

Special Feature

Cochlear Implant Soft Failures Consensus Development Conference Statement

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COCHLEAR IMPLANT SOFT FAILURES CONSENSUS DEVELOPMENT CONFERENCE STATEMENT

This Consensus Statement was prepared by a panel of experts representing the fields of otolaryngology, audiology, speech and language pathology, communication science, and engineering. Representatives to the conference were appointed by professional organizations including the American Academy of Otolaryngology—Head and Neck Surgery, the American Otological Society, the American Neurotology Society, the William House Cochlear Implant Group, the British Cochlear Implant Group, and the European Academy of Otolaryngology and Neurotology.

The statement is based on 1) preliminary research and consultation by a steering committee selected for their relevant experience representing the professions of individuals working with cochlear implants; 2) presentations by representatives of this working group on issues relevant to the consensus questions during an open session at the Consensus Conference on Cochlear Implant Soft Failures held in conjunction with the 10th Symposium on

Cochlear Implantation in Children (Dallas, Texas, March 15–19, 2005); 3) closed deliberations by members of the steering committee; and 4) input from attendees during the open session of the Consensus Conference. This statement is an independent report and is not a policy statement of any organization.

The statement reflects the panel's assessment of relevant information available at the time it was written. It is to be expected that new information and data constantly are being generated that may alter the recommendations of this panel. The list of references accompanying this report includes the primary sources used by the panelists in developing their preliminary statements (1–19).

OBJECTIVES

To provide professionals working in all areas of cochlear implantation with a current consensus on the terminology, definition, diagnosis, and management of suspected cochlear implant malfunctions widely referred to as soft failures.

PARTICIPANTS

The panels consisted of 18 individuals directly involved in development, manufacturing, and clinical application of cochlear implants. Representatives from the specialties of otolaryngology, audiology, bioengineering, speech and language pathology, communication sciences, and industry participated. Interactive presentations were made during an open session in the Consensus Conference to an audience of approximately 190 professionals.

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Participating Organizations: American Academy of Otolaryngology—Head and Neck Surgery, William House Cochlear Implant Study Group, British Cochlear Implant Group, American Neurotology Society, American Otological Society, European Academy of Otolaryngology and Neurotology, Advanced Bionics Corporation, Cochlear Americas, MED-EL Corporation.

EVIDENCE

Three separate panels composed of representatives from the several disciplines involved in cochlear implantation researched, discussed, and formed a preliminary statement on one of three questions. Data and peer-reviewed publications were prioritized over expert opinion. The three groups were charged with investigating relevant literature in this area, gathering clinical data and drawing on the experience of each of the selected members to develop a preliminary joint statement. These statements were presented in an open forum for consideration and discussion by interested attendees.

CONSENSUS

The panel, answering predefined questions, developed its final consensus based on the evidence presented by each of the three committees as well as from pertinent attendee comments presented during the open forum.

CONSENSUS STATEMENT

The steering committee composed a draft statement that was circulated to all panelists for comment. Conflicting positions then were resolved by the panel chairs after which a summary statement is to be published in *Otology and Neurotology* and a full statement in *Cochlear Implants International*.

CONCLUSIONS

Cochlear implant soft failure is an uncommon occurrence in which a device malfunction is suspected but cannot be proven using currently available in-vivo

methods. The working diagnosis of soft failure is arrived at after painstaking evaluation by the cochlear implant team, manufacturer, and patient and is based on the principles set forth below. The working diagnosis can only be confirmed by removal, examination of the suspect device, and identification of a failure mechanism.

Reimplantation of another device with subsequent alleviation of symptoms strongly supports the diagnosis, but cannot conclusively confirm a device malfunction. For one reason, the replacement electrode position cannot be demonstrated to be identical to the initial electrode position and, in many cases, replacement devices provide upgraded hardware or software. For another, emerging data suggest that neural adaptation to long-term electrical stimulation may cause nondevice related intermittency and declining performance. In addition, functional hair cells may cause desynchronization of auditory nerve fibers during electrical stimulation, giving the appearance of device malfunction. These clinical variables underline the need to take a conservative approach to diagnosing soft failure.

The diagnosis of soft failure begins with awareness of common presentations including declining performance, aversive symptoms such as a popping or shocking sensation or intermittent function. All medical and programming issues should be ruled out and external components of the device exchanged with components known to be functioning properly. Finally, establishing the working diagnosis of soft failure requires normal device imaging and integrity testing. Diagnosis of soft failure in children is substantially different than in adults due to the inability of many young children to report aversive symptoms as well as the variability in rates of hearing and language development. Figures 1 and 2 were developed from the combined experiences of several implant centers and are offered as examples for tracking patient complaints.

