Acta Kinesiologica 20 (2026) Issue.1
DOI. 10.51371/issn.1840-2976.556

Original Investigation

Effects of a 6-week Lokomat® intervention on paretic and non-paretic lower-limb force in subacute stroke patients

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Purpose: The main purpose of the study was to investigate the effects of Lokomat® intervention on paretic and non-paretic lower-limb force (L-FORCE) in subacute stroke patients.
Methods: For this observational, case-control study, we recruited 13 subacute stroke patients (age = 53.38 ± 8.78 years, 38.50% women) who experienced a stroke <2 months prior an intervention. Pre-post changes for Lokomat® system in hip and knee flexion and extension movements were observed.
Results: At baseline, no significant differences between left and right leg in hip flexion (*Z* – value = 0.002, *P*= .998), hip extension (*Z* – value = 0.526, *P*= .609), knee flexion (*Z* – value = -1.056, *P*= .314) and knee extension (*Z* – value = 0.043, *P*= .967) were found. Over a period of 6 weeks, the Lokomat® guided intervention non-significantly increased hip flexion torques in paretic leg (ES = .18, *P*= .716) and non-paretic leg (ES = .38, *P*= .056). For knee flexion, non-significant increases for paretic leg (ES = .24, *P*= .225) and non-paretic leg (ES = .22, *P*= .291) were observed. Results for hip extension indicated non-significant increases for paretic leg (ES = .23, *P*= .269) and non-paretic leg (ES = .35, *P*= .095). Similar to other movements, non-significant increases were shown for paretic leg (ES = .15, *P*= .744) and non-paretic leg (ES = .26, *P*= .229) in knee extension. Non-significant differences in pre-post changes between paretic and non-paretic leg were observed for hip flexion (*P*= 0.442), hip extension (*P*= .055), knee flexion (*P*= .477) and knee extension (*P*= .554).
Conclusions: A 6-week Lokomat® intervention produced small positive changes in flexion and extension hip and knee movements for paretic and non-paretic leg in subacute stroke patients. Thus, the Lokomat® is able to detect and measure changes within a certain joint and between paretic and non-paretic limb.

Key words: Biomechanics; Force; Neurorehabilitation; Locomotion therapy; Stroke.

Introduction

Stroke is considered the second leading cause of death globally, with a mortality rate between 11 and 12%.[1] It is estimated that in 2020, the incidence of stroke was around 68 million people.[2] On the economic side, the medical costs associated with stroke are projected to double by 2035, from 36.7 to over 90 billion US dollars, making it one of the diseases with the highest cost of hospitalization and treatment.[2] Although the incidence of stroke has decreased in the last few decades due to the good implementation of effective strategies for the prevention of cerebral and cardiovascular risk factors,[3] the positive trend is most often seen in developed countries.[4] On the other hand, evidence suggests that stroke rates are still high, but remain partially unknown in transitional countries, because of undefined protocols for effective rehabilitation. After a stroke development, research has shown that 70 to 80% of patients require rehabilitation and long-term health care.[6]

Continuous and professionally guided rehabilitation is the foundation of rapid recovery after stroke.[7] Available rehabilitation techniques such as drug therapy, physical and proprioceptive musculoskeletal manual therapy have not received convincing evidence of their full effectiveness, most often due to the pathophysiological heterogeneity of patients, the certain complexity and cost of the intervention, and the indecision about the recommended dose, time period of therapy application and duration.[8] In the last few years, robotic-guided therapy has become an innovative and relatively new approach based on exercise using robotic devices that allow for training with modifications of load, duration and objective data collection in real time. Previous evidence suggests the effective use of robots for rehabilitation purposes after stroke using subjective methods, such as the Fugl-Meyer assessment of stroke recovery.[9] However, it is less well known the effectiveness of using robots for functional purposes of the lower extremities through walking and maintaining balance.[10,11] The above parameters represent frequently tested outcomes after stroke, due to reduced postural control, muscle strength, and connections of the lower extremities, and an increase in the asymmetry of the left and right sides of the body and disproportionate load transfer and energy consumption.[12]

