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Poly-methyl methacrylate (PMMA) augmented fenestrated pedicle screw fixation for reduction and stabilization of symptomatic spondylolisthesis

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Abstract
Not many studies evaluate the clinical outcome of Poly-methyl methacrylate (PMMA) screws for reduction of spondylolisthesis and there are no studies discussing the relation of bone mineral density in patients requiring PMMA screws. This retrospective study involves 32 patients who required PMMA augmented screws during surgery of the 165 patients operated for symptomatic spondylolisthesis. The average T-score of patients requiring PMMA augmentation was -2.52 in male and -2.364 in female groups. Overall outcome was good. PMMA augmented screws for reduction of listhesis in osteoporotic spines is a safe and effective technique and it cannot be preplanned with T-score value alone.

Keywords: PMMA screws, spondylolisthesis, bone mineral density, osteoporosis

Introduction
Instrumented fusion using pedicle screws is the best option available for surgical correction of spondylolisthesis in indicated cases [1] as it provides three column fixation. The key to fixation lies in the strength of purchase in the pedicle and trabecular bone of the vertebral body [2]. Osteoporosis which affects the trabecular bone becomes more common with age, affecting white and Asian people commonly [3]. There is increased risk for stripping during insertion and loosening at a later date [2].
Several cadaveric studies [4, 5] have evaluated the pull-out strength of Poly-methylmethacrylate (PMMA) cement augmented screws and have shown improved acute and fatigue strength in osteoporotic vertebra [6]. The use of PMMA augmented screws for osteoporotic patients is increasing [7].
The purpose of this study is to review the clinical outcome when these screws are used.

Materials and Methods
In this retrospective study, 165 patients operated for spondylolisthesis between March 2014 and March 2015 were evaluated. Thirty two patients required PMMA augmented screws. All types of listhesis which required PMMA screws for reduction were taken into consideration.
All cases were operated by the same surgeon. The decision for using the PMMA cement augmentation for pedicle screws was taken when there was screw pull out or loosening during attempted reduction of listhesis. The normal pedicle screws were changed to PMMA screws. The PMMA augmented screw used were all poly axial fenestrated screws from Medtronics-Legacy (USA Inc.). The screws had holes only in the distal end thereby minimizing the risk of cement leak into spinal canal.
Care was taken to prevent any perforation in the anterior cortex during screw insertion. The screw length was chosen such that, the screw traverses up-to 80% of the vertebral body. Once the screw positions were confirmed under imaging, about 1.5 to 2 ml of radiopaque bone cement was injected into each screws under image guidance. During injection, care was taken so that there is no extravasation of cement into the canal or through anterior cortex. Some cement can escape through the sinusoidal veins. In case, if there was any extravasation, the injection is stopped temporarily and was resumed after about a minute, to prevent further extravasation.

Once the cement is set, then the rods are fixed to the screws and reduction of listhesis achieved. Complete reduction was attempted. Posterior decompression was done and Trans-foraminal lumbar inter-body fusion (TLIF) was done for all the patients. Post-operatively, the patients were started on medications for osteoporosis.

The patients who required PMMA augmentation during surgery were subjected to bone mineral density (BMD) examination. The body mass index was also calculated.

All patients were followed up between 24 to 36 months period. Serial x-rays were taken to study the radio-logical fusion and complications. Visual analogue scale (VAS) and Oswestry Low back disability questionnaire [8] were given and the clinical outcome measured.

Results

Of the 165 patients surgically treated for spondylolisthesis, 32 patients required PMMA augmented screws. Four patients were male and 28 were female. Of the types, 22 were isthmic or spondylolytic, eight were degenerative and one dysplastic type. One patient had post-laminectomy instability (Table 1).

Thirty one patients were aged between 43 and 68 years (Mean = 56.4). The patient with post laminectomy instability was a 38 year old female. Twelve patients had grade I listhesis, 18 patients had grade II listhesis and one patient had grade III slip. The grade III slip was of dysplastic type.

In the lysis group, 15 were at L5S1 level, eight were L45 level and one fixation was for L34 level. In the Degenerative type, three were at L5S1, four were L45 and one at L34 levels. The dysplastic listhesis was at L5S1 level and the post-laminectomy patient had L45 instability.

One patient with L5S1 listhesis had L4 lysis and had Stabilization done for two levels with six cemented screws. One patient with L34 and L5S1 isthmic listhesis had L3-S1 Stabilization and fusion done with eight cemented screws. The grade III dysplastic listhesis patient had hypo-plastic left L5 pedicle, so two cemented screws were inserted in L4, normal screws one in L5 right pedicle and bi-cortical S1 screws without cement augmentation were inserted.

