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The Effectiveness of Cervical Spondylosis Therapy with Saunders Traction Device and High-Intensity Laser Therapy: A Randomized Controlled Trial

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Background: Among all spinal therapies, treatment of the cervical segment is the most difficult. The cervical segment is particularly sensitive to injuries and pain, and it also requires special care due to its great mobility and most delicate construction. The aim of this research was to evaluate analgesic efficacy and improvement of active mobility of the cervical spine after traction therapy with the Saunders device and high-intensity laser therapy (HILT) immediately after therapy, and in short-, medium-, and long-term follow-up in patients with cervical spondylosis.

Material/Methods: The study included 174 patients (114 women and 60 men) aged 24–67 years. The patients were divided into two randomized groups. In group I (88 subjects) traction therapy with the Saunders device was applied, and in group II (86 subjects) HILT was applied. The measurement of the range of cervical spine movement, a subjective visual scale for pain (Visual Analog Scale [VAS]), and the Neck Disability Index-Polish Version (NDI) questionnaire were used.

Results: The results obtained by the Saunders and HILT methods were similar immediately after the therapy and after 4 weeks (the medium-term follow-up). However, in long-term follow-up, there was a significant increase in the maintenance of positive therapeutic effects with the HILT method.

Conclusions: Both therapeutic methods improved the efficiency and demonstrated analgesic efficacy in patients with cervical spondylosis immediately and in the medium term after the therapy. HILT was more effective than the Saunders method in long-term follow-up.

MeSH Keywords: Heavy Ion Radiotherapy • Neck Pain • Spondylosis

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Background

The World Health Organization (WHO) considers degeneration of the spine the epidemic of our time. Among all spinal therapies, treatment of the cervical segment is the most difficult. The cervical segment is particularly sensitive to injuries and pain, and it also requires special care due to its great mobility and the most delicate construction [1]. Circulatory insufficiency within the vertebral artery, poor posture, trauma, hormonal and emotional disorders, and damage to the intervertebral disc, mostly within C7, C6, or C5, cause compression changes of the spinal nerve roots and neuropathic pain induced by irritation of sensory fibers [2]. In the literature, these changes are referred to as cervical radiculopathy (brachialgia).

Considering the variety of physical therapy procedures, there is a problem in assessing their effectiveness. This encourages a comparison of two methods of treatment: traction therapy with the Saunders device and high-intensity laser therapy (HILT).

The aim of the study was to evaluate the analgesic efficacy and the improvement of active mobility of the cervical spine after traction therapy with the Saunders device and HILT immediately after completion of the therapy, and in short-, medium-, and long-term follow-up in patients with cervical spondylosis.

Material and Methods

Trial design and study population

Initially 203 individuals were enrolled in the study on the basis of confirmed diagnosis and the patient's written consent to participate in research and the therapy. Furthermore, the criteria for inclusion were lack of contraindications for physical procedures and the patient's good general condition. A positive de Kleyn test and coexisting diseases that could have an additional impact on pain and limited mobility of the cervical spine (torticollis, scars), hypermobility of vertebral-motor segments, severe osteoporosis, major operations in the area of the head, cancer, epilepsy, acute inflammation, or other comorbidities that could affect the patient's condition, could affect the interpretation of the results, or could be a contraindication for the proposed procedures were the exclusion criteria. No epidural steroid injections were administered. The participants did not use other methods to prevent ailments typical of cervical radicular syndrome such as neck braces or pharmacotherapy. However, 29 patients were excluded from the trial as a result of the lack of their appropriate cooperation.

Finally, 174 patients were included in the trial, and in order to eliminate the impact of uncontrolled variables on the results of the experiment, the patients were randomly divided into two groups. Group I consisted of 88 subjects (56 women and 32 men) and group II of 86 subjects (58 women and 28 men); they were aged 24-67 years with a mean age 45.5 years. Demographic characteristics of the investigated patients are presented in Table 1.

Group I patients were subjected to axial traction of the spine with the Saunders cervical traction device, whereas group II patients were exposed to HILT with BTL-6000 HILT 7W.

