A NOVEL IMPLANTABLE HEARING SYSTEM WITH DIRECT ACOUSTICAL COCHLEAR STIMULATION (DACS)

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Direct Acoustical Cochlear Stimulator (DACS) is a new, implantable hearing system, which works on the principle of direct acoustic stimulation of the inner ear fluid by the means of a power driven stapes prosthesis. It is intended for patients suffering from a combined conductive and sensorineural hearing loss. In a first clinical study, three patients were implanted with the DACS device. The DACS transducer is implanted behind the ear, using a retro-meatal microsurgical approach, developed especially for this device. Preliminary results show an improvement of the speech recognition threshold in quiet of 52.5, 47,5, and 46 dB 3 months after activation of the DACS device.

Introduction

Hearing losses are usually classified as a conductive, sensorineural or combined hearing loss. In conductive hearing loss, sound is not transmitted efficiently through the external and middle ear. In a sensorineural hearing loss, there is damage in the inner ear (cochlea) or at the level of the auditory nerve.

Severe combined, i.e. conductive *and* sensorineural hearing losses are a difficult problem in rehabilitation. Such hearing problems can be caused e.g. by otosclerosis, where the stapes (the ossicle, which is attached to the oval window of the inner ear) becomes pathologically fixed and an additional inner ear hearing impairment occurs. These patients are often treated with conventional hearing aids which, however, mostly do not offer sufficient gain to overcome the conductive loss problem. Otological microsurgery [1] such as stapedectomy allows treatment of the conductive component of the hearing loss if caused by otosclerosis. In this surgery, the fixed stapes is removed and replaced by a stapes prosthesis. This prosthesis performs a motile coupling to the inner ear fluid. Patients have improved hearing because of reduction of the conductive hearing loss component but the sensorineural hearing loss remains untreated [2,3].

The aim of our research was to develop and evaluate a novel implantable hearing system which would be effective in the treatment of severe to profound combined hearing loss. It works on the principle of a power-driven stapes prosthesis combining both of the above mentioned therapies in one single device. A conventional stapes prosthesis is directly coupled to the inner ear fluid treating the conductive hearing loss component. The additional sensorineural component is corrected by attaching this stapes prosthesis to an implanted transducer which generates the necessary vibrating amplification. This innovative implantable hearing system is called DACS, an abbreviation for Direct Acoustical Cochlear Stimulator. The DACS device was developed as a result of a close cooperation between specialists in microtechnology, otological microsurgery as well as the hearing aid and cochlear implant industry.

Materials and Methods

Description of the DACS device: The DACS investigational device consists of the DACS-implant and the externally worn DACS audio-processor.

The DACS-audio-processor consists of a microphone, an amplifier with an electrical output and a battery. It receives sound by the means of a microphone and calculates the individual electrical output which is transmitted via the percutanous plug to the DACS implant.

The DACS investigational implant device consists of a percutaneous plug and a miniaturized hermetically sealed electro-mechanical driving system, so called a transducer (Fig. 1). The mechanical output of the DACS transducer drives a tiny rod. At the end of the rod, a special crimping zone allows the fixation of the stapes prosthesis during surgery (Fig. 1).

Surgery: The surgery for the DACS implantation was developed on isolated human temporal bones and human heads. It presents a combination of conventional middle ear surgery and cochlear implant surgery and can be divided in three major parts i.e. (1) positioning of the transducer, (2) coupling to the inner ear and (3) fixation of the percutaneous plug. For the positioning of the transducer, a special microsurgical procedure, the so called retro-meatal approach, was developed, whereby a small tunnel is drilled in parallel behind the external auditory canal. A fixation system is adapted in the tunnel in such a way that the crimping zone of the clamped transducer is located in the free space of the tympanic cavity next to the incus.

