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CLINICAL RESEARCH

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S Da Statist Data In Manuscripi Liter	s' Contribution: Study Design A ta Collection B tical Analysis C terpretation D t Preparation E fature Search F ds Collection G	ABDEF 1 ABDEF 1 ABD 1 ABDEFG 2 ABCD 2 ACDEFG 3	Katarzyna Rajfur Joanna Rajfur Tomasz Matusz Karolina Walewicz Robert Dymarek Kuba Ptaszkowski D Jakub Taradaj		 Institute of Health Sciences, University of Opole, Opole, Poland Department of Physiotherapy, Wrocław Medical University, Wrocław, Polanc Institute of Physiotherapy and Health Sciences, Academy of Physical Educa Katowice, Poland 	
Funds Collection G		according to the number of FIZ/3	University of Opole in Polar /2022. Also, the study was	nd and the Academy of Physical Education in Katowice subventions supported by the Ministry of Health subventions according to the ne Wrocław Medical University in Poland		
	Back Material/M	-	musculoskeletal conditions. T ciency of ESWT in low back p ESWT (fESWT) in reducing pa The study involved 40 patie groups: group A (n=20, mear A was an experimental group 4 Hz). Group B was a control ed identical stabilization train pain with a visual analog sca Disability Index (ODI). Measu	There are still limited dates the still limited dates and improving the function of the still states and the states of the still states and the states of the states with L5-S1 discoped and the states of the states are states with an fESWT group, treated with an fESWT group, treated with a states of the states	dern physiotherapeutic method that is useful for treating ata from well-designed studies evaluating the clinical effi- is study aimed to assess the effectiveness of the focused unctional status of patients with chronic LBP. thy with chronic LBP pain who were randomized into 2 s) and group B (n=20, mean age of 45.4 ± 14 years). Group at the lumbar and sacral spine (0.15 mJ/mm ² , 1000 pulses, nam fESWT. The treatment protocol in both groups includ- a day, 5 days a week). Study outcomes included subjective ain Scale (LPS), and functional status using the Oswestry efore and after treatments, as well as follow-up observa-	
		Results: clusions:	form (no. ISRCTN13785224). There was a significant analy the experimental group com pain (VAS and LPS) was obse ter 1 and 3 months), there w cant effect in terms of functi revealed no statistically signi	gesic effect (VAS and LP pared to the sham grou erved immediately after vere no significant betw onal state (ODI) for bot ificant differences (P>0.	was prospectively registered at the ISRCTN registry plat- S) in both groups; however, it was significantly greater in up (P <0.05). A more significant decrease in the perceived r the active fESWT therapy. In follow-up observations (af- eeen-group differences (P >0.05). Also, there was a signifi- h groups (P <0.05); however, between-group comparisons 05). ective in patients with chronic LBP. ESWT allows reducing	
	Ke	ywords:	pain, although it does not se	em to significantly imp	rove a patient's functional state.	
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Background

Extracorporeal shock wave (ESWT) is a modern physiotherapeutic method which is useful for musculoskeletal conditions. Despite some evidence from recent systematic reviews, metaanalyses [1-4], and the Cochrane recommendations [5], there are still inconclusive results on ESWT. Moreover, the literature on ESWT in low back pain (LBP) treatment in the Web of Science Core Collection, PubMed, and MEDLINE databases is limited. There are only 6 randomized clinical trials (RCTs) showing the effect of ESWT on LBP [6-11] that went through methodological quality analysis using the Physiotherapy Evidence Database (PEDro) score (Table 1). Based on objective data, levels of methodological quality of these randomized clinical trials vary from medium to low. Furthermore, most studies did not meet the essential criteria of Evidence-Based Physiotherapy (no Cochrane recommendation and PEDro indexation), suggesting that this topic still requires in-depth investigation. Therefore, in practice, it is not easy to objectively analyze the clinical effectiveness of such procedures, together with precise recommendations regarding doses, treatment parameters, duration of the procedure, and other relevant aspects of the treatment protocol. For example, it is unclear how to evaluate radial vs focused techniques.

