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## SHAW SCALPEL IN REVISION COCHLEAR IMPLANT SURGERY

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The use of traditional electrocautery is prohibited in revision or replacement cochlear implant surgery because of the concern for end organ tissue damage. Additionally, electrical current spread to the malfunctioning device could interfere with an accurate cause-of-failure analysis. Clinical reports have confirmed the utility of the Shaw scalpel for dermatologic, ophthalmic, and head and neck surgery. The Shaw scalpel is a thermally activated cutting blade that provides a bloodless field through immediate capillary and small vessel hemostasis. Avoidance of wound and flap complications is of primary concern in cochlear implant surgery. The long-term wound healing compared favorably to that of other surgical cutting instruments in several experimental reports. We have routinely used the Shaw scalpel in revision cochlear implant surgery and in primary surgery whenever electrocautery was contraindicated. We have retrospectively evaluated 22 cases in which the Shaw scalpel was used for cochlear implant revision and primary surgery. The chart review included patient demographics, the indication for surgery, the contraindication for electrocautery, intraoperative surgical notes, the wound healing evaluation, the evaluation for alopecia, and postoperative speech understanding. No significant complications occurred intraoperatively, and the long-term wound healing results were no different from those obtained with conventional surgical techniques. The explanted devices were undamaged, and valuable diagnostic information could be obtained. All patients performed at or better than their preoperative levels on speech recognition testing. Our results indicate that the Shaw scalpel is a relatively safe, easy-to-use, and effective instrument.

### INTRODUCTION

Two conditions exist in which electrocautery may be contraindicated in cochlear implant patients: 1) revision and other head and neck surgery in a patient with a cochlear implant and 2) primary cochlear implantation in a patient with another electronic medical device. Electrocautery instruments are used in nearly all surgical procedures. Monopolar devices rely on electrical current passing from a small-tipped, handheld instrument to a large

grounding pad applied to the patient at a distance from the operative field. Heat generated at the tip enables vessel coagulation for hemostatic purposes. In a bipolar device, the current only passes between 2 points at the instrument tip. Current spread through or near an implanted medical device could damage the device, cause device discharge, cause device heating, and potentially damage the organ or tissue to which the device is attached.

The use of electrocautery in the patient with a cochlear implant is potentially harmful to the patient and the device. Current spread through the device would undoubtedly cause changes in the device settings and possibly cause permanent device damage. Severe morbidity has occurred in pacemaker patients when electrocautery was used during a procedure.<sup>1,2</sup> Additionally, the transmission of current and heat to the spiral ganglion cells might have severe obvious consequences. It is for these reasons that all electrocautery machines are turned off and disconnected from the patient once the device is brought onto the sterile field during primary cochlear implant surgery. Fortunately, all needs for hemostasis have been satisfied at the point in the operation when device electrode insertion occurs.

In performing revision cochlear implant surgery and other head and neck surgery in patients with cochlear implants, an alternative to electrocautery must be used for hemostasis. Possibilities include standard clamp and tie techniques, bipolar electrocautery, laser, and the Shaw scalpel. The Shaw heated scalpel (Hemostatix Medical Devices) can provide better hemostasis than a regular sharp scalpel without the transmission of current to the patient (Fig 1). This device utilizes a sharp heated cutting



Fig 1. Shaw scalpel consists of Teflon-coated regular-size 15 or 10 blade with microcircuitry that is attached to handle with controls for increasing and decreasing temperature. Additional control on superior knife surface provides surge to increase temperature for larger-vessel coagulation. Handle is connected to control box by way of wire cable. Adjustable current passes through blade, causing heating without current's passing into patient.

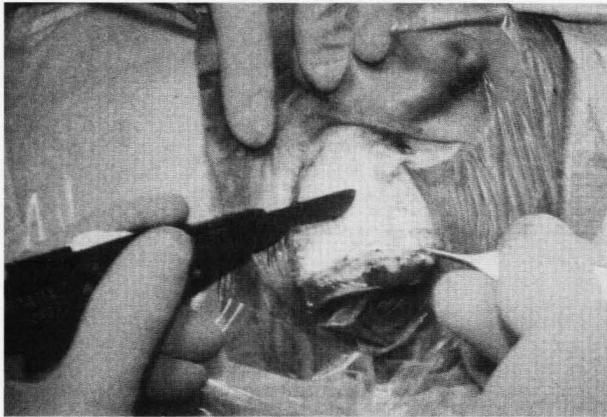


Fig 2. Bloodless incision is made and posteriorly based postauricular flap is raised with Shaw scalpel.

blade for simultaneous cutting and coagulation (Fig 2). Histologic analysis of wounds caused by any device that generates heat has shown delays in the early phases of healing without complications or ultimate reduction in strength.<sup>3,4</sup> Several reports attest to the safety and lack of wound healing complications with the Shaw heated scalpel.<sup>3,5</sup>

To evaluate the effects of the Shaw scalpel on wound healing and on patient and device outcome, we retrospectively reviewed cases in which electrocautery was contraindicated and the Shaw scalpel was used.

