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Original Research Article

Comparison of outcome in lumbar spine instability treated surgically with pedicle screw fixation with or without interbody fusion device (cage)

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ABSTRACT

Background: Lumbar spinal fusion was introduced approximately 70 years ago and has evolved as a treatment option for symptomatic spinal instability, spinal stenosis, spondylolisthesis, and degenerative scoliosis. Broader applications including use as a treatment of chronic low back pain and recurrent radiculopathy have resulted in a dramatic increase in the rates of lumbar fusion procedures within the last decade.
Methods: A retrospective and prospective study to be carried out for 40 patients who were assigned in the following groups: Group 1 (n=20) consisted of patients who underwent lumbar interbody fusion with pedicle screw and bone graft, and Group 2 (n=20) consisted of patients treated by lumbar interbody fusion with pedicle screw and interbody cage.
Results: Most of patients with lumbar spine instability were in 4th and 5th decade of life with average age of 46.75 yrs and female predominance with 26 (65%) cases.65% of Instability was found due to Spondylolisthesis. PLIF with Cage showed better scores than BG in terms of ODI, VAS, SF-36, Benzel's modified Japanese scores at end of 1 year, which is statistically not significant.
Conclusions: Lumbar spine instability is more common in 4th and 5th decade of life with female predominance, commonest level of instability being L4-L5 and commonest mode was Spondylolisthesis. PLIF with Cage is associated with greater operative time and lesser blood loss. Patients with PLIF + Cage had better neurological improvement, pain reduction, reduced disability, generalised well-being and satisfaction as evident by Modified Benzel's Japanese scales, VAS, ODI, and SF-36 scores respectively, which is statistically not significant. Addition of an interbody fusion device (Cage) helps in greater stability, lower implant failure, higher fusion rate and better functional outcome in patient treated with PLIF for lumbar spine instability.

Keywords: Cage fusion, Comparision between bony and cage fusion, Interbody fusion, PLIF

INTRODUCTION

Stability of the spine is defined as the ability of the spine under physiological loads to limit patterns of displacement so as to not damage or irritate the spinal cord and nerve roots and, in addition, to prevent incapacitating deformity or pain due to structural changes.[1] Conversely, clinical instability of the spine as the loss of the spine's ability to maintain its patterns of displacement under physiologic loads so there is no initial or additional neurologic deficit, no major deformity, and no incapacitating pain.[1] Motion of a spinal segment is defined by the biomechanics of the intervertebral disc, facets, and ligaments, each of which offers a level of

stability. Abnormal behaviour of any one of these three structures can alter the motion of the other two, and thus the entire motion segment.[2]

Categories of lumbar segmental instabilities

Spondylolisthesis

It is rarely progressive in teenagers or adults and can therefore be considered as stable in these age groups[1.] However, it has been suggested that concurrent severe disc degeneration at the level of listhesis may lead to progression of slip and convert an asymptomatic and stable lesion into a symptomatic one.[2]

Degenerative instability

It occurs in three sequential phases: dysfunction, instability and restabilisation. During the early phase of degeneration (dysfunction), small annular tears and early nuclear degeneration appear in the disc, and ligamentous strains develop in the posterior ligaments and in the capsules of the zygapophyseal joints. The unstable phase includes reduction of disc height, gross morphological changes in the disc, and laxity of the spinal ligaments and facet joints. These changes lead to an increased and abnormal range of movement and to increased liability to disc displacements. During the restabilisation phase, further physiological changes in the disc, such as increased collagen and decreased water content, together with the development of spinal osteophytes and gross osteoarthrosis of the zygapophyseal joints, result in increased stiffness of the spine and consequent stabilization.

Fusion

Spinal fusion is a procedure in which two or more vertebral bodies are fused together using a bone graft and some form of stabilizing device. The majority of fusions are performed in an attempt to alleviate pain or correct disorder in the region of the intervertebral disc space, and success of this procedure relies on the type of instrumentation, bone graft material, and the individual biological factors of the patient.[3] The biomechanical result of a successful fusion is the elimination of movement at the instrumented segment.[4]

Fusion drastically changes the mechanics of the spine. The main problem results from the fact that it does not change the total amount of load placed upon the lumbar spine. The angular requirements for movement of the spine are then met by fewer segments, which have greater bending moments applied to them as a result. This can easily speed up the degeneration process at other segments, especially those adjacent to the fusion site.[5]

Over the past 25 years, surgical treatment for low back pain has rapidly evolved from un-instrumented fusions with varying results.[6]

The advent of transpedicular fixation revolutionized spine surgery, allowing rigid fixation and enhancing the likelihood that fusion will occur. Previously, lumbar fusions were performed using the intertransverse technique, necessitating wide exposure and possible use of iliac crest graft.[7]

Use of machined allograft is an alternative to threaded fusion cages, as well as non-machined allograft or autograft.[8]

Machined allograft spacers often require less bone removal for insertion and allow surgeons to visualize bone incorporation with standard radiographic techniques.

