Improving Spinal Fusions: Redesigning the Pedicle Probe to Prevent Vertebral Breaches

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Introduction

Pedicle probes are medical devices used by surgeons to create pilot holes to guide the placement of pedicle screws in vertebrae during spinal fusions for patients with conditions such as scoliosis and spinal fractures. The screws are then connected with a metal rod to stabilize the spine. Twenty-nine percent of patients who undergo spinal fusions suffer from vertebral breaches – accidental damage to the spinal cord – which cause complications such as infection, motor defects, and in many cases paralysis. My goal was to make spinal fusions safer by redesigning the pedicle probe to provide surgeons with instantaneous feedback on the probe's location, enabling them to more accurately place pedicle screws.

Design and Implementation

The electro-mechanical pedicle probe I developed takes advantage of the difference in density between the inner cancellous (spongy) bone and the outer cortical (compact) bone found in vertebrae. Cortical bone is avoided by monitoring the cannulation force – the force required to insert the probe. When the probe contacts denser cortical tissue, it warns the user by providing tactile and visual feedback through a vibration motor and an LED. This enables the surgeon to redirect the probe and advance down the optimum path, preventing a possible cortical breach. Trials to simulate actual use were conducted on lamb cervical and lumbar vertebrae (obtained from a butcher), which closely resemble human vertebrae.

Results and Evaluation

The prototype probe functions as designed. It is able to measure force with more than sufficient accuracy to detect the difference between cancellous and cortical bone and was successful in warning the user at a preset force value. When tested on lamb vertebrae, the probe gave sufficient feedback to prevent both medial and lateral breaches. This novel device improves feedback to the surgeon and eliminates the need for costly and potentially harmful ionizing radiation exposure. Furthermore, it does not depend on, or require, any preoperative imaging. The cost per unit of manufacturing the improved pedicle probe is estimated to be $56 CAD (€37), which could be significantly reduced if components were purchased in bulk. Results of patent searches for Canada, the United States, and Europe suggest that the redesigned probe is unique in quantifying and communicating the live tissue type that the tip is touching. The probe is also unique in the sense of incorporating guided, personalized procedures in spinal fusions for those with complications, through calibrating a control (force) limit based on tissue samples prior to the procedure.

Conclusions

Enhancing a surgeon's ability to determine an appropriate path for pedicle screws through a sensor-enabled probe has the potential to significantly reduce the incidence of vertebral breaches during spinal fusion surgery. I am currently developing an enhancement that would actively prevent the penetration of cortical bone regardless of the surgeon's actions. My ultimate goal is for the new probe to significantly reduce, and ideally, eliminate human error in spinal fusion surgeries and related procedures.