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Surface electromyography vs clinical outcome measures after robot-assisted gait training in patients with spinal cord injury after post-acute phase of rehabilitation

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Abstract

Introduction and Objective. Surface electromyography (sEMG) measurements are a valid method for sublesional muscle activity following spinal cord injury (SCI). In the literature there are few reports evaluating the effect of robotic assisted gait training (RAGT) on the sEMG properties change in SCI patients. The aim of this study was to evaluate the influence of RAGT on observed change of sEMG, and in 64 incomplete SCI patients in the sub-acute stage in relation to functional scales.

Materials and Method. In the presented single-centre single arm, single-blinded study, the patients were divided into two groups: experimental group with RAGT (exoskeleton EKSO-GT or Locomat-Pro) and the control group with dynamic parapodium training (DPT). The therapy was conducted in two cycles of three weeks for six days a week, with a seven day break between cycles. Obtained measurements were averaged peak muscle amplitude (AMA) in sEMG and maximal torque (MT) on Luna apparatus (muscle strength testing) and functional scales.

Results. Statistically significant differences between S0 and S1 were only observed for the change in MT values at the knee joint during extension, and positively correlated with American Spinal Injury Association Impairment Scale, lower limb motor score, and functional scales. A statistically increased value of the Walking Index for Spinal Cord Injury (WISCI-II) and motor score after rehabilitation relative to the initial value, was seen after RAGT in comparison to patients with DPT, but AMA did not differ between patients.

Conclusions. sEMG did not provide sufficient information about SCI outcome after RAGT rehabilitation.

Key words

rehabilitation, SCI, sEMG, robotic gait therapy

INTRODUCTION

Although spinal cord injury (SCI) is a relatively rare condition, 20.6 million individuals worldwide experienced SCI in 2019, with an incidence of 0.9 million new cases [1]). However, the injury incurs severe consequences [2], often resulting in permanent disability and limitations in social functioning [3]. The trend of increasing incomplete SCI cases observed in recent years [4] and the better prognosis in these cases [5] have led to new attempts at innovative treatments, and improvement of existing treatments.

Several reports exist regarding the effectiveness of robotic training in improving the functionality of patients with SCI [6–10]. More pronounced effects of robot-assisted gait training (RAGT) are observed in patients with incomplete and early SCI [10]. RAGT may also improve pain relief, spasticity, and cardiopulmonary, urinary, and bowel functions [8, 9, 11], consequently enhancing patient functioning.

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Surface electromyography (sEMG) is a safe and non-invasive diagnostic method for assessing muscle activity. In the literature, the role of sEMG in muscle function assessment proves useful for outlining the abnormal timing of muscular actions during movements (e.g. gait and motor tasks), detecting muscular fatigue, assessing muscle activation appropriateness in specific motor acts, identifying pathological patterns of motor unit behaviour and maximal voluntary activation, and characterising involuntary muscle activations (spasticity) [12]. Only a few studies have evaluated the effects of RAGT on motor function in patients using sEMG [13–18]. Dynamic parapodium training (DPT) is used for conventional gait training in SCI patients, mostly at the thoracic level. However, no study has evaluated sEMG in patients with SCI using DPT.

To the best knowledge of the authors, this is the first comparison in the literature concerning gait training using RAGT vs DPT in the context of sEMG and other outcome measures.

The aim of the study was to evaluate the usefulness of sEMG for outcome measures in patients with subacute SCI

who underwent RAGT, compared with those who underwent DPT. A secondary aim was to correlate sEMG changes with clinical status, as tested using functional scales (including spasticity) and muscle strength testing.

MATERIALS AND METHOD

Study protocol. This study was approved by the Ethics Committee of the District Medical Chamber in Szczecin (Poland) (Approval No. OIL-Sz/MF/KB/452/05/07/2018; Nr OIL-SZ/MF/KB/450/UKP/10/2018).

The study was conducted at the Research Institute for Innovative Methods of Rehabilitation of Patients with Spinal Cord Injury in Kamień Pomorski, Poland. Initially, 121 patients with SCI were included; participation was voluntary, and participants completed an official consent form. Inclusion and exclusion criteria are summarised in Table 1.

Intervention. The study was prospective and single-arm. Patients were assigned according to the toss of a coin to one of two groups: experimental RAGT group (S1), and the control group who underwent DPT (S0). The therapy consisted of a two-stage course, conducted for seven weeks, with a one-week break in the middle (six days/week).

All patients underwent an exercise programme based on conventional therapy, including one hour of exercises using the proprioceptive neuromuscular facilitation method, and additional classical massage, hydromassage, electrostimulation, laser therapy, and dry-CO2-baths. Patients in the S1 and S0 groups underwent 30-minute sessions with the RAGT-exoskeleton EKSO-GT (Model EKSO 1 by Ekso Bionics, San Rafael, CA, USA, manufactured in 2014) or Locomat-Pro (Model LO218 by Hocoma AG, Zürich, Switzerland, manufactured in 2014), and DPT, respectively. A blinded investigator (a physiotherapist who was not involved in the treatment process) was responsible for group allocation. Most patients were allocated to the Locomat group because of a lack of grasping capabilities and trunk stabilisation. The Locomat group with incomplete SCI started with 60% bodyweight support and an initial treadmill speed of 1.5 km/h. Patients with complete SCI started with 90–100% body weight support. For patients using the EKSO-GT, a minimum of 100 steps per session was required.

Classical massage, hydromassage, electrostimulation, laser therapy, and dry-CO2 baths were used as complementary therapies. Electrostimulation was used to strengthen the muscles of the lower limbs at doses ranging from 2–20 Hz and a treatment time of 20 min. Hydromassage and classic muscle massage were performed to reduce muscle tension, treatment duration – 15–30 min. A dry carbonic acid bath was used to improve venous and lymphatic circulation in patients with lower limb oedema, duration of treatment – 10 min. Laser therapy was used to treat inflammation of the tendons, fascia, and tendon sheaths using the following parameters: IR dose/808 nm, 4.0 J/cm^2, treatment time – 5–10 min.

