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Comparison of peek cage vs bone graft only in anterior cervical discectomy and fusion

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Abstract
Anterior Cervical Discectomy and Fusion (ACDF) is the most frequently performed surgical treatment for several cervical spinal diseases. Including herniated disc, trauma and degenerative diseases [5, 8]. We have collected data of 31 patients admitted and operated between November 2017 to June 2019 having degenerative cervical disc disease who underwent ACDF reinforced with anterior cervical plate [11, 20]. All ACDF operations were performed using Smith-Robinson anteromedial approach using a surgical microscope [5, 16].
Approach Philadelphia collar were applied for 1 month post operatively. In our study we observed that ACDF achieves favourable radiologic results. The whole study data shows that there is a significant change in alignment of affected cervical spine after performing ACDF. Surgery related complications were not observed. No graft malposition, migration or mechanical failure of instruments.
Objective: To evaluate radiologic result of anterior cervical discectomy and fusion.
Methods: Retrospective review of clinical and radiological data of 31 patients. Cobb's angle, C1-C2 angle, C2-C7 angle, Vertebral height were measured and followed.

Keywords: Peek cage, ACDF, bone graft

Introduction
Anterior cervical discectomy and fusion (ACDF) is the most frequently performed surgical treatment for several cervical spinal diseases. Including herniated disc. Compressive myelopathy trauma and degenerative disease. After decompression of spinal cord or nerve roots, interbody fusion should be performed for spinal stabilization. Autologous bone has achieved favourable fusion but it results in an additional wound of the harvest side with risk of morbidity. Another fusion material is polyetheretherketone (PEEK) cage and has been used with or without anterior cervical plate augmentation. Without the anterior plate, higher subsidence rate has been reported. Besides the PEEK cage, allograft, autograft ACDF are usually performed with anterior plate augmentation.

Materials and Methods
Patient Selection

Type of Study: Retrospective study

Sample Size: 31

Inclusion Criteria
- ACDF done for Single level disease
- No prior cervical surgery
- Cervical degenerative disease or intervertebral instability of discogenic origin with decreased segmental lordosis.

Exclusion Criteria
- Multiple level disease requiring use of different impants on different segments to be treated.

- History of Posterior instrumentation.
- Major instability or traumatic instability
- Metabolic bone disease, major osteoporosis, severe osteopenia, osteochondrosis.

In our study we have collected data of 31 patients operated between November 2017 to June 2019 for having degenerative cervical disc disease underwent ACDF.

Surgical Procedure

A single surgeon performed all operations with a standard Smith-Robinson anteromedial approach using a surgical microscope. After discectomy and decompression of the neural component, the graft bone was inserted into the disc space during gentle distraction of vertebral bodies. A Philadelphia neck collar was applied in all patients for 1 month after surgery.

Table 1: General Characteristics

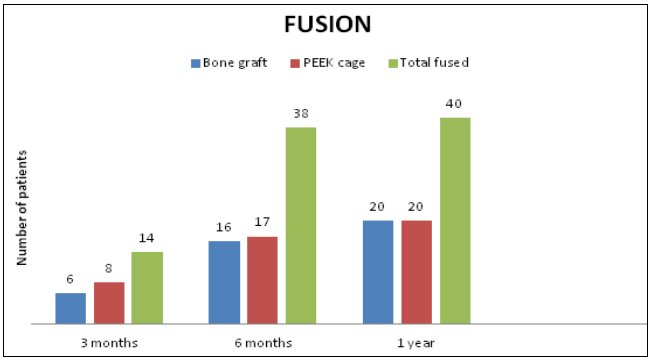
Demographic Data	Bone Graft	PEEK Cage
Total number of patients	20	20
Male	18	19
Female	2	1
Average age of Patients	44	46
Maximum age	65	52
Minimum age	19	37
Bone graft taken from Iliac crest	20	5
Months of Follow up	12	12

In the present study, there are a total of 40 patients with 20 patients in each group.
Most of the patients in this study are male (92.5%).
Average age of the patients is 45 years and ages range from 19 years to 65 years.
Bone graft was taken from the iliac crest in 25 patients, in which 20 are of bone graft only group and 5 are from PEEK cage group.
There is a total of 12 months of follow up in all patients.

Table 2: Cervical Level

Level	Number of patients
C2-C3	1
C3-C4	5
C4-C5	8
C5-C6	17
C6-C7	9

Most common Level: C5-C6
Fusion at operated Level

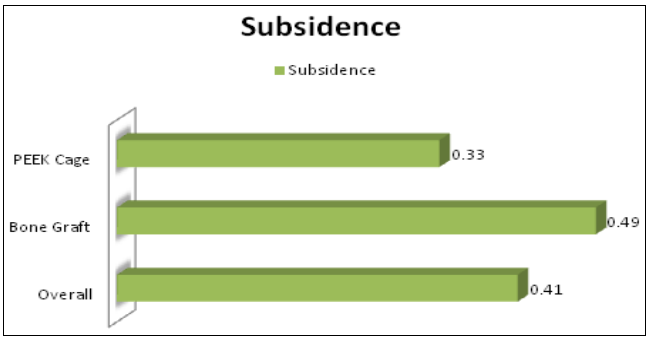


Fusion among PEEK Cage and Bone graft group were similar in outcomes (p>0.05).
Fusion in PEEK cage group was seen relatively earlier than Bone graft only group.
All patients in both groups achieved fusion by 1 year of follow up.

Fig 2: Pre OP x ray

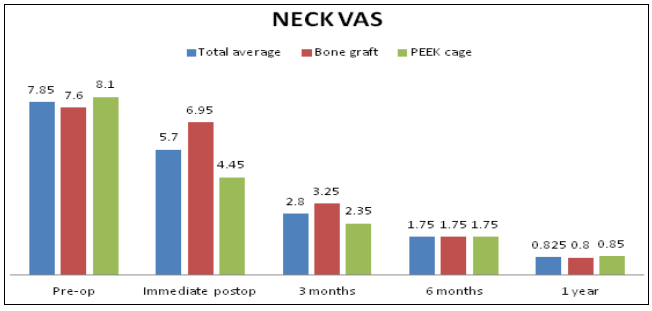
Fig 22: X ray Showing Fusion at 12 Months

1. Subsidence at 1 year



Subsidence at 1 year among PEEK cage group was significantly less than the Bone graft group (p<0.05).
Overall mean subsidence at 1 year follow up was found to be 0.41mm.

