

Personalized guiding templates for pedicular screw placement

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¹ University Medical Center Ljubljana, Department of Traumatology, Zaloška 7, 1000 Ljubljana ²Ekliptik d.o.o, Teslova ulica 30, 1000 Ljubljana Pedicle screw fixation is a standard procedure of spinal surgery! Accurate peducular screw placement is essential to avoid injury to the adjacent structures - the vessels, nerves, and viscera.

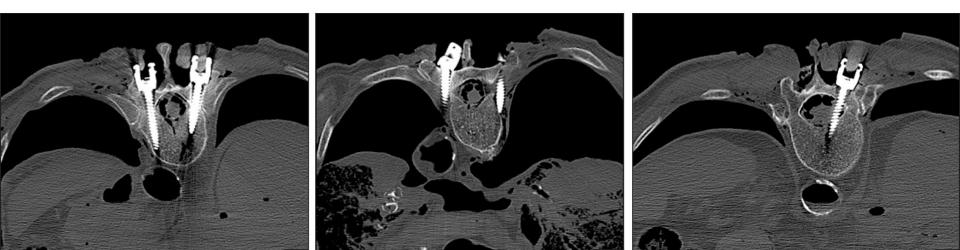


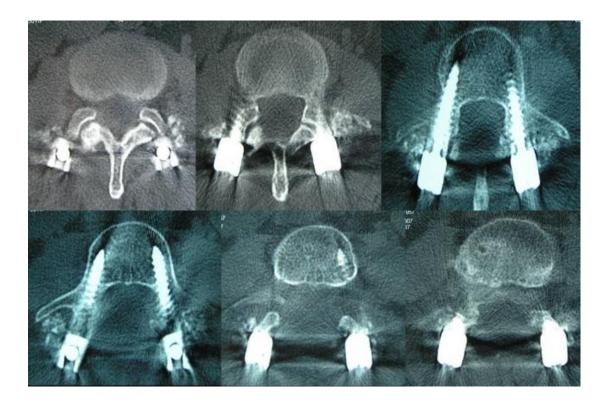
Pedicle screw placement is complex and technically demanding procedure with a steep learning curve. There is limited visibility of spinal anatomical landmarks during surgery; so, it is important to gain a conceptualization of anatomy of spinal structures that are hidden from direct view.



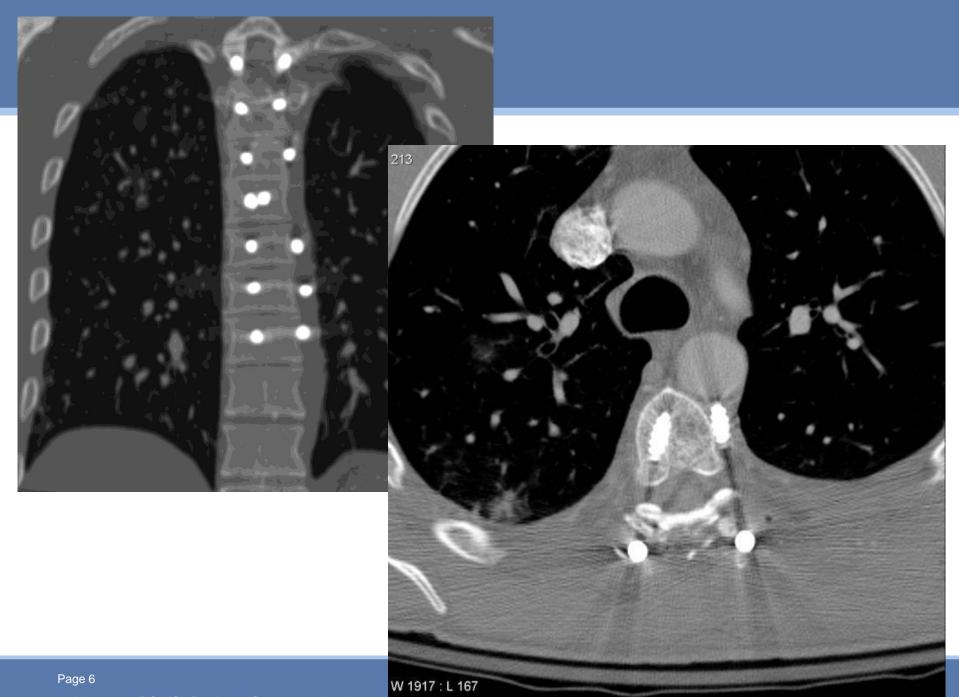
The accuracy with which screws are inserted in the pedicle has a direct effect on the surgical outcome.

