

Single-Institution Retrospective Review of Post-operative Care and Next Day Cochlear Implant Activation in Adults

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ABSTRACT

The topic of when to activate a cochlear implant following surgery has been debated and practice has been variable for many years. The “standard” for initial activation of a cochlear implant remains 2-4 weeks after surgery despite numerous advances in surgical technique and technology over the past 25 years. The concept of initial stimulation timed closer to the date of surgery has developed with the advent of smaller incisions and progress toward incurring fewer wound complications. The reluctance to complete initial stimulation sooner has been historically based on fear of wound complications and poor hearing outcomes. We have been performing initial stimulation the day after surgery in adult and pediatric patients for the past 10 years without an increase in complications. This report details the complications and hearing outcomes in adult patients whose initial stimulation was performed on the first post-operative day. A retrospective chart review was conducted on all adult cochlear implantations performed from 2005-2015. Sixty-nine patients met inclusion criteria. There were no adverse wound complications. The mean post-operative Pure Tone Average (PTA) was 24 dB HL with mean Word Recognition Score (WRS) of 60 % at the second mapping session. Cochlear implant activation performed on the day after surgery in adult patients is safe and does not impede hearing results.

INTRODUCTION

Cochlear implantation is a safe and reliable treatment option for unilateral and bilateral severe to profound sensory hearing loss in children and adults. Since the FDA approved adult cochlear implantation in 1984, improvements have occurred in terms of technology and surgical technique. The current use of a small post-auricular incision has resulted in fewer post-operative complications [1]. Specifically, smaller incisions allow for less post op swelling and fewer wound healing problems. Despite these advances, most patients still wait 2-4 weeks prior to having their device activated. A prospective randomized control trial by Alsabellha, et al. looked at 23 patients of various ages undergoing cochlear implantation [2]. There were two groups of randomized patients; one group had their cochlear implant activated 5 days post-operatively and the other group activated four weeks after surgery. In their study, none of the patients in either group experienced adverse events. The authors reported early activation (within one week of surgery) may be an option to serve individual needs. Another prospective study by Hagr, et al. utilized an intrasubject comparison and noted no adverse events for cochlear implant activation completed one day post-operatively compared to data for activation at one month [3]. It is the opinion of the

senior author that cochlear implant activation beginning one day after surgery is safe for patients. We have been performing initial stimulation the day after surgery in adult and pediatric patients for the past 10 years without complications. This report details the complications and hearing outcomes in adult patients whose initial stimulation was performed on the first post-operative day.

METHODS

A retrospective chart review was conducted on all adult cochlear implantations performed from 2005-2015. Sixty-nine patients were identified with ninety-four implants (some patients had bilateral sequential or bilateral simultaneous cochlear implant fittings) that met inclusion criteria, which was defined as having adequate chart information for analysis. IRB exemption was obtained through the Western IRB. Each case was reviewed specifically for amount of time from surgery to initial activation and time until the second programming session. Adverse events from surgery through the second visit were recorded, including skin irritation, skin breakdown, incisional drainage, pain and implant extrusion. Three initial stimulation groups were identified and labeled based on timing of activation after surgery: post-operative activation day one (POD 1) group (n=64), post-operative activation day 2 -14 (POD 2 -14) group (n=28), and post-operative activation 15 or more days (POD 15+) group (n=2).

Behavioral measures, in accordance with the manufacturer's recommendations, were used to determine loudness comfort levels or loudness comfort levels and threshold levels (Cochlear America's recommends loudness comfort levels and threshold levels be measured. Advanced Bionics and Medel recommend that only loudness comfort levels be measured; threshold levels are set to 10 to 20% of the loudness comfort levels). The behavioral measures were then used to generate four progressive MAPs that gradually increased the level of stimulation until the maximum stimulation level was equal to the stimulation levels used to generate the loudness comfort level measurements. Patients were counseled to progress through one MAP each week; patients were expected to reach MAP 4 by the second programming session (four weeks post-activation). Aided sound field testing was completed at the second appointment. Patients were seated 0 degrees azimuth to the speaker and approximately one meter away. A modified