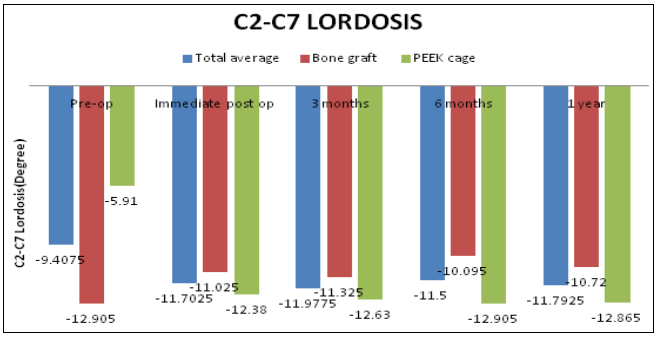
2. Neck pain vas score



On One Way ANOVA for repeated measures, the F-ratio value is 230.82538. The p-value is < .00001. The result is significant at p < .05, showing that neck pain is significantly less post operatively and at subsequent follow ups.

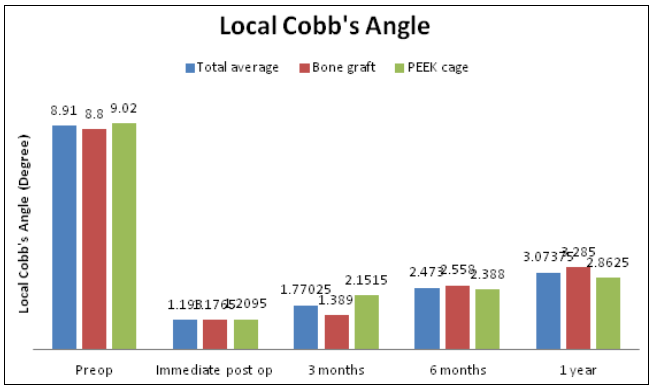
Neck pain among both the groups has decreased significantly over the period of 1 year.

3. C2-C7 Lordotic Angle



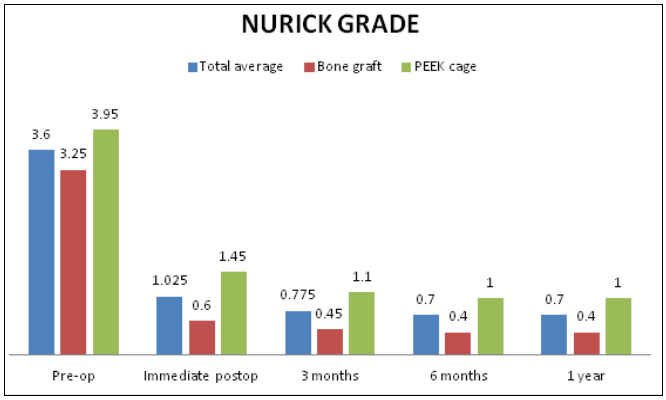
ON applying One Way ANOVA for repeated measures, the F-ratio value is 0.54139. The p-value is .705557.
The result is not significant at $p < .05$. Which means that C2-C7 lordotic angle was significantly improved among both groups, and both the groups do not differ significantly in terms of lordotic angle maintenance.

4. Local Kyphotic Angle or Cobb's Angle



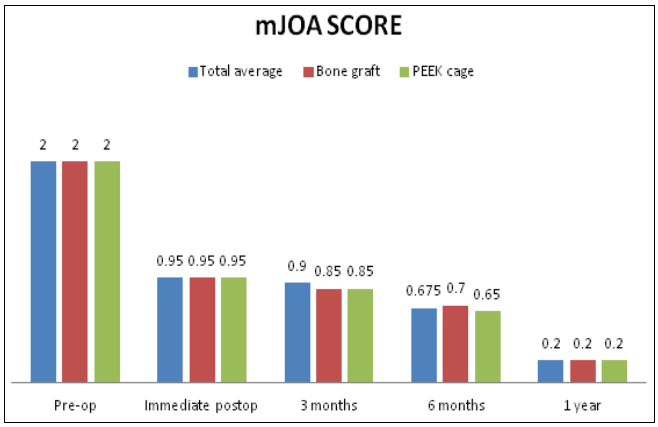
On applying One Way ANOVA for repeated measures, The F-ratio value is 20.76834. The p-value is < .00001. The result is significant at $p < .05$.

5. Nurick Grade



On applying One Way ANOVA for repeated measures, the F-ratio value is 198.42531. The p-value is < .00001. The result is significant at $p < .05$. Showing that there is significant improvement in Nurick grades post operatively and at subsequent follow ups and no signs of any deterioration.

6. mJOA Grade

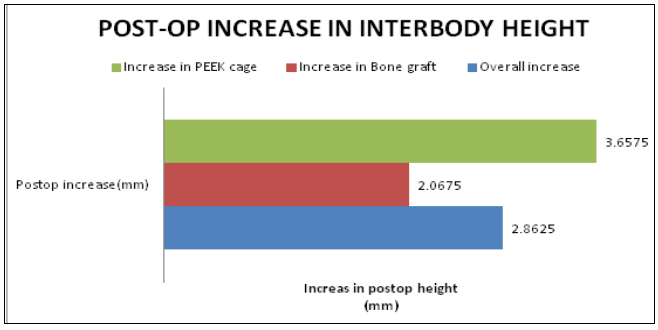


This shows that the F-ratio value is 207.88073. The p-value is < .00001 on applying One Way ANOVA for repeated measures. The result is significant at $p < .05$. Which means that mJOA score has improved significantly among post op group and maintained at subsequent follow ups.

7. Interbody Height

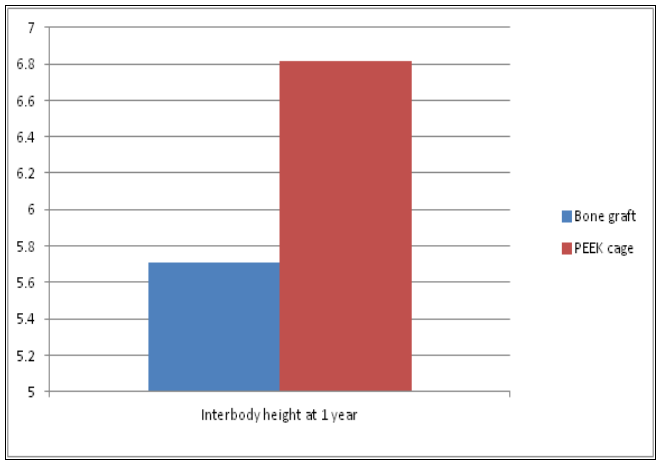
On applying One Way ANOVA for repeated measures, the F-ratio value is 37.67264. The p-value is < .00001. The result is significant at $p<.05$. Showing that interbody height has increased significantly among post op group and maintained in follow ups.

