

Multicenter Study With a Direct Acoustic Cochlear Implant

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Objective: To confirm the clinical efficacy and safety of a direct acoustic cochlear implant.

Study Design: Prospective multicenter study.

Setting: The study was performed at 3 university hospitals in Europe (Germany, The Netherlands, and Switzerland).

Patients: Fifteen patients with severe-to-profound mixed hearing loss because of otosclerosis or previous failed stapes surgery.

Intervention: Implantation with a Codacs direct acoustic cochlear implant investigational device (ID) combined with a stapedotomy with a conventional stapes prosthesis

Main Outcome Measures: Preoperative and postoperative (3 months after activation of the investigational direct acoustic cochlear implant) audiometric evaluation measuring conventional pure tone and speech audiometry, tympanometry, aided thresholds in sound field and hearing difficulty by the Abbreviated Profile of Hearing Aid Benefit questionnaire.

Results: The preoperative and postoperative air and bone conduction thresholds did not change significantly by the implantation with the investigational Direct Acoustic Cochlear Implant. The mean sound field thresholds (0.25–8 kHz) improved significantly by 48 dB. The word recognition scores (WRS) at 50, 65, and 80 dB SPL improved significantly by 30.4%, 75%, and 78.2%, respectively, after implantation with the investigational direct acoustic cochlear implant compared with the preoperative unaided condition. The difficulty in hearing, measured by the Abbreviated Profile of Hearing Aid Benefit, decreased by 27% after implantation with the investigational direct acoustic cochlear implant.

Conclusion: Patients with moderate-to-severe mixed hearing loss because of otosclerosis can benefit substantially using the Codacs investigational device. **Key Words:** Auditory implants—Acoustic implant—Direct acoustic cochlear implant—Middle ear implant—Otosclerosis—Surgery—Stapedotomy. *Otol Neurotol* 34:1215–1225, 2013.

Acoustic implants can be divided into 3 categories: middle ear implants (MEI), bone conduction implants (BCI), and direct acoustic cochlear implants (DACI). The transducers of MEI are coupled to the ossicular chain and make use of the ossicles to transmit the amplified vibration to the cochlea. They were originally developed for pure sensorineural hearing losses but have been indicated to be beneficial in mixed hearing loss when coupled to the round or oval window. BCI couple to the cranium and make use

of the cranial bone to transmit vibrational energy to the cochlea, thereby circumventing the outer and middle ear and directly stimulating the cochlea. Their main indication is pure conductive and mixed hearing loss. The strongest BCI transducers are able to partially compensate for the sensorineural component of the hearing loss as well (overclosure of the air-bone gap). DACI directly couple to the inner ear, that is, via the oval or round window or via a surgically created window. They were developed to compensate for severe-to-profound mixed hearing losses.

Mixed hearing loss combines sensorineural and conductive hearing loss and can possibly cause high hearing thresholds. Hearing devices that make use of the natural sound transmission structures of the ear (i.e., the external and middle ear), such as acoustic hearing aids or MEI, must provide a correspondingly high power output to compensate for the conductive hearing loss component and

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must still be able to provide a sufficiently amplified broadband signal to the cochlea to compensate for the sensorineural hearing loss. The coupling of MEI to the inner ear is also an important issue for effectiveness.

A more efficient approach might be to bypass the natural sound transmission structures of the ear and directly provide an amplified signal to the cochlea. In this approach, conductive losses no longer have to be compensated by increased output power, and the required amplification is determined by the sensorineural hearing loss only. This can be done with a BCI or a DACI. The BCI available today has limited power and can therefore compensate for the sensorineural component of the hearing loss only to a limited level. A DACI provides its power directly to the inner ear by vibrating the perilymph. However, a good coupling of the DACI to the perilymph is essential. In 2008, Häusler et al. (1) presented a new DACI, an implantable hearing system, which included a newly developed transducer, the direct acoustic cochlear stimulator (DACS). This transducer coupled directly to the perilymph via a conventional stapes prosthesis. The device consisted of the transducer, a fixation system, and a percutaneous plug, to which an externally worn sound processor was connected. It was implanted in 4 patients with severe-to-profound mixed hearing loss during a clinical trial. The trial proved the concept and showed that the hearing and speech intelligibility of those patients improved substantially after implantation with the DACS compared with the preoperative unaided condition.

Since the initial clinical trial with the DACS system, Cochlear has further developed the device to improve upon important aspects of the design and functionality. These development steps have included the development of custom implantable electronics, an electronics packaging, and a transcutaneous communication and power link with the external sound processor. In addition, surgical tools to aid the surgeon to place the implant have been developed together with a modified fixation system, which allows more degrees of freedom. Cochlear Nucleus Freedom sound processor (Cochlear Ltd., Sydney, Australia) was adapted to deliver acoustical information to the implantable electronics by using custom firmware. Finally, custom fitting rules have been developed together with investigational

software to optimize treatment results. All these efforts resulted in the new Codacs direct acoustic cochlear implant. Cochlear’s Codacs investigational device (ID) is depicted in Figure 1.

Between November 2009 and May 2011, the Codacs investigational device has been successfully implanted in 15 patients during a European multicenter trial. This publication presents the results of the clinical trial.

METHODS

Device Description

The concept of DACS was introduced by Häusler et al. (1). As the concept of the Codacs ID is the same, it will only be shortly illustrated again. The Codacs investigational device consists of an externally worn behind-the-ear sound processor with radio frequency (RF) coil. The implantable part consists of a receiver coil, the implant electronics, and the electro-magnetic transducer (2). The sound processor is Cochlear’s Freedom sound processor with a modified firmware to allow for acoustic signal processing. Sound is picked up by the sound processor’s directional microphone and converted into a digital signal. The signal is then broken down into its constituent frequency components (20 bands), amplified, and resynthesized. The whole path from analysis to synthesis runs at a sampling rate of 19.6 kHz. The resynthesized audio is then streamed over the RF-link into the implant. The RF link encoding and power transmission is copied from the Cochlear Nucleus Freedom implant (Cochlear Ltd.) high-rate protocol. The implant decodes the incoming RF and sends a stimulating current to the electro-magnetic transducer. The transducer (Fig. 2) vibrates the off-the-shelf stapes prosthesis, thereby mechanically stimulating the perilymph in the inner ear and leading to sound perception. The actuator design was described in Häusler et al. (1) and Bernhard et al. (2) and has not been changed from its earlier design.

The fixation system that keeps the transducer firmly in place within the mastoid cavity has been optimized to allow greater flexibility for the placement of the device (Fig. 3).

