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Cage vs autologous bone grafting in PLIF surgery for spine fusion- randomized control trial

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Abstract
Introduction: Posterior lumbar interbody fusion (PLIF) is been used increasingly for degenerative lumbar spine disease to achieve a 360 degree fusion. With the advent of newer techniques and instrumentations the results are good.
Aim: To study the outcome of PLIF with cages and that with bone graft for degenerative Lumbar spinal canal stenosis.
Material and Methods: We did a double blinded randomized controlled trial at single center. All patients who met with our inclusion criteria and operated from 2007 to 2010 were included in our study. The patients were followed up serially for 5 years for the final outcome. Modified Oswestry low back score and final CT scan based interpretations were applied.
Results: Totally 101 patients were included in the study of which 53 underwent PLIF with titanium cage and rest 48 underwent PLIF with bone grafting. We found the results of union rates in both the groups were gratifying, but early and better results with fewer complications were in group with titanium cages.
Conclusion: We fairly conclude that better and faster fusion rates with good ambulation can be achieved with titanium cages rather than bone grafting in degenerative lumbar spine disease.

Keywords: degenerative lumbar spine disease, posterior lumbar interbody fusion (plif), titanium cages, autologous bone grafting

Introduction
Fusion operations in the lumbar spine have become very popular and useful over the past 20-30 years. Though the procedure and instrumentation has evolved largely over past two decades but the main indication of this procedure has still been a single segmental degenerative disc disease with instability and spinal canal stenosis. Posterior lumbar interbody fusion (PLIF) has been used in a very well established manner in cases with weak dorsal osseous structures of the lumbar spine. Advantages of PLIF are dorsal approach, and reaching and stabilizing the anterior spinal column, achieving a 360 degree fusion, while avoiding the risks involved in the morbid anterior approach [1]. The PLIF with autologous bone grafting provided good fusion rate. But on the other hand, major complications like, collapse, retropulsion of the grafted bone and pseudoarthrosis were reported with a variability of 1 % to 40 % [2, 3].The PLIF with cages were designed in 1991 to resolve these complications. Many studies reported that the PLIF with cages could provide satisfactory clinical results and better fusion. However, new problems such as adjacent segment degeneration (ASD), fine motion and mote of cages, and implants damage were said to be complications of cages [4, 5].

Methodology
Study design and sample population
We did a double blinded randomized controlled trial at a single centre for PLIF with titanium cages compared to PLIF using autologous bone grafting between years 2007 to 2010. The study was started after ethical committee clearance. The patients whose age was above 40 year, single level lumbar spine disease with low back pain and severe neurological claudicating (distance 50-100 meters), with grade III/IV power, with no cervical or thoracic spine disease, with no tandem stenosis, with degenerative spine and those who have undergone

minimum of 3 month of conservative treatment pre-op. were included. Randomization was done by using simple randomization method (random number table). Patients who were not willing to participate or give consent, who have traumatic/pathological/infective lumbar spine disease, paraparesis with inability to stand or walk, not willing to undergo surgery, any recent concomitant fractures or recent onset debilitating ailments, with other neurological conditions who fail to comply PLIF at more than two levels, a lumbar kyphosis (lordosis L1/S < 0°) or spondylolisthesis > grade III (> 50%), a previous attempt at fusion at the intended surgical level, chronic smokers were excluded.