8. Post-Op Interbody Height Increase



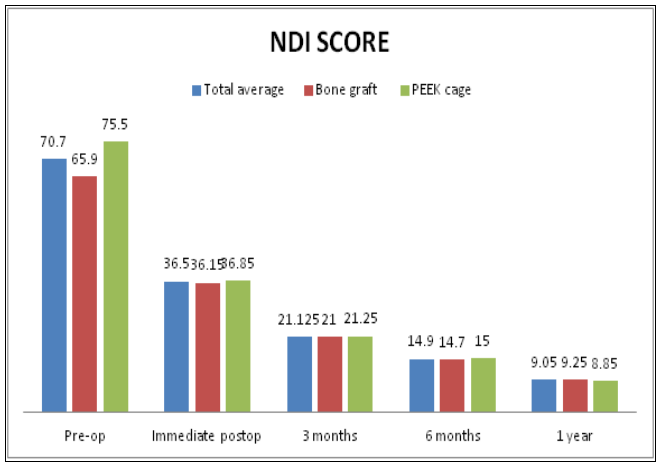
On applying paired t-test the t-value is -4.4196. The p-value is .00004. The result is significant at $p < .05$., which depicts that overall increase was significantly more among PEEK cage group, which shows that PEEK cage has optimal properties for maintenance of interbody height.

9. Interbody height at 1 year bone graft vs peek cage group



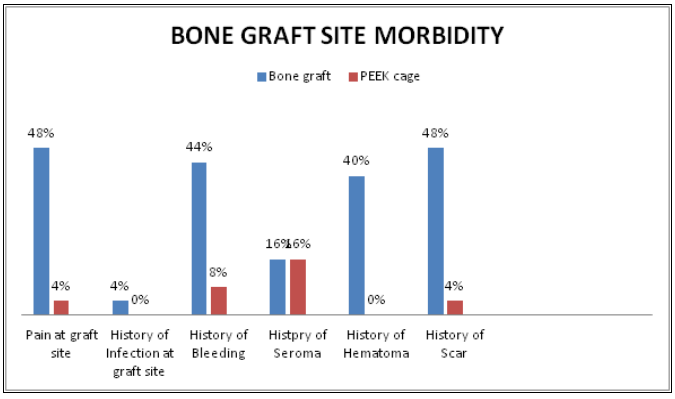
On applying paired t-test, The t-value is -4.61712. The p-value is .000022. The result is significant at $p < .05$. Which shows significantly higher interbody hight maintenance among PEEK cage group than bone graft group.

10. NDI Score



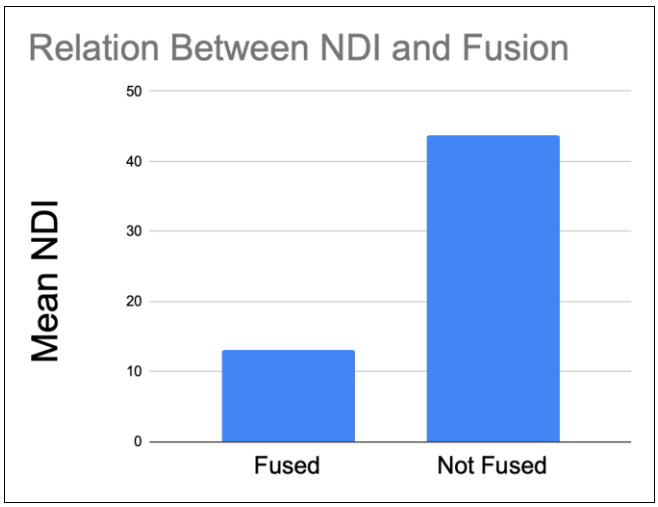
On applying One Way ANOVA for repeated measures,the F-ratio value is 656.29412. The p-value is < .00001. The result is significant at $p < .05$. Showing improved clinical outcome among both groups and similar results among both PEEK cage and bone graft group.

11. Bone Graft Site Complains



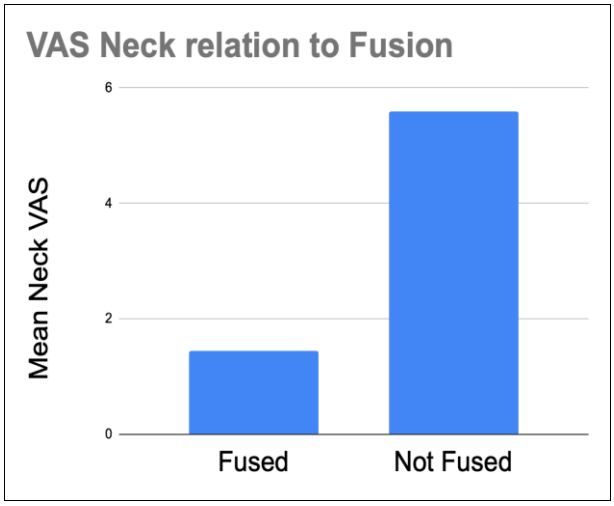
This figure shows that bone graft site complains are higher among the bone graft group.

12. NDI Vs Fusion



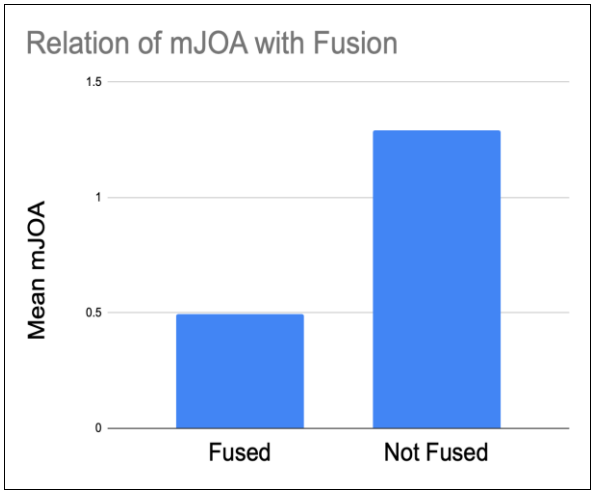
The t-value is -12.07329. The p-value is < .00001. The result is significant at $p < .05$.