version of the Hughson-Westlake method was used to obtain audiometric thresholds (250 to 8000 Hz) and Speech Reception Thresholds (SRT). A four frequency PTA was calculated using the following frequencies: 500, 1000, 2000, and 3000 Hz. Word recognition testing was only performed if the patient was able to complete SRT testing. NU-6 word lists were presented at 50 to 55 dB HL (i.e. conversational levels) using Monitored Live Voice (MLV) to obtain word recognition scores.

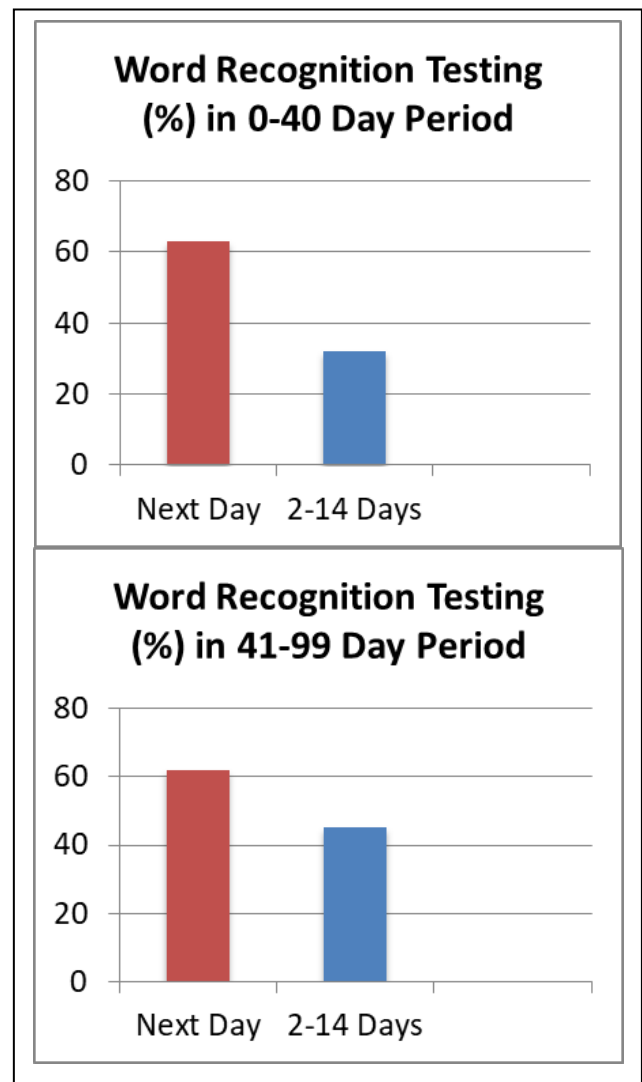
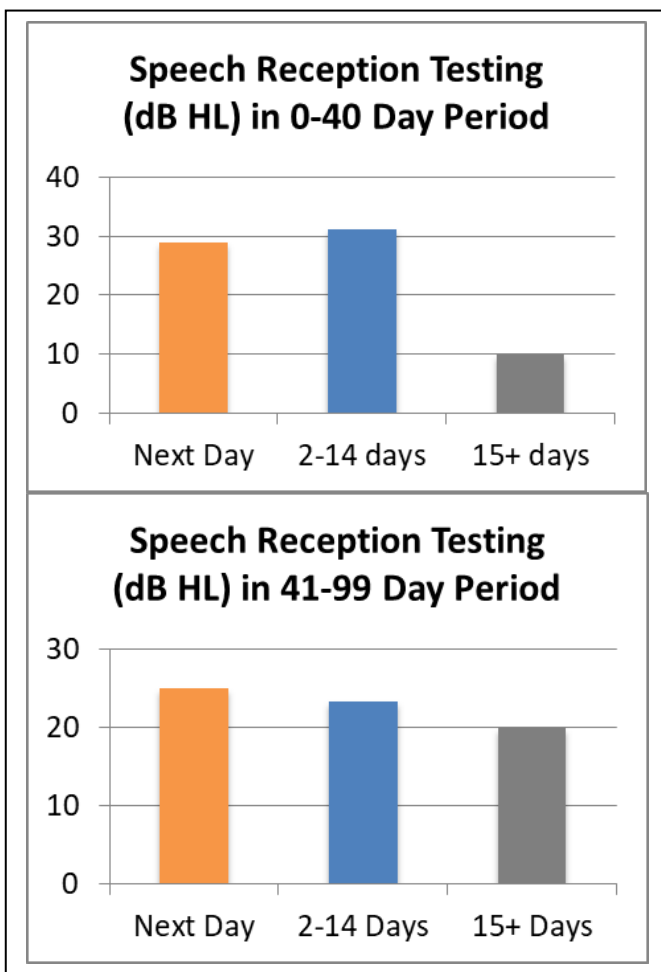
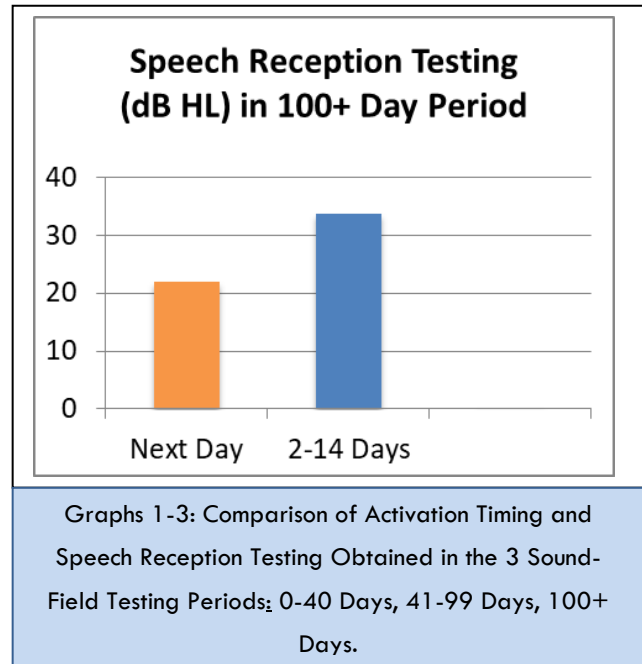
The patients who underwent aided testing were placed into three distinct groups for analysis: group one had aided testing performed less than 40 days after initial stimulation (n=43), group 2 completed aided testing 40 to 100 days after initial stimulation n=34, and group three completed aided testing more than 100 days after initial stimulation (n=17).