At the beginning (immediately before the intervention) and at the end (immediately after the intervention) of each phase of the treatment programme, patients underwent a thorough clinical examination including scales, such as the American Spinal Cord Injury Association (ASIA) Impairment Scale (AIS) [19], Spinal Cord Independence Measure, version-III (SCIM-III) [20], Walking Index for Spinal Cord Injury WISCI-II [21], Barthel index (BI) [22], and the Modified Ashworth Scale (MAS) [23].

Patients with AIS-A also underwent sEMG, considering the potential risk of progression between the groups, as observed in the literature. Most AIS conversions and motor recoveries occur within the first 6–9 months [5].

The sEMG examination was performed using the Noraxon EMG & S Sensor System twice, at the beginning and end of the seven weeks of therapy. The examination was performed by trained personnel experienced in testing and examining patients using sEMG. Neuromuscular activity was examined in the supine and prone positions. In both positions, body positioning was appropriate to enable free execution of movement, generating tension in individual muscle groups. The actions of the selected muscles were presented in the form of a graph and bar chart (average and maximum activity of the selected muscle during voluntary movement).

The study began with the placement of surface electrodes in previously selected areas of the anatomical fields for superficially located muscles (SENIAM). After shaving, scrubbing, and cleaning the skin surface with isopropyl alcohol, electrodes were placed over the muscle belly at an inter-electrode distance of 20 mm, according to the SENIAM guidelines [24]. The electrode application sites were preprogrammed using Noraxon software. Wireless sensors were attached to the electrodes which transmitted the signals generated by the muscles to a computer. During the test, the patient performed a planned movement of the lower limbs, which was repeated four times. In the last trial, the patient attempted to perform maximal contraction of the tested muscle. The test was performed at the beginning and end of therapy.

Table 1. Study inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
(1) time since injury: from 3 months to 2 years.	(1) high complete tetraplegia and very low paraplegia.
(2) general condition of the patient: conscious, awake and with efficient circulatory and respiratory function.	(2) lack of completed bone fusion after spinal surgery.
(3) patient adapted to upright position (maintaining the upright position for 30 minutes).	(3) burden of general illnesses which are contraindications for rehabilitation (respiratory failure, circulatory failure III and IV class of New York Heart Association (NYHA) and the aforementioned medical conditions).
(4) complete or incomplete SCI (cervical, thoracic or lumbar) with preserved flexion and extension function at the elbow and wrist.	(4) osteoporosis (confirmed by a densitometric test).
(5) no contraindications to rehabilitation, e.g. thrombophlebitis, pulmonary embolism, orthostatic drops of blood pressure, epilepsy, infection.	(5) lower limb length discrepancy of more than 2 cm.
(6) body weight below 120 kg, height from 155 cm to 190 cm.	(6) status post-hip surgery.
	(7) presence of decubitus ulcers.
	(8) presence of skin lesions that may be aggravated by robotic systems.
	(9) severe spasticity (Modified Ashworth Scale (MAS) 4 points) and presence of contractures, which makes it impossible to conduct robotic rehabilitation.
	(10) pre-existing conditions causing neurological disorders, e.g. previous history of traumatic spinal cord injury, spinal stroke, multiple sclerosis, infantile cerebral palsy and others
	(11) symptoms of recurrent autonomic dysreflexia

The incremental amplitude of sEMG potentials measured in microvolts (μV) were evaluated. Data were obtained from the average of the 10 highest peaks in the EMG signal (from a total of four sessions) recorded from the rectus femoris muscle, tensor fasciae latae, and tibialis anterior (from the results obtained from the sEMG examination). The coefficient ratio was calculated as follows: ratio before treatment (average amplitude [muscle] / averaged maximum amplitude) × 100%. The same procedure was applied to the results after rehabilitation.

A Polish robotic device, the LUNA EMG (EGZOTech, Gliwice, Poland), which facilitates muscle strength testing, was used, equipped with integrated torque and position sensors that enable the assessment of dynamometric strength. Luna EMG is used to evaluate and treat patients with neurological deficits [25–32]. With the aid of special extensions placed on a limb, the device records movement parameters (range of motion and force of movement). The movement speed can be limited and set to a constant value.

For both strength tests – the hip joint test (flexion or extension) and the knee test (flexion or extension) – the patients were placed in the supine position. During knee joint testing, the patient's lower leg was placed beyond the edge of the treatment table. To evaluate the hip joint, the axis of extension was placed at the level of the axis of rotation of the joint near the greater ileum of the femur. The pressure point was placed at the distal extension near the knee joint. During knee evaluation, the axis of rotation was aligned with the knee joint axis, and the pressure point was positioned at the level of the upper ankle joint.

Muscle force was tested using the isokinetic mode of the device and visualised using torque, which is the length of the arm (distance between the rotation point of the device extension, to which the limb has been attached, and the pressure point) and the force exerted by the patient, expressed in Nm. The length of the force arm was a constant value for each patient at pre-test and post-test. The only variable measured during the study was the force generated by the patients.

The maximum muscle force torque (MT) was recorded when the patient performed three consecutive movements in the joint. During the tests, the evaluator instructed the patients to perform certain movements as fast as possible to evaluate the maximum strength and preset maximum speed of the movements, which was set at 50 °/s.

Statistical analysis. The collected data were summarised using the mean and standard deviation for normally distributed continuous variables or the median and interquartile range (IQR) for skewed continuous variables. The number of observed cases and percentages were presented as nominal variables. Groups were compared using the Mann–Whitney U test or regression analysis, with the baseline value of the response variable as a confounder. Pearson's linear correlation was used for normally distributed variables, and Kendall's or Spearman's rank correlation was used for skewed and ordinal variables, respectively. The results were considered significant at a significance level of $p<0.05$.

