Design and Thermal Testing of an Automatic Drill Guide for Less Invasive Cochlear Implantation[1]

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1 Background

Cochlear implants (CIs) can restore the perception of sound to individuals with severe to profound sensorineural hearing loss. The implanted component of a CI system is an electrode array inserted into the cochlea where it electrically stimulates the intracochlear nerve. Sound is picked up from the environment by an external microphone, filtered, processed, and then converted to electrical signals which are sent to the electrode array. The traditional surgical approach is invasive. A mastoidectomy is performed, in which a fairly large volume of the mastoid region of the temporal bone (approximately $40\,\text{mm} \times 30\,\text{mm} \times 25\,\text{mm}$) is milled away with a high-speed surgical drill to gain access to the cochlea. Vital anatomical structures such as the facial nerve and chorda tympani are embedded within the bone in this region and must be carefully avoided, making the surgery slow and challenging. Due to the invasiveness, risk, and expense of the procedure, many CI candidates do not receive an implant.

An alternative less invasive approach to CI surgery has been investigated by several research groups (e.g., Refs. [1] and [2]) in which a narrow hole is drilled from the skull surface directly to the cochlea, obviating the mastoidectomy. In addition to decreasing the invasiveness of the procedure, this approach has the potential to reduce costs, decrease operating room time, and allow less specialized surgeons to perform the surgery, enabling additional CI candidates to receive the implant.

The less invasive system discussed in this paper uses a patient-specific microstereotactic frame, called a microtable, to align the surgical drill along the desired drilling trajectory (see Fig. 1). Pre-

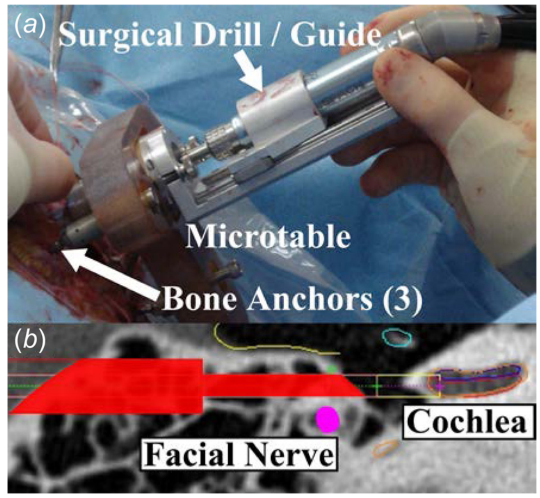

Fig. 1 (*a*) Less invasive CI surgical system consisting of a microtable and drill guide attached to the patient's skull and (*b*) CT scan showing two-stage drill path to cochlea passing close to facial nerve

operative imaging enables planning of a safe drill path to the cochlea that avoids the vital anatomy. Bone-implanted fiducial markers, which also serve as microtable mounting points, are inserted around the mastoid region in the operating room. The microtable is manufactured in several minutes based on an intraoperative computed tomography (CT) scan and the pre-operative planning. It is then assembled, sterilized, and mounted to fiducial markers on the patient. A custom drill guide is attached to the microtable and the surgeon manually moves the drill downward into the skull (see Ref. [1] for further system details). After the cochlea is accessed, the implant is inserted using specialized tools [3,4].

A challenge in this approach is to minimize the temperature rise associated with drilling through the mastoid bone. The drill path must pass very close to the facial nerve and chorda tympani (0.5 mm between the nerve and drill surface for some patients) so a large spike in temperature has the potential to damage these nearby nerves [5]. During earlier clinical trials using this system, one patient experienced temporary facial paralysis, believed to be caused by excessive heat at the facial nerve [6]. Like any material, the temperature rise in drilling through bone is related to the drilling parameters (spindle speed, feed rate, etc.) and material properties. Considering all of these factors such that the heat generation is kept at a safe level while manually drilling can be difficult. Thus, we hypothesize that an automated drill guide and trajectory can decrease the temperature rise, and thus the likelihood of heat-related trauma to the patient. Additionally, results from testing various drilling strategies can be used to guide the surgeons when performing the surgery manually with the current system.

2 Methods

The objective of this design was to develop an automatic drill guide that fits within the current minimally invasive CI surgical system used at Vanderbilt as well as a method for measuring the temperature rise at the facial nerve during the procedure. The motivation is twofold: first, the automatic guide can be used to test a variety of drilling strategies to help inform the surgeons when performing the drilling manually, and second, the automatic drill press may be integrated easily into the existing surgical protocol if there is a clear benefit over the manual approach.

