based on the modular 84 platform concept from the offer of different modules and therapeutic options,¹¹ such as motion 85 segmentation, gait and stair simulation and switching between modes. passive, active-assisted 86 87 and active.¹⁰ Among the adjustable and controllable parameters that allow treatment 88 effectiveness are: step length and width, gait cadence and speed, ankle angle, step height, dynamic weight support body mass movement, center of body mass movement and horizontal 89 activation of the hips, as well as the detection of the individual's weight loss through the 90 91 platforms,¹⁰ providing detailed reports that allow the assessment of the individual's progress and 92 the progression of the behaviors with the individual.¹¹

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94 GS-powered robotic therapy offers gait training through electrically driven movement 95 mechanisms through two footrest platforms, a bodyweight support structure, an operation panel,

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96 and a computer-controlled operation and control unit.¹⁰ Thus, GS moves the lower limbs of 97 individuals according to a pattern previously determined by the physiotherapist, from the 98 possibilities provided by the software,¹¹ where the mechanics distributed to the feet through the 99 platforms transmit to the lower limbs the stimulus of the lower limbs ground or up and down 100 steps,¹⁰ making the necessary adjustments to bring the walking pattern closer to the functional.⁹

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102 OBJECTIVE

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Thus, The aim of the present study is to investigate the combined effects of physiotherapy and GS robotic therapy on gait functionality in relation to balance and gait speed. The findings may contribute to confirm the efficiency of the protocol used or improve it, as well as increase clinical knowledge in the area and assist in the clinical practice of professionals working with robotic therapy.

110 METHODS

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A retrospective observational study was carried out through the analysis of medical records of institutionalized patients at the IMREA HC FMUSP, São Paulo – Brazil, being approved by the Research Ethics Committee of the University of São Paulo, under opinion CAAE: 96949118.0.0000.0068.

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Thus, 51 records were initially selected for analysis, referring to individuals with ISCI, who 117 performed at least one robotic training session in the GS from July 2013 to December 2018. Of 118 119 these, 10 were excluded for not completing the 20 sessions. therapy in robotic equipment, 3 due to clinical complications during the sessions, 3 for not presenting pre- and post-protocol 120 evaluation data, 2 for being in therapy sessions during the data collection period, 2 for not 121 meeting the eligibility criteria, 2 for having performed GS robotic therapy after the end of physical 122 123 therapy and 1 for participating in an experimental protocol involving the use of biofeedback with 124 the GS.

125 126 Thus, 28 records remained of individuals who completed the 20 robotic therapy sessions, where 127 14 were later excluded due to failure to perform assessments at the beginning of physiotherapy 128 and before or after the 20 sessions of GS. Thus, the analysis of the results was based on a 129 sample of 14 individuals in the chronic phase of ISCI, with a mean age of 42.35 \pm 14.49, 10 men 130 and 4 women.

- The GS robotic gait¹⁰ associated with conventional physical therapy was used as a therapeutic intervention, so that the participating individuals performed two sessions in the week of conventional physical therapy, lasting 50 minutes each, consisting of stretching, strengthening and global mobilization exercises body awareness exercises, independence and safety training for daily living activities, functional, cardiorespiratory and task-oriented training, including the use of functional electrical stimulation, lower limb cycle ergometer.
- For robotic GS therapy, 20 sessions of 20 minutes each, twice a week, were performed, which may include gait, up and down steps, being at the discretion of each physiotherapist about the modality used according to each patient's assessed need. In addition, because this study was retrospective, it was not possible to control the length of time individuals spent performing each GS modality. In addition, the body weight support provided by the suspension present in the equipment was used only as a safety device, through a vest attached to the individual during training.

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As an analysis of the effect before and after robotic gait therapy associated with conventional 146 physiotherapy, we used the 10WT¹² and the BBS.¹³ The medical record evaluations were 147 performed by different researchers who performed the application of the scales during the 148 participation period of the rehabilitation protocol. Data analysis was performed using the 149 150 SigmaStat program, where the normality of the distribution of variables was tested by the 151 Kolgomorov-Smirnov method. However, due to the non-normal distribution of variables, to 152 compare pre and post intervention effects, the Wilcoxon test was used, where p values <0.05 153 were considered statistically significant.

155 **RESULTS**

The sample consisted of 14 individuals, with an average of 33.14 ± 22.01 months of injury, from the episode of the injury and the beginning of robotic therapy, where all had incomplete paraplegia and were classified according to the American Spinal Injury Association (ASIA)¹⁴ as ASIA C and D, that is 3 individuals were identified with an incomplete sensory and motor injury, ASIA C; and 11 as ASIA D due to an incomplete injury with preserved motor function below the injury level.

