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Dr. Rajaneesh B
Assistant Professor, Orthopaedic
Department, Vydehi Institute of
Medical Sciences

Dr. Varun GBS
Professor Orthopaedic
Department, Vydehi Institute of
Sciences

Dr. Sujith
Resident, Orthopaedic
Department, Vydehi Institute of
Medical Sciences

Radiological outcome of PLF surgeries in lumbar spine using DBM

Dr. Rajaneesh B, Dr. Varun GBS and Dr. Sujith

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Abstract

Introduction: Spinal fusion has become one of the most popular methods of treating spinal diseases such as trauma, deformity and degenerative disc disease. Ideally, in order to promote fusion, the bone graft or bone substitute should have both osteoinductive and osteoconductive properties. The demineralized bone matrix (DBM) of demineralized allosteric bone is processed by comprehensive decalcification procedures. These procedures include chemical and radiological steps to reduce the immune response and the risk of infection. The bone inductive activity of demineralized bone matrix (DBM) has been well demonstrated. DBM also appears to support new bone formation through bone conduction mechanisms. Case reports and analyzes of several retrospective non-randomized clinical series indicate that DBM in combination with autologous marrow or bone marrow demonstrate similar performance characteristics to autograft in posterior lumbar spinal fusion. The purpose of this study is to assess radiological outcomes of PLF in lumbar spine using demineralized bone matrix (DBM).

Purpose: To see Radiological Outcome of PLF (posteriolateral Fusion) Surgeries In Lumbar Spine Using Demineralized Bone Matrix (DBM).

Methods: 30 patients were included in the study Patients were followed up postoperatively at one year follow up. The participants were evaluated for Radiological Outcome in the study group was assessed by using Lenke Classification of Posterolateral Fusion Surgeries In Lumbar Spine Using Demineralized Bone Matrix (DBM).

Results: All patients followed up for one year. Radiological evaluation of Lumbar fusion rates assessed with Lenke fusion Classification for PLF at the end of one year was 83.33% Grade. A fusion rates which is excellent. Younger patients of either sex had better outcomes compared to the older age group patients.

Conclusions: The average improvement across the board was 81.40% which is excellent. The available literature shows similar results compared to an iliac bone graft which is the gold standard for spinal fusion. DBM can be considered a reliable alternative to the autograft when used as a graft expander in combination with the autograft.

Keywords: PLF surgeries, posteriolateral fusion, similar results compared

1. Introduction

Spinal fusion has become one of the most popular methods of treating spinal diseases such as trauma, deformity and degenerative disc disease. Recently, the spinal fusion technique has been enhanced with autologous bone grafting, but with the additional complications of donor site morbidity and graft size limitations, rates of pseudo arthritis remain between 5 and 43% [1]. It is estimated that the number of spinal fusions performed in the United States, can be greater than 200,000 annually, and most are lumbar fusions [2]. Ideally in order to promote fusion, the bone graft should have osteoconductive and osteoinductive properties.

The demineralized bone matrix (DBM) of demineralized allosteric bone is processed by comprehensive decalcification procedures. These procedures include chemical and radiological steps to reduce the immune response and the risk of infection. The bone inductive activity of demineralized bone matrix (DBM) has been demonstrated [3]. Decalcification of cortical bone exposes osteoinductive growth factors buried within the mineralized matrix, thus promoting bone formation. DBM also appears to support new bone formation through bone conduction mechanisms. Case reports and analyzes of several retrospective, non-randomized clinical series indicate that DBM in combination with autologous marrow or bone marrow demonstrates similar performance characteristics to autograft in posterior lumbar spinal Fusion [4].

Corresponding Author:
Dr. Rajaneesh B
Assistant Professor, Orthopaedic
Department, Vydehi Institute of
Medical Sciences

Recent studies also indicate that the clinical level of evidence supporting the use of DBM in trauma surgery and Orthopedics is limited and consists primarily of poor quality, retrospective case series [5].

The purpose of this study is to reduce donor site morbidity, obtain adequate grafts and achieve DMB efficacy in terms of anatomical and functional outcomes. The use of a demineralized bone matrix with a more biologically active local graft is likely to correlate the fusion process and its quality.