Opposed to conventional approaches of using drugs or physical therapy, several studies have confirmed small but significant effects of use robot-guided training to increase muscle strength,[13] and restore adequate movement functionality.[14] Although robotic-guided therapy has proven to be an effective method for adequate rehabilitation and improvement of neuromotor functions,[11,13-15] a smaller number of studies have sought to determine the intervention effectiveness on resistive torque changes being predominantly tested in the hip and knee areas during maximal flexion and extension voluntary isometric torque.[16] These movements are directly related to neuromuscular weakness and spasticity in stroke patients, and are good indicators for rehabilitation processes.[17]

To date, only a handful of evidence has examined the effects of robotic-assisted interventions on joint torque changes in children[16,18] and general/older population.[17] For example, findings from the study by Chaparro-Rico *et al*.[17] suggest that flexion and extension movements in the hips and knees of both paretic and non-paretic side of the body improved over a course of four weeks of daily 30 min flat training sessions with Lokomat Pro V6. In specific, a pre-post measurement showed that the joint torque values of both paretic and non-paretic legs at one-month follow-up were greater than those at basal assessment for hip and knee flexion and extension movements, but these changes were not statistically significant, except for knee flexion for paretic leg.[17] Interestingly, the same study compared differences in basal and one-month follow-up between paretic and non-paretic leg and confirmed, that the joint torque values in hip and knee flexion and extension remained consistently lower for paretic, compared to non-paretic leg.[17] Similar observations have been obtained previously, where leg flexors and extensors in paretic leg exhibited poorer values during voluntary isometric contraction.[19] Despite the fact that the paretic leg has lower hip abduction, less vertical stiffness and increased angular input then the non-paretic leg,[20] the heterogeneity of study samples and different methodological approaches to assess the level of torque in the hip and knee areas has led to inability to make general conclusions about the robotic-induced changes for flexion and extension movements in subacute stroke patients is scarce.[21-23] The subacute phase of stroke is often characterized by a rehabilitation period which is more challenging to implement and carry out, due to already impaired neuromuscular functions.[24] Moreover, evidence of comparing the effectiveness of robot intervention between paretic and non-paretic leg is scarce.[17]

By examining the effects of robot-assisted rehabilitation on torque characteristics of lower limb muscles in frontal plane would give new information regarding possible beneficial changes for neuromuscular restoration in health-care settings. Moreover, an interaction between changes in flexion and extension torque movements in the hip and knee areas regarding paretic and non-paretic leg in subacute stroke phase could be directly related to future intervention programs. In that way, the possibility of implementing strategies considering the affected side of the body would help health-related professionals to monitor and track neuromuscular functions and given output.

Because of previous contradictory findings and lack of studies, the main purpose of this study was to examine the effectiveness of a robot-guided intervention program over a 6-week period on flexion and extension torques in the hips and knees. The second purpose was to establish which leg (paretic or non-paretic) exhibited larger pre-post changes in force outcomes.

Materials and methods

Study participants

In this observational, cross-over study, we recruited 13 subacute stroke patients (age 53.38±8.78 years, stature 172.46±12.22 cm, body mass 76.24±10.15 kg, 38.50% women). Based on previous studies, the inclusion criteria were as follows: i) an ischemic or hemorrhagic stroke which led to hemiparesis; ii) time since stroke <2 months; iii) being able to understand and complete all procedures and test measurements during an intervention; and iv) having a functional ambulatory classification category ≥1.[25] Exclusion criteria included having ≥2 strokes during lifetime, the inability to perform flexion and extension movements, and the use of injection treatments, which could alter the intervention effects. Prior testing procedures, participants did not have previous experience with Lokomat® walking. All were eligible to use the Lokomat® unless they had one of the following contraindications: obesity (>130 kg), major cognitive disability, hemianopia, and disturbances other than hemiparesis that would preclude gait training, a urinary catheter or gastrostomy, or major spasticity. After all the participants were informed about the purpose of the study, they signed a written consent form before entering into the study. The G*power sample size calculator[26] and a repeated measures analysis of variance showed that a two-tailed significance of $P< .05$, effect size of f = .50 (calculated from pre-post changes in the study by Chaparro-Rico *et al*.[17]), one group (n = 1) measured at two time points (To and T1) and a statistical power of $1–\beta = .80$. the appropriate sample size was n = 10. To avoid the possible drop-out rate, we increased the sample by 30%. All procedures in the study were anonymous and in accordance with the Declaration of Helsinki.[27]