Manbachi A, Cobbold RS, Ginsberg HJ. Guided pedicle screw insertion: techniques and training. Spine J. 2013 Apr 25









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Multiple methodes for improving the accuracy of pedicle screw placement were developed.

The first attempt to do this with the aid of a computer was the work published in 1995 by Nolte et al.



Some examples of currently available guided screw insertion include, but are not limited to:

- intraoperative fluoroscopy,
- both fluoroscopic and CT-guided computer-assisted surgery (CAS),
- special pedicle guiding probes,
- electrophysiological monitoring techniques.



Freehand technique

- Kotil and Bilge reported correct pedicle screw insertion rate of 94.4% without using any fluoroscopic guidance,
- but Shin et al. reported 21% of misplaced screws with this technique.





- currently a gold standard
- Fu et al. reported a correct pedicle screw insertion rate as high as 93.2% using fluoroscopy



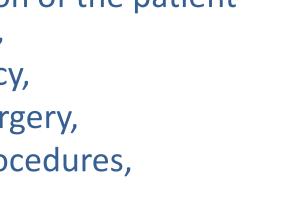
- Using this technique, Ito et al. reported a success rate of 97.2% for screw insertion and that none of the cortical bone perforations (2.8%) were clinically problematic.
- at the cost of even greater doses of ionizing radiation than standard fluoroscopy

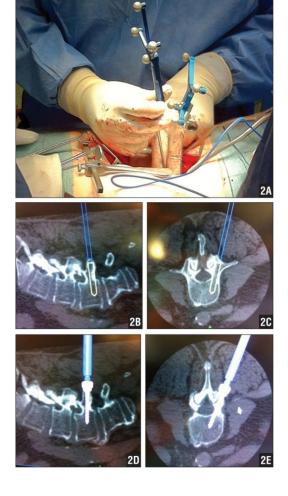


Computer assisted surgery (3D fluoroscopic or CTguieded)

- easier visualization of the patientspecific anatomy,
- over 95% accuracy,
- less revisional surgery,
- lengthy setup procedures,
- expensive.

- Shin MH, Hur JW, Ryu KS, Park CK. Prospective Comparison Study Between the Fluoroscopy Guided and Navigation Coupled with O-arm[®] Guided Pedicle Screw Placement in the Thoracic and Lumbosacral Spines. J Spinal Disord Tech. 2013 Apr 3
- Luther N, Iorgulescu JB, Geannette C, Gebhard H, Saleh T, Tsiouris AJ, Härtl R. Comparison of Navigated Versus Non-Navigated Pedicle Screw Placement in 260 Patients and 1434 Screws: Screw Accuracy, Screw Size, and the Complexity of Surgery. J Spinal Disord Tech. 2013 Mar 26



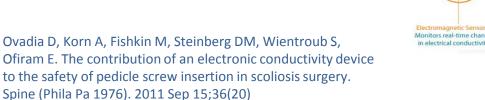




Ling JM, Dinesh SK, Pang BC, Chen MW, Lim HL, Louange DT, Yu CS, Wang CM. Routine spinal navigation for thoracolumbar pedicle screw insertion using the O-arm three-dimensional imaging system improves placement accuracy. J Clin Neurosci. 2013 Sep 30

Measuring the electrical conductivity (impedance) of tissues

- average screw placement accuracy of 97%
- limits radiation exposure by 25-30%
- decreases by 15% the time for pedicle screw placement







