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Quality standards for adult cochlear implantation in single-sided deafness and asymmetric hearing loss

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ABSTRACT

Objective: To establish a set of quality standards that will help implant centers provide each adult with single-sided deafness (SSD) or asymmetric hearing loss (AHL) with the best possible hearing rehabilitation option and professional care. These standards are the minimum that implant clinics can implement realistically.

Methods: Members of the HEARRING network used the Delphi method approach to discuss and agree on the minimum outcome measures for the evaluation of patients with SSD or AHL.

Results: These quality standards define SSD and AHL propose team structures and the minimum levels of experience and expertise necessary for their members, describe the resources and facilities that clinics should possess or have access to, and cover each stage of the patient journey, from referral to trials with nonimplanted devices to postoperative follow-up–in the case of cochlear implant provision–and long-term maintenance. Conclusion: This set of quality standards can help implant centers provide comprehensive and state-of-the-art pre, intra, and postoperative care for adults with SSD or AHL.

Keywords: Asymmetric hearing loss, cochlear implant, consensus statement, quality standard, single-sided deafness

Introduction

Cochlear implants (CIs) are a viable and effective treatment option for individuals with single-sided deafness (SSD) or asymmetric hearing loss (AHL). The difference between SSD and AHL is that SSD can be defined as moderate to profound hearing loss in the ipsilateral ear and normal hearing or a mild hearing loss in the contralateral ear, whereas AHL is defined as moderate to profound hearing loss in the ipsilateral ear and mild to moderate hearing loss in the contralateral ear. The classification criteria for SSD and AHL in terms of average pure-tone thresholds, as defined by Van de Heyning et al. (1), are presented in Table 1.

Several interventions are possible for SSD and AHL, the most common of which is the use of contralateral routing of signals hearing aid (CROS-HA) or hearing aids with bone-conduction devices (BCDs) or a CI. A CROS-HA and BCDs are the traditional treatments; however, only a CI can restore bilateral input to the auditory system and thereby enable binaural hearing.

To provide each CI candidate who has SSD or AHL with the best possible hearing solution, the HEARRING network has established a set of quality standards that are the realistic minimum standards attainable by any implant clinic/unit and which should be employed alongside current best practice guidelines. It is now customary in some places for both children and adults with SSD

Table 1. Audiological Classifications of SSD and AHL

Type	Ear	dB HL
SSD	Poorer ear	PTA ≥70
	Better ear	PTA ≤30
	Interaural threshold gap	≥40
AHL	Poorer ear	PTA ≥70
	Better ear	PTA >30 and ≤55
	Interaural threshold gap	≥15

PTA: Pure-tone average (0.5, 1, 2, and 4 kHz), dB HL: Decibel hearing loss, SSD: Single-sided deafness, AHL: Asymmetric hearing loss

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to receive a CI; however the provision of a CI is traditionally more common in adults with SSD/AHL (2) than in children; therefore, this set of quality standards will focus only on adults.

One nomenclature note for this paper is that people are referred to as CI candidates before implantation, as CI recipients between surgery and initial fitting, and as CI users after implantation. As noted throughout this paper, the cognitive abilities and health (mental and physical) of a candidate/user must be considered because these may influence how some of the procedures detailed in this paper are carried out.

Finally, this quality standard is the latest edition of a series of quality standards (3-10), that covers an aspect of medical devices and hearing health care. Each quality standard is intended to be a stand-alone document whose completeness does not necessitate readers having the others to hand. There is some inevitable overlap in content because several aspects of the standards are the same regardless of the topic (e.g. between an electric-acoustic stimulation CI provision in an adult and CI provision in a child).