Bone can be impacted to allow restoration of disc space height and provide anterior column support. Iliac crest grafting, with its potential complications, is not required.[9]

The machined allograft can be supplemented with bone removed during decompression, which can be placed in either the interbody or inter-transverse space.

A successful biological cage needs to both address the lordosis of the lumbar spine and provide stability to the spine. The quality of the bone graft, both biologically and as a load-bearing device, is crucial in achieving solid fusion.[10]

In current practice, bone grafting and instrumentation are often used concurrently based on the expectation that internal fixation of spine enhances the success of bone fusion while a successful bone fusion eliminates the possibility of hardware failure by reducing the chronic biomechanical stresses on the hardware construct.

A variety of techniques are available for the application of interbody grafts, and each technique has its particular advantages, disadvantages and complications.

METHODS

Forty (40) patients were assigned in the following groups: Group 1 (n=20) consisted of patients who underwent lumbar interbody fusion with pedicle screw and bone graft, and Group 2 (n=20) consisted of patients treated by lumbar interbody fusion with pedicle screw and interbody cage.

Inclusion criteria

- Patients with lumbar instability secondary to fracture and degeneration
- Patient aged 18 years or more will be included in the study.
- Patient with features of instability as per defined criteria.

Exclusion criteria

- Patient with co-morbid conditions.
- Patient with congenital spinal deformities, polio and cerebral palsy.
- Patient with active localised or systemic infection.
- Pregnancy and lactating mother.
- Immunosuppressive disorder.

Radiographic assessment of instability

The following 3 criteria are used to assess radiological instability of the lumbar spine

- Angular motion of 20 degrees,
- Translational motion of 5 mm,
- Intervertebral end-plate angle on the flexion film of < 5 degrees.

Although these criteria represent absolute evidence of instability, indirect evidence may be seen in the patient who following surgery has developed

- Progressive deformity in either the sagittal or frontal planes
- Short-segment angular collapse at the level of the decompression

Radiographic assessment of fusion

Brantigan- Steffee classification is used to confirm the existence of fusion.[11]

These criteria include

- The bone infusion area is more dense and more mature than originally achieved during surgery,
- No interspace between the cage and the vertebral body, and
- Mature bony trabeculae bridging in fusion area.

If one of the three criteria was not met, the patient being in a non-fusion state.

Brantigan- Steffee classification

- Obvious collapse of construct due to pseudoarthrosis, loss of disc height, vertebral slip, broken screws, displacement of the cage, resorption of bone graft
- Probable significant resorption of the bone graft due to pseudoarthrosis, major lucency, or gap visible in fusion area (2 mm around the entire periphery of graft)
- Uncertain non-union, bone graft visible in the fusion area at approximately the density originally achieved at surgery. A small lucency or gap may be visible involving a portion of the fusion area with at least half of the flat area
- Probable fusion bone bridges entire fusion area with at least the density achieved at surgery. There should be no lucency between the door and vertebral bone. Fusion bone in the fusion area is radiographically more dense and mature than originally achieved by surgery
- Optimally, there is no interface between the donor and vertebral bone, although a sclerotic line between the graft and vertebral bone indicates fusion. Other signs of the solid fusion include mature bony trabeculae bridging the fusion area, resorption of the anterior traction spur, anterior progression of the graft within disc space, and fusion of facet joints.

RESULTS

Table 1: Baseline characteristics of the patients.

Baseline characteristics of the patients (n=40)	
Characteristics	**Number (n)**
Mean age	46.75 years
Sex	
Male	14
Female	26
Preoperative diagnosis	
Spondylolisthesis	26
Lumbar canal stenosis (LCS)	2
Spondylolisthesis + LCS	4
LCS + FBS	4
Failed back syndrome (FBS)	2
Degenerative disc disease	2
Number of level fused	
1 level	38
2 level	2

Statistical analysis

All quantitative data is expressed as mean ± SD, the significance of difference in means was evaluated by 1 tailed student's t test. All qualitative data were expressed as percentages and the significance was evaluated by Chi-square test with age correction.

