Bridging innovation and practice: the journey of FAROS from technical design to in-vivo animal validation

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Keywords: Robotic ultrasound, pedicle screw placement, conductivity sensing, lumbar spine, 3D reconstruction

Key information:

1. Research question: Can robotic pedicle screw trajectories be accurately, autonomously executed based on a 3D reconstructed ultrasound navigation by the FAROS robotic system?
2. Findings: In most cases, pedicle screw trajectories can be drilled with clinical acceptance. Further, ultrasound can achieve accurate results for reconstructing anatomical features to navigate said trajectories.
3. Meaning: The FAROS system shows promise for future robotic autonomous applications.

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Introduction

Due to the complex spinal anatomy and the need for high precision, existing spinal navigation systems utilize ionizing radiation to generate high-resolution bone imaging. However, these systems result in a substantial radiation burden to patients and healthcare professionals. In the European Union project FAROS, we aimed to leverage non-visual sensing technology to improve the autonomy of robotic pedicle screw (PS) drilling while eliminating the need for ionizing radiation.[1] We report the results for final validation, including ex-vivo human and in-vivo animal experiments.

Material and methods

The FAROS robotic system integrates a robotic arm (LBR-Med-7, KUKA, Augsburg, Germany) with ultrasound (US) (ML6-15 (15MHz) linear probe, GE Logiq, GE Healthcare, Illinois, USA) for anatomy reconstruction and trajectory planning, optical breathing compensation, a robotic drill, and conductivity sensors (DSG, SpineGuard, Paris, France) for real-time breach detection of the spinal canal while drilling.[2] The FAROS robotic system is based on several steps for robotic spine surgery. Initially, fiducial markers (Clear Guide Medical, Baltimore, MD, USA) were placed on the anatomy for motion tracking using an RGBD camera (ZED-2i, Stereolabs, Paris, France). Next, a US probe was attached to a robotic arm to scan the entire spine using a pre-defined path (Figure 1).[3,4] The bone anatomy of the 2D US images was segmented with U-NET, 3D-reconstructed, and ICP-registered with preoperative CT data containing the preoperative planning information.[5] The end effectors' US probe was then replaced by a drilling tool (Figure 2). After spine exposure, the system drilled autonomously to the preoperatively specified depth. During drilling, DSG monitors conductivity changes to stop drilling if a spinal canal breach is detected.

The following validation studies were performed:

1. Ex-vivo human validation:
   Ten PS trajectories were planned on L1 to L5 vertebrae using preoperative 3D CT models. After executing the workflow, the accuracy of the drilled canals was assessed surgically and radiologically through pedicle palpation and CT image evaluation. The placements were categorized based on their proximity to pedicle walls using the Gertzbein-Robbins (GR) classification.[6]

2. In-vivo animal validation:
   The reliability of the DSG technology was tested on live animals due to the unreliable tissue conductivity signals in ex-vivo specimens. This involved using an in-vivo porcine specimen to compare the DSGs' breach detection capabilities with postoperative CT scans.

3. The accuracy of the 3D US reconstruction:
   This was evaluated in separate ex-vivo human experiments. A 200 x 100 mm skin area was scanned using an S-shaped US protocol to cover vertebrae from L1 to L5, repeated thrice. The US images were registered with a preoperative CT model using an iterative closest point algorithm to evaluate the reconstruction quality of the anatomical features.[7]

Results

In the ex-vivo system validation, seven (77.78%) screws were placed with GR grade A, while one screw each achieved grades B and C (Table 1, Figure 3). One screw was excluded due to soft tissue proximity and surgical approach issues. The US navigation faced challenges in the in-vivo experiments due to increased spine curvature and breathing. Time constraints led to skipping preparation steps, resulting in technical errors. The separate evaluation of the 3D US reconstruction accuracy revealed an error of 1.74 ± 0.89 mm.[3]

Discussion and Conclusion

The system demonstrated clinically acceptable outcomes in 8 of 9 pedicle drillings, underscoring its potential for future autonomous robotic applications in spine surgery. Despite the promising results, the prototype is still in its developmental phase, with drawbacks like lengthy setup and preparation times posing challenges for immediate clinical adoption. Efforts are focused on refining the preparation process and advancing toward a minimally invasive technique to fully leverage the systems' capabilities and enhance their clinical applicability.