Surgical Procedure

Patients were placed prone on a surgical frame (i.e., Jackson table) to accentuate a lordotic position of the lumbar spine. After the levels of interest were exposed, the posterior spinal elements were removed to expose the traversing nerve roots and lateral extent of the disc space. The dorsal third of the interspinous ligament may be preserved to act as a fulcrum for a dural retractor and to preserve a tension band posteriorly. The thecal sac and traversing nerve roots were mobilized and retracted to the midline, after proper and adequate decompression with care taken to protect the dural and neural contents with a retractor. After exposure of the posterior annulus, a complete discectomy was performed using rongeurs, disc shavers, and down biting curved curettes. Only by completely removing the disc and denuding the cartilaginous endplates can an environment conducive to fusion be provided. In addition, disc height may be restored through the use of distracters with serially increasing heights. Pedicular screws were inserted with standard technique of adequate size. Entry point of pedicular screws were taken at junction of mid transverse process line and line parallel to facet joint. Pedicle screws were then inserted and attached to the rods. By increasing the disc height, tension was placed on the annulus fibrosis, and the bone graft was placed under a compressive load, which will help the fusion process. In the case of cylindrical cages, specialized tube retractors were used to introduce serial reamers into the disc space, and this was followed by a bone tap to allow recessing of the cage. With rectangular ramp-type cages, a square channel was prepared in the disc space to accept the cage, which was then tamped into place to engage the vertebral endplates. Cage devices were filled with materials that were osteoinductive or osteoconductive (procured during decompression) and provide scaffolding for bony fusion to occur from endplate to endplate. When placing interbody fusion devices, care was taken to preserve the vertebral endplates upon which the devices will rest and gain their stability. The so-called ‘‘insert-and-rotate’’ technique for graft implants was similar to the impacted wedge technique (as done for bone grafting procured from iliac crest) but does not require the same amount of distraction or involve the cutting of any channel through the posterior endplates. Using interbody devices that have more contact with adjacent endplates provides more immediate stability to the construct. Implants may be made quite lordotic, especially at the L5– S1 segment. Once in place, the pedicle screws were compressed along a lordotic rod in an attempt to reduce any kyphosis caused by interdiscal distraction. A standard closure in layers was then performed. The only difference in procedure between bone grafting and cage was that for bone grafting separate incision was taken over the iliac crest and cortico-cancellous wedges were made.

Rehabilitation and antibiotic and pain management

In order to avoid the any bias in the results all the antibiotic, pain management and rehabilitation protocols were kept the same for both the group of patients.

Antibiotic and Pain management – All the patients were given for pre-operatively a single shot of Injection Cefoperazone + Sulbactum 1.5 gms. Along with that Injection Tranexamic acid 500 mg was given. Post operatively 8 hours after the surgery again Tranexamic acid injection was repeated. For pain management patients were given Inj Paracetamol 1gm Thrice a day for two day and there after Tab Paracetamol 1 gm twice a day for next 10 days. Injection Tramadol was given if pain increased. Patient on day 1 on surgery was supplemented with Ketaflam patch and Buta – patch was applied on discharge on day 5 post op that is on the day of discharge. The Prior mentioned antibiotic was given twice daily for 2 days post-operatively. Drain was removed on day 2 post –op. Thereafter no oral antibiotics were given. Patients were given a single shot of 1 gm solumedrol intra-operatively. Pregabalin 75 mg (sustained release formulation) was given once at night for 10 days post-operatively. All suture removal was done on day 14 post-operatively.

Rehabilitation

Rehabilitation and post-operative physiotherapy protocol were kept the same for both sets of patients.

Day 0 (day of surgery) Static back and Abdominal exercises, Chest PT and ankle pump exercises were given.

Day 1- Patient was mobilized bed side. Patient was made to sit. All patients were given Lumbosacral frame corset belt before mobilization. All back exercises were continued.

Day 2- Patient was made to stand and walk (supervised) on walker with the belt applied and was given commode and toilet training.

Day 3- Patient was made to walk independently on walker in the lobby. Dynamic back exercises were started.

Day 4- Stair climbing up and down training exercises were given along with the dynamic back exercises.

Patients were given clear instruction to avoid flexion of spine, rotation and avoid doing any strenuous activities like lifting heavy weight for first 3 months post-operatively.

Data collection and analysis

We had 101 patients included in this studies and followed up serially up to 5 years. They were assessed using Modified Oswestary low back score and CT scan. Our study included 48 females and 53 males. All the patients were operated at a single center by a single team of spine surgeons. They were screened pre-operatively and then followed up serially by an independent surgeon not a part of the operative team. Modified Oswestry low back scores [5] were noted pre-operatively, at 6 months, at 1 year, at 3 years and lastly at 5 years. Of 101 patient, 53 underwent PLIF with cages and rest 48 underwent PLIF with bone grafting [6]. All patients at the end of five years were subjected to undergo Computed tomographic analysis [7] so as to determine the fusion after the PLIF procedure, Complications associated with the procedure in both the groups were noted. Data analysis was done by using SPSS 16 software.

