

**Accuracy of Multilevel Registration in Image-guided  
Pedicle Screw Insertion for Adolescent Idiopathic Scoliosis**

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**Running Head:** Accuracy of Multilevel Registration

**MINI ABSTRACT**

Accuracy of multilevel registration for skip pedicle screw placement during image-guided, computer-assisted spine surgery, in adolescent idiopathic scoliosis was assessed. Mean surgical time: 310 min. Pedicle violation observed in only 4/265 screws (1.5%). Mean registration error after point merge:  $1.69 \pm 0.52$ ; after surface merge  $0.51 \pm 0.16$ . Multilevel registration may decrease operative time without compromising accuracy of pedicle screw placement.

**KEY POINTS**

- Multilevel registration employs more than 6 registration points for two, three or four consecutive vertebra to shorten the surgical time.
- Pedicle violation was observed in 1.5% of inserted screws.
- Multilevel registration may decrease operative time without compromising accuracy of pedicle screw placement afforded by this technique in the setting of adolescent idiopathic scoliosis.
- Mean correction rate of skip pedicle screw instrumentation was 66.2%.

## STRUCTURED ABSTRACT

**Study Design:** Retrospective clinical study.

**Objective:** To assess the accuracy of multilevel registration for skip pedicle screw placement during image-guided, computer-assisted spine surgery, in the setting of adolescent idiopathic scoliosis (AIS).

**Summary of background data:** Computerized frameless stereotactic image-guidance has been used recently to improve pedicle screw placement accurately and safety during spine surgery. Because of possible intervertebral motion and usual difference in patients' position between preoperative imaging and surgery, the imaging model and the surgically exposed spine may be significantly discordant. Consequently, current protocols suggested separate registration of each spinal level (single-level registration) before respective pedicle screw placement, a time-consuming process. Moreover, although multilevel registration for lumbar spine has been reported, that for thoracic spine has not.

**Methods:** Nineteen patients (1 male, and 18 females; mean age, 13.9 years) with AIS who underwent multilevel registration for skip pedicle screw placement were included. Variables including surgical time, blood loss, preoperative and 2-year post-operative Cobb angle, correction rate, and post-operative screw position by CT image were evaluated. Mean registration error (MRE) after point merge and again after surface merge were recorded for each consecutive vertebra of each case.

**Results:** Mean surgical time was 310 min. (range, 168-420 min.). Mean blood loss 1138 g (range, 300-2300 g). Cobb angle before operation and at 2 years post-operation was 62.4 (43-100) degrees and 21.6 (9-42) degrees, respectively. Mean correction rate 66.2% (39.7-84.5%). Total 265 screws were inserted with CT-based navigation system. Pedicle violation was observed in only 4 screws (1.5%). No neurovascular complication occurred. After point merge, average MRE of all cases was  $1.69 \pm 0.52$  mm, and after surface merge was  $0.51 \pm 0.16$  mm.

**Conclusions:** Multilevel registration may decrease operative time without compromising accuracy of pedicle screw placement afforded by this technique in the setting of AIS.

**Key Words:** computer-assisted surgery, pedicle screw, registration, multilevel, adolescent idiopathic scoliosis, spinal navigation

## INTRODUCTION

The application of a spinal navigation system to surgery represents a major technological advance. Computer-assisted implantation of pedicle screws has been primarily limited to the lumbar spine<sup>1-3</sup>, and recently the efficiency of screws for thoracic and cervical pedicles has been reported<sup>4-8</sup>. There are several methods for computer-assisted pedicle screw placement including frameless stereotaxy<sup>9</sup> and fluoroscopic navigation<sup>10</sup>, while the clinical application of 3-dimensional computer-assisted surgery has significantly reduced the misplacement rate of screws over the last decade<sup>1, 11-13</sup>. Clinical studies demonstrated an improved accuracy in pedicle screw insertion using a computed tomography (CT)-based navigation system, which eliminates exposure to fluoroscopic radiation<sup>14</sup>.