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Disclosures

F. Teyssere, J.A.P. Velásquez, and T. Chandanson are employed by SpineGuard S.A.

APPENDIX

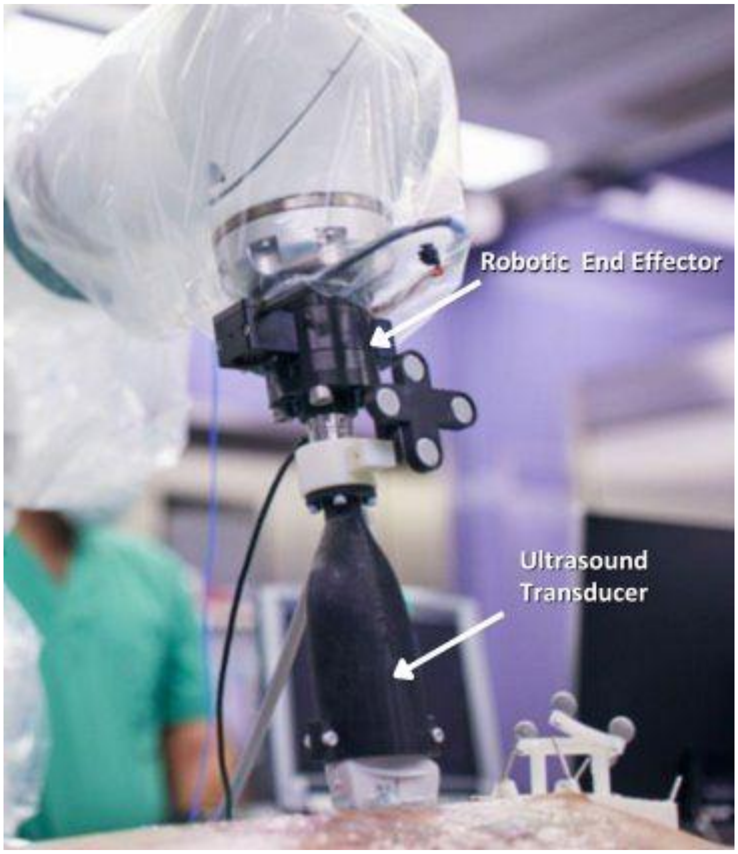

Figure 1: The FAROS robotic system with the robotic ultrasound end effector attached.

