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ORIGINAL ARTICLE

Bone Graft Alone Versus Cage with Bone Graft in Lumbar Spine Interbody Fusion.

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ABSTRACT

Background: Posterior lumbar interbody fusion (PLIF) is a fusion technique with reliable and rapid fusion results. This prospective, controlled, randomized clinical study critically compared the clinical and radiological outcomes in patients surgically treated by PLIF with bone graft alone versus those treated by PLIF with cage with bone graft.

Objectives: The purpose of the current study is to assess the safety and efficacy of lumbar interbody fusion.Also,direct comparison of both materials in terms of clinical and radiological outcomes. **Patients & Methods:** In the period between November, 2018 and July, 2019, 24 cases of degenerative lumbar spine disorder selected according to the inclusion and exclusion criteria for posterior lumbar interbody fusion. **Results**: The follow-up period was 9 months. Pain and functional Visual analogue scale (VAS) scores showed marked improvement. from 7.1to 2.25 in group I (bone graft alone), while Group II (cage with bone) decreased from 7.5 to 2. The mean Oswestry Disability Index (ODI) decreased from 45 to 18 in group I, while group II decreased from 51 to 22. The fusion rate was 83.3% in the first group and 91.7% in the second group. There was no statistically significant between both groups. In both groups, changes in disc height, and whole lumbar lordosis between the pre-and postoperative periods were significant in both groups. **Conclusions:** Both techniques after PLIF produced satisfying clinical and radiological outcomes such as maintaining the proper intervertebral disc space restore lumbar lordosis, good bony union, rigid stability and a high fusion rate. but no statistical difference between both groups.

Keywords: LBP= Low back pain, PLIF= Posterior lumbar interbody fusion, VAS= Visual analogue scale, and owestry disability index (ODI),LL =lumbar lordosis.

INTRODUCTION

Posterior lumbar interbody fusion (PLIF) is traditionally indicated in wide range of lumbar spinal pathologies including patients with degenerative lumbar spine disorder. Since Cloward's original description numerous modifications of the PLIF technique have been reported to improve the surgical ease along with the arthrodesis rates. These circumferential fusion techniques have some distinct theoretical advantages over other posterolateral techniques [(1)].

PLIF has many advantages over other forms of stabilization and fusion. An interbody graft is better suited to resist axial loads, prevent movement across a motion segment, and provide structural support. Placement of an interbody graft restores the height of the disc space, improves sagittal balance, and preserves patency of the intervertebral foramen and lateral canal. Problems associated with PLIF with iliac bone graft have traditionally included donor site morbidity like hematoma formation, infection and consistent pain at the donor site, with additional surgery time needed to obtain the bone graft. Other risks included posterior extrusion of the bone graft, dural injury, Cerbro Spinal Fluid (CSF) leak, and nerve root injury during interbody graft insertion or retraction. This is can be solve by using collected bone from decompression posterior neural arch during laminectomy (lamina , and facets joints)and cleaned of any attached soft tissue[(2)(3).]

Despite theoretical advantages of an interbody fusion, whether one type of the interbody graft or implant is superior to the other in terms of fusion rate and, more important, clinical outcome is an area of great debate, the successful fusion rate of PLIF varies widely, ranging from 56% to 99% [(4).]

PATIENTS AND METHODS

Between November 2018 and July 2019, at alzagazig University Hospitals, a total of 24 consecutive patients with degenerative segmental instability on clinical and radiological basis and indicated for PLIF with posterior screw fixation were included in this prospective study (degenerative spondylolithesis, degenerative disc disease with mechanical back pain, spndylosis and recurrent lumbar disc herniation). Twelve patients were operated by PLIF with bone graft alone **(Group I)** and another twelve patients were operated by PLIF with cage and bone graft **(Group II).**

Written informed consent was obtained from all participants and the study was approved by the research ethical committee of faculty of medicine Zagazig University. The work has been carried out in accordance with the code of Ethics of the world medical association (Declaration of Helsinki) for studies involving humans.

Inclusion criteria: Patients admitted to neurosurgery department for lumbar fixation and fusion in degenerative lumbar spine disorder.

Exclusion criteria: any patient less than 18 years and above 70years old, active infections, pregnancy and malignancy.

The groups of patients included Patients' ages ranged from 24 to 55 years. The mean age was 41 years. There were 14 (58.33%) female patients and 10 (41.67%) male patients.

Methods:

Preoperatively: patients were assessed as regards to: It included a detailed history and a full physical examination..