Study variables

To assess the level of flexion and extension torque movements, we used a reliable and valid Lokomat® system (Hocoma, Volketswil, Switzerland), a driven gait orthosis attached on the hip and knee areas for an automatic locomotion therapy. The Lokomat® uses servomotors to support the weight of a patient during standing or gait and to assist with hip and knee effort.[16,28] For the purpose of this study, the software generated the data required for torque evaluation in the lower-limb force (L-FORCE) based on the treadmill speed of 1.5 km·h^{-1} with 100% body weight support. The L-FORCE tool determines bilateral joint torques in hip and knee flexors and extensors. Following previous methodologies,[17] an experienced physical therapist (>5 years) installed the Lokomat® on each patient. The position of joint angles were pre-set at 20° hip flexion and 20° knee flexion with respect to frontal axis). After the signal "3-2-1-go", the patient was instructed to generate as much force as fast as possible and to hold maximum force for 5 sec. Joint torques in flexion and extension movements were displayed. The final score was based on maximum hip and knee flexion, and extension torques for paretic and non-paretic leg measured in Nm.

Experimental design

Before the intervention, each patient was part of the rehabilitation process in the multicenter of policlinic Glavić (Zagreb, Croatia). The rehabilitation included a multilevel approach regarding physiotherapy, verbal, occupational, and neuromuscular therapy and psychological guidance. After the initial testing, a rehabilitation procedure was implemented for 6 weeks (5 × week) and included the use of a robotic device for the lower extremities for 60 min. The total time of the intervention per week was 300 minutes on the robotic device for the lower extremities. According to the standard protocol for isometric force assessment, the participants were required to wear a belt fixed to the device with straps around the torso and pelvis. Mechanical orthoses were attached to the participants' legs with cuffs around the upper and lower legs. The proximal and distal structures of the robot orthoses were adjusted to align the participants' hip and knee joints with the joint axes of the device. Each participant was lifted above the treadmill with a mandatory 100% body weight offload, then the software device was brought to a predetermined fixed position. In this position, the participant was instructed to perform isotonic flexion or extension movements in the hip or knee joint in the left or right leg according to a defined sequence of tests. During this time, the robot system controlled the motors to maintain the specified position and successfully measured the forces acting on the force transducers. The test was performed within a 5-minute time frame, with a recommendation to provide a short break to the subjects between each test. Also, the participants had their arms relaxed alongside their bodies during the test, without holding onto the handrails, not to generate additional forces through the compensatory mechanics of the upper extremities.

Statistical analysis

Data normality was calculated using the Kolmogorov-Smirnov (K-S) test. The K-S test showed that the data were normally distributed (critical *D* value between .16 and .20, *P*> .200). Data were presented as mean ± standard deviation (SD). To acknowledge small sample size (n = 13) and large SD, pre-post changes within paretic and non-paretic leg in hip and knee flexion and extension torques were calculated with a Wilcoxon singed-rank test for dependent samples. Main effects for 'TIME' and 'TIME × LIMB' were examined using Friedman's test, which is equivalent as the parametric repeated measures analysis of variance (RM ANOVA). The Cohen's effect size (ES) determined the magnitude of the change with the following threshold values: < .2 (trivial); .2 – .6 (small); .6 – 1.2 (moderate); and >1.2 (large).[29] The ES was measured as follows: $r = Z / \sqrt{n}$, where Z denoted z-statistic and *n* was the total sample size.[30] Differences in pre-post changes between paretic and non-paretic leg were examined with a Man-Whitney test for independent samples. All analyses were performed in Statistical Packages for Social Sciences ver. 26 (SPSS Inc., Chicago, Illinois, USA). The significance was set at *P*< .05.