13. Neck Vas Vs Fusion



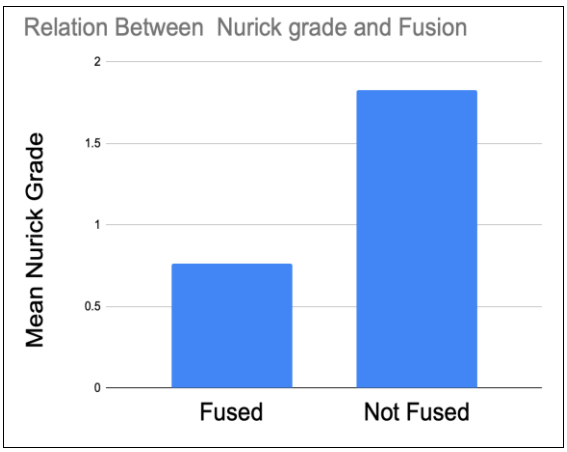
The t-value is -14.00328. The p-value is < .00001 The result is significant at $p < .05$.

14. mJOA vs Fusion



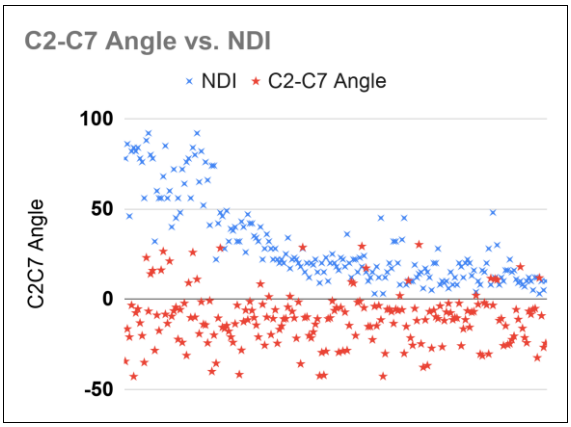
The t-value is -10.23695. The p-value is < .00001. The result is significant at $p<.05$.

15. Nurick Grade Vs Fusion



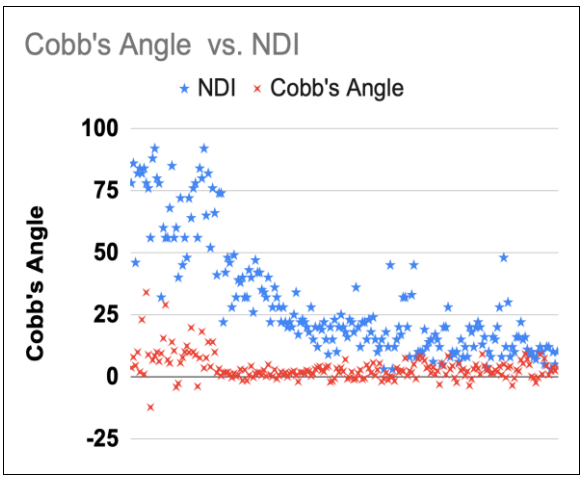
The t-value is -5.42692. The p-value is < .00001.
The result is significant at $p < .05$.

16. C2-C7 Angle Vs NDI



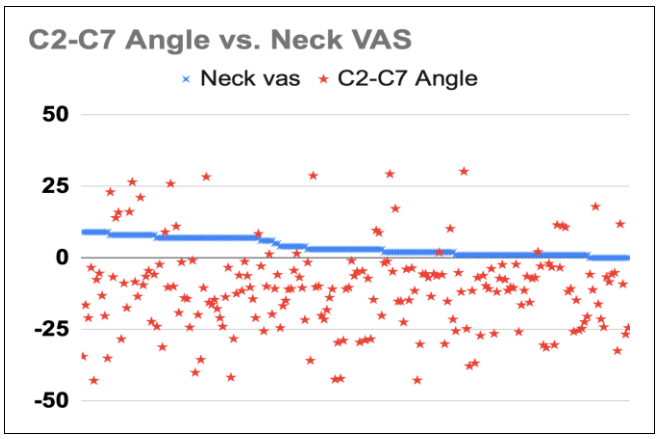
The value of R is 0.119
The P-Value is .093282.
The result is not significant at $p < .05$

17. Cobb's Angle Vs Ndi



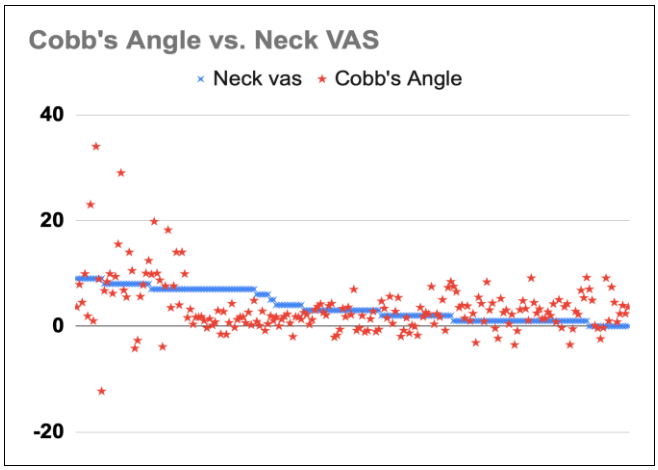
The value of R is 0.453
The P-Value is < .00001.
The result is significant at $p < .05$.

17. Neck Vas Vs C2-C7 Angle



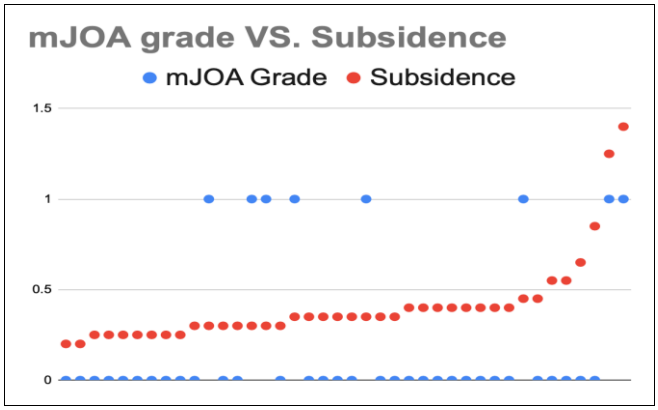
The P-Value is .663009.
The value of R is 0.031.
The result is not significant at $p < .05$

18. Cobb's Angle Vs Neck Vas



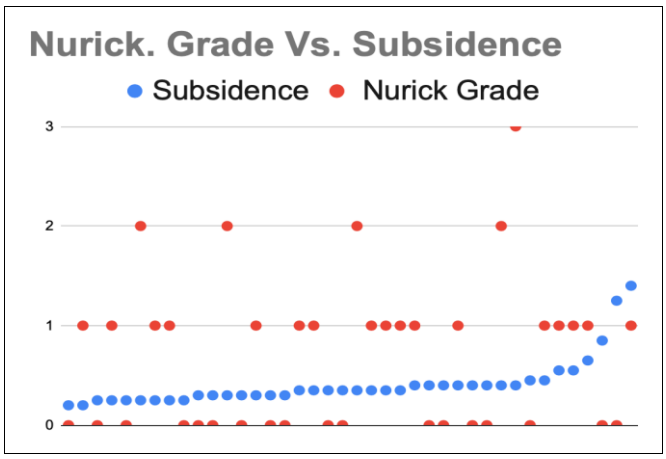
The value of R is 0.2956
The P-Value is .000021.
The result is significant at $p < .05$.

