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Metrological Support of Medical Drillings at the Lateral Skull Base

Refinement of a drill with integrated temperature sensor technology

Abstract: For minimally invasive drilling processes, the temperature development in the drilling ground is of crucial importance for patient safety. To monitor the temperature during drilling, a drill prototype was developed by BREDEMANN ET AL. which can record the drill temperature in parallel to the process and in real time. The measurement principle of the thermistor (temperature sensor) integrated in the drill could be validated. [1] The prototype must be refined for use in the operating room, as the drill does not yet meet all the medical requirements that need to be fulfilled. In further development, the recorded temperature data in particular must be processed and communicated to the surgeon in order to provide added value for the surgical procedure.

Keywords: Cochlear implant; minimally invasive; medical technology; temperature development; drilling process; risk model

https://doi.org/10.1515/cdbme-2021-1037

1 Introduction

In head and neck surgery, as in many other medical fields, there is a desire for minimally invasive surgical processes to minimize trauma to the patient. To accomplish this, new surgical approaches and surgical methods are often necessary when conventional instruments do not meet the requirements. A promising approach for minimally invasive surgery at the base of the skull, e.g. for cochlear implantation, is multiport bone surgery (MUKNO) [2]. In this approach, multiple linear drill channels are introduced into the skull to create access, meeting at a rendez-vous point in front of the target area. The creation of singular drill channels, e.g. for sampling from unclear changes in the skull base, is also conceivable.

Temperature development at the drill bit during insertion of these minimally invasive approaches is of increased interest, as drill channels in this area must inevitably pass through temperature-sensitive structures, such as the facial nerve or the organ of balance [3]. If surrounding tissue is exposed to a threshold temperature of 47 °C or higher for more than one minute, permanent damage may occur [4]. While the long-term effect of temperature damage to bone remains largely unexplored, damage to nerves leads to paralysis, e.g., in the facial region [3,5,6]. Therefore, real-time monitoring of the drilling temperature is needed.

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2 State of the Art

In preliminary work for real-time monitoring of temperature in the drilling ground, BREDEMANN ET AL. as part of the interdisciplinary team of WZL and the Department of Otorhinolaryngology from the University Hospital Düsseldorf cooperating in the DFG funded project Mambo - Metrological safeguarding of a drilling process in image-guided minimally invasive procedures using the example of the otobase, developed a concept for temperature monitoring during drilling using the IDENT method [7]. Since the highest temperatures are expected at the drill bit tip, the integration of a temperature sensor into the tip of a drill bit was aimed at. For this purpose, a thermistor (Semitec, Japan) was placed through a cooling channel at the drill tip of an industrial drill with a diameter of 5 mm and glued. Via an electronic unit attached to the drill, the temperature data can be transmitted wirelessly via Bluetooth Low Energy to an evaluation computer during drilling. The energy required for this is generated via the rotation of the drill. In addition, sound data is sent through a microphone (Knowles Electronics, USA). [1] These data can be used, for example, to detect the drilling bit's intrusion into material as well as the transition of materials of different densities.

Figure 1 shows the drill integrated into the robot-guided demonstrator setup for performing reproducible experiments to investigate temperature development in bone-equivalent material (Synbone, Switzerland).

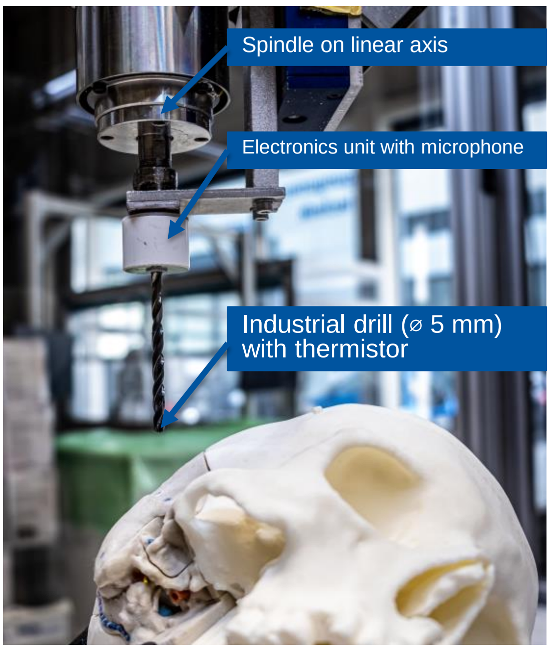

Figure 1: Demonstrator setup for robot-guided drilling experiments

As a basis for the experiments, calibration of the drill was first performed in a static condition in a climate chamber. The calibration tests showed a repeatability of 0.02 K [1].