It consists of a bone plate, a ball joint, and a clamping mechanism, which hold the actuator. During implantation, the bone plate is fixed to the temporal bone with bone screws. The ball joint allows a precise positioning of the clamping mechanism, and like this the actuator, in the mastoid. The ball joint and the clamping mechanism can be manipulated with the help of 2 torque-limiting screwdrivers.



FIG. 1. Codacs investigational device.

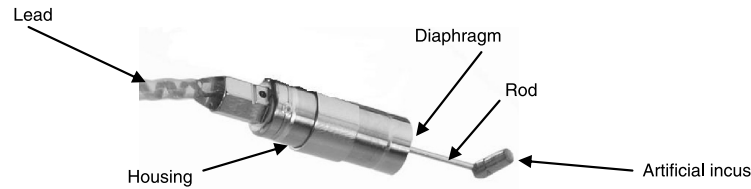


FIG. 2. Codacs ID actuator.

Throughout the text the Codacs investigational device will be referred to as DACI investigational device.

Surgical Procedure

The surgical procedure to implant the DACI investigational device was based on the retromeatal approach taken during the clinical trial with the percutaneous DACS described by Häusler et al. (1).

In a first step, the location of the implant and the sound processor were marked on the skin using the surgical templates. After a postauricular incision, the underlying periosteum and lower portion of the temporalis muscle were incised, and a flap was formed. A mastoidectomy in the shape of a kidney was performed, and the bone of the posterior external ear canal was thinned. A bony bed for the implant body and a bony canal were drilled. A tympanomeatal flap was created, after which, the middle ear structures could be assessed and otosclerosis could be confirmed. To have a direct view on the whole footplate, a segment of the posterior canal wall was removed. A large posterior tympanotomy was performed to expose the middle ear. The ossicular chain was disrupted, and the suprastructure of the stapes was removed using a laser. A small canal for the ball joint of the fixation system was drilled in the mastoid, and the fixation system was placed and fixed with bone screws. A template of the actuator was used to find a good position of the fixation system. The ball joint was fastened with a screwdriver. A perforation of the stapes footplate was performed by laser or by drill. The implant body was placed in the bony bed, and the actuator was positioned using the applicator. Once a good position for the actuator with no contact to the surrounding structure was found, the actuator was fixed in its position. A conventional stapes prosthesis was inserted in the perforation of the stapes footplate and crimped to the artificial incus of the actuator via the ear canal. The actuator cable was protected by securing it in a bony canal and covered with bone paste and fibrin glue. Intraoperative testing was performed to check the functionality of the actuator and implant. The wound was closed subsequently.

The surgical approach is a transmastoid approach with an additional transcanal approach in some cases where the exposure of the stapes footplate is not adequate through the posterior tympanotomy. In 6 cases, it was possible to perform the stapedotomy

completely through the posterior tympanotomy after removal of the stapes suprastructure. In those cases, the elevation of a tympanomeatal flap and the partial removal of parts of the superior and posterior outer ear canal bone could be avoided, and no reconstruction of the posterior ear canal wall with cartilage was necessary, that is, there was less manual work, less bone dust in the middle ear cavity, and less risk of infection. However, the advantages of the combined approach (transmastoid and transmeatal) are a better view on the stapes footplate and no need to expose the facial nerve. The transmastoid approach is described by Lenarz et al. (3).

Study Protocol

The Codacs ID Clinical Trial was designed as a prospective, multicenter study in up to 15 patients. Study centers were the Hannover Medical School (MHH) in Hannover/Germany, the Radboud University Nijmegen Medical Centre (RUNMC) in Nijmegen/The Netherlands and the Inselspital at the University of Bern/Switzerland. The study protocol was submitted to and approved by the responsible ethics commissions and competent authorities. The presented results concern all fifteen included patients. No patients were withdrawn or lost to follow-up.

Adult subjects with otosclerosis and a severe to profound mixed hearing loss and subjects with a failed stapes surgery were considered for inclusion in the clinical trial. The bone conduction thresholds had to be 30 dB or worse in the audiometric frequencies 0.5, 1, 2, 3, and 4 kHz and had to be measurable at those frequencies. The air-bone gap had to be at least 30 dB in 3 of those 5 frequencies.

All patients were informed about alternative treatments. For some patients, stapes surgery and wearing a hearing aid would have been the best alternative treatment; for others, a cochlear implantation would have been the only alternative solution. All patients who took part in the clinical trial chose to have a DACI investigational device implanted, as they would have needed surgery anyway and the DACI ID combines stapes surgery and acoustic amplification.

All subjects needed to complete 5 study visits and were followed up to 3 months after initial activation of the DACI investigational device. Preoperatively and postoperatively, medical and audiological evaluations were performed. These included

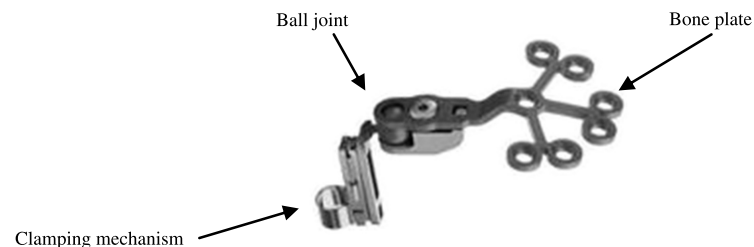


FIG. 3. Codacs ID fixation system.

a physical examination, a tympanometry, measurements of the air conduction (AC), and bone conduction (BC) thresholds at standard audiometric frequencies and a measurement of the unaided sound field thresholds using warble tones. Preoperatively, the uncomfortable loudness levels were measured, and a CT scan was performed to verify a sufficient mastoid size. Aided thresholds in sound field were measured preoperatively using warble tones if the patient was wearing a hearing aid and postoperatively with the DACI investigational device. The unaided and aided speech reception thresholds (SRTs) and word recognition scores (WRS) were obtained preoperatively and postoperatively in the sound field using recorded speech. The SRT was measured at the lowest intensity level at which the subject could correctly repeat 50% of the speech. The WRS were measured at 50, 65, 80, and 95 dB SPL, if the uncomfortable loudness level was not reached at those levels. In Germany and Switzerland, the WRS were measured with the Freiburger word lists. In the Netherlands, the WRS were measured with the NVA word lists (word list from the Dutch Society for Audiology).