Total of 115 PMMA augmented screws were used. Bi-cortical S1 screws without cement augmentation were inserted for eight patients with L5S1 isthmic listhesis, five with grade II and three with grade I. Complete reduction of listhesis was achieved in all patients except one with grade III dysplastic listhesis, whose listhesis was reduced to grade I.

The average Body Mass Index (BMI) was 25.425 (24.2 to 27.8) for males and 27.175 (21.4 to 32.8) for females. The average T-score in male group was -2.52 (-1.2 to -4.2) and in the female group it was -2.365 (-0.7 to -3.8). The average Bone Mineral Density (BMD) was 0.895 (0.711 to 1.101) for males and 0.897 (0.73 to 1.098) for females.

It was noted that only 14(43.7%) of the 32 patients had T-score $\leq$ 2.5. Eighteen (56.2%) of 32 patients were not fitting in the osteoporotic criteria and still required PMMA screws when reduction of listhesis was attempted.

No major complications except that 3 patients had inconsequential cement embolization during the procedure into the sinusoidal veins (Fig 1). All three were followed up for signs of pulmonary embolization and the patients fared well.

The mean follow up was 30 months. All the patients had good fusion and there was no screw pull-out or breakage. No incidence of cage subsidence was noted in any of the patients during the followup period. The visual analogue scale showed good reduction of pain from average of 8 pre-operatively to about 3 post-operatively (P value < 0.05). The Oswestry low back disability questionnaire scores [8] reduced from an average 63.5% stating crippled to an average 18.0% indicating minimal disability (P value < 0.05).

Table 1: Morphology of all listhesis included in the study

Type of Listhesis	Meyerding Grades		
	I	II	III
Degenerative	4	4	-
Isthmic	7	15	-
Dysplastic	-	-	1
Post-laminectomy instability	1	-	-

Discussion

The three column fixation provided by the pedicle screws has made it to be the best option available for reduction of vertebra in spondylolisthesis. Pedicle screws rely primarily on cancellous bone for purchase with the pedicle providing approximately 60% of the pull-out strength [9]. In 1990 Coe *et al.* have stated that Bone mineral density (BMD) is directly proportional to the maximum pull-out strength in pedicle screw fixation.

In osteoporosis, the pedicle screw hold is compromised due to the absence of a dense cancellous bone. Achieving reduction of one vertebra over another, by pulling them can result in screw pull-out and loosening, which we had experienced before, and this made us choose fenestrated screws for usage in listhesis reduction in osteoporotic spines. Revising a pulled out screw by injecting cement in the screw track, is a possible option but it has increased risk of cement leakage which can be avoided with fenestrated screws. Cadaveric studies [6, 10, 11] have proven that cement augmentation increased the pull-out strength of screws in osteoporotic spines.

Some research studies [7, 10] use screws with both proximal and distal holes in which the cement is spread equally throughout the body of vertebra and some into the pedicle which provides strong hold for the screws. However, the chances of cement leakage into the spinal canal or inter-vertebral foramen is high with proximal holes and also the cement flow monitoring will be difficult due to overlapping of pedicle and spinal canal [7]. At present the screws available in the market have only distal holes. In our study, we have used screws with 6 distal holes and one more hole at the tip.

Burval *et al.* [6] have used vertebroplasty to fill the cement after making a screw track, but the risk of neural injury due to the cement escaping into the spinal canal is high. Pull out strength of a PMMA filled fenestrated screw is lesser than vertebroplasty cement injected screws. Chang *et al.* [12] used fenestrated screws which has less pull out strength compared to screws inserted after vertebroplasty but is technically safer. The cement augmentation increases the pull out strength by 49-200% as stated by various cadaveric studies [4, 5].

Zhuang *et al.* [13] reported that the anchoring strength of bi-cortical sacral pedicle screw is comparable with that of the PMMA augmentation technique for BMD values >0.7g/cm. For values between 0.6-0.7g/cm, the PMMA-augmented technique is more beneficial for improving the fixation strength than bi-cortical fixation and for BMD values <0.6g/cm, early screw loosening may occur in both bi-cortical and PMMA-augmented screws. In our study we have used bi-cortical S1 screws without cement augmentation for eight patients among 19 patients with LS1 listhesis. Though all patients BMD values were >0.7g/cm, we preferred using PMMA augmented screws for S1 also.

The risk of cement extravasation and complications like

embolism and difficult revision have deferred many surgeons from using cement augmentation and attempting reduction of listhesis. PMMA screws are a boon in these situation.