The tests and therapy were performed in the Rehabilitation Center specializing in the treatment of spinal pain and dysfunction in Piotrków Trybunalski (Poland) within the period from January 10 to May 25, 2015. All the patients were referred to rehabilitation by a neurologist from Nicolaus Copernicus Independent Regional Hospital in Piotrkow Trybunalski (Poland).

The study protocol was approved by the Bioethics Committee of the University of Social Sciences in Lodz No: 281/A/S from 10.01.2015.

Interventions

Group I patients were subjected to cervical axial traction using the Saunders device [3,4]. The procedure was performed in the supine position once per day, 5 days per week for 3 weeks in accordance with the applicable rules [5–8]. Altogether, 15 traction procedures were performed in each patient. According to the methodology for this kind of treatment, the traction force in each patient was constant and it was 16–18 kg [5]. Mild increase of stretching was possible by a pneumatic hand pump. To increase security, each patient was able to reduce the traction force personally. While monitoring the traction therapy, no pain, discomfort, or deterioration of well-being were reported. The duration of the procedure ranged from 8 to 15 minutes, and it was increased gradually with successive sessions. Traction treatment sessions 1–3 were 8 minutes; sessions 4–6 were 10 minutes; sessions 7–9 were 12 minutes; and sessions 10–15 were 15 minutes. The head pad was set at an angle of 15–20°, and traction forces directed to the back of the head (occiput) additionally prevented compression of temporomandibular joints, which contributed to the comfortable and stable positioning of the patient during the procedure [3,4,7,8].

The therapy program for group II consisted of analgesic application in acute state patients or biostimulation in patients with subacute and chronic conditions. Using laser therapy, the procedure was performed in a position unburdening the cervical spine, i.e., in a prone position and the head slightly bent to the front. Analgesic treatment, optimal for pain control, was performed in a pulse mode of 25 Hz, wavelength=980 nm, radiation power density P=600 mW, energy density Ed=5 J/cm^2. The treatment was started at a distance of 3-5 cm, directly above

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Table 1. Demographic characteristics of the investigated patients.

Number of patients		Women		Mean Women	Men		Mean Men	Mean age total
		Group I	Group Ii		Group I	Group II		
174		56	58	57	32	28	30	45.5
Age 24–30 years		4	6	5	2	2	2	27
Age 31–36 years		7	5	6	6	3	4.5	33.5
Age 37–42 years		11	12	11.5	3	6	4.5	39.5
Age 43–48 years		7	7	7	6	3	4.5	45.5
Age 49–54 years		10	8	9	10	4	7	51.5
Age 55–60 years		6	11	8.5	5	7	6	57.5
Age 61–67 years		11	9	9.5	0	3	3	64
Place of residence		**Women**		**Mean**	**Men**		**Mean**	**Mean total**
	Town	38	35	36.6	21	19	20	28.2
	Village	18	23	20.5	11	9	10	15.2
Professional activity								
Worker	Physical	18	17	17.5	15	11	13	15.2
	Office	21	23	22	8	7	7.5	14.7
Disability living allowance/pension		17	18	17.5	9	10	9.5	13.5

Source: own calculations.

the transverse processes of each of the cervical vertebrae, from the C4 to Th4. The handpiece was moved contact-free in a continuous spiral motion, slightly inward of each of the spinal segments. Within 3.5 min of treatment, 195 J of energy was provided [9]. Biostimulation application was carried out paraspinally in a continuous wave mode, using radiation power density P=300 mW, and continuous handpiece motion parallel to muscle fibers, from C4 to Th4. The average energy density was Ed=50 J/cm^2 at a wavelength of 980 nm and procedure duration of 6.5 minutes with provided energy of 1250 J. Analgesic and biostimulation procedures were applied 10 times in one series (1 per day, 5 times a week for 2 weeks) [9,10]. Methodology of the procedures was in accordance with the policies applied in physiotherapy.

