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Guideline "Implantable hearing aids"—short version

German S2k guideline of the Working Group of German-Speaking Audiologists, Neurootologists and Otologists (ADANO), of the German Society of Oto-Rhino-Laryngology, Head and Neck Surgery (DGHNO) in collaboration with the German Society of Audiology (DGA), the German Society of Phoniatrics and Pediatric Audiology (DGPP), and patient representatives

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I. Todt is the coordinating author of this guideline.

In the interest of readability the masculine form has been chosen in the text, nevertheless, the details provided refer to members of both sexes.

1. Preamble

This guideline covers preoperative investigations, indications, contraindications, operative and postoperative phase of implantable hearing aids for hearing loss in adult and pediatric patients (abbreviation: ImplHA guideline). Simultaneously requirements for structures, processes and quality measurements are described. This guideline furthermore describes the framework, personal requirements and documentation requirements.

The treatment with cochlear implants (including auditory brainstem implants) is covered by the respective guidelines of the German Society for ENT, Head and Neck Surgery and the German Society for Phoniatrics and Pediatric Audiology.

2. Interdisciplinary decision and evaluation process

The decision and evaluation process in preparation for implantation of a hearing aid should be interdisciplinary. The team

involved in the decision should comprise an ENT specialist and in children a specialist for speech, language and pediatric hearing disorders, as well as a hearing aid specialist (engineer, audiologist, hearing aid acoustician) during the pre- and postoperative evaluation.

If needed, further specialties should be consulted (e. g. educator, speech and language therapist, psychologist). The decision should be made by the surgeon, based on individual findings and in agreement with the involved specialties. Postoperative evaluation should be done in an interdisciplinary setting to ensure appropriate quality control.

3. Classification of implantable hearing aids

The ImplHA guideline covers all active implantable hearing aids in which the transmitted signal to the cochlea is not processed in a conventional acoustic or electric way, but transmitted via mechanical stimulation of the cochlea. These implantable hearing aids in general consist of 5 components: signal receiver, signal processor, signal transmitter, signal output and a power source. They differ with regards to arrangement and implantability of the individual components. The signal output is achieved via mechanical transmission, meaning all systems are acoustic–mechanic transducers. Signal processing can be individually tailored to the patients' needs by means of programming.

Active middle ear implants

The signal transmission is located in the middle ear, whereby the signal transducer is coupled with an intact ossicular chain [19], parts of an intact ossicular chain or the round window membrane. Systems that are in direct contact with the perilymphatic fluid via penetration of the membrane are also included in the definition [10]. Fixation can be achieved via coupling elements [13, 14, 33], additional prosthesis, and autologous or allogeneic materials [28].

Partially implantable active middle ear implants

The power source and the microphone as well as the signal processor are placed in an external audio processor. The signal is transmitted wireless to the implantable component, which is transducing the signal. The external audio processor is typically fixed via a magnet to the implantable part. The skin remains intact [19].

Fully implantable active middle ear implants

All 5 components are implanted. The microphone is located either within the intact middle ear or subcutaneously. The power is supplied by transdermal chargeable batteries or replaceable batteries [24].

Bone conduction hearing aids

In this device, the signal is transduced to the skull. The mechanical oscillations of the signal transducer are transmitted to the inner ear via bone. Both inner ears are stimulated; however the signal transmitted to the contralateral ear is attenuated, depending on the frequency.

Active bone conduction hearing aids

In this device, the power source, microphone and signal processing are located in an external audio processor. The signal transmission is wireless to the implantable component of the hearing aid. The implanted component is responsible for signal transduction. The transducer is located in the skull bone. Typically, the audio processor is fixed via a magnet to the implanted component. The skin remains intact [12, 26].

Passive bone conduction hearing aids

Similarly, the power source and microphone as well as signal processing are located in an externally worn audio processor. The implanted component is passive.

Passive transcutaneous bone conduction hearing aids

The signal from the external audio processor is transmitted via the magnets of the external unit and the implantable unit (magnet coupling). The implantable component is screwed to the bone of the skull [17, 29] and is responsible for signal transduction.