MATERIALS AND METHODS

A chart review was conducted on the 400 cochlear implant recipients fitted with implants at the New York University Medical Center Cochlear Implant Program. The study population consisted of 22 patients in the following groups: 17 patients were identified who underwent revision or reimplantation cochlear implant surgery, 1 patient underwent device removal, 1 patient was reoperated for a cerebrospinal fluid leak, 1 patient had an acoustic neuroma removed from the side opposite an existing cochlear implant, 1 patient had cochlear implantation performed

in the side opposite an auditory brain stem implant, and 1 patient had a pacemaker in place. The Shaw scalpel was used in place of electrocautery in all patients in the study population.

Patient demographics, indication for surgery, length of time from original implantation until second surgery, contraindication to electrocautery, explanted device, implanted device, postoperative wound healing, and evaluation for alopecia were recorded. Wound healing was recorded as either delayed or normal. Alopecia was recorded as either present or absent. Postoperative speech understanding scores were recorded as the same as, better than, or worse than the preoperative levels. Postexplantation cause-of-failure analysis was recorded as either possible or not possible. Additionally, the intraoperative surgical and nursing notes were reviewed for mention of unusual complications and blood loss.

RESULTS

The results of this retrospective analysis are presented in the Table. There were no wound healing delays, and alopecia was not observed. The cause-of-failure analysis was obtainable in all applicable cases. The speech understanding results were the same as or better than the preoperative results in all 22 patients. A cause-of-failure result of "not applicable" relates to patients with older Ineraid and House 3M single-channel devices, in whom no failure analysis was conducted or no device was explanted. Patient 10 was operated on to reposition an electrode array that was originally placed in an extracochlear position at another institution. She had severe cochlear dysplasia. Patient 17 had a pacemaker. Patient 18 had neurofibromatosis type 2 and a nonfunctioning auditory brain stem implant on the opposite side. Patient 20 had acoustic neuroma surgery on the side opposite a well-functioning cochlear implant. Patient 22 was reexplored for a cerebrospinal fluid leak after cochlear implantation. She also had severe cochlear dysplasia. In all cases, a review of the operative notes and nursing notes failed to reveal complications, and subjectively, blood loss was minimal.

RESULTS

	Patient Number																					
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Age (y)	36	34	64	72	62	68	3	7	3	5	3	12	53	43	5	38	73	53	11	36	43	2
Sex	M	F	M	M	M	M	M	F	M	F	F	M	F	M	F	F	M	F	M	F	F	F
Cause of deafness	U	U	U	O	T	U	C	CMV	C	C	C	U	O	U	CMV	T	O	NF2	C	RAN;	M	C
Reason for surgery	F	F	I, U	U	F, U	I, U	F	F	F	RP	F	F	F	F	F	F	1°	1°	F	1°	F, U	CSF
Time from implant to 2nd surgery (y.mo)	10.2	6.11	7.11	8.6	8.1	6.9	4.4	4.6	1.8	0.5	0.2	0.3	0.1	0.4	0.3	9.0	NA	NA	0.3	NA	1.8	0.5
Contraindication to electrocautery	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	P	ABI	D	D	D	D
Failure analysis	+	+	NA	NA	NA	NA	+	+	+	NA	+	+	+	+	+	+	NA	NA	+	NA	NA	NA
Speech result	0	+	+	+	0	+	0	+	+	+	+	+	+	0	+	0	+	+	+	+	+	+
Explanted device	N22	N22	IN		3M	IN	N22	N22	N22		N22	N22	N22	N22	N22	N22			N24	N24		3M
Implanted device		N22	N22	N22	N22	N22	N22	N22	N22		N22	N24	N24			N22						

Wound healing was normal (not delayed) in all patients, and alopecia was absent.