A control card was used in both groups to evaluate the range of cervical spine motion, on which there was recorded the range of motion from the anatomical position, i.e., the Frankfurt plane (a plane passing through the inferior margin of the left orbit and the upper margin of each ear canal or external auditory meatus) to the end position in active movements of flexion, extension, lateral flexion, and rotation in both directions, and in standing position [11].

The tests of the range of active cervical motion were performed by measuring the distance from the characteristic measurement points. Thus, during flexion of the head the distance was measured between the external occipital protuberance and the spinous process of C7. The extension of the head was measured as the distance from the top of the mental protuberance to the jugular notch of the manubrium sterni, and lateral flexion movement from the mastoid process of the temporal bone to the acromion process of the scapula. However, during turning movement (rotation) of the head, the distance from the mental protuberance to the acromion process of the scapula was measured [12]. These measurements were performed in a straight line with the use of Stanley Power Lock® Digital Tape Rule (Stanley Tools Product Group, New Britain, Connecticut, USA). Each measurement was repeated twice with an accuracy of 1 mm, and the final result was the mean of two measurements. The tests of cervical spine mobility in active movement were performed before and immediately after the therapy and in the fourth and twelfth weeks of the follow-up.

The Visual Analog Scale (VAS) was used for subjective assessment of the intensity of pain experienced by the patients [13]. The patients personally reported their pain on the day of the therapy and marked its severity on a 10-cm long horizontal line from 0.1 cm to 10 cm, starting with “no pain” at one end and “severe pain” at the other. Then, four groups were distinguished among the subjective results: group I: score of 0 (no pain); group II: scores of 1-3 (mild pain); group III: scores of 4–7 (moderate pain); and group IV: scores of 8–10 (severe pain).

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The evaluation of the level of pain severity was conducted four times, i.e., before the start of the proposed therapy, immediately after the sessions, and in two subsequent situations (4 weeks and 12 weeks after the therapy).

Moreover, for a thorough evaluation of the effectiveness of the therapy, all patients completed Neck Disability Index-Polish Version (NDI) questionnaire, which is an indicator of disability caused by cervical pain. This evaluation was also performed four times in both groups of patients. The NDI questionnaire consists of 10 parts, and each patient can select one of six different answers. The major part of this questionnaire is related to pain intensity, personal care (washing, dressing, etc.), lifting objects, reading, headaches, concentration, work, driving, sleeping, and recreation. The results are converted into percentages, which allowed us to distinguish five groups based on the level of functional disorders for patients with cervical pain. Group I (0–20%) included patients who did not require treatment. These patients did not have significant functional disorders of the cervical spine, with slight pain that minimally limited some activities. Group II (21–40%) were patients with mild disability; they had problems with lifting and traveling, and were temporarily unable to work. Group III (41–60%) were patients with disability; their pain affected daily living (limits on practicing their profession, sex, and social life, etc.). Group IV (61–80%) were patients with severe disability; pain interfered with all aspects of their life and they required appropriate treatment. Group V (81–100%) were patients with complete disability; they were not self-reliant and were bedridden.

Statistical analysis

All the results obtained in both groups were subjected to statistical analysis in which basic descriptive statistics and tests of the significance of differences were used. Student's t-test for independent samples (factor, group) was used to compare the obtained results of treatment by the Saunders versus the HILT method (separately for the measurement before and in three periods after the therapy). Student's t-test for dependent samples (factor, time) was used to compare the results obtained before and after the therapy (separately for patients treated by the Saunders versus the HILT method). Taking into account both factors simultaneously, a two-factor analysis of variance was applied for repeated measures; the effects of interaction of factors, sample, and time were tested by applying the Greenhouse-Geisser test. The study assumed a significance level of α=0.05. The calculations were performed using IBM SPSS Statistics 22.0.

Results

Group I consisted of 88 subjects (56 women and 32 men) and group II of 86 subjects (58 women and 28 men); they were aged 24–67 years, with a mean age of 45.5 years. Group I patients were subjected to axial traction of the spine with the Saunders cervical traction device, whereas group II patients were exposed to HILT with BTL-6000 HILT 7W.

