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EMA compatibility of the Clarion 1.2 cochlear implant system

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Abstract: Three experiments examined whether the Clarion 1.2 S-Series cochlear implant could be safely and effectively used within a Carstens Medizinelektronik EMA (electromagnetic articulography) system. Experiment 1 indicated no measurable effects of EMA magnetic fields on implant function. Experiment 2 showed no influence of the implant on the accuracy of EMA measurements. Experiment 3 found no indication of reduced sentence repetition abilities when EMA fields were present. The results suggest experiments with the Clarion 1.2 cochlear implant and the Carstens AG100 articulograph are safe and feasible.

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1. Introduction

EMA (or EMMA, electromagnetic midsagittal articulography) is a relatively low-cost technique for measuring the movement of points on the surface of the tongue and other articulators.^{11,12} In the EMA procedure, a talker wears a helmet containing electromagnetic transmitter coils that establish three alternating magnetic fields (ranging between 10–30 kHz) around the head. Tiny sensors are glued to the subject's articulators, and these sensors connect to a computer by means of fine wires led from the corner of the subject's mouth. As the sensors move through the alternating magnetic fields, small voltages are induced. These voltages are converted to distance values, yielding an on-line, midsagittal image of articulator movement.

EMA has become an important tool for basic research into speech production by healthy adults^{2,3,4,6,8} and children.^{5,9} EMA also has been used in a recent study to investigate speech production changes after some aspects of hearing are restored with a cochlear implant (CI).⁷ However, this particular study was restricted to a single individual using an Ineraid CI with a percutaneous connector devoid of implanted electronics, magnetic or radio frequency links.

In general, EMA has not been used with cochlear-implanted subjects because of concerns about (1) possible harm to the subject's nervous system or cochlear implant from exposure to EMA's magnetic fields, and (2) potential problems with EMA measurement accuracy resulting from the presence of the cochlear implant itself, particularly from those devices that have implanted electronics and a magnetic link between transmitter and receiver.

Cochlear implants detect sound by a microphone that is worn externally behind the ear (like a hearing aid) and is connected to a speech processor. In most systems, the processed

signals are sent internally through the skull by magnetic induction to the receiver coil placed in an excavation of the outer lamina of the skull near the mastoid process. The electric signals are then delivered to the cochlea via an electrode array. These transcutaneous systems use magnets of variable sizes to connect the external and internal receiver coils. Alternatively, there are a few CI models that use a special headpiece to physically align the transmitter and receiver (e.g., Clarion magnetless 1.2 system) or a percutaneous connector (Ineraid).

Although one study has suggested EMA may be safely used with percutaneous connector technologies⁷, it was not known whether commercial devices relying on implanted electronics with magnetic and RF links (e.g., Clarion, Nucleus, or Med-El CIs) would fare as well. There is good *a priori* reason to believe EMA would cause little signal artifact in these cochlear implants: EMA systems operate in the VLF (very low frequency) frequency range, whereas cochlear implants typically operate in the VHF (very high frequency) range (10.7- 49 MHz for the Clarion 1.2 S). However, the hardware in magnetic coupling devices could potentially affect EMA measurement, possibly in a manner analogous to the distortion ('artifact' or 'signal void') commonly noted in MRI images of cochlear-implanted subjects.^{13,14}

Three experiments were conducted to address these issues. Experiment 1 asked whether there were induced voltage artifacts in the output of the Clarion CI when placed in the magnetic field of a Carstens AG-100 EMA articulograph. Experiment 2 investigated if EMA accuracy was affected by the presence of the CI in the magnetic field. In Experiment 3, cochlear-implanted adult listeners were given speech repetition tasks in EMA-on and EMA-off conditions to determine whether speech perception was adversely affected by EMA fields.

2. Experiment 1. Effects of EMA magnetic fields on a Clarion cochlear implant device

2.1 Materials and methods

Materials included a Clarion 1.2 S-series speech processor with external microphone, transmitter, and decoding unit (Advanced Bionics Corporation), and a Carstens Medizinelektronik AG100 electromagnetic articulograph. The output of the eight-channel decoding unit traveled through approximately 7 cm of adapters and connectors, then was connected by a 1m twisted-pair lead to a custom-built bank of 20 k Ω resistors designed to simulate electrode impedances in the cochlea. Clarion 1.2 electrode arrays are approximately 6 cm long, with the first 2 cm helically wound and the last 4 cm portion straight. The purpose here was to provide a maximal test of possible electromagnetic interference by using a greater than normal amount of conductive wiring between the receiver and electrode array.

SCLIN 2000 software (Advanced Bionics Corporation) was used to program the CI device with three commonly used strategies (CIS, MPS, SAS).^a Different processing strategies were used in two experiments: Experiment 1 focused on the two pulsatile strategies (CIS and MPS), and Experiment 2 examined CIS and SAS. The bandwidth of the speech processor was approximately 6.3 kHz. This bandwidth was divided into eight channels, such that all channels had approximately the same width on a logarithmic frequency scale (center frequencies: 416, 587, 828, 1168, 1648, 2326, 3281, 5544 Hz).