Passive percutaneous bone conduction hearing aids

The signal of the externally worn audio processor is transmitted via a rigid coupling to an osseo-integrated bone anchor [30].

4. Preoperative investigations

The responsibility regarding the necessary preoperative investigations lies with the surgeon. These investigations can be done in an outpatient or inpatient setting. The following requirements should be kept in mind:

- general patient condition,
- history,
- ENT findings,
- imaging (high resolution CT, DVT or flat panel tomography, FpT), always perform an MRI (exclusion of neurodegenerative disorders, retrocochlear lesions) except in cases where a percutaneous hearing implant is planned,
- pure tone audiometry including bone and air conduction thresholds as well as impedance audiometry and if necessary specific audiometry in pediatric cases,
- audiometric topodiagnostic including otoacoustic emissions and early evoked response audiometry (exclusion of retrocochlear hearing loss or auditory neuropathy) if needed in individual cases,
- speech audiometry, including speech in noise audiometry,
- adjustment and testing of existing hearing aids in noise and in quiet (if necessary in situ measurements),
- preoperative simulation of expected hearing result with the planned implantable hearing aid—if possible,
- if necessary psychological/psychiatric consultation to diagnose potentially treatment delaying conflicts,
- if available, questionnaires (e. g. APHAB, HHIE, IOI-HA, SSQ, BBSS) should be used [1, 15, 21].

5. Indications (medical and audiological indications, patient-based indications)

The indication for a device-based hearing rehabilitation according to the German hearing aid guideline ("Richtlinie des Gemeinsamen Bundesausschusses über die Verordnung von Hilfsmitteln in der vertragsärztlichen Versorgung (Hilfsmittel-Richtlinie/HilfsM-RL)") must be fulfilled. In the case of a *unilateral hearing rehabilitation* this includes:

- hearing loss of the worse ear in pure tone audiometry (DIN ISO 8253-1) of at least 30 dB (SPL) at at least one of the tested frequencies between 500 and 4000 Hz,
- in speech audiometry the SRS („Speech Recognition Score") with head phones (DIN ISO 8253-3) of the worse ear at 65 dB (HL) should not exceed 80%.

In case of *bilateral hearing rehabilitation*:

Standard of care should be a bilateral hearing rehabilitation. Prerequisite for bilateral rehabilitation is:

- hearing loss of the *better* ear in pure tone audiometry (DIN ISO 8253-1) of at least 30 dB (SPL) at at least one of the tested frequencies between 500 and 4000 Hz, and
- in speech audiometry the SRS with head phones (DIN ISO 8253-3) of the better ear at 65 dB (SPL) should not exceed 80%.

Hilfsmittel-Richtlinie, version: 17th December 2015

The indication criteria for implantable hearing aids are fulfilled in patients in whom a conventional hearing aid either due to medical or audiological reasons cannot be used, and if by using an implantable hearing aid long-term rehabilitation can be expected [19, 30]. Prior to any implantation a documented conventional hearing aid trial is mandatory, including professional setup and optimization and follow-up taking into consideration the individual hearing pattern.

The hearing aid chosen should be the optimal choice given the medical and audiological factors to provide the best possible rehabilitation [25]. The expected aided SRS is most important. If bilateral hearing rehabilitation is indicated both sides should be aided. Bimodal hearing aids are possible. The indication should be made team based, after thorough counselling of the patient by the surgeon and in consideration of the available interdisciplinary information.

Limitations and indication criteria set by the producer are to be considered [25]. In comparison to conventional hearing aids one or more of the following criteria should be met:

Conductive hearing loss.

Wearing conventional hearing aids causes recurrent external ear canal inflammation (e. g. chronic otitis externa, inflammatory meatal fibrosis), sensitivity (e. g. pruritus) and other medical symptoms (such as external auditory canal eczema, pain in the ear canal) which prevent a lasting use of the conventional hearing aid [19, 27].

Furthermore, if the conventional hearing aid does not sufficiently compensate the existing hearing loss, an implantable hearing could be indicated.

Conductive hearing loss and combined hearing loss.