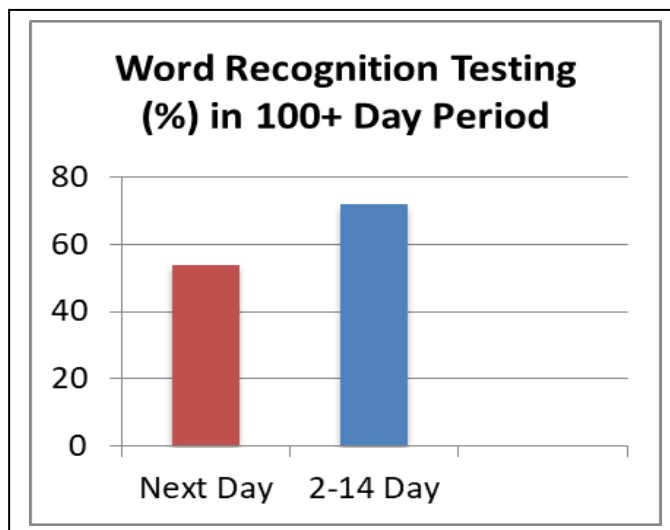
RESULTS

One hundred and seven adults were identified who underwent cochlear implantation from 2005-2015. Sixty-nine patients met inclusion criteria, with a total of 94 implants. Of the 94 implanted ears, 64 implants had initial stimulation on the first post-operative day. An additional 28 implants had their initial stimulation within the first 14 days after surgery. Two implants had initial stimulation between 15-90 days. The timing of follow up visits were highly variable due to many factors, but primarily geographical distance from the implant center. In the study group, there were no immediate or long term wound complications identified. Flap edema did not prevent or delay stimulation in any patient. Occasionally, flap edema required increased magnet strength, which was lowered at a subsequent session. Prolonged flap edema was not seen. No patients stopped wearing their processor due to pain.

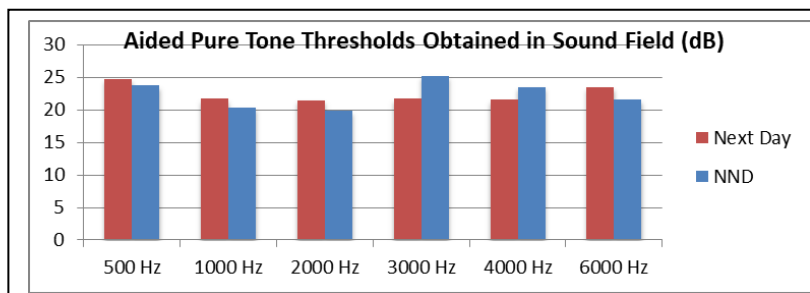
Implant electrode impedance testing on POD 1 revealed only 3 open electrodes throughout the study population which were disabled at initial activation. Of these, one normalized at the subsequent mapping session and two remained open long term. All three were disabled at the initial stimulation, and the one that normalized was activated at the second session. Hearing results were good overall. In the POD 1 group whose sound field testing was executed within 40 days of initial stimulation (n=27), the mean aided PTA was 24 dB HL, and SRT was 29 dB HL. The mean aided WRS was 63%, however only six patients had speech testing performed at this first visit. In the POD 1 group tested between 41-100 days after initial

stimulation (n=23), the mean aided PTA was also 23dB, and the mean SRT was 25dB. The mean aided WRS in the patients tested was 62%. Similar results were seen in the 14 POD 1 implantstested late (>100 days); mean aided PTA 21 dB, SRT22dB, and WRS 54%. In POD 2-14 the study group having had their initial stimulation between 2 and 14 days post-operatively, the hearing results were quite similar to those whose initial stimulation was on POD 1. When tested between 40 days of initial stimulation, the mean aided PTA was 24 dB, SRT was 31 dB, and the mean aided WRS was 32% (n=15). Those tested between 41-100 days after initial stimulation (n=10), the mean aided PTA was also 22 dB, and the mean SRT was 23dB, while the mean aided WRS was 45%. In the final group (n=2), POD 15+, whose initial stimulation was performed more than 15 days post operatively, the hearing results were also similar. When tested within 40 days following initial stimulation (n=1), the aided PTA was 18 dB and the SRT was 10 dB. When tested between 41 and 99 days after initial stimulation (n=1), the aided PTA was 18 dB, and the SRT 20 dB (Graph 1-6).