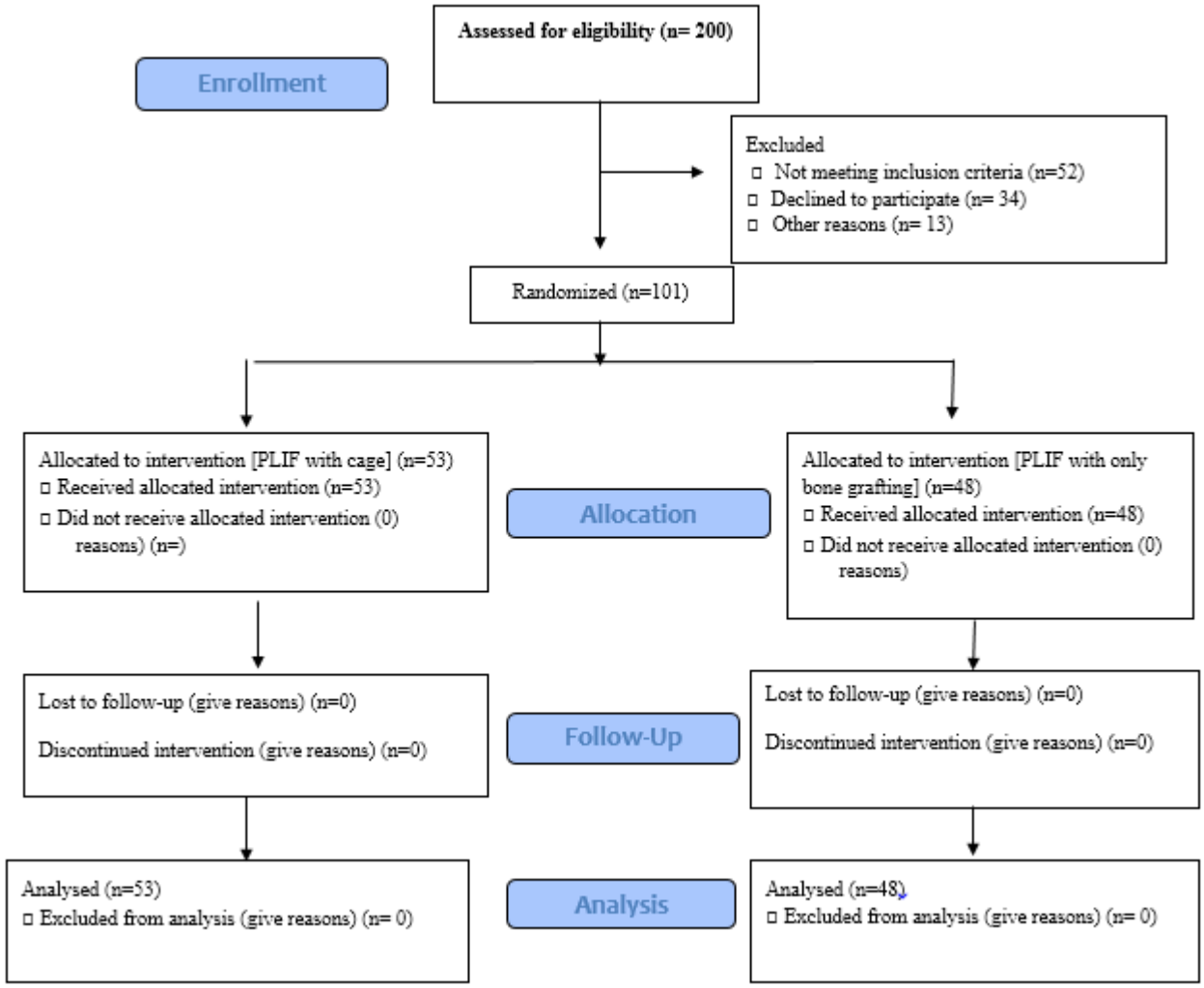

Fig 1: CONSORT Flow diagram of the study

Results

The age old technique of PLIF with Autologous bone grafting showed good results but not superior when compared to technique of PLIF with cages. The mean pre-op age was 59 years with minimum of 42 and maximum of 74. The mean Body mass Index was 29. Mean blood loss was approximately 390 ml. In our study the blood loss and surgical time for PLIF with BG was more than for PLIF with cage, but it was statistically not significant. Our trial depicted early healing and good fusion rates in case of cages. Modified Oswestry score at 3 years and 5 years showed significant association in group of patient who underwent PLIF with cages as compared to those who underwent PLIF with BG (Table 1). This indicated that the the healing was early and disability was less in case of PLIF with BG. In case of CT analysis at the end of 5 years of follow up almost 81 % of PLIF with cages showed solid union as compared to 55 percent in case of Bone grafting (Table 2). Disc height (as calculated on final CT) was well maintained in cases of PLIF with cage as compared to PLIF with autologous bone grafting but this was not attributed statistically. The association between fusion rates by CT and PLIF with Cages and BG both were significant (Table 2).