Results

At baseline, no significant differences between left and right leg in hip flexion (*Z* – value = .002, *P*= .998), hip extension (*Z* – value = .526, *P*= .609), knee flexion (*Z* – value = -1.056, *P*= .314) and knee extension (*Z* – value = .043, *P*= .967) were found. Means of the L-FORCE measures at baseline (T0) and after 6 weeks (T1) for paretic and non-paretic leg are presented in Table 1. Over a period of 6 weeks, the Lokomat® guided intervention non-significantly increased hip flexion torques in paretic leg (mean diff. = -3.00, 95% CI -23.04 – 17.04, ES = .18, *P*= .716) and non-paretic leg (mean diff. = -9.57, 95% CI -18.77 – 0.37, ES = .38, *P*= .056). For knee flexion movements, non-significant increases for paretic leg (mean diff. = -8.83, 95% CI -25.24 – 7.57, ES = .24, *P*= .225) and non-paretic leg (mean diff. = -3.79, 95% CI -11.79 – 4.22, ES = .22, *P*= .291) were observed. Results for hip extension indicated non-significant increases for paretic leg (mean diff. = 1.08, 95% CI -14.22 – 13.15, ES = .23, *P*= .269) and non-paretic leg (mean diff. = -14.64, 95% CI -32.74 – 3.45, ES = .35, *P*= .095). Like other movements, non-significant increases were shown for paretic leg (mean diff. = -2.12, 95% CI -18.30 – 13.97, ES = .15, *P*= .744) and non-paretic leg (mean diff. = -7.18, 95% CI -20.30 – 5.94, ES = .26, *P*= .229) in knee extension. No significant differences in pre-post changes between paretic and non-paretic leg were observed (*P*< .05).

Non-significant differences in pre-post changes between paretic and non-paretic leg were observed for hip flexion (mean diff. = 6.57, 95% CI -11.58 – 24.72, *P*= 0.442), hip extension (mean diff. = 23.56, 95% CI -0.67 – 46.44, *P*= .055), knee flexion (mean diff. = -5.05, 95% CI -20.14 – 10.04, *P*= .477) and knee extension (mean diff. = 8.20, 95% CI -13.04 – 23.06, *P*= .554).

Table 1. Hip and Knee Flexion-Extension Torque: Comparing Paretic and Non-Paretic Limbs.

Variables	**Paretic leg**		**Non paretic leg**		**Main effects**	
Movements	**T0**	**T1**	**T0**	**T1**	**Time** $P\ (\eta_p^2)$	**Time × limb** $P\ (\eta_p^2)$
Hip-flexion (Nm)	41.58±24.81	44.58±27.80	41.57±25.43	51.14±23.13	0.156 (0.17)	0.442 (0.06)
Hip-extension (Nm)	44.17±34.38	45.25±36.05	35.43±25.46	50.07±29.30	0.593 (0.03)	0.055 (0.32)
Knee-flexion (Nm)	25.17±13.84	34.00±18.50	38.43±27.84	44.21±26.06	0.093 (0.24)	0.477 (0.05)
Knee-extension (Nm)	36.58±17.21	38.75±16.48	36.14±19.58	43.32±23.21	0.279 (0.11)	0.554 (0.03)

Note: data are presented as mean±SD.

Discussion

The main purpose of this study was to examine whether a 6-week intervention using the Lokomat® could positively affect torques in hips and knees in subacute stroke patients. The second purpose was to examine differences in paretic and non-paretic leg exhibited after the intervention. Results showed that the robot-assisted Lokomat® intervention over 6 weeks led to non-significant improvements in flexion and extension torque movements in the hip and knee areas, except for the flexion in the right knee. When differences in changes between paretic and non-paretic leg were observed, only extension movement in the left hip was statistically significant, and other variables failed to achieve significance.