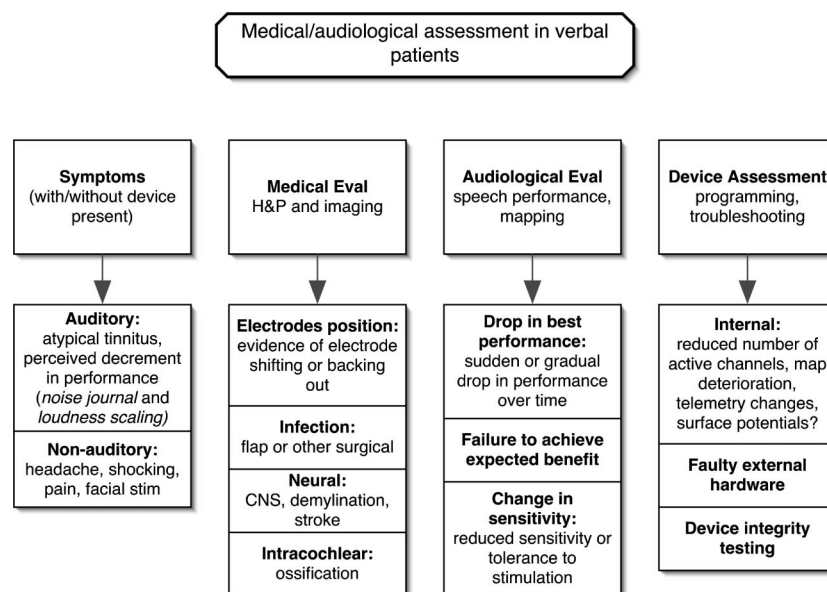


FIG. 1. This image presents an overview of the panel's consensus, outlining information useful for clinical decision-making in the diagnosis of a soft failure in patients with well established linguistic abilities.

Suggested Checklist for Assessment of Soft Failures

ADULT/OLDER CHILDREN		YOUNG CHILDREN
AUDITORY	MAPPING	BEHAVIORAL
<input type="checkbox"/> atypical tinnitus	<input type="checkbox"/> Changes in levels over time	<input type="checkbox"/> Increase in "bad" behaviors
<input type="checkbox"/> Buzzing	<input type="checkbox"/> Changes in pulse width/dur	<input type="checkbox"/> Aggressiveness
<input type="checkbox"/> Roaring	<input type="checkbox"/> Loss of channels	<input type="checkbox"/> Unwilling to wear device
<input type="checkbox"/> Engine-like	<input type="checkbox"/> Changes in impedance	<input type="checkbox"/> Head hitting
<input type="checkbox"/> Static	<input type="checkbox"/> Shorts/open circuits	<input type="checkbox"/> Inattentiveness
<input type="checkbox"/> Popping		<input type="checkbox"/> Regression in language/speech
<input type="checkbox"/> Other		
NONAUDITORY	HARDWARE	TEACHER/THERAPIST CONCERNS
<input type="checkbox"/> Pain over implant site	<input type="checkbox"/> Replacement of all externals	<input type="checkbox"/> Intermittent responsiveness
<input type="checkbox"/> Pain down neck		<input type="checkbox"/> Frequent appearance of being "off-task"
<input type="checkbox"/> Shocking		<input type="checkbox"/> Deterioration in grades/school performance
<input type="checkbox"/> Burning		<input type="checkbox"/> Plateau in performance
<input type="checkbox"/> Itching		<input type="checkbox"/> Fails to meet appropriate expectations
<input type="checkbox"/> Facial stim		
PERFORMANCE	OBJECTIVE ASSESSMENT	OTHER FACTORS
<input type="checkbox"/> Sudden drop	<input type="checkbox"/> Surface potential testing	<input type="checkbox"/> Educational placement
<input type="checkbox"/> Decrement over time	<input type="checkbox"/> Neural response measures	<input type="checkbox"/> Type and amount of therapy
<input type="checkbox"/> Fails to meet expected performance	<input type="checkbox"/> Stimulus artifact	<input type="checkbox"/> Family involvement
<input type="checkbox"/> Intermittent performance	<input type="checkbox"/> Evoked potentials	<input type="checkbox"/> Puberty
		In addition, the adult checklist should be applied to a child whenever possible.

FIG. 2. A suggested checklist and assessment guideline for clinicians that the panelists felt could be useful in evaluating patients with suspected device malfunction. Presence and severity of the various aversive symptoms can be confirmed and rated by the patient. The guidelines remind clinicians to search for changes in performance and mapping as well as to change all external equipment.

