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A Novel Implantable Hearing System with Direct Acoustic Cochlear Stimulation

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Key Words
Auditory prosthesis · Hearing impairment · Speech intelligibility · Stapes · Vibration · Mixed hearing loss

Abstract
A new implantable hearing system, the direct acoustic cochlear stimulator (DACS) is presented. This system is based on the principle of a power-driven stapes prosthesis and intended for the treatment of severe mixed hearing loss due to advanced otosclerosis. It consists of an implantable electromagnetic transducer, which transfers acoustic energy directly to the inner ear, and an audio processor worn externally behind the implanted ear. The device is implanted using a specially developed retromeatal microsurgical approach. After removal of the stapes, a conventional stapes prosthesis is attached to the transducer and placed in the oval window to allow direct acoustical coupling to the perilymph of the inner ear. In order to restore the natural sound transmission of the ossicular chain, a second stapes prosthesis is placed in parallel to the first one into the oval window and attached to the patient's own incus, as in a conventional stapedectomy. Four patients were implanted with an investigational DACS device. The hearing threshold of the implanted ears before implantation ranged from 78 to 101 dB (air conduction, pure tone average, 0.5–4 kHz) with air-bone gaps of 33–44 dB in the same frequency range. Postoperatively, substantial improvements in sound field thresholds, speech intelligibility as well as in the subjective assessment of everyday situations were found in all patients. Two years after the implantations, monosyllabic word recognition scores in quiet at 75 dB improved by 45–100 percent points when using the DACS. Furthermore, hearing thresholds were already improved by the second stapes prosthesis alone by 14–28 dB (pure tone average 0.5–4 kHz, DACS switched off). No device-related serious medical complications occurred and all patients have continued to use their device on a daily basis for over 2 years.

Introduction

Active hearing implants are a dynamic area of research [Chen et al., 2004; Colletti et al., 2006; Jorge et al., 2006]. When compared to conventional hearing aids, implantable aids hold the promise of substantial improvements regarding sound quality, speech recognition, sound distortion, reduced feedback and less discomfort due to absence of ear canal occlusion [Zenner and Leysieffer, 1997; Kasic and Fredrickson, 2001; Ko et al., 2001].

The single most important component of an implantable hearing aid is the transducer, i.e. the equivalent of the loudspeaker in conventional hearing aids, providing a direct mechanical interface to the human ear, typically at the level of the ossicular chain [Huttenbrink, 1999]. Today, several types of implantable hearing aids are either available or have been proposed [Ball et al., 1999;

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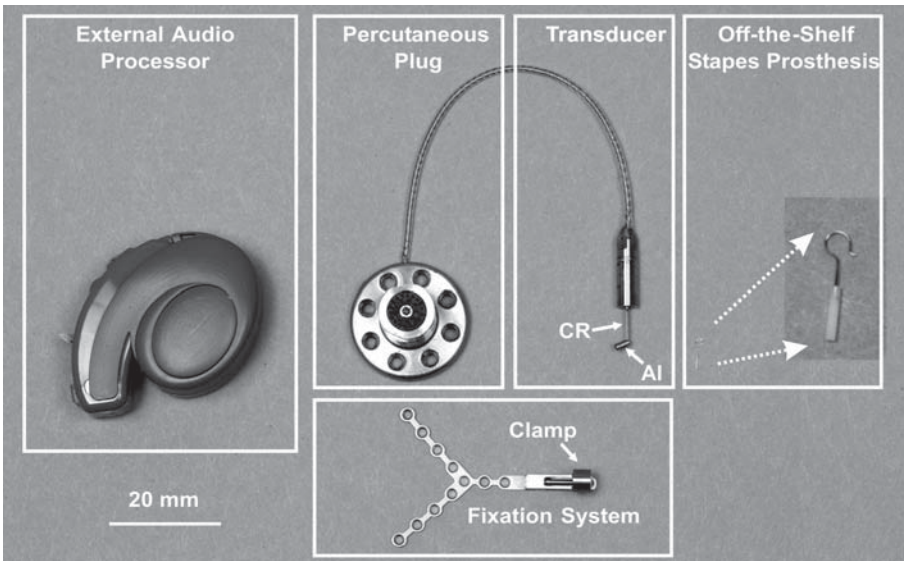

Fig. 1. Investigational DACS device used in the pilot study. CR = Coupling rod; AI = artificial incus.

Kasic and Fredrickson, 2001; Chen et al., 2004]. However, they currently provide either limited hearing gain or they may induce an additional hearing impairment [Needham et al., 2005] when the system is inactive. Furthermore, treatment of severe mixed hearing loss is the difficult part. This type of hearing problem can be caused by advanced otosclerosis, with an additional inner ear hearing impairment.

This group of patients is usually treated with conventional hearing aids, which, however, often do not offer sufficient gains. Alternatively, stapedectomy allows the treatment of the conductive component only. Although the combination of stapedectomy and conventional hearing aids further improves hearing, it will be shown in this paper that there is a single treatment resulting in better aided hearing thresholds.

We present a new transducer for an implantable hearing system, the DACS, an abbreviation for direct acoustic cochlear stimulator. In this report, the DACS device, the surgical procedure required for implantation and the outcome of the first clinical trial with an investigational device are presented.