19. mJOA Grade vs Subsidence



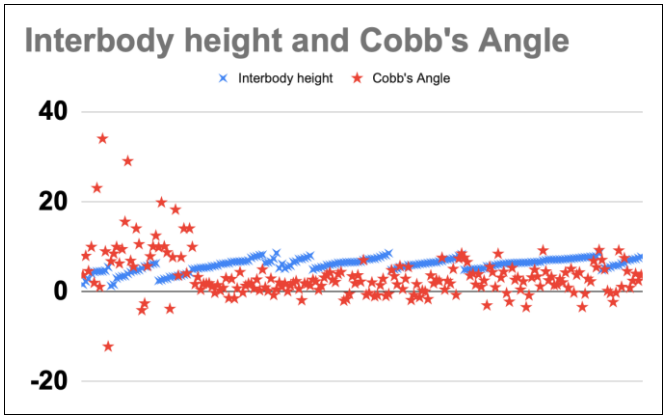
The P-Value is .020458.
The value of R is 0.3653.
The result is significant at $p < .05$

20. Nurick Grade Vs Subsidence



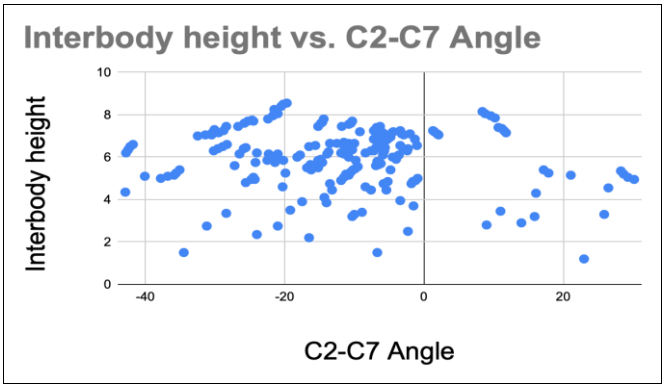
The P-Value is .854201.
The value of R is -0.0385.
The result is not significant at $p < .05$.

21. IBH Vs Cobb's Angle



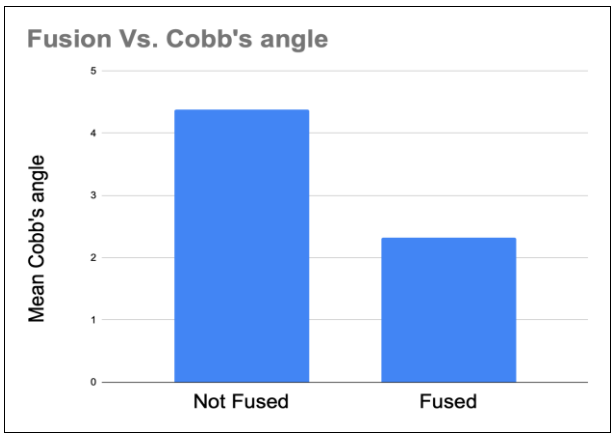
The value of R is -0.4078.
The P-Value is < .00001.
The result is significant at $p < .05$

22. C2-C7 ANGLE VS IBH



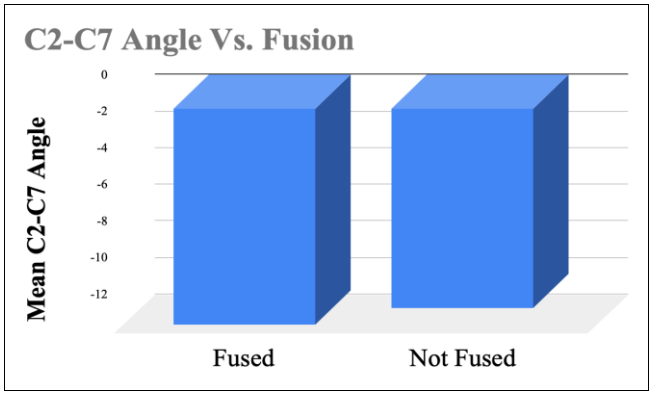
The P-Value is .120659.
The value of R is -0.1101.
The result is not significant at $p < .05$.

23. Fusion Vs. Cobb's Angle



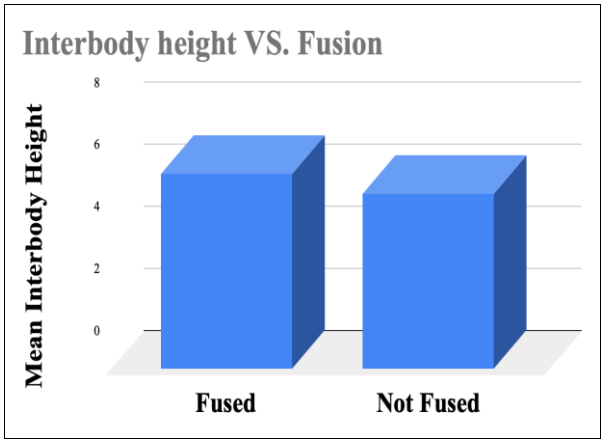
The t-value is -2.8534.
The p-value is .002393.
The result is significant at $p < .05$.