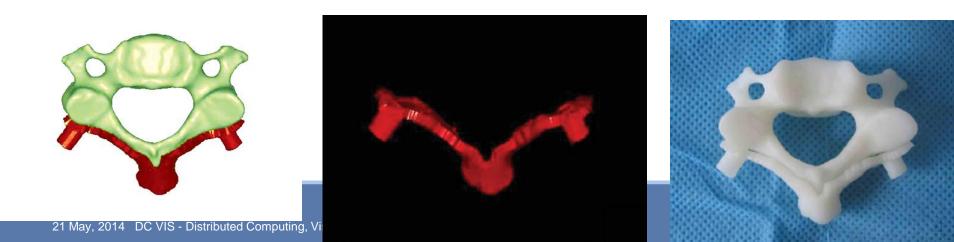
Other techniques – spinal monitoring

- Electromyography (EMG),
- somatosensory-evoked potentials (SSEPs).

- require the employment of extra trained personnel
- the cost associated with that is high
- often indicate the presence of a problem such as a nerve or spinal cord injury after it has occurred and (would not help reduce the risk of neurological injury)



In the last 5-6 years the idea of personalised guiding templates for pedicular screw placement has evolved.



These templates are designed (using preoperative CT) to fit in a unique position on the individual's bone, and they have carefully designed holes to guide the drill through a preplanned trajectory.

A rapid prototyping device is used as a threedimensional printer to produce the shape of reference areas on bone surfaces.



Known problems with this technique:

- a relatively lengthy manufacturing process,
- possible manufacturing faults
- incorrect positioning during the operation
- multilevel template not accurate enough
- can not be used for MIS

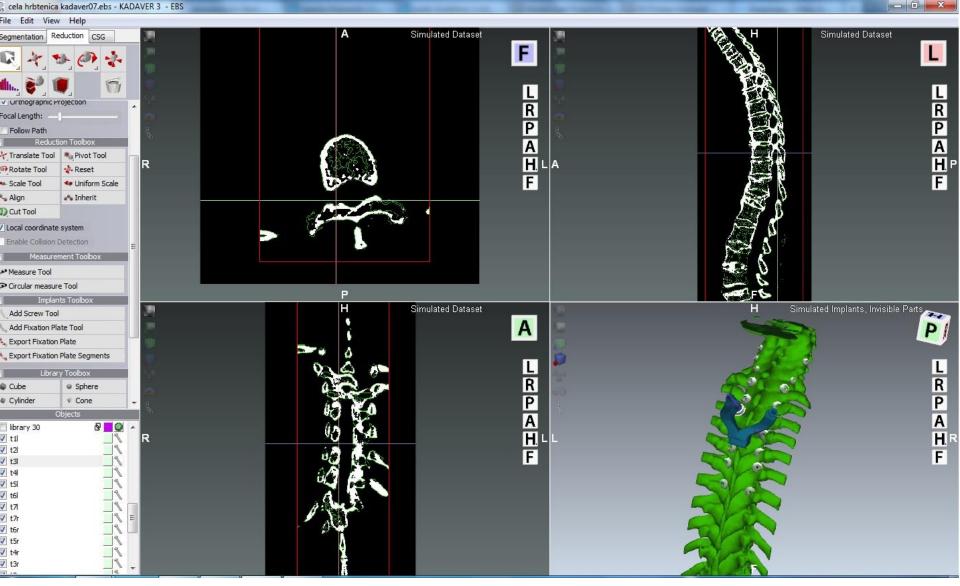
- Lu S, Xu YQ, Zhang YZ, Li YB, Shi JH, Chen GP, Chen YB. Rapid prototyping drill guide template for lumbar pedicle screw placement. Chin J Traumatol. 2009 Jun;12(3):177-80
- Lu S, Xu YQ, Zhang YZ, Li YB, Xie L, Shi JH, Guo H, Chen GP, Chen YB. A novel computer-assisted drill guide template for lumbar pedicle screw placement: a cadaveric and clinical study. Int J Med Robot. 2009 Jun;5(2):184-91
- Merc M, Drstvensek I, Vogrin M, Brajlih T, Recnik G. A multi-level rapid prototyping drill guide template reduces the perforation risk of pedicle screw placement in the lumbar and sacral spine. Arch Orthop Trauma Surg. 2013 Jul;133(7):893-9
- Sugawara T, Higashiyama N, Kaneyama S, Takabatake M, Watanabe N, Uchida F, Sumi M, Mizoi K. Multistep pedicle screw insertion procedure with patient-specific lamina fit-and-lock templates for the thoracic spine: clinical article. J Neurosurg Spine. 2013 Aug;19(2):185-90



One cadaveric spine specimen was obtained for the purpose of this study.