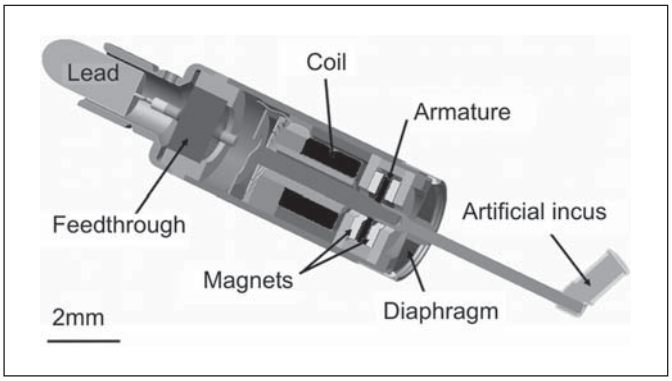

Fig. 2. Cross-section of the DACS transducer (schematic).

Methods

Concept of the DACS System

The DACS concept is based on the principle of a power-driven stapes prosthesis. In contrast to other active hearing implants, it directly vibrates the fluid of the cochlea. Figures 1–3, which are discussed in detail later in this text, show different views of an investigational DACS system. An implantable transducer converts an electrical input signal into a movement of a coupling rod, which couples to the inner ear fluid, e.g. at the level of the oval window, therefore bypassing all structures which may cause a conductive hearing loss. The transducer itself is driven by a fully or partially implantable signal processor unit, which provides appropriate amplification and signal processing to overcome the sensorineural component of the hearing loss.

In this way, the DACS unites two concepts of treatment of hearing impairments in one single system: mechanical amplification and established otological microsurgery.

Investigational Device

The investigational device of the clinical trial is shown in figure 1. It consists of an externally worn audio processor and an implanted part, consisting of the DACS transducer, a percutaneous plug, a fixation system and an 'off the shelf' stapes prosthesis.

The external audio processor contains two microphones, a digital signal processing unit and a battery. It is based on a state-

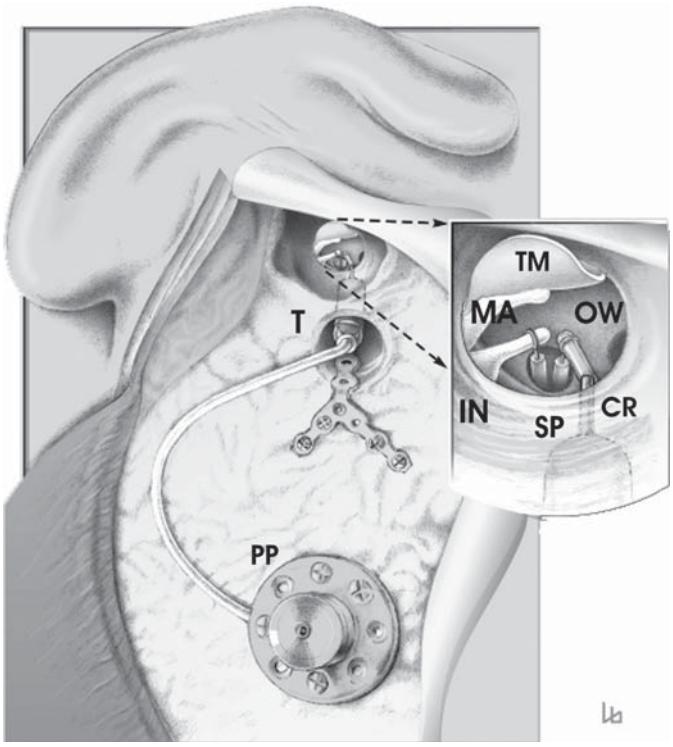

Fig. 3. Artist's rendition of the DACS towards the end of implantation surgery. PP = Percutaneous plug; T = transducer; SP = stapes prostheses; CR = coupling rod; OW = oval window; TM = tympanic membrane; IN = incus; MA = malleus.

of-the-art digital multi-channel hearing aid system Savia 211 (Phonak AG, Switzerland). It features multichannel compression, noise and feedback canceling, and a multimicrophone noise reduction system. The fitting software was specifically adapted for the DACS.

In contrast to conventional hearing aids, the electrical output of the audio processor drives the transducer by means of a percutaneous plug, which was already being used in the Ineraid cochlear implant system [Parkin and Parkin, 1994]. The transducer itself consists of a miniaturized electromechanical driver. A so-called balanced armature principle, which is often used for acoustic devices such as hearing aid speakers, was chosen. The employed balanced armature principle best meets the requirements considering the demanding dynamic characteristic of the human middle ear [Heiland et al., 1999; Voss et al., 2000; Stieger et al., in press]. It provides vibration amplitudes of up to 25 μm [Bernhard et al., 2006b] corresponding to a maximal power output of more than 125 dB SPL over the entire frequency range from 100 Hz to 10000 Hz. Figure 2 shows the main functional components of the transducer: armature, magnets and coil.