Discussion

Briggs and Milligan in 1944 first pioneered the PLIF procedure using Laminectomy and bone chips in disc space as interbody graft. Later Jaslow used excised portion of spinous process and place it with intervertebral space. Clowar however, popularized this technique in1953 by using Impacted Iliac crest auto graft and showed gratifying results. Though technically demanding, PLIF procedure showed good fusion rates about 85 %. It had few disadvantages like Graft extrusion, dural injury, Nerve injury, arachnoiditis and excess blood loss [8, 9, 10]. Once the cylinders are screwed into position, they give remarkably good fixation. This seems to alleviate the back pain quite quickly, as there is very little motion between the vertebrae after the cage is in place. It has also been documented that the fusion rate seems to be quite high. Without the cages, historically the fusion rate has been around 60-70%. At this point, it is felt that the fusion rate with the cages is over 90%. Another important reason to use the cages is that the bone graft comes in smaller pieces. Our study too had its own set of complication but showed good fusion rates of about 81 % with early clinical improvements in case of PLIF with cages. PLIF was introduced to decrease the neurogenic pain due to dura/nerve root compression and offer stability to the spine in cases of deformity and degeneration. In the initial period when patients came with low back pain, radiating pain to lower limb, neurologic claudication resulting due to spondylolisthesis or degenerative Spinal canal stenosis conservative treatment would be started. Generally if no neurodefecit, significant number of patients improve with conservative treatment. Its only when this symptoms disable the patient in doing their normal daily routine activities PLIF (surgery) was the final option [11, 12, 13]. We too in our trial selected patients who underwent conservative treatment and had no improvement and were severely disabled with above symptoms. Posterolateral fusion showed complication of

muscle fibrosis caused due to extensive release of muscles adjacent to the transverse process with more loss of blood and postoperative wound healing issues due to a lengthened operative time. But inter body fusion showed higher fusion rates with les muscle release around the transverse process, along with early stability as in PLIF with pedicular screws [14, 13]. Our study too showed good fusion rates with PLIF irrespective of cage or Bone grafting and we did not supplement any cases with posterolateral bone grafting.

Three common types of PLIF techniques are there-bilateral laminectomy and implantation of two cages, unilateral laminectomy and implantation of two cages, unilateral laminectomy and implantation of one cage [15, 16].

Oxland *et al*, Zhao *et al* reported that single-cage PLIF with pedicular screws provided high stability in flexion, was technically easier than the two-cage PLIF. Two cage PLIF increase risk of damage to the bilateral nerve roots where-as retraction of the nerve roots and the dura mater of the asymptomatic side could be avoided with unilateral placement of a cage in patients with unilateral sciatica. Other merits like reduced blood loss, the operative time and the hospital were documented in single cage PLIF [17, 18]. We used single cage technique and decompressed only the affected side and our long term results with respect to patients symptoms and disability were optimistic as evident by good Modified oswetry scores on follow up. In our trial we used autologous bone graft from Posterior iliac crest site in patients who underwent only PLIF with Bone grafting. Where as in other group which underwent PLIF with titanium cage local bone graft acquired from laminectomy and spinous process was used. The use of local bone has the advantage of avoiding the necessity to harvest from iliac bone, and this advantage is connected with less operating time and blood loss though in our study this was not statistically significant. But our study showed some donor site morbidities in case of Bone grafting from iliac crest [19]. Also fusion rates in case of cage with bone grafting was higher than in case of autologous strut bone grafting alone and was statically significant at end of 5 years post- op. Also there was better clinical outcome in patients with cages as evident by follow up evaluation and scoring system. Certain trials have shown comparable fusion rates between bone obtained during posterior decompression as graft, and autologous iliac bone graft. However, whether local bone is an alternative to iliac bone grafting is still debatable issue as there are no prospective randomised control studies comparing fusion rates using long-term longitudinal radiological evaluation [22, 21]. Though in our study we have not done serial Xrays or CT scan but being a prospective randomized study it shows good comparable fusion rates between the autologous bone graft and the local bone grafts acquired from laminectomy or spinous process. Traditionally used Iliac crest autologous graft have frequent complications following fusion surgery such as pseudarthrosis and donor site morbidity. Despite the use of rigid instrumentation, the rate of pseudarthrosis remains significant with iliac crest autograft [22, 23] Our trial which though showed only 11 % of pseudoarthrosis at the end of 5 years but it was certainly greater than Cage with Bone grafting which showed approximately 5 % of pseudoarthrosis. One of the main reason postulated by us for lower rates of pseudoarthrosis is the long term nature of study and a single CT scan done at end of 5 years instead of serial CT scans. Donor site problems, may be long term or short term, like pain, paresthesias, hematoma, and infection, have been reported in up to 50% of patients in certain studies. Our study too showed similar problems in autologous bone graft group but they were statistically not significant. The harvesting of posterior iliac crest autograft seems to be less morbid than that of anterior iliac crest graft. Given the proximity of the posterior iliac crest donor site to the lumbosacral spine, however, it is questionable as to whether patients can accurately differentiate from harvest site and surgical site pain in the case of lumbar lumbosacral fusion surgery [24]. The interbody spacer plays an important role in the initial stability for fusion. Higher axial stiffness is predicted for the model when the spacer was shifted posterior with resulting bigger fusion volume, but the stiffness remained almost constant [25]. So the problems of adjacent segment degeneration do persist with instrumentation and cages. But more stability is present when instrumentation and cages are done hence better fusion rates. At the end of 5 years we had 4 cases of adjacent segment degeneration but all were asymptomatic. Interbody fusion is now a definite and popular surgery and is the treatment of choice for a number of lumbar spinal disorders, including discogenic pain. CT provides better evaluation of fusion progression and status than dynamic radiography [25]. Several trials have noted that CT is better than plain radiographs for assessing fusion, whether metallic or non-metallic interbody cages are used. Although the consensus is that thin-section helical CT is the best technique for identifying bony bridging, there is concern that it may overestimate its presence if carried out early after surgery [26, 27, 28]. Hence for our prospective trial we used plain CT to evaluate the Fusion. Lastly results of our trail were similar study by DH Kim *et al* to certain other studies too. We completely agree that stability and less donor site morbidities are advantages of PLIF with Cage [29].

