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Prospective Evaluation of Intra operative Nucleus 22-channel cochlear implant Radiographs

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Abstract: *To investigate the clinical utility of intra operative plain radiographs in cochlear implant surgery. Eighty consecutive adult and pediatric cochlear implant operations at a facility capable of intra operative radiographs were evaluated over 06 months. A carefully designed study to evaluate the performance of individuals who received the Nucleus 22-channel cochlear implant. All patients were profound-totally deaf, adults with a post lingual onset of impairment. The preoperative evaluation, prosthesis fitting, training, and postoperative testing were consistent across clinics . Single- subject studies, where each patient acted as his/her own control, revealed that of the 80 subjects, 16–24 obtained significant improvement (P~0 .001) on unpracticed, unfamiliar recorded speech tests from the Minimal Auditory Capabilities (MAC) Battery, when using hearing alone (no lip-reading). In addition, virtually all patients showed improvement in recognition of speech material with lip-reading. The data support the efficacy of a feature extraction coding system where specific formant and amplitude information are transmitted via direct electrical stimulation to the cochlea.*

I. Introduction

The two most common approaches have been to stimulate the cochlea with one electrode (single channel) or more than one electrode (multichannel). Both systems can be divided into those that deliver the speech signal without speech specific processing or those that extract the speech features in some way (2) . The primary rationales for multichannel stimulation are to provide more information and to take advantage of the tonotopic organization of the cochlea.

The purpose of this paper is to provide a description of a technologically advanced 22-electrode speech feature extraction type cochlear prosthesis and to present some preliminary results of the clinical study to date.

Preoperative Patient Selection

The primary criteria for selection of cochlear implant candidates are

1) Postlingually deafened;
2) Profound deafness, bilaterally ;
3) 18 years of age or older;
4) No benefit from any sensory device (tactile or hearing aid) as defined by less than 1 percent open-set discrimination when aided; and
5) Positive CAT scan or tomogram demonstrating patency of the basal turn of the scala tympani.

There are three stages of evaluation. If the patient is considered suitable after completing the first stage, he or she progresses to the next. The initial steps Stage I are those taken to evaluate patients before they are considered as implant candidates. During this stage the degree of hearing loss is established and trials with new hearing aids are conducted if inappropriate amplification has been provided in the past. It is in stage I that promontory stimulation is performed. It is administered by placement of an electrocochleography needle electrode on the promontory. Those patients who do not obtain any sensation of sound in response to electrical stimulation are not considered candidates, at this time.

Stage II considers results obtained from speech discrimination testing using the Minimal Auditory Capabilities Battery and selected subtests from the Iowa Cochlear Implant Battery (4, 7) . These tests are prerecorded by an Unfamiliar speaker and are presented to potential candidates in a controlled fashion (i .e., using standard audiometric Equipment in a sound field presentation) . All tests are performed with a sensory device. For baseline purposes a measure of speech reading is also obtained.

Stage III is the final step in patient selection and occurs only if the candidate meets stages I and II criteria. It involves counseling for appropriate expectations, both with the patient and the family. Further, a tinnitus questionnaire is administered, the surgical procedure is fully explained, and the patient is scheduled for implantation.

Prelingually deafened adults consist of a very heterogeneous group of patients. A substantial number of individual factors, such as etiology of deafness, communication mode, residual hearing, and educational experience, could all affect the post implantation outcomes. Consequently, a valid assessment of the effectiveness of CIs would require a study with a large number of patients or a very well-controlled group of subjects. The speech recognition scores of these patients were examined longitudinally over the 06-month clinical trial period to evaluate the effectiveness of cochlear implantation in providing auditory perceptual benefits. Undertaken to prospectively

II. PATIENTS AND METHODS

In a prospective manner, 73 consecutive adult and pediatric cochlear implant patients (undergoing 80 consecutive cochlear implant operations) were studied at a tertiary care referral center. Patients underwent implantation in standard fashion via a facial-recess approach. All patients were examined with an intra operative plain radiograph obtained in a Tran orbital view. The use and timing of the intra operative radiograph was at the discretion of the surgeon. The surgeon evaluated

the radiograph before final skin closure. In addition, the implanting surgeon completed a questionnaire regarding the device implanted, patient anatomy, surgical procedure, timing of the intra operative radiograph, manner in which the intra operative radiograph was used, and whether the radiograph changed the course of the surgery.

III. RESULTS

The patients included in this study are summarized in Table 1.