The transducer features a titanium diaphragm (fig. 2) that allows a movable but hermetically sealed interface between armature and coupling rod [Bernhard et al., 2006a]. The generated vibrations are transferred to the artificial incus by means of a coupling rod 0.4 mm in diameter. The artificial incus is coated with a thin silicone layer. Its size and shape correspond to the incus long process of the human ossicular chain. A conventional stapes prosthesis can be attached by crimping in the same way as in routine stapedectomy.

All transducer parts that are in contact with human tissue are made of implantable grade materials (titanium, platinum-iridium and silicone). The nonbiocompatible parts (magnets, coil and soft magnetic alloys) are hermetically encapsulated.

The fixation system that anchors the transducer to the mastoid surface of the patient (fig. 1 and 3) is based on a micro-titanium bone plate – as used for craniomaxillofacial trauma surgery – augmented with a special clamping mechanism for the DACS transducer. The fixation system can be bent by the surgeon to fit the curvature of the skull and bring the transducer into the correct position. Conventional titanium bone screws are used to fixate the plate. The fine positioning of the transducer is effected by inserting the transducer in the clamp and choosing the optimal orientation and insertion depth before closing the clamp with a torque screwdriver. The clamp is designed to be opened and closed several times, if necessary, during implantation, although it was rarely required in the implantations performed so far.

Surgical Procedure: Implantation by the 'Retromeatal Approach'

The surgical procedure was tested and refined first using temporal bones and a total of 27 anatomical specimens of entire human cadaver heads. A detailed surgical 50-step protocol was developed interactively by surgeons and the designers of the implant. The surgical procedure is focused on patient safety first and on the optimal configuration and placement of the implant and its components as a close second.

A special 'retromeatal approach' derived from a minimally invasive cochlea implantation procedure [Häusler, 2002] was developed to place the transducer at its intended position in the mastoid bone (fig. 3).

In this approach, the electromechanical transducer is implanted behind the ear. After drilling a bony tunnel behind the external auditory canal down close to the facial nerve (corresponding to a small mastoidectomy), a posterior tympanotomy by facial recess approach is performed at the level of the oval window.

The transducer is then placed in the tunnel by positioning the rod close to the long process of the incus in the tympanic cavity. The otosclerotically fixed stapes is totally removed. To allow acoustical coupling of the DACS to the perilymph, a conventional, commercially available stapes prosthesis is placed in the open oval window and crimped onto the artificial incus of the transducer.

As an inherent part of the surgical 50-step procedure, the DACS is tested intraoperatively. It is required to pass a simple electrical test as well as a mechanical vibration test using laser Doppler vibrometry. For a clinical application, these tests will not be strictly necessary. They take about 15 min.

In order to restore the natural sound transmission of the ossicular chain, a second stapes prosthesis is placed in parallel to the first one into the oval window and attached to the patient's own incus, as performed in conventional stapedectomy. The oval window with the two stapes prostheses is sealed with autologous adipose tissue.

Table 1. Patient assessment in the pilot study

Patient No.	Gender	Age at implantation, years	Implanted ear	Study center
1	male	35	right	Inselspital Bern
2	female	60	right	Inselspital Bern
3	male	54	left	Inselspital Bern
4	female	71	right	Medizinische Hochschule Hannover

Again, the second stapes is not strictly necessary for the functionality of the DACS device itself, but it provides improved hearing for the patients even if the DACS system is turned off.

Study Protocol

A study protocol for the initial clinical trial was established and approved by the local ethical committees of Berne, Switzerland, and Hanover, Germany.

Adult subjects with otosclerosis and a severe to profound mixed hearing loss were considered for inclusion in the study. Preoperative CT scans were performed. All were required to be experienced hearing aid users. They were implanted in the ear with the poorer hearing threshold. Standard intraoperative facial monitoring was performed in all patients. Pre- and postoperatively, medical and audiological evaluations were performed according to long-term audiological evaluation up to 2 years after implantation.

At every pre- and postoperative visit, pure tone audiograms, including air conduction (AC) and bone conduction (BC) thresholds and speech tests, were performed. Speech tests in quiet included the measurement of the speech reception threshold for 50% ($SRT_{50\%}$) speech intelligibility of German two-digit numbers (Freiburger number test) and the measurement of monosyllabic word understanding at 60, 75 and 75 dB SPL (Freiburger monosyllables). For French speaking patients, the disyllabic and monosyllabic Fournier tests were used, as they are regarded as largely equivalent to the above German tests [Kompis, 2004a]. To test speech intelligibility in noise, the Basler Sentence Test [Tschopp and Zust, 1994] was used. In this adaptive test, speech babble noise at 70 dB is held constant, and 15 test items are presented using presentation levels according to an adaptive algorithm to find the SRT for 50% speech understanding.

Tests were performed with earphones and in the sound field under aided and unaided conditions. The contralateral side was masked when necessary. Sound field measurements were performed under three different conditions: in condition I, the contralateral ear was occluded with an earplug (E-A-R Classic, Aearo Company, Indianapolis, Ind., USA) with a specified average attenuation between 24.6 and 41.6 dB in the range of 250–4000 Hz. The DACS was switched off. Condition II was the same as condition I, but with the DACS switched on. In condition III, both ears were plugged, but the DACS device was active. This last condition was included to examine the effect of potential interferences between direct sound and the output of the DACS system.