The speech reception thresholds in noise were established preoperatively and postoperatively in sound field using the Oldenburg Sentence test (OLSA, developed by Wagener et al. [4]) in Germany and Switzerland, and the Plomp test (developed by Plomp et al. [5]) in The Netherlands. The signal-to-noise ratios (SNRs) at which 50% correct scores could be achieved were assessed via an adaptive test procedure. The stimuli were presented at 0-degree azimuth, and the noise level was fixed at 65dB. For all tests, the contralateral ear was masked when necessary. A positive signal-to-noise ratio means that the speech had to be louder than the noise for the patients to be able to understand 50% of the speech. A negative signal-to-noise ratio means that the speech could be softer than the noise for the patient to be able to understand 50% of the speech. Normal-hearing subjects can understand 50% of the speech at a SNRs of -7.1 or -5.5 dB SNR for the OLSA and Plomp, respectively (4,5).

The Abbreviated Profile of Hearing Aid Benefit (APHAB) (6) was completed by all study subjects preoperatively and at the 3-month follow-up visit. The benefit was calculated by comparing the patient's reported difficulty in the preoperative condition with their amount of difficulty when using amplification (with the DACI investigational device). The APHAB produces scores of 4 subscales: ease of communications (EC), reverberation (RV), background noise (BN), and aversiveness (AV). The global score can be calculated by averaging those 4 subscales.

Intraoperatively, the functionality of the implant was measured with a laser Doppler vibrometer and a free movement of the artificial incus was confirmed.

A surgical questionnaire had to be completed by the surgeon after each implantation to give feedback on the surgical procedure.

The DACI investigational device was fitted initially approximately 6 weeks after implantation. Part of the fitting process included an in situ audiogram using implant stimuli. The fitting parameters were prescribed based on a fitting rule developed by Cochlear. At each study visit, the subject was asked for adverse events that might have occurred.

Subjects

Fifteen subjects aged 47 to 79 (mean \pm standard deviation [SD], 61 ± 9.4 yr) were included in the clinical trial. Eight subjects were implanted at the Hannover Medical School, 5 patients at the Radboud University Nijmegen Medical Center and 2 patients at the Inselspital of the University of Bern. The surgeries were performed between November 2009 and May 2011. All study subjects, 10 women and 5 men, had otosclerosis and a severe-to-profound

mixed hearing loss. The duration of hearing impairment was between 10 and 55 years (mean \pm SD, 24 ± 12.9 yr). Eleven subjects had a hearing aid on the implanted ear preoperatively, which they had used between 1.5 and 32 years (mean \pm SD, 9.7 ± 9.4 yr). On the contralateral ear, 11 subjects had a hearing aid, 3 patients had a cochlear implant, and 1 patient did not use any amplification. Six subjects had undergone a previous ear operation on the implanted ear (stapes surgery [3], tympanoplasty type III [1], ventilation tubes [1], and middle ear inspection [1]). Each subject agreed to participate in the study by giving written informed consent. Table 1 presents an overview of the patients' demographics.

Statistics

The statistical analysis was done with PASW 18.0 (SPSS Inc., Chicago, IL, USA) and included a normality test and a test on significant differences between pairs. Depending on the outcome of the normality test and the number of complete data sets, the paired Student's *t* test (Student's *t* test) or the Wilcoxon matched-pairs signed-rank test (Wilcoxon) was used to test statistical significance. The significance level was set to $p = 0.05$.

RESULTS

Audiologic Outcome

All postoperative results shown and explained are the data from the 3 months' follow-up visit, that is, 3 months after activation of the device.

Preoperative and Postoperative Audiometry

The mean preoperative and postoperative air and bone conduction thresholds of all 15 subjects are shown in Figure 4. The error bars indicate the standard deviation.

Preoperatively, the patients, on average, had a severe-to-profound mixed hearing loss with a moderate sensorineural component and a mean air-bone gap of 46 dB. The pure tone average (PTA, average of air conduction thresholds at 0.5, 1, and 2 kHz) did not change significantly by the Codacs ID procedure (90 dB HL preoperative versus 88 dB HL postoperative; $p > 0.05$ in all frequencies). The bone conduction thresholds, however, improved significantly at 750 Hz (Wilcoxon, $p = 0.041$), 1 kHz (Student *t* test, $p = 0.01$), and 1.5 kHz (Wilcoxon, $p = 0.016$) compared with the preoperative bone conduction thresholds. The air-bone-gap increased significantly at 1 frequency only (500 Hz, Wilcoxon, $p = 0.044$).

Sound Field Audiometry

Preoperatively, the sound-field thresholds were measured monaurally unaided and aided with the subject's hearing aid (if the subject wore a hearing aid preoperatively). Postoperatively, the sound-field thresholds were measured monaurally aided with the DACI investigational device. An overview of the results is shown in Table 2.

Figure 5 shows the mean sound-field thresholds and standard deviations of all patients measured preoperatively unaided and postoperatively aided with the DACI investigational device at the subject's 3 months' follow-up visit. The mean (250 Hz to 8 kHz) preoperative unaided sound field threshold was 86 dB HL, whereas the mean postoperative aided sound-field threshold was 38 dB HL. Thus, the mean improvement of the sound-field thresholds by

TABLE 1. Patient's demographics

No.	Study number	Sex	Age	Duration of hearing impairment (yr)	Implanted Ear	Duration of hearing aid use in implanted ear (yr)	Previous ear operations in implanted ear	Contralateral ear
1	GE10-XEP-01	Female	69	25	Right	17	No	HA
2	GE10-XRK-02	Female	56	55	Left	4	No	/
3	GE10-XJH-03	Male	47	13	Right	2	No	CI (2008)
4	GE10-XAS-04	Female	59	20	Right	No hearing aid	No	CI (2009)
5	GE10-XJR-05	Male	62	10	Left	10	No	HA
6	GE10-XWH-06	Male	73	22	Right	5	No	HA
7	GE10-XRZ-07	Female	56	30	Right	No hearing aid	Yes	HA
8	GE10-XHS-08	Female	65	15	Left	No hearing aid	No	HA
9	NL06-GWK-01	Female	57	32	Right	32	No	HA
10	NL06-JPV-02	Female	57	11	Left	11	Yes	HA
11	NL06-XJH-03	Male	71	15	Left	No hearing aid	No	HA
12	NL06-JCJ-04	Male	52	Unknown	Right	14	No	HA
13	NL06-GHP-05	Female	79	Unknown	Left	unknown	No	HA
14	CH02-XSM-01	Female	62	40	Right		Yes	CI (2010)
15	CH02-XFL-02	Female	48	25	Right	1.5	Yes	HA

the DACI investigational device was 48 dB. The improvement is significant in all frequencies (Student's *t* test or Wilcoxon, $p \leq 0.005$ in the frequencies up to 4 kHz, $p = 0.008$ for 6 kHz and $p = 0.043$ for 8 kHz).