The radial method (rESWT) is based on pneumatic technology, using the principle of accelerated cartridge impact by compressed air under high pressure. In this way, the shock wave penetrates the body with a radiated beam, and its energy decreases with the depth of penetration. The pulse lasts a maximum of 5 ms, and the pressure reached by the wave does not exceed 1 MPa [12]. The focused technique (fESWT) is characterized by a stronger stimulus, having a more intense effect on the tissues. Unlike the radial method, the focused technique uses electroacoustic technology. Under the influence of high voltage, an acoustic shock wave is created in the applicator,

Table 1. A randomized clinical trial addressing the treatment of LBP using ESWT.

Researchers	PEDro score	Study limitations
Taheri et al 2021 [6]	4/10	No random allocation No baseline comparability No blinded subjects No blinded therapists No blinded assessors No adequate follow-up
Walewicz et al 2019 [7]	7/10	No concealed allocation No blinded therapists No blinded assessors
Moon et al 2017 [8]	7/10	No blinded therapists No adequate follow-up No intention-to-treat analysis
Schneider 2018 [9]	6/10	No concealed allocation No blinded subjects No blinded therapists No blinded assessors
Notarnicola et al 2018 [10]	3/10	No concealed allocation No baseline comparability No blinded subjects No blinded therapists No adequate follow-up No intention-to-treat analysis No point estimates and variability
Han et al 2015 [11]	3/10	No sham therapy No placebo No blinded subjects No blind therapists No blinded assessors No adequate follow-up No intention-to-treat analysis

PEDro – Physiotherapy Evidence Database.

forming a focused stimulus using a special lens. This stimulus with special coupling attachments is introduced into the patient's body at an appropriate depth, at the assumed pressure of up to 100 MPa, and the pulse duration up to $0.2 \ \mu s$ [13,14].

In 2020, our research team published clinical data on radial ESWT in treating patients with chronic LBP [15] that had the methodologically highest level (9/10 points) according to PEDro score. Our results showed that the ESWT technique might be especially used in maintaining remission of symptoms and preventing recurrence of disease. Therefore, our team has decided to examine an fESWT, which theoretically might have greater technological possibilities than the radial technique. Thus, the study aimed to assess the effectiveness of focused ESWT in reducing pain intensity and improving functional efficiency in patients with chronic LBP.

Material and Methods

Study Design

The research was carried out in the Clinical Research Laboratory of the Institute of Health Sciences of the University of Opole. The study was conducted in cooperation with the Department of Physiotherapy of the Wrocław Medical University in Poland. The local and independent Bioethics Committee of the University of Opole approved the study protocol (no. KB/90/FI/2018). The study was prospectively registered at the International Standard Randomized Controlled Trial Number (ISRCTN) registry database (no. ISRCTN13785224). Each participant provided their written informed consent prior to the study. The studies were conducted in accordance with the Helsinki Declaration and Good Clinical Practice guidelines.

Randomization and Blinding

Patients were selected for this randomized and single-blinded project by an internist, radiologist, neurologist, neurosurgeon, orthopedist, and physiotherapist. After a positive qualifying procedure, participants were randomly assigned to real or sham ESWT treatments using a computer random number generator (<u>www.random.com</u>). Both groups also performed basic central spine stabilization exercises. The allocation to the group did not depend on the research staff implementing the therapy and analyzing the results. The same therapist conducted all tests and surveys. One physiotherapist performed all treatments and stabilization exercises.

Participants

Patients with L5-S1 discopathy, chronic pain, and no spinal surgical intervention were qualified. The participants were of

legal age and had current magnetic resonance imaging (MRI) scans confirming the LBP syndrome – type 3 changes in section L5-S1 according to Modic classification (MC), which describes vertebral endplate lesions.

The exclusion criteria were: discopathy beyond the L5-S1 (MC type 1 and 2), no pain and reduced mobility in the lumbosacral segment, other spinal conditions (fractures, tumors, spondylolisthesis, rheumatic diseases, cauda equina syndrome), pregnancy or ovulation, neurological deficits, implanted cardiac pacemaker, blood coagulation disorders, metal implants within the application site, sensory disturbances, mental disorders, cancer, skin lesions within the treatment site, viral and bacterial infections, painkillers, and anti-inflammatory drugs.