Statistical analysis, data preparation, and visualisation were performed using R software (R Core Team, 2021; R – Language and environment for statistical computing (R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/), supplemented with the following packages: readxl [33], ggplot2 [34], qwraps2 [35], rmarkdown [36], ggpubr [37], huxtable [38], and tidyverse [39]).

RESULTS

Participants. Overall, 121 participants met the inclusion criteria and were included in the study. A total of 16 patients did not complete the initiated cycle of therapy owing to the lockdown related to the COVID-19 pandemic (Fig. 1). These patients were excluded. The study finally included 105 patients with SCI (41 with complete SCI and 64 with incomplete, respectively), aged 12–68 years. No significant differences were observed between the S0 and S1 groups. The characteristics of the complete and incomplete SCI groups are presented in Tables 2 A and 2 B, respectively.

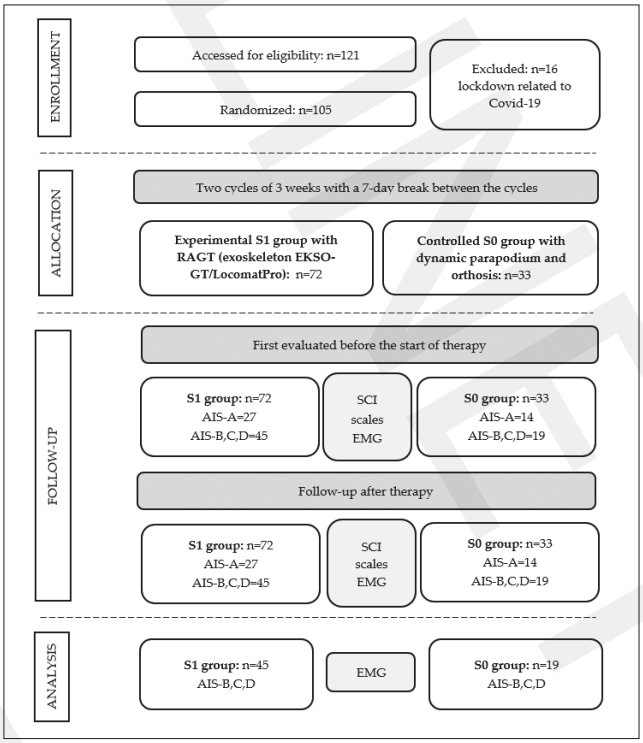


Figure 1. Flowchart of patient recruitment

Outcome measures. Table 3 shows the comparison of AMA and MT values after rehabilitation from the baseline between patients with incomplete and complete SCI. Patients with incomplete SCI showed a significantly greater increase in MT after rehabilitation than at baseline. Statistically significant differences in MT were observed in hip joint flexion and extension, right knee flexion, and extension in bilateral movements in patients with SCI (Tab. 3). Moreover, a greater increase in AMA levels was observed in patients with incomplete SCI. The difference was statistically significant only for the left hip flexor of the rectus thigh ($p=0.025$) (Tab. 3).

The effectiveness of S1 versus S0 rehabilitation in patients with incomplete SCI was evaluated by comparing changes in sEMG and muscle force torque values for each muscle and parameters of movement relative to baseline. The analysis did not reveal significant differences in the change of AMA ratios between the S1 and S0 groups (Tab. 4). However, regarding

Table 2. Characteristics of S1 and S0 groups of patients with complete (A) and incomplete (B) SCI

A

	S0 (N = 14)	S1 (N = 27)
Age		
n; Median (3rdQ, 1stQ)	37.00 (29.25, 45.50)	25; 36.00 (29.00, 49.00)
Gender		
Female	2 (14.29%)	4 (14.81%)
Male	12 (85.71%)	23 (85.19%)
Cause of the injury		
traffic accident	5 (35.71%)	9 (33.33%)
fall from a height <1 meter	0 (0.00%)	2 (7.41%)
fall from a height >1 meter	6 (42.86%)	13 (48.15%)
jump into water	1 (7.14%)	0 (0.00%)
crushing	1 (7.14%)	0 (0.00%)
other	1 (7.14%)	3 (11.11%)
Level of neurological damage		
cervical	1 (7.14%)	0 (0.00%)
thoracic	11 (78.57%)	23 (85.19%)
lumbar	2 (14.29%)	4 (14.81%)
Time from accident to start of training (months)		
Median (3rdQ, 1stQ)	12.50 (8.00, 22.75)	13.00 (9.50, 16.50)
Initial WISCI II		
Median (3rdQ, 1stQ)	0.00 (0.00, 0.00)	0.00 (0.00, 3.00)
Initial SCIM III		
Median (3rdQ, 1stQ)	63.00 (44.75, 67.50)	63.00 (58.50, 65.50)
Initial Barthel		
Median (3rdQ, 1stQ)	70.00 (48.75, 70.00)	65.00 (55.00, 70.00)
Initial MS		
Median (3rdQ, 1stQ)	50.00 (50.00, 54.00)	50.00 (50.00, 52.00)

B

	S0 (N = 19)	S1 (N = 45)
Age		
Median (3rdQ, 1stQ)	36.00 (53.25, 26.25)	34.00 (43.00, 29.00)
Gender		
Female	3 (15.79%)	10 (22.22%)
Male	16 (84.21%)	35 (77.78%)
Cause of the injury		
traffic accident	8 (42,11%)	15 (33,33%)
fall from a height <1m	2 (10 %)	2 (4.44%)
fall from a height >1m	3 (15.79 %)	11 (24.44%)
jump into water	0 (0 %)	4 (8.89%)
crushing	3 (15.79%)	0 (0 %)
other	3 (15.79 %)	13 (28.89 %)
Level of neurological damage		
cervical	6 (31.58%)	17 (37.78%)
thoracic	6 (31.58%)	9 (20.00%)
lumbar	7 (36.84%)	19 (42.22%)
Time from accident to start of training (months)		
Median (3rdQ, 1stQ)	13.00 (20.00, 12.00)	13.00 (22.00, 10.00)
AIS		
B	4 (21.05%)	7 (15.56%)
C	11 (57.89%)	13 (28.89%)
D	4 (21.05%)	25 (55.56%)
Initial WISCI II		
Median (3rdQ, 1stQ)	3 (5.5, 0)	12 (15, 5)
Initial SCIM III		
mean ±sd	57.58±19.55	70.56±18.05
Initial Barthel		
Median (3rdQ, 1stQ)	55 (70, 37.5)	80 (95, 65)
Initial MS		
mean ±sd	67.5±14.45	71.47±14.08

