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Correlation between intraoperative insertional torque of pedicle screws and bone mineral density in thoracic and lumbar spine injuries

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Abstract
Introduction: Pedicle screw fixation is becoming one of the standard methods of instrumentation in the thoracic and lumbar spine. The advantage of immediate rigid fixation with a minimum number of fused segments has been demonstrated in numerous studies
Methodology: Patients will be chosen as per inclusion and exclusion criteria. They will have radiological examination in the form of standard x-rays, CT scan of the spine and DEXA scan for bone mineral density
Results: Total 120 pedicle screws in 30 patients were inserted and available for the current study. The mean insertional torque of 120 screws was 2.72 ± 0.37Nm. There was no significant difference in the insertional torque of upper and lower pedicle screws at each fracture level. Quantitative evaluation of bone mineral density with DEXA scan was done of all patients. The mean BMD was found 856.7 ± 55.35 of 30 patients.
Conclusion: A high correlation was found between the mean insertional torque and Bone mineral density (r^2=0.6979, p<0.0001)

Keywords: Pedicle screw fixation, thoracic and lumbar spine

1. Introduction
Critical from a clinical standpoint, bone strength is an entity primarily dependent upon the mass of the bone. This is largely governed by the metabolic activity and turnover of the bony skeleton, which has the capacity to alter the bone architecture. These physiologic homeostatic processes affect the dynamic constituents of the bone, including the fat quotient in the marrow, the ratio of red to yellow marrow, and the architecture of the trabeculae, and, in effect, the vigour of the bone, and the bone mineral density (BMD). Until now, bone strength has primarily been measured in terms of BMD. A measure of the amount of matter per cubic centimetre of bones, the clinical utility of BMD lies as an indirect determinant of osteopenia and osteoporosis, which, in actuality gauge the fracture risk. Studies have found a strong statistical association between low bone mass with Microarchitectural deterioration of bone tissue and enhanced bone fragility with a higher probability of bony fractures, especially of the vertebra, pelvis, femora are a significant public health problem. Particularly common in elderly women. They result in huge medical costs, negatively influence the quality of life indices, and carry a sizeable risk of death [1, 2].
Traditionally, the standard tool used for measuring the bone mineral density has been Dual Energy X-ray Absorptiometry (DEXA). Considered a safe, simple, painless, short procedure, DEXA, however, is essentially a radiation based technique fraught with its inherent risk, even though such risks may be minimal [3, 4].
Unfortunately, these diagnostic tools are often unavailable before or during an operation, thus anchorage of an implant or possible failure of Osteosynthesis cannot really be estimated by the orthopaedic surgeon before surgery [5].
Pedicle screw fixation is becoming one of the standard methods of instrumentation in the thoracic and lumbar spine. The advantage of immediate rigid fixation with a minimum number of fused segments has been demonstrated in numerous studies. Despite this advantage, implant failures of fixation still occur. The common problems are screw bending, breakage, loosening (radiolucency in the bone–screw interface), and other related failures. In a selected survey of the American Back Society, the rate of screw loosening and breakage was observed in 0.81%

And 2.9% of 617 patients, and ranged from 0.6% to 11% and 0.6% to 25% in the literatures reviewed by Esses *et al*. [6]

Screw loosening was caused mainly by cyclic caudocephalad toggling at the bone-screw interface, and screw breakage was caused by cyclic axial stress concentration at the base of the pedicle screw which could be minimised by anterior interbody support in the form of a cage and bone graft [7, 8].

Incidences of screw bending or breakage currently are decreasing with shank tapering and the increase in screw diameters [7, 9]. However, problems with screw loosening and other related failures still develop even when PLIF is performed with pedicle screw fixation, especially in osteoporotic spines [10]. The stability of pedicle screws depends mainly on the bone–screw interface. If pedicle screws are anchored inadequately in the vertebral body through the pedicle, loosening of the screws can occur, which could lead to a loss of correction and nonunion. Therefore, to predict development of screw loosening, objective evaluation of the stability in the bone–screw interface is very important.