Every visit included an otoscopy and a tympanometry. A single patient visit took approximately 3 h.

In addition, in 3 patients, sound field thresholds were measured postoperatively with a conventional hearing aid, at the DACS-ear with the DACS switched off. Again, the contralateral ear was occluded. The hearing aid used had the same signal processor and fitting strategy as the sound processor of the hearing aid in order to minimize bias from different signal processing strategies [Todt et al., 2005].

An Abbreviated Profile on Hearing Aid Benefit (APHAB) [Cox and Alexander, 1995] was completed by all subjects preoperatively and 12 months postoperatively. The APHAB questionnaire consists of 24 questions, classified into four scales. Ease of communication (EC) describes the effort in communication under relatively easy listening conditions. Reverberation (RV) describes understanding in moderately reverberant rooms. Background noise (BN) describes the speech understanding in the presence of multitalker babble or other environmental competing noise. Aversiveness of sound (AV) describes whether loud environmental sound is tolerated or results in negative reactions.

Patients were asked to rate their hearing under their usual everyday conditions, i.e. with the DACS and a contralateral hearing aid, if one was used, and with the DACS alone, if no contralateral hearing aid was used.

Subjects

Four patients, ages 35–71, participated in the study. Table 1 shows a synopsis of patient-related data. All subjects agreed to participate in the study after giving their informed consent in writing. All were experienced but dissatisfied hearing aid users and all suffered from a severe to profound mixed hearing loss due to advanced otosclerosis (cf. preoperative audiograms in fig. 5), which was confirmed intraoperatively. The sensorineural component was 30 dB or more for all frequencies above 500 Hz and no notable progression of the hearing loss during the last 12 months was observed. The DACS was implanted in the audiologically poorer ear.

Results

Surgery

The predefined surgical procedure was followed in all 4 patients, resulting in uneventful implantation at both of the centers involved. The total time of surgery was 5 h for the first implantation and 2.5–3.5 h for the next 2 sur-

Table 2. $SRT_{50\%}$ in quiet for multisyllabic test items (numbers) of patients 1–4

SRT, dB SPL	Patient			
	1	2	3	4
Unaided				
Before operation[1]	93.5	93.5	96.5	105
After operation[1]	85.5	61	73.5	98
Aided				
Ipsilateral ear open[1]	53.5	46	43.5	55
Ipsilateral ear closed[2]	51.5	43.5	43.5	55

[1] Ipsilateral ear was open, contralateral ear was occluded with an earplug.

[2] Ipsilateral ear and contralateral ear were occluded with an earplug.

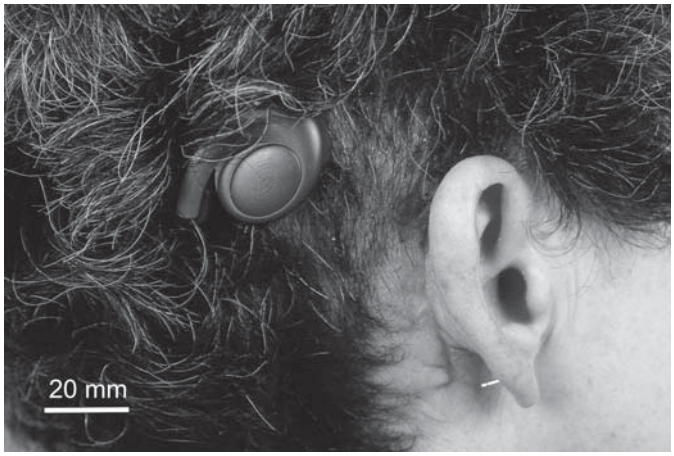

Fig. 4. Patient 2 with the audioprocessor of the investigational device in situ.

geries. The experience gained during the initial surgery yielded a considerably shorter implantation time for the second and the third patient in Berne. The implantation of patient 4 in the second center (Medizinische Hochschule Hannover, MHH, Th. Lenarz, Germany) took approximately 4 h.

Patient Postsurgical Recovery

All patients went through surgery without notable problems. In particular, none of the surgeries led to any additional hearing loss, additional tinnitus or facial palsy. Type A tympanograms were measured in all patients postoperatively. Figure 4 shows a postoperative photograph of patient 2 with the audio processor in situ.

Patient 1 reported some postoperative pain and transitory dizziness and a temporary dysgeusia. Patient 2 reported no problems whatsoever. Patients 3 and 4 experienced temporary inflammation of the tissue surrounding the skin perforation of the percutaneous plug during rehabilitation. These were treated successfully with antibiotics.

Audiological Outcome

Figure 5 shows the pure tone audiograms of all 4 patients. Using insert earphones proper masking was applicable without masking dilemma [Kompis, 2004b] in all patients. Preoperative pure tone average (PTA) for the frequencies 500, 1000, 2000, and 4000 Hz for the DACS-designated ear ranged between 78 to 101 dB HL (AC) with air bone gaps between 33 and 44 dB. BC thresholds ranged from 35 to 75 dB SPL in the frequency range of 500–4000 Hz. Postoperatively, unaided AC thresholds (fig. 5) were improved by 14 and 28 dB (PTA) due to the stapedectomy alone. Air bone gaps were decreased in all patients by 10–25 dB (PTA). BC thresholds were improved in patients 2 and 3 in the vicinity of the frequencies expected for a Carhart notch [Carhart, 1964].