1stQ – lower quartile; 3rdQ – upper quartile; AIS – American Spinal Cord Injury Impairment Scale (types A, B, C, D); N – number of respondents; SCIM-III – Spinal Cord Independence Measure, version III; S0 – control group; S1 – experimental group; sd – standard deviation; WISCI-II – Walking Index for Spinal Cord Injury, version II

MT, better outcomes were associated with S1 rehabilitation for the right knee joint during extension movement (average of 4.26 for patients assigned to S1 rehabilitation), compared to S0 ($p<0.05$) (Tab. 4).

Figure 2A-B illustrates the correlations between MT and the functional and neurological scales for left and right knee extension. There was no correlation between MT and WISCI-II, SCIM-III, BI, MS (right or left hip joint), or AMA and WISCI-II, SCIM-II, or BI (right or left knee or hip joint). Similarly, no correlation was observed between the investigated changes in AMA and MT and age or time since the accident ($p>0.05$). Left hip flexion data were not provided because of a lack of correlation.

Comparison was made between the percentages of patients with different levels of spasticity measured using the MAS before and after rehabilitation in patients with complete and incomplete SCI, based on rehabilitation types S1 and S0. No significant differences were observed, either before or after rehabilitation in any of the analysed groups. Subsequently, it was investigated whether the spasticity status after rehabilitation changed from baseline. No patient with complete SCI showed an improvement in spasticity after rehabilitation. Additionally, most patients with incomplete SCI (Fig. 3) exhibited the same level of spasticity before and after rehabilitation (Fig. 3, green areas). However, a higher percentage of RAGT patients showed improvement compared to the DPT group, but the difference was not statistically significant. There was no correlation between spasticity level and sEMG parameters.

DISCUSSION

Uniqueness of the study. To the authors' knowledge, this is the first study to report sEMG testing of the lower limb muscles in a large group of patients with SCI undergoing RAGT. There are also no comparative studies of RAGT and DPT. This topic is important because DPT is still used in Poland at home for patients with SCI. Moreover, this is the first study utilising the LUNA EMG device to evaluate

Table 3. Comparison between sEMG changes - averaged muscle amplitudes (AMA) ratios in % (using the Noraxon EMG&Sensor System) and maximal muscle force torque (MT) expressed in Nm (using LUNA); after rehabilitation from baseline in patients with incomplete and complete spinal cord injury.