Figure 6 shows the mean sound-field thresholds and standard deviations of the 11 subjects who used a hearing aid (HA) preoperatively. The sound field thresholds were measured preoperatively both unaided and aided with their hearing aid and postoperatively aided with the DACI investigational device at the subject's 3 months' follow-up visit. The mean (250 Hz to 8 kHz) preoperative unaided sound field hearing threshold was 83 dB HL, the mean preoperative HA aided sound-field hearing threshold was 52 dB HL, and the mean postoperative DACI investiga-

tional device aided sound field threshold was 37 dB HL. Thus, the mean improvement of the sound-field thresholds by the hearing aid was 31 dB and by the DACI investigational device was 46 dB, that is, an improvement of 15 dB compared with the hearing aid. The improvement with an acoustic hearing aid is significant in all frequencies (Wilcoxon, $p \leq 0.026$) except for 8 kHz. The improvement with the DACI investigational device is significant in all frequencies (paired Student's *t* test or Wilcoxon, $p \leq 0.005$ in the frequencies 250 Hz to 4 kHz, $p = 0.008$ for 6 kHz and $p = 0.043$ for 8 kHz). The improvement of the DACI investigational device aided sound-field thresholds postoperatively compared with the HA aided sound-field thresholds preoperatively is significant in all frequencies (Student's *t* test, $p \leq 0.028$) except at 2 and 8 kHz (Wilcoxon, $p > 0.05$). At 8 kHz, the number of pairs was only 5, which might explain why the difference is not significant.

Figure 7 shows the effective gain that is delivered to the inner ear by the DACI investigational device. The effective gain is defined as the difference between the postoperative aided sound-field thresholds and the preoperative bone conduction thresholds. It reflects the gain which the DACI investigational device delivers to the inner ear and which is accepted by the patient. The average gain over all subjects and frequencies (0.5–4 kHz) is 17.2 dB. The greatest gain is achieved at 1,500 Hz, the smallest at 500 Hz.

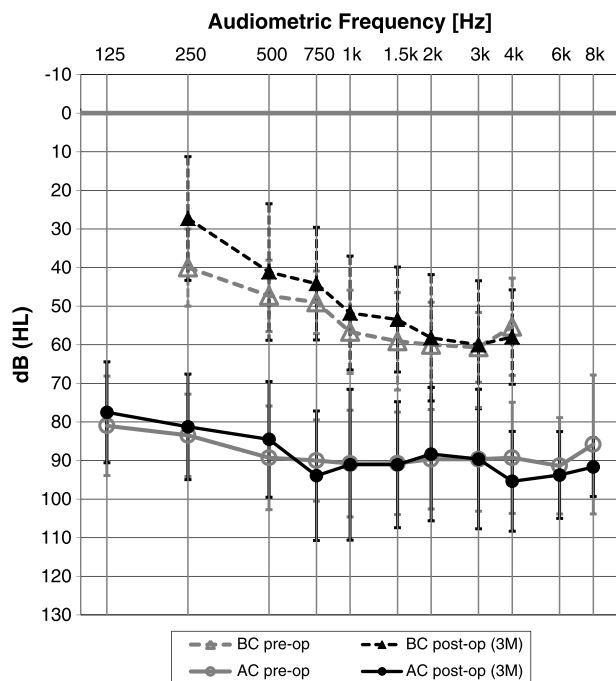


FIG. 4. Mean (n = 15) preoperative and postoperative air and bone conduction thresholds. Error bars represent SD.

TABLE 2. Mean unaided and aided sound field thresholds and improvements by Codacs ID and hearing aid

Mean sound field thresholds/improvement	n = 15	n = 11
Preoperative unaided (dB HL)	86	83
Preoperative aided by HA (dB HL)		52
Postoperative aided by Codacs ID (dB HL)	38	37
Improvement by HA (dB HL)		31 ^b
Improvement by Codacs ID (dB HL)	48 ^a	46 ^a
Codacs ID improvement compared with HA		15 ^b

There is a significant improvement in all (^a) or most (^b) frequencies. HA indicates hearing aid.

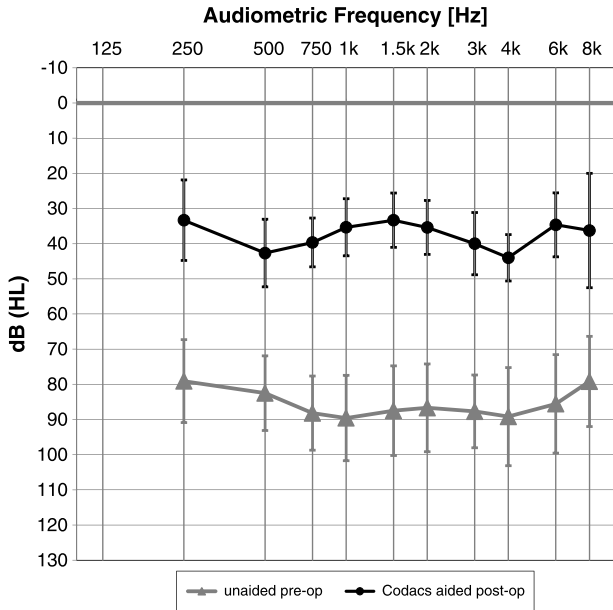


FIG. 5. Mean (n = 15) unaided and Codacs ID aided sound field thresholds. Error bars indicate SD.

Speech Audiometry

To evaluate the speech recognition with the DACI investigational device, the speech reception thresholds (SRTs) and the word recognition scores (WRS) were measured using recorded speech (Fig. 8).

The SRT improved significantly (Wilcoxon, $p = 0.008$) by 40.7 dB from 91.9 dB SPL preoperatively to 51.2 dB

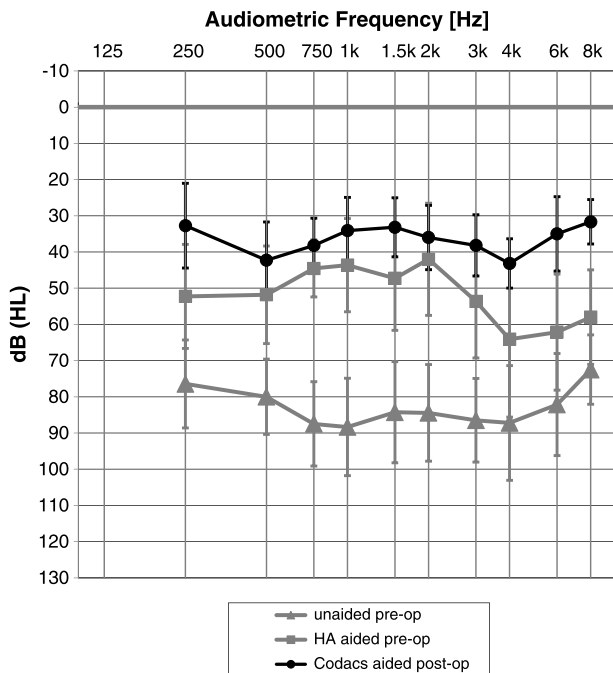


FIG. 6. Mean (n = 11) preoperative and postoperative unaided and aided sound-field thresholds. Error bars indicate SD.