We did a computer tomography (CT) scan of the spine specimen to acquire 3D reconstruction data.

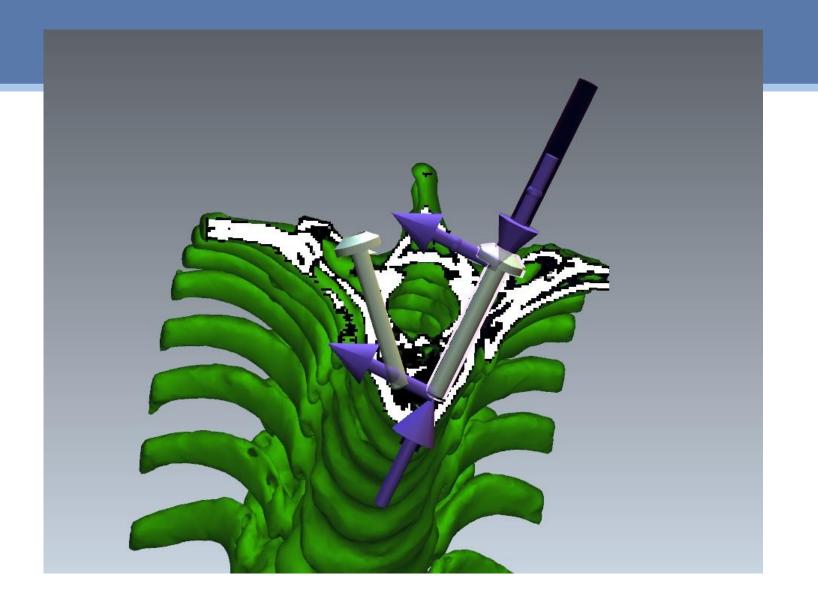




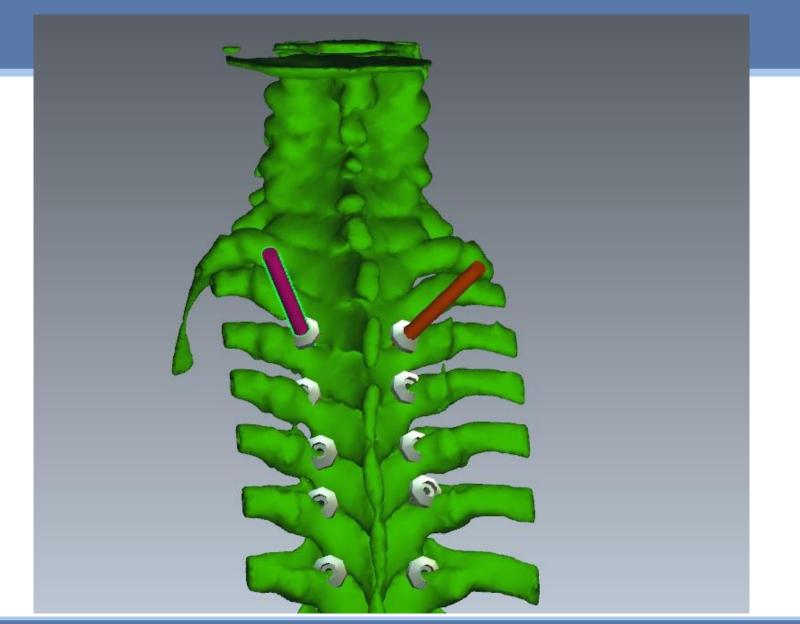
Specialized computer software(EBS[™], Ekliptik, Slovenia) was then used to design laminar drill templates according to pedicle trajectories.



