e-ISSN: 0975-5160, p-ISSN: 2820-2651

Available online on www.ijtpr.com

International Journal of Toxicological and Pharmacological Research 2024; 14(6); 161-172

Original Research Article

Functional and Radiological Outcome and Compare the Results after Surgical Fixation of Lumbar Spine Instability with Pedicle Screw with (Cage) or Without (Bone Grafting) Devices.

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Received: 29-03-2024 / Revised: 17-04-2024 / Accepted: 24-05-2024
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Conflict of interest: Nil

Abstract

Background & Objectives: Lumbar spine instability has been surgically managed by posterior lumbar interbody fusion devices using pedicle screw and rod fixation. Many surgeons advocate the use of an interbody fusion device (Cage) to assist in fusion and increase the stability of the construct.

The aim of the study is to assess and compare the functional and radiological outcome of patients undergoing surgical fixation with or without interbody cage.

Methods: 20 Patients were studied in Department of Orthopaedics in teaching hospitals Department of Orthopaedics, Shri Atal Bihari Vajpayee Medical College and Research institute, Bengaluru, who are diagnosed with instability of lumbar spine and willing for surgery. Clinical follow-up at 6wks, 3months, 6months, 12months intervals regarding pain, fusion and the functional outcome will be evaluated by visual analogue scale (VAS) pain rating, and Oswestry Disability Index (ODI) and AP, Lateral and Flexion - Extension radiographs.

Results: In our study, 10 patients were included in each of two groups treated with PLIF with Cage or Bone graft alone. Average age was 46.3 yrs in BG group and 47.4 yrs in cage group. Both groups showed improvement in pain and disability scores as measured by VAS, ODI, SF-36. Fusion rates 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. 30% had sensory disturbance in BG group and 10% in Cage group. Complications were screw loosening 20%, non-union 10%, Urinary disturbance 10% in BG group and Deep infection 10% in Cage group. Both groups had intra-op CSF leak of 10% each. All patients returned to Pre-injury status except 1(10%) in BG group.

Conclusion: 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. We conclude solid fusion would correlate with good functional outcomes in patients with unstable lumbar segments. PLIF with Cage is associate with lesser complication rate and better patients satisfaction in terms of pain relief.

Keywords: Lumbar spine instability; Interbody Cage; Interbody fusion; Bone graft; Pedicle screw.

Introduction

Low back pain is the most common cause of work-related disability and one of the most common contributors to missed time at work [1]. This back pain can be aggravated by activity, which then leads to avoidance of activity and eventually disability. Back pain is also one of the most expensive burdens on the health care system. Low back pain (LBP) is a common medical problem. There is a 50–70% chance of a person having LBP pain during his or her lifetime [2].

Non-specific low back pain can be characterized as acute if lasting less than six weeks, sub-acute if lasting between six weeks and three months, and chronic if lasting for longer than three months. Pain is often initiated by instability at a single motion segment, or the result of abnormal motion of vertebral bodies [2].

Lumbar Spine Instability.

Lumbar spinal instability is defined as the loss of ability of the spine to maintain its pattern of displacement under physiologic loads with no initial or additional neurological deficit, no major deformity, and no incapacitating pain. [3]

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. Often conservative treatments are exhausted before surgery is considered. A significant portion of the problem is of mechanical origin. It is often referred to as clinical spinal instability it is helpful to differentiate between mechanical instability and clinical instability. The former

defines inability of the spine to carry spinal loads, while the latter includes the clinical consequences of neurological deficit and/or pain [3].

To enumerate a few causes leading to instability are [1],

1. Disc Degeneration

Normal discs act as a hydrostatic fluid, absorbing energy from the compression of two vertebral bodies and distributing this energy in a controlled manner. Degenerated discs are often lacking or devoid of this fluid and as a result display high stress concentrations. The outer region of the annulus fibrosis contains nerve endings which can transmit pain signals. As a result, pain may surface when the outer region of the annulus is irritated. When discs become degenerated, the result is often abnormal movement and instability at that joint. The abnormal motion itself may not cause pain, but higher stresses on the endplates, stretching of the ligaments, or disc impingement on nearby nerves or the spinal cord can all result in pain.

