

Very early activation of cochlear implants: A review of the literature

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Abstract Cochlear implantation (CI) has become the standard treatment for patients with severe-to-profound hearing loss. To date, an estimated 750,000 individuals spanning the entire lifecycle have benefited from this life-changing technology. Traditionally, the device is not "activated" for 3 to 4 weeks after surgery. However, an increasing number of centers have recently begun to question the conventional wisdom that several weeks are necessary and are activating their patients' device sooner after CI. This review aimed to provide a comprehensive insight to better understand the feasibility, outcomes, benefits, and limitations of very early cochlear implant activation. Data sources from published medical literature were reviewed. A detailed examination and summary were provided. History and safety were also emphasized. It was observed that approximately 20 studies have reported their experience with very early cochlear implant activation, ranging from the day of surgery to 1 week. Outcome measures are disparate, although there is general agreement that early activation is not only feasible but also provides some real-life benefits to patients and caregivers. The surgical, electrophysiological, audiological, and other outcomes were also reviewed. Very early activation is safe and beneficial in patients with cochlear implants. Many CI centers believe that such a process can lead to improvements in both patient-centered and fiscally responsible care. Although not ideal for all patients, cochlear implant programs may consider this option for their patients.

Keywords: Activation; Cochlear implantation; Impedance; Safety

1. INTRODUCTION

Over the past 40 years, cochlear implantation (CI) has become the standard treatment for patients with severe-to-profound hearing loss. During the same period, outcomes for CI have demonstrated remarkable improvements in speech understanding for recipients. To date, an estimated 750,000 individuals spanning the entire lifecycle have benefited from this life-changing technology. Most children with congenital hearing loss who are implanted young are expected to be fully mainstreamed in school (without any speech and language services). In addition, implanted adults can not only benefit from better hearing, hearing in noise, sound localization, and music appreciation,^{1,2} but mounting evidence also suggests additional benefits to memory, mood, cognition, and in older adults, mitigation of dementia.

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Despite remarkable technical and surgical advances over the decades, CI remains a multidisciplinary endeavor, requiring the expertise of not just surgeons but also audiologists, speech and language therapists, educational counselors, and many others to obtain optimal results. In addition, as with many stimulating biointerfaces, frequent and continued monitoring, evaluation, and adjustments are critical for early and sustained benefits.

Cochlear implants currently consist of two main components. The internal device (known as the receiver/stimulator) is placed within the subperiosteal space of the temporoparietal scalp, and a stimulating array is inserted through the mastoid into the scala tympani of the cochlea. The external device (known as the processor) contains a microphone and microprocessor that convert sounds to a digital signal that is then transmitted transcutaneously to the internal device. Both internal and external devices have magnets within, thereby allowing the devices to align and communicate. The surgery lasts for approximately 60 minutes, and patients are frequently discharged on the same day. Traditionally, the device is not "activated" for 3 to 4 weeks after surgery. During activation, the internal and external devices are paired and "programmed" by a CI audiologist, allowing the system to go live when the patient will hear for the first time through the CI.

There are several rationales for this 3- to 4-week interval prior to activation, some grounded in tradition and others based on mitigating perceived risks, though few, if any, are based on sound evidence-based research. As such, some centers have recently begun to question the conventional wisdom that several weeks are necessary and are activating their patients' device sooner, some within 24 hours of surgery. What follows is a ۲

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review of the outcomes, benefits, and limitations of such early activation (<2 weeks).

2. HISTORY

Several groups have reported their experiences with activation prior to the traditional 3- to 4-week interval. The first published report was by Chen et al in 2013, although this retrospective analysis of 58 adults and children included patients from as early as 2004.³ Shortly thereafter in 2014, Marsella et al reported their experience of 20 CI surgeries in 17 children; the authors reported their experience of activation at approximately 1 week postoperatively (range 5-9 days).⁴ In the same year, Alsabellha et al also published their findings in 10 children and young adults, activating the device 5 days postoperatively.5 Over the years, several other groups have published their experiences with early activation, ranging from 13 days to the day of surgery in the recovery room.⁶⁻²¹ An increasing number of publications from a select group of CI centers suggest increased acceptance of these protocols, although no data exist as to how common this practice is in reality.