Figure 6 shows the threshold measured with warble tones in the sound field with the nonimplanted ear being occluded. In the unaided condition, postoperative thresholds were better than preoperative thresholds in all 4 patients. The PTA was improved by 8–37.5 dB. With the DACS system active, the sound field thresholds were improved by 41, 49, 50 and over 62 dB PTA (patients 1, 2, 3 and 4), respectively, when compared to preoperative measurements. Hearing thresholds were equal or better (average improvement: 7.5 dB PTA) with the activated DACS than they were with the stapedectomy and a conventional hearing aid with the same signal processing in the same ear (fig. 6).

Table 2 shows the $SRT_{50\%}$ in quiet for all patients preoperatively as well as postoperatively unaided and postoperatively with the DACS activated. $SRT_{50\%}$ improved by 42–52 dB when DACS was activated and between 10–32.5 dB with the DACS switched off, due to the stapedectomy alone. Additional occlusion of the ipsilateral ear did not significantly change the $SRT_{50\%}$.

For the measurement of the $SRT_{50\%}$ in noise, subjects must be able to understand 50% of the speech material [Kompis et al., 2007]. As a consequence, only patients 2 and 3 were able to complete this test and postoperatively in the aided and unaided condition. The $SRT_{50\%}$ in noise

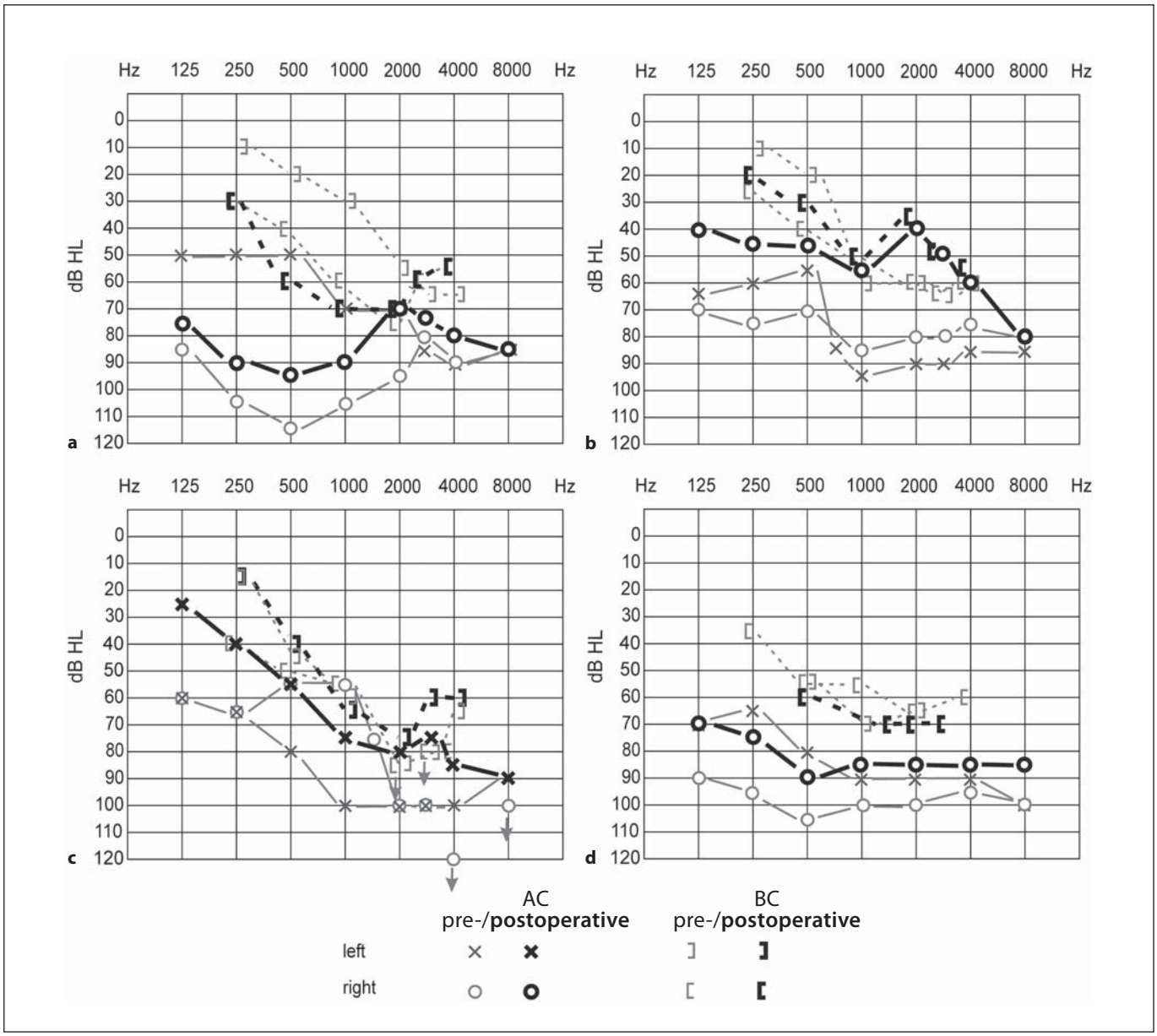

Fig. 5. Pure tone audiograms of patients 1 (**a**), 2 (**b**), 3 (**c**) and 4 (**d**).

improved by 7.2 and 13.8 dB when the DACS was activated.