Clinically: General, Systematic and neurological examination.

Personal history (name, age, sex, occupational…etc), Complaint of the patient, Past history,

General examination, Neurological status (Motor examination, Sensory examination, Reflexes examination, Visual analogue scale (VAS), Oswetry Disability Index (ODI).

Routine labs work up. (e.g. CBC, PT, PTT, INR, Liver and kidney Function Test , and viral markers).

Radiologically:

X-ray lumbosacral spine (AP & Lateral & Dynamic views): to identify and grading of instability and to identify the Disc height and degree of lumbar lordosis.

CT lumbar to assess disc height and pars interarticularis.

MRI lumbar spine for neural tissue evaluation.

Approach: Posterior lumbar interbody fusion (group I bone graft alone and group II cage with bone).

Diagnosis: degenerative lumbar spine disorder.

Statistical analysis

Data collected throughout history, basic clinical examination, laboratory investigations and outcome measures coded, entered and analyzed using Microsoft Excel software.

Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) **(**Statistical Package for the Social Sciences) software for analysis. According to the type of data qualitative represent as number and percentage , quantitative continues group represent by mean ± SD , the following tests were used to test differences for significance;. difference and association of qualitative variable paired by Mac Nemmar . Differences between quantitative paired groups by paired t test. P value was set at <0.05 for significant results & <0.001 for high significant result.

RESULTS

Table (1): Comparing Low Back Pain (LBP) VAS scale between the two studied groups-There was statistically significant decrease in LBP- VAS scale pre-operative, at 3months and at 6 months follow up in both groups.

There was no statistically significant difference in LBP- VAS scale pre-operative, at 3 and at 6 months follow up between bone and cage graft groups

Table (2): Comparing Leg- VAS scale between the two studied groups:-

There was statistically significant decrease in LEG - VAS scale pre-operative, after 3month and after 6 months in both groups(7.5 preoperative VS 1.5 after 6 months and 7.5 preoperative VS 1.25 after 6 months) in group I and II respectively.

There was no statistically significant difference in LEG - VAS scale pre-operative, after 3month and after 6 months between bone graft and cage with bone graft groups.

Table (3): Comparing ODI between the two studied groups:-

There was statistically significant decrease in ODI pre-operative, after 3month and after 6 months in both groups (45 preoperative VS 18 after 6 months and 51.2 preoperative VS 18.2 after 6 months) in group I and II respectively.

There was no statistically significant difference in ODI pre-operative, after 3month and after 6 months between bone and cage graft groups.

Table (4): Comparing radiological assessment (fusion) between the two studied groups:-

In this table, there was no statistically significant difference in fusion between bone and cage graft groups**.**

A 42-year-old patient, worker, with no past history of medical illness or special habbits, Complaining sever LBP associated with intermittent tingling and numbness of both lower limb for 6 months duration and no history of significant trauma. Neuroimaging was done and diagnosed as lumber spondylosis L4-L5, bone graft with pedicular screw fixation has done Fig (1).

A 47-year-old patient, worker , hypertensive. Complaining of severe LBP associated with intermittent tingling and numbness of both lower limb and neurogenic caludication for 6 month duration. Neuroimaging was done and diagnosed as *spondylolesthesis L4-L5 grade II* Fig (2), cage with bone graft with pedicular screw fixation has done Fig (3).

Table (1): Comparing LBP- VAS scale between the two studied groups-

Variable	Group I (12) mean ± SD (Range) median	Group II (12) mean ± SD (Range) median	t-test	p-value
LBP- VAS scale pre-operative	7.1±1.16 (5-9) 7.1	7.5±1.17 (6-9) 7.5	0.0	1
LBP- VAS scale at 3months	3.16±0.57 (2-4) 3	3±0.73 (2-4) 3	0.6	0.5

Variable	Group I (12) mean ± SD (Range) median	Group II (12) mean ± SD (Range) median	t-test	p-value
LBP- VAS scale at 6months	2.25±0.45 (2-3) 3	2±.073 (1-3) 2	1	0.3
F-test	11.5	12.8		
value	**01****	**01****		