3. FEASIBILITY AND SAFETY

Despite the primary concern regarding the rationale behind delayed activation and the mounting body of literature on this subject, there still remains a relative paucity of surgical outcome data. Most studies do not provide granular information on postoperative clinical concerns, electing to use terms such as "no surgical complications."^{3-6,10,12,16,20,21} Other studies did not include any surgical outcome information, as their analysis focused on electrophysiological changes over the postoperative period.^{9,13-15,17,18} A handful of studies have published clinical information that sheds some insight on this issue. Günther et al reported 23 CIs in 21 patients, with a median activation of 2 days postoperatively.¹⁰ They found only one patient who could not tolerate the fitting after 2 days. They also found that early activated patients had slightly less overall usage (9 hours/d vs 13 hours/d) of their device during the first few months compared with those activated later. However, this difference was nullified after 3 months of use. In addition, the early activated group had a slightly higher incidence of postoperative pain (23.8% vs 16.7%), which also became equal by the end of 3 months. They noted no difference in balance complaints between the two groups and found high satisfaction in the early activated cohort, which increased over time. Bruschke et al reported a higher rate of "minor medical complications" in the early cohort, where 2 of 67 adults could not be fit early due to "wound swelling."19 Of note, 35% of early activated patients required a weaker magnet over time compared with only 5% of the control group. Wolf-Magele et al found that 1 of 40 patients could not be fitted at 2 weeks and that most patients required weaker magnets over time.7 Taken together, these data suggest that early activation is not only safe but also feasible in the vast majority of both adult and pediatric CI recipients.

4. ELECTROPHYSIOLOGICAL DATA

Measurement of electrophysiological data during and after implantation is crucial for optimizing outcomes and diagnosing potential problems. One of these measurements is electrode impedance, which is the resistance to the flow of current between the intracochlear electrode and, usually, the extracochlear ground. Typically used to determine open or malfunctioning electrodes, impedance can be used to set ideal stimulation parameters that allow for more comfortable loudness levels and lower power consumption. Therefore, understanding the factors that can affect impedance changes is of substantial interest.

One of the many lessons learned from early activation is the insight afforded to the intracochlear milieu in the hours and days following implantation. Typically, impedance measurements are lowest during the surgery itself.22 These levels rise during the postoperative period and are largely attributed to fibrous buildup and inflammation around the electrode array as a foreign body reaction in the intracochlear space.²³ However, until early activation was performed, little was known about what happens in the immediate postoperative period. Interestingly, many studies have detected a drop in impedance during the immediate postoperative period. First reported by Chen et al, multiple subsequent studies have confirmed this drop within 24 hours, followed by an increase 1 week after surgery.^{3,9,24} Both Parreño et al and Marsella et al demonstrated that the decrease continued for multiple days postoperatively.^{4,24} Such findings are most likely due to surrounding air bubbles or even the continued effects of perioperative steroid administration.7,25 Even in cases of sameday activation, impedance continues to drop over 24 hours, suggesting that such changes occur irrespective of the early presence of the current.²⁰ In fact, the duration of the current appears to make little difference in the long-term as well. Multiple studies have found no significant impedance differences between early and traditionally activated patients at 1 month post activation.^{3-5,8-11} These findings suggest that long-term impedance levels are not affected by early electrical stimulation. In addition, several authors have compared the manufacturer and array types, with most findings showing no differences in impedance patterns over time.^{6,11,17,19} Recently, however, Sunwoo et al presented their data for a new slim modiolar electrode, suggesting that faster stabilization of impedance may have theoretical implications for performance.17

The exact cause of the early drop in impedance remains unclear. The mechanism likely lies within the cochlea, and Saoji et al demonstrated that impedance drops in both the monopolar and common ground modes, thus ruling out the extracochlear ground electrodes as being responsible. Other possibilities include protein adsorption or changes at the electrode surface. Some insights can be gained from Li et al in their analysis of early activation in patients with isolated enlarged vestibular aqueduct.²¹ Paradoxically, in this patient population, the authors found that impedance was higher intraoperatively, returning to levels commensurate with controls within 24 hours. Citing previous animal work, the authors theorize that differences in the electrolyte composition in the inner ear fluids may affect endocochlear potentials, and thus, the measurement of electrical resistance.²¹ Irrespective of the anatomy, it may not be necessary to let the intracochlear milieu "settle," and it would appear that this already occurs within 24 hours.

The evoked compound action potentials (e.g., Neural Response Telemetry) were investigated by some authors, with most finding a drop in the first 24 hours commensurate with impedances.^{3,4}

5. AUDIOMETRIC OUTCOMES

Irrespective of the early electrophysiological changes that may occur within the cochlea, early activation appears to have many potential clinical benefits. The main outcome measures reported in the literature are the factors most important to performance, namely, speech understanding, thresholds, maximum comfort levels (MCL), and dynamic range (DR). Despite a number of studies that have investigated the feasibility of early activation, only two reported speech understanding compared to control groups activated later, finding no difference at 3 months and 1 year.^{10,19} Threshold, MCL, and DR were further investigated,

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with all studies finding an increment over the course of the first month following implantation.^{5,8,15,18} Although this would be expected with rising impedances, there was no significant relationship between threshold or MCL levels and impedance measured at 1 day or 1 month postoperatively.⁸

