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# The Effects of a Suggested Early Physical Therapy Rehabilitation on Pain and Functional Performance After Lumbar Fusion Surgery

# Hossam M. Elghannam<sup>1\*</sup>, Mona M. Ibrahim<sup>2</sup>, Mostafa M. Abulkhair<sup>3</sup>, Elsadat S. Soliman<sup>2</sup>

<sup>1</sup> Physical therapist, Al Hussein University Hospital, Al Azhar University, Cairo, Egypt.

<sup>2</sup>Department of physical therapy for musculoskeletal disorders and its Surgeries, Faculty of Physical Therapy, Cairo University, Cairo, Egypt.

<sup>3</sup>Departement of Neurosurgery, Faculty of Medicine, Al Azhar University, Cairo, Egypt.

	Abstract:
*Correspondence to	Introduction: Lumbar Spine Fusion (LSF) is a common surgery for treating
Hossam Eldein Mostafa	lumbar spine disorders like degenerative disc disease, spondylolisthesis, and
Elghannam. Physical therapist,	spinal stenosis. Postoperative rehabilitation is necessary to optimize
Al Hussein University	outcomes and reduce the risk of complications.
Hospital, Al Azhar University, Cairo, Egypt.	<b>Purpose</b> : This study aims to investigate the effect of a suggested early
Tel: 002-01150351548	physical therapy program compared to standard care on pain and functional
Email:	performance post-surgery.
dr.hossam1993.hm@gmail.com	Methods: This study is a controlled clinical trial including a two-group
	pretest-posttest design, all of the patients were undergoing posterolateral
Published online:	fusion of 1–3 levels in the early stage (4 to 6 weeks post-operative). Group A
	(Control) (n=21): Patients received standard care; Group B (Experimental)
	(n=21) Patients received a suggested early physical therapy protocol in
	addition to the standard care. Pain intensity was measured by the Visual
	Analogue Scale (VAS) and functional disability by Oswestry Disability
	Index (ODI) at week 4 to 6 post-surgical (pre-treatment) and at week 10 to
	12 post-treatment.
	<b>Results</b> : There were no significant differences in the VAS of group A
	(control) compared to that of group B (treatment) at the pre-treatment ( $p =$
	0.176) and at the post-treatment ( $p < 0.056$ ). There were significant
	differences in functional status between groups in the post-treatment
	measures in favore of the treatment group $(p < 0.001)$ .
	Conclusion: Adding a physical therapy program to the standard care protocol
	in the early stage post lumbar fusion surgery has favorable significant effect
	for 3 months post-surgery (a short term) on both the pain intensity and
	functional status in terms of mobility-related activities.
	Keywords: Early physical therapy; lumbar spine fusion; pain; Oswestry
	disability index; rehabilitation.

# **1. Introduction:**

Lumbar spine fusion (LSF) is a frequent surgical procedure used to treat lumbar spinal problems including degenerative disc degeneration, spondylolisthesis, and spinal stenosis (1).

While LSF can provide significant improvements in pain and functional

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performance, it may alter the adjacent segment's mobility in levels above and below the fusion level (2).

Postoperative rehabilitation is necessary to optimize outcomes and reduce the risk of complications and improve muscle strength which may be affected pre or post-surgery (3,4).

Most of the rehabilitation research focuses on post-discectomy patients in the post-operative phase (5). However, few articles offered detailed and accurate postoperative rehabilitation plans after lumbar fusion. None of them could be evaluated because there wasn't enough they information, so were all examined collectively and there is no unified vision about a specific rehabilitation program post-LSF (6,7).

A growing body of research on the benefits of rehabilitation after surgical treatment for low back pain. Because of worries that early exercise could overload the internal fixation, there is some conflict in the research about when to intervene after LSF (8).

In a randomized controlled trial conducted in 2013, there was no difference in the patient's physical performance measured by fitness and walking distance when rehabilitation was started six or twelve weeks following LSF (9).

Otherwise, growing evidence suggests early rehabilitation be started before the third month, with a focus on patient education, neurodynamic therapy, and a gait training for long distances as tolerated. This can be started preoperatively and post-surgery in acute care setting (3). This rehabilitation can be intensified after the third month once the process of bone and soft tissue healing is complete, according to the surgeon's agreement in an environment of support to achieve patient autonomy (10).

Kernc and his colleuges had established that supervised physiotherapy rehabilitation is superior to the standard care protocol in improving pain, fear avoidance and patients functional impairment post LSF (11).

Physiotherapy was intended to assist people with impairments or those who are at risk of developing them to achieve and sustain maximum functioning in their contexts (12).

Following spine surgery, patient activation defined as the willingness to participate in healthy behaviours is a crucial recovery modulator that improves outcomes and improves adherence to physical therapy treatment (13).