Table 3 shows speech understanding of monosyllabic words at 60, 75 and 90 dB SPL. The nonimplanted ear was occluded for all measurements. Preoperatively, all patients had 0% intelligibility at all presentation levels. Postoperatively, the subjects achieved discrimination levels of 30, 70, 55 and 0% (patients 1, 2, 3, 4) when the DACS was not activated.

With the activated DACS, monosyllabic speech understanding improves for all patients at all presentation levels by 15–100%. Patients 2 and 3 even achieved speech recognition scores of 100% at 75 dB. Patient 4, with the poorest performance, reached 40% at the same presentation level.

Figure 7 shows the summary of the pre- and postoperative APHAB scores for all patients. A difference of 10% or more in any of the three subscales EC, RV and BN is

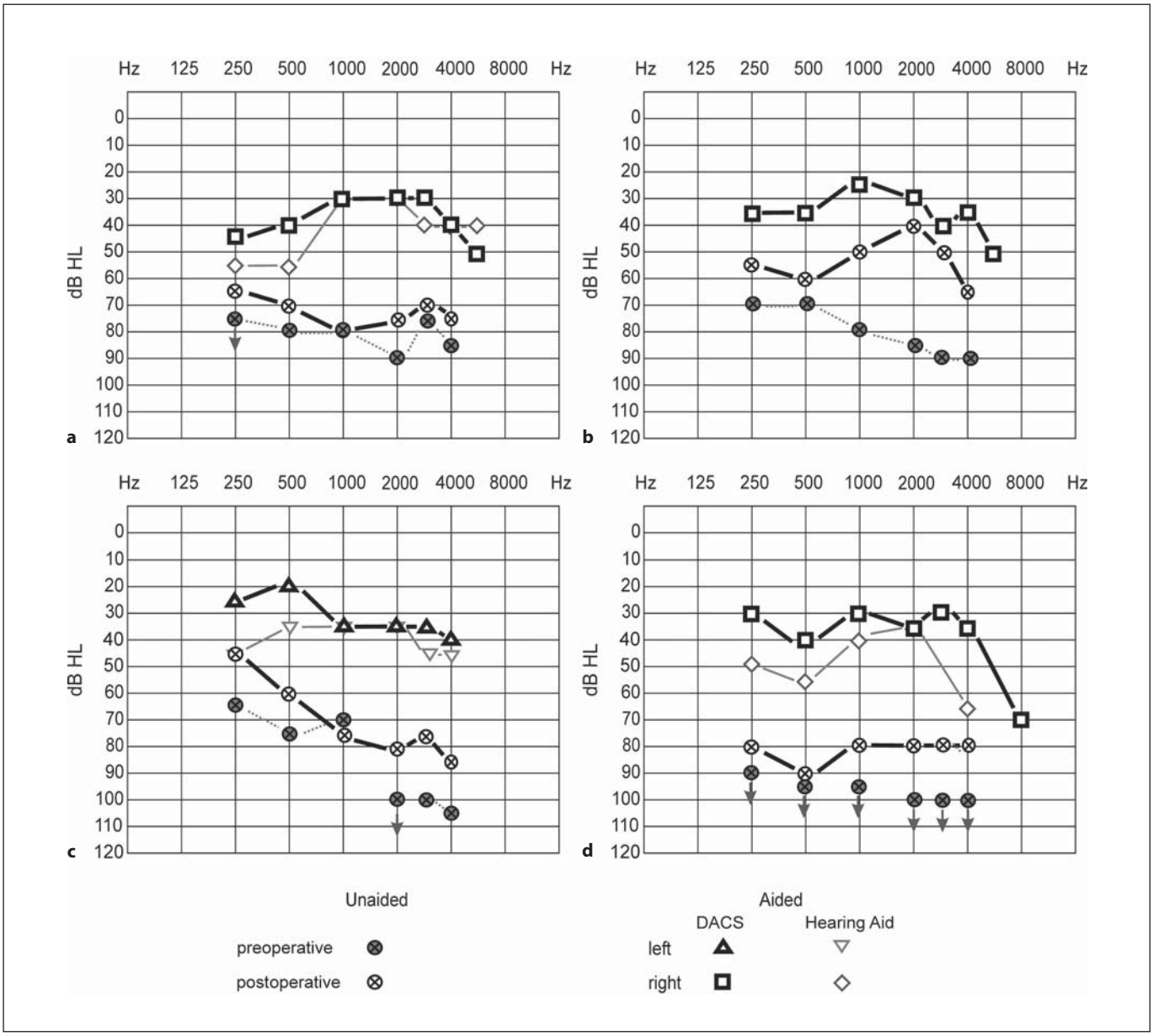

Fig. 6. Sound field thresholds of patients 1 (**a**), 2 (**b**), 3 (**c**) and 4 (**d**). The hearing aid, to which the DACS was compared, featured the same signal processing capabilities and was fitted in the same implanted ear.

considered a significant difference between different conditions at the 95% confidence level [Cox and Alexander, 1995]. For the last subscale, AV, no or only a small difference is expected. Lower values denote more favorable assessments in all subscales.