This study comprise of two groups: the bone graft (BG) group (n = 20) and the Artificial cage (Cage) group (n = 20). For patients in the BG group, local host bone chips were used only for PLIF. For patients in the Cage group, interbody cages packed with morselized auto graft bone chips were used for PLIF.

Age and sex distribution

In our series of 40 patients, 14(35%) were males and 26(65%) were females. In Bone graft group (BG), 8(40%) were males and 12(60%) were females. In Cage group, 6(30%) were males and 14(70%) were females.

Average age of patients in BG group was 46.45 years and in cage group was 47.05 years respectively. The overall

sex ratio males: females was (7:13), the mean age was 46.75 years (28 to 68 years).

Table 2: Sex distribution.

	Bone graft	Cage	Total
Males	8 (40%)	6 (30%)	14 (35%)
Females	12 (60%)	14 (70%)	26 (65%)

Level of instability

In our series, we had 2 (4.76%) L3-L4 level instability, 30 (71.42%) L4-L5 level instability and 10(23.8), L5-S1 level instability. In both the groups, 1 person had L4-L5, L5-S1 (2 level) instability.

Table 3: Level of instability with distribution of procedure done.

Level	Bone graft	Cage	Total
L1-L2	0	0	0
L2-L3	0	0	0
L3-L4	0	2	2
L4-L5	13	17	30
L5-S1	8	2	10

Mode of instability

Table 4: Mode of instability.

Mode	Bone graft	Cage	Total	%
Spondylolisthesis	14	12	26	65
Lumbar canal stenosis(LCS)	1	1	2	5
Spondylolisthesis + LCS	2	2	4	10
LCS + FBS	2	2	4	10
Failed back syndrome FBS	1	1	2	5
Degenerative disc disease	0	2	2	5

Blood loss

In our study average blood loss is 345 ml in BG group and 310 ml in cage group.

Table 5: Average blood loss during surgery.

	Bone graft	Cage
Blood loss	345 ml	310 ml

Functional result

Visual analogue scale (Average)

Table 6: Visual analogue scale scores.

Group	Pre OP	3 mnth	6 mnth	1 year	0 vs 3	0 vs 6	0 vs 12
Bone graft	5.9	3.1	2.1	1.4	<0.0001	<0.0001	<0.0001
Cage	5.6	2.9	1.9	1.2	<0.0001	<0.0001	<0.0001
P value	0.122847	0.231292	0.2902	0.189426			

VAS scale (0-10) taken at pre-op, 6 weeks, 3months, 6 months and 1 year showed statistically significant improvement in pain reduction in both the groups after surgery. However, there is no significant between the BG and Cage groups.

Oswestry disability index (ODI)

Table 7: Oswestry disability index scores.

Group	Pre OP	3 mnth	6 mnth	1 year	0 vs 3	0 vs 6	0 vs 12
Bone graft	53.6	36.2	25.6	16.2	<0.00001	<0.00001	<0.00001
Cage	54.1	35.2	21.8	12.3	<0.00001	<0.00001	<0.00001
P value	0.424835	0.393081	0.98704	0.05			

Benzel's modified Japanese orthopaedic association scale

Table 8: Benzel's Modified Japanese orthopaedic association scale scores.

Group	Pre OP	3 mnth	6 mnth	1 year	0 vs 3	0 vs 6	0 vs12
Bone graft	14	15	15.7	16.5	<0.00278	<0.00001	<0.00001
Cage	13.8	15	15.8	16.5	<0.00001	<0.00001	<0.00001
P value	0.294516	0.5	0.387406	0.448506			

ODI scale (0-100) taken at pre-op, 6 weeks, 3months, 6 months and 1 year showed statistically significant improvement in disability in both the groups after surgery. However, there is no significant between the BG and Cage groups. Benzel's Modified Japanese orthopaedic association scale (0-18) taken at pre-op,6 weeks, 3months, 6 months and 1 year showed statistically significant improvement in daily activities in both the groups after surgery. However, there is no significant between the BG and Cage groups.

Clinical evaluation

Table 9: Clinical scores.

End points evaluated	Bone graft (n=40)		Cage group (n=40)		P value
	Preoperative	**Postoperative**	**Preoperative**	**Postoperative**	
ODI	53.6	16.2	54.1	12.3	0.05
VAS	5.9	1.4	5.6	1.2	0.189426
Modified Benzel's score	14	16.5	13.8	16.5	0.448506

There is a significant decrease in pain, disability and improvement in patients treated with PLIF which was evident by VAS scores ($p < 0.001$), ODI scores ($p< 0.002$) and Modified Benzel's Japanese scores ($p<0.005$) taken pre-operatively and after surgery, which is statistically significant. However, there is better clinical outcome in Cage group patients in terms of VAS, ODI, SF-36 and modified Benzel's scores as compared to BG group which is not statistically significant($p>0.05$).