If the surgeon can get intraoperative information indicating that screw loosening may develop, with the potential increased risk of nonunion, then supplementary augmentation can be used. Bone mineral density (BMD) in the lumbar vertebra, the diameter of the pedicle, the design or length of the anchored screws, and so forth have been demonstrated to affect the stability of pedicle screws *in vitro* [11-14]. Furthermore, some authors have reported that insertional torque of pedicle screws is correlated highly with stability [15-17]. In previous study using cadaveric spines, they also suggested that the insertional torque of pedicle screws can predict stability.[18] However, specified data of the insertional torque found in pedicle screws have rarely been proposed *in vivo*.

Hence, this *in vivo* study is proposed to study the correlation between intraoperative insertional torque of pedicle screw and bone mineral density of thoracic and lumbar spine

2. Methodology

Patients will be chosen as per inclusion and exclusion criteria. They will have radiological examination in the form of standard x-rays, CT scan of the spine and DEXA scan for bone mineral density. After obtaining written and informed consent and attaining anaesthetic fitness, patient will be posted for surgery. Patients will undergo standard and uniform surgical procedure of one-stage short-segment posterior pedicle screw fixation and anterior decompression with interbody fusion using titanium cage. A sterile torque wrench attached to the pedicle screw driver which will measure the insertional torque when the screw shank is completely anchored into the entrance point. Torque at the final point of tightening is noted down and recorded for each screw inserted. Patients will be managed post operatively and followed up at regular intervals.

Patients will be followed up at 6 weeks, 3 months and 6 months interval from the date of surgery. Clinical and Radiological evaluation will be done for loosening of pedicle screws and related implant failure.

Statistical analysis will be performed between the insertional torque and the parameters of the radiographic assessments. Two-tailed unpaired *t* test and simple regression will be used. A p value less than 0.05 will be chosen as the cut off point for significance

3. Results

This study was conducted at Central Institute of Orthopaedics, Safdarjung hospital, New Delhi during the period of October 2013 to march 2015.

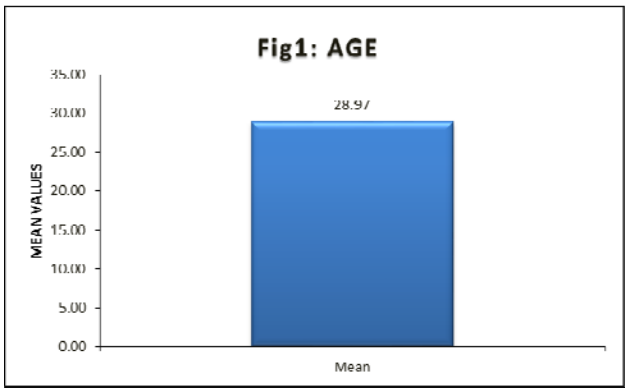
30 patients were included in the study after proper written and informed consent.

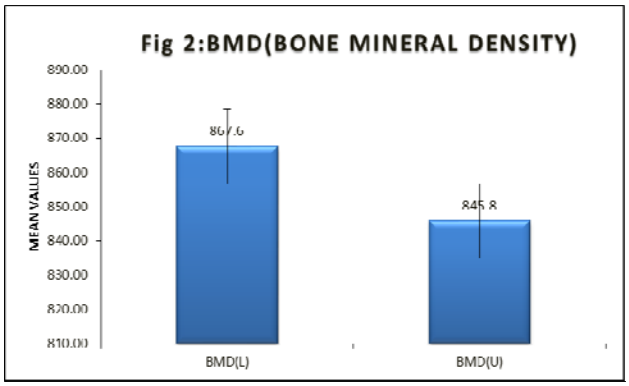
All patients were followed up religiously. No patient withdrew from study and followed up to 6 weeks, 3 months and 6 months. In all no screw was loosened. The only complication observed was post operatively pain in 24 patients.

