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Research paper

Indication of direct acoustical cochlea stimulation in comparison to cochlear implants

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ABSTRACT

The new implantable hearing system Codacs™ was designed to close the treatment gap between active middle ear implants and cochlear implants in cases of severe-to-profound mixed hearing loss. The Codacs™ actuator is attached to conventional stapes prosthesis during the implantation and thereby provides acoustical stimulation through a stapedotomy to the cochlea. Cochlear implants (CIs) on the other hand are an established treatment option for profoundly deaf patients including mixed hearing losses that are possible candidates for the Codacs™.

In this retrospective study, we compared the clinical outcome of 25 patients with the Codacs™ (≥3 month post-activation) to 54 CI patients (two years post-activation) with comparable pre-operative bone conduction (BC) thresholds that were potential candidates for both categories of devices. The word recognition score (Freiburg monosyllables test) in quiet was significantly ($p < 0.05$) better in the Codacs™ than in the corresponding CI patients for average pre-operative bone conduction below 60 dB HL and equal in patients with a pre-operative BC PTA between 60 and 70 dB HL. Speech in noise intelligibility (HSM sentences test at +10 dB SNR) was significantly ($p < 0.001$) better in Codacs™ (80% median) than in CI patients (25% median) in all tested groups.

Our results indicate for patients with sufficient cochlear reserve that speech intelligibility in noise with the Codacs™ hearing implant is significantly better than with a CI. Further, results in Codacs™ were better predictable, encouraging the extension of the indication to patients with less cochlear reserve than reported here.

1. Introduction

The Direct Acoustic Cochlear Implant (DACI) stimulation device Codacs™ (Cochlear Ltd.) was developed to close the treatment gap between active middle ear implants with vibratory stimulation and cochlea implants with electrical stimulation. Circumventing the middle ear and stimulating the cochlea fluids mechanically with an actuator driven conventional stapes piston through the stapes footplate, it opens new possibilities for the treatment of patients with severe-to-profound mixed hearing loss (Lenarz et al., 2013, Lenarz, Schwab, Maier, Kludt, 2014, Lenarz, Verhaert et al., 2014). In contrast to cochlea implants it relies on vibrational acoustic stimulation and requires sufficient residual hearing for a successful treatment. By design the device has a possible maximum output >120 dB SPL (Bernhard et al., 2011) and is able to cover the residual dynamic range even in severe cases of hearing loss. Here the question arises what the necessary residual hearing needed is for successful treatment and how it can be determined. A multitude of sophisticated standard audiological diagnostic instruments exist, very few can be used in this patient group with mixed hearing loss, often having AC thresholds beyond the audiometer limits. The measurement of speech intelligibility could offer additional insight, but is prevented by the pronounced air-bone gap and the technical

Acronyms and abbreviations: BC, bone conduction; CI, cochlear implant; DACI, direct acoustic cochlear implant; HSM, Hochmair-Schulz-Moser test; MV, mean value; PTA, pure tone average; SD, standard deviation; SNR, signal to noise ratio; SRT, speech reception threshold; WRS, word recognition score

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limitations of available audiometers and headphones. Currently the only feasible method to estimate the "cochlear reserve" is bone conduction (BC) pure-tone-audiometry. Although this method is not able to cover the relevant thresholds range >90 dB HL completely with available bone vibrators (e. g. B71) and distinction between both ears may be difficult, it provides a potential preoperative predictor for Codacs™ implantation outcomes.

Cochlear implants (CIs) are an established treatment option for profoundly deaf patients including mixed hearing losses that are now possible candidates for Codacs™. Steady technical improvements have increased the speech intelligibility outcome after cochlear implantation. In particular, electro-acoustical stimulation has pushed the indication criteria for cochlear implantation towards patients with significant residual hearing.

Due to the overlapping indication criteria, some patients are potential candidates for both treatment options. Our hypothesis in the analysis here was that in patients with sufficient residual hearing speech intelligibility results especially in noise are better when treated with acoustic stimulation than with electric or electro-acoustic stimulation. Hence the aim of the present study was to compare the outcome of patients with the Codacs™ to patients with a cochlear implant with a preoperative cochlear reserve within the current Codacs™ indication criteria.

