Monopolar Cautery and Adverse Effects on Cochlear Implants

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IMPORTANCE The use of monopolar cautery has been widely regarded as a contraindication in the setting of a cochlear implant because of presumed risk to the implant device. There are very limited data to support this contraindication.

OBJECTIVES (1) To evaluate the effects of monopolar cautery on cochlear implant devices. (2) To determine whether monopolar cautery changes the endocochlear temperature in an implanted cochlea.

DESIGN Sixteen cochlear implants from 3 manufacturers (Advanced Bionics LLC, Cochlear Americas Ltd, and Med-El Ltd) were implanted into 2 unembalmed, fresh cadavers. Monopolar cautery was applied to either the tongue or abdomen at coagulation settings of 10 W or 50 W for 30 minutes. Impedance and integrity testing were performed before, during, and after 30 minutes of cautery. The temperature in the endocochlear perilymph was measured during cautery. After explantation, devices were returned to the manufacturer for an in-depth “failure” analysis according to each manufacturer’s current protocol evaluating explanted devices.

SETTING Basic science laboratory, tertiary medical center.

PARTICIPANTS Cadaveric study.

INTERVENTION Application of monopolar cautery to implanted cochlear implants in a cadaveric model.

MAIN OUTCOME AND MEASURE (1) Changes to the implanted devices either during electrocautery or following failure analysis. (2) Changes in the intracochlear temperature.

RESULTS No change in impedance, integrity testing, or failure analysis occurred at any cautery setting when applied to either the oral cavity or abdomen. The temperature of the cochlea did not increase with up to 30 minutes of cautery at a setting of 50 W. Comprehensive device analysis did not show any evidence of device damage at the conclusion of the study.

CONCLUSIONS AND RELEVANCE Monopolar cautery did not produce detectible damage to any of the cochlear implant devices or produce detectible temperature change in the cochlea at low or high levels of cautery in the oral cavity in this experimental model.
The use of monopolar cautery has been widely regarded as a contraindication in the setting of a cochlear implant because of presumed risk to the implant device. Each of the 3 cochlear implant manufacturers has issued statements advising against the use of monopolar cautery once the implant is in place. There are, however, very limited data cited to support this contraindication, and reports in the literature are conflicting regarding the safety of electrosurgery in these patients.

The concerns are 2-fold. First, the electrical current may damage the device itself; second, the heat generated through electrosurgery may damage the auditory neurons when the electrode array is within the cochlea.

Cochlear Americas Ltd\(^1\) is the most clear in their statement regarding the use of electrosurgery in implanted patients. They state that

> Electrosurgical instruments are capable of inducing radio frequency currents that could flow through the electrode array. Monopolar electrosurgical instruments must not be used on the head or neck of a cochlear implant patient as induced currents could cause damage to cochlear tissues or permanent damage to the implant. Bipolar electrosurgical instruments may be used on the head and neck of patients, however, the cautery electrodes must not contact the implant and should be kept more than 1/2 in (-1 cm) from the extracochlear electrodes.

Med-El Ltd\(^2\) issued the following statement: “Monopolar electrosurgical instruments, including cautery, must not be used in the vicinity of the cochlear implant, as they can induce current levels in the implant electrodes that may cause damage to the neural tissues and/or destroy the implanted device." Advanced Bionics LLC\(^3\) stated that “Electrosurgical instruments must not be used within the vicinity of the implant or electrode. Electrosurgical instruments are capable of producing radiofrequency voltages of such magnitude that a direct coupling might occur between the cautery tip and the electrode. Induced currents could cause damage to the cochlear tissues or permanent damage to the implant.”

A prior study\(^4\) has examined the effects of monopolar electrosurgery on cochlear implant devices implanted into cadaveric pigs and found no damage to the implants. The objective of this study is to determine whether monopolar cautery after placement of a cochlear implant damages the cochlear implant or produces thermal change in the cochlea in a human cadaver model.

### Methods

Advanced Bionics LLC, Cochlear Americas Ltd, and Med-El Ltd were contacted and asked to donate cochlear implant devices for a study to test the effects of monopolar cautery on the device. All 3 manufacturers agreed to participate. Advanced Bionics LLC donated 4 HiRes 90K devices. Med-El Ltd donated 4 Concert devices and 4 Pulsar devices. Cochlear Americas Ltd donated 4 Nucleus Freedom devices. Each of the 3 companies sent a representative to perform intraoperative integrity and impedance testing. All of the manufacturers had knowledge of the protocol of the study but were blinded as to which device underwent which protocol. All manufacturers performed their own blinded analysis but did not participate in the data analysis or preparation of the manuscript.

Two fresh, unembalmed, human cadavers were used for the experiment. Two cadavers were used for the study because it was completed on 2 separate days. The cadaver was positioned supine, and the grounding pad was placed on the right leg. A skin incision was made and followed by mastoidectomy and drilling of the facial recess by standard methods. A cochleostomy was made anterior to the round window. One device from each company was used for each separate protocol. Full insertion was achieved for each implant.