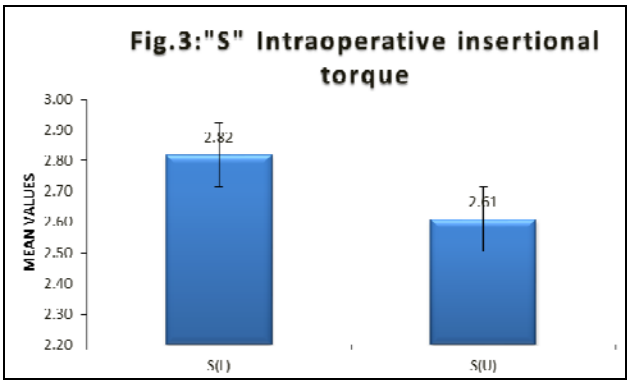
Total 120 pedicle screws in 30 patients were inserted and available for the current study. The mean insertional torque of 120 screws was 2.72 ± 0.37Nm. There was no significant difference in the insertional torque of upper and lower pedicle screws at each fracture level.

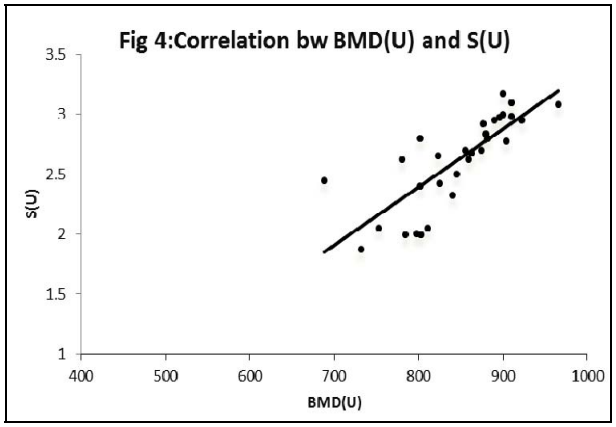
Quantitative evaluation of bone mineral density with DEXA scan was done of all patients. The mean BMD was found 856.7 ± 55.35 of 30 patients.

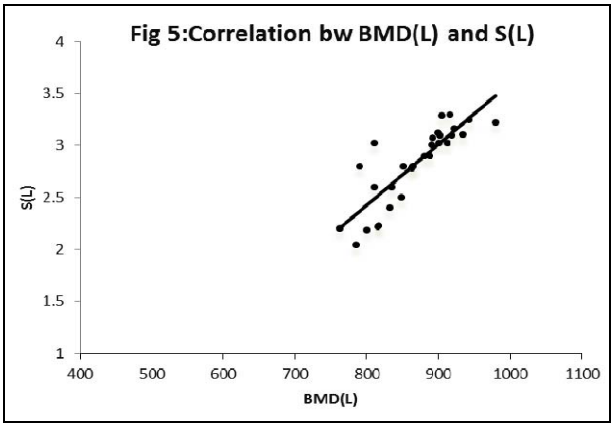
A high correlation was found between the mean insertional torque and Bone mineral density (r^2=0.6979, p<0.0001).











Correlations				
	Mean ± Stdev	**Median**	**Min-Max**	**Inter quartile Range**
BMD	856.7 ± 55.35	866.5	757.5-973	809.500 - 899.000
S	2.72 ± 0.37	2.79	1.96-3.24	2.500 - 3.030
	Correlation coefficient r	Significance level	95% Confidence interval for r	
BMD & S	0.8352	<0.0001	0.6793 to 0.9189	

4. Discussion

Problems of screw loosening, which may lead to a loss of correction and non-union, have not been solved in pedicle screw fixation, and its rate was still ranging from 0.6% to 11% of the cases in the literature reviewed by Esses *et al* [6]. Furthermore, the risk of screw loosening would be an inevitable concern when this procedure is performed in osteoporotic spines. Therefore, to predict development of screw loosening, objective evaluation of the stability in the bone-screw interface is very important *in vivo*. *In vitro*, several factors affecting the stability of pedicle screws such as the length, outer diameter, Design of implant, fitness in the pedicle, BMD, elasticity of the cancellous bone, and so forth have been mentioned. In particular, a very high correlation between BMD and the stability of pedicle screws has been confirmed. Therefore, BMD supposedly is a very important parameter influencing the stability of pedicle screws. Some thresholds for implant failures in pedicle screw fixation also have been proposed from a viewpoint of BMD.

Wittenberg *et al* [19] concluded that early loosening of pedicle screws may be expected at a BMD less than 90 mg/mL, as measured by quantitative computed tomography (CT) scan. We have reported that vertebra with an average BMD of 856.7 ± 55.35 mg/cm2, as measured by DEXA scan, anatomically stabilized by pedicle screws. The insertional torque of the screw, generated primarily by the shearing force and friction in the bone-screw interface, is defined as an angular moment of the force required to advance the screw into the bone.