Pedicle screws have been recognized as a powerful option for deformity constructs. Segmental pedicle screw instrumentation in adolescent idiopathic scoliosis (AIS) enables a shorter fusion length and a better correction<sup>15,16</sup>. However, both neurovascular and visceral structures are at potential risk from screw misplacement owing to pedicle drift caused by significant deformity<sup>17-20</sup>. Liljenqvist *et al*<sup>21</sup> demonstrated that pedicle screw instrumentation on the concavity in the apical region is critical because of the small endosteal pedicle width, which precludes safe screw placement in that area.

During preoperative data acquisition scans, patients are most often supine; however, during surgery they are most often prone. Intervertebral motion resulting from this may result in a significant discordance between the imaging model of the spine and the surgically exposed spine<sup>22</sup>. Consequently, current manufacturer protocols recommend registering each spinal level (single-level registration) separately before pedicle screw placement at that level. This is intended to increase the accuracy of the registration process but may be associated with an increased operative time. Although the accuracy of multilevel registration for multilevel pedicle screw placement during image-guided, computer-assisted lumbar spine surgery has been reported<sup>23</sup>, that for thoracic spine has not. Use of multilevel registration can potentially decrease operative time. The purpose of this study was to assess the accuracy of multilevel registration during computer-assisted, image-guided spinal surgery, in the setting of AIS.

## MATERIALS AND METHODS

This study reviewed 19 consecutive patients with AIS who underwent correction with posterior skip pedicle screw instrumentation performed by a single spinal surgeon (J.T.), with minimum 2 -years follow-up. The mean age at the time of surgery was 13.9 (11 to 17) years, and the male-to-female ratio was 1 to 18. Nine curves were classified as type 1, five as type 2, and five as type 3, according to the system Lenke, *et al*<sup>24</sup>. The mean preoperative magnitude of the major curve measured by the Cobb angle was 62.4±13.9 (mean ± standard deviation) (range, 43-100) degrees. The mean preoperative kyphotic angle from T5 to T12 was 6.6±10.2 (range, -14-35) degrees. Preoperative apical vertebral rotation of main curve using CT<sup>25, 26</sup> was 19.8±8.1 (range, 7-36) degrees. A total of 265 pedicle screws were placed using the multilevel registration. Intraoperative neuromonitoring using motor evoked potentials was performed in all patients. Preoperative, 1-week postoperative and 2-year postoperative radiographic parameters and clinical data was examined. Mean registration error (MRE) after point merge and again after surface merge were recorded for each consecutive vertebra of each case. Patient satisfaction at

2-year postoperatively was investigated through question 21 of SRS-22r Patients Questionnaire, “Are you satisfied with the results of your back management?”

### Navigation and surgical procedure

A frameless stereotactic image-guidance system (Stealth Station TREON™; Medtronic, Sofamor Danek, Memphis, TN, USA) was used for planning the pedicle screw diameter and length as well as correct screw placement and fixation of the thoracic and lumbar spine. This group’s procedure employs more than 6 registration points for two, three or four consecutive vertebra, to shorten the surgical time (multilevel registration) (Fig. 1). More accurate positioning is possible through use of the top of the spinous process and bilateral transverse process tip as points. Pedicle screw insertion to the upper and lower end was performed bilaterally, and insertion to the other points was basically performed with zigzag fashion. Pedicles with outer diameter of 4.5 mm or less were skipped by evaluation during navigation plan. If an upper end was skipped, a hook was used, and if three or more pedicle at other levels were skipped, sublaminar wiring with ultra-pliable polyethylene cable (Nespron cable system; Alfresa Pharma, Co. Osaka, Japan) was performed (Fig. 2, 3).

### Postoperative assessment of screw placement

Screw position was evaluated one week after operation using an axial CT scan at each screw axis. Following the scheme of Rao *et al*<sup>27</sup>, the evaluation of screw malposition was classified as grade 0 (no apparent violation of the pedicle), grade 1 (<2 mm perforation of the pedicle, with 1 screw thread out of the pedicle), grade 2 (between 2 and 4 mm of perforation of the pedicle, with half of the diameter of the screw outside of the pedicle), grade 3 (>4 mm or complete perforation of the pedicle), with grades 2 and 3 representing “violation.” On the basis of this grading system, screw misplacement rates were determined. The medial or lateral perforation of the pedicle wall was also evaluated.