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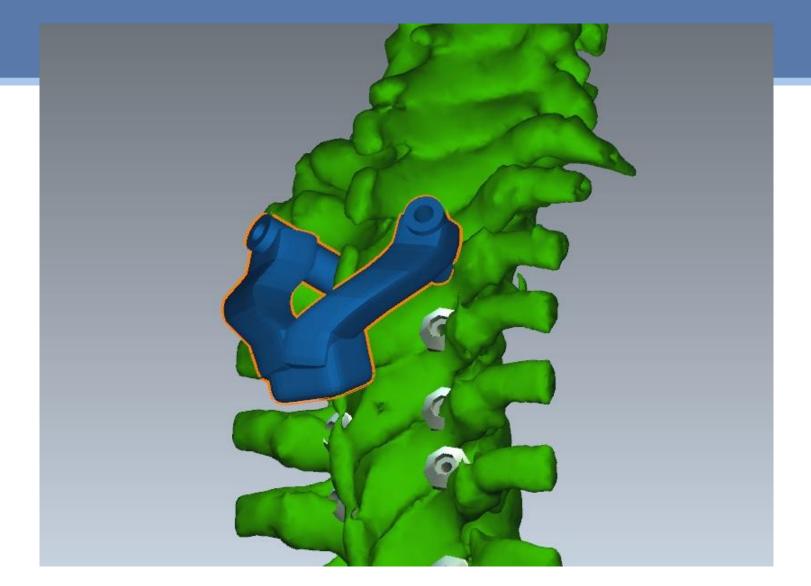




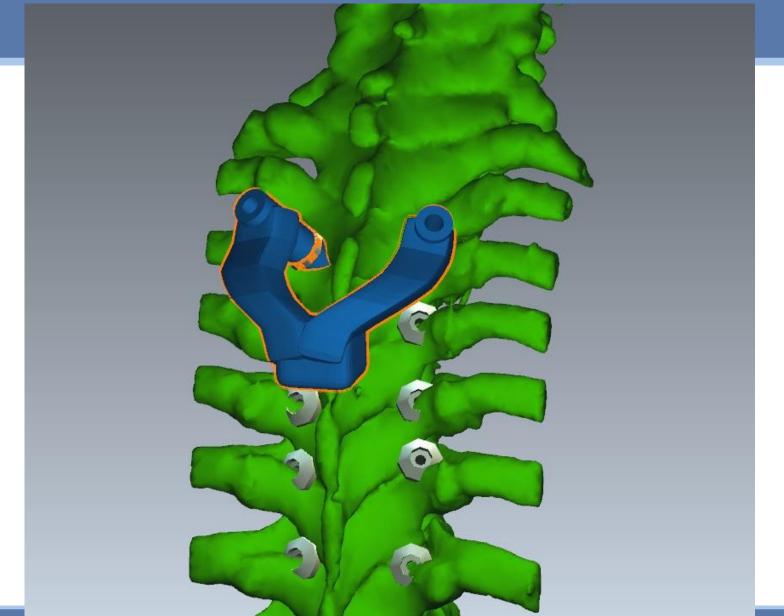




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Templates were specially designed to fit and lock on the lamina during the procedure.



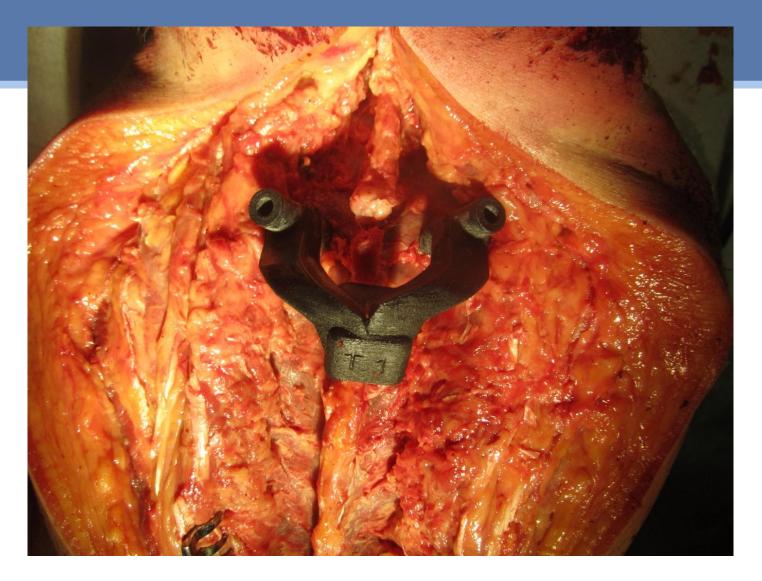


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Personalised guiding templates were then printed using 100 micron 3D thermoplastic printer.