The study involved 40 patients with L5-S1 discopathy of the spine with chronic pain lasting at least 12 weeks. Patients were randomized into 2 groups: group A (n=20) with a mean age of 42.3 ± 13.1 years and group B (n=20) with a mean age of 45.4 ± 14 years. The groups were homogeneous regarding demographic characteristics (**Table 2**) and initial pain and functional status assessments. Following the Consolidated Standards of Reporting Trials (CONSORT) guidelines for registered randomized clinical trials, the patient flow over the entire period of the study is shown in **Figure 1**. In both groups, all participants completed treatment. All patients were assessed 1 month later and 3 months after the end of the study. It should be noted that 1 person in group A (business trip at the time of taking the measurements) and 2 people in group B (taking painkillers) were excluded from the statistical analysis.

Treatment

Group A was an experimental group treated with an fESWT shockwave using the Duolith SD1 Tower device (Storz Medical, Switzerland; **Figures 2, 3**). Each procedure was performed using the contact method at the lumbar and sacral spine level in the area of greatest pain indicated by the patient (**Figure 4**). The following parameters were used for the therapy: energy flux density 0.15 mJ/mm² (1000 pulses), frequency 4 Hz. An ultrasound gel was used as a coupling substance between the applicator and the patient's skin to reduce tissue resistance. Treatments were performed twice a week (Monday and Thursday) for 5 weeks (10 treatments in total). The therapy was conducted under ultrasound guidance.

Group B was a control group, treated with a sham fESWT. Stimulation took place using a special polyethylene insert mounted on the top of the applicator, which absorbed energy and limited its spread in the tissue. The treatment procedure was identical to condition A in terms of the audible signals and the technical parameters used in the actual procedure.

Variable		Ex	perime	ntal fES	WT gro	up			Control fESWT group							
variable	π	Me	Min	Max	Q1	Q3	SD	π	Me	Min	Max	Q1	Q3	SD	P value	
Age [years]	4.3	43.0	18.0	64.0	33.0	49.0	13.1	45,4	49.0	22.0	76.0	36.0	55.0	14.0	0.490	
Body weight [kg]	72.8	73.0	57.0	90.0	61.0	83.0	11.6	74.5	77.0	55.0	87.0	72.0	81.0	9.2	0.989	
Body height [cm]	172.6	173.0	156,0	186.0	164.0	178.0	7.9	168.1	170.0	150.0	182.0	163.5	172.0	8.8	0.068	
BMI [kg/m²]	24.3	23.6	18.3	30.5	21.8	27.8	3.9	26.5	27.1	22.0	32.0	24.3	27.8	3.0	0.102	
Disease duration [months]	57.5	48.0	3.0	204.0	24.0	84.0	50.9	61.8	60.0	3.0	180.0	24.0	72.0	53.1	0.989	
Sex		=10; 50. n=10; 50							=10; 50. n=10; 50						1.000	

Table 2. Characteristics of the study groups.

fESWT – focused extracorporeal shock wave; n – number of individuals; $\overline{\chi}$ – mean; Me – median; Min – minimum value; Max – maximum value; Q1 – lower quartile; Q3 – upper quartile; SD – standard deviation; F – female; M – male. * U-Mann-Whitney; ** Chi-square test.

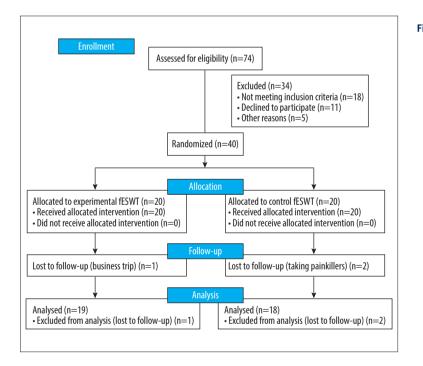


Figure 1. CONSORT flow chart of study participants. fESWT – focused extracorporeal shock wave.

