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Improvement of the automatic bone breach detection using electrical conductivity for spine surgery

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INTRODUCTION

Current studies conducted by various companies in the field of robotic-assisted spinal surgery are focused on utilizing navigation as a tool for optimizing pedicle screw placement. At present, numerous robotic solutions have been developed, such as Mazor SpineAssist[®] (Mazor Robotics), ROSA[®] Spine (Zimmer Biomet), and Excelsius GPS (Globus Medical) [1], [2], [3]. However, these developments primarily concentrate on outlining and securing the trajectory. The next advancement in robotic-assisted spinal surgery involves optimizing the drilling process in the vertebrae. Previous studies conducted by the medical device company SpineGuard[®], in collaboration with the ISIR robotic laboratory, laid the groundwork for implementing a robotic drilling process including automatic breach detection [4], [5].

This paper aims to extend this research by improving the methodology and demonstrating its performance in a more clinically relevant setup. This paper presents the outcome of 50 drillings performed in pig vertebrae, using an improved breach detection algorithm applied to a trajectory starting from the pedicle and ending in the spinal canal.

MATERIALS AND METHODS

The setup is composed of a container filled with a saline solution to reproduce the electrical conductivity of the cerebrospinal fluid (CSF) and a robot LBR Med 7 of KUKA (7 DOF robot) equipped with a threaded drill bit embedded with the DSG Technology developed and marketed by SpineGuard[®] (Fig. 1).

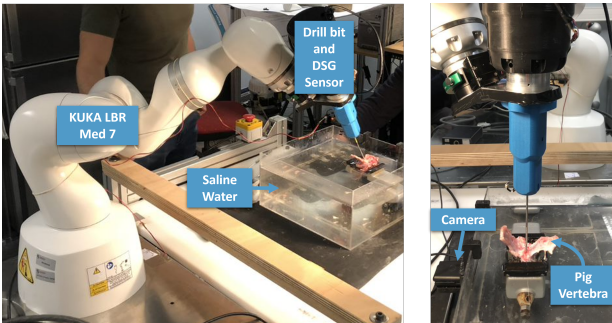


Fig. 1: Setup for the drillings of pig vertebrae (left) and detail of the drill placed at the entry point (right)

The experiments were conducted on fresh pig lumbar vertebrae due to their comparable pedicle morphology with human ones [6]. The vertebrae were positioned in a clamping vice inside a transparent box and facing a camera allowed to inspect the canal during the drilling procedure. An entry point was made manually then the robot was hand-guided to the entry point.

The robot was controlled to apply a constant 10N force along the axis of the drill, maintaining its manually defined orientation. The power drill was rotating at 30 rpm and had an allowable descent speed of 50 mm/s.

Parameters of *Algorithm 1* were adjusted with the help of a dataset provided by the ISIR laboratory, collected during prospective drillings of pig vertebrae using a similar setup. This data suggested that in thin pedicles breaches could happen before the end of the previously defined measurement collection window of 5 mm [5]. So the collection window was changed to start at 2 mm and allowed to trigger an alert as early as at 3 mm depth.

Algorithm 1 Bone breach detection, called for each new conductivity measurement; Initially *Alert* = false, $\sigma_r = 0$ and Σ, Z are empty lists. **Blue values** are the modified parameters

Input: σ_k , conductivity signal in mV
Input: Z_k , depth insertion in the bone in mm
Output: *Alert*, flag used to stop the drilling
 $\Sigma \leftarrow [\Sigma \ \sigma_k], Z \leftarrow [Z_k]$ \leftarrow Constructing lists
if $Z_k > 3$ **then**
 $A1 \leftarrow \sigma_k > \max(\min(500, 2.4 \ \sigma_r), 150)$
 $m \leftarrow \underset{i \in \{1 \dots k\}}{\operatorname{argmin}} |Z(i) - Z(i) - (z_k - 2)|$
 $n \leftarrow \underset{i \in \{m \dots k\}}{\operatorname{argmin}} \Sigma(i)$
 $A2 \leftarrow ((\underset{i \in \{m \dots k\}}{\max} \Sigma(i)) - \Sigma(n)) > 230mV$
 $Alert \leftarrow Alert \ || \ A1 \ || \ A2$
Else if $Z_k < 2$ **then**
 $j \leftarrow k$
else
 $\sigma_r \leftarrow \frac{(k-j-1) \cdot \sigma_r + \sigma_k}{k-j}$
end if

Based on previous work [5] was defined the modified breach detection algorithm (*Algorithm 1*) was taken as input conductivity measurements σ and drilling depth z . It uses an adaptive threshold σ_r , computed with conductivity measurements gathered during the first millimetres of drilling. Due to the pig vertebrae properties a minimum threshold σ_{min} was added to avoid the false positives. The alert, and subsequent robot stop, are triggered either by an electrical conductivity value or by a variation of

conductivity ($\Delta\sigma$) over the last few millimetres (Δz).