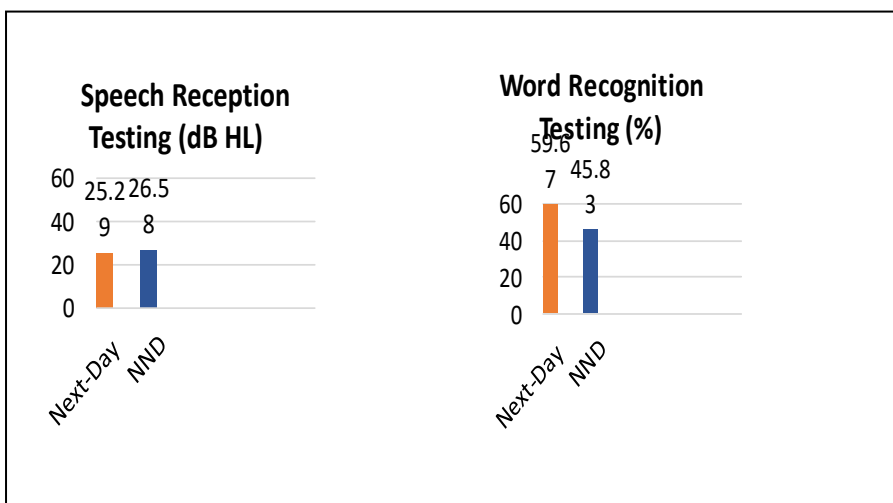




Graphs 4-6: Comparison of Activation Timing and Word Recognition Testing Obtained in the 3 Sound-Field Testing Periods: 0-40 Days, 41-99 Days, 100+ Days (100+ day group had no data available).



Graph 7: Overall comparison of aided pure-tone testing in next day activation versus non-next day (NND) activation groups.



Graphs 8 and 9: Overall comparison of speech testing between next day activation and non-next day activation (NND).

DISCUSSION

Cochlear implantation is a routine surgical procedure, often performed in the outpatient setting. Over the past 30 years, incisions have changed, reducing complications. Initially, with the C shaped incision, and to a lesser degree, with the S shaped post auricular incision, the most common complications were flap related [4]. With the advent of smaller incisions, scalp flap complications have become rare [1]. Given this, mapping the cochlear implant shortly after surgery would appear practical. For many patients, traveling great distances to/from an implant center is difficult; therefore, performing the initial stimulation the day after surgery offers tremendous convenience. Lastly, patients' and families of recipients are anxious to begin the process of "hearing" with the implant. Allowing the patient to use the implant the day after surgery is well received.

Safety and success of first post-operative day mapping was determined by the following considerations: no wound or incisional complications, no delayed healing, neural response telemetry/neural response imaging (NRT/NRI) responses, and favorable audiometric results (determined by PTA, SRT, and WRS). In the current study group, no wound or incisional complications were identified. There was no case of delayed wound healing. When flap edema was present, a stronger magnet was used to allow successful transmission from the coil processor to the internal implant. The magnet site was monitored at all follow-up visits and changed to a lower strength as flap edema subsided. Prevention of initial stimulation due to pain or swelling was not noted.

NRT/NRI is generally performed intra-operatively and post-operatively. It is not uncommon for NRT/NRI responses to be higher when obtained in the operating room versus at follow up visits. The current study showed documentation of good NRT/NRI responses at the first post-operative day mapping session. These measures can be used to assist in the initial mapping of the cochlear implant. Furthermore, only 3 open electrodes were identified on impedance testing at the initial stimulation. Of these only 1 normalized at a subsequent mapping session.

Audiometric testing was determined by sound field aided testing (PTA calculated) and monitored live voice speech recognition testing/speech awareness thresholds using NU-6

word lists. Patients with follow up testing within 40 days of initial stimulation had a mean aided PTA of 24 dB, and SRT of 29 dB. All groups demonstrated normal/near normal pure tone thresholds (Graph7-9). These results show strong evidence that first post-operative day activation has no adverse effect on the patient's improved hearing potential. There is no evidence to suggest that a prolonged delay until activation has a positive impact on hearing outcome.

CONCLUSION

Cochlear implantation is a routine procedure, and it is often performed in the outpatient setting. In the current study group, neither wound nor incisional complications were identified. Neither post-operative pain nor swelling prevented initial implant stimulation on the first post-operative day. This review adds evidence that next day cochlear implant activation in adults carries no additional risk of wound healing or decrement to hearing outcome.

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