2. Patient demographics

The Codacs™ patient group presented here consisted of 25 patients. Fifteen were implanted during two phases of the clinical trial between 2009 and 2013 and 10 were implanted after the device became commercially available in 2013. A new speech processor (CP810, Cochlear Ltd., Australia) and new fitting software (Cochlear Codacs™ Fitting Software, Cochlear Ltd., Australia) was introduced with the market release of Codacs™. All Codacs™ patients analyzed here were either directly fitted or upgraded between two and four years after the initial Codacs™ implantation to the CP810 with the new fitting software. The postoperative measurements of the Codacs™ group presented in this study were performed three months after the fitting of the CP810 speech processor. Within the investigated group six patients were already implanted with a CI on the contralateral side one to three years before the Codacs implantations. The demographic data of this bimodal patient group is presented in Table 1.

2.1. Codacs™ test group

The pre-operative BC pure tone average (PTA_4; 0.5, 1, 2, 4 kHz) of all Codacs™ patients was below 50 dB HL in four, between 50 and 60 dB HL in twelve and between 60 and 70 dB HL in nine cases. Because the Codacs™ is indicated for severe-to-profound mixed hearing loss most patients had an additional air-bone-gap $\geq$ 20 dB HL that was not taken into account for the analysis here. The preoperative average BC was not altered by the implantation (see Results section for details). The average age at implantation of the Codacs™ was 63 $\pm$ 10 years (mean value (MV) $\pm$ standard deviation (SD), min. 44, max. 80 years).

2.2. Cochlea implant reference group

For the CI reference group, patients implanted between 2005 and 2013 within the indication range, having a preoperative BC equal or better 80 dB HL at 0.5, 1, 2 and 4 kHz were selected from existing clinical files. The average preoperative BC PTA_4 of these patients was between 50 and 60 dB HL in 13, between 60 and 70 dB HL in 26 and between 70 and 80 dB HL in 15 cases. The air conduction PTA_4 of CI patients was worse than 70 dB HL due to a pronounced air-bone gap. Due to air-bone gaps or rather pantonal hearing losses, most patients were not considered for EAS stimulation and were implanted with conventional CI electrodes. Even though some patients had a sufficient cochlear reserve at low frequencies, the air-bone gap prevented effective use of an acoustic component. Out of 13 patients with a Hybrid or Med El Flex who could potentially use the acoustic component only 2 patients in the CI reference group were actually using it. An overview of the devices in the reference group is given in Table 2. CI patients older than 80 years, non-native German speakers or those having additional cognitive disabilities were excluded from this study. The average age at implantation in the CI reference group was 63 $\pm$ 11 years (MV $\pm$ SD, min. 33 yrs., max. 78 yrs.). No selection was made regarding the manufacturer or cochlea implant type.

3. Methods

Pure tone BC thresholds were determined using a KHL 96 bone conductor (CB-Elmec GmbH, Germany) on the mastoid. The technical limit of this device at 0.5, 1, 2 and 4 kHz was 60, 75, 80 and 70 dB HL at the respective frequencies. At frequencies where no response could be obtained due to the limitations of the audiometer (8 frequencies in 7 Codacs™ patients, pre- and postoperative measurements), the threshold was approximated by a value 5 dB HL worse than the audiometer limit at this frequency. BC thresholds were measured one day before the implantation in all patients and three month after fitting with the CP810 speech processor for Codacs™ patients. Preoperative BC thresholds in the CI reference group as taken from clinical files were determined during the week before the CI implantation.

Speech in quiet was assessed using the Freiburg monosyllable test at 65 dB SPL and speech in noise was determined using the Hochmair-Schulz-Moser (HSM) sentence test at +10 dB SNR (65 dB SPL speech level with 55 dB SPL noise level). All speech intelligibility measurements were performed in sound field with speech and noise coming from the front (S_0, S_0N_0) during routine visits at our clinic three months (Codacs™) and two years (CI patients) post activation. According to our experience, patients implanted with a Codacs™ adapt very rapidly to the acoustic stimulation, whereas speech intelligibility with CIs levels up to a plateau after two years (Lenarz et al., 2011). To reflect the obtainable long term benefit these time points were chosen for the comparison.

To detect dependencies of the achieved results on preoperative

Table 1
Demographics of bimodal (Codacs/CI) patients.