Patient 1 reported improvement of communication in all 4 subscales by 12–40 percent points using the DACS device in combination with his conventional hearing aid in the contralateral ear.

In patient 2 wearing the DACS system alone, there was a substantial improvement by 24–48 percent points in the EC, RV, BN subscales when compared to the preoperative situation with a conventional hearing aid alone. Only the AV scale showed a slight deterioration of 2%.

Similarly, patients 3 and 4 improved in all subscales, EC, RV and BN, by up to 29%, with disparate results in the AV subscale.

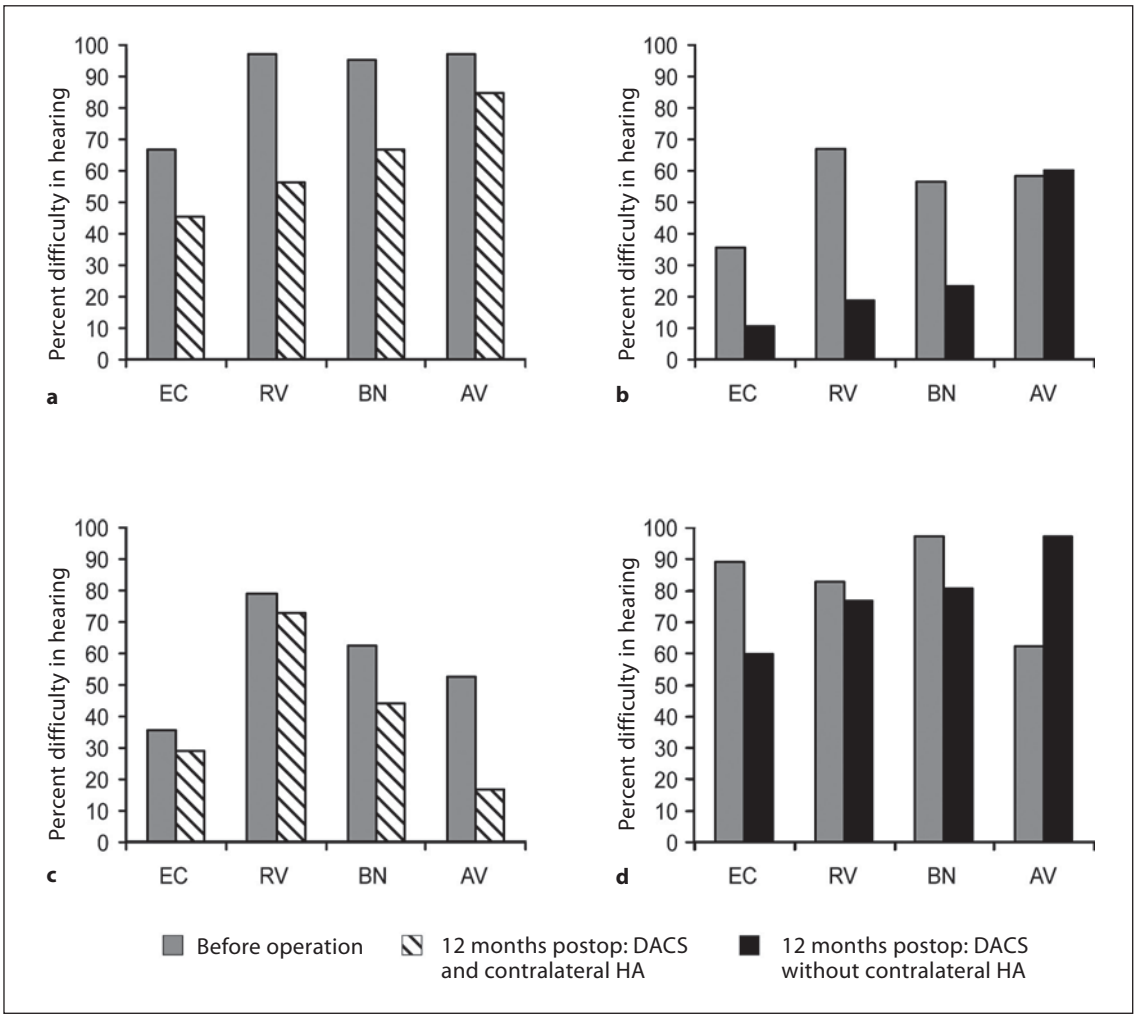

Fig. 7. Scores of the APHAB questionnaire for patients 1 (**a**), 2 (**b**), 3 (**c**) and 4 (**d**). Lower scores denote a better assessment by the users.

Discussion

The aim of this study was to demonstrate the proof of concept of the DACS. It was shown that it is possible to develop and implant such a device. In our study, hearing and speech understanding was improved substantially in 4 patients with severe to profound mixed hearing losses.