TABLE 1. *Patients and cochlear implant operations*

Condition	No. of patients
Patient age	
Adult patients (mean, 58 ± 3 yr)	40
Pediatric patients (mean, 4 ± 3 yr)	33
Total No. of patients	73
Operation	
Primary cochlear implant operation	75
Bilateral cochlear implant operation	7
Revision cochlear implant operation	5
Total No. of cochlear implants	80
Morphology of inner ear	
Normal	71
Abnormal	5
Postmeningitic ossification	4
Total No. of operated ears	80

Forty adult patients and 33 pediatric patients were studied. Seventy-five operations were performed for initial cochlear implantation and five operations were performed for revision cochlear implantation. Of the initial cochlear implantation surgeries, seven operations were performed as bilateral cochlear implantations. For the purposes of this study, the bilateral operations were considered as two initial cochlear implants. The morphology of the implanted inner ears was normal in 71 ears, abnormal in 5 ears, and ossified in 4 ears. On the basis of surgeon questionnaires, the number of insertions of the electrode array and the use of the intra-operative radiograph were compared (Table 2).

TABLE 2. *Electrode insertions and radiographs* Electrode insertion attempts

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Electrode insertion attempts	No. of imaging studies	No. of implants
Single	Single	53
Single	Multiple	11
Multiple	Single	10
Multiple	Multiple	6

In 53 patients, the electrode array was inserted completely into the cochleostomy in a single attempt and a single radiograph was obtained. In 11 patients, the electrode array was inserted into the cochleostomy in a single attemptand multiple radiographs were obtained. Ten patients required multiple insertions of the electrode array to achieve complete insertion and a single radiograph was obtained. In six patients, multiple insertions of the electrode array were required and multiple imaging studies were obtained. The utility of the intraoperative radiograph was assessed through the surgeon questionnaire. In 79 operations, the radiograph was used to confirm the normal operative findings of electrode insertion into the cochlea, and patient management was not changed on the basis of radiographic findings

TABLE 3. Management decisions and radiographs

Condition	No. of implants
Radiograph confirmed normal operative findings	79
Radiograph changed intraoperative management	1
Postoperative CT scans obtained	4

CT, computed tomographic.

In one operation, the intra operative radiograph was used to alter the management of the patient. This case was a second revision cochlear implant performed on a patient who had been ossified from meningitis. The revision was performed for intractable headaches at the site of the ground electrode. On inspecting the round window area, it was observed that there had been two previously performed "cochleostomies."

In this case, the first intra operative radiograph was obtained of an insertion test device in an attempt to confirm the site of the true cochleostomy before reimplantation. Four patients required postoperative computed tomography (CT) scans to aid in their management despite adequate intra operative plain radiographic evaluation. One adult patient received significant facial stimulation at initial device settings and a CT scan was obtained to further clarify device placement. One pediatric patient with significant inner ear malformations and a lack of normal surgical landmarks was evaluated with CT scanning after implantation to verify insertion of the electrode array into the severely abnormal cochlea. Two other pediatric patients underwent CT scanning several months after implantation as part of the evaluation for apparent no stimulation with the implant device. In each of these cases, the CT scan showed correct intra cochlear placement of the electrode arrays. In one revision surgery, the intra operative plain radiograph was useful for confirming the cochleostomy site. In the remaining 79 operations, no changes in the electrode arrays were made on the basis of the information provided by intraoperative plain radiographs.

IV. Conclusions

In this cohort, intra operative plain radiographs were not useful for uncomplicated implant operations; however, they may be useful for complicated operations. These results may have implications for surgical cost and patient radiation exposure. Cochlear implants are a common and well-accepted method for habilitation of hearing in the profoundly hearing-impaired population. The traditional facial recess approach to cochlear implantation provides an adequate view of the middle ear space and round window niche to accomplish electrode insertion. The insertion of the electrode array into the cochlea is often verified with a plain radiograph obtained in the intra operative or early postoperative period (1–9). Accumulated experience with cochlear implants at the study institution has suggested plain radiography may not be useful in assessing implant placement. This study was undertaken to prospectively assess the utility of intra operative plain radiographs in cochlear implantation. In this prospective analysis of intra operative plain radiographs, there appear to be several interesting findings. First, in primary cochlear implant operations, the utility of plain radiographs in patient management is negligible. In no primary implant cases were management decisions changed on the basis of the appearance of the intra operative plain radiograph. A second finding concerns revision cochlear implant surgery. This study included five revision implant cases. In four of the five revision cases, the intra operative radiograph was of negligible utility, confirming what was already known from the procedure. In the remaining revision case, an intra operative radiograph was used to determine which of two previously drilled cochleostomies was the proper one to use for reimplantation. In this case, the electrode array had been removed without visualization from the proper cochleostomy site earlier in the operation. Had the electrode array been left in the true cochleostomy with removal under direct visualization of the promontory, the need for the intra operative radiograph may have been eliminated. A third finding concerns more complicated implant cases. In severely malformed inner ears, the utility of the plain radiograph is questionable. Numerous malformed inner ears were implanted during this study. Specifically, two patients with complete aphasia of the vestibular system, one patient with enlarged vestibular aqueduct, one patient with bilateral facial nerve cysts of the descending segment (10), and one patient with severe cochlear hyperplasia resulting from branchio-oto-renal syndrome underwent implantation during this study. In addition, four patients with post meningitis cochlear ossification underwent implantation during the study period. Of these complicated implant cases, one patient with a malformed inner ear and intra operative questions regarding electrode placement progressed to CT scanning despite the appearance of an adequate intra operative plain radio-Postoperative CT scans obtained 4 CT, computed tomographic. graph. A second patient with inner ear malformations and an adequate intra operative plain radiograph progressed to CT scan evaluation in the postoperative period for apparent lack of stimulation from the implant. Both of these CT scans revealed intra cochlear placement of the electrode array. On the basis of these findings, an argument can be made that CT scan is the study of choice for evaluating cochlear implants in the malformed inner ear when questions arise as to electrode placement because the plain radiograph, again, did not alter management decisions. In 13 of the 17 operations with