Nunamarker and Perren [20] found a correlation between the maximum axial compression force and the insertional torque of cortical screws in the bovine cancellous bone. It also has been reported that the insertional torque of pedicle screws is highly correlated with both BMD and pullout strength in cadaveric studies.

Moreover, Zdeblick *et al* [17] stated that a screw with an insertional torque value less than 4 inch-pounds (0.452Nm) led to early pullout failure based on their cyclic cephalocaudad toggling test *in vitro*.

Daftari *et al* [16] also demonstrated a high correlation between the insertional torque and the pullout strength of pedicle screws in a study using synthetic bone material and calf vertebrae, concluding that if the insertional torque were actually measured intraoperatively, an anticipated load failure for the screw could be predicted using a mathematical relation, although they have not proposed a specific threshold. Meanwhile, data on the *in vivo* insertional torque of pedicle screws are very rare. It has been confirmed that the mean insertional torque of pedicle screws is significantly different among groups defined by the Jikei scale for spinal osteoporosis, and a positive linear correlation was found between insertional torque and BMD in the study. The mean insertional torque of 2.72 ± 0.37 Nm in the current study was approximately 2 times higher than the other previous studies, *in vitro* abd *in vivo*. This difference may be attributed to the absence of degenerative changes in the collagen fibers and the presence of intraosseous pressure in the bone marrow of the vertebra *in vivo*. *In vitro*, it has been demonstrated that loosening of pedicle screws is caused by a cyclic cephalocaudad toggling motion of the screw in the bone-screw interface

When an axial compression load is transmitted through the plate or rod to the screw.

Law *et al* reported that a mean axial compression load of 199 +/- 70 N (caudad) and -211 +/- 37 N (cephalad) developed a 4.93 +/- 3.60-mm toggling motion of pedicle screws.

In this study, no loosening was recorded in any of the screws.

As in this study no screw loosening was occurred, additional research with a larger number of patients is needed to verify the capability of method to indicate screw loosening. In this study, definitive non unions had not developed in any of the patients. This result implies that other factors such as the angle of insertion, screw length, screw diameter, quality of the bone, difference of placement of pedicle screws in vertebral body i.e subchondral/cancellous bone or any compromised (minimum breach) in vertebral body/pedicle, postoperative management of the patient, and so forth play some role in the development of non-union and screw loosening.

Yerby *et al* [23] demonstrated that usage of a laminar hook with pedicle screws can significantly reduce migration of the screw into the endplate in osteoporotic cadavers.

Furthermore, Hasegawa *et al* [24] reported that stiffness in the bone-screw interface is significantly enhanced by adding a laminar hook.

Hilibrand *et al* [25] reported the efficacy of the pediculolaminar fixation in the compromised pedicle bone. These biomechanical studies support an advantage in using the

laminar hook to reduce the risk of screw loosening. But the supplementary instrumentation procedure should be used only for patients in whom screws are going to loosen. Considering the result in the current study, a mean BMD less than 752 +/- 59 mg/cm2 in a patient could be indicative because clinical outcome of patient is good above this level.

Compression fractures in the upper vertebra adjacent to the fixed segment were detected in the osteoporotic study patients with significantly low values of insertional torque (0.87 +/- 0.27 Nm) and BMD (545 +/- 87 mg/cm2). These values of insertional torque and BMD should be considered clinically as a risk zone. It could not be explained theoretically why screw loosening was not observed in these patients at the time. Some other hidden factors should be there. Use of a new implant or interbody cage with less stiffness, or injection of other augmentation materials into the upper vertebra adjacent to the fixed segment, such as carbonated apatite, may be encouraged in the near future.

5. Conclusion

A high correlation was found between the insertional torque and bone mineral density of the lumbar spine. Though there is a direct relation between intra operative insertional torque and bone mineral density detected by DEXA scan but intraoperative insertional torque was significantly affected by any compromised (minimal breach) vertebral body in the same vertebra. The insertional torque could not objectively predict screw loosening

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