Computer-aided design/computer-aided manufacturing skull base drill

William T. Couldwell, MD, PhD,¹ Joel D. MacDonald, MD,¹ Charles L. Thomas, PhD,²
Bradley C. Hansen, PhD,² Aniruddha Lapalika, MS,² Bharat Thakkar, MS,² and
Alagar K. Balaji, PhD²

Departments of ¹Neurosurgery and ²Mechanical Engineering, University of Utah, Salt Lake City, Utah

The authors have developed a simple device for computer-aided design/computer-aided manufacturing (CAD-CAM) that uses an image-guided system to define a cutting tool path that is shared with a surgical machining system for drilling bone. Information from 2D images (obtained via CT and MRI) is transmitted to a processor that produces a 3D image. The processor generates code defining an optimized cutting tool path, which is sent to a surgical machining system that can drill the desired portion of bone. This tool has applications for bone removal in both cranial and spine neurosurgical approaches. Such applications have the potential to reduce surgical time and associated complications such as infection or blood loss. The device enables rapid removal of bone within 1 mm of vital structures. The validity of such a machining tool is exemplified in the rapid (< 3 minutes machining time) and accurate removal of bone for transtemporal (for example, translabyrinthine) approaches.

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KEY WORDS surgical drill; computer-aided design/computer-aided manufacturing; CAD-CAM; skull base

AUTOMATION in the field of surgery has been growing in the past decade. Medical robots have been built to assist in critical surgeries in diverse specialties such as orthopedic surgery (hip replacement), spine surgery (pedicle screw placement, vertebroplasty), and otorhinolaryngology (implantation of hearing aid devices), among others.^{1–5,11,14,18,20} Despite the advances in medical robotics, many surgical procedures continue to be performed manually by surgeons and are therefore more time consuming, adding to surgical expense, and are susceptible to human error. In many cases, robot assistance could reduce the overall duration of surgeries as well as minimize human error and the cost of surgery. In neurosurgery, the use of robots to assist with precise positioning of microsurgical tools and video navigation has been described.^{6,12,13,17} We assessed the need for automated systems for assisting

in neurological and other surgeries that involve machining through bone, tissue, and other anatomical structures. We developed a computer-aided design/computer-aided manufacturing (CAD-CAM) device that uses an image-guided system to define a cutting tool path in bone. Here we describe this automated skull base drill and demonstrate its proof of principle by machining the temporal bone opening for a translabyrinthine approach.

Description of the Device

The CAD-CAM drill system is an integrated surgical system with the capacity to use 2D CT scans of any portion of the body. As shown in Fig. 1, a processor connected to the output of the CT scan accepts the images and generates a 3D image of the respective part of the body. The sur-

ABBREVIATIONS CAD-CAM = computer-aided design/computer-aided manufacturing; CNC = computer numerical controlled.

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FIG. 1. Schematic of a method for using the automated drill system for surgery. NC = numeric control.

geon then uses these 3D images in a graphic interface to indicate the portion of bone or soft tissue to be machined in surgery (Fig. 2). The surgeon can use the integrated system software to define a location on the targeted portion of the patient to be drilled and can define the parameters of the machined hole, feature(s), or surface(s) (for example, the axis, radius, and depth). The processor will then generate an optimal tool path based on input from the surgeon, and this tool path is then delivered to a surgical tool (in most cases a drill; Fig. 3).

This automated surgical device is generally related to other computer-controlled systems for use in surgical applications involving machining of bone, other tissue, and/or other anatomical structures. The device provides a ro-

bust yet simple computer numerical controlled (CNC)² surgical cutting system interfaced with 3D medical image data.

The surgical machining system is configured to allow the machining tool to operate within a simple yet robust 5-degrees-of-freedom operating environment, which allows the hole or finished surface to be machined at any angle and any position as defined by the surgeon. The surgical machining system interfaces with software that controls the surgical cutting system.

In the proof of principle, the surgical machining system uses a cutting tool such as a drill. The system is registered in three-dimensional space following fixation to the Mayfield head holder. Safety features include an emergency

FIG. 2. The 3D images are displayed in a graphic interface so the surgeon can indicate the portion of bone or soft tissue to be machined.

switch to turn off the drill in case of difficulty and electromyography feedback from facial nerve monitor activity, which will turn off the drill with a statistical increase in facial nerve irritation (dead man cutoff). The surgical machining system is based on a rigid mechanical design associated with multi-axis kinematics enabling motion along the designated surgical path. An appropriate safety zone around the drill can be designated at the planning stage based on the 3D image-based data and integration, with added specific input that will limit the motion of the drill only within this space.

Proof of Principle

The device has been used to drill cadaveric temporal bone in a preclinical model (Video 1).

VIDEO 1. Video demonstrating the function of the prototype drill.

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The translabyrinthine approach is commonly used for the removal of vestibular schwannomas of all sizes, usually in patients with significant hearing loss. This situation represents an ideal application for the automatic drill because the shape of the removed bone is essentially a complex funnel. Proximity to the major venous sinuses (sigmoid and transverse) and the facial nerve in this approach demands surgical expertise and slow, careful progressive drilling to avoid injury. With the current manual process, the patient is susceptible to injuries to these structures from human error. Having the surgical wound open for a longer period of time also increases the chance of infection, which can further complicate postoperative care. In addition, it can take a long time (hours) to drill the hole in the temporal bone for intracranial access in temporal bone procedures.