Findings of this study are in line with previous studies.[17] In the study by Chaparro-Rico *et al.*,[17] the L-FORCE for both paretic and non-paretic leg showed hip and knee flexion, and extension movements increased over a period of 4 weeks, but these changes remained statistically non-significant, except for hip flexion. This would suggest that values for flexion and extension movements for paretic leg improved their overall stiffness and joint torque, but these changes were likely to occur by chance, due to the low number of patients which influenced the statistical significance. Also, the study methodologies regarding body support was equal, where Chaparro-Rico *et al.*[17] set the body weight support to 100%. Although ESs were small to moderate, a lack of significance might be explained by a low sample size (n = 10) and a great heterogeneity between the participants in terms of age (36 – 73 years), the number of days since stroke occurrence (10 - 60 days), higher proportion of men (80% vs. 20% women), and the etiology and clinical picture of each participant. However, the tendency of torque improvements could be attributed to robot-guided interventions comprised of exoskeletons and providing them with body support to compensate for weaknesses and ensure adequate gait patterns.[31] For example, a study by Agrebi *et al*.[32] showed that an 8-week ballistic training and peak torques at different angular velocities significantly improved the concentric peak torques for both dominant and non-dominant in internal and external movement protocols. The same study concluded that strength-based training composed of ballistics compound movements might be a good stimulus for improving isokinetic and eccentric peak torques for both dominant and non-dominant hand in handball players. This would suggest that passively controlled movements in flexion and extension are equally important for both sides of the body, including paretic and non-paretic side affected by stroke. However, a 6-week training protocol with small sample size is apparently not adequate to yield significant pre-post changes. Although we generally found no significant improvements in flexion and extension of the hips and knees, evidence suggests that the integration of robot devices in lower limb rehabilitation may offer a neural musculoskeletal reorganization and a proper new education.[33] Interestingly, the consistency of the high dosage and intensity of task-specific exercises during interventions facilitates motor learning and can be an optimal tool for the restoration of normal movement patterns.[33] Other studies have been consistent in their findings, where the stroke participants undergoing robot-assisted training intervention improve gait speed, balance, and overall walking ability.[12-14] Unfortunately, we were unable to measure psychological output of each participant, as the level of motivation and persistence to complete the intervention process are key determinants of its effectiveness.[34] Also, the potential shortcoming of robot-assisted intervention comes from a comprehensive and individual approach to each patient. This could be interpreted as creating tailored interventions to match the need on an individual level, based on the level of impairment, expected goals and achievements obtained.[14] However, the benefit of using exoskeletons, like the Lokomat® robotic system, is its ability to adjust for the movement patterns, like resistance and speed, to be adequate for the patient's current capabilities. Nevertheless, the results of this study are closely related to previous studies on the same topic,[17] showing that the Lokomat® device may detect torque changes at individual and group levels in subacute stroke patients.

Similar to the results of pre-post changes in flexion and extension torque movements, we found no differences in changes between paretic and non-paretic leg, which is also in line with previous studies.[17] Again, a study by Chaparro-Rico *et al*.[17] tried to examine and compare the magnitude of change between paretic and non-paretic leg after 4 weeks of follow-up intervention. Although the paretic leg exhibited larger improvements in both hip and knee flexion and extension torque movements, compared to non-paretic leg, *post-hoc* analysis failed to detect significant differences in these changes.[17] The consistency between findings comes from similar methodologies in terms of intervention periods (4 weeks[17] vs. 6 weeks), the number of participants (10[17] vs. 13) and the same instrumentation to measure L-FORCE outcomes. Despite the non-significant differences between paretic and non-paretic leg, both sides of the body improved the joint torques, leading to the conclusion that interventions implemented in the health-care systems for subacute stroke patients need to be consistent and intensive. This has been supported previously, where studies conducted among animals demonstrate a limited timeframe of heightened plasticity after focal brain injuries.[35] However, similar changes in both paretic and non-paretic leg in this study indicated that the participants used both affected and unaffected sides of the body at the same rate during the intervention, training both legs to the best of their ability. When it comes to knee extension movements, it should be highlighted that kinematic and kinetic chains associated with knee includes increases in hip and ankle mobility, enhancement in ankle dorsiflexion and foot stability, and good proprioception maintenance around the hips, ankles and feet.[36] The abovementioned mechanism is based on joint-by-joint training approach that focuses on knee injury prevention strategies, including similar load distribution and decreasing peak knee valgus position, a significant predictor of anterior cruciate ligament (ACL) injury.[36] From a practical perspective, subacute stroke patients tend to lose dynamic postural change response and rely on static posture correction following intervention.[17] By applying a multicomponent training procedures, where the focus is based on upper and lower joint functionality and muscle re-activation, the prevention of certain injury related to knee area is commendable. A study by Dhahbi *et al*.[36] showed that mechanisms for knee injury prevention included strong hip abductor control, adequate hip rotation, a proper foot arch support to prevent excessive foot pronation and balance and proprioceptive foot muscle training for better mobility and control. Thus, it is suggested that future training approaches towards gait and balance improvements in stroke patients need to be based on multi-joint interaction between hips, knees, ankles and feet, since isolated knee strengthening often tends to fail to address these risk factors.[36]

