Automatic bone breach detection for spine surgery based on bio-electrical conductivity sensing: Ex-vivo experimental validation

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INTRODUCTION

Several procedures in spine surgery require the surgeon to insert screws in vertebrae to immobilize some parts of the spine with metallic rods, *e.g.,* for scoliosis correction. The drilling trajectory is chosen to pass via a narrow anatomical part called the pedicle. Misplacing the pedicle screws can induce many complications due to the proximity of critical neural or vascular elements [1].

The main difficulty associated to the manual free-hand procedure is that the precise location of the tool is not directly visible. To assist surgeons, X-ray imaging systems have been coupled to marker-based optical tracking devices to provide a real-time visual estimation of the tool position in Virtual or Augmented Reality. Recently, spine surgery robots have been introduced to these technologies to position autonomously a drill guide on top of the patient. However, these robots do not perform the drilling themselves.

To better understand what is happening at the tool tip, SpineGuard, a medical device company, designs tools embedding local bio-electrical conductivity sensing thanks to a bipolar sensor pulsing current flow at the tip of their instruments [2], [3]. The measured signal varies with the bone density and allows discriminating between cortical bone (dense), cancellous bone (spongious), and soft tissues (blood, muscles, etc).

With the idea to provide additional on-line safety check for robotized spine surgery, we proposed a new concept showcasing a robotic arm using a tool equipped with conductivity sensing in [4]. The present paper describes a more thorough experimental investigation of the concept. It discloses a set of 104 experimental drillings performed on *ex-vivo* lamb vertebrae, where 100% of the drillings were autonomously stopped at the interface between the bone and the spinal canal thanks to bio-electrical conductivity measurements.

MATERIALS AND METHODS

The mechatronic setup consisted of an LBR 7 Med redundant robotic manipulator from KUKA, a custom-made power drill, and a threaded drill bit embedding a conductivity sensor, prototyped by SpineGuard.

All the experiments were conducted on fresh lamb lumbar vertebrae acquired at the butcher shop. The *ex-vivo* pieces, once at room temperature, were fixed in a clamping vice, which was placed inside a transparent box. The container was filled with a saline solution to reproduce the conductivity of the cerebrospinal fluid (CSF), usually present in the vertebral canal during real surgeries. A camera was positioned right outside the box to record the interior of the spinal canal and look for potential bone breaches. The overall setup is shown in Fig. 1.

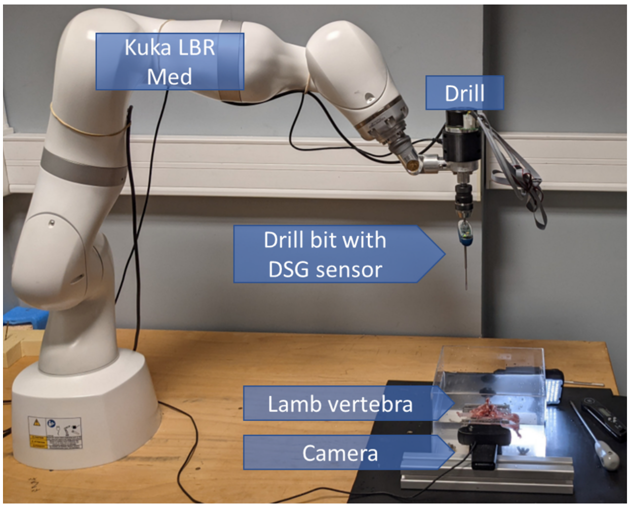


Fig. 1: Experimental setup.

An entry point was made manually in the spinous process for each trial. Then the tool was hand-guided to the entry point, and oriented towards the spinal canal. Next, the robot was controlled to keep the orientation fixed and apply a constant force of 10N, while drilling with the threaded instrument with a 1mm pitch. The power drill was controlled at a fixed rotation speed of 30 rpm, leading to almost a constant insertion speed (see Fig. 2c) of 0.5mm/s., thanks to the threads on the instrument.

A preliminary experiment, performed on 100 continuous drillings of lamb spinous processes, allowed for gathering electrical conductivity signals corresponding to bone breaches. Then, the collected data was used to develop and tune a bone breach detection algorithm to stop the robot for all drillings in a ±2mm zone from the border between the bone and the vertebral canal. Such breaches would correspond to grades A and B of the Gertzbein-Robbins classification of pedicle screw misplacement [5].