Monopolar electrosurgery was performed with the Valley Laboratory Force FX electrosurgery generator with the E2515 electrosurgery pencil and E1650 tip (commonly called the “Colorado tip”) (all from Covidien).

Each device was tested at the factory prior to shipping to ensure normal function. Integrity and impedance testing was performed by standard methods before implantation, after implantation, and before electrosurgery. Using the first device from each of the 4 models, monopolar cautery in coagulation mode at a setting of 10 W was applied to the tongue. Using the second device of each model, monopolar cautery in coagulation mode at a setting of 50 W was applied to the tongue. Using the third device from each of the 4 models, monopolar cautery in coagulation mode at a setting of 10 W was applied to the abdominal skin and subcutaneous tissues. Using the fourth device of each type, monopolar cautery in coagulation mode at a setting of 50 W was applied to the abdominal skin and subcutaneous tissues.

Impedance and integrity testing was repeated after 1 minute of electrosurgery, 5 minutes of electrosurgery, 10 minutes of electrosurgery, and at completion of 30 total minutes of electrosurgery for each device. The testing was done by a trained representative from each manufacturer who was blinded to the cautery setting and the site of application during testing.

Temperature was measured using an Omega thermocouple probe (model No. SC-TT-K-30-36) and Omega electronic reader (model No. HH11b). After inserting the cochlear implant, the thermocouple probe was inserted into the basal turn of the cochlea. Temperature was measured throughout the 30 minutes of electrosurgery and recorded. Temperature was measured in conjunction with each of the 4 Cochlear Americas devices. Temperature measurements were incorporated into the second day of testing. Only the 4 Cochlear Americas devices were tested on the second day of testing.

After device removal, devices were repackaged, sealed, and returned to the manufacturer for in-depth, piece-by-piece analysis to look for any damage caused by electrosurgery. The manufacturer was blinded to the setting and location of cautery used for each device.

Of note, 1 of the Med-El Concert cochlear implant devices was structurally damaged during shipping prior to the experiment, rendering it unusable. Therefore, electrosurgery at setting of 10 W to the abdomen was omitted for this device.
Monopolar Cautery & Adverse Effects on Cochlear Implants

Results

The protocol was completed for 15 devices. As stated in the Methods section, 1 Med-El Concert device was structurally damaged in shipping and could not be implanted. Full insertion of all electrodes was achieved for each device.

Cochlear Implant Analysis

At each measured time point and at the end of 30 minutes of cautery, there was no change in the impedance or integrity testing for all 15 implants tested. In-depth analysis of each component of the cochlear implant did not show any evidence of electrical or thermal damage to the device.

Cochlea Temperature Analysis

Temperature at the basal turn of the cochlea was measured for each of the 4 Cochlear Americas Nucleus Freedom implants. This included 30 minutes of cautery at a setting of 10 W and 50 W to either the tongue or abdomen. There was no increase in temperature in the cochlea at any point during 30 minutes of cautery. The Table lists the starting, final, and interval temperature measurements for each of the 4 devices.

Discussion

Many patients who receive a cochlear implant will require an additional surgical procedure in their lifetime. Though less common, some patients with cochlear implants may even require emergency surgery. Concern that surgical devices may render a cochlear implant unusable may create anxiety in patients or parents. Our goal is to determine whether electrosurgery is potentially harmful in patients with cochlear implants. This initial study from our laboratory found no damage to any of the cochlear implant components to electrosurgery in patients with a cochlear implant.

Electrocautery is the use of electricity through an alter- nating current to heat the tip of an object, such as a Shaw scalpel, that can be used to burn tissue. Electrosurgery devices, such as the Bovie, however, use radiofrequency energy delivered through an electrode and applied directly to tissues. The energy is transferred to the tissues, and heat is generated through the electrical resistance of these tissues. The ability to alter tissues relies on the electrical current density. The operating tip electrode has a small contact area and generates higher current density and therefore higher heat. In monopolar electrosurgery, the electrical signal travels through the patient’s body to a distant electrode (the dispersal or grounding pad) containing an electron reservoir with a larger contact surface area. The density of electrons diminishes rapidly as the distance from the operating electrode increases, even within a few cell layers. Therefore, cellular damage is limited to the area of dissection. In addition, the electric current always travels in the path of least resistance, from the operating electrode to the dispersal pad. In bipolar surgery, the 2 electrodes are in close proximity, such as in the 2 tines of forceps, and the current travels only between these 2 electrodes, not through the body.

The cochlear implant devices also use a radiofrequency current to transmit signal from the external transmitting coil to the receiver-stimulator implant. The receiver-stimulator then delivers electric stimulation pulses to the electrode array. The electrodes stimulate neural elements within the cochlea through a series of bipolar current pulses.