Conclusion

To conclude both techniques produced satisfying clinical outcomes and radiological outcomes but better intervertebral disc space, good boney union, rigid stability and a high fusion rate were achieved in case of PLIF with Cage as compared to PLIF with Autologous bone grafting.

Table 1: Association between groups on basis of Modified Oswestry score.

Score	Intervention	Scores				Significance
Modified Oswestry score at 3 years	PLIF with cage	14.79	9.37	12.00	7.00	-3.519
	PLIF with only bone grafting	20.79	11.01	19.00	11.50	(p <0.001)
Modified Oswestry score at 5 years	PLIF with cage	10.11	9.37	8.00	4.00	-2.893
	PLIF with only bone grafting	15.46	12.82	12.00	13.00	(p <0.01)

Table 2: Association of fusion rates in between groups by CT analysis at 5 years

CT Grading at end of 5 years		Procedure		Total
		PLIF with cage	PLIF with only bone grafting	
I-Complete fusion	n	43	26	69
	%	81.1%	54.2%	68.3%
II-Partial Fusion^	n	7	17	24
	%	13.2%	35.4%	23.8%
III-Unipolar Pseudoarthrosis^	n	3	4	7
	%	5.7%	8.3%	6.9%
IV-Bipolar Pseudoarthrosis^	n	0	1	1
	%	0.0%	2.1%	1.0%
Total	n	53	48	101
	%	100.0%	100.0%	100.0%
Chi-Square tests	Value	df	p-value	Association is-
Pearson Chi-Square$	9.273	3	0.02587	Significant
Pearson Chi-Square^	7.262	1	0.007	Significant

$4 cells (50.0%) have expected count less than 5. ^Row data pooled & Chi-Square Test reapplied with Continuity Correction**.**

Table 3: Complications associated with procedure

Complication	No.	Percentage	PLIF with Cage	PLIF with BG
CSF leak healed spontaneously	4	4.0%	2	2
Delayed wound healing due to skin necrosis	3	3.0%	0	3
Wound infection	3	3.0%	2	1
Graft displacement	2	2.0%	0	2
Re-surgery due to pseudo arthrosis	2	2.0%	0	2
Bipolar pseudarrthrosis	1	1.0%	0	1
Cage backout	1	1.0%	1	0
Adjacent segment degeneration	4	4.0%	3	1
Delayed wound healing	1	1.0%	1	0
Nil	80	79.0%		
Total	101	100.0%		

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