24. C2-C7 Angle Vs. Fusion



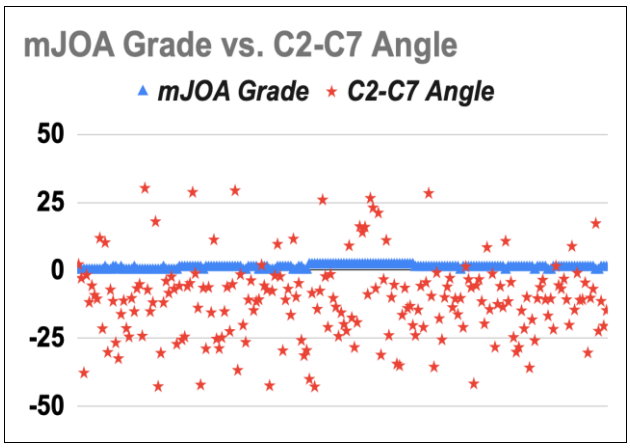
The t-value is -0.4443.
The p-value is .328655.
The result is not significant at $p < .05$

25. IBH Vs. Fusion



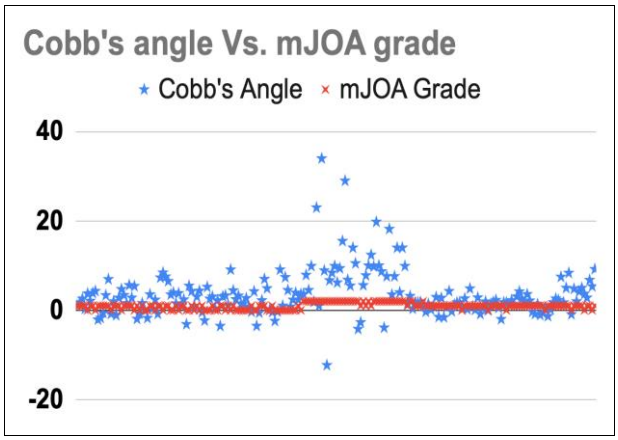
The t-value is 3.11202.
The p-value is .001066.
The result is significant at $p < .05$.

26. MJOA Grade Vs. C2-C7 Angle



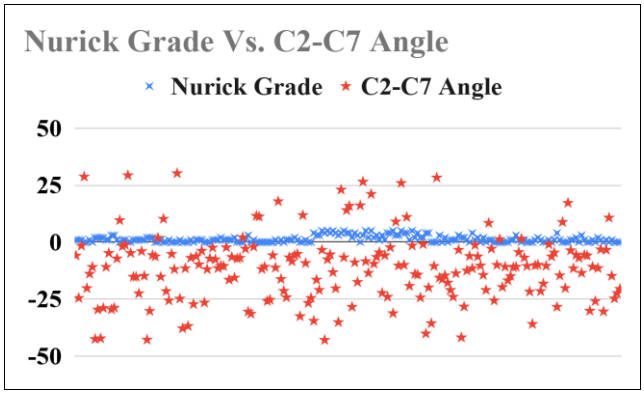
The P-Value is .473254.
The value of R is 0.051.
The result is not significant at $p < .05$.

27. Cobb's Angle Vs. Mjoa Grade



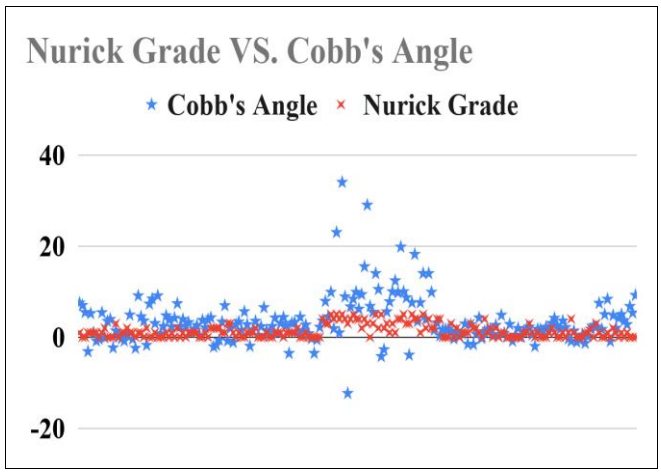
The value of R is 0.3728
The P-Value is < .00001.
The result is significant at $p < .05$.

28. Nurick grade vs. C2-c7 angle



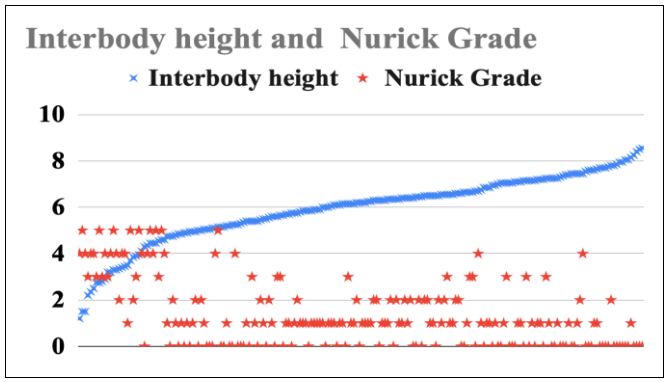
The P-Value is .746488.
The value of R is -0.0233.
The result is not significant at $p < .05$.

29. Nurick Grade Vs. Cobb's Angle



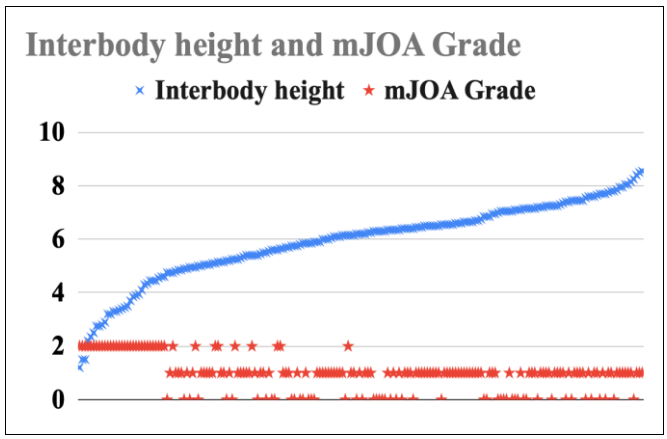
The value of R is 0.4054
The P-Value is < .00001.
The result is significant at $p < .05$.

30. IBH VS. Nurick grade



The P-Value is < .00001.
The value of R is -0.5937.
The result is significant at $p < .05$

31. IBH VS. MJOA Grade



The P-Value is < .00001.
The value of R is -0.5736.
The result is significant at $p < .05$.

Discussion

Anterior cervical discectomy with fusion is a very common and successful surgical procedure for cervical myelopathy, radiculopathy, and degenerative disease that has failed to be corrected with conservative therapy [113]. Medicare data documented a 206% increase in 1-level fusion procedures for degenerative spine pathology performed between 1992 and 2005 [114]. When a procedure is performed so often, it is appropriate to review methods and analyze efficacy, cost, clinical outcomes and cost-effectiveness.