Numerous articles and authors have raised concern regarding the use of electrosurgery in patients with cochlear implants. However, none of these articles cite an explanation for this contraindication or data to support it. Many opponents to electrosurgery in patients with a cochlear implant cite the demonstrated potential for detrimental effects to cardiac pacemakers and extrapolate this to cochlear implants.

Antonelli and Baratelli performed a study in cadaveric pigs, applying monopolar electrical current at a setting of 50 W for 15 minutes to the nasopharynx. They tested 12 Cochlear Americas and Med El devices and found no damage to the implants. Poetker et al evaluated neural response telemetry before and after the use of monopolar electrosurgery during open heart surgery in a single living patient. They found no damage to neural integrity or the cochlear implant device.

A single published study has shown damage to an implant device following electrosurgery. Roberts et al performed a human cadaveric study looking at the effect of dental devices that emit radiofrequency on cochlear implants. A human cadaver head was used, but this study does not specify whether the cadaver was embalmed or preserved, which could alter the electrical current transmission. Roberts et al found irreparable damage when monopolar cautery was applied to the gingiva at a high setting (7 W) but not at low settings (3 W and 5 W) using a Dento-Surg model 90 FFP device (Ellman) and no damage with bipolar cautery. It is unclear how these settings compare with the more commonly used electrosurgical devices in the operating room. The site of the return electrode, or grounding pad, was not stated. In addition, a single cochlear implant was tested, and this single implant was used to test numerous electric current emitting dental devices. While this study does find that interference or damage may be in-

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Abbreviation: ND, no data.

*All data are given as temperature readings in degrees Celsius.

b The temperature probe fell out of the cochlea, and when checked at the end of 1 minute the reading was 18.5°C. The room temperature was also measured at 18.5°C.
duced by monopolar electrosurgery, it does not provide definitive evidence or usable guidelines.

Monopolar electrosurgery settings of 10 W and 50 W were chosen for the present study. A setting of 10 W was selected to study a low current that would still be clinically useful. A current of 50 W was chosen because settings at or higher than 50 W are rarely used at head and neck sites. Although sometimes higher settings may be used in a general surgery setting, we chose 50 W for the abdominal site as well to maintain a consistent protocol.

To our knowledge, this is the first study to examine heat changes in an implanted cochlea during electrosurgery. Previous authors have hypothesized that electric current coupling to the cochlear implant electrode array could lead to heat generation and thereby damage to the stria vascularis or other aspects of the cochlea. Our study did not demonstrate any heat changes to suggest a potential mechanism for thermal cochlear damage.

There are several limitations to our study. The most significant limitation is the use of cadavers for the study. Although the cadavers were unembalmed, there may be differences in the current flow between living and nonliving tissues. Second, heat changes were measured only at the basal turn owing to the configuration of the thermocouple probe and in only 4 of the devices. A small amount of saline was added to the cochlea to ensure that all electrodes of the implant were covered. Because the cadaver was lower in temperature than the saline, the temperature actually decreased throughout the 30 minutes of cautery.

The third limitation is that only electrosurgery in coagulation mode was tested. In cutting mode, there is a uniform, constant sinusoidal output of current to the tissues. In coagulation mode, higher voltage peaks are used, but these alternate with periods of no current flow. The coagulation mode results in a higher peak voltage than the cutting mode. Further research is needed to determine whether electrosurgery in the cutting mode affects cochlear implants.

We are not advocating use of monopolar cautery in patients with a cochlear implant. There are not enough data at this point to show whether this is safe. The importance of this study, however, is significant. The data in this study provide grounds to encourage further research into this area. Multiple additional investigations must be performed to determine what effects, if any, monopolar electrosurgery has on either the cochlear implant device or the implanted cochlea. Additional investigations are currently under way in our laboratory to study this further.

In conclusion, monopolar cautery did not produce detectable damage to any of the cochlear implant devices or produce detectable temperature change in the cochlea, at low or high levels of cautery in the oral cavity, in this experimental model. Prior to advocating any change of the current recommendations regarding electrosurgery and cochlear implantation, further study is necessary of different electrosurgical settings, current flow, and in vivo analysis.

ARTICLE INFORMATION
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Study concept and design: Jeyakumar, Wilson, Brickman, and Arriaga.
Acquisition of data: Jeyakumar, Wilson, Sorrel, McIntire, Jones, Brickman, Arriaga.
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Additional Contributions: Cochlear implant devices were provided free of charge from Advanced Bionics LLC (4 devices), Med-El Ltd (8 devices), and Cochlear Americas Ltd (4 devices). Analysis of the devices was performed free of charge by each respective manufacturer. The costs of specimen preparation were paid by all 3 manufacturers. We thank Richard Whitworth, PhD, for providing the temporal bones and for his full support of the study, Cochlear Americas Ltd for their technical support and provision of the devices, Med-El Ltd for their technical support and provision of the devices, and Advanced Bionics LLC for their technical support and provision of the devices. The study would not have been possible without the donors of the cadavers and their families.
REFERENCES