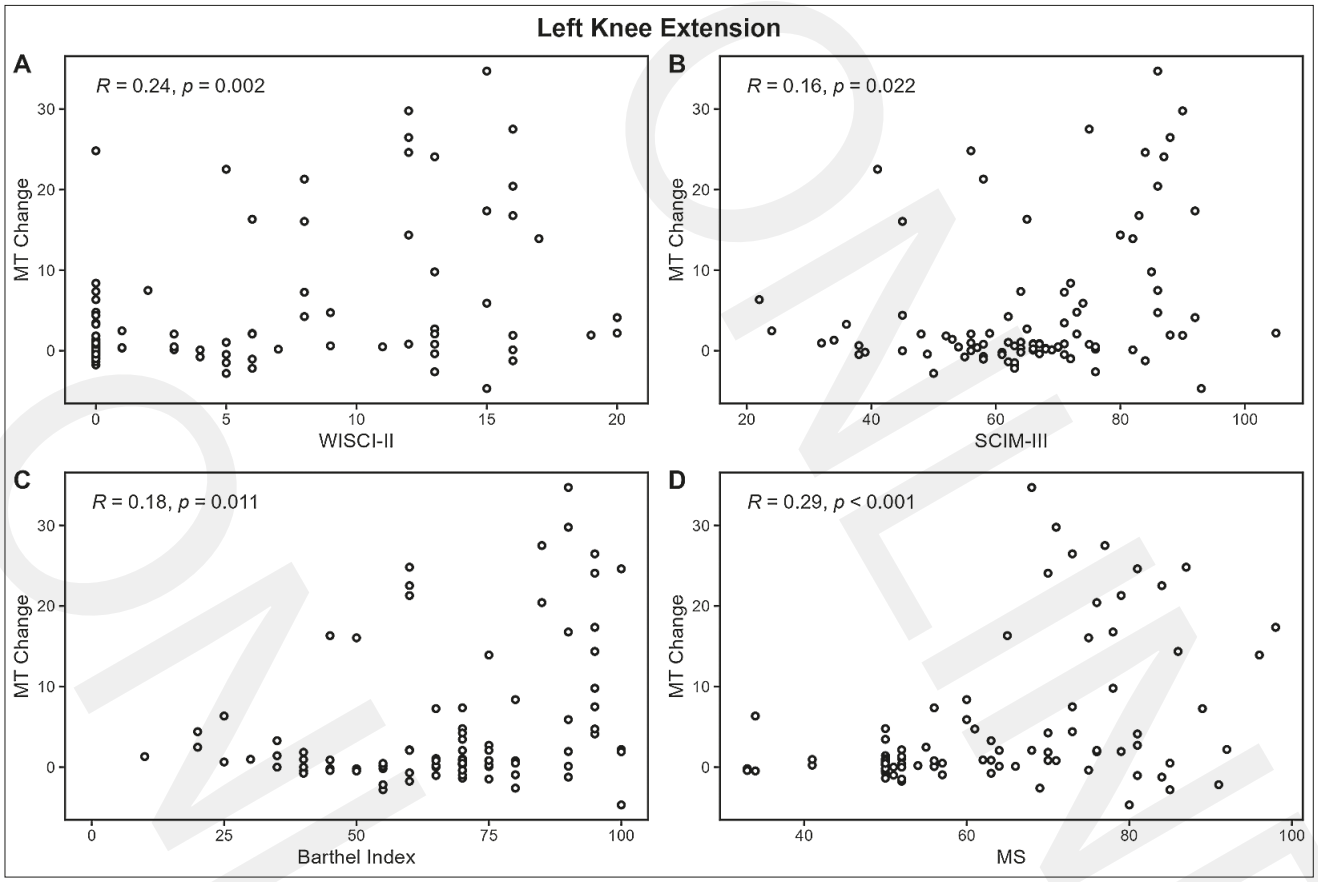
		COMPLETE SCI (N = 41) MEDIAN (IQR)			INCOMPLETE SCI (N = 64) MEDIAN (IQR)			
		Baseline mean – max Ratio [%]	After rehabilitation mean – max Ratio [%]	Change after rehabilitation from baseline [%]	Baseline mean – max Ratio [%]	After rehabilitation mean – max Ratio [%]	Change after rehabilitation from baseline [%]	p-Value*
AVERAGED MUSCLE AMPLITUDES (AMA)	Hip flexors Rectus femoris Right	69.255 (38.720)	65.253 (35.048)	-7.647 (20.152)	42.722 (12.128)	42.941 (12.740)	-1.923 (31.732)	0.278
	Hip flexors Rectus femoris Left	64.687 (30.947)	58.307 (35.077)	-13.948 (33.778)	40.648 (15.043)	42.382 (15.376)	-2.328 (29.167)	**0.025**
	Hip flexors Tensor fasciae latae Right	45.697 (35.949)	53.375 (30.826)	-5.167 (57.255)	40.346 (12.372)	41.329 (14.311)	3.664 (36.025)	0.798
	Hip flexors Tensor fasciae latae Left	54.811 (32.196)	49.451 (27.470)	-26.656 (61.161)	40.494 (17.118)	43.980 (15.460)	-11.260 (47.140)	0.152
	Knee extensors Rectus femoris Right	69.558 (31.259)	62.786 (30.905)	-10.633 (35.548)	44.164 (12.437)	45.462 (10.047)	-1.155 (32.603)	0.320
	Knee extensors Rectus femoris Left	63.953 (39.070)	65.368 (32.201)	-4.183 (41.756)	43.496 (14.713)	45.333 (11.360)	1.639 (26.135)	0.567
	Foot dorsal flexors Tibialis anterior Right	71.951 (25.728)	72.354 (33.010)	1.357 (41.257)	43.317 (17.620)	46.345 (19.961)	9.395 (33.146)	0.267
	Foot dorsal flexors Tibialis anterior Left	69.426 (34.131)	70.588 (32.319)	-9.158 (50.135)	44.570 (15.533)	45.809 (24.451)	1.774 (44.482)	0.766
MAXIMAL MUSCLE FORCE TORQUE (MT)	MT Hip joint Right flexion	1.95 (5)	1.53 (5.62)	**0.09 (1.98)**	21.75 (28.02)	31.12 (41.57)	**3.05 (9.78)**	**0.002**
	MT Hip joint Left flexion	1.48 (5.67)	2.39 (8.38)	**0.29 (2)**	17.09 (27.73)	23.04 (31.87)	**1.36 (9.47)**	0.29
	MT Hip joint Right extension	2.47 (5.42)	2.49 (6.03)	**-0.01 (2.02)**	24.45 (35.31)	43.51 (51.76)	**2.68 (15.88)**	**0.002**
	MT Hip joint Left extension	1.48 (7.19)	2.2 (10.22)	**0.09 (1.77)**	30.66 (33.01)	39.32 (29.35)	**1.46 (5.13)**	0.08
	MT Knee joint Right flexion	1.38 (0.81)	1.54 (1.47)	**0.1 (1.33)**	10.79 (25.16)	11.38 (24.77)	**0.5 (4.08)**	0.81
	MT Knee joint Left flexion	1.29 (1.16)	1.26 (1.04)	**0.14 (0.94)**	7.13 (11.17)	9.36 (15.29)	**0.97 (5.43)**	**0.035**
	MT Knee joint Right extension	1.31 (0.79)	1.36 (0.96)	0.12 (1.09)	14.63 (40.22)	27.38 (43.3)	1.19 (6.04)	**0.008**
	MT Knee joint Left extension	1.39 (1.15)	1.41 (1.34)	0.22 (1.34)	11.03 (31.8)	16.35 (41.9)	2.13 (13.54)	**<0.001**

Abbreviations: IQR – Interquartile Range, L – left side, N – number of respondents, p – statistical significance level, R – right side, SCI – Spinal Cord injury, MT maximal torque; *p value for comparison of "Change after rehabilitation from baseline" between patients with complete and incomplete SCI.
Change after rehabilitation from baseline = Value after rehabilitation – Baseline Value

Table 4. Changes in sEMG (AMA: averaged muscle amplitudes of selected muscles ratios in %, using using the Noraxon EMG&Sensor System) and maximum and averaged muscle force torque parameters (MT expressed in Nm assessing the strength of extensor and flexor muscles at the hip and knee joints during joint extension and flexion movements, using LUNA) after rehabilitation relative to baseline between groups in incomplete SCI patients