The magnetically linked transmitter and decoding unit were placed behind the 'ear' of a life-size, styrofoam mannequin head. The mannequin head was positioned in an EMA helmet mounted on a calibration bench, at an angle and orientation corresponding to a typical adult in an experimental session. To provide the strongest possible test of EMA interference,

^a In the CIS (Continuous Interleaved Sampling) strategy, trains of biphasic pulses are delivered to the electrodes in a nonoverlapping fashion. The amplitudes of the pulses are derived by extracting the envelopes of band-passed waveforms. Output channels were stimulated in an apex-to-base order at a rate of 833 pulses/sec/channel. In the MPS (Multiple Pulsatile Stimulation) strategy, two electrodes, spaced widely enough to avoid channel interaction, are simultaneously stimulated. MPS stimulation was delivered at 1,444 pulses/sec/channel. Unlike the CIS and MPS strategies, the SAS (Simultaneous Analog Stimulation) strategy stimulates all electrodes simultaneously.

the settings of the AG100 transmitter coils were increased to maximum value (E value = 255), generating a magnetic field strength of approximately 35 μT at a distance of 7.5 cm from the axis of each transmitter coil.¹ This maximum field strength was approximately twice that normally used in speech production experiments.

EMA-off versus EMA-on comparisons were made for three input conditions: baseline (white noise), 1 kHz sine wave, and 3 kHz sine wave. In the baseline condition, inputs were saturated with white noise by increasing the processor unit's input gain controls to near maximum threshold. This yielded overall channel outputs averaging 4.3 V. In the sine wave input conditions, the output of a digital function generator was connected to the auxiliary input jack of the speech processor, and 125 mV peak-to-peak sine waves (1 kHz, 3 kHz) were delivered. In these two conditions, the overall output averaged 3.3 V and 3.03 V, respectively.

EMA transmitters reach full transmission power within a minute or two of being turned on. To ensure sufficient warm-up time, EMA-on versus EMA-off comparisons were made in blocked fashion, with a minimum of 5 minutes between conditions.

The output of the CI device was displayed on a Tektronix model TDS-224 oscilloscope with an effective accuracy of ± 0.08 V. For each channel, a single pulse was first visually inspected to ensure correct pulse shape, polarity, duration, and symmetry. Second, multiple pulses in the same channels were examined to verify correct periodicity and rate of stimulation. Third, multiple channels were inspected to ensure that the order of stimulation was correct. Finally, EMA-on versus EMA-off differences for each channel were measured directly from the oscilloscope display.

2.2. Results

In the 48 comparisons (2 strategies x 3 input conditions x 8 channels), there were no recorded differences in the output of the CI above measurement threshold as a function of the EMA system being switched on or off. Because there were clear voltage increases from baseline (*i.e.*, silence) as the 1-kHz and 3-kHz signals were fed into the unit, the CI responded in an expected manner to input sound but yielded no measurable response to the external magnetic field generated by the EMA transmitter coils.

3. Experiment 2. Effects of a cochlear implant device on EMA measurement

3.1 Materials and Methods

The Carstens Medezinelektronik AG100 helmet was placed in a calibration stand, a platform that holds the helmet in place and has a positioning device that allows sensors to be moved in 1 cm increments through the geometric center of the transmitted electromagnetic fields. Sensors are moved 4 cm (in 1 cm increments) in a trajectory through the midsagittal plane at a 60-degree angle relative to the horizontal. The positioning device approximates sensor placement at regions in the vocal tract ranging from the "high back" to "front low" places of articulation. As in Experiment 1, a life-size Styrofoam mannequin head was fixed in the EMA helmet at an angle and orientation corresponding to a typical adult in an experimental session. The CI was fitted into a slot located just behind the 'ear.'

Two tests of accuracy of measurements were made. The first test examined whether a transducer placed at two fixed positions was estimated differently with an implant in or out of the EMA field. A sensor was fixed at each endpoint of the positioning device, and EMA estimates were compared across the following conditions: "baseline" (no implant or no styrofoam mannequin head), "implant-off" (mannequin present with the physical hardware of the CI in place), and "implant-on" (mannequin with cochlear implant programmed to resemble typical configurations used by cochlear-implanted subjects). In this test of fixed sensor position, the electrode array of the CI was simulated by a resistor bank configured to accommodate the CIS strategy. In the implant-on conditions, stimulation was delivered to this

resistor bank. There were two repetitions of each condition, yielding a total of 12 data sets (2 endpoints x 3 conditions x 2 repetitions). All data were collected in a single test session.

A second test examined EMA accuracy in measuring sensor displacement. Using the central positioning device, a sensor was moved 4 cm through the midsagittal plane (at a 60-degree angle to the horizontal) and that distance was compared with the estimated displacement. This was done for the baseline, implant-off, and implant-on conditions described above. In this test, the electrode array of the CI was simulated by a resistor bank configured to accommodate the CIS and SAS strategies. Three trials were conducted in each test session. This step provided test/re-test reliability for accuracy within each test session.

