Development of a test arrangement for the validation of signal transmission quality in a solid

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During clinical operations in the area of the ear, nose, and throat (ENT), there is a significant risk of an axonal injury. Through intraoperative neuromonitoring (IONM) this risk is highly reduced. As part of the innosuisse-project with Bien-Air Surgery SA and the support of inomed Medical technology GmbH an ENT-IONM-handpiece is in development. The goal of this project is to develop a test arrangement for the further validation of this handpiece.

Introduction

The IONM handpiece in development uses electromyography (EMG). A stimulation signal goes through the tool onto the rotating milling spindle attaining up to 80'000 RPM. This signal triggers the action potential of the nerve in proximity, if the tissue/bone layer is not too thick. Otherwise the electrical impulse goes to the ground electrode. This triggered nerve activates the corresponding muscle, which can be measured trough EMG, warning the surgeon of the nerve-proximity so that surgery-induced damages can be reduced.

The test arrangement shows the programmed robot guiding the prototyp drill into the head-phantom

Motivation

In medical technology development phases are especially long and costly due to many regulations. Therefore, the system has to be thoroughly tested and improved before submission. The signal transmission quality might be affected by the applied force on the tool, which is dependent on many influences including drill spindle speed, cutting depth, drill angle and irrigation. To our best knowledge, no studies concerning this issue are publicly available, therefore testing is inevitable. The results and the eventual product will be of great interest to the medical technology industry and benefit patients in the long run.

Status quo

In 2016 a first test arrangement was designed. During the pre-study and the first weeks of the bachelor the test arrangement was updated to simulate the surgery more closely. In contrast to its predecessor the burr now mills into a solid, resembling actual bone. Additionally, the handpiece is now attached onto a robot to allow for repeatability and tracking of position.
A catch basin has also been designed to allow for continuous irrigation.
To measure the upcoming forces, a force sensor has been attached on the robot's outer wrist. Signal transmission quality is measured simultaneously to the force through a high-end oscilloscope. Both measurements are aligned by an algorithm.

Outlook

After completion of the setup, the signal transmission quality (noise variance and possibly more criteria) will be measured in function of the applied force under various parameters. We expect chips to arise while milling, resulting in chip-clogging, which might affect the conductivity and therefore the signal transmission quality. To validate the viability of the system, we have thus to assure that this effect is neglectable. In the future bovine temporal bone will be used as probe material to mimic the cochlear surgery more closely.

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