## RESULTS

The time required to insert all screws using multilevel registration was  $79.2 \pm 17.5$  (range, 55-118) minutes. Total surgical time was  $310.1 \pm 79.1$  (range, 168-420) minutes. Total blood loss was  $1137.9 \pm 51.3$  (range, 300-2300) mL. The average number of instrumented spinal segments was  $11.2 \pm 1.7$  (range, 8-14) vertebra. The mean 1-week and 2-year postoperative magnitude of the major curve measured by the Cobb angle was  $20.1 \pm 9.7$  (range, 8-40) degrees and  $21.6 \pm 10.5$  (range, 9-42) degrees, respectively. Correction rate was  $66.8 \pm 10.2$  (range, 51.4-84.9) % and  $66.2 \pm 11.9$  (range, 39.7-84.5) %, respectively. The mean 1-week and 2-year postoperative kyphotic angle from T5 to T12 was  $12.9 \pm 5.4$  (range, 2-22) degrees and  $13.5 \pm 7.1$  (range, 4-30) degrees, respectively. The mean 1-week and 2-year postoperative apical vertebral rotation of main curve was  $16.5 \pm 7.4$  (range, 3-36) degrees and  $17.6 \pm 7.5$  (range, 5-36) degrees, respectively. After point merge, the average MRE of all cases was  $1.69 \pm 0.52$  (range, 0.7-2.8) mm. The mean MRE of all cases after surface merge was  $0.51 \pm 0.16$  (range, 0.3-0.9) mm. Of the 265 pedicle screws, 244 (92.1%) were categorized as grade 0, 17 (6.4%) were grade 1, 3 (1.1%) were grade 2, and 1 (0.4%) was grade 3 (Fig. 4). Only one grade 3 screw was seen, in a right T5 pedicle. Pedicle violation was observed in 1.5% of inserted screws. Pedicle violation in the lumbar, thoracolumbar, and thoracic spine was observed in 1.8% (1/56), 0.9% (1/115), and 1.4%

(3/209) of inserted screws, respectively. No intraoperative complications such as neurovascular injury or adverse clinical consequences occurred as a result of pedicle perforation. No wound infection was observed. Patient satisfaction at 2-year postoperatively by SRS-22r Patients Questionnaire resulted in 10 very satisfied cases and 9 satisfied cases.

## DISCUSSION

Vertebrae rotated toward the convex side that increase the angle of convergence of the pedicles and narrow pedicle width make it difficult to insert screws safely in the scoliotic rotated spine. There is a paucity of reports in the literature on the accuracy of pedicle screw placement in scoliosis surgery. In a report by Suk *et al*<sup>28</sup>, the perforation rate of pedicle screw inserted by free hand in AIS posterior fusion was 1.5%; however, only 10% of cases were evaluated by CT, and thus this reported rate is not highly reliable. In report by Kim and Lenke *et al*<sup>29</sup>, the perforation rate by free hand technique was 7.9%. The reported perforation rate by Halm *et al*<sup>16</sup> was as high as 18.3% and the rate by Lilijenqvist *et al*<sup>18</sup> who employed fluoroscopy, was also as high as 25%. In contrast, the perforation rates of reports of surgeries that employed navigation system<sup>30-32</sup> were between 1.8 and 11.4%. In the present report, the rate was as low as 1.5%. The perforation rate of our multilevel registration was comparable to that reported by Kotani *et al*<sup>31</sup>, where in the perforation rate was 1.8% in single-level registration. In the evaluation of screw placement, more than 2 mm of penetration was defined as pedicle violation, for the reason that up to a 2 mm breach was considered a well-positioned screw since there are slight scatter effects seen on CT scans, even for titanium implants<sup>33</sup>.