Therefore, this study examined the effect of adding early physical therapy rehabilitation to standard care on pain intensity and functional disability in terms of mobility-related activities for patients undergoing posterolateral spinal fusion surgery of 1–3 levels. The suggested early physical therapy rehabilitation is intended to maximise recovery through the provision of customised progressive exercises, education, and peer support, to aid in overcoming undesirable health beliefs.

# 2. Materials and Methods: Study design:

This study is a controlled clinical trial including a two-group pretest-posttest design. All patients were provided with sufficient information related to the current study including both assessment and treatment procedures. This study was conducted with the guidelines and approved by the local research Ethical Committee of the Faculty of Physical Therapy, Cairo University (No. P.T.REC/012/003952).

# **Participants:**

All of the patinents were undergoing posterolateral spinal fusion of 1-3 levels in the early stage (4 to 6 weeks post-operative). Fortytwo patients were assigned into two groups, Group A (Control) (n=21) in which patients received standard care and Group В (Experimental) (n=21) in which patients received a suggested physical therapy rehabilitation program in addition to standard care. All patients were evaluated for pain and functional disability at weeks 4 to 6 post-surgical, pre-physical therapy and at weeks 10 to 12 post-treatment. All assessment and treatment procedures were explained clearly to each patient and after their approval to participate, they were asked to sign an informed consent.

To detect the effect size of Cohen's d = 0.8 with 80% power (p = 0.05), G\*power software (version 3.1.9.7, Franz Faul, Universitat Kiel, Germany) was used to calculate a total sample size of 42 participants.

Study patients were assigned to either group (A) or group (B) and the patient allocation was based on labled blinded cards and their availability to apply the treatment protocol throughout the 6 weeks of sessions.

Patients were selected based on the following criteria: age between thirty to sixty years old, having one of the degenerative conditions including disc degeneration, lumbar spondylosis and canal stenosis with or without spondylolisthesis and undergoing LSF of 1 to 3 levels of fixation, even with vertebral cage or not, performed from an anterior, posterior or lateral approach.

Patients who had a previous lumbar spinal neoplasms, infections. metastases. fusion. metabolic bone disease, fractures, post-traumatic vertebral compression/deformity, or any known inflammatory arthropathies were excluded from the study. The following also were excluded; patients with a mental health condition (such as dementia, developmental delays, or substanceinduced cognitive impairment) as well as patients with other special conditions where the surgeon or an assessment such as "fragile due to very old age, extremely poor functional level, psychiatric disease, or other serious comorbidities" determined that the patient could not participate in the intervention.

#### Assessment of pain intensity:

Using the Visual Analogue Scale (VAS), the patient was asked to place a mark on the line that corresponds to the current pain intensity in which zero means no pain and ten means extreme killing pain (14). A ruler was used to measure the distance from zero and the marked point in centimetres.

## Assessment of back function disability:

The Arabic version of the Oswestry Low Back Pain Disability Index (ODI) was used for the assessment of functional disability which consists of a 10-item self-assessment questionnaire with six levels of response options that can be rated from 0 to 5. Pain, self-care, moving and lifting objects, walking, sitting, and standing; sleep difficulties brought on by low back pain; sex life; social life; and travel are among these functional outcomes. To determine the percentage of disability, the total score is multiplied by 100 and the percentage of disability varies from 0% (no impairment) to 100% (full disability). (15).

The scoring system is from 0 to 20% which represents minimal impairment; from 20 to 40%

which represents moderate disability, from 40 to 60% which represents severe disability, from 60 to 80% which indicates crippling LBP and above 80% which indicates the person is bed ridden.

#### **Treatment procedures:**

All patients are treated by the same physical therapist. Group A (control group) received standard care protocol with no active therapeutic intervention, which includes early ambulation, pain management, nursing service, wound monitoring, physical mobility instructions. and All patients were advised to avoid carrying any heavy (maximally a kettle-like weight weight), cardiovascular exercises like calf muscle pump or circulatory exercises and gradually progress their outdoor mobility (16).

Group B (treatment group) received the suggested early physical therapy program added to the standard care protocol for a frequency of two sessions per week for 6 weeks; the program intensity is increased every 2 weeks. The suggested program includes aerobic exercises such as free walking and stationary recumbent bike, lumbar stabilization exercises and mild manual soft tissue release for paralumbar muscles.

## Statistical analysis:

SPSS for Windows, version 26 was used for the statistical analysis (SPSS, Inc., Chicago, IL). The data were examined for normality, homogeneity of variance, and the presence of extreme scores prior to the final analysis, and the p-value was set at 0.05. This analysis was performed as a prerequisite for parametric testing of the difference analysis.

Comparison between mean values of the different parameters in the two groups was performed using repeated measure ANOVA test to determine the significant differences between both groups at the two times testing interval (pre and post-treatment). Post hoc test used to confirm where the differences occurred between groups.