Table (2): Comparing Leg- VAS scale between the two studied groups:-

Variable	Group I (12) mean ± SD (Range) median	Group II (12) mean ± SD (Range) median	t-test	p-value
Leg- VAS scale pre-operative	6.5±1.16 (6-9) 7.1	7.5±1.16 (6-9) 7.5	0.0	1
Leg- VAS scale at 3months	2.4±0.5 (2-3) 2	2.25±0.45 (2-3) 2	0.8	0.4
Leg- VAS scale at 6months	1.5±0.4 (1-2) 1.5	1.25±0.3 (1-2) 1	1.2	0.2
F-test	19.7	28.8		
p-value	**0.001****	**0.001****		

** Statistically highly significant difference ($P \leq 0.001$)

Table (3): Comparing ODI between the two studied groups:-

Variable	Group I (12) mean ± SD (Range) median	Group II (12) mean ± SD (Range) median	t-test	p-value
ODI pre-operative	45±11.6 (30-60) 45	51.2±7.7 (40-60) 52.5	1.5	0.1
ODI At 3months	20±4.6 (14-26) 20	22±3.8 (16-30) 22	1.8	0.4

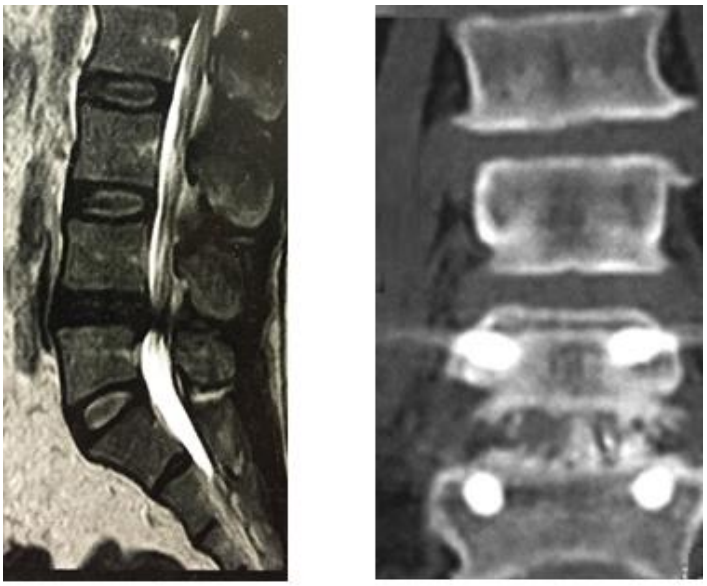
Variable	Group I (12) mean ± SD (Range) median	Group II (12) mean ± SD (Range) median	t-test	p-value
ODI at 6months	18±4.6 (12-24) 17	18.2±2.8 (14-21) 19	0.1	0.8
F-test	14.5	13.6		
p-value	**0.001****	**0.001****		

** Statistically highly significant difference (P ≤ 0.001)

Table (4): Comparing radiological assessment (fusion) between the two studied groups:-

Fusion	Group I No(12)	%	Group II No(12)	%	χ^2	p-value
Yes	10	83.3%	11	91.7%	FET	0.2
No	2	16.7%	1	8.3%		

Case 1 PLIF (bone graft)



A B

Figure (1):pre Pre operative L.S MRI T2 sagital view view(A) and Post operative L.S CT scan cronal view(B) at 6 months follow up.

Case2 PLIF(Cage with bone graft):

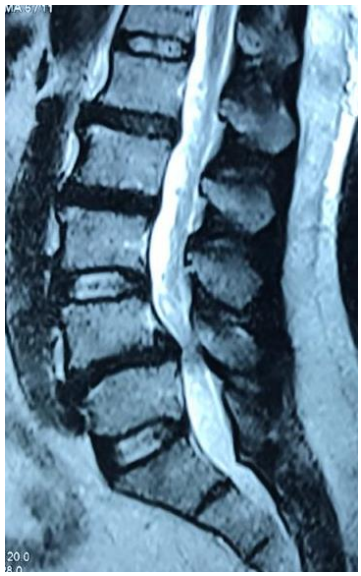
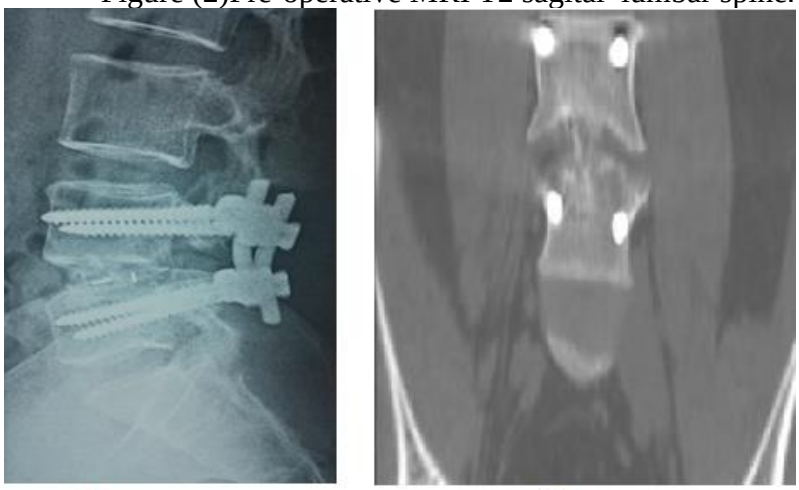