Use of three-dimensional, image-guided technology requires that anatomic landmarks revealed during routine surgical exposure be matched to corresponding anatomic landmarks (fiducials) selected on a three-dimensional model of the spine created by a computer system using pre-acquired images, a process known as point merge. After the point merge process, the workstation reports the discordance between the exposed anatomic landmarks and the three-dimensional computer model as an MRE. The MRE is not the actual error that will be observed clinically but a projected error estimated by the computer. The surgeon then identifies multiple bony points on the exposed spine, allowing the workstation to create a three-dimensional map of the exposed spine, a process known as surface merge. Utilization of a greater number of bony points for anatomic correlation is intended to further improve accuracy of the navigation systems (ie, a more accurate three-dimensional volumetric representation of the vertebral levels). The computer workstation again reports the discordance between the demarcated spinal anatomy and the three-dimensional computer model as an MRE. The complete process, involving point merge and surface merge, is known as registration. The burden of registration resulted in prolonged surgical time, thus the value of the procedure from the standpoint of invasiveness was unclear. Papadopoulos *et al*<sup>23</sup> reported that the mean MRE after point merge by single-time multilevel registration in degenerative disorders of the lumbar spine was 1.78 mm and the average MRE after the surface merge was 0.70 mm. In the AIS patients in our report, mean MRE by multilevel registration was as low as 1.69 mm and 0.51 mm, and therefore these results show feasibility of this technique for the AIS patient.

This protocol with two sets of CT imaging was accepted by the study team to ensure the safety of surgery. Entrance surface dose of preoperative CT (Light Speed VCT; GE Yokokawa Medical Inc. Hino, Tokyo, JAPAN) for navigation is about 10 mGy in the region between T1

and L5. Intraoperative fluoroscopy for one minute results in an entrance surface dose of about 20 mGy, which is twice that of preoperative CT. Postoperative CT (SIEMENS SOMATOM Sensation 16; SIEMENS Asahi Meditec Inc. Shinagawa Tokyo JAPAN) had an entrance surface dose of about 23 mGy in the region between T1 and L5. Though CT imaging for two sets results in a higher entrance surface dose, the dose is acceptable if CT imaging is limited to that for navigation.

The reported surgical time was as follows: the mean surgical time of segmental pedicle screw fixation by free hand technique was reported to be 186 minutes and 341 minutes by Suk *et al*<sup>17</sup> and Kim *et al*<sup>34</sup>, respectively. The mean surgical time with navigation system was reported to be 443 minutes by Sakai *et al*<sup>32</sup>. The reported intraoperative bleeding was as follows: the mean intraoperative bleeding with conventional methods for screw insertion was reported to be from 640 mL to 1241 mL<sup>17, 34-37</sup>. The mean intraoperative bleeding with a navigation system was reported to be 1013 mL and 1100 mL by Sakai *et al*<sup>32</sup> and Rajasekaran *et al*<sup>30</sup>. In our study, the mean surgical time and mean intraoperative bleeding in multilevel registration using the navigation system was 310 minutes and 1138 mL, respectively, and it was sufficiently less invasive.

This study had limitations in that it was retrospective and the number of patients was small. Additionally, we did not provide a comparative series of either the patients operated without a navigational device, or operated with registration at every level. However, most patients showed satisfactory results using the multilevel registration method of the CT-based navigation system. This technique may decrease operative time without compromising accuracy of pedicle screw placement.

### CONCLUSION

Multilevel registration may decrease operative time without compromising accuracy of pedicle screw placement afforded by this technique in the setting of adolescent idiopathic scoliosis.

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**FIGURE LEGENDS**

**Figure 1:** Three consecutive vertebrae between T3 and T5 were registered together. Nine points were employed and mean registration error after point merge was as low as 1.1 mm.

**Figure 2:** A 14-years-old girl received computer-assisted skip pedicle screw instrumentation using multilevel registration. The thoracic curve was corrected from 53 degrees to 10 degrees by Cobb angle. The correction rate was 81%.

**Figure 3:** All pedicle screws showed grade 0.

**Figure 4:** Of the 265 pedicle screws, 244 (92.1%) were categorized as grade 0, 17 (6.4%) were grade 1, 3 (1.1%) were grade 2, and 1 (0.4%) was grade 3. Only one grade 3 screw was seen, in a right T5 pedicle.