- Better SRS through an implantable hearing aid could be achieved:
  - Especially in cases of conductive hearing loss and combined hearing loss, in which conventional air conduction hearing aids do not sufficiently aid hearing. This includes malformations, acquired hearing loss as a result of middle ear surgery and temporal bone surgery as well as sclerosing middle ear conditions [3].
  - In cases of acquired conductive hearing loss, all conventional surgical means should be exhausted.

The regular use of conventional hearing aids can cause ear canal inflammation (e. g. chronic otitis externa, inflammatory meatal fibrosis), sensitivity (e. g. pruritus) and other medical symptoms (such as external auditory canal eczema, pain in the ear canal) which prevent a lasting use of the conventional hearing aid.

Single sided deafness.

- Single sided deafness can be regarded as a special case: an indication could be set in patients who do not fulfill the indication for a cochlear implant (missing or destroyed vestibulocochlear nerve) and in whom satisfying hearing rehabilitation with conventional CROS/BiCROS ((bilateral) contra lateral routing of signal) hearing aids can not be achieved. The indication in these cases exists exclusively for bone conduction hearing aids [16].

5.1 Distinction of indications of the existing systems

There is an overlap of indications and spectrum of use of the currently available implantable hearing aids. The patient should be thoroughly counselled about the existing implants, in order to be able to form an informed decision. The following criteria could help in choosing the right system:

- The aim should be a long-term hearing rehabilitation of more than 30 dB respective the augmentation characteristics of the system [25]. To achieve sufficient speech recognition the dynamic range of the system should be of at least 30–35 dB [25].
- CROS effects should be taken into consideration [4].
- The preoperative bone threshold should not be planned at the maximum output level of the implantable hearing aid; a reserve should be available to enable sufficient rehabilitation in case of progressive hearing loss.
- Advantages and disadvantages of a transcutaneous vs. a percutaneous implantation should be considered [32].
- MRI safety and possible imaging artefacts in individual implants should be considered [22].

5.2. Special notes on aiding children with dysplasia

Early stimulation of the affected ear should be aimed for children with dysplasia. Like in other forms of hearing loss a selective and direct stimulation of

the affected ear should be aimed for, as far as the morphology permits.

A temporary transcutaneous bone conduction system (e. g. held by a headband) from birth should be considered, until the patient has fulfilled the criteria for an implantable hearing aid (see also: German guideline on peripheral hearing disorders in children). In individual cases an implantable hearing aid can be considered without a trial of a conventional hearing aid. The audiologic approvement of the cochlear function is mandatory. Depending on the chosen implantable hearing aid, a preoperative simulation can be done [5, 20].

The selection of the implantable hearing aid should be based on age, anatomic and audiologic criteria. The inner ear threshold determines the audiological–technological criteria of the implant [25]. Scoring systems are available for objectifying anatomical findings [8]. For preoperative planning and positioning of bone conduction hearing aids, CT-based simulations could be helpful [2, 23, 31]. The implantation of a hearing aid should be performed considering possible plastic reconstructive surgery of the pinna at a later stage [6, 9, 11].

5.3. Contraindications

The following conditions are absolute contraindications:

- severe or profound sensorineural hearing loss,
- considerable progression of the hearing loss, which will lead to insufficient hearing rehabilitation by the implantable hearing aid.

The following conditions are relative contraindications (existing or expected):

- impairment of wound healing,
- dermatologic disorders,
- implant rejection,
- can't use the implant.

5.4 Consent taking

Prior to implantation the patient has to be consented for the following issues:

- advantages and disadvantages/special risks of the available implantable hearing aids (e. g. including the MRI safety),
- indications and contraindications,
- treatment alternatives,
- risks and side effects of the surgical procedure,
- aftercare and follow-up,
- necessary technical aids.

6. Operative procedure

The implantation should be done in an inpatient setting.

6.1. Requirements on the surgeon and surgical equipment

The following minimum requirements are to be fulfilled by the implanting surgeon:

- experience in special microsurgery of the temporal bone over many years.

Prior to performing this type of surgery for the first time, an attachment to an experienced unit, supervision by an experienced surgeon and an introduction by the respective manufacturer is mandatory.

The implanting center has to document the number, outcome and complications in all cases, preferably via a database.

