

# Pedicle screw placement accuracy in thoracic and lumbar spinal surgery with a patient-matched targeting guide: A cadaveric study

[ based on the homonymous paper from Prof.Lamartina et al. Anticipated publication in December 2015 in the European Spine Journal Supplement ]



## Introduction

Pedicle screws placement in spine surgery is a demanding procedure where complications are mainly related to the inaccurate screw positioning; to overcome these limitations in free-hand procedures, several guided techniques have been developed.

**MySpine technology** is a **patient-matched thoracic and lumbar posterior pedicle targeting guide**, made according to a CT-based **pre-operative planning** (Fig.1), capable to guide the pedicle screws placement as per the planned model.

**Goal of the study:** To examine the **accuracy** of pedicle screw placement using this system, a **cadaveric study** was conducted in which 3D preoperative plans were compared with 3D reconstructions of the final screw positions obtained during spinal surgery [1].

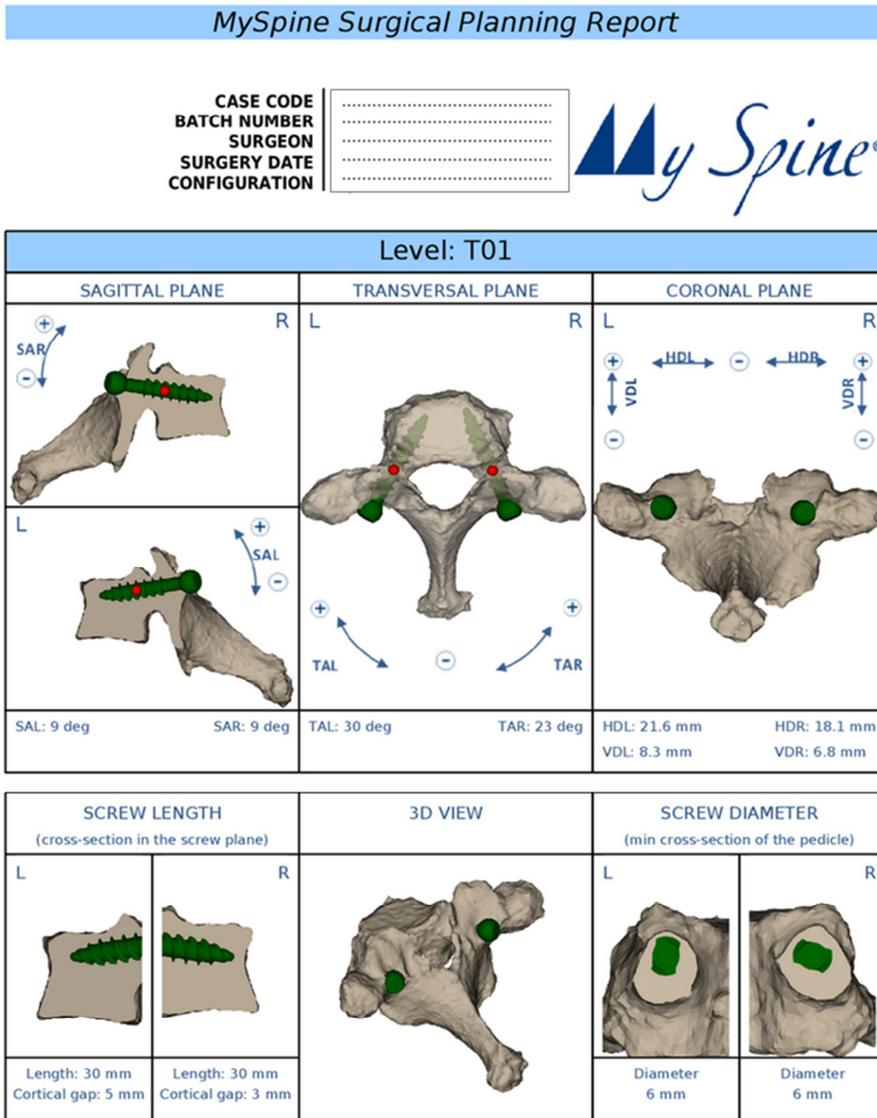


Fig 1. The MySpine Surgical preoperative planning allow surgeons to adjust the pedicle screws entry points, trajectory and their size i.e.length and diameter

## Methods

A three-dimensional (3D) preoperative plan was constructed from spinal computed tomography scans of three cadaveric specimens from adults without any spine pathology. Individualized guides were developed for the placement of Medacta M.U.S.T. pedicle screws (Fig.2). In the first experiment, an experienced surgeon used the MySpine system to place pedicle screws in a cadaveric spinal specimen; in the second one, two surgeons, new to the technique, performed screws placements on two cadaveric samples. Following to the screws placement, the 3D positioning of the screws was compared to the preoperative plan against a series of pre-defined criteria.