2. Materials & Methods

We conducted a prospective hospital-based study at Vydehi Institute of Medical Sciences and Research Centre, Whitefield, Bangalore. A purposive sampling technique was employed. The study population consisted of 30 patients of both genders, between 18-65 years of age that have been admitted for low back ache. All patients of either sex undergoing primary posterior stabilization with posterolateral fusion in lumbar spine for degenerative spondylolisthesis and canal stenosis were included in the study. Patients that have a systemic infection, osteoporosis or osteomalacia to a degree to which spinal instrumentation would be contraindicated were not included in the study. Further, if the patient was undergoing cancer treatment, if patient had lytic spondylolisthesis below 18 years of age, or if the patient had high grade spondylolisthesis, the patient was excluded from the study. The participants were evaluated clinically and radiologically before surgery and post operatively at 3 months, 6 months, 9 months and 12 months. Only those patients who were available for 1 year follow up were included in the study. A detailed case history, subjective and physical findings of the patient was recorded as per the questionnaire. Routine plain roentgenograms of the lumbar spine with erect flexion and extension views were obtained and the results recorded. An MRI scan of Lumbosacral spine was done in presence of radicular pain or neurological deficits. Based on all available information, a therapeutic and surgical plan was then laid out with a predetermined goal in mind for the surgery. Intra-operative findings confirm or alter the pre-operative plan and modifications are made accordingly. Consent was taken for surgery from the patient and his/her guardian. The surgical procedure was planned

individually based on patient's age, symptoms and radiological features.

In the operating room, the back was prepped and draped in the usual fashion. A midline incision was made over operative level (example: L5/S1). Once the lumbar fascia was identified, dissection was carried down onto the appropriate level spinous process. A hemostat was placed between the spinous processes and its position was confirmed on a lateral radiograph which included the sacrum. Dissection was then carried down the lamina bilaterally to the level of the facet joints and transverse processes. Transverse processes were decorticated in PLF, which will act as bed for bone graft. Segmental, bilateral polyaxial pedicle screw fixation will be placed at all levels treated, by free hand technique. Reduction screws are used selectively as per preoperative planning. The starting point was identified at the juncture of two lines drawn down the transverse process and up the pars. This was at the most inferior portion of the superior facet. The starting point was made with an awl and the pedicle entered with a blunt gear shift up to midpoint of the vertebral body. The hole was tapped to the same level. A feeler was used to confirm solid superior, inferior, medial, and lateral walls and to confirm the presence of bone at the end of the tunnel. Next the screw was inserted. All the screws were inserted in the same manner. Final screw position is confirmed using image intensifier.

Decompression was performed for PLF. Connecting rod fixation was performed. Bone grafts were harvested from local bone (Laminectomy Bone Chips) and was morselized and mixed with morselized DBM placed posterolaterally between the facets and transverse processes of the vertebrae. We procured our demineralized bone matrix from bone bank at Ramaiah Advanced Learning Center, Bangalore. DBM was prepared and procured fresh and was customized based on the individual patient need from the bone bank and patient was explained about the benefits associated with it and detailed personal information was taken of the patient and were explained about the complications of the surgeries and to contact immediately if any antigenic response were encountered.

Fusion was measured by analysing radiographs. Fusion in PLF is graded by Lenke classification which is shown in Table 1.

GRADE A	Definitely solid	Bilateral trabeculated stout fusion masses present
GRADE B	Possibly solid	Unilateral large fusion mass and a contralateral small fusion mass
GRADE C	Probably not solid	Small fusion mass bilaterally
GRADE D	Definitely not solid	Bone graft resorption or obvious pseudarthrosis bilaterally

Table 1: Lenke classification of posteriolateral fusion success



Fig 1, 2: shows the DMB Reconstitution with Local Bone Graft. Figure 1 shows the local bone graft and Figure 2 shows the DMB.



Fig 3-5: show the mixing process, the final mixture, and the placement of the graft respectively.