		S0 (N = 19)			**S1 (N = 45)**			
		Baseline mean – max Ratio [%] Median (IQR)	After rehabilitation mean – max Ratio [%] Median (IQR)	Change after rehabilitation from baseline [%] Median (IQR)	Baseline mean – max Ratio [%] Median (IQR)	After rehabilitation mean – max Ratio [%] Median (IQR)	Change after rehabilitation from baseline [%] Median (IQR)	P value
AVERAGED MUSCLE AMPLITUDES	Hip flexors Rectus femoris Right	42,504 (12,814)	47,515 (10,033)	6,712 (26,863)	42,966 (11,966)	42,484 (11,588)	-3,342 (33,141)	0,743
	Hip flexors Rectus femoris Left	38,623 (17,934)	41,748 (11,069)	5,002 (49,622)	41,632 (15,049)	43,243 (17,052)	-4,511 (28,043)	0,722
	Hip flexors Tensor fasciae latae Right	38,655 (14,733)	43,396 (13,706)	9,969 (50,937)	42,097 (11,308)	40,816 (14,774)	0,379 (31,597)	0,180
	Hip flexors Tensor fasciae latae Left	40,494 (14,75)	46,644 (12,439)	-13,165 (46,419)	40,948 (19,279)	41,525 (14,334)	-7,047 (40,233)	0,667
	Knee extensors Rectus femoris Right	42,074 (6,53)	43,763 (9,503)	0,274 (26,101)	45,457 (13,066)	45,829 (10,01)	-1,155 (31,088)	0,809
	Knee extensors Rectus femoris Left	38,743 (9,879)	45,727 (6,688)	7,891 (44,862)	45,517 (13,077)	44,851 (11,409)	-0,032 (26,665)	0,253
	Foot dorsal flexors Tibialis anterior Right	49,815 (20,281)	44,797 (22,024)	19,809 (21,927)	41,642 (16,092)	47,236 (19,193)	9,06 (31,822)	0,859
	Foot dorsal flexors Tibialis anterior Left	51,323 (26,194)	53,333 (26,517)	-3,322 (42,46)	43,786 (13,187)	44,151 (16,645)	3,688 (41,267)	0,302
		S0 (N = 19) Mean ± SD or median (1stQ, 3rdQ)			S1 (N = 45) Mean ± SD or median (1stQ, 3rdQ)			Unadjusted Analysis	Adjusted Model$
		Baseline	After rehabilitation	Change after rehabilitation from baseline	Baseline	After rehabilitation	Change after rehabilitation from baseline	S1-S0 Difference of Change after rehabilitation (SE)	S1-S0 Difference of Change after rehabilitation (SE)
MAXIMUM MUSCLE FORCE TORQUE (MT)	Knee Extension Right	7.64 (2.20, 16.52)	5.46 (1.56, 15.55)	0.12 ± 4.35	29.50 (4.48, 44.74)	41.05 (4.18, 46.87)	4.60 ± 6.72	4.482 *(1.809)	**4.258 *** (1.651)
	Knee Extension Left	5.33 (2.58, 16.09)	6.59 (2.72, 16.34)	4.81 ± 9.18	17.24 (4.19, 40.82)	33.04 (7.80, 51.47)	8.03 ± 9.99	3.220 (2.856)	1.668 (2.971)
	Knee Flexion Right	7.72 (2.22, 11.41)	3.05 (1.56, 9.51)	-0.14 ± 3.52	14.98 (4.56, 30.32)	15.13 (2.81, 32.78)	1.41 ± 8.73	1.550 (2.256)	1.848 (2.413)
	Knee Flexion Left	4.66 (1.89, 8.09)	4.97 (3.15, 8.97)	1.55 ± 3.17	9.66 (3.39, 16.70)	10.09 (3.83, 23.10)	3.15 ± 5.72	1.606 (1.513)	1.191 (1.585)
	Hip Extension Right	13.23 (6.08, 30.87)	14.51 (2.69, 44.91)	3.15 ± 10.07	27.06 (14.61, 54.31)	48.36 (22.00, 62.23)	8.88 ± 14.81	5.730 (3.909)	6.548 (4.037)
	Hip Extension Left	14.93 (6.41, 19.73)	12.94 (4.82, 40.07)	0.93 ± 7.40	37.55 (14.55, 40.83)	40.47 (16.54, 43.12)	4.11 ± 10.10	3.184 (2.697)	4.676 (2.765)
	Hip Flexion Right	9.81 (4.13, 22.01)	9.90 (7.34, 32.87)	3.63 ± 7.28	28.60 (12.64, 49.53)	35.66 (20.47, 52.80)	11.92 ± 46.66	8.291 (11.427)	4.135 (12.069)
	Hip Flexion Left	13.00 (4.53, 16.17)	14.71 ± 14.47	0.94 ± 7.28	24.76 ± 18.16	29.30 ± 19.76	4.77 ± 8.21	3.832 (2.276)	3.924 (2.391)

Abbreviations: 1stQ: lower quartile; 3rdQ: upper quartile, SD: standard deviation; sEMG: surface Electromyography, S0: Control Group, S1: Study Group; *p value for comparison of "Change after rehabilitation from baseline" between patients after S1 and S0 rehabilitation; *** p < 0.001; ** p < 0.01; * p < 0.05; (SE – standard error); $ Regression analysis adjusted to Baseline AT.