Team structure

Structure of the cochlear implant team working with adults: The structure for CI teams working with adults with SSD/AHL is similar to the structure for those working with other adult CI users, which has been described by Müller & Raine (3). Additional personnel are required to address physical and cognitive/mental health needs particular to older adults. A CI team working with adults is a multidisciplinary team made up of the following key personnel:

Otologists: The senior ear, nose, throat surgeon will have experience in otology and CI surgery and is responsible for cochlear implantation and overseeing the completion of the required diagnostic procedures. Newly appointed surgeons will have had extended subspecialty training at an advanced level in otology and CI surgery, which will include having attended a temporal bone dissection course and working as a member of a CI surgical team with 12 months of supervision/mentorship under a senior surgical colleague.

Audiologists, Clinical Scientists, Physiologists, Rehabilitation Therapists, Hearing Therapists, Speech and Language Therapists, Clinical Physiologists, Engineers, Coordinators: These personnel must be qualified to the post-graduate level and have extensive clinical experience within the field of cochlear implantation. Coordinators will have a high level of clinical, organizational, leadership, and professional skills. They are responsible for the day-to-day management of the program and will ensure that appropriate services are provided for each candidate throughout the CI recipient pathway.

Main Points:

- This consensus statement proposes a series of minimum outcome measures for evaluating those with acquired single-sided deafness (SSD) or asymmetric hearing loss (AHL).
- For adults with SSD or AHL, a cochlear implant is the only device capable of restoring bilateral input to the auditory system and therefore capable of possibly providing binaural hearing.
- With treatment through cochlear implant provision becoming increasingly common, it is important that implant clinics do their utmost to ensure that each candidate/recipient receives a state-of-the-art level of care. These quality standards should help clinics obtain and maintain such a level.

Anesthetists for Older Adults: Anesthetics should be administered by appropriately qualified and experienced personnel. Preanesthetic assessment and optimization of comorbidities are essential, particularly in older adults.

Consulting Specialists for Older Adults: Neurologists, neuropsychologists, geriatricians, gerontologists, ophthalmologists, social workers, physical therapists, occupational therapists, and nursing home personnel may be consulted.

Cochlear Implant Head of Service* and *Administrator/Secretary: The Head of Service (or Manager) is accountable for the delivery of the multidisciplinary service. They will provide scientific and clinical leadership and have managerial responsibility for service design, forward planning, finances, patient management, and human resources. The administrator/secretary will have a high level of organizational, communication, and information technology skills. They will work closely with the Head of Service.

The CI team personnel should be members of the relevant national and/or international CI professional groups. Clinical team members should receive regular training on developments within the CI field. Furthermore, personnel requirements for cochlear implantation should be in line with national standards and guidelines. One person can perform several of the roles described above.

Cochlear Implant Team: Additional Support

The core team should include individuals with skills and experience in fitting hearing aids or should have access to such a person. In addition, the team should include or have access to professionals specializing in audiological medicine, tinnitus, balance, radiology, medical physics, genetic counseling, psychology, and psychiatry. CI teams may develop partnership services with local services where appropriate. Such partnership services must have appropriate training and expertise.

Accommodation (Where Applicable)

To ensure ease of communication, there should be suitable telecommunication access for candidates/users with hearing impairments and their families to contact clinics through several different media (e.g. speech-to-text and text-to-text applications, e-mail, short message services, WhatsApp).

All patient areas should be appropriate to the needs of a population with hearing impairments; for example, they should have visual alerts (such as that used to convey appointment information), visual alarms (e.g., fire alarms), and appropriate assistive listening devices in the clinic.

Clinic areas should be large enough to comfortably accommodate the candidate/user, family members, clinicians, and observers or interpreters in addition to necessary equipment including wheelchairs and walkers.

Examination rooms should be sufficiently separated from waiting areas so that noise from the latter does not disturb counseling and treatment and privacy is maintained.

Printed and electronic materials should be suitable for adults with vision loss and/or mild cognitive impairments. Issues such as font size, sentence structure, and presentation, in both printable and electronic materials, should be considered carefully.