## 3. Results:

Forty-two patients after posterolateral spinal fusion of 1-3 levels surgery in the early stage (4 to 6 weeks post-operative) participated in the current study. Patients were subdivided into two groups,

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n= 21 in Group A (control) received standard care and n= 21 in Group B (treatment) received a suggested physical therapy rehabilitation program in addition to standard care. The distribution of males and females in the control group was 66.7 % (14) and 33.3 % (7) respectively, while in the treatment group, it was 61.9 % (13) and 38.1 % (8) respectively. Using the Chi-square test to compare the gender distribution of all patients in the control and treatment groups found no significant differences between groups (p =0.064). Using the independent sample t-test, the mean values of age, weight, height, and BMI for all patients in the control groups indicated no significant differences in age (p = 0.791), weight (p = 0.785), height (p = 0.615), and BMI (p = 0.615)0.295), as shown in (Table 1).

Table 1: Descriptive statistics and the independent sample t-test for the demographic data

Variable	Mean ± SD		t-	<b>P-</b>	Sig.
	Control	Treatment	value	value	
	group	group			
	N = 21	N = 21			
Age	$45.24 \pm$	$44.48 \pm$	0.266	0.791	NS
(years)	9.88	8.61			
Weight	$91.14 \pm$	$92.10 \pm$	0.507	0.615	NS
(kg)	11.79	10.88			
Height	170.48	$169.19 \pm$	-	0.785	NS
( <b>cm</b> )	$\pm 8.45$	7.98	0.275		
BMI	$30.94 \pm$	$32.32 \pm$	-	0.295	NS
(kg/m <sup>2</sup> )	3.90	4.51	1.062		

\*SD= Standard deviation, \*t-value=t-statistic, \*P-value=probability, \*Sig. =Significance, \*NS=non-significant.

## **Repeated measure ANOVA:**

Repeated measure ANOVA was conducted to study the effect of rehabilitation timing on VAS and ODI in both groups. There was a significant interaction effect of treatment and time for VAS (p = 0.005) and ODI (p < 0.001). There was a significant main effect time for VAS (p < 0.001) and ODI (p < 0.001) (Table 2). The estimated marginal means of VAS and ODI in both groups were illustrated Figure (1,2). in

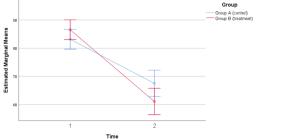


Figure 1: Estimated marginal means of VAS

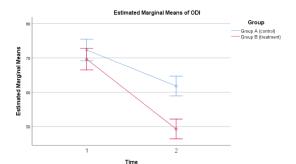


Figure 2: Estimated marginal means of ODI of the control and treatment group

Table 2: Effect of timing of rehabilitation on VAS and ODI.

<b>Repeated measure ANOVA</b>					
Interaction effect (Group * time)					
VAS	F = 8.933	p = 0.005*			
ODI	F = 37.10	p < 0.001*			
Effect of time					
VAS	F = 156.42	p < 0.001*			
ODI	F = 362.46	p < 0.001*			

The differences between groups and the results of testing will be presented as follows:

The mean differences between the pre-treatmet VAS and post-treatment VAS in the control and treatment groups was 15.62 mm and the percentage of change was 19% and 25.42 mm and the percentage of change was 29%, respectively. There was a significant decrease in VAS between preand post-measure in the control group (p < 0.001) and the treatment group (p < 0.001). There was no significant difference in the VAS of group A (control) compared to that of group B (treatment) at the pre-tratment (p = 0.176) and at the posttreatment (*p* < 0.056) (**Table3**).

The mean difference between the ODI pre and ODI post in the control and treatment groups was 10.48 % and the percentage of change was 14% and 20.33 % and the percentage of change was 29% respectively. There was a significant decrease in the ODI between pre- and post-measure in the control group (p < 0.001) and the treatment group (p < 0.001). There was no significant difference in the ODI of group A (control) compared to that of group B (treatment) at pre-rehabilitation protocol (p = 0.232). There was a significant difference in the ODI of group A (control) compared to that of group B (treatment) at post-rehabilitation protocol in favor of group B (p < 0.001) (**Table 3**).