Figure (2)Pre-operative MRI T2 sagital lumbar spine.



A B

Figure (3):Post-operative lateral x-ray (A), sagittal and coronal CT lumbar spine (B) showed bony trabeculae bridging the fusion level (after 6 month)

DISCUSSION

In our study, the clinical outcome was assessed by visual analogue scale (VAS) for back pain and lower limb pain and Owestry Disability Index (ODI) after 3 and 6 month from surgery. We have found that: there was no statistically significant difference between both study groups regarding LBP VAS score, after 3month and 6 months follow up from surgery in comparison to the pre-operative same score. Within each group; there was statistically significant decrease in LBP- VAS score after 3 and 6 months in both groups.

In group (I): LBP- VAS scale in the pre-operative assesment was (7.1±1.16). After 3 months it was (3.16±0.57). At 6 months it decreased more to (2.25±0.45). According to the p-value ($p< 0.001$**) there was a significant improvementin LBP at 3 and 6 months follow up. In group (II) LBP- VAS scale in the pre-operative assesment was (7.5±1.17) .After 3 month it was deacresed to (3±0.73) . At 6 months follow up it was dropped to (2±0.73). In this study there was a marked improvement for LBP assesed by VAS as p-value was ($p<0.001$**)

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Regarding the leg -VAS in this study In group (I): preoperative leg-VAS was (6.5±1.16) while at 3 months was dropped to

(2.4±0.5). At 6 months follow up it was (1.5±0.4). As P-value was (p< 0.001**) significant improvement for sciatica was obvious. In group (II): leg-VAS in the pre-operative examination was (7.5±1.16) and after 3 months follow upw was (2.25±0.45) . At 6 months follow up it was (1.25±0.3) . P-value was (p <0.001**) which is indicate marked improvement for sciatica.

In the current study; ODI between for the two groups of patients ; was estimated without any significant statistically difference for the ODI in comparing to 3 and 6 months follow up. The ODI was improved in each individual study group as following; In group (I): preoperative ODI was (45±11.6), while in the 3 months follow up was decreased to (20±4.6) and within 6 month was (18±4.6). (p-value was <0.001**) which mean a significant improvement. In group (II):the preoperative ODI was (51.2±7.7) in 3 months duration (22±3.8), and in 6 month was (18.2±2.8). (p <0.001**) impling that improvement was significant.

Our results coincide with the results of **cheng et al** [5]. In this study an average of 3 years follow up who stated that PLIF which stated significant improvement in Visual analog scale (VAS) score before and 3years follow up after the surgery, 6.8 to 2.6 and Oswestry score disability index (ODI) was 31.3 and postoperative 14.1 .

In agreement with our study **KIM et al**., [6] in retrospective study of 18 patients undewent PLIF , found the Mean VAS for patients was 6.83 (range 9.03-4.63) before surgery and this improved after surgery to 2.50 (range 0.6-4.4).The mean ODI was 46.4%range (26.8-66%) before surgery and this too improved after surgery to 21.5% range (18.3-24.7%) Mean VAS at last follow up assessments improved by 53.3% . Mean ODI at last follow -up assessments improved by of 45.4%. VAS improvements found to be significantly related to postoperative lumbar lordosis (P=0.003). Similarly,ODI improvements were also found to be significantly associated with postoperative lumbar lordosis (P= 0.024) .

In the current study the disc space height was measured in radiological images of all patients and compared between the two groups. There was no statistically significant difference in disc height pre-operative and after 3 and 6 months follow up between the two groups. **In group (I):** there was increase in disc height at 6 months follow up. Pre-operatively, it was (7.6±1.1), 3 months (12.4±1.7) and at 6 months follow up became (12.25±2.03) **(P-valu <0.001****) this is indicate a significant increase in disc height which correlates with clinical improvement. **In group (II):** there was increase in disc height at 6 months follow up. Pre-operatively, it was (7.8±1), 3 months (12.7±1.6) and at 6 months follow up became (12.5±1.8).(**P-value <0.001****) this is indicate a significant increase in disc height which correlates with clinical improvement.