Clinical facilities

Clinical facilities should have pure-tone audiometry, speech perception testing in silence and noise, sound field audiometry, sound localization testing, hearing aid fitting and testing, probe-tube microphone measurements, tympanometry, otoacoustic emissions testing, objective measurements, balance function testing, rehabilitation, and imaging facilities.

All audiological equipment must meet nationally recognized standards and calibrated to national standards as required, on an annual basis, using recommended methods.

Referral and selection criteria

1. Candidate selection criteria and guidelines for referring candidates for an assessment of their suitability for CI should be available, in writing, on request.
2. In general, adults with prelingual SSD/AHL are not ideal CI candidates. Special circumstances for implantation may apply after intensive counseling on realistic expectations and if alternative treatment options provided insufficient benefit.
3. Adults with postlingual SSD/AHL and moderate to profound hearing loss are good candidates to benefit from CI if CROS-HAs or BCDs on soft bands were insufficient. This is particularly true for adults with SSD caused by sudden idiopathic sensorineural hearing loss and who are looking to restore binaural hearing, improve localization, or reduce tinnitus in the ear with poorer hearing.
4. Candidacy criteria for CI provision are generally the same for those with SSD/AHL as for those with bilateral deafness except that the functionality of the contralateral ear is ignored.
5. Referral and selection of candidates should be in line with relevant national standards and guidelines.
6. If a candidate falls outside selection criteria but is recommended for CI by the CI team, the latter should apply to a local funding authority for financial support via an individual candidate Case of Need, if necessary.
7. Candidate selection criteria should be reviewed regularly by the HEARRING network to keep national authorities informed regarding recommendations for future developments in this area.
8. The referring physician should be informed that their referral has been accepted. This must be undertaken according to the current targets and mechanisms set by the National Health Authority and comply with local agreements.

The Process of Assessment

The process of assessment must be performed in the most efficient and timely way possible. Overall, it should not exceed 18 weeks. The following are recommended:

1. Unless clinically contraindicated, all candidates must have a comprehensive CI assessment to assess the functional hearing abilities of their poorer ear and determine whether these are likely to be significantly improved via CI. An important part of the assessment process is the demonstration of the anatomical and functional integrity of the auditory nerve. This is particularly true for candidates with an etiology that may have compromised the integrity of the auditory nerve through disease, trauma, and/or surgery.
2. Service delivery should consider the aims and objectives of the national government authority frameworks.
3. The assessment track for each candidate must be followed according to a written checklist and recorded in their hospital file.
4. After the preoperative assessment, a written report detailing its outcome will be sent to the referring physician within the appropriate reporting time scales.
5. Waiting times for diagnostic testing and treatment should be as short as possible and comply with current national and local targets. Current HEARRING targets are 6 weeks for diagnostics and 18 weeks for treatment.
6. Details on locally agreed patient pathways should be available on request.
7. Fast tracking of candidates through the assessment process must be available when clinically indicated.

Preoperative Assessments

Medical assessments

1. All candidates referred to a CI center should have a medical consultation with the team otologist. The otologist should follow current recommendations provided by their national medicines and health care products agency.
2. Candidates should undergo a magnetic resonance imaging or computed tomography scan, or both if needed, to ensure nerve viability for electrical stimulation. If these are inconclusive, promontory stimulation or evoked auditory brainstem response testing shall be conducted to evaluate the functional integrity of the auditory nerve in the dysfunctional ear. A CI is contraindicated in candidates with SSD owing to an absent or highly dysfunctional auditory nerve. In such cases, a BCD or CROS-HA is recommended.
3. Appropriate referral for balance/vestibular assessment should be available if indicated.
4. For each candidate, it is the responsibility of the surgeon, either alone or through an appropriately trained nurse, to conduct a medical consultation during the assessment process and preadmission to ensure that the candidate is medically fit to undergo the treatment; discuss with the patient all pre and postsurgical risks associated with the treatment and the necessity for vaccination to minimize the risk of pneumococcal meningitis; refer the candidate for genetic counseling, if required; and obtain fully informed verbal and written consent from the patient for the treatment.