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From this, Table 1 indicates the initial results of conventional physical therapy, and pre and post
20 sessions of GS robotic therapy associated with it.

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167 It was observed that the individuals showed significant differences in the tests performed. The 10WT presented a mean velocity at the beginning of conventional physiotherapy of 2.60 m / s 168 169 (± 1.72) and at the end of 20 GS sessions of 1.57 m/s (± 0.80) , with p = 0, 0424. At the beginning of GS robotic therapy, it presented a mean velocity of 2.04 (\pm 1.37), with p = 0.0152 when 170 compared to the beginning of conventional physiotherapy and p = 101, which was not significant, 171 comparing at the end of the 20 sessions. GS Regarding BBS, the mean value at the beginning 172 173 of conventional physical therapy was 31.85 points (± 12.50) and 42.35 (± 14.25) at the end of 174 the 20 GS sessions, with p = 0.0096.

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At the beginning of GS robotic therapy, it presented a mean value of $37.57 (\pm 13.05)$, with p = 0.0148 when compared to the beginning of conventional physiotherapy and p = 0.1278, when compared to the end of the 20 GS sessions.

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Table 1. Comparison of results at the beginning of conventional physiotherapy, before and after
 GS robotic therapy

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Scales Used	Variable	N = 14	≠ Start, Pre and Post
		Mean and Standard Deviation	p Value
10WT (m/s)	Start FC	2,607 ±1,72	0,56; p = 0,0152*
Ÿ	Pre 20 sessions GS	2,047 ±1,37	0,473; p = 101*
	Post 20 sessions GS	1,574 ±0,80	1,033; p = 0,0424*
BBS	Start FC	31,857 ±12,50	5,714; p = 0,0148*
	Pre 20 sessions GS	37,571 ±13,05	4,786; p = 0,1278*
	Post 20 sessions GS	42,357 ±14,25	10,5; p = 0,0096*

183 10WT: 10 meter walk test; m/s: meters per seconds; FC: conventional physiotherapy; GS: G-EO System; *: Wilcoxon

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185 **DISCUSSION**

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As mentioned earlier, gait recovery and related functions, such as balance and mobility, are priorities for people with ISCI.¹⁵ Thus, there is a paradigm in the rehabilitation process, where

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specific task training is expected the recovery of an identified and / or desired function.¹⁶ The 189 190 use of conventional physiotherapy together with the GS robotic therapy has brought the 191 possibility of increased gait speed, as well as improvement of static and dynamic balance in different postures in individuals in chronic phase of incomplete paraplegic spinal cord injury. Gait 192 193 training, climbing and descending steps allows task-oriented training and reinforcement of motor memory in the performance of these activities.¹⁷ In addition, the practice of these exercises 194 helps in strengthening the core and lower limb muscles,¹⁷ So that these muscles are essential 195 196 for maintaining balance and consequently influence gait.

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In addition, the use of gait training through robotic therapy is an additional treatment opportunity for individuals with axial disorders, increasing the challenge of training by imposing specific kinematic parameters, and providing intensive and somatosensory cues.¹⁸ Along with this, a good balance is essential for individuals with spinal cord injury (SCI) to regain their mobility and independence.¹⁹

The GS is considered as a robot that has the *end-effector* feature that is through modular platforms attached to the feet of individuals, it modulates the gait in relation to speed and stride length. This equipment allows the person to remain freer to perform the activity when compared to exoskeleton robots. Thus, the GS allows greater trunk oscillations and voluntary activation of the core and lower limb muscles, so that the individual can perform the task with maintaining balance and voluntary control of the adjacent structures.²⁰

With the motor limitations installed after SCI, individuals who remain with the ability to move, 211 212 move with decreased gait speed and resistance, directly impacting their social participation and functional independence.²¹ Therefore, these are indicative important for, since the goal of 213 treatment is to enable them to safely and easily walk with a good functional speed as far as 214 possible.²² Thus, the association of conventional physiotherapy with robotic therapy GS, proved 215 to be effective in improving these aspects in the sample, because the robotic device generates 216 a precise, repetitive and intense cycle of gait phases, also helps in motor relearning through 217 218 neuroplastic promotion of the pathways involved in this process, and functional improvement of 219 this skill.20