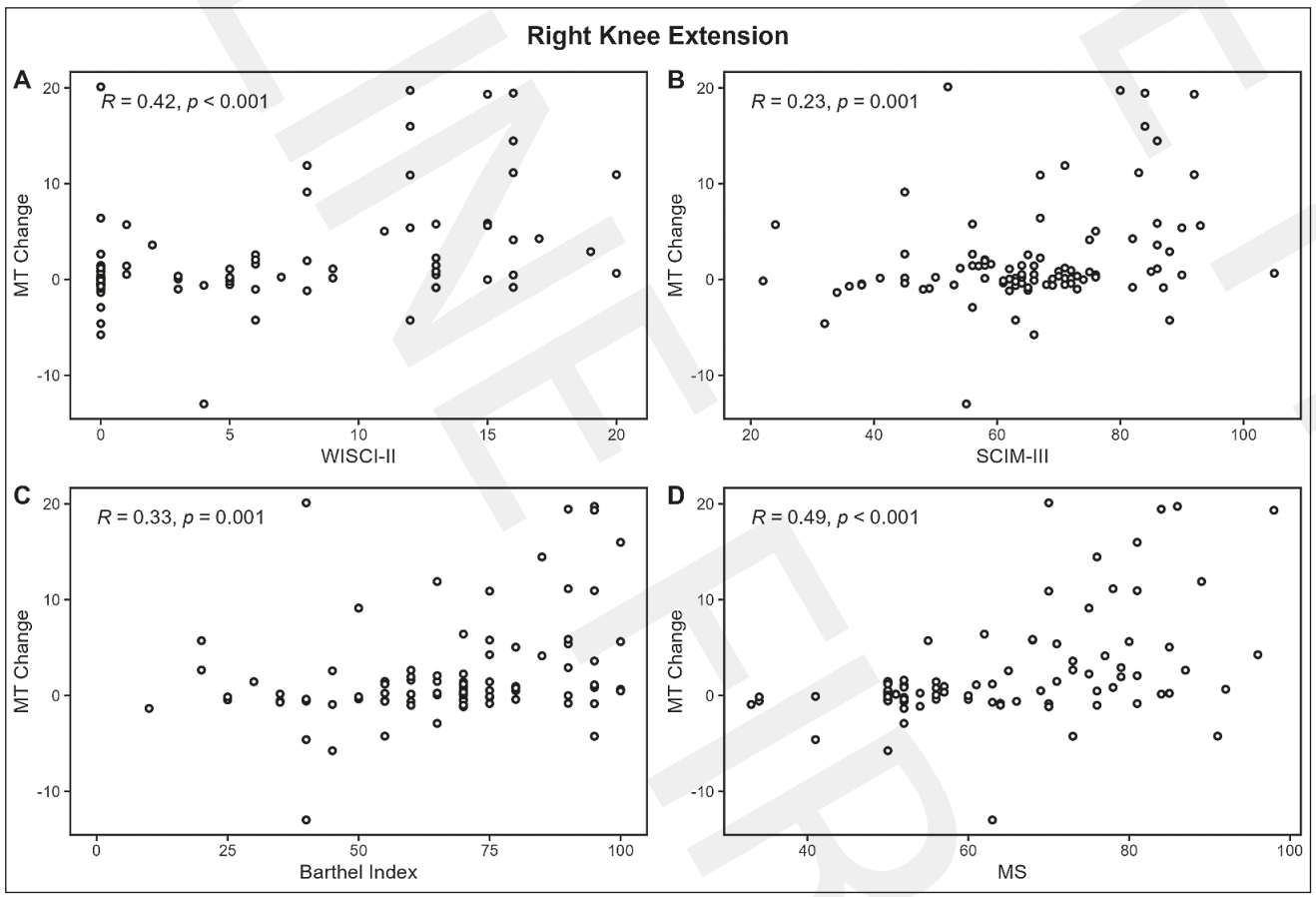


Figure 2. Correlation between functional parameters (scales) for muscle force torque (MT) values changes after rehabilitation from baseline. (A) Left knee extension (B) Right knee extension; ns p>0.05; *p≤ 0.05; ** p≤ 0.01; *** p≤ 0.001

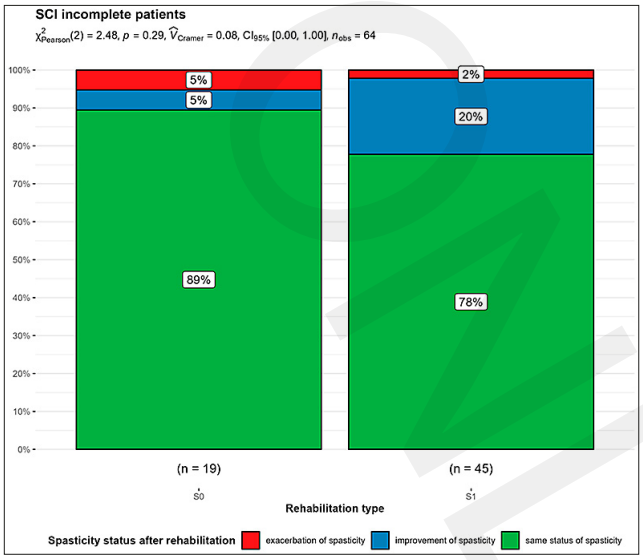


Figure 3. Spasticity in the Modified Ashworth Scale after rehabilitation in investigated groups, and changes from baseline in patients with incomplete SCI

patients with SCI. This apparatus has proven to be more sensitive for studying muscle-related changes in patients compared to a device with only surface EMG evaluation functions.

sEMG changes and types of rehabilitation (RAGT vs DPT) in patients with SCI. sEMG parameters can be used as relevant measures of muscle activity in post-SCI patients [40]. Additionally, reports suggest that the usefulness of sEMG in neuro-rehabilitation is currently more important for researchers than for clinicians, and that sEMG provides information on neuromuscular function that is not provided by other assessment techniques or tools in neurorehabilitation [12].

In the current study, greater increases in sEMG parameters (especially MT using LUNA EMG from EGZOTech) were observed in patients after RAGT. RAGT has proven to be a superior method, as evidenced by changes in WISCI-II and MS in both types of rehabilitation (RAGT compared with DPT). Conversely, the observed negative increase in AMA (using the Noraxon EMG&S and Sensor System) after rehabilitation relative to baseline in patients with incomplete or complete SCI, may be attributed to the high level of muscle fatigue after seven weeks of therapy, which was observed clinically in the current study, especially in patients who underwent RAGT. Calancie et al. observed moderate levels of deterioration in EMG findings at time-points more than one year after SCI in 21% of patients with incomplete SCI from C- and Th-segment levels, with no 'delayed deterioration' observed in patients with complete C-segment SCI [41]. Chronic SCI may also be associated with long-term complications. In this study, approximately 65% of patients in the study groups with chronic SCI (>12 months post-SCI) had incomplete SCI; however, no long-term study was performed.