Before the therapy, patients treated by the Saunders method did not differ significantly from those treated with HILT. A t-test for independent samples showed p=0.640 for VAS and p=0.978 for NDI. For the ranges of motion (flexion, extension, rotation to the right and left, lateral flexion to the right and left), the differences also were not significant. Measuring the ranges of motion globally (averaged range of motion), they also were insignificant (p=0.700, Table 2).

On the average, the range of motion before the therapy was assessed at 2.42 in patients treated with the Saunders method compared with 2.90 in those treated with HILT. Also the pain scores on the VAS scale and NDI were similar in both groups (Table 2). Both therapies resulted in significant improvement; changes between the results of individual measurements were statistically significant (Table 3). What is more, in both groups, on the basis of post-hoc tests, there were significant differences for each measurement in relation to the others (p<0.0001).

As can be concluded from the data presented in Figure 1, immediately after completion of the therapy the global range of motion was higher in patients treated with the Saunders method (on average it was an increase of 2.9 cm, i.e., almost 80%) than in those treated by the HILT method (mean increase of 2.3 cm, 60%). The results in both groups were equal 4 weeks after the therapy (increase of the range of motion of approximately 55%, i.e., by 2.1 cm, compared with that at baseline); but in the longer period of time (12 weeks) the Saunders method was less effective (increase in the range of motion reached on average 34%, i.e., approximately 1.2 cm, versus 50%, approximately 1.9 cm, with the HILT method). The interaction effect was statistically significant (p<0.0001 by the Greenhouse-Geisser test), which confirms that in the statistical sense, in both groups there was a different course of changes in the global range of motion.

Comparing the results obtained immediately after the therapy, not very distinct differences between the two groups of patients were observed when other mobility parameters were evaluated (Table 2), but – which is of importance – these differences were statistically significant (for VAS p=0.013, for NDI p<0.001). However, Figure 1 indicates that in the longer period, therapy with the Saunders method may be less effective than therapy with the HILT method.

Immediately after the therapy, the pain score decreased by more than 50%, that is, over four scores in both groups. However, if we compare the results 12 weeks after the therapy with the

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Table 2. Comparison of the distribution of selected parameters of mobility of patients treated by Saunders and HILT methods.

		Baseline		Immediately after therapy		4 weeks after therapy		12 weeks after teraphy	
		Saunders	HILT	Saunders	HILT	Saunders	HILT	Saunders	HILT
Global range of movement	Min	2.42	2.58	4.00	3.92	3.50	3.67	3.25	3.67
	Max	6.67	6.50	11.75	10.92	10.42	10.42	8.58	10.00
	Mean	3.91	3.97	6.83	6.23	6.04	6.02	5.15	5.83
	Median	3.75	3.83	6.46	5.67	5.75	5.50	4.75	5.29
	SD	0.96	0.89	1.71	1.69	1.42	1.58	1.11	1.48
	Skewness	0.828	0.817	0.588	0.911	0.679	0.887	0.763	0.924
	Kurtosis	0.253	–0.113	–0.408	0.145	–0.108	0.213	0.013	0.347
	p	0.700		0.021*		0.910		0.001*	
VAS	Min	2.00	3.00	1.00	1.00	2.00	2.00	2.00	2.00
	Max	10.00	10.00	6.00	6.00	6.00	6.00	7.00	6.00
	Mean	7.26	7.14	3.10	3.56	3.89	3.77	4.56	3.88
	Median	7.00	7.00	3.00	4.00	4.00	4.00	4.00	4.00
	SD	1.90	1.51	1.32	1.09	0.92	0.92	0.87	0.83
	Skewness	–0.314	–0.410	0.239	–0.041	0.322	0.389	0.144	0.097
	Kurtosis	–0.472	–0.387	–0.535	–0.434	–0.264	–0.247	0.356	–0.016
	p	0.640		0.013*		0.393		<0.001*	
NDI	Min	40.00	42.00	19.00	16.00	20.00	13.00	23.00	16.00
	Max	64.00	68.00	40.00	27.00	40.00	26.00	44.00	25.00
	Mean	53.44	53.42	23.74	21.42	27.99	20.98	33.39	20.65
	Median	55.00	56.00	23.00	21.00	28.00	21.00	34.50	20.50
	SD	5.85	5.65	4.20	2.07	4.35	2.02	4.72	1.70
	Skewness	–0.443	–0.219	10.930	0.196	0.553	–0.469	–0.053	–0.111
	Kurtosis	–10.024	–0.913	40.503	0.185	0.677	20.317	–0.768	0.396
	p	0.978		<0.001*		<0.001*		<0.001*	