	Gender	Previous surgeries	Age at CI implantation [yrs.]	Time between implantation [yrs.]	BC PTA_4 CI side [dB HL]	BC PTA_4 Codacs side [dB HL]
1	Male	–	46	1	BC not measureable; AC: 97.0	47.0
2	Female	–	58	1	60.0	63.8
3	Female	stapedotomy both sides	66	3	deaf (failed stapedotomy)	51.3
4	Female	stapedotomy Codacs side	52	2	55.0	42.5
5	Male	–	43	1	62.5	61.3
6	Female	tympanoplasty CI side	20	3	deaf (failed tympanoplasty)	52.5

Table 2
Overview of cochlea implant types in the CI reference group.

Manufacturer	Cochlea implant type	Number of implants
Advanced bionics (USA)	HiRes90K	7
Med El (Austria)	SONATA TI100	3
	Concerto Flex EAS	4
	Concerto Standard	3
Cochlear (Australia)	Nucleus CI24RE Contour Advance	5
	Nucleus Hybrid L24	9
	Nucleus CI422	18
	Nucleus CI512	5

Table 3
Number of Patients, preoperative average air-bone gap (ABG_4, 0.5, 1, 2, 4 kHz) and median speech intelligibility grouped by their preoperative BC PTA_4.

	BC PTA_4 [dB HL]	41–50	51–60	61–70	71–80
Codacs	Number of patients	4	12	9	–
	ABG_4 [dB HL]	34	30	24	–
	WRS [%]	83	75	65	–
	HSM [%]	87	87	78	–
CI	Number of patients	–	13	26	15
	ABG_4 [dB HL]	–	19	7	4
	WRS [%]	–	60	63	60
	HSM [%]	–	21	21	33

residual hearing Codacs™ patients were divided into three groups according to their preoperative BC pure tone average (PTA_4; 0.5, 1, 2, 4 kHz): (1a) better than 50 dB HL, (2a) worse than or equal to 50 dB HL and less than 60 dB HL, (3a) worse than or equal to 60 dB HL (Table 3). In the same manner CI patients were divided into three groups according to their preoperative BC PTA_4: (1b) better than 60 dB HL, (2b) worse than or equal to 60 dB HL and less than 70 dB HL, (3b) worse than or equal to 70 dB HL. In the overlapping groups (2a, 1b) and (3a, 2b) a statistical comparison of the outcome in terms of intelligibility of speech in quiet and noise was performed.

Additionally, in bimodal patients implanted with a Codacs on one and with a CI on the other side for which audiological results for both devices was available (Table 1) a direct comparison of the outcome in both groups was performed.

4. Results

When comparing preoperative BC pure-tone thresholds ($PTA_4 = 56.5$ dB HL) to BC pure-tone thresholds at three month post activation ($PTA_4 = 54.1$ dB HL) in Codacs™ patients, no statistically detectable differences were found ($p > 0.05$, Shapiro-Wilk Normality Test, t- Student's t-test). Frequency specific BC thresholds remained unchanged (Fig. 1) and no obvious decrease was found at the second measurement 3 months after fitting of the CP810.

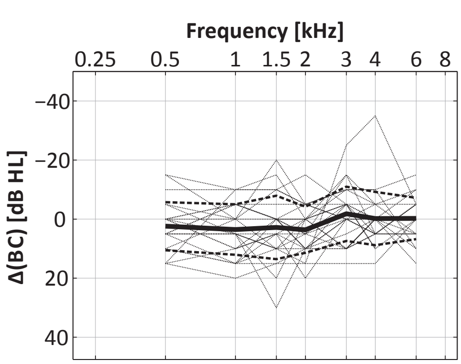

Fig. 1. Change of BC PTA_4 thresholds in Codacs™ patients between preoperative and the evaluation 3 month after the CP810 fitting. Negative values indicate an increase in threshold (preoperative − postoperative). Individual results are depicted as thin grey lines and the thick the line indicates the mean with the standard deviation (dashed).

4.1. Speech in quiet

The average speech intelligibility outcome of the Freiburg monosyllables for the entire Codacs™ patient cohort was 72% (mean, median = 70%). The performance of these patients related to their preoperative BC PTA_4 is presented in Fig. 2. The Codacs™ patients showed a significant performance decrease with increase in BC ($p < 0.02$; Jonckheere-Terpstra-Test), indicating a correlation with their cochlear reserve: Whereas the median Freiburg monosyllables word recognition score (WRS) was 83% in the group with the smallest hearing loss (1a) it declined to 65% in the group with most pronounced sensorineural hearing loss (3a). Nevertheless, all Codacs™ patients achieved at least a 50% WRS in the Freiburg monosyllabic test. In the CI patient cohort the average WRS in the Freiburg monosyllable test was 60% (mean and median) with individual results varying between 20% and 95% WRS (Fig. 3). The analysis of the CI patients in groups (1b) – (3b) according to their preoperative BC threshold showed no significant correlation between the cochlear reserve and speech intelligibility in quiet (Jonckheere-Terpstra-Test).