Audiological assessments

Each candidate must undergo a full audiological assessment performed according to professionally accepted protocols. This includes an otoscopic examination, determination of hearing thresholds bilaterally using pure-tone audiometry or other recognized methods suitable for the candidate, determination of uncomfortable loudness limits and bilateral middle ear function, an objective hearing threshold assessment, aided and unaided speech perception testing in a quiet environment and in noise with appropriate masking of the better ear when required, and hearing aid testing and evaluation. The tests must be sensitive enough to avoid ceiling effects.

Further testing that should be conducted includes bi-CROS-HA fitting, testing, and evaluation, preferentially with a follow-up period of at least 3 weeks; BCD soft band fitting, testing, and evaluation, preferentially with a follow-up period of at least 3 weeks; tinnitus disturbance evaluation; sound localization testing; and a quality of life assessment via validated questionnaires.

Candidates who use a hearing aid on their ipsilateral ear should have their current hearing aid configuration re-evaluated and either have their settings revised or have the best available new hearing aid fitted. The suitability of amplification should be verified.

Candidates fitted with a new hearing aid or whose ipsilateral ear hearing aid settings have been changed may require access to a structured program of auditory rehabilitation. For some candidates, the period may be extended to several months for clinical reasons.

Bi-CROS-HA evaluation: As part of the preoperative audiological assessment, each candidate shall be fitted with a CROS-HA or, if the candidate wears a hearing aid on their better ear, a bi-CROS-HA. Candidates shall wear this device for at least 3 weeks. At follow-up, the suitability of the bi-CROS solution should be verified using the same minimum set of test measures as defined earlier in this paper. These measures include the following:

1. Unaided sound field hearing threshold testing
2. Speech perception tests using standardized prerecorded speech materials. Speech testing in a quiet environment and in noise shall be conducted for both aided and unaided bi-CROS listening conditions; the latter with contralateral hearing aid alone, if applicable. The test configurations for speech in noise shall include S_0N_0, S_0N_{SSD}, $S_{SSD}N_{AH}$ (AH: acoustic hearing)
3. sound localization testing
4. assessment of the quality of life and tinnitus, if applicable, using validated questionnaires

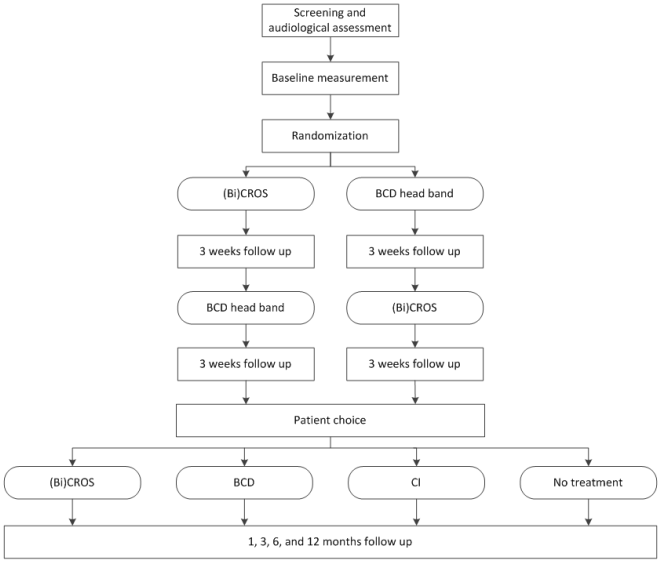

Figure 1. Recommended clinical assessment, decision, and follow-up tree (1).

BCD soft band evaluation: As part of the preoperative audiological assessment, each candidate shall also be fitted with a BCD soft band. Candidates shall wear this device for at least 3 weeks. At follow-up, the suitability of the BCD solution should be verified using the same minimum set of test measures as defined earlier in this paper.