The drill guide design is a simple lead screw driven slide that holds the surgical drill (see Fig. 2). A brushless motor drives the slide and the guide mounts to the microtable using a coupling that aligns the drill along the target axis. The drill trajectory parameters, e.g., continuous versus peck drilling, plunge speed, retraction

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Fig. 2 The automatic drill guide mounts to the microtable and is programmed to drill from lateral skull surface to the cochlea

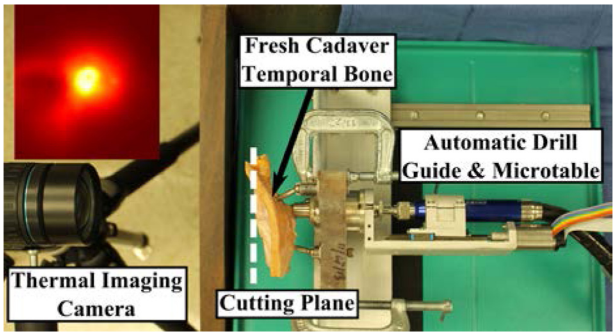

Fig. 3 Experimental setup for evaluating the temperature rise near the facial nerve during minimally invasive CI surgery, and image of heat distribution as the drill enters the middle ear for one trial

speed and distance, etc., can be selected easily by the surgeon in software. A computer interface allows the surgeon to control when the drilling starts and pause/stop the drilling at any time.

To evaluate the heat rise near the facial nerve for various drilling strategies, an experimental setup using ex vivo temporal bone specimens was developed. Bone anchors and fiducial markers were attached to the temporal bone specimen, a CT scan was acquired, and the standard trajectory planning and microtable manufacturing processes were completed. Using the mounted microtable as a reference, the temporal bone was cut perpendicular to the planned trajectory at the middle ear where the facial nerve is closest to the drill path (plane location measured in CT scan). The temporal bone was clamped to a table and a thermal imaging camera (FLIR A655sc with 50 μm close-up lens) was positioned such that it could monitor the temperature of the plane containing the facial nerve throughout the procedure (see Fig. 3).

Several trials were performed to evaluate the system and the experimental setup. Fresh human cadaveric temporal bones were used and different drilling strategies were employed, including constant velocity drilling at various rates and peck drilling. No irrigation was used in these trials, which represents a worst-case scenario and the bones were initially at 20 °C. For each bone, two trials were performed: one directed at the cochlea and another parallel to the first trajectory offset by 7 mm. The data were exported to MATLAB and the temperature distributions throughout the trajectories were analyzed.

3 Results

The initial experimental results indicate that high temperatures can arise near the facial nerve during this procedure when irrigation is not used. Figure 4 shows a plot of the temperature rise at a distance of 0.5 mm from the edge of the drill path on the cut plane.

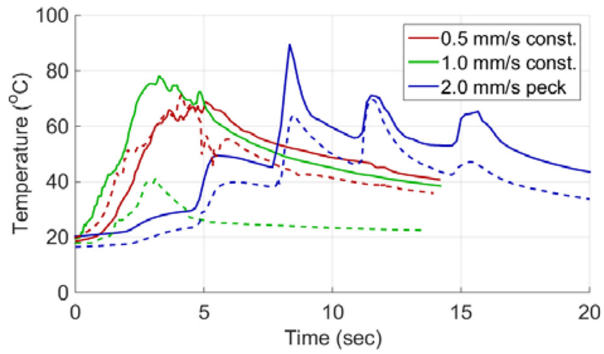

Fig. 4 Mean temperature on plane at a distance of 0.5 mm (average distance of facial nerve) from edge of drill path at middle ear throughout the drilling procedure. The solid and dashed lines represent the first and second trial for the parameter set, respectively.

It is clear that the temperature rise can be high for certain drilling strategies. Comparing the temperature distributions to the bone density (via image intensity values), higher temperatures are observed when drilling through denser bone. In particular, the 1 mm/s continuous velocity trajectory through the offset path (dashed line with peak at approximately 40 °C in Fig. 4) contained highly porous bone near the facial nerve and resulted in the lowest recorded temperatures at the cut plane in the middle ear.

4 Interpretation

The design developed is a very simple device that fits within the current framework of the minimally invasive surgical system and provides the ability to plan a variety of drilling trajectories. Currently, the automatic drill press is being used to test a range of drilling parameters in the laboratory to develop a surgical protocol for the manual drilling approach. Eventually, it may be incorporated into the clinical system. Initial experiments indicated that high temperatures are possible at the facial nerve with nonoptimized drilling parameters and no irrigation. Many more trials must be performed before any meaningful conclusion can be reached regarding the optimal drilling parameters, and various irrigation strategies must be explored to improve cooling at the drill tip. Additionally, it is likely that a patient-specific drill trajectory should be employed based on a thermal model that incorporates bone density information from the CT scan.

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