Only the Codacs™ group (2a) was found significantly ($p < 0.03$, U-Test) better than the corresponding CI patient group (1b) in the Freiburg monosyllabic test. The median in the Freiburg monosyllabic test for patients with preoperative BC PTA_4 between 60 and

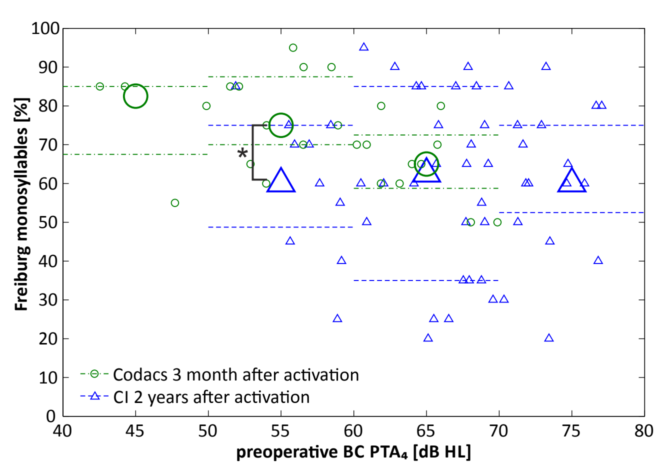

Fig. 2. Aided speech intelligibility in quiet determined with the Freiburg monosyllable Test as a function of preoperative BC PTA_4. Individual results are presented as small symbols (○ Codacs™, △ CI) and median of 10 dB HL interval groups (1a: 40–50 dB HL; 2a, 1b: 50–60 dB HL; 3a, 2b: 60–70 dB HL; 3b: 70–80 dB HL) are indicated by large symbols with the quartiles as dashed (CI) and dash-dotted lines (Codacs™).

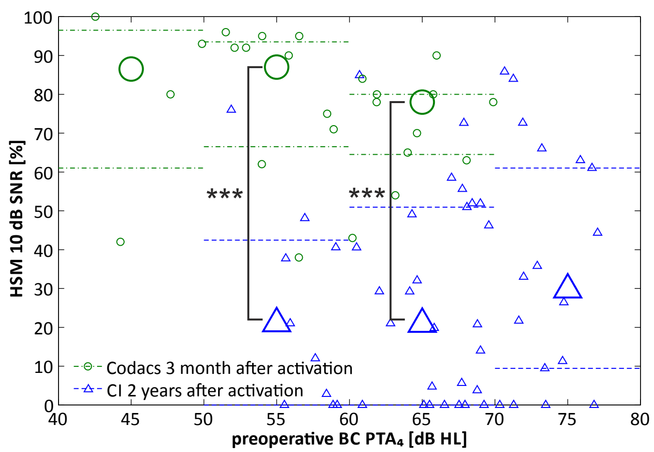

Fig. 3. Aided speech intelligibility in noise determined with the HSM test at +10 dB SNR as a function of preoperative BC PTA_4. Individual results are presented as small symbols (○ Codacs™, △ CI) and median of 10 dB HL interval groups (1a: 40–50 dB HL; 2a, 1b: 50–60 dB HL; 3a, 2b: 60–70 dB HL; 3b: 70–80 dB HL) are indicated by large symbols with the quartiles as dashed (CI) and dash-dotted lines (Codacs™).

70 dB HL was only 2% better for the Codacs™ than for CI group (65% vs. 63%). Nevertheless, the Codacs™ outcomes were much more reliable. All Codacs™ patients achieve at least 50% WRS in quiet in contrast to the CI results that were 15% WRS in some patients.

4.2. Speech in noise

The average score in the HSM sentence test at +10 dB SNR was 76% mean (80% median) in the whole Codacs™ cohort. Comparison of speech in noise performance in groups with different cochlear reserve revealed 78% median score in the group with the worst cochlear reserve (3a, BC $PTA_4 \geq 60$ dB HL) compared to 87% median in both other Codacs™ patient groups (Fig. 3). The minimum speech in noise performance of all Codacs™ patient was 38%.