Causes of deafness: U — unknown, O — otosclerosis, T — ototoxicity, C — congenital, CMV — cytomegalovirus, NF2 — neurofibromatosis type 2, AN — acoustic neuroma, M — meningitis. Reasons for surgery: F — failure, I — infection, U — upgrade, RP — reposition, 1° — primary surgery, CSF — CSF leak. Contraindications to electrocautery: D — device, P — pacemaker, ABI — auditory brain stem implant. Failure analysis: + — analysis possible, NA — not applicable. Speech results: 0 — unchanged, + — improved. Explanted/implanted devices: N22 — Nucleus 22, IN — Ineraid, 3M — House 3M single-channel, N24 — Nucleus 24M.

## DISCUSSION

Concerns about electrocautery-induced damage and the need for hemostasis led to the utilization of the Shaw scalpel in revision cochlear implant surgery. The original surgical wounds were reopened in all revision cases, and standard surgical approaches were used in the other cases. Subjectively, we have found this instrument to be easy to use with only slight modifications in surgical technique over the use of a regular scalpel blade. Surgery on the acoustic neuroma patient did not require more time because of the lack of electrocautery availability, and total blood loss was no different from that in other, similar procedures.

Because the blade temperature is adjustable and can reach a maximum temperature of 280°C, the surgeon should use caution when working near important structures. This is especially prudent in very young children, in whom the facial nerve is in a more superficial position near the mastoid tip. The use of the Shaw scalpel was found to be a significant risk factor for facial nerve weakness in primary parotid surgery.<sup>6</sup> The heat generated from the electrocautery is of similar risk in regions in which the facial nerve is in close proximity. Heat generated in the blade might also melt the silicone covering of some cochlear implants, and therefore the heated blade should not contact the device. Interestingly, one report in the literature outlines the advantages of using the Shaw scalpel to achieve a smooth contour in carving silicone blocks for various implants.<sup>7</sup>

All explanted devices are returned to the factory for cause-of-failure analysis. There was no evidence of further thermal or electrical device damage from the explantation process in the returned devices. Electrical current

or mechanical forces might further damage an explanted device, preventing the acquisition of helpful analysis information.

There was no evidence of damage to the spiral ganglion cells or their central projections in this study. All patients tested at levels equivalent to or better than their preoperative performance. Any instrument that has the potential to damage the neural elements of the auditory system should be avoided in primary and secondary cochlear implant procedures.

## CONCLUSION

The Shaw scalpel is a relatively safe and effective instrument for revision cochlear implant surgery and for use in patients with other implanted medical devices.

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## MASTOIDITIS AND ACUTE OTITIS MEDIA IN CHILDREN WITH COCHLEAR IMPLANTS: RECOMMENDATIONS FOR MEDICAL MANAGEMENT

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Acute otitis media (OM) or mastoiditis is a very dangerous condition for the ear after cochlear implantation. However, acute OM is very common in childhood and can occasionally occur in an implanted ear. Most cases of acute OM can be successfully treated with intravenous high-dosage antibiotics. In cases of mastoiditis and clinical signs of mastoid abscess, retroauricular drainage is necessary to prevent infection of the implant bed. In a series of 366 children given implants (1 to 14 years), acute OM occurred in 5.6% during a follow-up period of 1 to 8 years. Seven ears had to be opened by means of myringotomy. Five ears were opened by retroauricular incision with mastoid revision on the implanted side. Adenoidectomy and use of ventilation tubes before cochlear implantation, as well as careful subtotal mastoidectomy during the implantation, can reduce the incidence of acute OM in children after implantation. Early and subsequent treatment with operative mastoid drainage can prevent implant loss and should be performed at the implantation center.

## INTRODUCTION

Over a period of more than 12 years, cochlear implantation has been performed in more than 1,250 patients at the Department of Otolaryngology, Medical University of Hannover. In most cases, a Nucleus device (Cochlear Pty Limited, Lane Cove, Australia) was used. For the last 4 years, the intracochlear Clarion device (Advanced Bionics) has additionally been used in children, as well as in

adult patients.<sup>1</sup> Complications in cochlear implantation are defined as minor (no or conservative treatment), major (revision surgery, meningitis, implant loss, facial nerve injury), intraoperative (gusher, obliteration), early (immediately and up to 3 months after surgery), and delayed (more than 3 months after surgery, eg, cholesteatoma, electrode dislocation, device failure). For this investigation, we evaluated the rate and outcome of severe postimplan-