Also, reduction and stabilization of the injured segment is the basic principle in the treatment of subaxial cervical spine. Until now, surgical strategies have reported successful outcomes in the treatment of subaxial cervical spine injuries using an anterior [115, 116] posterior [117], or combined approaches; [118, 119] however, the optimal approach has not yet been established.

Posterior stabilization techniques have been employed with good results using wires, hooks, screws, and rod systems [120, 121]. The advantages of posterior cervical approach include direct visualization of facet dislocations and decompression of the central canal and neural foramina [122]. However, disadvantages include a relatively longer operative duration, increased muscle dissection, postoperative neck pain, increased blood loss, and a relatively higher risk of surgical site infection. Moreover, although the incidence of disc disruption may be as high as 40% in unilateral facet dislocation and 80% in cases of bilateral cervical facet dislocation [123], the approach is unable to address ventral compressive disc disruption [124, 125]. Without appropriate management, disc disruption could cause neurological deterioration and anterior collapse of the disc space, which could lead to a kyphotic deformity.

On the other hand, anterior cervical approach enables decompression of the spinal canal by removing the disc, thus avoiding neurological deterioration by further disc displacement [126, 127].

Additionally, anterior plate fixation after ACDF could provide effective stabilization with the advantage of single motion specific segment fusion in cervical facet dislocation. Whereas, posterior screw fixation disadvantage was seen with posterior element fractures, often necessitate longer fusion levels. Biomechanical studies however, have reported the suitability of posterior screw fixation over anterior plate fixation for subaxial cervical spine injuries [128, 129]. Despite these studies, the use of ACDF and plate fixation as the primary method of stabilization for subaxial cervical spine injuries is gaining popularity among spinal trauma surgeons, with a high success rate and good clinical results [130-133].

In this study, all patients were successfully stabilized through the anterior approach, and there was no instability at the last follow-up. The stabilization rate in this study is favorably comparable to previous literature reports, which range from 86.2% to 100% [134-137]. Therefore, ACDF and plate fixation could be an excellent treatment option for traumatic subaxial cervical spine injuries.

If there is some disadvantage of ACDF, autologous bone graft has been considered as the gold standard, causing harvest site morbidity such as chronic pain, hematoma, infection, injury of adjacent nerves, visceral herniation, and iliac crest fracture [138]. These risks of autologous bone graft morbidity have been widely reported, suggesting the need for an alternative fusion method that obviates iliac crest harvest [139]. Various materials have therefore been developed and used for interbody grafts with the ACDF, in order to avoid the morbidity associated with autologous bone grafts. Representatively, PEEK material cages have been developed to achieve immediate stability and successful bone fusion [140, 141]. Titanium spikes provide immediate solid fixation between the cage and the vertebral body, reducing the risk of cage migration. Many of the complications associated with iliac crest harvest have been significantly reduced with the use of the cages. Additionally, DBM, which contains bone morphogenic proteins, was introduced as a bone inductive substance. Some types of DBM have both osteoinductive and osteoconductive capability [142].

In this study mean Local Cobb's angle pre-operatively, at discharge, at 3 month follow up, at 6 month follow up, and at 1 year follow up were 8.91°, 1.193°, 1.77°, 2.473°, and 3.073° respectively and improvements in Cobb's angle was significant, the F-ratio value is 20.76834, the p-value is < .00001. The result is significant as $p < .05$, which correlates clinically with the improvement in neurological outcome, and no hardware complications as seen with this study. In the present study, Cobb's angle is found to be strongly correlated to NDI, Neck VAS, mJOA grade, and Nurick grade of the patients. In this study NDI was found to be strongly dependent on local Cobb's angle, Pearson coefficient(R) is 0.453, and p is <0.05, hence significant. Neck VAS score was also found significantly correlated with the local Cobb's angle, Pearson coefficient(R) was 0.2956, and $p<0.05$.mJOA and Nurick grades too are strongly dependent on local Cobb's angle as discovered in this study, Pearson coefficient(R) for mJOA grade was 0.3728, and Pearson coefficient(R) for Nurick grade was 0.4054, for both $p<0.05$, and hence are strongly correlated with Cobb's angle.

Sagittal cervical alignment is often regarded as a parameter for correlation with clinical outcome of a cervical instrumentation and fixation, with assessment of lordosis and segmental Cobb's or kyphosis angle [146-148]. In this study mean pre operative, at discharge, at 3 month follow up, at 6 month follow up, and at 1 year follow up C2 C7 lordosis angle (normal -5°+/- 12°) were -9.4075°, -11.7025°, -11.9775°, -11.5°, and -11.7925° respectively. A mean increase of -2.385° lordosis is seen from preoperative to last follow up. There is no significant loss of lordosis as compared to previous follow ups, the change in cervical lordosis from preoperative to last follow up is also not significant, (p= .705557).

ACDF using an intervertebral cage is credited with promoting instant stability, restoration of the neural foraminal height and interbody fusion by providing an environment for bone growth [149-151]. However, recent studies have shown that cage subsidence is a major complication of ACDF using stand-alone cages regardless of the composite materials [152-156]. PEEK cages are currently the most preferred. Compared with titanium and carbon fiber cages, PEEK cages are more biocompatible [157] and radiolucent, which allows for precise radiological evaluation of bony union. In addition, PEEK cages are expected to result in lower subsidence rates than that with using metal cages because their modulus of elasticity is similar to that of bone [158]. However, various degrees of subsidence have been reported after ACDF using stand-alone PEEK cages. This can be partly attributable to the errors from measurement methods and the magnification differences on radiographs. Based on the report that ≤ 2 mm cage subsidence into the vertebral body can occur during the bone remodeling process after ACDF using cages [159], the segments with ≥ 2 mm decrease in the anterior or posterior segmental height were classified as the subsidence group in

this current study. Considering that ≥ a 3 mm [160-162] decrease, as well as ≥ 2 mm [163, 164] decrease, has been used as a criterion for subsidence in many studies [165].

In this study it is seen that mean interbody height pre-operatively, at discharge, at 3 month follow up, at 6 month follow up, and at 1 year follow up were 3.81 mm, 6.6725 mm, 6.51625 mm, 6.38375 mm, 6.2625 mm respectively, average collapse at 1 year follow up was found to be 0.41 mm. The total change in height from pre-operative phase to 1 year follow up was found to be significant with a mean increase of 2.8625 mm is significant (p<.00001). Among both groups the mean increase in interbody height was 1.90875 mm post operatively, with a mean increase in peek cage group being 2.8625 mm and in the bone graft group being 3.6575 mm which is found to be statistically significant, (p<0.05). The mean height at 1 year follow up was 5.7075 in the bone graft group and 6.8175 in PEEK cage group which is also significant (p<.05).