SPL postoperatively, aided with DACI investigational device. Comparing the aided results from the subjects who wore a hearing aid preoperatively, the SRT improved significantly (Wilcoxon, $p = 0.044$) by 12.2 dB, from 61.3 dB SPL preoperatively aided to 49.1 dB SPL postoperatively aided.

The word recognition scores (WRS) were measured preoperatively unaided and aided with the subject's hearing aid (if the subject wore a hearing aid preoperatively, $n = 11$) and postoperatively aided with the DACI investigational device. The mean ($n = 15$) preoperative unaided word recognition scores at 50, 65, and 80 dB SPL were 0%, 0%, and 5.3% (SD, $\pm 15.2\%$), respectively. Postoperatively, the mean aided (with DACI investigational device) word recognition scores for all patients were 30.4% (SD, $\pm 31.8\%$) at 50 dB SPL, 75% (SD, $\pm 27.3\%$) at 65 dB SPL and 85.5% (SD, $\pm 25.3\%$) at 80 dB SPL and improved significantly by 30.4%, 75%, and 78.2%, respectively, compared with the preoperative unaided condition (Student's t test, $p = 0.002$ for 50 dB, $p < 0.001$ for 65 and 80 dB).

For the patients who used a hearing aid preoperatively, the mean ($n = 11$) preoperative unaided word recognition score at 50, 65, and 80 dB SPL were 0%, 0%, and 7.3% (SD, $\pm 17.5\%$), respectively. The mean ($n = 11$) preoperative HA aided word recognition scores at 50, 65, and 80 dB SPL were 6.7% (SD, $\pm 11.2\%$), 41.8% (SD, $\pm 32.8\%$), and 61.8% (SD, $\pm 35.9\%$). The improvement was 6.7%, 41.8%, and 54.5%, respectively, compared with the preoperative unaided condition. The mean ($n = 11$) postoperative DACI investigational device aided word recognition scores were 36% (SD, $\pm 34.6\%$) at 50 dB SPL, 77.3% (SD, $\pm 30.4\%$) at 65 dB SPL, and 87.5% (SD, $\pm 26.5\%$) at 80 dB SPL and improved by 36%, 77.3%, and 80.2%, respectively, compared with the preoperative unaided condition and 29.3%, 35.5%, and 25.6%, respectively, compared with the preoperative aided condition. Postoperatively, the mean ($n = 11$) aided (with C-DACS ID) word recognition scores were 36% (SD, $\pm 34.6\%$) at 50 dB SPL, 77.3% (SD, $\pm 30.4\%$) at 65 dB SPL, and 87.5% (SD, $\pm 26.5\%$) at 80 dB SPL and improved by 36%, 77.3%, and 80.2%, respectively, compared with the preoperative unaided condition and 29.3%, 35.5%, and 25.7%, respectively, to the preoperative aided condition. The aided sound-field thresholds

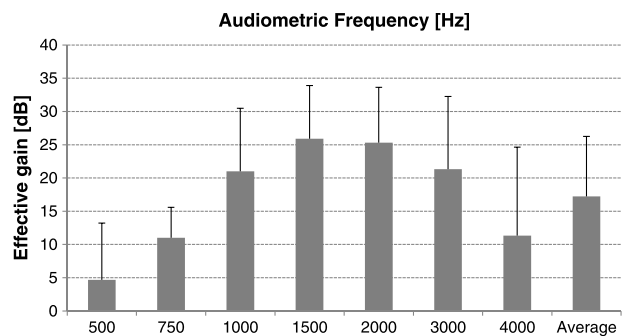


FIG. 7. Mean (n = 15) gain delivered to the inner ear for the frequencies 0.5 to 4 kHz and the average of those frequencies. Error bars indicate SD.

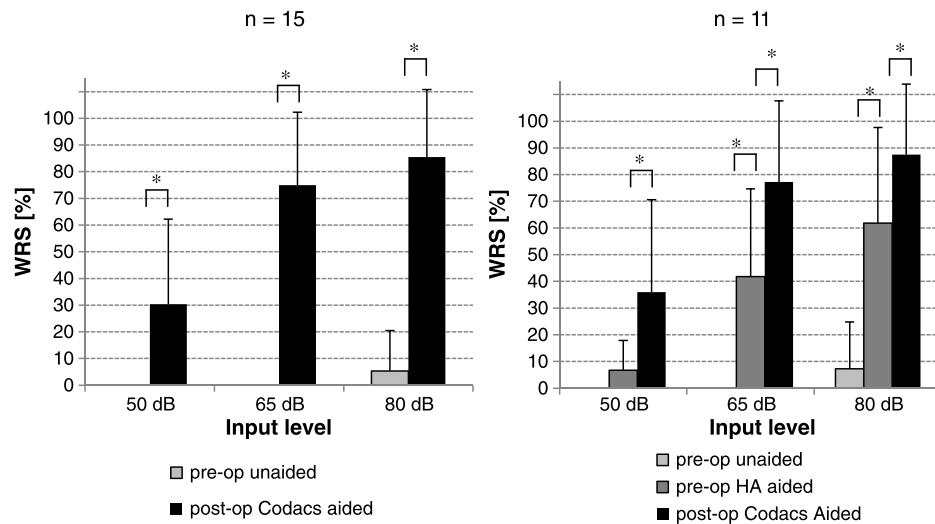


FIG. 8. Mean word recognition scores (WRS in % correct) for presentation levels of 50, 65, and 80 dB SPL for the preoperative unaided condition (preop unaided), the preoperative aided condition with hearing aid (preop HA aided), and the postoperative aided condition with the Codacs ID at the 3 months follow-up visit (postop Codacs ID aided) for all patients (n = 15, left graph) and the 11 patients that used a hearing aid preop (right graph). Error bars indicate SD. * $p \leq 0.05$.

improved significantly at all levels (50 dB: Wilcoxon, $p = 0.027$; 65 and 80 dB: Student's t-test: $p \leq 0.015$) compared with the preoperative aided condition. An overview of the word recognition scores is shown in Table 3.