The order in which bi-CROS-HA and BCD headband trials are conducted should be randomized as described in the consensus protocol recommended by a group of clinicians experienced at treating SSD/AHL (1). After the trials (Figure 1), the candidate should be carefully counseled on the various treatment options before choosing to pursue treatment with a bi-CROS-HA, BCD, CI, or no treatment.

Communication

Preoperative assessment should include a full assessment of the candidate's communication and social strategies. These assessments may take the form of observation, subjective description, or evaluation through formal testing after the candidate's age and hearing status are taken in to account.

Psychological Status

Referral to a qualified psychologist or psychiatrist should be initiated if there are concerns regarding the candidate's mental health, learning ability, personality and motivation, adaptation to deafness or unrealistic expectations about cochlear implantation that cannot be adequately addressed in counseling by the CI program team.

A psychological assessment is mandatory in candidates with intractable tinnitus. Candidates with depression and/or a Beck Depression Inventory score >16 should not be recommended for a CI (11).

Cooperation of the CI team with other services

The CI program should cooperate, as appropriate, with other services, including other hospital departments such as audiology, radiology, medical physics, wards, and ambulatory care; local/national support groups; social services; and community and educational services. Furthermore, services provided for older adults should include neurology, neuropsychology, geriatrics, gerontology, ophthalmology, physical and occupational therapy, and home care. Contact with support services and the candidate's employers should only be made with the candidate's permission and at the discretion of the CI team.

Preoperative information and counseling

1. Basic information and counseling should be given to the candidate according to a written checklist and recorded in the candidate's hospital file.
2. The surgeon should discuss with the candidate the necessity for vaccination to minimize the risk of pneumococcal meningitis.
3. Teams should continuously monitor, review, and update the quality and quantity of the information they provide and should have a written protocol to determine when certain types of information are given to the candidate.
4. Verbal information should be supported by a written summary for the candidate whenever required.
5. Throughout the assessment period, candidates should have a clear understanding of the main benefits and limita-

tions of alternative treatment options, i.e., bi-CROS-HAs and BCDs. Unrealistic expectations regarding outcomes with these devices (e.g., that they can reinstate binaural hearing, spatial sound awareness, or spatial hearing) must be avoided. If possible, a measurement tool such as an expectations questionnaire should be included in the general assessment protocol.

6. Throughout the assessment period, candidates should obtain a clear understanding of the main benefits and limitations of CI use. Unrealistic expectations regarding CI use must be avoided. The importance of compliance with systematic rehabilitation and training with the CI should be addressed.
7. It is recommended that candidates–and when possible, their family and friends–should meet with experienced CI users who have SSD or AHL. Matching candidates and users in terms of age, duration of hearing loss, and type of CI may be beneficial.
8. The candidate's family and friends should be encouraged to become involved in all aspects of pre- and post-implant management. This should be done only with the permission of the candidate and at the discretion of the CI team.
9. All issues regarding CIs, including possible stigmatization, should be discussed and, if they wish, candidates should have an opportunity to meet people who have decided against implantation.
10. Waiting times for surgery and information about the hospital stay and postoperative follow-up should be outlined at the end of the assessment.
11. A final discussion between the candidate and key CI team members should be scheduled for the end of the assessment, at which an agreement will be reached about which, if any, treatment option to pursue.
12. If the outcome of the assessment is that implantation with a CI or BCD is not recommended, an exit clinic appointment should be offered to explain and discuss this recommendation and provide candidate support. If the outcome of the assessment is that a bi-CROS-HA is recommended, the candidate should be referred to a hearing aid professional. If no treatment is sought, the discussion should include recommendations for future management and an opportunity for re-referral in the future.

The cochlear implant device

The candidate should be given information on the technical specifications and the advantages and disadvantages of the CI models currently available regardless of their manufacturers. The candidate should be given an explanation of why they have been offered a particular CI or choice of CIs. Written information on the CI(s) offered should also be made available to the candidate.