The treatment protocol in both groups included identical stabilization training (45 minutes, once a day, 5 days a week, Monday to Friday) with myofascial relaxation of the extensors of the spine, activation of the lumbo-sacro-pelvic complex and deep muscles, stimulation of proper breathing, and dynamic postural exercises.

Measurement

Therapeutic progress was assessed by analyzing subjective pain sensations using a visual analog scale (VAS), on which the patient-rated the symptoms on a numerical scale from 0 to 10 (0 indicated no pain, 10 indicated the strongest pain).

The Laitinen Pain Scale (LPS) was also used, which measures 4 criteria of pain: its intensity, frequency of its occurrence, use of



Figure 2. Duolith SD1 Tower device for high-energy fESWT.



Figure 3. fESWT applicator used in this study.

painkillers, and limitation of motor activity. Patients assigned points from 0 to 4 (0 – no pain, 4 – severe pain) to each of the determined indicators.

Functional fitness was assessed using the Oswestry Disability Index (ODI), which consists of 10 sections, with 8 related to activities of daily living and 2 related to pain concerns; responses are graded from 0 to 5, and the total ODI score is presented on a scoring system of 0-50 or a percentage system of 0-100% indicating the degree of disability.



Figure 4. Treatment session using the fESWT applicator.

Tests and questionnaires were administered in both groups at the beginning, after treatment, and during follow-up visits after 1 and 3 months. During this time, the patients were not receiving any other treatment.

Sample Size

The sample size was based on group differences in primary outcomes (means and standard deviations of pain experience), estimated at 26 participants (13 in each group). A 20% loss to follow-up was allowed for in calculations. The decreasing sample size also applied to historical information from our unit because 45% of patients offered conservative management (physical therapy agents) for LBP opted for ESWT within 6 months.

Statistical Analysis

Statistical analysis was performed using the Statistica 13 program (TIBCO, Inc., USA). Arithmetic means, medians, standard deviations, quartiles, and the range of variability (extreme values) were calculated for measurable variables. For qualitative variables, the frequencies were calculated (the results were given as percentages). Quantitative variables were subjected to the Shapiro-Wilk test to determine the normality of distribution. Comparisons between groups were made using the chi-square test (χ^2). Within-group comparisons for measurement conditions 1, 2, 3, and 4 were performed by Friedman's analysis of variance and a post hoc test (Dunn's test). Finally, the comparison between the experimental and placebo groups was assessed using the Mann-Whitney U test. The level for statistical significance was α =0.05.

Table 3. VAS scores in both groups.

Variable	Manager		Ex	perime	ntal fES	WT gro	up	Control fESWT group								
	Measure	π	Me	Min	Max	Q1	Q3	SD	π	Me	Min	Max	Q1	Q3	SD	
VAS score	Before	7.2	8.0	4.0	10.0	5.0	8.5	1.9	7.3	7.0	5.0	10.0	6.0	9.0	1.7	
	After	1.5	1.0	1.0	3.0	1.0	2.0	0.6	2.9	3.0	1.0	6.0	2.0	3.0	1.3	
	1 month FU	1.7	1.0	1.0	5.0	1.0	2.0	1.1	3.1	3.0	1.0	7.0	2.0	4.0	1.7	
	3 months FU	2.0	1.5	1.0	5.0	1.0	3.0	1.2	3.3	3.0	1.0	8.0	2.0	4.0	1.9	
P value (main effe	ect*)	<0.00)1					<0.001								
p-value (multiple comparisons**)		Before vs after: p<0.001 Before vs 1 month: p<0.001 Before vs 3 months: p<0.001 After vs 1 month: p=1.000 After vs 3 months: p=1.000 1 month vs 3 months: p=1.000							Before vs after: p<0.001 Before vs 1 month: p<0.001 Before vs 3 months: p<0.001 After vs 1 month: p=1.000 After vs 3 months: p=1.000 1 month vs 3 months: p=1.000							

fESWT – focused extracorporeal shock wave; n – number of individuals; $\bar{\chi}$ – mean; Me – median; Min – minimum value; Max – maximum value; Q1 – lower quartile; Q3 – upper quartile; SD – standard deviation; FU – follow-up. * Friedman's ANOVA; ** Dunn's test.