The resulting Algorithm 1 uses the conductivity σ and the depth z measurements to create a security flag $Alert$ enabling to stop the system. Parameters $\sigma_{\max}$ and α are used to create an adaptable threshold on the conductivity signal. At the same time, $\Delta\sigma$ and Δz are used to monitor

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 parameters tuned from calibrating experiments

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

$\Sigma \leftarrow [\Sigma\ \sigma_k]$, $Z \leftarrow [Z\ z_k]$ ▷ Constructing lists
if $z_k < 5$ **then**
  $Alert \leftarrow$ **false**
  if $z_k < 3$ **then** $j \leftarrow k$
  else $\sigma_r \leftarrow \frac{(k-j-1)\sigma_r + \sigma_k}{k-j}$ **end if**
else
  $A_1 \leftarrow \sigma_k > \min(500, 2.4\ \sigma_r)$
  $m \leftarrow \underset{i\in\{1\cdots k\}}{\text{argmin}} |Z(i) - (z_k - 2)|$
  $n \leftarrow \underset{i\in\{m\cdots k\}}{\text{argmin}}\ \Sigma(i)$
  $A_2 \leftarrow \left(\left(\underset{i\in\{n\cdots k\}}{\max}\ \Sigma(i)\right) - \Sigma(n)\right) > 230$ mV
  $Alert \leftarrow Alert || A_1 || A_2$
end if

the conductivity increases over a few millimeters.

All parameters have been tuned to post-operatively trigger a stop for the data of the preliminary experiments, ±2mm around the interface between cortical bone and the vertebral canal.

Then, a second experiment, comprising 104 new vertebrae, was performed with the previously defined automatic bone breach detection algorithm and parameters, with the intent to stop the threaded drill bit right around the interface between the cortical bone and the spinal canal.

The final position of the tool relatively to the bone/canal interface was then evaluated for each trial by using the synchronized data (robot displacement and videos) acquired during the experiment. To do so, we measured, in post-processing, the number of millimeters of robot displacement after seeing bone movement on camera. False positives (stops happening before reaching the interface) were assessed thanks to post-operative CT scans.

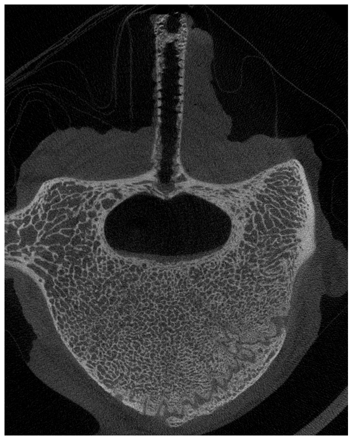
RESULTS

The presented robotic system successfully drilled all the 104 lamb lumbar vertebrae autonomously without breaching outside of the bone.

For each drilling, a surgeon verified via palpation with a ball-tip feeler that the instrument did not fully breach outside the bone. Moreover, the recorded video feed from the webcam allowed to visually verify that the instrument did not pass the vertebral wall (see Fig. 2b).

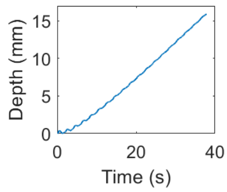
Also, a post-experiment CT scans analysis confirmed that all drillings were stopped within less than 2mm from the canal (0% false positive). A few vertebrae were passed through a micro-CT scan to better visualize the resulting hole drilled in the spinous processes (see Fig. 2a).

The post-processing of the synchronized robot logs and webcam videos permitted to estimate the amount of bone



(a) Micro-CT scan

(b) Webcam view



(c) Measured depth

Fig. 2: Results on one autonomously drilled vertebra.

pushed inside the vertebral canal. The mean displacement inside the canal was 0.65mm, with a standard deviation of 0.4mm.

CONCLUSION AND DISCUSSION

A total of 204 vertebrae were drilled with the same robotic setup. The 100 first tests were unstopped drillings, used to collect data on bone breaches. The last 104 drillings were automatically stopped at the bone interface thanks to a detection algorithm.

The CT scans and the recorded videos showed that the detection happens when the cortical bone starts to crack, *i.e.,* before the hole is thoroughly drilled. The videos of the preliminary experiment also allowed to visualize the bone deformation (bump) happening in the vertebral canal before bone perforation.

The trajectory used in this experiment was perpendicular to the spinal canal. Even in this worst-case scenario, all the drillings were graded A or B with the Gertzbein-Robbins classification, which is clinically acceptable. Nonetheless, future work will need to validate the algorithm on actual pedicle trajectories.

ACKNOWLEDGEMENTS

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