The bone-conduction hearing device

The candidate should be given information on the technical specifications and the advantages and disadvantages of the BCD models currently available regardless of their manufacturers. The candidate should be given an explanation of why they have been offered a particular BCD or choice of BCDs. Written information on the device(s) offered should also be made available.

The BCD offered to the candidate should have a proven track record of safety and reliability, conform to the recommendations of the national regulatory agency, have the highest quality clinical and technical support available from the manufacturer; and meet national purchasing requirements where applicable.

Surgery and in-patient care

The surgical team, which may include an appropriately trained nurse, is responsible for conducting a comprehensive discussion with the CI recipient, before the operation, on the surgical procedure potential complications; they must also obtain informed consent for the procedure from the recipient. The consultant CI surgeon is responsible for the overall medical care of the CI recipient.

The surgical techniques employed should reflect the latest knowledge and be state-of-the-art. Every effort should be made to protect the inner ear/cochlea of the CI recipient and preserve any residual hearing they have. The surgeon will continue to monitor the progress of the CI recipient postoperatively and will be responsible for dealing with any surgical or medical problems that may arise in relation to the CI. An intra or postoperative radiological examination should be considered to check the position of the device and the electrode array. In addition, information regarding the surgical outcome must be documented and made available to the audiological and rehabilitation teams as soon as reliable data are available. Before discharge from the hospital, the CI recipient should receive written information regarding postoperative care of the wound/ear and pain management and what to do if medical/surgical problems arise. Further information on health and safety with a CI and a patient identity card should be provided to the CI recipient.

Postoperative fitting and tuning of the audio processor

Before fitting and programming, the surgical team should provide the audiologist with a copy of the implant registration and/or surgical report to ensure that they are aware of any complications, e.g., extracochlear electrodes. The audio processor should be fitted and programmed once the CI recipient's wound has healed satisfactorily. This should only be performed by experienced clinical personnel who have been fully trained in the relevant protocols and procedures (see the section on team structure). If there are any medical concerns preventing activation, a medical opinion should be requested. Each CI should be fitted and programmed according to the procedures recommended by the CI manufacturer to maximize the benefit for the CI recipient. An appropriate number of programming sessions should be offered to each CI recipient based on clinical need.

During these sessions, CI recipients and their family/caregivers, as appropriate, must be provided with a comprehensive explanation of the use of the audio processor and printed materials on its handling, operation, and care. CI recipients should be encouraged to contact the CI team if they have any questions or concerns. A written report, including a current audiogram (unaided and aided conditions), should be sent to the referring physician after initial processor fitting and at the 1-year treatment interval. A written report should also be sent to the referring physician if any serious problems arise.

Postoperative rehabilitation and assessment

Systematic postoperative rehabilitation should begin after initial fitting according to the individual needs of the user, to:

1. Facilitate acclimatization to the new sensation of sound and the integration of the CI with the contralateral acoustic ear. Extensive rehabilitation and training of the CI ear alone–for instance, through a direct signal input to the audio processor–is mandatory.
2. Reassure the user and their family/caregiver.
3. Outline the rehabilitation program.

The rehabilitation program should be tailored to the individual needs of each user. Counseling should support users and their families regarding expectations, rehabilitation procedures, and continuing commitment to the rehabilitation program. The rehabilitation program may include an evaluation of and training in localization skills, hearing tactics and listening skills, and speech intelligibility and social skills. Sufficient rehabilitation sessions should be offered to optimize the use of the CI. The user must have open access to the CI center (or a designated local partner service) for rehabilitation and counseling as required.

To allow progress to be monitored, appropriate standardized audiological, speech perception, and quality of life measures should be performed after initial tuning; this should be done at least twice but preferably 4 times (Figure 1) in the first year following implantation and at regular intervals thereafter. After the first year following implantation, the user should be offered an annual audiological review. This structured schedule can be adapted to the wishes of the user if necessary. Users should have access to additional appointments for examination as required.