p – probability in the Studentt-test for independent samples. Source: own calculations.

Tabela 3. Evaluation of the significance of differences between the results for selected parameters of mobility in patients treated by HILT and Saunders method in four measurements (before and in three time points after the therapy).

	Saunders				HILT			
	Baseline	After therapy	4 weeks later	12 weeks later	Baseline	After therapy	4 weeks later	12 weeks later
Global range of motion	F=429.609; df=1.172; p<0.0001***				F=203.297; df=1.038; p<0.0001***			
VAS	F=216.652; df=1.999; p<0.0001***				F=370.734; df=1.884; p<0.0001***			
NDI	F=1123.877; df=1.809; p<0.0001***				F=2381.547; df=1.147; p<0.0001***			

Analysis of variance repeated measures. Due to non-sphericity of variance-covariance matrix the test of within-subject effects in Grenhouse-Geisser version was used. Source: own elaboration.

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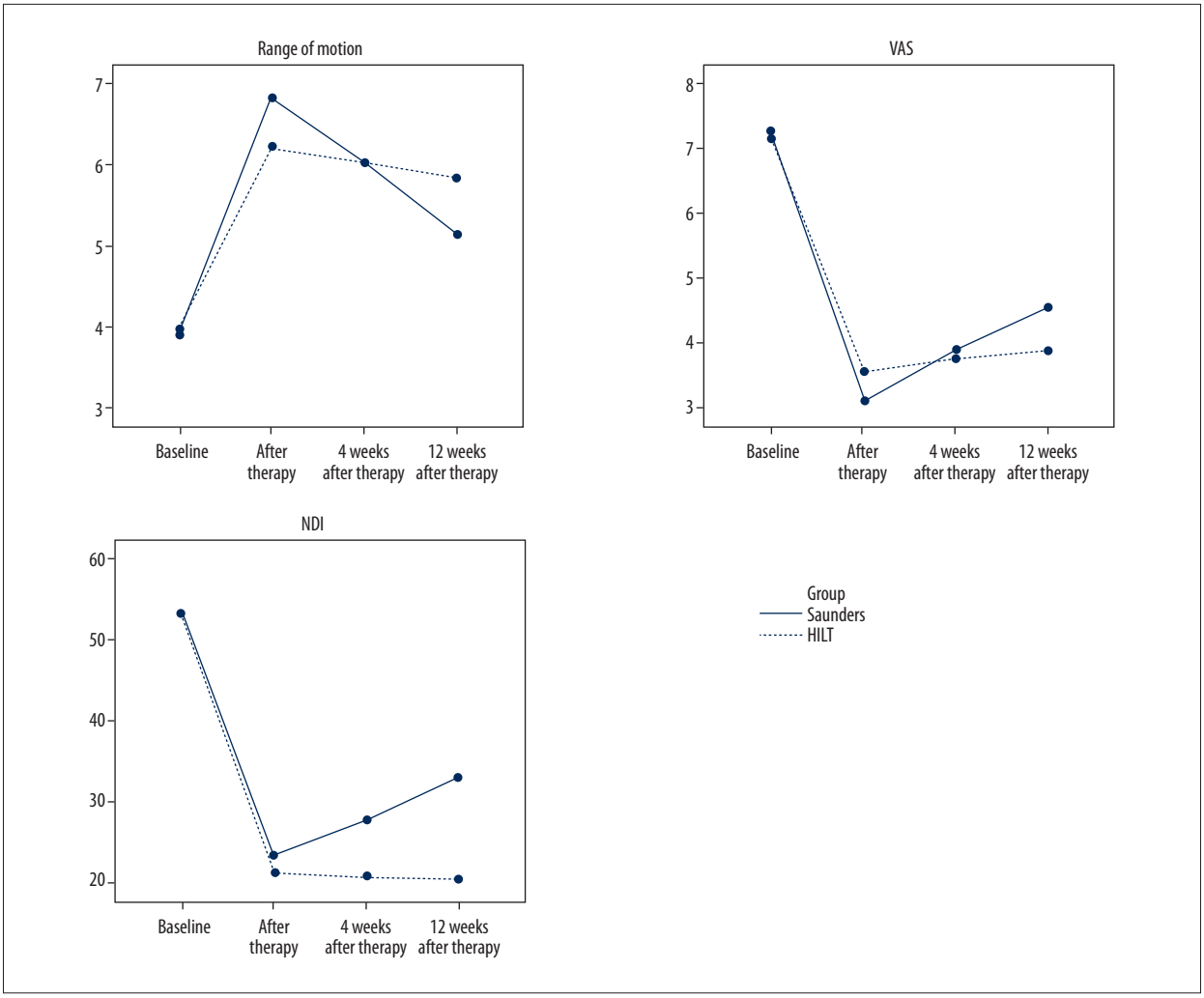