Cadaveric spine specimen was prepared for the procedure.

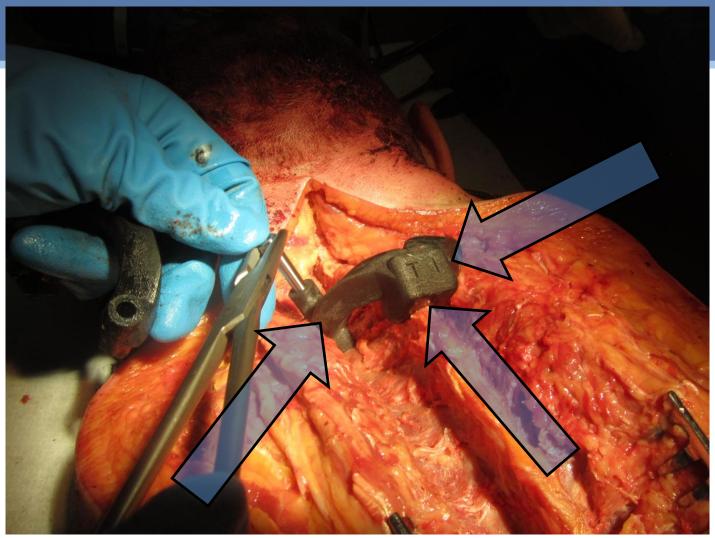




3D drill guide templates were placed on the vertebras anchoring at three sites



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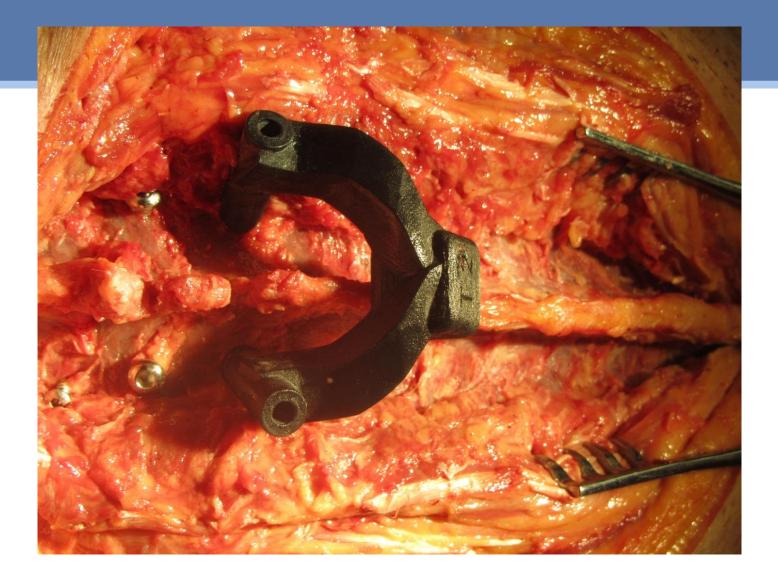


- on the lamina at the base of the superior articular process on both sides
- at the tip of the spinous process