To monitor the progress of the user and offer additional support when needed, follow-up outcome measures are recommended after 1, 3, 6, and 12 months. These measures include the following:

1. Pure-tone audiometry: Unaided air-conduction hearing thresholds (averaged over tone frequencies of 0.5, 1, 2, and 4 kHz) shall be measured pre and postoperatively on the nonimplanted ear. Monitoring the thresholds of the better ear is important for the early detection of progressive hearing loss, particularly in users with AHL.

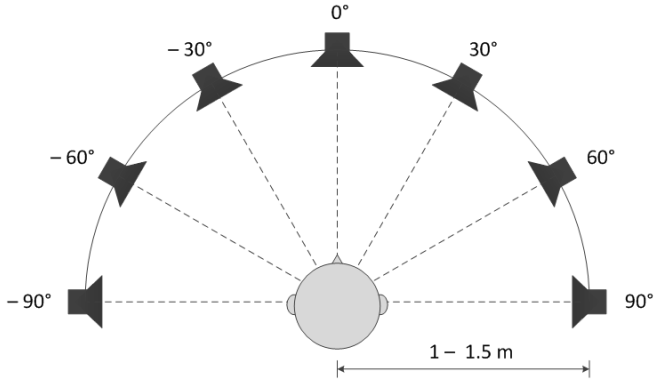

Figure 2. Test setup for sound localization. The radius of the loudspeaker ring should be at least be 1 m and 1.5 m if possible (1).

2. Masked speech perception: Speech perception should be assessed with a standard audiometric and validated sentence test, using a free-field setup in a sound-treated room. Listening conditions should include 1) the ipsilaterally unaided and contralaterally best-aided condition, i.e., with the CI off and the hearing aid on (the latter in the case of AHL) and 2) the bilaterally best-aided condition with the CI and hearing aid on (again, the latter in the case of AHL). The masker should be presented at a fixed level of 65 dBA and the speech level should be varied adaptively to determine the speech reception threshold (SRT) at which the user correctly understands 50% of the sentences. In CI users with AHL who are unable to wear a contralateral hearing aid, the resulting SRT can be highly positive, i.e., the speech level can increase to high levels. In such cases, the adaptive procedure should be reversed by presenting the speech at a fixed level of 65 dBA and adapting the noise level. If possible, same-sex 2-talker babble should be used as a masker. As shown below, a total of 3 different spatial configurations should be assessed, both in the CI-aided and in the CI-unaided conditions (the contralateral ear should always be aided if the user wears a hearing aid in the ear, e.g., if they have AHL):

   i. $S_{SSD}N_{AH}$: Signal on the CI side, masker on the side with acoustic hearing;
   ii. S_0N_{SSD}: Signal from the front, masker on the CI side; and
   iii. S_0N_0: Signal and masker from the front.

Using these configurations, the following measures can be derived for the following binaural effects (where a positive effect size in decibel indicates a binaural benefit of CI use):

i. Head shadow (dB) = SRT $S_{SSD}N_{AH}$ unaided – SRT $S_{SSD}N_{AH}$ aided;
ii. Squelch (dB) = SRT S_0N_{SSD} unaided – SRT S_0N_{SSD} aided;
iii. Summation (dB) = SRT S_0N_0 unaided – SRT S_0N_0 aided; and
iv. Spatial release of masking (dB) = SRT S_0N_0 aided – SRT S_0N_{SSD} aided.