221 Along with gait training, the main differential of the GS is the step up and down training, which 222 can in turn increase the muscle strength, coordination, balance and cardiorespiratory conditioning of individuals practicing this mode.¹⁹ concomitantly Therefore, ground gait training 223 224 performed through conventional physiotherapy has been suggested as a positive reinforcer of the tasks performed during robotic therapy, bringing benefits to gait balance and functionality in 225 individuals with incomplete chronic SCI,²² based on In principle, they will not be coupled to a 226 body weight adjuster during their daily gait and associated tasks, where independent weight 227 bearing assists in obtaining physiological adaptations through progressive overload, improving 228 the maintenance of postural orientation and balance during functional walking.²² 229

230 231 Finally, this was the first study conducted and found in the literature using the GS as an adjuvant 232 therapy in the rehabilitation process of the population with chronic incomplete spinal cord injury. In addition, the study has several limitations, including the individual delimitation by each 233 234 physiotherapist of the robotic therapy protocol performed. It is worth remembering that, by 235 performing a retrospective analysis on equipment routinely used in the institution, it was not 236 possible to control the speed used, length of stay in each type of equipment. It was not possible 237 to use a control group, thus making it impossible to describe and separate motor gains due to 238 robotic therapy and conventional therapy. Thus, the present study group is in the process of

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- conducting new research with advances in these aspects, so that in the future new studies areproduced with less limitations.
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Therefore, gait training through robotic therapy and using body weight support has shown promising results, but it is still unclear whether these results are superior to conventional physiotherapy,²³ but what this study shows are the good ones results towards the improvement of the functionality of the individual, from the combined therapies.

246 247 **CONCLUSION**

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The use of GS robotic therapy in gait, climb and descent steps in addition to conventional physiotherapy has been shown to be effective in promoting balance and gait speed in chronic phase individuals with incomplete spinal cord injury, with significant increases in 10WT scores and the BBS. Thus, robotic therapy as a form of intervention made evident the good use of the resource as a complementary therapy to the conventional rehabilitation process, directly implying the improvement of quality of life and functional independence of individuals.

256 257 **REFERENCES** 258

- Taub E, Uswatte G, Elbert T. New treatments in neurorehabilitation founded on basic research. Nat Rev Neurosci. 2002;3(3):228-36. DOI: <u>http://dx.doi.org/10.1038/nrn754</u>
- 262 2. Car JH, Shepherd R. A motor relearning programme for stroke. London: Butterworth
 263 Heinemann; 1987.
- 265 3. Dobkin BH, Firestine A, West M, Saremi K, Woods R. Ankle dorsiflexion as an fMRI paradigm to assay motor control for walking during rehabilitation. Neuroimage. 2004;23(1):370-81. DOI: <u>http://dx.doi.org/10.1016/j.neuroimage.2004.06.008</u>
- Liepert J, Bauder H, Wolfgang HR, Miltner WH, Taub E, Weiller C. Treatment-induced cortical reorganization after stroke in humans. Stroke. 2000;31(6):1210-6. DOI: http://dx.doi.org/10.1161/01.str.31.6.1210
- Luft AR, McCombe-Waller S, Whitall J, Forrester LW, Macko R, Sorkin JD, et al. Repetitive
 bilateral arm training and motor cortex activation in chronic stroke: a randomized controlled
 trial. JAMA. 2004;292(15):1853-61. DOI: <u>http://dx.doi.org/10.1001/jama.292.15.1853</u>
- Barbeau Barbeau H, Wainberg M, Finch L. Description and application of a system for
 locomotor rehabilitation. Med Biol Eng Comput. 1987;25(3):341-4. DOI:
 <u>http://dx.doi.org/10.1007/bf02447435</u>
- 7. Visintin M, Barbeau H, Korner-Bitensky N, Mayo NE. A new approach to retrain gait in stroke patients through body weight support and treadmill stimulation. Stroke.
 1998;29(6):1122–1128. DOI: <u>http://dx.doi.org/10.1161/01.str.29.6.1122</u>
- 285 8. Dobkin BH. Strategies for stroke rehabilitation. Lancet Neurol. 2004;3(9):528-36. DOI: http://dx.doi.org/10.1016/S1474-4422(04)00851-8
- 287