2. Degeneration of Posterior Elements

When speaking of pain or degeneration of posterior elements, the facets are the structure which is most commonly involved. The superior articular facets of one vertebra and the inferior articular facets of the vertebra above form the zygapophysial joints. These joints are synovial joints with the articular surfaces coated with hyaline cartilage .With time; the degeneration of the cartilage can cause more pressure on the bone, leading to osteophytes caused by increased loading. All of these factors can alter the range of motion of the segment and the mechanics of other areas of the motion segment.

3. Stenosis

Lumbar spinal stenosis is defined as a narrowing of the spinal canal. It most often is a result of degeneration of the disc and facet joints in older patients. The first mechanism would be the disc bulging and protruding into the canal space and applying pressure to the spinal cord. The other may be caused by an increase in stresses in the region of the facet joint resulting in bone hypertrophy in the foraminal space. The pressure on the spinal nerves can cause pain and numbness radiating to the buttocks and legs. [4]

4. Degenerative Spondylolisthesis

The true deformity of degenerative spondylolisthesis does not seem to be pure translation, but rather a rotary deformity that may distort the dura and its contents and exaggerate the appearance of spinal stenosis. Existing theories to explain the development of degenerative spondylolisthesis include the primary occurrence of sagittal facets and disc degeneration, with secondary facet changes accounting for anterolisthesis. The sagittal facet theory suggests a predilection for slippage because of facet orientation that does not resist anterior translation forces and, over time, results in degenerative spondylolisthesis. The disc degenerative theory proposes that the disc narrows first and subsequent overloading of the facets results in accelerated arthritic changes, secondary remodelling and anterolisthesis.

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[4]. The biomechanical result of a successful fusion is the elimination of movement at the instrumented segment [5].

Fusion is defined as "the presence of bridging trabecular bone between the vertebral bodies". The most reliable radiographic indication of fusion postoperatively is the sentinel sign, or the presence of bridging bone anterior to the fusion cage [6]

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 [7].

Over the past 25 years, surgical treatment for low back pain has rapidly evolved from uninstrumented fusions with varying results [8].

While instrumentation increased the fusion rate, this was not necessarily indicative of a more successful outcome. Fusion remains one of the most common surgeries for several spinal pathologies but comes with risks and deficiencies [9].

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 [10].

Recent technological advances in cage, instrumentation and revision surgery is often difficult. Because of these drawbacks, surgeons looked for other surgical means of treating back pain. Earlier use of allograft bone required time-consuming by the surgeon.

Use of machined allograft is an alternative to threaded fusion cages, as well as non machined allograft or autograft [11].

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 [12].

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 [13].

The PLIF biological cage, used since January 1999, is an innovative lumbar interbody allograft, harvested and processed by the Musculoskeletal Transplant Foundation (MTF, Edison, NJ) and designed and available through Synthes Spine (West Chester, Pa) [12].

Fusion remains one of the most common surgeries for several spinal pathologies but comes with risks and deficiencies. While the goals of fusion are common no matter the technique, there are several different approaches which a surgeon may take to fuse one or more segments.

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. Hence I would like to do a comparative study to assess the pedicle screw and interbody fusion with (cage) or without (bone grafting) devices.

Material and Methods

20 Patients were studied in Department of Orthopaedics in teaching hospitals Department of Orthopaedics, Shri Atal Bihari Vajpayee Medical College and Research institute, Bengaluru,who are diagnosed with instability of lumbar spine and willing for surgery. Clinical follow-up at 6wks, 3months, 6months, 12months intervals regarding pain, fusion and the functional outcome will be evaluated by visual analogue scale (VAS) pain rating, and Oswestry Disability Index (ODI) and AP , Lateral and Flexion - Extension radiographs.

Inclusion Criteria:

- Patients with lumbar instability secondary to fracture, degeneration and congenital conditions will be included in the study.
- Patient aged 18 years or more will be included in the study.
- Patient with features of instability as per defined criteria.
- Patient willing to give consent for surgery.

No response to conservative treatment modalities for 6 months (minimum) preceding enrolment.

Exclusion Criteria:

- Patient with co-morbid conditions and not fit for surgery.
- Patient with spinal deformities, polio and cerebral palsy.
- Patient with active localised or systemic infection.
- Previous interbody fusion attempt at target level.
- Pregnancy and lactating mother.
- Immunosuppressive disorder.