The implementation of robotic devices for intervention purposes in stroke patients has risen in the last decade.[37] The advantages of such technology are individualized approaches to each patient, regarding their needs and possibilities based on their current neuromuscular function. The Lokomat® robot-assisted training seems to play a significant role in improving muscle re-activation and decrease asymmetry between paretic and non-paretic limb. The nature of biomechanical understanding of torque production and muscle activation patterns has to be observed from unilateral and bilateral sides. Because of complex movements produced by muscles during walking, the central nervous system (CNS) is able simplify the muscle synergy by activating functional groups of muscles rather than individual muscles independently.[38] For patients who are unable to adequately achieve dynamic postural control (like stroke patients), it is important to firstly overcome static muscle optimization, which can minimize the activation of multiple muscles, and provide with more efficient estimates of muscle coordination patterns. This would imply that joint-by-joint coordination and muscle activity dynamics may be responsible for synergy patterns for lower limbs. Although therapeutic robots have merit for effective targeting of spasticity, function, range of motion (ROM) and overall walking ability, they fail to be affordable to clinics specialized for rehabilitation and intensive care of stroke patients. For example, data from Slovakia show that only six clinics offer robotic rehabilitation, while >17,000 residents are affected by strokes annually.[39] In Croatia, only a few clinics utilize robotic technology to enhance post-stroke recovery and improve motor skills. Since effectiveness of robotics in stroke rehabilitation in both upper and lower extremities have been confirmed,[9-12,40] the affordability of such devices has yet to be determined. Nevertheless, robotic-assisted therapy for rehabilitation purposes in stroke patients, like the Lokomat® is sensitive to detect even small clinical changes in torque values.

This study is not without limitations. Despite the sample size calculation using objective methods (G*Power software), the absence of statistically significant changes pre to post intervention was likely attributed by this. Also, the age range, the proportion of men vs. women, and paretic vs. non-paretic leg decreased statistical power even more. However, the explanation of non-significant changes could be influenced by the early stages of the disease, where flexion and extension movement patterns were somewhat difficult to restore in such short timeframe.[17] Second, as mentioned in the 'Discussion' section, the implementation of robotic devices like the Lokomat® might be complicated to achieve, due to high costs, the need of experienced health-related professionals, and data analysis generated from the software. Thus, this could lead to the reduction of its widespread use.

Practical Applications

According to study findings, a short-term intervention of 6 weeks was able to enhance the values in L-FORCE output, including hip and knee flexion and extension torque moments in a relatively small sample of subacute stroke patients. However, these changes remained statistically non-significant. Moreover, the Lokomat® exoskeletal system was able to detect changes for both paretic and non-paretic leg without significant differences between them. Although the study limitations were well-acknowledged, the use of robotic-guided interventions during rehabilitation process might be a practical tool for assessing important neuromuscular components of torque patterns in the hip and knee areas of the body. Also, the device had multifunctional purpose of adjusting the weight support and helping the patient throughout the recovery, directly affecting symmetrical distribution of force and torque, irrespective of the side affected by stroke.

Conclusions

In summary, this study shows that over a period of 6 weeks, increases in hip and knee flexion and extension torque patterns occur, but these changes fail to reach significance. Furthermore, similar rates of change in pre-post measurement of L-FORCE between paretic and non-paretic leg are observed, indicating that flexion and extension torque changes in both legs were not statistically significant. Despite these negative findings, due to study limitations, the Lokomat® L-FORCE tool is capable and sensitive enough to estimate torques in the hip and knee areas of the body using motor impairment patterns and weaknesses in subacute stroke patients at individual level. Despite the effort to examine the cross-over effectiveness of the robotic-assisted rehabilitation therapy, future research should use a larger sample size, a longer follow-up duration to establish a 'true' effectiveness of the Lokomat® in clinical settings.

Acknowledgments

The authors gratefully thank all the participants for their cooperation during the study.

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Ethical Committee approval

Ethical review board of the Faculty of Kinesiology, University of Zagreb, Zagreb (Croatia) approved this investigation (ethical approval code: 01/12 - 2024).

Topic

Physical therapy

Conflicts of interest

The authors have no conflicts of interest to declare.

Funding

No funding was received for this investigation.

Author-s contribution

Conceptualization, N.P. and L.Š.; methodology, N.P., L.Š. and I.Z.; software, L.Š.; validation, N.P.; formal analysis, N.P. and L.Š.; investigation, N.P.; resources, N.P.; data curation, N.P. and L.Š.; writing—original draft preparation, N.P., L.Š. and I.Z.; writing—review and editing, N.P., L.Š. and I.Z.; visualization, N.P. and L.Š.; supervision, N.P.; project administration, N.P. All authors have read and agreed to the published version of the manuscript.

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Received: 20.07.2025.
Accepted: 01.09.2025.
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