		Group A (Control) N = 21 $\overline{X} \pm SD$	Group B (treatment) N = 21 $\overline{X} \pm SD$	Between-group comparison		
				MD	p-value	Sig
post MD	Pre	83.14±8.77	86.52±7.03	-3.37	0.176	NS
	post	$67.52 \pm 12.04$	61.10±8.93	6.42	0.056	NS
	MD	15.62	25.42			
	p-value	< 0.001*	<0.001*			
	Sig	Sig	Sig			
ODI	Pre	72.29±7.001	69.62±7.24	2.67	0.232	NS
	post	$61.81 \pm 5.71$	49.29±7.30	12.52	< 0.001*	Sig
	MD	10.48	20.33			
	p-value	<0.001*	<0.001*			
	Sig	Sig	Sig			

Table 3: Mean, within and between-group comparisons for all pain and function

X : Mean t value: Unpaired t value SD: Standard deviation *p*-value: Probability value MD: Mean difference NS: Non-significant

# Discussion

The present study aimed to investigate the effect of a suggested early physical therapy rehabilitation program based on a selected protocol which includes aerobic exercises such as free walking and stationary recumbent bike, lumbar stabilization exercises and mild manual soft tissue release for paralumbar muscles. Patients were assessed for pain and functional disability firstly after 4 to 6 weeks post-operative in pre-treatment phase and the intervention was 12 sessions twice weekly for 6 weeks: the second assessment was conducted after 10 to 12 weeks post-operative. The patients' pain intensity was measured using VAS and his/her functional disability level was measured by the Arabic version of ODI.

Patient safety was the major challenge at the postoperative stage, therefore, the selected exercises were designed carefully to optimize the physical function of the patients while keeping them safe.

During the rehabilitation process, there was some sort of difficulty in some exercises, which led to modify each of them to be affordable to keep the patients safe and motivated to continue the program. Some previous studies were focused on the rehabilitation protocol and type of intervention regardless of the timing of those interventions if early or late (10,16,17,18). On the other hand, other studies were primarily focused on the time.

To start the rehabilitation program without designing a specific protocol considering the safety and effectiveness of the program (3,9,19).

In the present study, the design of the selected exercise program considered the time of rehabilitation at the early stage by selecting appropriate and safe training such as lumbar stabilization exercises from neutral positions, aerobic training, flexibility training and gentle massage. Furthermore, patient safety was considered an important factor in addition to the effectiveness of the intervention.

A previous study examined 53 patients who underwent spine surgery for a degenerative lumbar disease at 6 weeks, 3 months, and 6 months after the procedure. They evaluated physical activity and patient-reported physical function. Mean daily steps and time spent in moderate to vigorous physical activity (MVPA) were used to measure physical activity. Oswestry Disability Index (ODI) was the measurement scale of physical function. Individuals who underwent lumbar spine surgery for degenerative illnesses had low levels of physical activity in the early postoperative period, according to the data. Despite moderate to significant gains in physical function, there was little to no improvement in objectively assessed physical activity from 6 weeks to 6 months following spine surgery (20).

In a recent study, a clinic-based 12-week lumbar stabilization exercise (LSE) dramatically increased back extensor muscle strength, low back pain, functional impairment, and health-related quality of life (QOL) scores after LSF of 1 or 2 spinal levels, without causing any negative side effects. Mean isometric strengths in all patients showed a small decline from preoperative to three months after surgery before considerably increasing at six and twelve months. However, patients in the LSE group experienced a considerably greater increase in back strength at the most recent follow-up (64.2%) than patients in the control group (21.7%). In addition, the LSE group noted a greater reduction in back pain (58.2%) than the control group (26.1%) (21).

Another RCT with 144 patients who were undergoing LSF at 1-2 levels are being developed for low back pain caused by lumbar spine degeneration. Throughout 10 weeks, the patients would be randomly selected to receive either standard care or standard care with graded activity and pain education (GAPE) (22). In comparison to the "usual care group," they found that GAPE significantly reduced sedentary behaviour and, secondarily, disability, pain intensity, and fear of movement. It also improved patients' self-efficacy for physical activity and quality of life.

A previous study in 2018 started the rehabilitation very early (3 weeks following surgery) with 27 patients between the ages of 45 and 70 enrolled in the study. Three weeks following surgery, the strength training group began their rehabilitation. Over nine weeks, patients engaged in a twice-weekly exercise session with an emphasis on lumbopelvic stabilisation muscle activation. The control group adhered to the accepted postoperative protocol, which excluded exercise at that point in the healing process. After the surgery, functional results and plain radiographs were assessed at 3 weeks, 3 months, and finally 18 months (3). The an early study found that postoperative rehabilitation program based on strength training principles is safe 3 weeks after lumbar spine fusion and results in faster functional recovery than the standard treatment.

The study has a few limitations to note. One of the limitations of this study is the restricted randomization in patients' selection, it may be due to the difficulty for a few patients to enroll in the treatment group due to the difficulty of attending the treatment sessions regularly because they live away from the hospital which led us to allocate them to the control group. Another limitation was the high BMI for the patients who participated in the study had a significantly which may affect the improvement process. To determine the efficacy of carrying out these program early, a long-term follow-up may be required at 6 months and 1 year. **Conclusion:** 

Adding a physical therapy program to the standard care protocol in the early stage post lumbar fusion surgery has favorable significant effect for 3 months post-surgery (a short term) on both the pain intensity and functional status in terms of mobility-related activities.

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