To further validate the drill prototype, drilling tests were performed in stacked blocks of bone-equivalent material (Synbone, Switzerland) of different densities to mimic the structure of the skull with different bone structures. The temperature curve in figure 2 shows the constant increase in temperature as the drill advances further into the material. The constant temperature at the beginning corresponds to the time required to establish a Bluetooth connection between the drill and the computer. The temperature drop at the material transition can be explained by the lower density of the following material.

The determined standard deviation of the drilling tests of 2.7 K as well as the good repeatability in static condition further show that the drill prototype is suitable for a process-parallel determination of the drilling temperature. [1]

To make the temperature data recorded by the drill usable, VOIGTMANN AND BREDEMANN ET AL. developed a

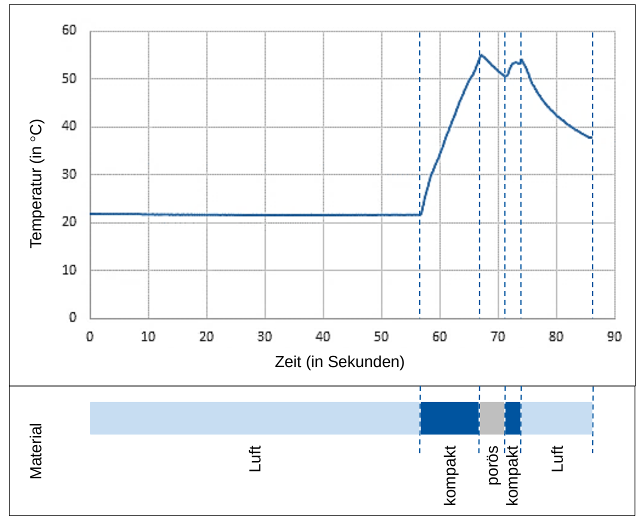

Figure 2: Evaluation of drilling experiment with temperature measurement [1]

risk model for real-time determination of the patient's risk of injury [8,9]. In addition to temperature data, the model incorporates the mechanical risk of a direct hit and imaging uncertainty.

3 Development Needs

The prototype developed by BREDEMANN ET AL. was able to show that the concept of real-time temperature measurement in the drilling ground is possible and that the measurement provides plausible results. A risk model allows the evaluation of the safety of the drilling process for the patient. [1,8–10].

Due to the prototype status of the drill, there are still issues that need to be addressed in further research. For example, the drill with a diameter of 5 mm cannot currently be applied in the surgical scenario.

The aim of the first rework of the drill is therefore to implement the requirements from medicine as well as the integration of the sensor technology with regard to the drill diameter as well as the shaft length. In addition, a drill must be selected that generates as little heat as possible during drilling due to its geometry. The current procedure for integrating the temperature sensor into the drill requires a cooling channel in the drill. The cooling channel must be dimensionally suitable to incorporate the temperature sensor.

This contradicts the maximum reduction of the diameter, since a drill with a smaller diameter is expected to generate less heat. [11]

The diameter and length of the drill are dictated by the target area and region of the trajectory (Stenin et al. 2014). For example, to reach the middle ear and visualize the round window of the cochlea, a drill trajectory through the facial recess is usually necessary. This refers to the area between the facial and gustatory nerves and is on average 2.4 mm (95 % CI 2 - 2.7) wide. With an assumed system accuracy of 0.39 mm (μerror+3σerror), 47 % of the adult population would be safely operable with a 1.8 mm thin drill according to analyses by SCHNEIDER ET AL. [12]. The most distant surgically relevant area within the skull base is the petrous apex, which can be an average of 62.5 mm from the skull surface, but can range from 44 mm to 84 mm depending on the region selected [13].

Other characteristics of the drill that influence heat generation are mainly to be found in the drill geometry. Therefore, the drill geometry must be systematically designed with respect to the influence of each geometry parameter on heat generation.

In addition to the geometry parameters shown in Figure 3, other parameters such as the number of cutting edges and the grinding angle influence the heat generated during drilling. [14,15] A smaller point angle, for example, leads to a longer main cutting edge. On the one hand, this has the advantage of facilitating the centering of the drill and making it more difficult to slip from the desired position. On the other hand, the thrust required for penetration into the bone is reduced, which in turn reduces the heat input into the tissue.