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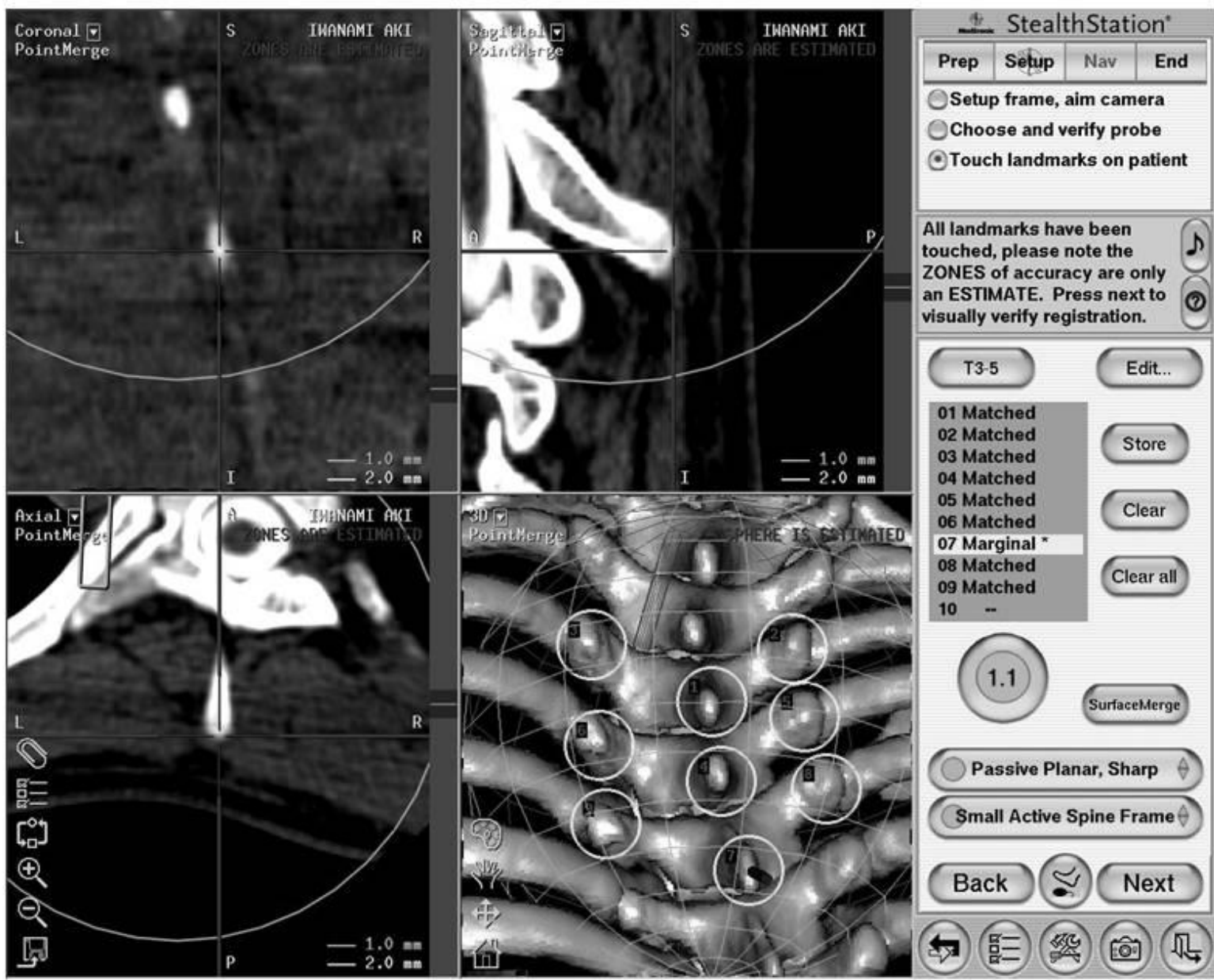