Interbody height is found to be the determining factor for many variables, namely, Cobb's angle, C2-C7 angle, Nurick Grade, and mJOA grade. IBH was strongly found correlated to Cobb's angle, Pearson coefficient(R)= -0.4078, and p<0.05, showing improved Cobb's angle with increase in IBH. C2-C7 lordotic angle is not found dependent on IBH, Pearson coefficient(R) = -0.1101, p>0.05. Nurick grade and mJOA grade, both are found to be strongly dependent on IBH, Pearson coefficient(R) = -0.5937 for Nurick grade, and Pearson coefficient(R) = -0.5736 for mJOA grade, for both p<0.05, showing a negative correlation, that is, as IBH increases these grades improve (hence decrease).

In the present study, subsidence was measured as difference of IBH at 1 year follow up and immediate post operative IBH, it was found at 1 year to be a mean of 0.41mm overall, and in bone graft group it was found to be 0.49mm, and 0.33 in the PEEK cage group. Subsidence among bone graft group was found to be significantly higher than PEEK cage group, t-value is -2.14974, p-value is .019003, p<0.05. This shows that PEEK cage is excellent material at preventing collapse. Subsidence was found to be positively correlated to mJOA grades, Pearson coefficient(R) = 0.3653, p<0.05, showing improved mJOA grades with lesser subsidence. However, subsidence was not found to be correlated with Nurick Grades. (p>0.05)

A modification of the Oswestry Low Back Pain Index was conducted producing a 10-item scaled questionnaire entitled the Neck Disability Index (NDI). NDI achieved a high degree of reliability and internal consistency. As well, it appears to be sensitive to the levels of severity of complaint, and to changes in severity in the course of treatment. While further study is recommended, the NDI is offered as a potentially useful instrument in the assessment of neck pain complaints [166]. NDI in the present study was calculated according to the original questionnaire given by Vernon *et al*. In this study, the mean NDI among preoperative, immediate postoperative, at 3 month follow up, at 6 month follow up and at 1 year follow up were 70.7%, 36.5%, 21.125%, 14.9%, and 9.05% respectively. Among both groups there is no significant difference in NDI both preoperatively and postoperatively, however the NDI has decreased significantly post operatively and at final follow up (p<0.05), which is consistent with the fact that fusion leads to decreased motion at affected segment and thus decreased neck pain and discomfort.

Pain in the neck was also assessed by VAS scores which pre operatively, at discharge, at 3 month follow up, at 6 month follow up, and at 1 year follow up were 7.85, 5.7, 2.8, 1.75, and 0.825 respectively. Pain VAS has decreased significantly (p<0.05) in this study and consistent with the findings of neck disability index pointing towards a good clinical outcome in patients of acdf. There is no significant difference found among the PEEK cage and bone graft group with respect to VAS scores of neck pain (p>0.05).

For ACDF, iliac crest bone is an ideal and widely used construct substrate. Structural grafts harvested from the crest provide significant stability due to their bicortical or tricortical configuration with interposed osteoinductive and osteogenic cancellous bone. Few graft complications (eg, graft resorption) and no immunogenic or infectious complications have been reported for iliac crest bone. However, autologous iliac crest increases operative time, and donor-site morbidity has been reported [168, 169]. Use of local autograft with a PEEK spacer has all the advantages of iliac crest autograft along with the benefit of working within the same operative window as the ACDF, thus reducing the infection, bleeding, and pain risks that may be encountered with a bone graft site. In present study VAS scores were used to assess the graft site pain postoperatively and at subsequent follow ups.

Mean graft site VAS at post operative, at 3 month follow up, at 6 month follow up, and at 1 year follow up were 7.24, 4, 1.28, and 0.36 respectively. Among bone graft group mean graft site VAS immediately postoperative was 7.55, and among PEEK cage group was 6, which is significantly lesser in PEEK cage group as (p<0.05).

In the PEEK cage group, out of 20 patients only 5 patients needed extra bone graft from the iliac crest which was taken as cancellous graft different than the tricortical graft taken in case of Bone graft only group, incision and harvesting time was far shorter than the bone graft group, which required a long incision, causing higher bleed, and higher morbidity at the graft site. Other 15 patients of the PEEK cage group did not require any extra graft material and were implanted with local bone graft only, leading to avoidance of second incision at the graft site, and hence decreased surgical time and complications of a second surgical site.

A retrospective questionnaire-based investigation by Silber and colleagues, who evaluated iliac crest bone graft site morbidity in 1-level ACDF, found that 26.1% of patients had pain at the iliac crest harvest site, and 15.7% had numbness.24 Other complications, which occurred at lower rates, were bruising, hematoma, pelvic fracture, and poor cosmesis [170, 171]. In addition, osteoporosis and comorbid conditions have made it a challenge to acquire iliac crest autograft, contributing to the popularity of alternative substrates.

In the present study it was found that 52% of the patients in whom bone graft was taken had complaints of pain at the graft site, of which 48% were of bone graft group and 14 % were of PEEK cage. 52% patients reported bleeding from bone graft site at some point of time mostly during immediate post operative period, of which 44% were of bone graft only group and 8% were of PEEK cage group. 16% of total graft patients had a history of seroma or some serous discharge from surgical wound of which all patients were of bone graft group. 40% of the patients also had a history of hematoma formation of which all of the patients belonged to the bone graft only group. 52% of the patients reported poor cosmesis or bad scar at bone graft site, of which 48% were of bone graft only group and 14% were of PEEK cage group. There was only one case of graft site infection and was managed successfully with the help of local debridement and

antibiotics. In this study morbidity due to graft site is fairly low in the PEEK cage group as very few patients required graft and in bone graft only group the graft site lead to many complications, and patient dissatisfaction, with comparatively equal clinical outcome in both the groups. Use of local autograft with a PEEK spacer has all the advantages of iliac crest autograft along with the benefit of working within the same operative window as the ACDF, thus reducing the infection, bleeding, and pain risks that may be encountered with a bone graft site.

Complications

Surgery-related complications were not observed. No graft malposition, migration, or mechanical failure of instruments was observed, and there was no revision surgery.

Conclusion

ACDF with allograft bone block and plate augmentation achieves favourable radiologic results, which is seen in immediate post operative radiographs. This includes improved alignment of cervical vertebrae and increase in height post operatively. We hypothesise that to a certain degree, the maintenance of these parameters could contribute to reduce development of adjacent level change. A longer period of evaluation is needed, to see if all these radiographic changes will translate to symptomatic adjacent level disease, and to see the fusion rates.

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