RESULTS

A 100% success stop rate before the breach was obtained at the end of the experiences within the acceptance criteria of ± 2 mm between the bone and the spinal canal, according to grade "A" et "B" of Gertzbein-Robbins classification [7].

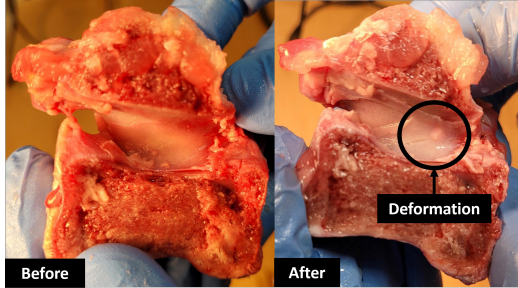


Fig. 2: Vertebra showing the deformation due to the drill tip

Multiple methods were used to verify the results. Firstly, to discard the existence of a breach a ball-tip feeler palpation was used. Subsequently, a visual inspection of the spinal canal was performed to verify the existence of deformation due to the drill bit tip (Fig. 2).

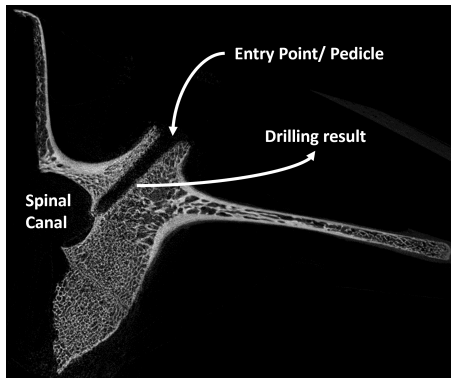


Fig. 3: μ CT-Scan

Finally, using CT-Scan and the inspection of the video recorded during the drilling, the absence of false positives was verified (Fig. 3). The mean deformation measured was 0.7 mm, with a standard deviation of 0.45 mm. All measured deformations were in a range of -0.9 mm to $+1.4$ mm (Fig. 4).

Figure 5 shows the DSG signal that indicates high values for the first millimetres of drilling in the entry point, this does not trigger the stop of the drilling process. Afterwards, the DSG value decreases at contact with the cancellous bone and then further decreases while going through cortical bone. Finally, it's observed a sudden increase in conductivity due to micro breach and the saline solution in contact with the tip.

CONCLUSION AND DISCUSSIONS

The improvement and implementation of a new automatic bone breach detection algorithm for spine surgery have been done and tested with a relevant clinical setup. The

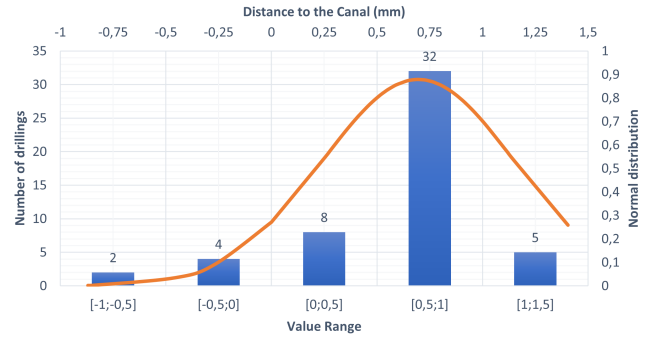


Fig. 4: Data Distribution deformation due to the drill tip in 50 specimens

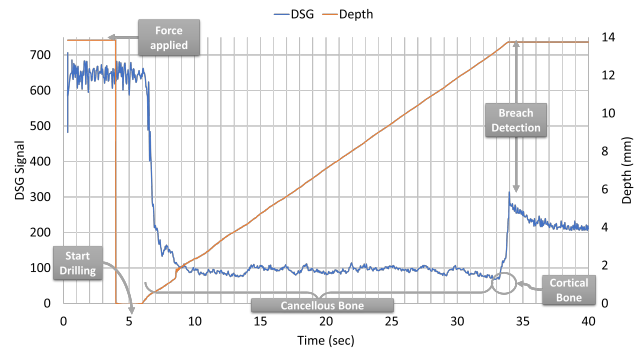


Fig. 5: Illustration of the evolution of the DSG signal and the penetration depth of the instrument

pig vertebrae have proven to be a good alternative to test pedicular trajectories given their similarities with human morphology.

Furthermore, experiences with a regular one are carried out to compare the results obtained in this study. Contrary to the threaded drill tip, the regular drill tip is a commonly used tool in the operation room. This tool is more aggressive, and its use allows high-speed drilling.

Finally, the effect of breathing was not considered in this study. The breathing cycle could induce a displacement of some millimetres in vertebrae and it would be interesting to introduce this effect for future experiments.

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