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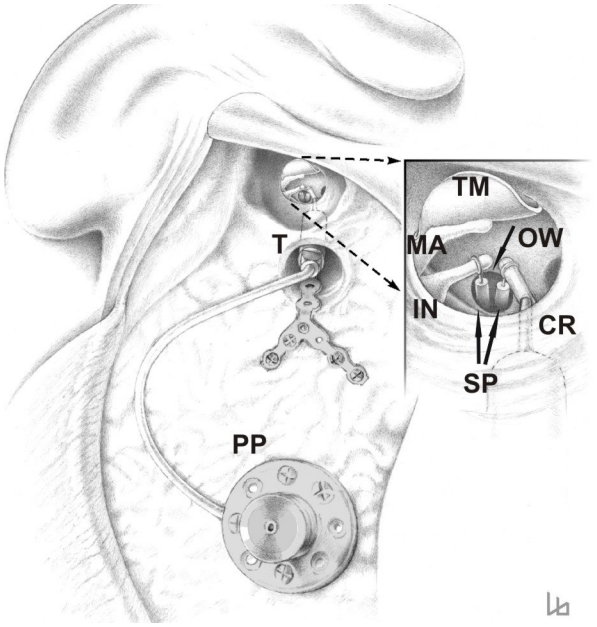

Figure 1: Schematic drawing of the DACS implant. View through the dissected external auditory canal (EAC) into the tympanic cavity with the ossicles malleus (MA), incus (IN) and the oval window (OW). The posterior part of the tympanic membrane TM is elevated and the stapes has been removed. The transducer receives the signals from the audio-processor (not in figure) by the mean of the percutanous plug (PP). Signals are transmitted from the transducer (T) via the coupling rod (CR) and stapes prosthesis (SP) through the oval window (OW) directly to the inner ear. For reconstruction of the natural sound transmission, a second stapes prosthesis is positioned in the oval window and conventionally fixed on the incus (IN).

For coupling to the inner ear, the ossified and fixed stapes is completely removed. Then, an off-the-shelf stapes prosthesis is crimped at the end of the rod on the crimping zone and placed in the open oval window to allow acoustical coupling to the liquid of the inner ear. To reconstruct the natural sound transmission by the ossicular chain, a second stapes prosthesis is placed in parallel to the first into the oval window and attached to the incus, as is performed in conventional stapedectomy. The open oval window with the two stapes prostheses is sealed with adipose tissue.

The percutaneous plug is fixed on the skull with self- taping titanium bone screws .

Laser Doppler Vibrometry (LDV): The order of magnitude of vibrations in middle ear mechanics are approximately 10^{-7} m for 100 dB SPL (sound pressure level) for frequencies below 1 kHz [4]. This relationship was used to convert displacements into "equivalent sound pressure level". Laser Doppler Vibrometry, providing measurements of such amplitudes, was used to determine the transducer output and to assure the functionality and integrity of the DACS implant during the surgery (Fig. 2).

The intraoperative testing is performed at the end of surgery. Thereby, the transfer function of the transducer is measured. The input of a 0.1 to 10 kHz sweep is given by a computer driven signal generator. A custom made insulation amplifier intersects the patient form the supply voltage of the computer. A sterile stimulation cable is connected to the percutanous plug of the DACS implant.

The coupling rod vibrations are measured by the Laser Doppler Vibrometer system HLV 1000 (Polytec, Waldbronn, Germany) mounted on the operating-microscope. The laser beam must be adjusted on the coupling rod by the surgeon using a small sterile joystick.

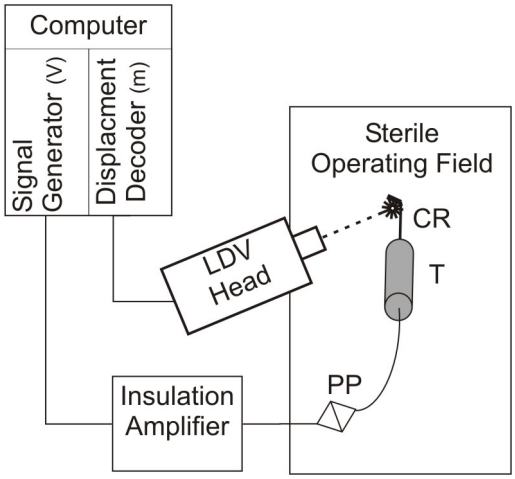

Figure 2: Setup of the intraoperative measurement of the DACS implant (T: transducer, PP: percutaneous plug). The Laser Doppel Vibrometer (LDV) measures the displacement of the coupling rod (CR) for an electrical input signal provided by a sterile and galvanic isolated connection to the signal generator.