The individual speech reception thresholds (SRTs) in noise for the preoperative condition (unaided or aided with HA) and the postoperative aided condition (with DACI investigational device) are shown in Figure 9. If the OLSA or Plomp test was not measurable, a value of +10 dB SNR was displayed with an arrow up, indicating that the real SRT was above +10 dB SNR. In 10 (66%) of 15 patients, the SRT in noise improved; in 2 patients, it was worse (Patients 2 and 13), and in 3 patients, it was not measurable preoperatively and postoperatively (Patients 11, 14, and 15). Individual results show impressive improvements of the SRT in noise of around 7 to 8 dB (Patients 1, 3, and 10) or even greater for those patients where the SRT was not measurable preoperatively but postoperatively (Patients 4–8). The mean SRT in noise results for the OLSA and Plomp test apart is shown in Table 4.

The SRT in noise for the Oldenburg sentence test improved, on average, by 4.2 dB, from +3.9 dB SNR (SD, ± 3.3 dB SNR) preoperatively to -0.3 dB (SD, ± 3.7 dB SNR) postoperatively, which is statistically not significant (Wilcoxon, $p > 0.05$). However, the critical test-retest difference for the OLSA is 1.4 dB SNR, and therefore, a significant benefit is confirmed when the

SNR of the speech reception threshold decreases by this value (7).

The SRT for the Plomp test improved, on average, by 2.4 dB, from +3.0 dB SNR (SD, 1.8 dB SNR) preoperatively to 0.6 dB SNR (SD, ± 4.3 dB SNR) postoperatively, which is statistically not significant either (Wilcoxon, $p > 0.05$). The standard deviation of the Plomp test is 1 dB, and therefore, a change of 2.4 dB can be seen as significant benefit.

It should be noted that the postoperative measurements were done without any preprocessing or noise suppression.

Figure 10 shows the average APHAB subscale scores and the average APHAB total scores for all subjects (n = 15) for their preoperative and their postoperative condition. Please be aware that the APHAB questionnaire is a measurement of the daily condition, that is, with both ears. That means that the condition of the contralateral ear (e.g., aided with hearing aid or CI) has an influence on the measurement results. Three subscales (EC, BN, and RV) and the

TABLE 3. Mean word recognition scores

	50 dB SPL (%)	65 dB SPL (%)	80 dB SPL (%)
Unaided (n = 15)	0	0	5.3
HA aided (n = 11)	6.7	41.8	61.8
Codacs ID aided (n = 15)	30.4	75	85.5

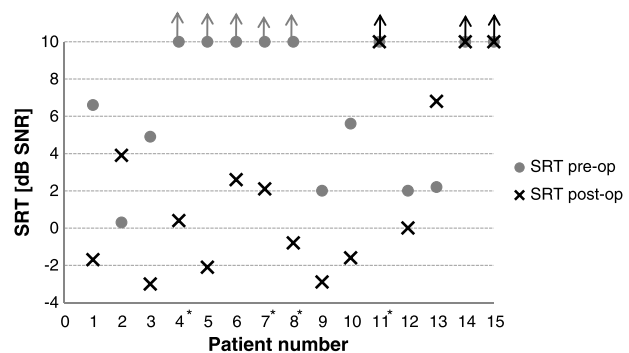


FIG. 9. Individual preoperative and postoperative SRT in noise for all 15 patients. Preoperative SRT is measured with hearing aid except for patients indicated with a asterisk.

TABLE 4. Speech in noise test results

	Mean speech reception thresholds preoperative (dB signal-to-noise ratio)	Mean speech reception thresholds postoperative (dB signal-to-noise ratio)	Improvement speech reception thresholds preoperative versus postoperative (dB signal-to-noise ratio)	<i>p</i>
Oldenburg Sentence test (n = 3)	+3.9	-0.3	4.2	>0.05
Plomp (n = 4)	+3.0	+0.6	2.4	>0.05

global score show a significant benefit with the DACI investigational device compared with the preoperative condition (Student's *t* test, $p \leq 0.002$). On average, the ease of communication improved by 29%, the communication in background noise and reverberation were 35% and 39% less difficult, respectively, and the aversiveness decreased by 5.2%. This results in a total benefit/less difficulty in hearing of 27% after implantation. The biggest benefit could be achieved for reverberation, the smallest for aversiveness. The aided APHAB scores are close to the median norm as presented by Cox and Alexander. (6)

Adverse Events

During the clinical study, 6 adverse events (AEs) and 5 serious adverse events (SAEs) occurred. The SAE were reported to the competent authorities involved. There were no device-related SAE. One SAE was rated as possibly procedure related, one as probably procedure related. During this SAE, the patient had a strange sound sensation after activation of the system, and hearing was rated as inferior to the preoperative hearing aid condition. The patient underwent revision surgery during which a potential contact of the artificial incus with the surrounding bone was found. After revision, the hearing was clearer but still not satisfying. The patient had better results in speech understanding in quiet but not in noise. All SAE are listed in Table 5.

There was 1 device-related AE and 2 possibly device-related AE. One AE was rated as probably procedure related and one as possibly procedure related. An overview of the AE can be found in Table 6. In the following, the device-related AE is explained in more detail. During surgery, the fixation system was deformed and had to be replaced by a new one, that is, it could be resolved directly during surgery. The surgery time was not prolonged significantly.

DISCUSSION

Audiologic Results

As presented in the results, no significant increase in averaged postoperative bone conduction thresholds was found but a significant improvement at 750 Hz, 1 kHz, and 1.5 kHz. However, some increase of the bone conduction thresholds was found in 3 patients (12.5, 11, and 16 dB). An explanation may be that the averaged results are balanced by the increase in postoperative bone conduction thresholds in the other subjects. An improvement of BC thresholds has been described by Arnold et al. (8) and Perez et al. (9) in regular stapes surgery. It is indicated that the inner ear function is, in fact, better than measured in the bone conduction testing caused by fixation of the stapes footplate in the oval window. After opening of the footplate and thereby relieving the fixation, better bone conduction thresholds were measured (8).

No changes were found for the averaged air conduction thresholds, which indicate that the maximum conductive component—or air-bone gap—was reached already before the disruption of the ossicular chain.