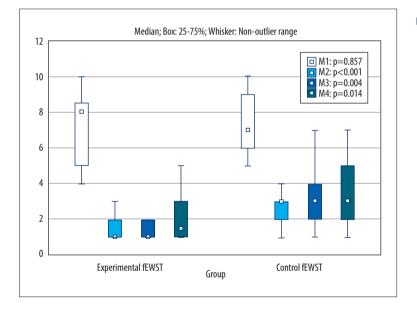


Figure 5. Comparison of VAS scores obtained in 4 measurements between the experimental and control group. fESWT – focused extracorporeal shock wave; M1 – before, M2 – after, M3 – after 1 month, M4 – after 3 months.

Results

Table 3 presents comparisons of pain (VAS) in both groups. There was a significant effect in both groups (P<0.05). The strongest analgesic effect was observed in the group treated with ESWT – by 5.7 points immediately after therapy, 5.5 points after 1 month, and 5.2 points after 3 months. In the sham ESWT (control) group, a significant decrease of 4.4 points occurred after therapy, then 4.2 points after 1 month, and 4.3 points after 3 months. Comparing pain between the groups (using the VAS scale showed differences immediately after treatment and 1 month after the end of treatment (**Figure 5**). For the ESWT group, there was a significantly greater improvement in VAS scores compared to the sham group (P<0.05 for all values), suggesting a clinical superiority of ESWT over the other group. There were no differences in the 3-month follow-up (P>0.05); however, the patients in the experimental ESWT group had greater improvement compared to the control group. The results confirmed the effectiveness of the analgesic effect immediately after treatment and a favorable outcome in long-term follow-up despite the slow recurrence of symptoms.

Table 4. LPS scores in both groups.

Variable		Experimental fESWT group Control fESWT								group					
	Measure	π	Me	Min	Max	Q1	Q3	SD	π	Me	Min	Max	Q1	Q3	SD
LPS	Before	8.8	8.0	4.0	15.0	7.0	11.0	3.2	7.1	6.0	4.0	12.0	5.0	9.0	2.6
	After	1.9	2.0	0.0	4.0	0.0	3.0	1.5	3.1	3.5	0.0	7.0	2.0	4.0	2.0
score	1 month FU	2.4	2.0	0.0	7.0	0.0	3.5	2.2	3.3	3.0	0.0	7.0	2.5	4.5	2.1
	3 months FU	2.8	3.0	0.0	5.0	1.0	5.0	2.0	3.7	4.0	0.0	8.0	2.5	5.5	2.4
P value (main effe	ect*)	<0.00)1					<0.001							
p-value (multiple comparisons**)		Befor Befor After After	re vs 1 re vs 3 vs 1 m vs 3 m	onth: p= onths: p	p<0.001 p=0.00 =1.000				Befo Befo After After	re vs 3 i vs 1 m vs 3 m	month: months: onth: p= onths: p	p<0.001 p=0.01			

fESWT – focused extracorporeal shock wave; n – number of individuals; χ – mean; Me – median; Min – minimum value; Max – maximum value; Q1 – lower quartile; Q3 – upper quartile; SD – standard deviation; FU – follow-up. * Friedman's ANOVA; ** Dunn's test.

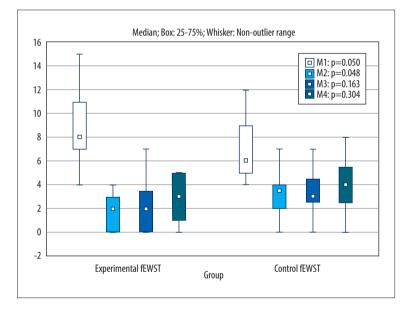


Figure 6. Comparison of LPS scores obtained in 4 measurements between the experimental and control group. fESWT – focused extracorporeal shock wave; M1 – before, M2 – after, M3 – after 1 month, M4 – after 3 months.