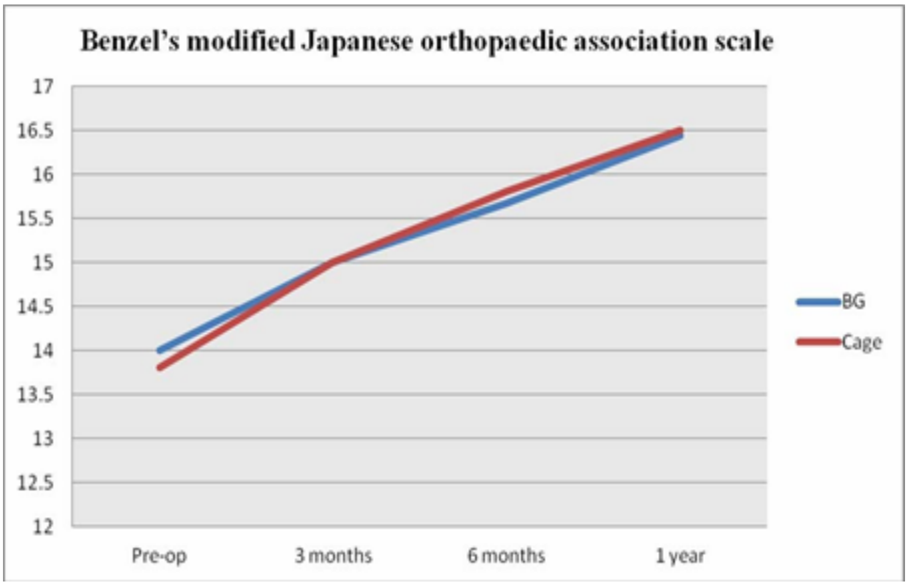
Results

Our study comprise of two groups, depending on the surgeon's choice: the bone graft (BG) group (n = 10) and the Artificial cage (Cage) group (n = 10). For patients in the BG group, we used local host bone chips only for PLIF. For patients in the Cage group, we used interbody cages packed with morselized autograft bone chips for PLIF.

A. Benzel's modified Japanese orthopaedic association scale

Table 1: showing Benzel's Modified Japanese orthopaedic association scale scores

Group	Pre-op	3 months	6 months	1 year	0 vs 3	0 vs 6	0 vs 12
BG	14	15	15.67	16.44	0.004	0.001	0.007
Cage	13.8	15	15.8	16.5	0.0001	0.0005	<0.0001
P value	0.292	0.5	0.393	0.472			



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.

2. Clinical Evualation:

Table 2: Comparing clinical scores

End points evaluated	BG group (n = 20)		Cage group (n = 20)		p Value*
	Preoperative	Postoperative	Preoperative	Postoperative	BG vs Cage
ODI	53.6	19.11	51.4	10.6	0.1123434
VAS (pain)	5.9	1.4	5.3	1.2	0.30263277
Modified Benzel's score	14	16.4	13.8	16.5	0.47292224

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.

3. Radiological Fusion:

In our study, we considered that fusion was complete as per the above defined criteria. In BG group 3(30%) of cases achieved radiological fusion at 6 months & 9(90%) of 10 cases at 1 year confirmed by CT scan. In cage group 5(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.

Average rate of fusion in BG and Cage group was 10 months and 8.5 months respectively. The fusion rate between BG and Cage groups were not statistically significant at 6 months and at 1 year.

Table 3: Showing Radiological fusion

	X rays			CT scan (1 Year)	No fusion	Average
	3 months	6 months	1 year			
BG	0	3	9	9	1	10 months
Cage	0	5	10	10	0	8.5 months
P value		0.388	0.331			