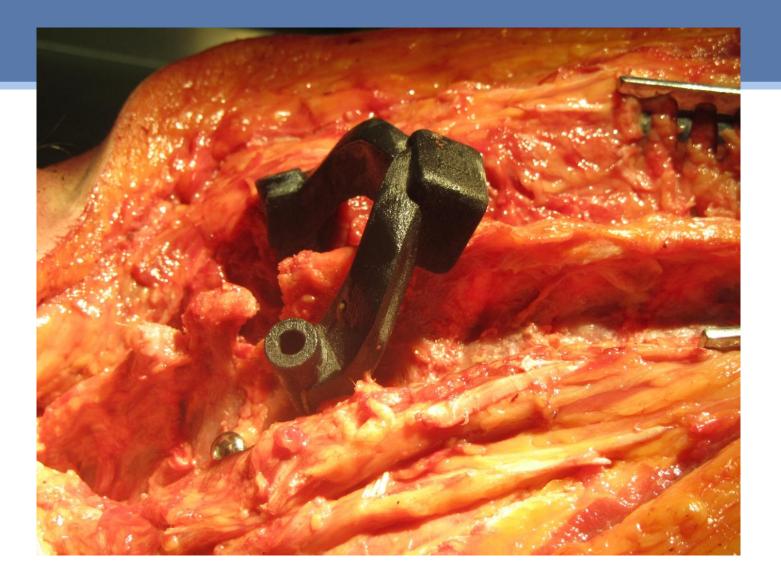
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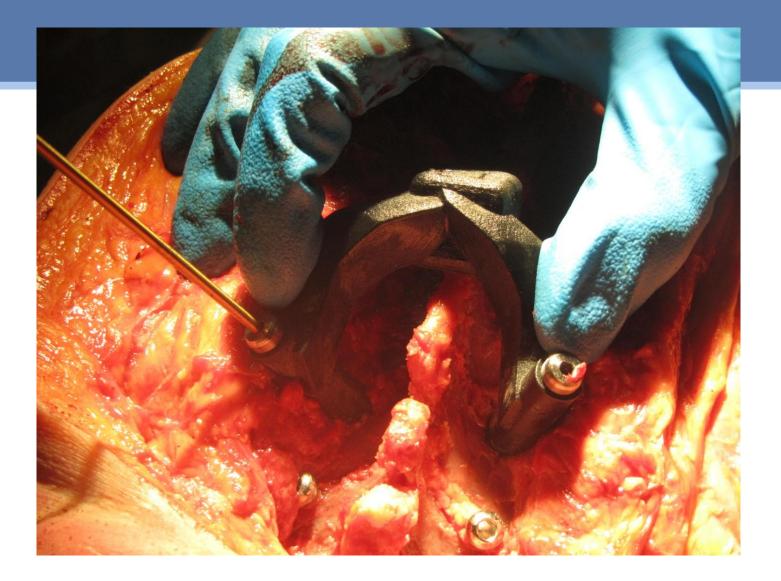








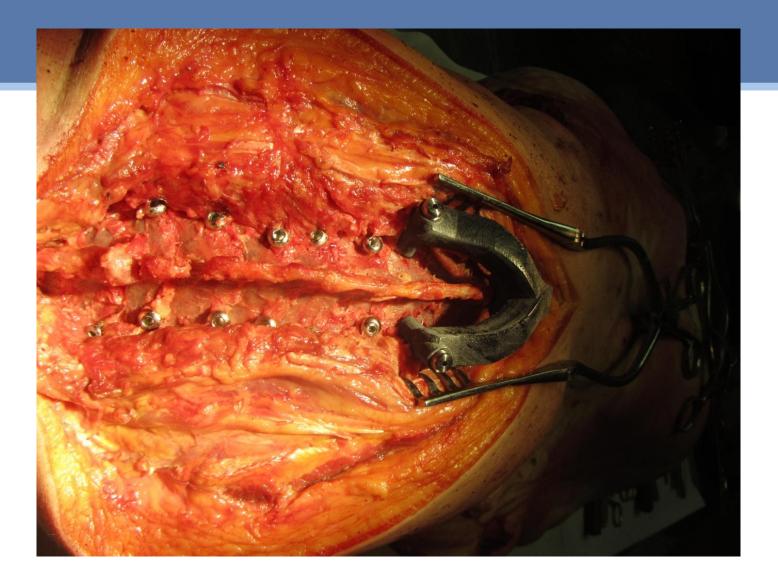
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Holes were drilled, probed and 3,5 mm screws were inserted.



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Screws were inserted from T1 do T7 (7 pairs) using custom template for each vertebrae.