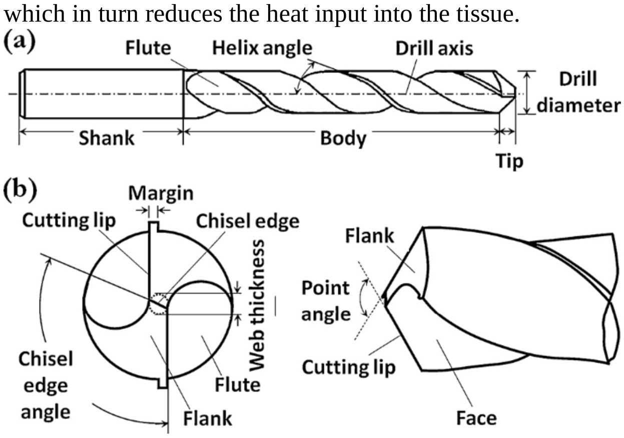

Figure 3: Parameters of the drill geometry of a twist drill [15]

In order to select the most optimized drill geometry, a literature review was conducted to summarize the effects of each geometry parameter on heat generation. The results were plotted in a morphological box. To select the most optimal parameter combination from the morphological box, a combination of a utility analysis and a TOPSIS (Technique for Order Preference by Similarity to Ideal Solution) analysis was performed [16]. The positively evaluated drills will be subjected to detailed investigation in drilling tests with external measurement of temperature in further studies. The drill that meets the medical requirements and generates the least heat during drilling will then be used for further development.

4 Discussion

In addition to the temperature-optimized selection of a drill that meets the medical requirements, the following points must be worked on in the further course so that the drill can be used in the real surgical scenario:

- Speeds of at least 3000 rpm are currently required to supply energy to the sensor system. [1] This means that the drill cannot record and transmit temperature or sound data when stationary. This limits the applicability and flexibility in the operation scenario, since, for example, a cooling process of the drill at standstill cannot be monitored in this way.
- The temperature data recorded during drilling is only sent as raw data to a computer for documentation. In order to provide added value for temperature-optimized control of the drilling process, the temperature data must be processed in real time, visualized and communicated to the user.
- For the drill to be applicable in a surgical scenario, the drill and electronic unit must be designed to be sterilisable. Currently, the capsule around the power supply and the electronic components are not designed in this respect.

The principle function and potential of a medical drill with integrated sound and temperature sensors could be demonstrated. In summary, the drill is currently not able to support patient safety during medical drilling e.g. at the lateral skull base. The further research approaches described below will make progress towards clinical applicability of the drill.

5 Conclusion and Outlook

Due to the short response time of the temperature sensor integrated in the drill, unpredictable temperature effects, such as those triggered by chips sticking together during the drilling process, are taken into account. In addition, changing environmental conditions and patient-specific bone characteristics can be taken into account, as these are reflected in the measured temperature. Thus, the further development of the drill with integrated sensor technology makes a valuable contribution to the understanding and investigation of the basic drill temperature during the drilling process. This reduces the risk of injury to endangered anatomical structures due to increased temperatures.

The goal of further research efforts is to further develop the drill in its clinical applicability. Furthermore, an intraoperative assistance system is being developed that processes the temperature data recorded during drilling and communicates it to the surgeon in the form of recommendations for action.

The focus of the following investigations is the working hypothesis that recommendations for action to optimize the process can be derived from the temperature data obtained during a medical drill using a model.

In order to be able to use the drill in the clinical environment, the material and geometry are adapted to the requirements of medical drilling. To this end, the diameter of the drill is being reduced and a study is being conducted to identify a drill geometry that generates as little heat as possible during drilling. The electronics that supply power to the data acquisition and sensor systems are being revised to achieve a wider speed operating range for the drill. This is particularly relevant for covering the widest possible parameter space for experimentation to determine the relationship between drilling base temperature and environmental as well as process parameters. In addition, data acquisition becomes possible even when the drill is at a standstill. Aspects of sterilizability and biocompatibility of the drill and its components must be implemented for use of the drill in the surgical scenario.

Experimental data will be used to determine the relationship between the base temperature of the drill and environmental and process parameters. To generate the data basis for the recommendations for action of the intraoperative assistance system, tests are carried out under reproducible test conditions on bone-equivalent material. The findings from the drilling tests must then be transferred to and validated on human bone. The validated test results are used to generate a model of the drilling process that depicts the relationship between drilling process, environmental and geometry parameters and the resulting drilling base temperature in such a way that the real-time temperature data can be used to derive recommendations for action to ensure a safe drilling process. Recommendations for action can, for example, suggest a reduction in the rotational speed if it is foreseeable that the current drilling process parameters will result in a critical temperature and exposure time being exceeded. In this way, a valid information basis can be made available to the surgeon during the operation. The surgeon can intervene in the process to control and reduce the risk of damage to the patient from the drilling process due to increased temperature.

Author Statement

The research project Mambo - "Metrological safeguarding of a drilling process in image-guided minimally invasive procedures using the example of the otobase" is funded by the DFG with a duration of 2 years.

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