Intraoperative facial nerve monitoring has to be available and should be used in cases where it is deemed useful.

A backup implant, screws and fixtures have to be available.

6.2. Possible complications of implanting hearing aids

The following possible complications could occur during the procedure and should be managed accordingly [7, 18, 34]:

- bacterial infections of the middle ear with possible spread to the implant bed (see below), impaired wound healing of the implant bed, the percutaneous screw and the suture,
- acute cochlea–vestibular disorders (sensorineural hearing loss, balance disorders, loss of residual hearing, labyrhintitis, tinnitus) (irreversible in individual cases),
- facial nerve damage,
- damage to the chorda tympani (taste disturbance),
- intracranial hemorrhage,
- intracranial abscess formation,
- liquorrhea,
- technical faults and complications.

6.3. Recognition of special rules on active medial products

According the German medical product law (Medizinprodukte-Betreiberverordnung (MPBetreibV, Abschnitt 2 § 10)), the surgeon has the responsibility of handing out written information regarding the implant after the implantation. This information should contain general advice using layman's terms. The content of this written information should comply with the MPBetreibV and the hand out should be documented.

7. Postoperative period and evaluation

7.1 First adjustment

After the procedure a follow-up, primarily by the ENT specialist, should be in place like in other middle ear procedures. Besides regular wound check-ups (dressing changes, bone conduction tests, removal of suture material) the postoperative follow-up should comprise the following:

- medical aftercare (see above),
- first adjustment of the audio processor and technical check-ups at latest 4 to 6 weeks post surgery (in non-complicated cases) by staff specially trained and experienced in audio processor adjustments,
- situation-dependent further optimization of the audio processor by staff specially trained and experienced in audio processor adjustments,
- hearing tests (see section "Preoperative investigations") (at least during the first adjustment of the audio processor and following all subsequent audio processor adjustments after 3, 6 and 12 months),

- technical and audiometric check-ups are the responsibility of the implanting unit (yearly, see below),
- documentation and evaluation of results,
- training in the use of the systems as well as additional systems.

The proof of special qualifications is to be done by proof of regular training: for specially trained staff via the implant manufacturer and in the case of external cooperation partners this has to be agreed on in the cooperation contract with the implanting clinic. Furthermore the specially trained staff has to attend indications and evaluation meetings.

The evaluation and documentation of the treatment process in implanted patients should be done by using quantitative and qualitative measures. With the help of these, individual treatment should be agreed on, checked and judged. Evaluation forms the base of quality control and the whole treatment. The evaluation is meant to capture the indication criteria, decisions during the treatment process and planning, including the postoperative period and complications.

7.2. Follow-up

Follow-up has to be done at regular intervals (usually once a year), or if new problems arise. It should, in a documented fashion, entail a technical check, counselling and a medical check as well as a pure tone audiometry. This is necessary to document long-term effects, complications, update on new available technologies and continued patient support. It furthermore helps to ensure continuous hearing rehabilitation, quality control and the setting of indications for further diagnostic, therapeutic or rehabilitative measures (e. g. audiotherapy). Private ENT practitioners can be included in the follow-up if coordinated with the implanting center. Extradepartmental hearing aid acousticians can be included if they gained the necessary qualifications (see above). The cooperation could entail the adjustment of the sound processor.

The proof of special qualifications is to be done by proof of regular training: for specially trained staff via the implant manufacturer and in the case of external cooperation partners this has to be agreed on in the cooperation contract with the implanting clinic. Furthermore the specially trained staff has to attend indications and evaluation meetings.

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Compliance with ethical guidelines

Conflict of interest. Information on the conflict of interest can be found under:https://www.awmf.org/fileadmin/user_upload/Leitlinien/017_D_G_f_Hals-Nasen-Ohrenheilkunde__Kopf-_und_Halschirurgie/017-073i_Implantierbare-Hoergeraete_2018-06.pdf

The information corresponds to the long version of the guidelines on the AWMF homepage, see link: https://www.awmf.org/uploads/tx_szleitlinien/017-073l_Implantierbare-Hoergeraete_2018-06.pdf

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