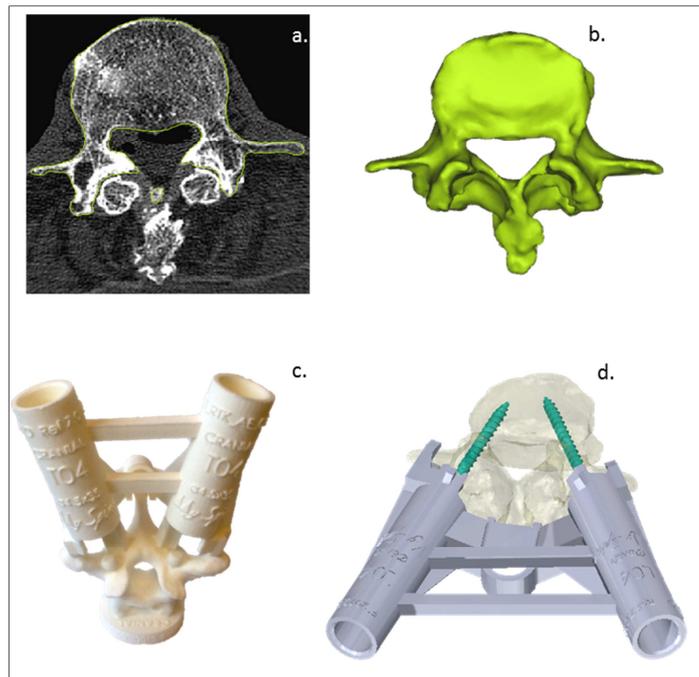


Fig 2. The MySpine chain: segmentation from the initial CT scan(a), 3D reconstruction of the vertebra(b), generation of pedicle screw placement guide (c), pedicle screws guided implantation.

Pedicle screws position accuracy was graded as: no perforation; Grade A, 0–2 mm; Grade B, 2–4 mm; and Grade C, >4mm pedicle perforation [2] (according to the Gertzbein scale). The **acceptance criteria** were established as follows: the mean deviation for the **screw depths was set at <2.5 mm**, while the mean deviation between the planned and actual screw position on the **coronal plane** at the midpoint of the pedicle had to be non-inferior to **0.87 mm**. This last criterion was set according to the results achieved by Sugawara et al. [3], wherein 58 pedicle screws were implanted into 10 patients with thoracic or cervico-thoracic pathologies using a screw guide template system.

## Results

Of a total of 54 inserted screws, 8 were excluded from the analysis due the pedicle being too small to avoid perforation (having therefore resulted with a pre-planned perforation).

42 pedicle screws were fully inside the pedicle, only 4 pedicle screws were graded A(0-2mm) and there were no cases of Grade B (2–4 mm) or C (>4 mm) pedicle perforation.

100% pedicle screws were placed within the 2mm breach zone. These results are detailed in Table 1.

| Within the pedicle | Grade A (0-2mm) | Grade B (2-4mm) | Grade C (>4mm) |
|--------------------|-----------------|-----------------|----------------|
| 91.3%              | 8.7%            | 0.0%            | 0.0%           |

Table 1. Screw position accuracy.

1. Lamartina C et al. Pedicle screw placement accuracy in thoracic and lumbar spinal surgery with a patient-matched targeting guide: A cadaveric study. Accepted in ESJ Dec.2015 Supplement.
2. Gertzbein SD, Robbins SE (1990) Accuracy of pedicular screw placement in vivo. Spine (Phila Pa 1976) 15:11-14
3. Sugawara T. et al. Multistep pedicle screw insertion procedure with patient-specific lamina fit-and-lock templates for the thoracic spine: clinical article. J Neurosurg Spine 19:185-190. doi: 10.3171/2013.4.SPINE121059