Pain reduced to a greater level in Cage group than BG group as measured by VAS scores, which is statistically not significant.

Radiological fusion

In our study, we considered that fusion was complete as per the above defined criteria. In BG group 6(30%) of cases achieved radiological fusion at 6 months & 19(95%) of 20 cases at 1 year confirmed by CT scan. In cage group 10(50%) of cases achieved fusion at 6 months and all 10(100%) at 1 year confirmed by CT scan. 1 case in BG group did not achieve fusion even at 1 year, confirmed on CT scan.

Table 10: Radiological fusion.

	X rays			CT scan/MRI (1 year)	No fusion	Average
	3 months	**6 months**	**1 year**			
Bone graft	0	6	19	19	1	10 months
Cage	0	10	20	20	0	9 months
P value		0.196706	0.311185			

Table 11: Fusion outcome.

End result	Bone graft (n=40)	Cage(n=40)	P value
Fusion rate	95%	100%	0.311185
Patient satisfaction	80%	90%	0.375825
Improvment in radiculopathy	80%	90%	0.375825

Average rate of fusion in BG and Cage group was 10 months and 9 months respectively.

The fusion rate between BG and Cage groups were not statistically significant at 6 months and at 1 year.

Neurological status

Motor

All patients recovered from motor weakness and no motor deficit seen in our study.

Sensory

Sensory disturbance in the form of paraesthesia persisted in 3(15%) of patients in BG group mostly over L4, L5 dermatomes and 1 (5%) patient developed paraesthesia over L5 dermatomes after surgery. 2 (10%) patient had persisted paraesthesia over L4 dermatome in cage group even after surgery. No new deficits seen.

SLRT

Improved in all cases after surgery.

Complications

There were no intra-operative complications such as bleeding or nerve root injury. Overall 6(30%) complications occurred in our study. 1(5%) deep infection in cage group which is subsided by intravenous antibiotics. In BG group 2(20%) case got implant loosening at 3 month, and 1(5%) of it ended in non-union with exaggeration of a previous urinary stress incontinence after surgery. There was 1(10%) case of CSF leak intra-operatively in both the groups.

Table 12: Complications.

	Bone graft	Cage	Total
Deep infection	0(0%)	1(5%)	1(2.5%)
Screw misplacement	1(5%)	0	1(2.5%)
Migration/loosening of implant	2(10%)	0	2(5%)
Urological	1(5%)	0	1(2.5%)
Pseudoarthrosis	1(5%)	0	1(2.5%)
CSF leak	1(5%)	1(5%)	2(5%)

DISCUSSION

Age and sex distribution

In our study we had 35% males (40% in BG and 30% in cage group) and 65% females (60% in BG group and 70% in cage group) and mean age of 46.45 yrs in BG group and 47.05 yrs in cage group. Ching-Hsiao Yu et al in their study had 56% males and 46% females in BG group, 23% males and 77% females in cage group with mean age 59% yrs.[12]

Table 13: Comparing age and sex.

	Our study		Hing-Hsiao Yu et al[12]	
	Bone graft (20)	**Cage (20)**	**Bone graft (34)**	**Cage (42)**
Males	8 (40%)	6 (30%)	19 (56%)	10 (23%)
Females	12 (60%)	14 (70%)	15 (44%)	32 (77%)
Mean age	46.45	47.05	58.7	59.4

Level of instability

In our study, in BG group 12(60%) at L4-L5 level, 7(35%) at L5-S1 and 1(10%) at two level instability. In Cage group 2(10%) at L3-L4, 16(80%) at L4-L5 level, 1(5%) at L5-S1and 1(5%) at two level instability. In both the groups, 1 person had L4-L5, L5-S1 (2 level) instability.

Dong yeob lee et al, in their study found 77% instability at L4-L5, 19 % at L5-S1 level and 4% at L3-L4 level.[13]

Table 14: Comparing level of instability.

Level	Our study		Dong yeob lee et al[13]	
	Bone graft (20)	**Cage (20)**	**Bone graft (34)**	**Cage (42)**
L3-L4	0	2	2	7
L4-L5	13	17	20	32
L5-S1	8	2	11	3

Clinical outcome

At 12 month follow-up, of 20 patients in BG group 80 % and of 20 patients in Cage group 90% reported decreased pain and disability as measured by VAS, SF 36 and ODI.