Considerable time can be saved with the CAD-CAM system, as compared with a manual approach, with equiv-

alent accuracy (within 1 mm) to decrease the risk of injury. This accuracy is ensured based on the rigidity of the designed system and the ability to incorporate a safety “no-fly” zone along the CNC drill path during surgical planning (Figs. 4–6). After the mobile drill system is affixed to the rigid head holder, registration of the device is performed in the same manner as in existing image-guided systems. The device is used to remove the majority of the bone quickly (Video 1), and the surgeon performs the final drilling (for example, unroofing the facial nerve canal).

The results indicate that the bone has been drilled with great accuracy, and vital structures are avoided with a buffer of 1–2 mm. This buffer is a function of the rigidity associated with the robotic drill’s structural platform, the inherent robustness of the CNC controller, and the detailed mapping of the 3D images. As long as the 2D images are scanned correctly and integrated into an accurate 3D image-based model, the rigidity of the surgical system and the robustness of the kinematics of the machining tool will enable a typical accuracy buffer well within 1 mm. The rigidity of the designed surgical system accords with the corresponding rigidity of anatomical features. Any changes in the position of bone will need to be accounted for at the registration step.

Discussion

Many medical robots are being developed to assist with surgery. The ROBODOC device, developed for use in orthopedic surgery, was initially associated with disadvantages related to muscle damage, high revision rates, and longer surgeries.⁹ Subsequent applications in hip replacement and knee arthroplasty have demonstrated improved results with newer designs.^{10,16,19} Applying the da Vinci robotic system, widely used in general surgery and urology,⁸ has revealed that the device has limited application

FIG. 3. Upper: Schematic demonstrating the software interface with the surgical machining system. **Inset:** An enlarged view of the machining tool. **Lower:** Photograph showing the surgical machining system with the attached surgical arm and machining tool. The tool is affixed to the Mayfield head holder prior to registration.

in intracranial surgery. Despite advances in medical robotics, many surgical procedures continue to be manually performed by surgeons and are therefore more time consuming, more expensive, and susceptible to human error. Drilling the temporal bone for access to skull base tumors is currently performed manually, often with enhancement by image guidance.

In a freehand drilling exposure through the temporal bone, the surgeon must rely on the information she or he has from any preoperative images and early recognition of vital structures, such as the facial nerve, internal auditory canal, and transverse or sigmoid sinus. Integrity of these structures is a surgical imperative. Reducing the possibility for human error for much of the bone removal will improve surgical outcome.⁷ The expense of having a surgeon perform the drilling of the temporal bone for several hours adds to the already high cost of these surgeries.

Additionally, having the lesion open for such long time periods makes the patient susceptible to infection, which can further complicate health issues. Thus, there is a justifiable need for automated systems and methods for assisting in neurosurgeries and other surgical procedures that involve machining through bone, tissue, and/or other anatomical structures. Recently, Lim et al. developed a robot for otological surgery that uses human-robot collaborative control.¹⁵ Our system eliminates the surgeon's involvement in the drilling steps once the drilling path information has been entered. The goal in developing and using these robotic systems is to reduce the duration of surgeries and to minimize human error and the overall cost of surgeries.

Conclusions

This simple, inexpensive CNC surgical cutting system

FIG. 4. Coronal (A) and axial (B and C) left temporal bone CT scans demonstrating the outline of the sigmoid sinus and jugular bulb. The sinus is outlined to develop a no-fly zone for the drill.

interfaces with 3D medical image data to enable computerized machining of complicated openings such as in a translabyrinthine approach. Such systems can provide accurate, rapid machining of the temporal bone to enhance accuracy, reduce operating time, and prevent complications (injury and infection) related to opening. The machine is designed to rapidly remove bone to within a 1-mm distance from vital structures (for example, transverse or sigmoid sinus and the facial nerve in the fallopian canal).

FIG. 6. Axial left temporal bone CT images (A–D) showing the course of the facial nerve (arrow) through the temporal bone to its exit at the stylomastoid foramen. The system software is designed to develop a no-fly zone for the drill.

This is performed with accuracy and speed (2 minutes 30 seconds to remove bone). Such rapid removal of bone will enable shorter anesthesia times, reducing the risk of surgery-related complications. Other tools such as an ultrasonic aspirator or a noncontact tool such as a laser can also be interfaced with the device for use in other surgical applications.

FIG. 5. Coronal left temporal bone CT scans demonstrating the course of the facial nerve (arrow) as it exits the internal auditory canal (A), through its course in the temporal bone (B–D).

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Disclosures

On February 24, 2015, the authors were issued Patent US8965485 B2 for the device discussed in this paper. The device is to be commercialized, but to date the inventors have received no royalties.

Author Contributions

Conception and design: Couldwell, MacDonald, Thomas, Balaji. Acquisition of data: all authors. Analysis and interpretation of data: all authors. Drafting the article: Couldwell, MacDonald. Reviewed submitted version of manuscript: Couldwell. Approved the final version of the manuscript on behalf of all authors: Couldwell. Administrative/technical/material support: all authors. Study supervision: Couldwell.

Supplemental Information

Videos

Video 1. <https://vimeo.com/207124380>.

Video Abstract. <https://vimeo.com/211353210>.

Correspondence

William T. Couldwell, Department of Neurosurgery, Clinical Neurosciences Center, University of Utah, 175 N Medical Dr. East, Salt Lake City, UT 84132. email: neuropub@hsc.utah.edu.