Figure 1

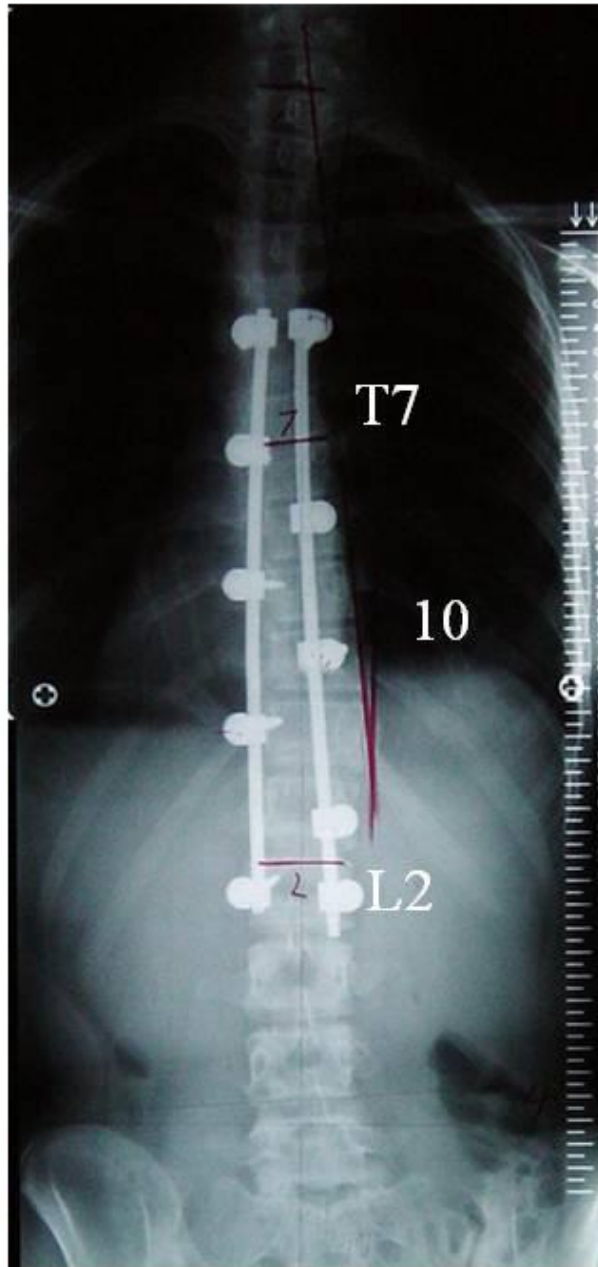
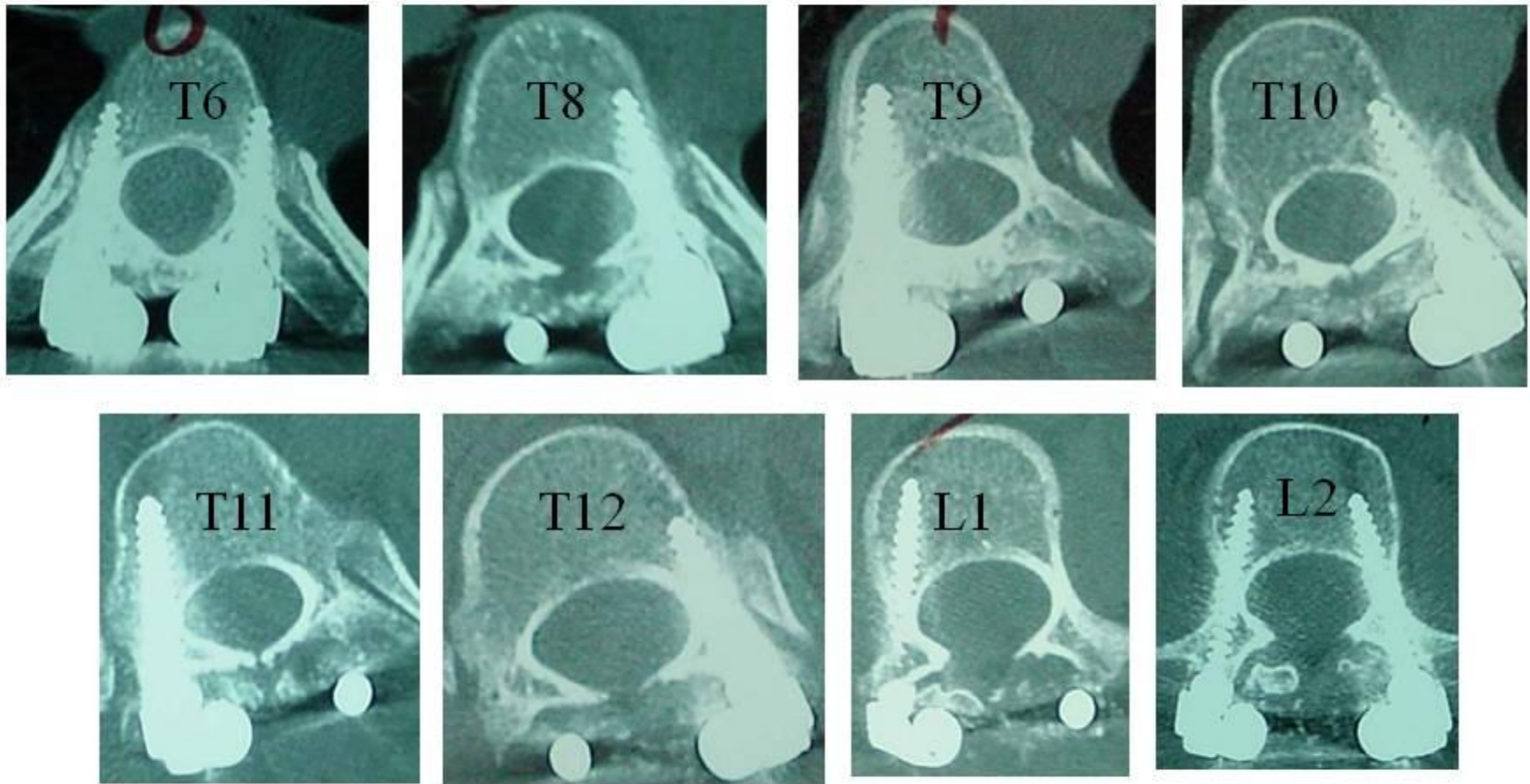