Patients with SCI may be at a higher risk of susceptibility to fatigability [42, 43] in response to activity due to the potential for altered autonomic nervous system function [44]. The intense muscle force associated with the DPT may lead to fatigue. Exaggerated movements of the upper torso and limbs were observed during DPT therapy. Because this device does not support movement, it requires more patient involvement. Excessive movement of the trunk and limbs during walking may result in higher energy expenditure for the patient. The half-hour motor training set for therapy may be excessively exhausting for patients undergoing DPT, and less exhausting for those undergoing RAGT.

Statistically significant differences between S0 and S1 were observed only for the change in the MT at the knee joint during extension. The change in MT at the knee joint during extension after rehabilitation also correlated with parameters related to MS, WISCI-II, SCIM-III, and BI. This indicates that knee joint kinematics and associated muscle strength may play a crucial role in patients with SCI. In contrast, the asymmetrical distribution of statistically significant changes in the sEMG of the lower limb muscles after rehabilitation relative to the initial value between the two study groups, confirms that good or better function of the quadriceps femoris in at least one lower limb is required for good motor function in patients after SCI [44].

Analysis of EMG parameters in patients with incomplete SCI has shown a greater benefit after RAGT [10]. Additionally, the observed differences in sEMG parameters coincide with improvements in clinical SCI-specific scales [40]. In the current study, positive correlations were observed only between MT changes in the knee joint and the clinical outcome parameters (AIS, MS, WISCI-II, SCIM-III, and BI). The finding of positive correlations of measurable results of the above-mentioned clinical parameters with LUNA EMG muscle strength testing undoubtedly emphasises its importance in the light of quantitative methods of assessing clinical improvement, and confirms its clinical significance in patients with SCI as an indicator of the return of muscle strength [41, 45].

Conversely, no correlation was observed in the current study between these parameters, and age or time since SCI. This result was inconsistent with those reported by other researchers [46, 47]. However, it should be noted that these studies included measurements of parameters other than sEMG, and were methodologically different from the current research. Furthermore, the aim of the study was not to track changes in EMG recordings over time, but to compare robotic therapy at two time-points.

Spasticity versus robotic gait training. Clinical analysis of muscle activity is necessary to determine whether intervention is warranted and, in particular, to ascertain the degree of post-treatment reduction of the spastic component. In this study of patients with incomplete SCI undergoing RAGT, spasticity diminished; however, the difference was not statistically significant. In a meta-analysis by Fang et al., the spasticity score significantly improved in the RAGT group in non-randomized controlled trials (non-RCT), whereas the RCTs did not show a significant reduction in spasticity in the RAGT group [48]. However, differences in the methodologies of the studies included in their meta-analysis, precluded a precise comparison with the current study.

LIMITATIONS OF THE STUDY

Study structure and design. This study was performed at a single centre, and a deeper analysis of the described problem would require multicentre or international studies. However,

the fact that the patients recruited for the study were from different parts of Poland is significant.

Moreover, the lack of long-term follow-up beyond the end of the intervention undoubtedly represents a limitation of tes study. The patients who participated at the research centre in Kamień Pomorski came from different parts of the country, including from remote corners of Poland. Conducting a follow-up of the patients would have been difficult because of the aforementioned geographical distance and severity of the clinical condition of the SCI itself. Therefore, follow-up assessments were omitted during the planning stage of this study.

Gait training in patients was performed using two different types of robotic therapies (exoskeleton EKSO-GT or Locomat-Pro). However, limitations in the applicability of the exoskeleton in patients with high cervical SCI and the severity of the SCI prompted the inclusion of Locomat, which can guide the patient's legs in an efficient and effective gait pattern. Thus, sEMG analysis is also possible in patients with severe SCI. Additionally, all factors that could potentially affect the statistical analysis, such as SCI complications and pain, were excluded.

Statistical analysis. A notable limitation of this study was the lack of a control group comparable in number to the study group. All patients who expressed interest in being allocated to the RAGT group withdrew from rehabilitation efforts post-randomisation. Therefore, those patients were excluded from the study and no data collection was conducted.

Further, the density of the bioelectrical signal was not assessed owing to mathematical analysis constraints.

Shortcomings of sEMG. Human locomotion is characterised by high intra-individual variability, and sEMG patterns may vary in patients with SCI [49]. Hence, some interpretative difficulties may arise in sEMG studies. Analysing sEMG during actual movements provides an opportunity to obtain more reliable results. Furthermore, a detailed analysis of a larger group of lower-limb muscles involved in walking, considering the action of both agonists and antagonists, may alter the study results. In addition, the results showed no correlation with the severity of spasticity in patients, which may have influenced the interpretation of the study results.

sEMG is an informative complement to current clinical testing and is mostly restricted to amplitude-based calculations; however, this has not yet been fully utilised. The development of sEMG systems and a wider range of metrics obtainable from such systems could contribute to a more comprehensive description of their effects on SCI motor function [50]. Additionally, other barriers limit the use of sEMG, such as the time-consuming aspects of sEMG, lack of confidence in using sEMG technology, lack of demand from clinicians for sEMG systems, and the need for a multidisciplinary approach for data interpretation [51].

CONCLUSIONS

sEMG may be a valuable addition to the basic examination of patients following SCI (functional and neurological scales). However, muscle fatigue, which is observed in patients with SCI after DPT more than after RAGT, may pose a challenge to conducting the sEMG test. The rehabilitation programme of six days per week may have been excessively intensive for many patients with SCI; therefore, perhaps cycles of three times per week, for example, should be recommended.

Knee joint kinematics is an important parameter for evaluating patients undergoing RAGT which has the potential to alleviate spasticity in patients with incomplete SCI.

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Conflict of Interest

A.P. and M.M. are employees of EGZOTech in Gliwice, Poland, which designed the Luna EMG device. This fact may be considered a possible conflict of interest; nevertheless, employees of EGZOTech were not included in direct activities related to 563+ study protocol (patient recruitment, data collection, and results analysis), but only supported the researchers by providing consultations regarding the surface EMG technology that EGZOTech developed as a company, and provided the equipment for the purpose of this study.

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