6. OTHER OUTCOMES

While speech understanding is the benchmark of performance by which success is judged in cochlear implants, several other factors contribute to user experience. With the feasibility of early activation already established, some authors have begun to investigate wearability, pain and comfort, quality of life, usage, balance, and patient satisfaction. In 2019, Batuk et al found approximately 6% rate of swelling, hyperemia, and pain among 230 patients, more so in the group fitted with "On-the-Ear" (OTE) processors compared with "Behind-the-Ear" (BTE) processors.¹¹ As such, they recommended that the use of OTE processor should be delayed for four weeks postoperatively. Saoji et al also reported some patients who were unable to retain an OTE, although in their cohort, all patients were able to wear a BTE with off-ear placement and an extra-long cable.²⁰ Such retention issues often necessitate alternate wearing options, delayed fitting, or the use of a stronger magnet. Günther et al found that 35% of 21 patients needed magnet reduction within 3 months of surgery in the early activation group and 5% in the control group.¹⁰ Two other studies found similar (but lower rates) need to decrease the magnet strength.^{7,19} Another study reported no change in magnet strength despite postoperative swelling.⁸ For this and other reasons, including pain or tenderness, patients having their device activated early may use their devices less than those having their device activated later (9 hours/d vs. 13 hours/d), although this difference appears to disappear by 3 months postoperatively.^{10,19} In the same study, the authors found pain with usage to be more common in the early activated cohort (23.8% vs 16.7%); however, it also became equal within 3 months.

Only one study investigated patient satisfaction and found high rates of satisfaction, with 84.2% reporting "highly satisfied" or "satisfied" with the early fitting, and only one patient requesting to delay their fitting.¹⁰ By 3 months, all 19 patients reported being "highly satisfied" or "satisfied" with early fitting. It should be noted that no control group was included in this analysis.

7. POTENTIAL BENEFITS

There are several potential benefits to early fitting that have not been properly studied but nonetheless make intuitive sense. The advantages of early activation are evident, with an increased focus on patient-centered care. This is especially true for patients who come from long distances (or for many centers, even internationally). The time and expense of travel to and from the CI center can place a substantial burden on both patients and their caregivers. The majority of the aforementioned studies were designed for the same (or fewer) number of office visits/programming sessions. There is also a psychological benefit among others to both patient and family about the question: "will it work?" The strategy of immediate initial switch-on within 24 hours postoperatively has led to a shortened duration of uncertainty and worry for patients and their families.^{3,6,17} Moreover, early switch-on can help patients return to normal activity and life as soon as possible, with earlier adaptation to their new circumstances.16

Likewise, health economics remains a reality for CI patients and centers. With a shift toward streamlining processes and maximizing efficiency, fields such as CI are ripe for improvements.²⁶ In the only study investigating the economic impact of early activation, Hajr et al analyzed nonmedical expenses in patients who traveled to their CI center. The authors found that, as the distance from the center increased, the cost of care increased. As such, they posit that this would "considerably inflate the indirect cost of implantation because patients/caregivers are required to either stay in the area or travel and return for their activation appointment after four weeks."¹³ The authors argued that inflation in costs could exceed the financial capacity of many of these patients, consequently affecting the decision to undergo implantation.

8. POTENTIAL LIMITATIONS

The factors most likely to affect early activation are pain and swelling. These occurrences in the immediate postoperative period can lead to an inability or aversion to use. The existing literature suggests that a small but not insignificant number of patients will be unable to tolerate early activation. Certainly, technical modifications such as "soft surgery"²⁷ with minimal incision, limited retraction, copious irrigation with clearance of debris, and avoiding monopolar cautery can limit postoperative pain and swelling. Furthermore, slow and meticulously clean (without bone dust or blood clots) insertion of the array can potentially decrease the risk of air bubbles and "open" electrodes that can negatively impact performance in early activated patients.

Imbalance and vertigo can also adversely affect the activation. For traditional activation timing, even those patients who have postoperative vestibular dysfunction are likely to clinically return to baseline. Although the only two studies that investigated balance found no differences between early activated patients and controls,^{10,19} clinical experience would again suggest that early activation may not be possible for all patients. In cases where early activation is planned, patients must be counseled preoperatively based on the possibility of delayed (nonearly) fitting.

Although one potential advantage of early activation is the psychological benefit of knowing that the device is functioning, there are potential psychological disadvantages of such a practice. Surgery days are often long and tiring, not only for the patient but also for their caregivers. The same or next-day activation can place additional mental strain on the patient, as large amounts of important information are being discussed. Indeed, there may be a psychological benefit to not overwhelming the patient. In their study of bone-anchored hearing implant patients, Caspers et al found that patient preferences for fitting time changed significantly after surgery.²⁸ Preoperatively, 43% of patients expressed the wish to be fit within 1 day of surgery. By 3 weeks postoperatively, this dropped to only 7.5% saying they would have preferred to get fitting within 1 day of surgery.

In conclusion, early activation of the CI is a safe and effective treatment option for many patients. More specifically, in the decision-making evaluation process of early CI activation, the distance from the patient's home to the CI center has always been a major concern, whereas the processor type has an insignificant effect on this issue. Although not ideal for all patients, many CI centers may feel that the adoption of such a process can lead to improvements in both patient-centered and fiscally responsible care.

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