In a study by **Wang et al.,** [7] it was found that the mean disc height was restored in group I (with a local facet joint autograft alone); this result was not significantly different from that in group II (with PEEK + autograft). Their study showed that the mean postoperative height of the intervertebral space of patients in both groups was significantly increased six months after surgery and that the height of the intervertebral space was decreased two years after the surgery.

In the current study between two groups, there was no statistically significant difference in degree of lordosis pre-operative, at 3 and at 6 months between bone and cage graft groups. As result within each group, there was statistically significant increase in degree of lordosis at 6 months in both groups (40.2 preoperative to 50 after 6 months and 42.3 preoperative to 52.1 after 6 months) in group I and II respectively. There was no statistically significant difference in level of PLIF between bone and cage graft groups.

kim J S et al.. [6] **revised** the literature radiological evidence of successful arthrodesis which was noted in 44 of 46 patients (95.7%) in the group 1(mini TLIF) and in 32 of 32 patients (100%) in the group 2(open TLIF). The postoperative radiological data did not show any significant difference in the degree of listhesis and segmental lumbar lordosis between groups. But, significant

difference in disc height disc height and whole lumbar lordosis whole lumbar lordosis were noted. The mean disc height changed from 9.55 to 12.11 mm (p<0.001) after surgery in the group I and from 7.46 to 15.48 mm (p<0.001)after surgery in the group II. The mean preoperative values for segmental lordosis (˚), whole lumbar lordosis (˚), and the degree of listhesis (%) in the group 1 were 15.75˚, 51.18˚ and 16.68% respectively; they were changed to 18.28˚ (p=0.0078), 52.61˚ (p=0.28) and 8.13% (p<0.0001) at last followup

In our study, there was no statistically significant difference in fusion between bone graft group and cage with bone graft groups. The fusion rate was 83.3% in the first group and 91.7% in the second group after 6 months follow up ; this difference was not significant (p >0.05).

Among entire cohort there were 3cases (12.8%) with nonfusion at 6 months, 2 patientes (16.7%) among group (I), and 1 patient (8.3%) among group(II) and statisticall there wasn't significant between two groups, and reason of this nonunion may due to short study period, as most literatures suggest 12 months and more for complete union .

In agreement with our results, the series of **Csecsei et al[(8)]**, they reported a 95.7% fusion rate in 46 patients with the use of posterior elements taken from the decompression procedure as bone grafts as was done**. La Rosa et al[(9)]** , reported a 100 % fusion rate in 17 cases using a titanium cage and autogenous iliac crest (AIC) bone graft**.**

Furthermore, **Zhao et** al**[(10)]**, reported 100% fusion rate in 27 patients using BAK cages and AIC bone graft. While **Kai et al[(11)]** , reported only 92.9% fusion rate in a study done on 42 patients using local bone graft**.**

Our study , in post-operative complications between the two groups, we had two cases of superficial wound infection in both groups and this represented 8.3% in each group that treated conservatively by systemic antibiotics (iv and oral) for two weeks and daily dressing with topical disinfectant (betadine).On discharge and follow up ,the wound was clean and drye.Therefore, was no statistically significant difference in post-operative complications occurrence between both groups.

In agreement to our study by **Hu M. W., et al** , of 36 PLIF cases of procedures using the patient's lumbar spinous process and laminae they reported that there were 6 complications, including five patients (13.9%) had a dural tear and one patient (2.8%) had a superficial wound infection**[(12)].**

CONCLUSION

PLIF can be used successfully to treat degenerative spinal disorders after good patient selection with high incidence of patient's satisfaction.

Both methods used in lumbar spine interbody fusion either graft alone or cage with bone graft showed statistically significant decrease in LBP and Leg VAS and ODI scale pre-operative, at 3 and 6 months follow up.

Both technique after PLIF produced satisfying radiological outcomes such as maintaining the proper intervertebral disc space, restore lumbar lordosis , good bony union, rigid stability and a high fusion rate.

Further studies are needed to correlate and prove (rather than assume) that solid fusion would, in fact, ensure clinical improvement and relief of symptoms.

Conflict of interest The authors declare that they have no conflict of interest.

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