Fig 6: Positioning of patient and draping

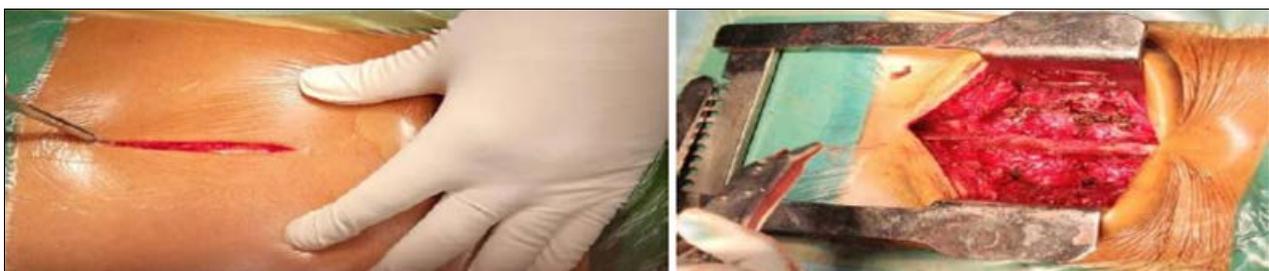


Fig 7: Incision and exposure



Fig 8: Pedicle screw insertion

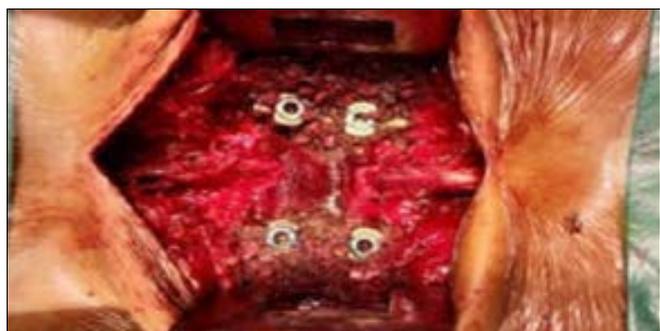


Fig 9: Decompression and posteriolateral



Fig 10: Confirmation of screw position and reduction under c- ARM

3. Results

The study was conducted in 30 patients with degenerative spondylolisthesis and canal stenosis who underwent posterior stabilisation with decompression with PLF using demineralised bone graft. The patients were followed up for a period of one year and the results were analysed. Table 2 shows the age distribution of the patients. Out of the total patients, 16 were males and 14 were females.

Table 2: The distribution of subjects by level affected and disease condition is shown in.

Age in years	Number of patients	Percentage
20-30	3	10.0
31-40	7	23.3
41-50	9	30.0
51-60	9	30.0
>60	2	6.7
Total	30	100.0

Table 3: Radiological Outcome using LENKE Grading was 83.33% the mean overall improvement in clinical, functional and radiological outcome was 81.40%.

LEVEL	Disease condition	
	Spondylolisthesis	Canal Stenosis
L3-L4	2 (12.5)	3 (21.4)
L4-L5	9 (56.3)	9 (64.3)
L5-S1	5 (31.2)	2 (14.3)
TOTAL	16 (100.0)	14 (100.0)

4. Discussion

The DBM procured in our study was sterilized using alcohol and acid without exposing them to radiation to remove the antigenic capacity of the allograft. These morselized DBM had bmp proteins which helped in the new bone formation. Bae *et al.* have pointed out that the variability of BMP concentrations among different lots of the same DBM formulation was higher than the inter-product variability or concentrations of BMP among different DBM formulations [6]. In the present study of 30 patients undergoing lumbar spinal fusion surgeries, posterior stabilisation with decompression with PLF using demineralised bone graft were trailed with conservative management for a period of two months and those who failed with it were evaluated clinically and radiologically and the need for the surgery was assessed. Subjects who met the inclusion and exclusion criteria and consented for the use of Demineralized Bone Matrix were included. In our study we saw L4-L5 were the most common level involved in condition like canal stenosis and degenerative spondylolisthesis. Our study showed younger patients of either sex had better improvement in the clinical, functional and radiological outcome compared to the older age group patients. In our study we observed a better improvement in the VAS of 6.6 which is approximately 90% improvement. Table 6 shows other studies that have used VAS for comparison.

In our study we observed a mean ODI score of 18.8 at the end of one year of follow up which is 70% improvement in the values and falls in the excellent category according to ODI Score interpretation. The ODI comparison with different studies is shown in Table 7.

The present study reported Lenke Grade A fusion rates of 83.33%. Our results showed excellent fusion rates which were at par with fusion rates of iliac crest bone graft crest bone graft in most of the studies. Table 8 shows the FUSION comparisons with different studies.

The pre op and post op comparison of VAS and ODI score showed p value <0.001 which is of statistical significance. Limitations of our study were a few as well. One of the limitations of the study was the sample size. Follow up duration of one year was also less compared to other studies.