3.2 Results

EMA estimates of fixed sensor position were recorded in 0.01 mm units. Euclidean distances were computed for the 6 EMA estimates (3 conditions x 2 repetitions) for each sensor position, yielding two matrices of 15 comparisons for each endpoint. Results indicated extremely small “distances” between successive measures of a fixed sensor (overall mean = .019 mm), with no systematic effects of condition (baseline, implant-on, implant-off), endpoint, or repetition. These findings suggest reliable measurement at two stationary points in the electromagnetic field, without effects from the presence or absence of a Clarion 1.2. cochlear implant.

Tests of estimated displacement were completed by two of the investigators on four different days. Because the results were similar, we present the results of a typical test session in which a sensor was moved 4 cm under seven different conditions generated consecutively.

Table 1. Percent error for estimated displacement under seven conditions conducted in one test session

Condition	Description	Trial 1	Trial 2	Trial 3	Mean
1	Baseline (mannequin only)	1.13	1.04	1.33	1.17
2	Implant-off	0.97	0.94	0.73	0.88
3	Implant-on / SAS strategy	0.67	0.72	0.99	0.79
4	Implant-on / CIS strategy	1.00	1.04	0.91	0.98
5	Implant-off	0.78	0.69	0.69	0.72
6	Baseline (mannequin only)	0.63	0.61	0.64	0.63
7	Baseline (no mannequin)	0.80	0.78	0.79	0.79
Mean:		0.85	0.83	0.87	0.85

The mean error rate was 0.85%. The error in the baseline conditions ranged from 0.61% (condition #6, trial 2) to 1.33% (condition #1, trial 3). These percentage errors correspond to measurement errors of approximately half a millimeter (0.244 mm to 0.532 mm) within the 4 cm displacement. There was slightly greater error variation across conditions than within conditions (*i.e.*, between trials). Measurement error did not systematically increase by placing the CI in the EMA field, or by manipulating its processing capability by turning it on or off or varying its processing strategies.

4. Experiment 3. Speech perception under EMA conditions

4.1 Subjects

Table 2 shows the biographical data for three adults fitted with Clarion 1.2 cochlear implants.

Table 2. Subject information

Subject	Sex	Age (yrs)	Age of deafness onset	Length of implantation (mo.)	Processor Strategy	Etiology
1	M	51	9 years	30	MPS	congenital
2	F	61	28 years	36	SAS	injury
3	F	57	54 years	18	CIS	unknown

4.2 Procedure

A listening test was conducted to determine whether EMA fields affect speech perception. Both tests were conducted in a sound-treated room at the University of Texas at Dallas Callier Center. This test examined listeners' performance on the Hearing in Noise Test (HINT)⁹ in EMA-off and EMA-on conditions. Sentences were played to subjects at 65 dBA, and the number of words correctly repeated were recorded by an investigator. Four lists (each containing 10 sentences) were randomly selected for each listener, with two blocks (20 sentences) assigned to EMA-off and two blocks (20 sentences) to EMA-on conditions. As in Experiment 1, there was a minimum of 5 minutes between EMA-on and EMA-off conditions to allow the EMA transmitters to reach full transmission power in EMA-on conditions. Sentences were presented at a rate of approximately one every 15 seconds (including time for the subject's repetition and scoring by the investigator).

4.3 Results

The results of the discrimination experiment indicate that the white noise versus silence pairs were discriminated with nearly perfect accuracy (99% average), whereas the EMA-off versus EMA-on pairs were discriminated at chance level (52% average). The results of the sentence repetition task (HINT) are shown in Table 3.

Table 3. HINT Performance

Subject	EMA-off	EMA-on	Off minus on
1	81.3%	79.4%	1.9%
2	79.6%	82.7%	-3.1%
3	79.0%	83.4%	-4.4%

For all listeners, there was less than 5% difference between the EMA-on and EMA-off conditions, suggesting no systematic effects of EMA fields on sentence repetition.

5. Discussion and conclusion

The results of Experiment 1 indicated there were no measurable effects of the EMA electromagnetic field, although robust output differences corresponded with varying sound input. This finding suggested there would be little chance of induced electronic malfunction or neurological harm for Clarion 1.2 users tested in a Carstens EMA system.

Experiment 2 examined the accuracy of the Carstens AG-100 articulo-graph with and without a Clarion CI in place. The results indicated almost no measurable differences in EMA measurement accuracy corresponding to the presence or absence of power to the CI. These findings suggest EMA measurements would not be adversely influenced by Clarion 1.2.-implanted talkers.

Experiment 3 investigated HINT sentence performance in EMA-on versus EMA-off conditions for three adult CI users. Results revealed EMA magnetic fields caused essentially no difference in speech perception (as indexed by sentence repetition) for any of three listeners. Collectively, these data suggest EMA studies using the Carstens AG100 articulo-graph appear safe for use in CI individuals using transcutaneous connectors. These findings should facilitate EMA studies of articulatory movement in CI subjects.

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