The aided sound field measurements reveal interesting results. For all 15 subjects, a significant benefit is achieved when the device is switched on. However, most interesting is the achieved gain in the higher frequency range. Compared with the preoperative hearing aid gain (Fig. 6, note $n = 11$), a substantially increase is achieved with the DACI investigational device, which is even significant in most measured frequencies. The most plausible explanation is that the higher frequencies need to be tuned down in the acoustic hearing aid configuration to prevent feedback of amplified sounds. An acoustic hearing aid has to bridge the air-bone gap in case of mixed hearing loss. Because of the high gain, the hearing aids have to deliver, they often work at their limit, and thus, the sound might be deteriorated. Also, an impedance mismatch in the outer ear canal might be a reason for an irregular transfer of sound to the inner ear for the high frequencies. This is not the case with the DACI investigational device because there is direct stimulation of the cochlea. Similar results were found in the study by Häusler et al., where the results of the DACS system were compared with acoustic hearing aid results after stapedotomy on the same ear. In that study, the hearing aid to which the DACS was compared featured the same signal processing capabilities and was fitted in the implanted ear (1). Not much has been published on MEI in otosclerosis. Venail et al. (10) presented data of 4 patients with otosclerosis using either the Vibrant Soundbridge (MED-EL, Innsbruck, Austria) or the Middle Ear Transducer (Otologics LLC, Boulder, CO, USA). From their figures, it is clear that amplification in the high

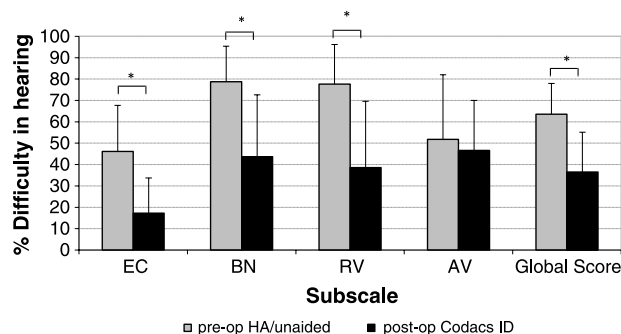


FIG. 10. Mean ($n = 15$) difficulty in hearing shown for the 4 APHAB subscales and the global APHAB score. Error bars indicate SD.

TABLE 5. Serious adverse events

No.	Patient	Serious adverse event	Procedure related?	Device related?	Outcome
1	GE10-XRK-02	Deterioration of bone conduction thresholds and tinnitus	No	No	Resolved
2	GE10-XJH-03	Facial palsy	Possibly	No	Resolved
3	GE10-XRK-02	Hearing of vibrating noise/feedback	Possibly	Yes	Resolved
4	GE10-XJH-03	Deterioration of bone conduction thresholds	No	No	Resolved
5	GE10-XJH-03	Heart attack	No	No	Resolved

frequencies is poor, significantly poorer than in the mid frequencies (in contrast to the presented results with the DACI investigational device). Other authors reported on the implantation of middle ear implants in otosclerosis patients as well, but mostly, the aided sound-field thresholds are not shown for 6 and 8 kHz or the average of a mixed group with various medical indications is shown (10–15). As the number of otosclerosis patients in those publications is low, there is insufficient data today to draw any firm conclusions yet.

As expected, the achieved WRS and SRT results in quiet with the DACI investigational device are significantly better than the unaided and aided preoperative results. It is plausible that most of this increase in speech recognition is due to better hearing thresholds and, thus, due to increased audibility. In the literature, no data were found on speech recognition after stapedotomy in combination with regular hearing aid fitting in severe mixed hearing loss. With the percutaneous DACS clinical trial (1), a comparison was possible with an acoustic hearing aid because 2 stapes prostheses were implanted in the cochlea (1). We believe that, in the current trial, a large component of the increase in speech recognition can be ascribed to the direct coupling to the inner ear by the DACI investigational device, surpassing the air-bone gap.

In contrast to SRT in quiet, which is directly related with audibility, the SRT in noise test is a measure of sound quality. The effects of the direct coupling to the inner ear are most clearly visible in the speech in noise test results. Although no significant difference was achieved because of a large preoperative as well as postoperative difference between the subjects, blunt evaluation of the data shows an impressive improvement of the SRT in the OLSA and Plomp tests. A reason for the improvement might be the better perception of high-frequency sounds and/or the reduced sound distortion because of the flat frequency transfer function of the DACI investigational device (2). In 3 patients, the SRT in noise could not be measured postoperatively. This can be related to the poor results those patients already have in their speech test in quiet postop-

eratively. At an input level of 65 dB SPL, these 3 patients did not reach a 50% score. The poor results in the speech tests of these 3 patients cannot be explained really, but it might be that the cochlear reserve and the otosclerotic involvement of the cochlea might play a role. It could be that for those 3 patients, a cochlear implant would be a better solution. Further research needs to be done to find the limits of the DACI investigational device system and to refine the inclusion criteria, for example, set a minimum preoperative aided WRS score. We recommend to measure the preoperative word recognition score via headphones up to 100 dB SPL to get an impression of the possible hearing gain by acoustic amplification. As was expected, evaluation of the subjective results by means of the APHAB questionnaire showed a significant improvement in the EC, BN, and RV subscales, whereas no significant difference was experienced in the averseness of sounds (AV) subscale. The DACI investigational device aided scores were close to the norm of Cox and Alexander (6).

Concerning the patient who underwent revision surgery, 2 points have to be mentioned. First, the device has to be properly placed with some degree of freedom to prevent a potential contact with surrounding bone structures. Second, this patient had very good speech recognition scores preoperatively with her hearing aid so that the incremental improvement, which could be achieved by the DACI investigational device was small. Indeed, this patient was initially not satisfied with the DACI investigational device, and it took long until she got adjusted to the different types of hearing she had with the DACI investigational device. After 2 years of use, she has accepted the sound and rated it as superior to her hearing with the hearing aid preoperatively. It shows us that in terms of the indications, one should not implant patients who are still doing well with their hearing aid and reach monosyllabic word score, which brings them close to values of normal-hearing people.