Inner ear function did not deteriorate in any of our 4 patients. Nevertheless, the surgical procedure may be expected to have a risk of deafness similar to stapedectomy [Shea, 1998; Häusler, 2000] or cochlear implantation [Green et al., 2004; Dutt et al., 2005]. In our patients, hearing thresholds were in an order of magnitude that approached those of cochlear implant candidates. Therefore, we believe that small risk of deafness might be justifiable in light of the expected improvement, as it is also viewed as justified in stapedectomy, where the hearing of ears with much better thresholds is at stake.

The newly developed retromeatal approach has the advantage of being a minor and relatively fast surgical procedure. The most time-consuming part of the implantation is the adaptation of the fixation system. The precise adaptation of the fixation system is important. However, further improvements in the fixation system design are possible and can further reduce implantation time. Several possibilities are currently being tested.

No problems or complications related to the transducer, the fixation system, the stapedectomy or the surgical procedure were observed in our patients. However, dur-

Table 3. Speech intelligibility for monosyllabic words (%)

	Presentation level dB SPL	Patient			
		1	2	3	4
Unaided					
Before operation[1]	60	0	0	0	0
	75	0	0	0	0
	90	0	0	0	0
After operation[1]	60	0	10	0	0
	75	0	50	0	0
	90	30	70	55	0
Aided					
Ipsilateral ear open[1]	60	25	80	70	10
	75	65	100	100	40
	90	70	90	90	25
Ipsilateral ear closed[2]	60	20	80	75	10
	75	55	100	95	40
	90	65	90	95	25

[1] Ipsilateral ear was open, contralateral ear was occluded with an earplug.

[2] Ipsilateral ear and contralateral ear were occluded with an earplug.

ing the first 2 years postoperatively, 2 patients suffered from minor infections around the percutaneous plug of the investigational system. The device design is currently being modified. Among other improvements, the percutaneous plug will be replaced by a transcutaneous radiofrequency transmission similar to cochlear implants.

The conventional stapedectomy was successful in all of our patients with improvements between 14 and 28 dB (PTA). This is consistent with our own experience of more than 1500 stapedectomies at Inselspital, University of Berne, with an average improvement of 22 dB [Häusler, 2000]. These improvements are reached already without the DACS being activated – a major difference compared to other implantable hearing systems, where patients may expect either unchanged thresholds or even some deterioration.

The DACS is a device with two acoustical inputs to the inner ear, namely through the DACS-driven stapes prostheses and the tympano-ossicular chain through the conventional stapedectomy prosthesis. Our data show that there is no substantial interference between the two sound paths (comparison of the results with the ipsilaterally external auditory canal plugged and open, tables 2 and 3). This is an expected result, as the signals differ by several orders of magnitude when the DACS is activated. In principle, the DACS can be implanted and would also work without the second stapes prosthesis.

The benefit of the DACS was measured using several methods: sound field hearing thresholds, speech intelligibility in quiet and in noise, as well as the assessment of subjective impressions using the APHAB questionnaire. A very encouraging result of our study is that all patients who participated in this study show better results in all of the above tests with the DACS than either preoperatively or when the DACS is switched off postoperatively. Our tests were taken 2 years after implantation, which suggests a stable long-term benefit. One of the most striking improvements in our data is the large increase in monosyllabic word recognition scores between 60 and 90 dB (table 3). Differences of 40 to as much as 100 percent points at 75 dB SPL indicate a substantial benefit in everyday life. Besides speech understanding in quiet, there is also a substantial improvement in noise.

Comparisons with other implantable hearing aids are difficult, as our group of patients suffers from considerably higher hearing loss (78–101 dB PTA) than published for other devices such as the fully implantable ossicular stimulator (MET) with 40–80 dB PTA [Jenkins et al., 2007] or the floating mass transducer at the round window (65–85 dB PTA) [Colletti et al., 2006]. Generally, the gain in terms of speech understanding and improved hearing threshold seems to be higher than reported for other implantable hearing aids, especially in the lower frequency range. A conclusive comparison is beyond the scope of this first report.

One of the results of our investigation is that current fitting algorithms for conventional hearing aids can be applied to the DACS, but they must be modified sensibly for best results. Neither the AC thresholds nor the BC thresholds alone offer a reliable base for initial fittings. In our limited experience, measurements of hearing threshold via the DACS yielded the best initial fits. However, this is still an area to be explored in further research.

Further work is also planned and required in other areas related to the DACS. An improved device featuring transcutaneous transmission is currently in test. Furthermore, other coupling sites, e.g. the round window or the mobile footplate, will be considered. Eventually, other groups of patients, e.g. patients with radical cavities, difficult or failed tympanoplasties, possibly even patients with pure sensorineural hearing loss, may be considered for implantation. In such cases, a single stapes prosthesis connected to the DACS would be inserted through a small stapedotomy perforation in order to further reduce

the risk of inner ear damage. The long-term goal is the development of a totally implantable system.

In summary, we presented data that show that implantation of the presented DACS system is a useful and efficient therapy for patients with severe to profound mixed hearing loss due to otosclerosis.

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