Table 4 shows the comparisons of perceived pain according to LPS in 4 measurements between the experimental and control groups. The mean pain scores changed significantly in both groups (main effect: P<0.05). A significant decrease in the perceived pain was observed immediately after the therapy by 6.9 points, after 1 month by 6.4 points, after 3 months by 6 points. However, in the control group, there was a significant decrease after the therapy by 4 points, after one month by 3.8 points, after 3 months by 3.4 points.

Patients from the experimental group differed from the control group immediately after treatment, indicating remission of pain

(P<0.05). In follow-up observations (after 1 and 3 months), there were no significant differences (P>0.05) (**Figure 6**), although the trend for therapeutic advantage was still maintained.

Table 5 shows the between-group comparisons of functional assessments taken with the ODI under 4 measurement conditions. There was a significant effect for both groups (significant effect: P<0.05). After the end of treatment in the experimental group, there was a decrease by 15.1 points, after 1 month by 16.1 points, and after 3 months by 15.1 points. The ESWT results suggested a stable clinical effect, taking into account the functional assessment of patients. On the other

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Table 5. ODI scores in both groups.

Variable			Ex	perime	ntal fES	WT gro	up			Control fESWT group							
	Measure	π	Me	Min	Max	Q1	Q3	SD	π	Me	Min	Max	Q1	Q3	SD		
ODI score	Before	33.4	34.0	25.0	47.0	30.0	38.0	6.3	32.5	29.5	23.0	54.0	28.0	33.5	8.6		
	After	18.3	16.0	9.0	31.0	12.0	24.5	7.5	19.5	20.0	10.0	35.0	15.5	23.0	6.5		
	1 month FU	17.3	14.0	9.0	31.0	12.0	23.0	7.1	18.7	19.0	10.0	32.0	14.0	21.0	6.6		
	3 months FU	18.3	16.0	11.0	31.0	12.0	24.5	6.8	19.9	19.0	10.0	36.0	15.5	23.5	7.4		
P value (main effe	ect*)	<0.001								<0.001							
p-value (multiple comparisons**)		Befor Befor After After	re vs 1 r re vs 3 r vs 1 m vs 3 m	nonths: onth: p= onths: p	p<0.001 p<0.00 =1.000				Befor Befor After After	re vs 3 r vs 1 m vs 3 m	nonth: nonths: onth: p= onths: p	p<0.001 p<0.00					

fESWT – focused extracorporeal shock wave; n – number of individuals; $\bar{\chi}$ – mean; Me – median; Min – minimum value; Max – maximum value; Q1 – lower quartile; Q3 – upper quartile; SD – standard deviation; FU – follow-up. * Friedman's ANOVA; ** Dunn's test.

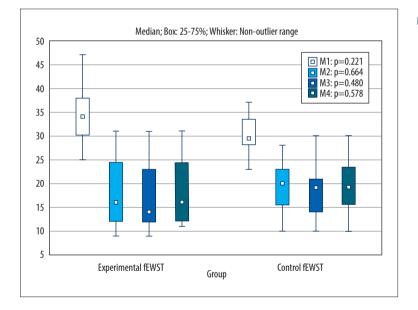


Figure 7. Comparison of ODI scores obtained in 4 measurements between the experimental and control group. fESWT – focused extracorporeal shock wave; M1 – before, M2 – after, M3 – after 1 month, M4 – after 3 months.

hand, there was a decrease after therapy by 13 points in the control group and conditions 1 month after, 13.8 points, and 3 months after 12.6 points. However, between-group comparisons revealed no statistically significant differences (**Figure 7**).

Discussion

Our experience with using rESWT [7,15] in LBP treatment procedures is far-reaching. Previous clinical studies have shown the high effectiveness of the procedure in reducing pain, enhancing the functional state of patients, and improving the stabilization of body posture. Notably, both publications showed that the therapeutic effect was maintained in long-term observation and was associated with longer remission of disease symptoms compared to standard physiotherapeutic methods.

However, the results of the present randomized clinical trial are not very promising. The analgesic effect was evident, but there was no strong improvement in functional status over the control group. Certainly, a more detailed analysis is needed, based on other research tools and scales of physical fitness, while maintaining the highest methodological levels (over 7 points on the PEDro scale).