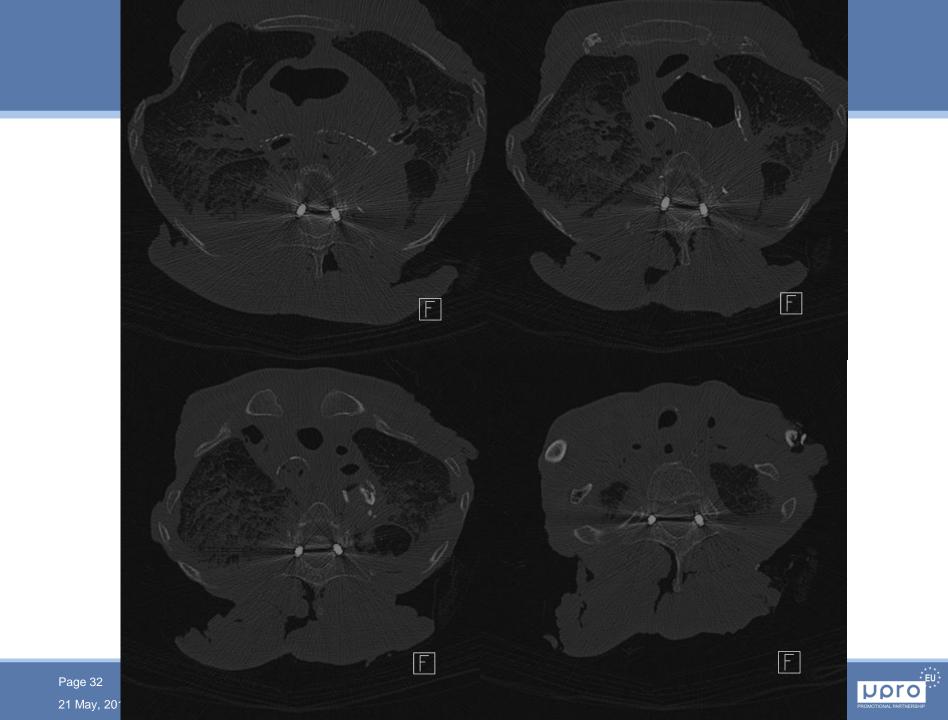


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CT scan was obtained after screw placement to evaluate screw positions.

- **13 screws (92,3%)** were inside of pedicle trajectory without violation of pedicle wall with the tip inside of the vertebral body.
- One screw (7,7%) perforated pedicle wall.









According to literature, in comparison with freehand technique, personalised templating:

- improves accuracy of pedicle screw insertion (over 95% accuracy)
- reduces the operating time
- reduces radiation exposure
- learning curve for the navigational template method was not obvious
 - Ryken TC, Owen BD, Christensen GE, Reinhardt JM. Image-based drill templates for cervical pedicle screw placement. J Neurosurg Spine. 2009 Jan;10(1):21-6
 - Owen BD, Christensen GE, Reinhardt JM, Ryken TC. Rapid prototype patient-specific drill template for cervical pedicle screw placement. Comput Aided Surg. 2007 Sep;12(5):303-8
 - Lu S, Xu YQ, Zhang YZ, Li YB, Xie L, Shi JH, Guo H, Chen GP, Chen YB. A novel computer-assisted drill guide template for lumbar pedicle screw placement: a cadaveric and clinical study. Int J Med Robot. 2009 Jun;5(2):184-91
 - M. Takemoto, M. Neo, S. Fujibayashi, T. Okamoto, E. Ota, T. Sakamoto and T. Nakamura; Designing individual templates for safe pedicle screw placement; J Bone Joint Surg Br 2012 vol. 94-B no. SUPP XLIV 28
 - V. Ferrari, P. Parchi, S. Condino, M. Carbone, A. Baluganti, M. Ferrari, F. Mosca and M. Lisanti. Optimal design of patient specific templates for pedicle spine screw placement. J Bone Joint Surg Br 2012 vol. 94-B no. SUPP XLIV 20



Our methodology appears to provide an accurate technique for pedicle screw placement in the thoracic spine.

We belive that tecnique is promising but needs to be thoroughly tested, optimised and evaluated before clinical application takes place.