multiple imaging performed, the further images were required because of suboptimal radiologic technique. (The four remaining cases with multiple imaging underwent subsequent CT scan evaluation in the postoperative period as detailed above.) Although each plain radiograph delivers 280 mrad of radiation to the lens, the cumulative exposure is concerning in the cochlear implant population. In addition to a preoperative CT scan (approximately 4,200 mrad), many patients (13 patients, 16% of the study population) required more than one intra operative plain radiograph to properly visualize the implant. The utility of the plain radiograph in choosing speech-processing strategies (12). Furthermore, the intra operative radiographs are often obtained at less-than optimal angles, given the constraints of patient positioning and the sterile nature of the procedure. This leads to difficulty in interpreting electrode movement on subsequent comparison films obtained at a later time. With no clear use for the intra operative plain radiograph in operative decision-making, initial postoperative programming, or as a basis for comparison with subsequent radiographs, the risks and costs of the plain radiograph deserve consideration.

REFERENCES

[1] Rosenberg RA, Cohen NL. Intraoperative verification of multi channel scale tympani electrode position. Laryngoscope 1986; 96: 1293–4.
[2] Rosenberg RA, Cohen NL, Reede DL. Radiographic imaging for the cochlear implant. Ann Otol Rhinol Laryngol 1987; 96:300–4.
[3] Gray RF, Evans RA, Freer CEL, et al. Radiology for cochlear implants. J Laryngol Otol 1991;105:85–8.
[4] Marsh MA, Xu J, Blamey PJ, et al. Radiologic evaluation of multichannel intra cochlear implant insertion depth. Am J Otol 1993; 14:386–91.
[5] Ito J. Considerations of cochlear implant surgery. Clin Otolaryngol 1993;18:108–11.
[6] Shpizner BA, Holliday RA, Roland JT, et al. Postoperative imaging of the multichannel cochlear implant. AJNR Am J Neuroradiol 1995; 16:1517–24.
[7] Czerny C, Steiner E, Gstoettner W, et al. Postoperative radiographic assessment of the Combi 40 cochlear implant. Am J Radiol 997; 169:1689–94.
[8] Lawson JT, Cranley K, Toner JG. Digital imaging: a valuable technique for the postoperative assessment of cochlear implantation.Eur Radiol 1998; 8:951–4.
[9] Wang CY, Lai CH, Huang TS. Image study on cochlear-implanted patients. In Kim CS, Chang SO, Lim D, eds. Updates in Cochlear Implantation. Basel: Karger, 2000:67–74.
[10] Pertzborn SL, Reith JD, Maucuso AA, Antonelli PJ. Epineural pseudocysts of the infratemporal facial nerve. Otol Neurotol 2003; 24:490–3.
[11] Wilde G, Sjostrand J. A clinical study of radiation cataract formation in adult life after gamma irradiation of the lens in early childhood.Br J Ophthalmol 1997; 81:261–6.
[12] Cohen LT, Xu J, Xu SA, et al. Improved and simplified methods for specifying positions of the electrode bands of a cochlear implant array. Am J Otol 1996; 17:859–65.
[13] CLARK GM, BLACK R, FORSTER IC, PATRICK JF, TONG YC: Design criteria of a multiple-electrode cochlear implant hearing prosthesis. J Acoust Soc Am 63: 631-633, 1978.
[14] MECKLENBURG DJ, BRIMACOMBE JA : An overview of the Nucleus cochlear implant program . Sem Hearing 41-51, 1985.
[15] OWENS E, TELLEEN C: Speech perception with hearing aids and cochlear implants . Arch Otolaryn 107 : 160-163, 1981 .
[16] TONG YC, BLACK RC, CLARK GM, FORSTER IC, MILLAR JB, O'LOUGLIN BJ, PATRICK JF : A preliminary report on a multiple channel cochlear implant operation . J Laryn Otol 93 : 679-695,1979.
[17] THORNTON AR, RAFFIN MJM : Speech discrimination scores modeled as a binomial variable . J Speech Hear Res 21: 507-518, 1978.
[18] TYLER RS, PREECE JP, LOWDER MW: The Iowa Cochlear Implant Test Battery. Department of Otolaryngology, Head and Neck Surgery, University of Iowa, 1983.