In contrast, the score of the entire CI patient cohort with 30% mean WRS in the HSM sentence test showed a strong floor effect and a considerably lower median of 25% (0% WRS in 14 out of 54 patients, Fig. 3). The analysis of the CI patients in groups (1b) – (3b), according their preoperative BC threshold showed no significant correlation between the cochlear reserve and speech intelligibility in noise (Jonckheere-Terpstra-Test).

Comparison of speech intelligibility in noise between Codacs™ and CI patients, revealed a highly significant benefit (both $p < 0.001$, U-Test) for Codacs™ implanted patients in both overlapping groups (2a/1b, 3a/2b) with BC PTA_4 between 50 and 70 dB HL.

The individual speech intelligibility outcome of six bimodal Codacs patients is presented in Fig. 4. The median performance of these patients with the Codacs is higher both in quiet (57% with CI and 82% with Codacs) and especially in noise (26% with CI and 88% with Codacs).

5. Discussion

In this retrospective study we selected a cohort of CI patients with severe to profound mixed hearing loss but sufficient residual hearing to be potential candidates for the Codacs™ to compare results of electrical stimulation to acoustical stimulation in patients. As can be estimated from the distribution of our investigated patient cohort here there is at least a substantial overlap for patients with a BC PTA_4 between 50 and 70 dB HL that can be treated either with a CI or the Codacs™. Whereas the implantation of a Codacs™ does not restrict the later implantation of a CI, the decision for a CI first prohibits the later implantation of an acoustic device and a strong need for evidence based decision criteria, anticipating the outcome of acoustical and electrical stimulation in patients is given.

The change in average BC thresholds after the surgery showed a small, but statistical non-significant trend for improvement. In cases of otosclerosis the bone conduction improvement after Codacs implantation may be due to the Carhart effect. On the other hand individual changes (Fig. 1) showed a broad variability, which may be attributed to the limited test – retest reliability of such thresholds and the changed geometry by the posterior surgical approach, although we could not detect changes in average BC threshold due to the intervention.

In a first step, the speech intelligibility in quiet determined with the Freiburg monosyllable test in Codacs™ or CI implanted patients was compared. According to our results, cochlea implanted patients have sufficient speech intelligibility in situations without background noise. Only Codacs™ patients with very good cochlear reserves (BC $PTA_4 < 60$ dB HL) achieved significantly better results in quiet than patients from the corresponding CI group. Although the 2% difference in median outcome in the group with a BC PTA_4 60–70 dB HL was clinically not relevant Codacs™ patients in this group (3a) had much more reliable outcomes achieving minimally 55% WRS in contrast to CI results (2b) covering a broad range between 85% and 25% WRS. Also overall results, independently of the preoperative BC threshold in the Freiburg monosyllable tests were much more reliable in Codacs™ patients than in CI patients: Codacs™ patients achieved at least a 50% WRS while results were highly variable in CI patients and some went down to 20% WRS in this task. Our obtained WRS in quiet is very close to Freiburg monosyllable results in a study investigating the outcome of the Nucleus CI24M (Cochlear Ltd.) on the better ear after 6 months (Laszig et al., 2004). Lenarz et al (Lenarz et al., 2011). reported on the performance of 511 CI patients implanted with a variety of different devices between 2000 and 2008 (HiRes90K, Advanced Bionics; Nucleus 24RE and Freedom, Cochlear Ltd.; C40 + and Pulsar, Med El). In this study an average WRS of 62% in the Freiburg monosyllables was found under the same conditions two years after implantation which is in accordance to the speech intelligibility of our CI reference group here. In a more recent study (Seebens and Diller, 2012) that compares two different Med-El devices, a similar WRS in quiet was found for the earlier model (TEMPO+) whereas the successor model (OPUS 2) showed a better performance. Here the longer experience of CI patients may have played a role.

Although the difference between the Codacs™ and CIs results in quiet was not pronounced, the speech intelligibility in noise was considerably better with the Codacs™ than in the corresponding CI groups. Even the worst Codacs™ result of 38% WRS in the HSM sentence test was better than the median CI patient in this task. Overall median scores 25% vs. 80% were distinctively better in the Codacs™ patients, reflected also by the highly significant difference between groups 2a/1b and 3a/2b. Analogue to the intelligibility in quiet, results for hearing in noise were less variable and better predictable in Codacs™ patients. While some CI patients achieved scores above 80% in noise, this task remained completely impossible (0% WRS) for about one fourth of CI patients even after two years of training. The mean speech in noise score of 30% WRS in the current CI cohort is considerably better than the 24% WRS in the earlier mentioned study (Lenarz et al., 2011) in a large cohort with a variety of different CIs two years after implantation for the HSM sentence test at +10 dB SNR. This difference can be explained by the better precondition of our selected CI patient cohort. First, the greater cohort included patients with profound long-term deafness in contrast to our selected CI reference group that had a distinct