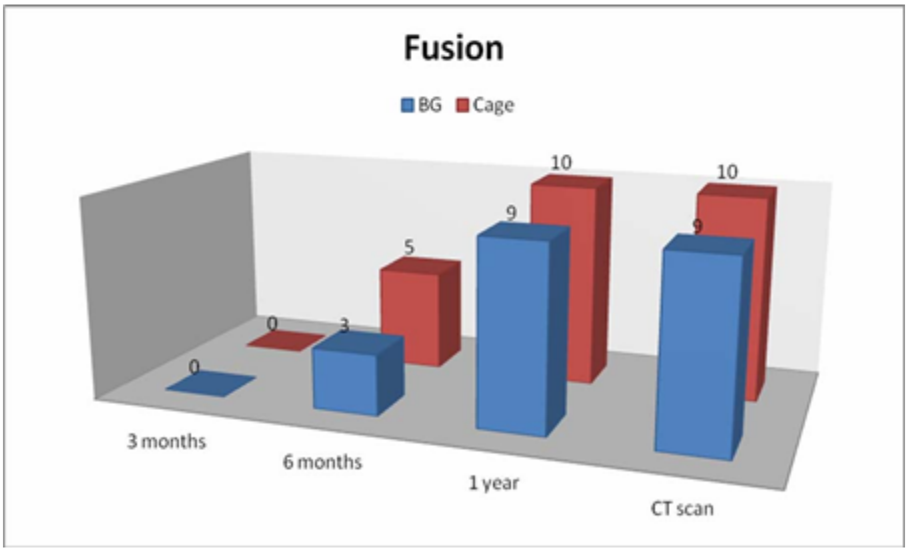


Table 4: showing fusion outcome

End results	BG group (n = 20)	Cage group (n = 20)	P value
Fusion rate	90%	100%	0.30
Patient satisfaction	80%	90%	0.53
Radiculopathy improvement	70%	90%	0.26

4. Neurological status:

Motor: All patients recovered from motor weakness and no motor deficiet seen in our study.

Sensory: Sensory disturbance in the form of paraesthesia persisted in 2(20%) of patients in BG group mostly over L4, L5 dermatomes & 1 (10%) patient developed paraesthesia over L5 dermatomes after surgery. 1 (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.

5. 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.

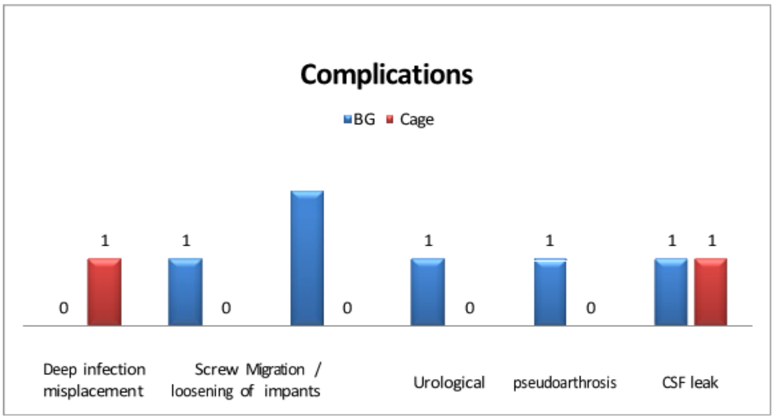
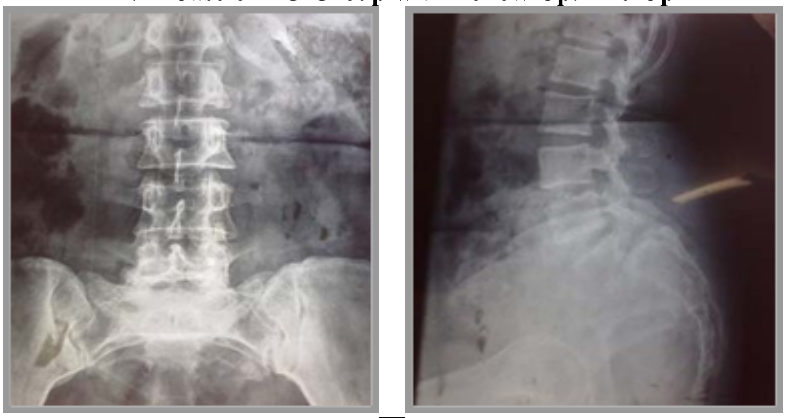