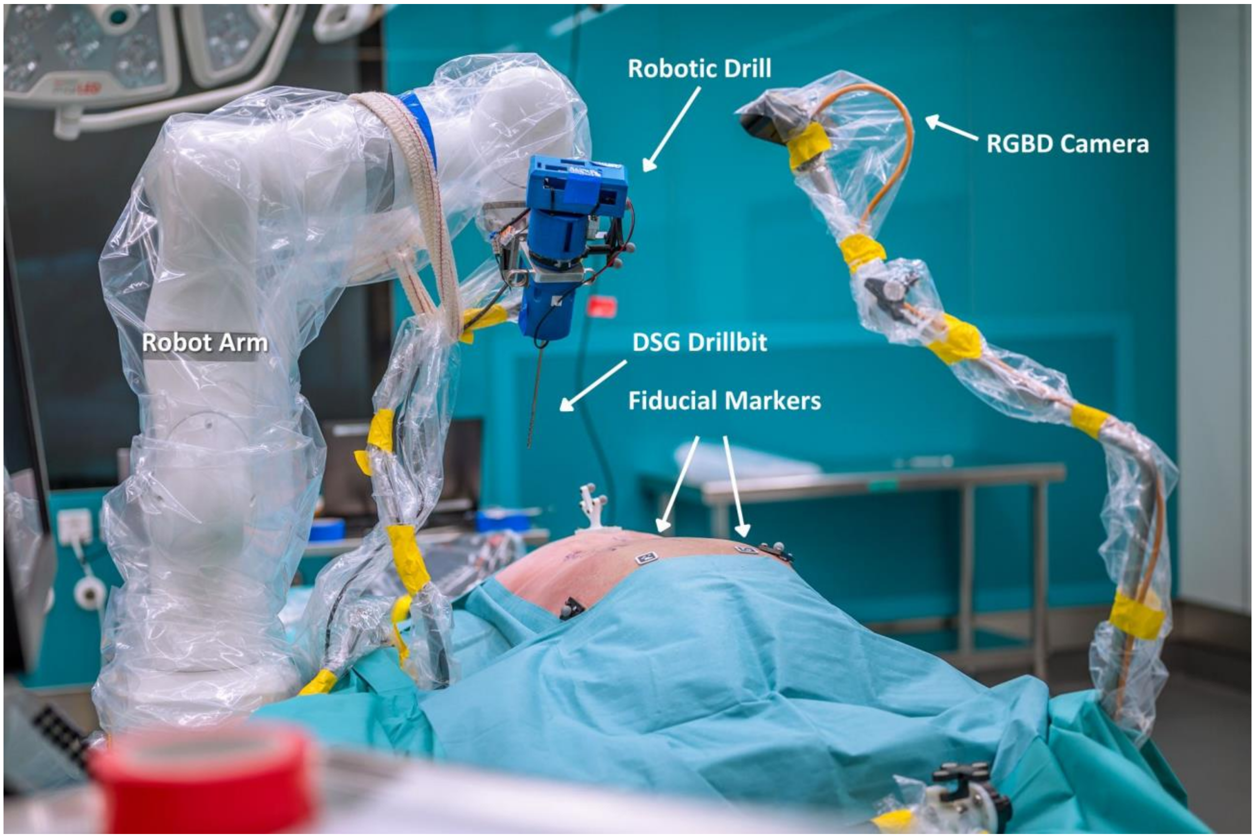

Figure 2: The FAROS robotic system with the robotic drill attached and fiducial markers placed for the optical (RGBD) camera.

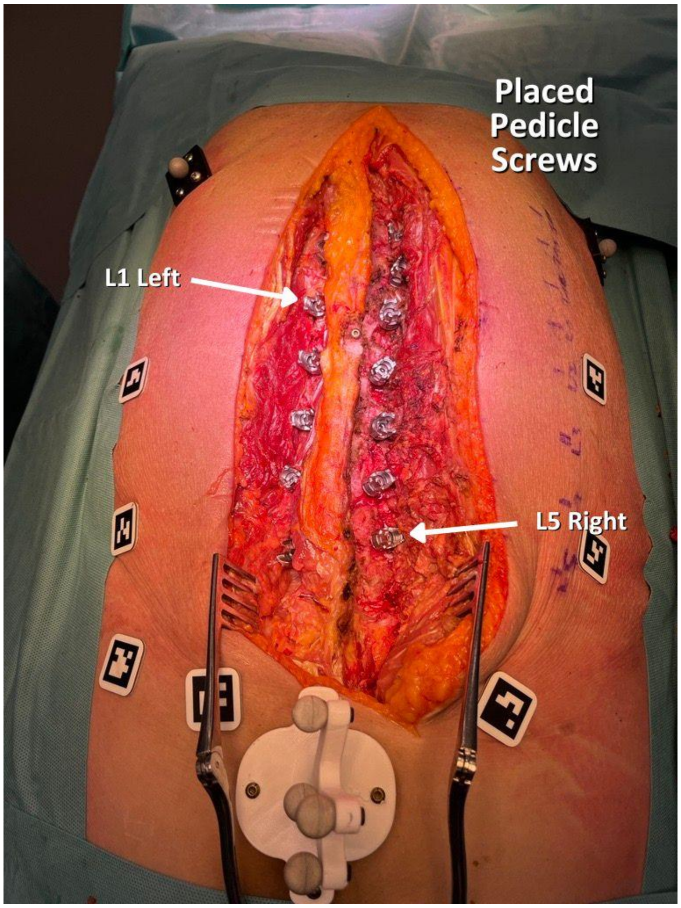

Figure 3: Placed pedicle screws after autonomous robotic drilling from L1 to L5. Thoracic screw placement was only performed for system training and not part of the validation experiment.

Table 1. Gertzbein-Robbins classification for the ex-vivo pedicle drilling experiments.

Pedicle drilling trajectories	*Gertzbein-Robbins Classification*
L1 right	A
L1 left	A
L2 right	A
L2 left	A
L3 right	C
L3 left	B
L4 right	A
L4 left	A
L5 right	A
L5 left	Excluded due to soft tissue proximity/ surgical approach issues