We avoid complications by choosing an intact track for the screws. When inserting the probe, we avoid perforating the anterior cortex. We insert our screws so that it stays 5 to 10 mm shy of the anterior wall of the vertebra. Cement injection will be deferred if we find any breach in the medial or anterior wall of the probe track. In the initial step of injecting the cement, we make sure there is no leakage anteriorly. In case, if we notice any cement extravasation, we skip the cement injection in that screw temporarily, inject cement in the other screws and by the time the extravasated cement had blocked the defect, then we slowly inject the cement into the screw with leakage. This helped us prevent any disastrous cement extravasation. We hypothesize, that intactness of the screw track, is one important factor in avoiding complications.

The timing of cement injection is also an important factor, as too early injection will result the cement in being in liquid state which in turn leaks into the anterior venous plexus resulting in embolism (Fig 1), and delaying cement injection can make injection difficult and can result in less than desirable cement being injected. In our theatre, we have standardized the timing for injecting cement as 6 minutes from the start of mixing. However, this cannot be generalized and the timing of injection has to be formulated individually for each theatre conditions even for the same brand of cement. There were three cement extravasations in our study, which happened during the initial period of our study, during which we had not standardized our timing of injecting cement.

There were no spillage into spinal canal and we had not noticed any cage subsidence during our follow up period. There was good fusion noticed in all our patients. No incidence of cage subsidence was noted in any patients and no screw loosening or pull-out were noted during our follow up (Fig 2). All the studies available in the literature have evaluated the usage of cement augmented screws for degenerated spines but, there were no studies in literature which have studied the outcome of cemented augmented screws in listhesis reduction, where a considerable amount of pull-out force will be required testing the real capability of these augmentation. Our study has evaluated the clinical outcome of the patients in such a scenario.

Studies by Aydogan *et al.* [2], Chang MC *et al.* [12], Dai. F *et al.* [14], Khan MM *et al.* [15] using PMMA augmentation for Stabilization of degenerative disc diseases have taken a T-score of < -2.5 as threshold for choosing fenestrated screws for their patients. In our study, of the 32 patients who required PMMA screws during surgery only 14(43.7%) were osteoporotic. So when listhesis reduction is attempted even osteopenic or near normal bones may require cement augmentation. This reveals that there are many factors involved in choosing cement augmentation for screws and only T-score cannot help in preoperative planning for cement augmentation.

Legends

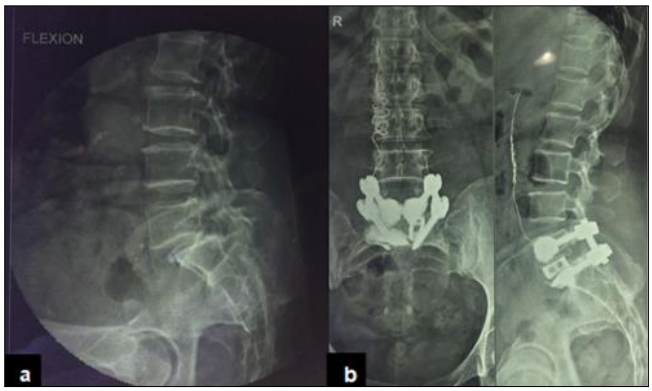

Fig 1: (a) Preoperative and (b) postoperative skiagrams of L5S1 isthmic listhesis grade 2 with cement extravasation into the anterior venous drainage. Her T-score was -2.6.

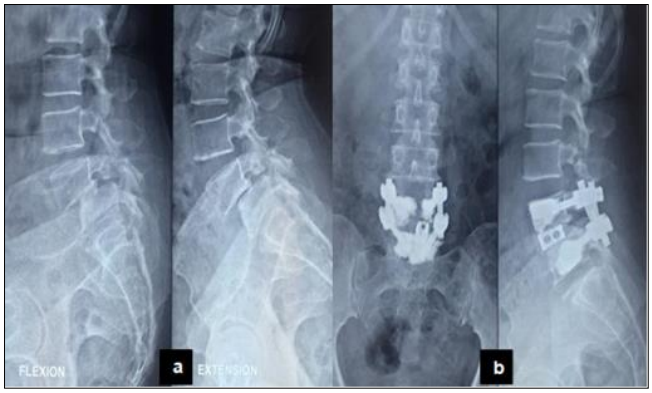

Fig 2: (a) Preoperative and (b) postoperative skiagrams of L45 isthmic listhesis grade 2. Her T-score was -1.8

Conclusion

The use of PMMA screws for reduction and Stabilization of listhesis in symptomatic patients is a safe effective method with good clinical outcome. Only T-score value cannot be relied upon, as, many factors are involved in choosing the right implant for the patient during reduction of listhesis.

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