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There is only 1 previous report like the present results. In an Iranian study, Taheri et al [6] (only 4/10 points on the PEDro scale) verified the effectiveness of focus shock waves in combination with oral medications and exercise in reducing pain in LBP patients. Ultimately, 38 people were randomly assigned to 2 groups. In the first group, ESWT was used with energy flux density 0.15 mJ/mm²; 1500 pulses, frequency 4 Hz, patients received 1 treatment weekly for 4 weeks); painkillers and exercise were also employed. The second group received a sham and standard therapy as the first group.

As in the above report, our study used ESWT with an energy flux density of 0.15 mJ/mm² (1000 pulses), frequency 4 Hz, and patients received a total of 10 treatments over a period of 5 weeks (twice a week). Taheri et al evaluated the therapy by measuring patients' pain using the VAS scale and assessing disability with the ODI scale. Control measurements were taken before treatment, 1 month, and 3 months later. Our study used the same length of follow-up (1 and 3 months). However, the Iranian study showed that the VAS and ODI parameters improved significantly in both groups. Researchers indicated that their shock wave therapy effectively treated LBP, combined with drug treatment and exercise. Still, interestingly, the beneficial outcomes did not apply to ODI, as in our project. It seems that usage of oral pharmacotherapy was the weakness of the present work. Notably, it was difficult to estimate to what extent pain reduction is due to the physical method or resulted from the biochemical action of the drug and analgesia. This observation certainly diminishes the credibility of our findings. Our participants used only physiotherapeutic methods.

In turn, Moon et al [8] compared the single application of ESWT and sham surgery in patients with LBP without complete treatment, as was the case in the present study. The ESWT group received 2000 pulses during the procedure with the maximum energy level tolerated by the patient (energy flux density=0.09-0.25 mJ/mm²), and the probe was positioned perpendicular to the posterior lumbar line and moved up and down along the connecting line. Therapeutic progress was assessed 1 and 4 weeks after surgery using the 10-cm numerical rating scale (NRS) and the ODI. At the end of the study, pain reduction and functional improvement were found, and there was a conclusion that ESWT may be suitable for therapy in reducing LBP. In addition, the study received 7/10 points on the PEDro scale, although the obtained results are challenging to apply to a complete treatment program.

Schneider's [9] study, with a PEDro of 6/10 points showed that manual myofascial (MT) therapy in combination with ESWT increased the physiotherapeutic efficacy in the management of chronic LBP. The studies of 2 groups compared the MT treatments combined with ESWT (1st group) with the MT treatment condition (2nd group). The therapy was carried out twice a week for 3 weeks, and there was no follow-up. Nevertheless, the short-term results were promising. Similar conclusions were reported by Notarnicola et al [10] and Han et al [11], whose short-term observations showed favorable analgesic effects and improvements in aspects of quality of life. However, these studies had low methodological PEDro levels (3/10 points).

In summary, focused ESWT can be effective in the analgesic effect in patients with LBP. Furthermore, the method can contribute to remission and lasting analgesia. However, despite some positive evidence, it is premature to reach a conclusion regarding the effectiveness of the focused technique in improving the functional state of patients. In this respect, our findings are not as promising and seem to be less convincing than outcomes from a less technologically advanced radial wave technique. However, this finding would require a single comparative analysis in joint clinical development for both methods.

Study Limitations

Future research should use other objective measurement methods (eg, stabilometric platform, surface electromyography) and include more participants over a longer period. Also, it is important to establish uniform treatment parameters that can be verified by other researchers. In subsequent studies, the questionnaire assessment of disability should be extended.

Conclusions

Focused ESWT in conjunction with an exercise program can be effective in patients with chronic LBP, both short- and longterm. In addition, focused ESWT allows reducing pain, although it does not seem to improve a patient's functional state significantly. Thus, ESWT cannot be a key enrichment method for a standard rehabilitation program at this stage. Therefore, further clinical trials should be conducted, especially regarding patient functional evaluation after applying focused ESWT.

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Department and Institution Where Work Was Done

Clinical Research Laboratory of the Institute of Health Sciences of the University of Opole, Opole, Poland.

Declaration of Figures' Authenticity

All figures submitted have been created by the authors who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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