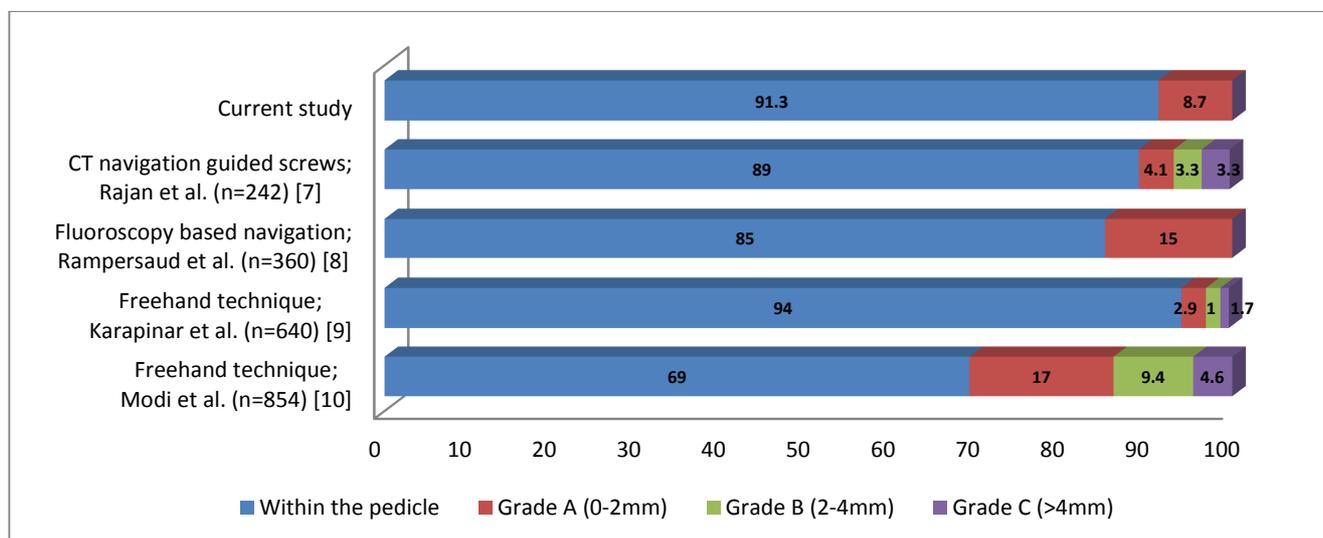
The mean deviation between the planned and actual screw position are shown in Table 2.

| Parameter                                 | Deviation per vertebra | Acceptance criteria | Delta (vs acceptance criteria) |
|---|------------------------|---------------------|--------------------------------|
| Deviation at pedicle midpoint (mm)        | 0.70±0.69              | 0.87                | -20%                           |
| Horizontal deviation (mm)                 | 0.60±0.63              | -                   | -                              |
| Vertical deviation (mm)                   | 0.77±0.65              | -                   | -                              |
| Angular deviation in sagittal plane (°)   | 1.74±1.61              | -                   | -                              |
| Angular deviation in transverse plane (°) | 1.32±1.31              | -                   | -                              |
| Deviation in screw depth (mm)             | 1.55±1.19              | 2.5                 | -40%                           |

Table 2. Mean deviation between planned versus actual screw positions. Values presented as mean ± standard deviation.

## Discussion and conclusion

The accuracy of screws placement was within the predefined criteria and mean deviations between planned versus actual screws position: these outcomes support the ability of MySpine guides to **reproduce the preoperative planning** and pursue an optimal pedicle screws positioning. The biological significance of screw malposition has been demonstrated in several studies, with medial and lateral pedicle cortex perforation associated with reduced pull-out strength [4, 5], as well as neurological, visceral and vascular complications [6, 7]. The results observed in this study suggest that the **MySpine** system have **comparable performance** with that of **navigation-based techniques** and **greater accuracy** than traditional **freehand approaches** (Graph 1).



Graph 1. MySpine accuracy: comparison with literature

- Weinstein JN et al. Anatomic and technical considerations of pedicle screw fixation. Clin Orthop Relat Res:34-46 (1992)
- Brasiliense LB et al. Quantitative analysis of misplaced pedicle screws in the thoracic spine: how much pullout strength is lost?. J Neurosurg Spine 12:503-508. doi: 10.3171/2009.11.SPINE0940
- Kim YJ, Lenke LG. Thoracic pedicle screw placement: free-hand technique. Neurol India 53:512-519 (2005)
- Lonstein JE et al. Complications associated with pedicle screws. J Bone Joint Surg Am 81:1519-1528 (1999)

## Quick Paper Analysis

1. To overcome the high levels of complications related to free-hand pedicle screw malpositioning, several guided techniques have been developed. Amongst these, Medacta has developed the MySpine Pedicle Screw guided technology.
2. MySpine technology is a patient-matched pedicle screw targeting guide based on individualised guide and made according to a CT-based pre-operative planning, capable to accurately guide the pedicle screw placement as per the planned model.
3. Of a total of 54 inserted screws on 27 cadaveric vertebrae, 91.3% screws were fully inside the pedicle while 8.7% were Grade A (0-2mm) perforation. There were no cases of Grade B (2–4 mm) or C (>4 mm) pedicle perforation. **100% screws were positioned within the 2mm breach zone.**
4. The observed results suggest the MySpine system have comparable performance with that of navigation-based techniques and **greater accuracy than traditional freehand approaches.**
5. The actually placed screws versus the pre-planned positions show a deviation of 0.70mm evaluated at the cortical midpoint, 1.3° in the transversal plane and 1.7° in the sagittal plane, far within the pre-set acceptance criteria.
6. The results of this study support the ability of MySpine guides to reproduce the preoperative planning and **pursue an optimal pedicle screw positioning.**