Robot-assisted spine surgery guided by conductivity sensing: first preclinical experiments demonstrate X-ray free breach detection

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INTRODUCTION

Inserting screws in vertebral pedicles is a major issue in spinal fusion surgery. Due to their proximity to critical anatomical regions (spinal cord, aorta), misplaced screws can induce complications [1]. Free-handed positioning results in high inaccuracy. To try to improve precision of this surgery, new medical robots and tools emerged from the research community and arrived in the market in the last few years [2], such as SpineAssist [3] from Mazor, ROSA [4] from Zimmer Biomet, iSYS 1 [5] from Interventional Systems.

Available systems rely on fluoroscopy or CT scans taken during the procedure for position checking. Notably, there is no real-time control of the gesture.

The current paper discloses a concept involving a robotic arm that holds a drill equipped with an electrical conductivity sensor. A control law couples the sensor to the robot control in such a way that vertebral breach can be avoided during vertebrae drilling. First *in vivo* experiments are shown.

MATERIALS AND METHODS

The experimental setup is a combination of the DSG technology developed by SpineGuard, a 7 DOFs robot arm WAM sold by Barrett Technology, and a motor. See Fig. 1.

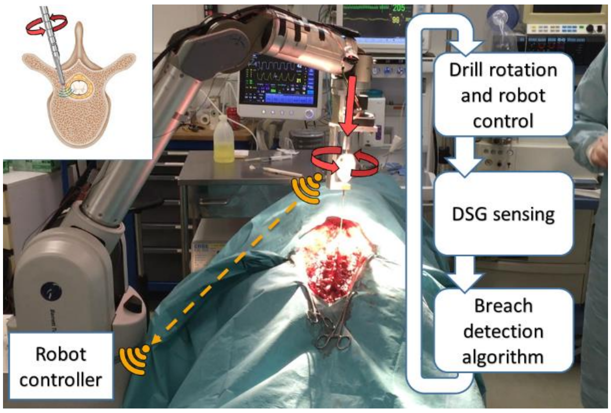

Fig. 1 Experimental setup

DSG technology [6,7,8] is a bipolar, local electrical conductivity sensor that pulses current flow at the tip of its probe. The current clinical setup is as follows: when manipulating a pedicle preparation tool equipped with DSG, a surgeon can distinguish between tissues and be alerted prior to an imminent cortical breach: this is achieved by changes in the pitch and cadence of an audio signal and a flashing LED light.

In this work, the DSG signal $s(t)$ is used to detect a breach as follows (see Fig. 2). It is assumed that the tool has initially been inserted in cancellous bone. The system then waits for the detection of an event: cortical bone penetration is detected when $s(t)$ gets below a threshold s_1. A breach alert is then produced when $s(t) > s_2$ with $s_2 = s_{min} + \delta s$, where $s_{min} = \min_{0\leq\tau\leq t} s(\tau)$ and δs is a given differential threshold.

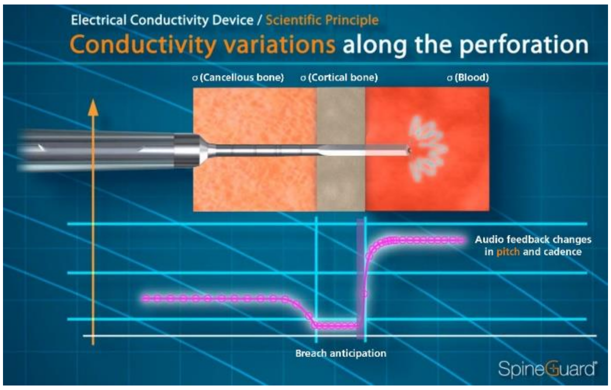

Fig. 2 DSG technology principle.

As for the robot control (see Fig. 3), at the beginning of the procedure, a transparent mode is provided to position the drill tip by comanipulation. A semi-transparent mode is then proposed allowing for orienting the drill around its tip. A simple click on a GUI starts the drilling algorithm at a constant speed v_{des}.