Figure 1. Boundary means for the assessment of the selected parameters of mobility of patients treated by the Saunders and HILT methods before, immediately after, at 4 weeks, and at 12 weeks after the therapy.

results at the baseline, this decrease reaches approximately 30%, i.e., 2.7 scores, in patients treated with the Saunders method versus more than 40%, i.e., 3.3 scores, in patients subjected to the HILT method (in the fourth week these changes were similar, 41% and 46%, respectively, with slightly more than three scores). In the case of NDI, a larger decrease was observed with long-term observation of patients treated with the HILT method; after 12 weeks the score reached, on the average, approximately 60% (33 percentage points) versus less than 40% (approximately 20 percentage points) with the Saunders method. Immediately after the therapy, the effects were similar in both groups (a decrease of approximately 30 percentage points, i.e., 60%), and the effect of therapy with the HILT method remained stable at this level 4 and 12 weeks afterwards. In the case of the Saunders method, despite the fact that the initial advantageous decrease of NDI was similar to that with the HILT method, there was a more pronounced tendency to the return to the status prior to the therapy already at week 4 and even more at week 12. The interaction effect was statistically significant ($p<0.0001$) for both parameters.

Discussion

According to some authors, women are more likely to suffer from cervical spine pain (7%) compared with men (5%) [14]. In our study, the number of female patients (n=114) subjected to the therapy was also higher than the number of male patients (n=60). The obtained results showed that both methods of therapy decreased the intensity of pain and increased the range of motion in cervical spine joints at a statistically significant level.

There are not many reports about the analgesic efficacy and the effect of the Saunders axial traction device on the improvement of the cervical spine mobility [4]. Fritz et al. [15]

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reported that 64 subjects (mean age 41.1 years, 56.3% females) with symptoms of nerve root compression received a 6-week treatment with Saunders traction. Centralization of neurological symptoms obtained after only 2 weeks was the achievement of this therapy. The authors emphasized the need for further research to validate the finding. In the study by Myśliwiec et al. [16], 45 patients with cervical radiculopathy and degenerative changes causing arm flexor muscle weakness were subjected to comparisons between the treatment with Saunders traction and transcutaneous electrical nerve stimulation (TENS). The results revealed that the most significant improvement of the weakened muscle strength and reduction of pain intensity were obtained after the treatment with Saunders traction. These findings are in compliance with the conclusions of our study because we found an average 50% decrease of pain intensity in patients treated with Saunders traction device. Myśliwiec et al. [17,18] proved that combined Saunders traction and TENS therapies had the most prominent effect on the improvement of the range of cervical spine motion. Our study also demonstrated an 80% increase of cervical spine range of motion in patients who were treated only with the Saunders traction device. This result is in compliance with the NDI results obtained in our study, where application of therapy with Saunders traction for a period of three weeks resulted in an improvement of 60% in the functioning of patients. After 4 weeks, the effect was still maintained at a significant 40% improvement and did not change after 12 weeks. We analyzed our long-term studies, which to our knowledge have not been reported in the available literature so far. The obtained results revealed that after 4 weeks the level of pain still remained reduced by 41% in the tested patients, but after 12 weeks the improvement was only 30%. With respect to maintenance of global range of motion, it should be noted that after 4 weeks it was higher by 55% than that immediately before the treatment, a difference that was statistically significant; after 12 weeks the difference was only 34%.