3. Sound localization: We recommend using the setup shown in Figure 2 to assess the ability to localize sound sources. Localization testing should be conducted in a sound-treated room with at least 7 loudspeakers distributed equally along a semicircle between a -90° (left) and 90° (right) azimuth. The recommended localization stimuli are single noise bursts with a duration of 1 s, including rise and fall times of 20 ms each. A total of 2 noise stimuli of different spectral shapes should be presented randomly to confound monaural spectral cues (1, 12).
4. Quality of life: A short, validated, and easy-to-use test, e.g., the 12-question version of the Speech, Spatial, and Qualities of Hearing questionnaire, should be used (13).
5. Tinnitus: In users with tinnitus in the ipsilateral ear, the tinnitus handicap should be assessed preoperatively and at all follow-up intervals. Our preferred tool for this is the Tinnitus Functional Index questionnaire because of its reliability, ease of scoring, and high sensitivity to change (14, 15); however, other tools such as the Tinnitus Questionnaire, Tinnitus Handicap Questionnaire, Tinnitus Handicap Inventory, or Tinnitus Reaction Questionnaire could also be used (16-18).

6. Daily device use: A daily-use criterion that reflects the hours of consistent device use should be included in the longitudinal data collection. This should be done either using a simple questionnaire on hours of use per day or via technical options such as data logging functions in the device.

The measures indicated above are intended as a minimum set of recommended outcome measures. Additional measures (e.g., monosyllabic speech recognition testing in a quiet environment or the Nijmegen Cochlear Implant Questionnaire for hearing-related quality of life) can also be included, particularly if they are already a part of the routine clinical evaluation. Presentation of sounds through direct input to the CI audio processor is recommended for assessing speech recognition in the implanted ear alone. The direct-input sound gain should be adjusted to comfortable loudness for the CI user. If a calibrated presentation level is mandatory, speech recognition with the CI alone should be assessed using a free-field setup: a 65-dBA speech-shaped masking noise should be presented to the better ear through an insert earphone and a circumaural earphone should be placed over the better ear to provide additional attenuation of the speech target.

Follow-Up and long-term maintenance

The user must have open access to the CI center (or a designated local partner service) for programming, rehabilitation, and surgical reviews as required. Adequate spare parts and external equipment replacements must be available as required. Arrangement for replacements of lost or damaged processors and upgrades to the audio processor should be equitable for all users according to national regulations and policies.

Device failure

If internal device failure is suspected, the CI manufacturer should be contacted and the user should be offered an appointment promptly (within 1 day) to check the internal and external components of the device. If indicated, a clinical/engineering representative from the manufacturer should be available at the user's next appointment to provide support. Upon confirmation of internal device failure, the clinical personnel (see the section on team structure) must inform the Otologist Surgeon and the Head of Service/Coordinator, and an urgent appointment with the implant Otologist Surgeon should be offered to the user to discuss reimplantation or other options. If reimplantation is agreed on with the user, it should be done as soon as medically possible and appropriate to minimize the burden of auditory deprivation.

The failure of the device should be reported to the relevant national authorities.

Clinical management

All aspects of the CI service should have adequate record keeping systems to facilitate auditing and planning. The CI program should perform regular audits and comply with the requirements of the responsible national authorities. Audits should cover clinical activity, staffing levels, user performance outcomes, medical and surgical complications, and device failures.

Transfer of care (national)

A protocol must be in place to transfer the care of a user to an alternative program or accept the care of a user from an alternative program if requested. Before a referral is made, the receiving center will confirm that they can support the type of CI worn by the user.

All the relevant documentation–including demographic information, information on the internal device and external processor used, recent programs, audiological outcomes, medical details of the surgery, and any complications–will be sent to the receiving center.

The receiving CI program will acknowledge the referral in writing and confirm that funding has been agreed on to continue supporting the user.

Generally, users will not be referred to another center<1 year after implantation. This is to allow for postoperative medical follow-up, establish suitable device programming parameters, and provide initial rehabilitation.

Feedback and complaints

The documentation provided by the CI program should include written information about complaints procedures within the hospital and other relevant services. Candidate/user and caregiver feedback should be collected systematically to inform service review and should be managed according to local policy.

Ethics Committee Approval: Ethics Committee Approval is not necessary due to the nature of this study.

Informed Consent: Informed consent is not necessary due to the nature of this study.

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