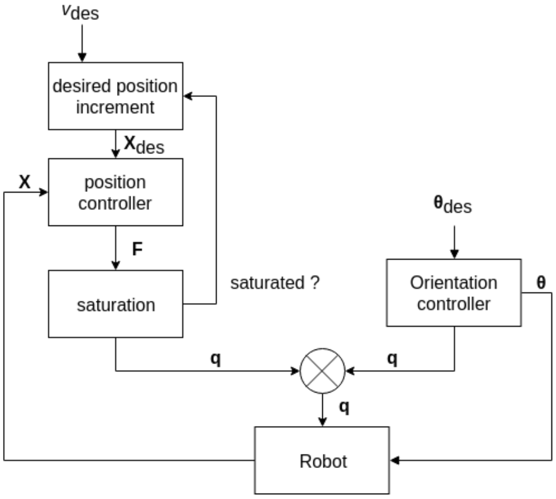

Fig. 3 Control scheme.

When the drilling starts, an operational space orientation and position controller starts running. The desired orientation θ_{des} is servoed to its initial value θ_{ini}. The desired position X_{des} is computed by:

$$X_{des}(t+dt) = X_{des}(t) + v_{des} dt\, z_{ini}, \qquad (1)$$

where dt is the control period, z_{ini} is the drill axis direction and v_{des} is an adjustable penetration speed. As a security, when the resulting control force $\|F_p\|$ reaches a given value $F_{p_{max}}$, then the position increment is nulled.

RESULTS

In vivo experiments have been performed on pigs, under the control of veterinary surgeons and after approbation of an ethics comity.

Parameters of the experiments were as follows:

- Drilling motor rotation = 300 rpm,
- $s_1 = 150mV$, $\delta s = 300mV$
- $dt = 2ms$
- $F_{p_{max}} = 10N$

The surgeon was asked to manipulate the robot arm in a transparent mode so that the drill bit could perforate the spinous process of the vertebra, then click on the GUI to start the drilling.

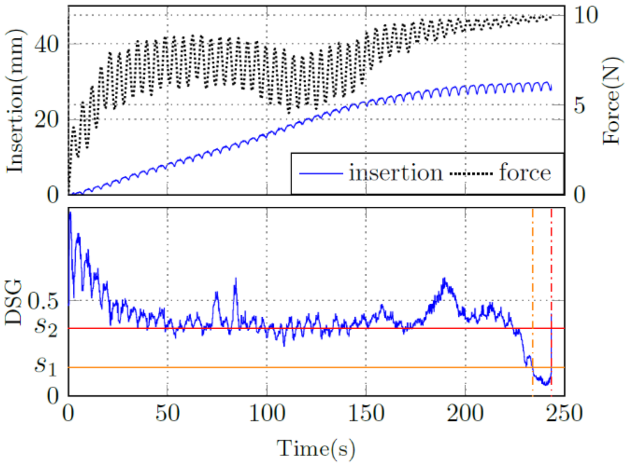

Fig. 4 Robot and DSG signals during an experiment

The curve of the DSG signal (Fig. 4) shows the expected signature: high signal at the entrance, then stabilization in the spongious phase, decrease in the cortical bone around s_1, followed by a fast rise stopped to s_2.

The force and position curves exhibit oscillations. These correspond to the breathing of the animal. Notice that the position controller involves a simple PD compensator without integral action, leading to compliance observable through the oscillations of the insertion (or penetration depth) signal.

Further, due to the force limitation, the velocity decreases when the resistance is getting higher, offering an extra layer of safety.

DISCUSSION

The current setup allows to stop the drilling right before breaching out.

An innovative system for radiation-free breach anticipation during spine surgery has been presented. It uses a measurement of the local conductivity to determine if a breach out of the bone is imminent.

The *in vivo* experiments were successfully performed but further improvements can be considered to increase robustness and accuracy.

For instance, the values of variables s_1 and δs have been manually set. Further experiments have shown that these values need to be adjusted depending on the patient's anatomy and bone state. A more sophisticated signal-processing algorithm needs to be defined in order to eliminate the tuning of these parameters and allow the recognition of a conductivity change pattern.

Further, the DSG technology could be used in many bone surgeries as a safety sensor to reduce the use of x-rays.

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