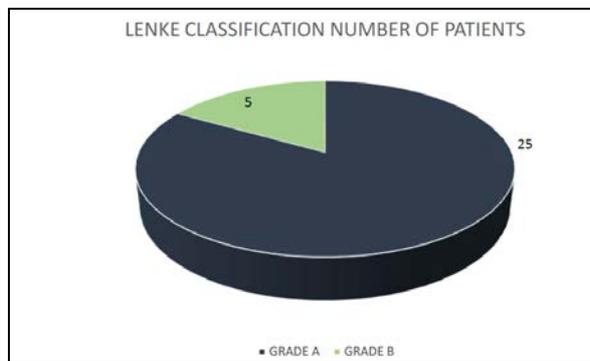
5. Conclusion

This study has highlighted the advantages of using DBM as an alternative to autograft when it used as a graft extender in combination with autograft. Radiological evaluation at the end of one year, using Lenke fusion classification, fell into Grade A which is excellent. Overall the complication rates were low. Mean improvement in clinical, functional, and radiological outcome was excellent (81.40%).

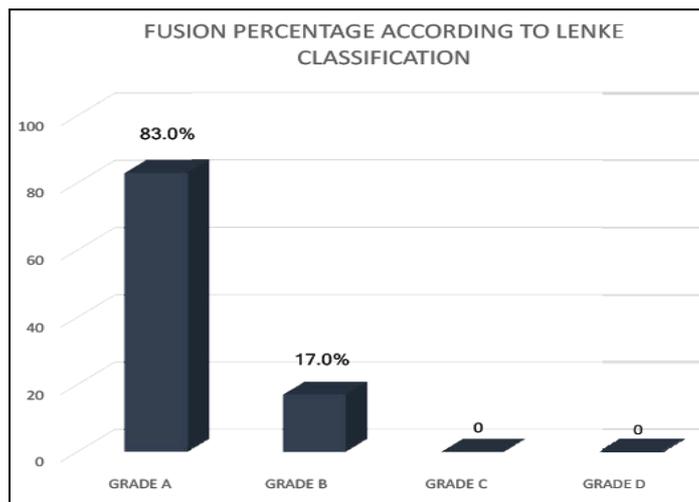
Table 4: The radiological outcome analysis at the one year follow up was assessed by using the LENKE fusion grade.

LENKE fusion classification	No. of patients	Percentage
GRADE A	25	83.3
GRADE B	5	16.7

At the end of one year 25 (83.3%) patients were having Grade A fusion, and 5 (16.7%) patients were having Grade B fusion and none of the patient had Grade C and Grade D fusion as depicted in Graph 8 & 9.



Graph 1: Distribution of subjects by fusion comparison using Lanke fusion classification



Graph 2: Fusion percentage according to LENKE classification

Radiography images for Cases





Case 1: L5-S1 Spondylolisthesis One Year Follow Up: Lenke Grade A

6. Discussion

Spinal arthrodesis is the primary goal of all fusion procedures for lumbar spinal disease. Even though Autologous iliac crest bone has long been considered the gold standard for these fusion procedures, increased operative time, increased blood loss, increased donor site morbidity, and a limitation to the amount that can be realistically harvested for multilevel fusion. The other readily available autologous bone source in these fusion procedures is local bone (LB) graft harvested at the time of decompression but have similar limitation. This calls for the need of some alternative bone graft substrates which is safe as well as produce similar results and can be harvested in considerable volume and we explored the potentials of demineralized bone matrix for this procedure. In our study the Demineralized Bone Matrix for our study was procured from Ramaiah Tissue Bank. DBM procured in our study was Sterilized using Alcohol and Acid without exposing them to radiation to remove the antigenic capacity of the allograft. These morselized DBM had bmp proteins which helped in the new bone formation, thus rendering it both osteoconductive and osteoinductive properties. Grafts were issued after sterility tests and culture reports. Bae *et al* have pointed out that the variability of BMP concentrations among different lots of the same DBM formulation was higher than the inter-product variability or concentrations of BMP among different DBM formulations.⁵² In the present study of 30 patients undergoing lumbar spinal fusion surgeries, posterior stabilisation with decompression with PLF using demineralised bone graft were trailed with conservative management for a period of two months and those who failed with it were evaluated clinically and radiologically and the need for the surgery was assessed. Subjects who met the inclusion and exclusion criteria and consented for the use of Demineralized Bone Matrix were included.

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