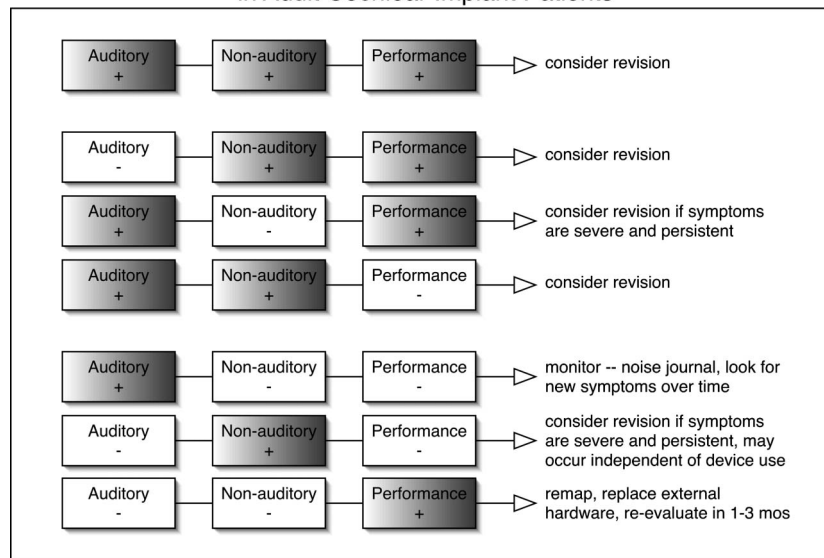
The appropriate management option for an individual is ultimately determined by the cochlear implant team, the patient and family, with input from other professionals actively involved with the implant user's health care. Management options may include 1) prolonged observation if the device continues to provide substantial benefit and aversive symptoms are tolerable; 2) removal and reimplantation; or 3) in rare cases, implantation of the contralateral ear when compromised auditory performance is the main issue. Figure 3 demonstrates one way of systematically determining an appropriate management strategy.

Future research directions include development of more accurate in-vivo device testing methods, validation of currently available in-vivo testing methodologies, animal modeling of specific device failure modes, prospective testing of a protocol for diagnosing soft failure, establishing criteria for determining clinical improvement following reimplantation, investigation of the potential harm that may be caused by leaving a failed device in

place (e.g., by current leakage) and postmortem recovery and evaluation of apparently normally functioning devices.

The panel recommends that a tool such as the Soft Failure Assessment Checklist (Fig. 2), or a modification of that instrument, be adopted by manufacturers and made available to clinicians. Use of such a tool can help move towards standardization of data sets for patients thought to have device failure. The panel also recommends adoption of criteria for establishing significant improvement following replacement surgery in adults (i.e., 15% improvement on CNC words, resolution of aversive symptoms). Determining the criteria for significant improvement in children is more complex. Expected outcomes vary widely based on the child's inner ear development, central auditory pathways, cognitive abilities, and post implant follow-up that it is difficult to provide a concise definition of clinical improvement. Complete resolution of aversive reactions to the device as evidenced by the child's acceptance and willingness

Diagnosis of Suspected Device Malfunction in Adult Cochlear Implant Patients



Auditory: atypical tinnitus, popping, buzzing or roaring, rate on a loudness scale of 1-100

Non-auditory: pain or shocking over the ICS, with or without the device on, rate on a pain scale 1-100.

Performance: drop in performance; performance worse than predicted

FIG. 3. The image presents a decision tree for the clinician evaluating a patient with the working diagnosis of a soft failure or suspected device malfunction once the existence of medical/surgical problems or device placement issues have been ruled out. Plus (+) signs indicate the presence of a sign or symptom where a minus (-) sign indicates its absence. The graded coloration of the (+) boxes indicates the relative severity of the symptoms for the patient. Although seven potential categories exist in this table, the variations in severity make the number of possibilities infinite. It is important to recognize that all decisions must be individualized for each patient and a cookbook approach is not possible. Those categories where revision surgery was recommended were considered to have a high likelihood of device-related problems based on the panelists' experience.

to wear the device, measurable response to auditory stimulation, and improved receptive and expressive language skills (based on the child's hearing age and developmental status) should be considered starting points as specific criteria are formed.

SUMMARY

In summary, CI soft failure is an uncommon occurrence in which a device malfunction is suspected but cannot be proven. It is a working diagnosis, based on characteristic symptoms such as shocking sensations, popping sounds, intermittency, or unexplained progressive decrement in performance. Complete otological evaluation, CT scan, expert re-programming, exchange of all external hardware, and integrity testing by the manufacturer are necessary before the working diagnosis is made. The usual management is device replacement when aversive symptoms are intolerable or performance becomes unacceptable as determined by the team and family.

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