Patients: Three patients have so far been included for this preliminary clinical study. All of them suffered severe profound combined hearing loss. Their conductive hearing loss component was due to otosclerosis. They were experienced hearing aid users. The preoperative hearing loss was 101, 95 and 77 dB in pure tone average PTA i.e. the average of the pure tones thresholds at 0.5 ,1 ,2 , 4 kHz.

Table 1: Overview of Patients under assessment

Patient No.	Gender	Age	Implanted Ear
01	M	35	Right
02	F	60	Right
03	M	54	Left

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Audiological test: Pure tone audiometry and speech audiometry, were performed pre-operatively and 1, 2 and 3 months postoperatively. Pure tone average (PTA) was measured as a mean value of the thresholds at 0.5, 1, 2, 4 kHz for bone conduction and air conduction.
Speech audiometry was used in order to quantify the overall hearing gain with the DACS device [5]. For this purpose, speech reception thresholds SRT have been measured. They represent the presentation levels which are required for 50% speech-intelligibility in quiet. It was assessed using headphone measurements and free-field measurements with and without the DACS.

Results

The DACS device was implanted first in isolated temporal bones and then in 27 isolated anatomical human whole head preparations. Measurements using contactless Laser Doppler Vibrometry showed an equivalent sound pressure of maximally 140 dB SPL (125 SPL broadband) applied to the inner ear fluid at a 1 mW power level.

After these successful preliminary experiments, the DACS device was implanted in 3 adult patients. Surgery and postoperative recovery was unremarkable. The DACS audio-processor was activated one month after implantation. It was fitted with a non-linear strategy, common today. Very low level input signals are suppressed in order to suppress background noise. On the other hand, the maximal output (MPO) is strictly limited to inhibit the potential of overstimulation for any input signal. Figure 3 shows patient no. 2 with the attached DACS audio processor.

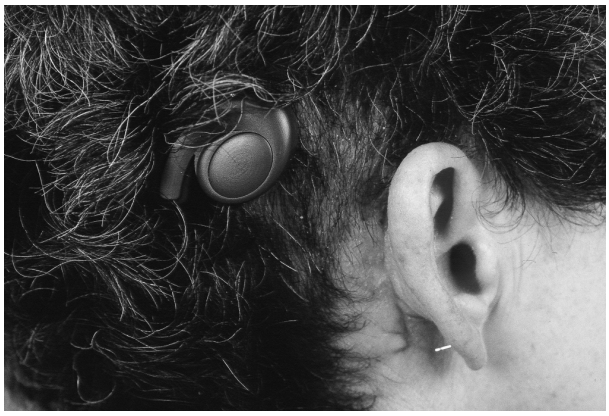

Figure 3: External worn DACS audio processor attached to the percutanous plug. Sounds are received by the microphone signal processed and transmitted to the implanted DACS transducer via the percutaneous plug.

Audiological testing after 3 months showed a PTA hearing improvement of 52.5, 30.5 and 55 dB for the activated DACS. Even when the DACS was not activated, patients had a postoperative PTA hearing improvement of 15, 20 and 24 dB because of the stapedectomy alone with fixation of the second stapes prosthesis on the incus. Speech reception thresholds are summerized in table 2. Subjectively, all patients indicate that their hearing had improved by the stapedectomy alone and that the activated DACS lead to a substantially improved gain and better quality of hearing compared to the preoperatively used conventional hearing aids.