In turn, the therapy conducted with HILT showed that the range of motion increased in all planes in 74.67% of patients and pain sensations subsided statistically significantly in 100% of patients. Conforti et al. [19] demonstrated that HILT was more effective for patients with whiplash injuries that were grade 1 and 2 of the Quebec Task Force Classification (QTFC) compared with conventional methods such as electrotherapy, analgesic pharmacotherapy, and the use of non-steroidal anti-inflammatory drugs (NSAIDs).

Using the VAS scale and Northwick Park Neck Pain questionnaire, Chow et al. [20] determined the efficacy of low-level laser therapy in 90 patients; in 48.5% of the study group irradiated with laser beams and 3.99% of the control group the range of motion significantly increased and pain decreased. Our study, also using the VAS scale, proved that in 174 patients undergoing treatment with the use of the two physical methods (Saunders, HILT), pain subsided on the average by 50%. To evaluate the effectiveness of laser therapy in patients with cervical spondylosis, Thoomes et al. [21] presented evidence of the usefulness, among others, of the Neck Disability Index (NDI) questionnaire and confirmed the improvement in everyday functioning of patients and the reduction of the level of pain. These conclusions are consistent with our research, in which the NDI questionnaire revealed that in patients undergoing HILT a statistically significant 60% improvement was observed in daily functioning. Furthermore, continuation of long-term studies showed that the functional improvement of the patients remained on the same level of 60% 4 and 12 weeks after the therapy.

The SF-36 survey is a sensitive and specific tool for assessing the quality of life of patients with radicular syndromes. It was used in diagnosing mental and physical aspects of the quality of life of 50 patients diagnosed with radiculopathy [22]. In a double-blind study, Dundar et al. [23] assessed the impact of HILT on the quality of life of women with chronic neck pain due to myofascial pain syndrome (MPS) of the trapezius muscle, based on responses to the SF-36 questionnaire. The patients were assigned to two groups, the first of which was subjected to HILT and kinesitherapy, and the second to sham therapy with placebo HILT and kinesitherapy. The results revealed that in the first group pain intensity, range of motion, and the quality of life showed a mean 23% improvement compared with the baseline. However, no statistically significant differences were observed between the results at weeks 4 and 12. Quite a different result was found in our research, where the difference in the results between week 4 and 12 was distinct.

Traction therapy with the Saunders device had better therapeutic efficacy immediately after the procedures compared with HILT only in relation to the range of movement, whereas the reduction of pain and disability index were the same. However, in the medium-term follow-up (after 4 weeks), declining effectiveness was observed in the case of HILT. In long-term follow-up (after 12 weeks), the advantage of HILT over the Saunders method increased even more. Therefore, it seems reasonable to suppose that the combination of these two therapeutic methods could bring the best therapeutic effects felt immediately on completion of the procedures as well as in the long-term outcome after the therapy. However, a limitation of this study is that the assessor-blind design could not be used because patients knew in which way they were treated.

Conclusions

Traction with the Saunders device and HILT demonstrated analgesic efficacy, and improved global mobility and efficiency in

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patients with cervical spondylosis. The Saunders method was similarly effective as HILT only in the first period, i.e., immediately after the procedures and in medium-term follow-up. HILT showed a better therapeutic effect in long-term follow-up.

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Conflict of interest

The authors have nothing to declare.

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