Surgical Results

The surgical procedure proved to be feasible. No adverse events occurred during the implantation procedure

TABLE 6. Adverse events

No.	Patient	Adverse event	Procedure related?	Device related?	Outcome
1	NL06-JPV-02	Nausea and vomiting	No	No	Resolved
2	NL06-XJH-03	Bronchitis	No	No	Resolved
3	NL06-XJH-03	Deformed fixation system	No	Yes	Resolved
4	NL06-XJH-03	Deterioration of bone conduction thresholds	Possibly	Possibly	Ongoing
5	CH02-XFL-02	Sensation at receiver site	No	No	Resolved
6	CH02-XFL-02	Tinnitus in new frequency	Probably	Possibly	Ongoing

itself. As mentioned in the methods paragraph, 2 different approaches were used by the surgeons. Some surgeons preferred the transmastoid approach with a posterior tympanotomy, whereas others preferred the combined approach (transmastoid + transcanal) and set out to implant the DACI investigational device using the combined approach from the start of the operation. The transmastoid approach gave sufficient exposure of the stapes footplate in the 6 patients where it was used, but it could happen that it is necessary to do the combined approach. The disadvantage of the combined approach is that parts of the posterior wall of the outer ear canal have to be removed to have a good view on the stapes footplate. To avoid contact between the tympanic membrane and the artificial incus, it is necessary to reconstruct the ear canal with cartilage. The ossicular chain was not reconstructed in any case using a second stapes prosthesis as has been done in the preliminary trial in 4 patients (1).

During the surgery, the most described notification was the shortage in length of the rod to which the artificial incus is attached (Fig. 2). In some cases, it was difficult to approach the stapes footplate close enough. Therefore, it was not possible in all cases to mount the actuator in the fixation system in the requested area of the actuator housing. In some cases, the size of the mastoid and the bulging of the sigmoid sinus limited the freedom of rotation for the fixation bracket by the ball joint. No postoperative wound complications occurred. It is crucial to place the transducer with the artificial incus right over the footplate in a distance similar to that of the natural incus to be able to place the piston of the stapes prosthesis perpendicular to the stapes footplate. It is also necessary to avoid any contact of the transducer housing, the rod, and the artificial incus with surrounding bone or other tissue to avoid damping or interference with the sound transfer through the eardrum.

The present implantation procedure took a considerable amount of time, namely, an average of 4 hours and 52 minutes (SD, $\pm 1h26$). Nevertheless, the operation time decreased during executive surgeries, and the eighth surgery in Hannover could be performed in 2 hours and 23 minutes. Time could be gained by the training effect, especially on finding a good position for the fixation system. An important phase is positioning the transducer in the mastoid toward the oval window, fixed in its bracket, avoiding any contact to the posterior bony canal wall. In relatively small mastoids, this may be time consuming. Contact with the posterior canal wall will lead to an inadequate transmission of energy to the inner ear, possibly necessitating revision surgery.

Adverse Events

In 3 patients, a deterioration of the bone conduction thresholds (drop in PTA of 12.5, 11, and 16 dB HL) was measured. In 1 patient, this happened shortly after surgery; in the other 2 patients, it happened after the DACI investigational device was switched on. In all these patients, surgery was uneventful, leaving no clear explanation for this phenomenon. These patients were treated with corticosteroids, and in 2 of the 3 patients, the bone conduction

thresholds recovered. The sound processor fitting of the patient where the bone conduction thresholds did not recover was adapted, and the patient reached the same word recognition scores as before the drop in bone conduction thresholds. Monitoring the sensorineural hearing loss component of the patients' mixed hearing loss is of importance to gather long-term data, to evaluate the effect of direct mechanical stimulation of the inner ear.

Limitations

The study protocol implied strict indication criteria for the application of the DACI investigational device. Consequently, the patient group is very specific. First, patients with otosclerosis and a mild sensorineural hearing loss will have no need for a DACI investigational device. They will have sufficient benefit of a stapedotomy, if necessary in combination with a hearing aid. In case of a small air bone gap and a moderate-to-severe sensorineural hearing loss, it is questionable whether a high power hearing aid is indicated or whether a DACI investigation device will provide better results. This has to be investigated in future studies. The word recognition score under headphones measured up to 100 dB SPL might give a hint whether patients will benefit from a DACI investigational device or would rather get a cochlear implant using a hearing preservation procedure. The most important criterion however is a measurable bone conduction between 500 Hz and 4 kHz. For patients with severe-to-profound sensorineural hearing loss and limited speech discrimination, a CI might offer better revalidation options. Therefore, counseling is of great importance.

Second, the implantation of the present investigational DACI required a considerably otologic experience, as it was technically challenging. Although the fixation system offered 3 degrees of freedom for the positioning of the actuator, the margins were small. Changes in the system design will have to improve versatility and reduce surgery time.

Furthermore, a weakness of the present study is the lack of standardization in the procedure of the preoperative acoustic hearing aids. Different types and models of hearing aids were used by the patients. Some of the patients used a cochlear implant contralateral. This might have led to different fitting settings. However, we experienced that some of the users gave up using their hearing aid because of an unsatisfactory benefit for the above-mentioned reasons. The other patients had a well-selected hearing aid and could benefit from the acoustic amplification.

Further Research

Half of the study patients would fulfill the indication criteria to get a cochlear implant. Three of them have a cochlear implant on the contralateral ear and prefer the sound of the DACI investigational device to the sound of their cochlear implant. Further research should have a closer look at this patient group and investigate quality of life and maybe additional subjective measures like music perception, with the DACI investigational device compared with cochlear implants. New coupling sites should also be investigated to be able to implant the DACI investigational device in patients with other medical indications like, for

example, radical cavities, severe sensorineural hearing loss, or other etiologies of mixed hearing loss.

Last, but not least, the long-term effect of mechanical stimulation of the inner ear fluid is unknown at the moment and needs to be investigated further. Long-term data of the subjects implanted during this clinical trial need to be assessed and analyzed. At the time of writing, the first patients have their DACI investigational device for more than 3 years. First long-term evaluations at the clinics show that the results are stable, that is, the bone conduction thresholds did not decrease, and the speech recognition in quiet and noise is the same or better than at the 3 months' follow-up visit. Once patients have more experience with their DACI investigational device, the fitting can be optimized, which might lead to further improvements in their hearing ability (16, 17).

CONCLUSION

Patients with severe-to-profound mixed hearing loss because of otosclerosis can benefit substantially using the Codacs investigational device. The most important criterion for success is that they still have measurable bone conduction thresholds and some speech recognition (via headphones or, e.g., BAHA) in the ear to be implanted. Ideal candidates are patients who had unsuccessful previous stapes surgery. For this nonrandomized patient group, the averaged audiometric results show better hearing thresholds in sound field, as well as a better speech understanding in quiet and noise with the Codacs investigational device when compared with preoperative unaided and aided conditions using a state-of-the-art conventional hearing aid. All patients are satisfied with their device and use it daily. The results were gathered up to 3 months after the first device fitting. Although that is a short evaluation period, it should be noted that previous research with the first-generation DACS showed stable results over time (1).

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