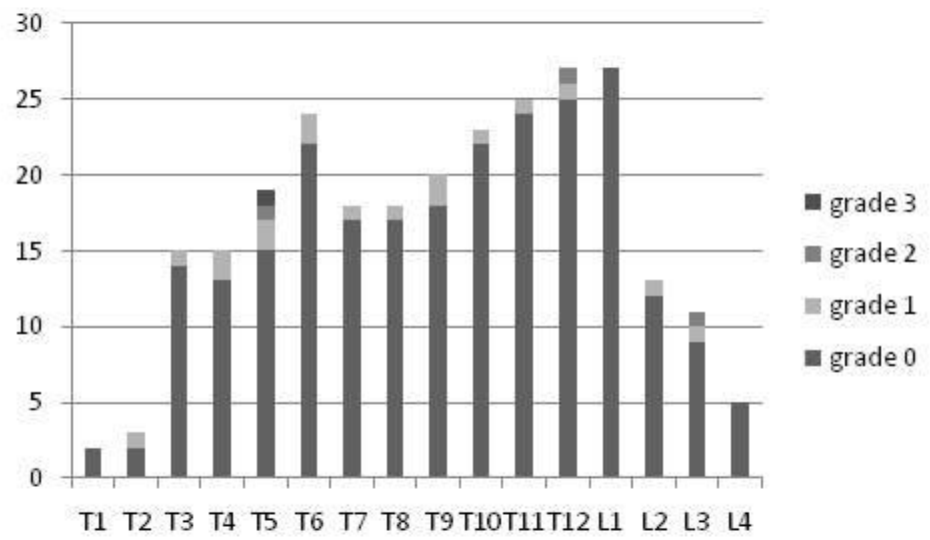


Figure 2



**Figure 3**



**Figure 4**