Article in Press

- Hesse S, Waldner A, Tomelleri C. Innovative gait robot for the repetitive practice of floor
 walking and stair climbing up and down in stroke patients. J Neuroeng Rehabil. 2010;7:30.
 DOI: <u>http://dx.doi.org/10.1186/1743-0003-7-30</u>
- 292 10. Reha Technology. G-EO System: training more, more effectively [text on the Internet]. Blue 293 Bell: Reha Technology [cited 2019 out 31]. Available from: 294 https://www.rehatechnology.com/wp-content/uploads/products/GEOSystem/G-EO-295 System-GS-PB 1806 EN web.pdf
- Hesse S, Tomelleri C, Bardeleben A, Werner C, Waldner A. Robot-assisted practice of gait and stair climbing in nonambulatory stroke patients. J Rehabil Res Dev. 2012;49(4):613-22. DOI: <u>http://dx.doi.org/10.1682/jrrd.2011.08.0142</u>
- Salbach NM, Mayo NE, Higgins J, Ahmed S, Finch LE, Richards CL. Responsiveness and predictability of gait speed and other disability measures in acute stroke. Arch Phys Med Rehabil. 2001;82(9):1204-12. DOI: <u>http://dx.doi.org/10.1053/apmr.2001.24907</u>
- 305 Miyamoto ST, Lombardi Junior I, Berg KO, Ramos LR, Natour J. Brazilian version of the 13. 306 balance scale. Braz Med Biol Res. Berg J 2004;37(9):1411-21. DOI: 307 http://dx.doi.org/10.1590/s0100-879x2004000900017
- 309 14. Silva GA, Schoeller SD, Gelbcke FL, Carvalho ZMF, Silva EMJP. Avaliação funcional de 310 pessoas com lesão medular: utilização da Escala de Independência Funcional – MIF.
 311 Texto Contexto Enferm. 2012;21(4):929-36. DOI: <u>https://doi.org/10.1590/S0104-</u> 312 07072012000400025
- Bach Baunsgaard C, Vig Nissen U, Katrin Brust A, Frotzler A, Ribeill C, Kalke YB, et al. Gait training after spinal cord injury: safety, feasibility and gait function following 8 weeks of training with the exoskeletons from Ekso Bionics. Spinal Cord. 2018;56(2):106-116. DOI: http://dx.doi.org/10.1038/s41393-017-0013-7
- 16. Van Kammen K, Boonstra A, Reinders-Messelink H, den Otter R. The combined effects of body weight support and gait speed on gait related muscle activity: a comparison between walking in the Lokomat exoskeleton and regular treadmill walking. PLoS One. 2014;9(9):e107323. DOI: <u>http://dx.doi.org/10.1371/journal.pone.0107323</u>
- 17. Lee SK. The effects of abdominal drawing-in maneuver during stair climbing on muscle activities of the trunk and legs. J Exerc Rehabil. 2019;15(2):224-228. DOI: http://dx.doi.org/10.12965/jer.1938056.028
- 328 Capecci M, Pournajaf S, Galafate D, Sale P, Le Pera D, Goffredo M, et al. Clinical effects 18. 329 of robot-assisted gait training and treadmill training for Parkinson's disease. A randomized Phys 330 controlled trial. Ann Rehabil Med. 2019;62(5):303-12. DOI: 331 http://dx.doi.org/10.1016/j.rehab.2019.06.016
- Morone G, Matamala-Gomez M, Sanchez-Vives MV, Paolucci S, Iosa M. Watch your step!
 Who can recover stair climbing independence after stroke? Eur J Phys Rehabil Med.
 2018;54(6):811-818. DOI: <u>http://dx.doi.org/10.23736/S1973-9087.18.04809-8</u>
- 336

332

291

296

304

308

313

323

327

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- 33720.Esquenazi A, Packel A. Robotic-assisted gait training and restoration. Am J Phys Med338Rehabil.2012;91(11Suppl3):S217-27.DOI:339http://dx.doi.org/10.1097/PHM.0b013e31826bce18
- Wu M, Landry JM, Kim J, Schmit BD, Yen SC, Macdonald J. Robotic resistance/assistance
 training improves locomotor function in individuals poststroke: a randomized controlled
 study. Arch Phys Med Rehabil. 2014;95(5):799-806. DOI:
 <u>http://dx.doi.org/10.1016/j.apmr.2013.12.021</u>

340

350

- 345 346 Neville BT, Murray D, Rosen KB, Bryson CA, Collins JP, Guccione AA. Effects of 22. 347 Performance-Based Training on Gait and Balance in Individuals With Incomplete Spinal 2019;100(10):1888-1893. 348 Cord Injury. Arch Phys Med Rehabil. DOI: 349 http://dx.doi.org/10.1016/j.apmr.2019.03.019
- Mehrholz J, Harvey LA, Thomas S, Elsner B. Is body-weight-supported treadmill training or robotic-assisted gait training superior to overground gait training and other forms of physiotherapy in people with spinal cord injury? A systematic review. Spinal Cord. 2017;55(8):722-729. DOI: <u>http://dx.doi.org/10.1038/sc.2017.31</u>.