Table 15: Comparing clinical outcome.

	Our study		Ching-Hsiao Yu et al[12]	
	Bone graft (20)	**Cage (20)**	**Bone graft (34)**	**Cage (42)**
Sensory disturbance	4 (20%)	2 (10%)		
Patient satisfaction (SF-36 scores)	80 %	90 %	79,4%	90.3%
Return to previous life style	19 (95%)	20 (100%)		

In study by Ching-Hsiao Yu et al, the artificial cages provided better functional improvement in ODI and VAS scales, than Bone chip group.[12]

All patients had uneventful motor recovery with 20% paresthesia in BG group and 10% paraesthesia in Cage group. All patients returned to previous lifestyle except 1(10%) patient in BG group.

Although both BG and cage groups showed significant functional improvement in ODI, VAS and Benzels score

after PLIF, the Cage group had greater improvement than the BG group, which is statistically not significant. Satisfactory outcomes were obtained in Cage group because there is better maintenance of disc space, vertebral height and no collapse. In BG group, bone graft alone is used, which is less rigid and lead to collapse before the fusion occurs. This was attributed to increase pain, disability and less satisfaction even after surgery.

Radiological Outcomes

In our study at 3, 6 months and 1 year in BG group fusion rates were 0, 30% and 90% as compared to Cage group were 0, 50% and 100% respectively.

Ching-Hsiao Yu et al reported average fusion rate ranges from 90% to 95.7% in patients with non-cage PLIF and from 90% to 100% in patients with cage PLIF.[12]

Table 16: Comparing radiological outcome.

	Our study		Ching-Hsiao Yu et al[12]	
	Bone graft (20)	**Cage (20)**	**Bone graft (34)**	**Cage (42)**
Fusion	95%	100%	88.2 %	93.6 % to 100%

Fusion was assessed by the operative surgeon and not by the radiologist.

Better fusion outcome in Cage group is attributed to a rigid spacer, which maintained disc space and prevents abnormal mobility till fusion occurs.

Also, the design of cage prevents any further slip and loss of reduction. There is no collapse of vertebral bodies and no complications of screw loosening or implant failures.

Complications

In our study, in BG group we found 2 screw loosening (20%) and 1(10%) of them had non–union at end of 1 year, same patient developed urinary stress incontinence which exaggerated after surgery.

In Cage group we encountered post-op deep infection (10%) which subsided with IV antibiotics. Both group had 10% CSF leak intra-op which was uneventful.

Ching-Hsiao Yu et al reported 6% screw breakage in BG group and high intra-op and post –op complications with Cage group.[12]

Noboru Hosono et al, reported a 0.4% deep infection, 6.7% screw misplacement and 8.8% CSF leak.[14]

Table 17: Comparing complication among studies.

	Bone graft	Cage	Total	Noboru Hosono et al[14]	Harri Pihlajamaki et al[15]
Deep infection	0(0%)	1(5%)	1(2.5%)	1 (0.4%)	2%
Screw misplacement	1(5%)	0	1(2.5%)	16(6.7%)	9%
Migration/loosening of implant	2(10%)	0	2(5%)		18%
Urological	1(5%)	0	1(2.5%)		
Pseudoarthrosis	1(5%)	0	1(2.5%)		20%
CSF leak	1(5%)	1(5%)	2(5%)	21(8.8%)	
Total	6(30%)	2(10%)	8(20%)		

CONCLUSION

This study was conducted to assess the functional and radiological outcome of PLIF with Cage or Bone graft alone in Lumbar spine instability.

We conclude,

- Lumbar spine instability is more common in 4th & 5th decade of life with female predominance, commonest level of instability being L4-L5 & commonest mode was Spondylolisthesis.
- PLIF with Cage is associated with greater operative time and lesser blood loss.
- Patients with PLIF + Cage had better neurological improvement, pain reduction, reduced disability, generalised well being and satisfaction as evident by Modified Benzel's Japanese scales, VAS, ODI, and SF-36 scores respectively, which is statistically not significant.
- PLIF with cage is associated with decreased post operative morbidity, motor improvement, reduced paraesthesia and improved SLRT.
- At the end of 1 year, fusion rate in PLIF with Cage is 100% and 95% with Bone graft alone which is statistically not significant.

- Complication rate observed in 30% in Bone graft group and 10% with cage group, overall complication rate were 20%.
- Addition of an interbody fusion device (Cage) helps in greater stability, lower implant failure, higher fusion rate and better functional outcome in patient treated with PLIF for lumbar spine instability

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