Table 5: showing complications

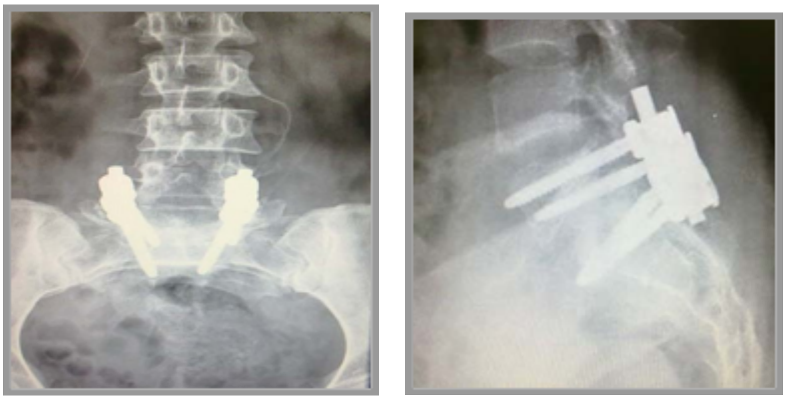
	BG	Cage	Total
Deep infection	0	1(10%)	1(5%)
Screw misplacement	1(10%)	0	1(5%)
Migration/ loosening of impants	2(20%)	0	2(10%)
Urological	1(10%)	0	1(5%)
Pseudoarthrosis	1(10%)	0	1(5%)
CSF leak	1(10%)	1(10%)	2(10%)

Figures. Clinical Photographs

A. Case of BG Group with Follow Up: Pre-Op

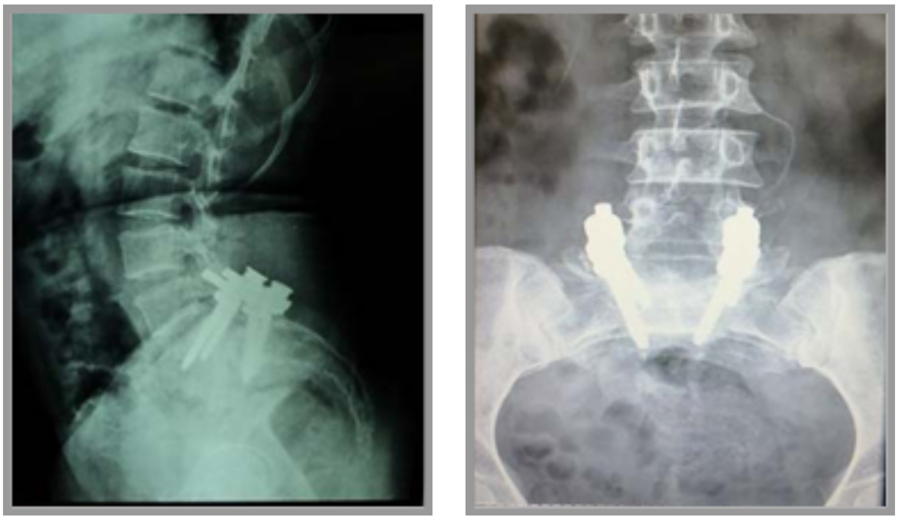


Post –Op:

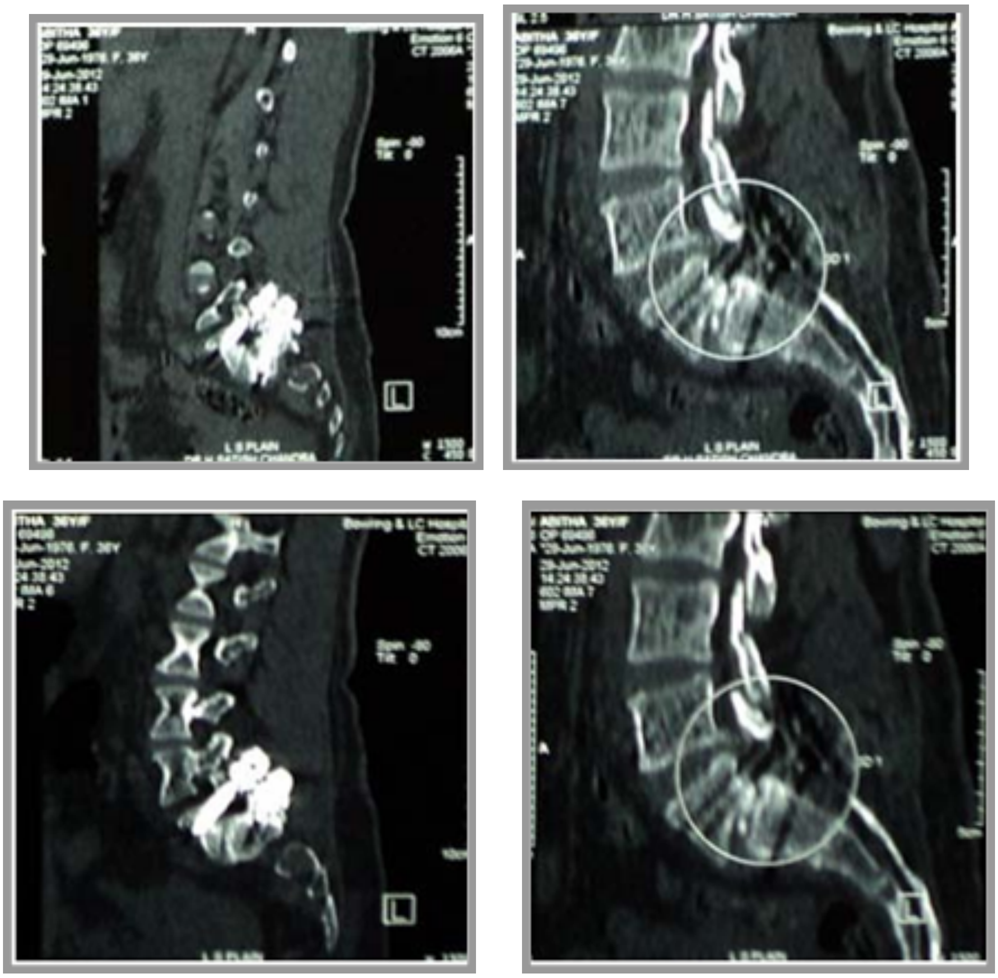


3 Months Follow-Up

6 Months Follow-Up



1 Year Ct Scan



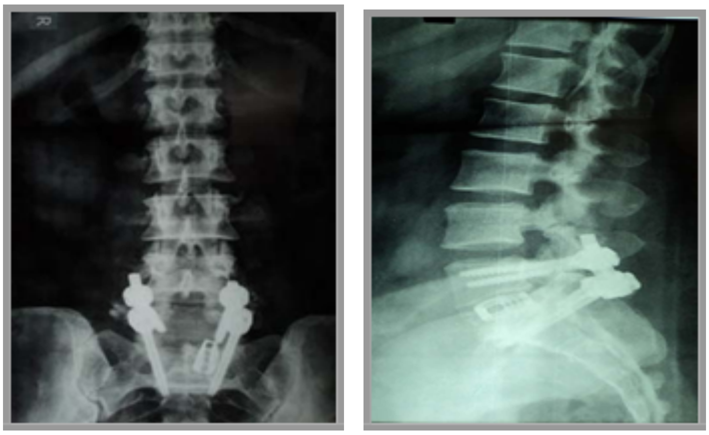
B. <u>Case Of Cage Group With Follow Up:</u> Pre-Op

Anterior Posterior **Lateral Flexion - Extension**

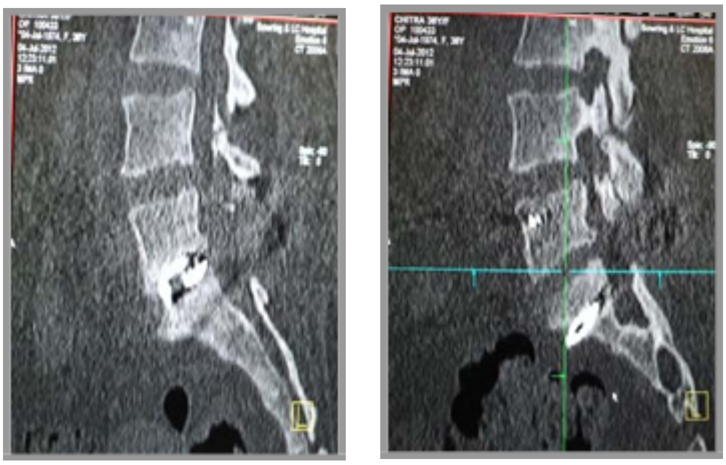
Post –Op: 3 Months

3 Months Follow-Up

9 Months



Ct Scan :



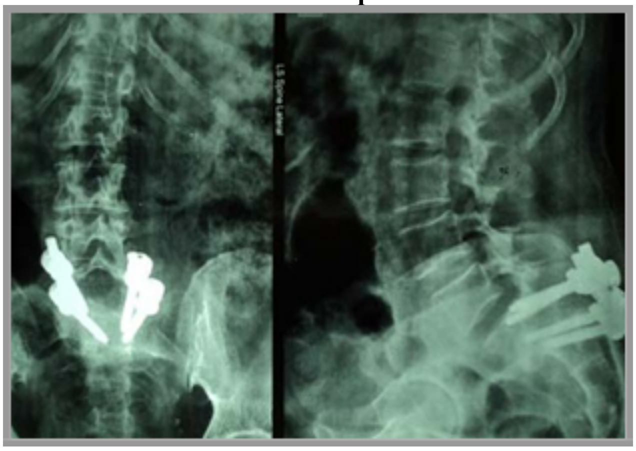
Complications:

1. Screw Loosening:

Figure 12: Showing Screw Loosening

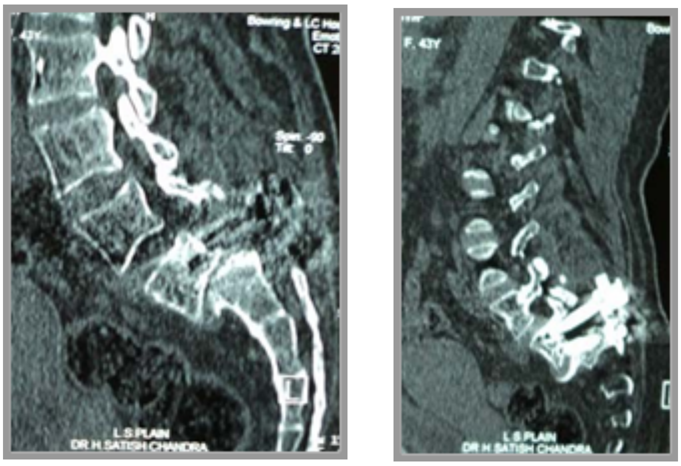
Pre - Op

Post - Op



2. Non-Union :

Figure 13: Showing Non –Union



Discussion

1. **Clinical outcome:** At 12 month follow-up, of 10 patients in BG group 80 % and of 10 patients in Cage group 90% reported decreased pain and disability as measured by VAS, SF 36 and ODI.

   In study by Ching-Hsiao Yu et al13, the artificial cages provided better functional improvement in ODI and VAS scales, than Bone chip group.

   All patients had uneventful motor recovery with 30% 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.

Table 6: Comparing Clinical Outcome.

	Our study		**Ching-Hsiao Yu et al[13]**	
	BG group (10)	**Cage group (10)**	**BG group (10)**	**Cage group (10)**
Sensory disturbance	**3 (30%)**	**1 (10%)**		
Patient satisfaction (SF-36 scores)	**8 (80%)**	**9 (90%)**	**79.4 %**	**90.3 %**
Return to previous life Style	**9 (90%)**	**10 (100%)**		

2. **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 al67 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. Our fusion result was comparable to those of other published studies. Paul M. Arnold et al9 reported in their study that unilateral PLIF, with local morselized bone graft fusion was 98% at 12 and 24 months.

Table 7: Comparing Radiological Outcome.

	Our study		**Ching-Hsiao Yu et al[13]**	
	BG group	**Cage group**	**BG group**	**Cage group**
Fusion rate	90%	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.

3. **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 groups had 10% CSF leak intra-op which was uneventful. Our results are comparable with Ching-Hsiao Yu et al [13] as they reported 6% screw breakage in BG group and high intra-op and post –op complications with Cage group. Noboru Hosono et al [14], reported a 0.4% deep infection, 6.7% screw misplacement and 8.8% CSF leak.

Table 8: Comparing complication among studies

	BG	**Cage**	**Total**	**Noboru Hosono et al. [14]**	**Harri Pihlajamaki et al.[15]**
Deep infection	0	1(10%)	1(5%)	1 (0.4%)	2%
Screw misplacement	1(10%)	0	1(5%)	16(6.7%)	9%
Migration/ loosening of implants	2(20%)	0	2(10%)		18%
Urological	1(10%)	0	1(5%)		
Pseudoarthrosis	1(10%)	0	1(5%)		20%
CSF leak	1(10%)	1(10%)	2(10%)	21(8.8%)	
Total	6(60%)	2(20%)	8(40%)		

4. **Follow up:** All patients were followed up for an average of 14 months one patient in BG group, which was lost to follow up after 1 year.

Conclusion

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. We conclude solid fusion would correlate with good functional outcomes in patients with unstable lumbar segments. PLIF with Cage is associate with lesser complication rate and better patients satisfaction in terms of pain relief.

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