Table 2: Speech reception threshold (SRT) at 3 month recovery time

Patient No.	Absolute post-treatment	Improvement via the second prosthesis	Improvement DACS device alone
01	40 dB	10 dB	52.5 dB
02	37.5 dB	27.5 dB	47.5 dB
03	32 dB	21.5 dB	46 dB

Discussion

The improvements and absolute levels in speech reception threshold (Table 2) demonstrate the functionality of the DACS device for the targeted group in this preliminary study. The analysis of these improvements shows one major advantage of the DACS principle. It allows a reduction of the two causes of combined hearing loss. While the stapes prosthesis attached to the DACS transducer is used for the therapy of the conductive part, the amplification of the DACS transducer treats the sensorineural aspect. The improvement by the stapes prosthesis of the DACS implant can be estimated by the second stapes prosthesis (table 2). In patient 01, the improvement of the SRT by the second stapedectomy alone was 10 dB and therefore an amplification of DACS transducer is in the order of 40 dB. On the other hand, patient 03 shows an improvement due to the stapes prosthesis of 21.5 dB and, therefore, an amplification of the DACS transducer of 24 dB. This implies that the DACS has the potential of being useful for any patient with audiologically measurable combined otosclerotic hearing loss. Principally, the DACS device has applications beyond otosclerorsis as it really by-passes the conductive hearing loss component of mixed hearing loss.

In contrast to conventional hearing aids, conventional implantable middle ear hearing aids and middle ear surgery, the DACS device provides a therapy for combined hearing loss with a single device.

The surgery for the implantation of the DACS device was developed hand in hand by otological surgeons and engineers respecting maximal safety for the patient. As the surgical procedure presents a combination of conventional middle ear surgery and cochlear implant surgery, it can be applied by experienced otological surgeons after initial training, including all steps of the surgical procedure.

In order to ensure that the implanted device is functional, the laser Doppler Vibrometry measurement was performed. This measurement is very sensitive and facilitates determining detailed state of the implant

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which was very useful for the implantation of this preliminary clinical study. However, the Laser Doppler Vibrometer system used is not yet standard equipment.

The percutaneous plug provides a direct electrical contact from the audio-processor to the DACS implant and is, therefore, the most efficient solution in terms of energy transmission. However, several potential patients have declined to participate in this study because of the percutaneous plug. For this reason, a transcutaneous RF transmission, today a standard for cochlea implants [6] or implantable hearing aids [7] is being developed for the DACS device.

Conclusions

The newly developed DACS (Direct Acoustical Cochlear Stimulator) device is an active implantable hearing system whereby patients with severe combined hearing loss can be treated with a single device.

Preliminary results with the DACS device show that direct stimulation of the inner ear fluid by the means of a vibrating implantable hearing system is possible and works well. The DACS device provides therapy for patients with severe combined hearing loss with a single instrument.

Postoperative measurements show that patients with severe combined otosclerotic hearing loss reach substantially higher hearing improvement with the DACS than obtained by otological surgery or conventional hearing aids alone.

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References

[1] HAEUSLER R. (1993): 'Surgical treatment possibilities of middle ear hearing loss', *Ther. Umsch.*, **50(9)**, pp. 653-62

[2] HAEUSLER R. (2000): 'Advances in stapes surgery', *Laryngol-Rhino-Otol.*, **79** (Supplement 2), pp. S95-139

[3] SHEA JJ. (1998): 'Forty years of stapes surgery', *Am J Otol.*, 1**9**, pp. 52-55

[4] WINTER M, WEBER BP, LENARZ (2002): 'Measurement method for the assessment of transmission properties of implantable hearing aids', *Biomed Tech (Berl).* ,**47** (Supplement 2 Pt 2), pp 726-7.

[5] KINKEL M., (2001): 'Hörgeräte', in LENARZ E., LASZIG R. (Ed): 'Praxis der Audiometrie', (Thieme, Stuttgart, New York), pp. 218.

[6] VISCHER M, KOMPIS M, SEIFERT E, HAEUSLER R, (2004): 'The cochlear implant--evolution of hearing and language with an artificial inner ear', *Ther. Umsch.*, **61(1)**, pp. 63-60

[6] aWENGEN D, (2004): 'Implantable middle ear hearing aids', *Ther. Umsch.*, **61(1)**, pp. 47-52

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