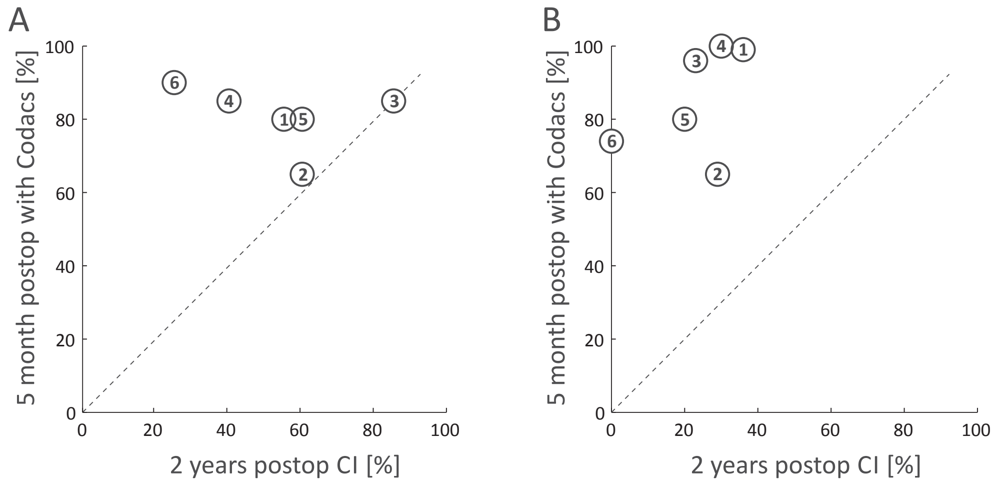

Fig. 4. Comparison of (A) Freiburg monosyllables in quiet and (B) HSM sentence test in noise at +10 dB SNR in bimodal patients.

cochlear reserve. Second, some of CI patients that are presented in the current study were implanted with the next generation of CIs and some could profit of electro acoustic stimulation (e.g. Hybrid-L from Cochlear or Concerto Flex EAS from Med El), although only two patients actually used this possibility. The speech processor technology as well as coding strategies made advances that were available for the later implanted CI patients. Our CI baseline in the HSM test at +10 dB SNR (65/55 dB SPL) is also in accordance with earlier studies that found 22% WRS in a four-loudspeaker diagonal configuration ($S_{45,225}N_{135,315}$ (Schon et al., 2002). Another study determined a mean WRS of 50% monaurally at +10 dB SNR, but at a higher level combination (70/60 dB SPL) 6 months after surgery (Laszig et al., 2004). A more recent study, investigating the benefit of a processor upgrade from TEMPO + to OPUS 2 (Med-El), found a mean WRS of 35% for the older processor which is close to our results. The same study indicated that an improvement to 52% WRS is possible by the more elaborate processing of the current device. In conclusion, the speech intelligibility results of the CI patients selected as reference cohort for the Codacs™ patients were within a reasonable range for the combination of devices and can be used for estimation of electrical stimulation outcome. Even the results found for the more recently introduced CI processor show that our results obtained with the Codacs™ in a noisy situation were superior to current cochlea implants.

The speech intelligibility outcome in patients implanted with CI on one and Codacs™ on the other side confirm this finding. Even though some patients had worse preconditions on the CI implanted side (e.g. due to failed previous surgeries) these patients still allow a limited comparison within the same subject. Patients 2 and 3 showed no speech intelligibility difference between the CI and Codacs™ side in quiet, but their speech intelligibility improved by 36% and 73% in noise. The four other patients improved both, in quiet and noise. Hence, the results in bimodal patients support our findings in separate CI and Codacs™ patients that the benefits of acoustic stimulation in noise predominate.

The advantage of acoustic stimulation crucially depends on the residual cochlear reserve. The BC PTA_4 thresholds showed stable inner ear function in an interval up to four years in the first Codacs™ patients. However, the sensorineural hearing loss tends to increase over time and could lead to performance reduction and the need for a CI implantation eventually. Additional long term studies of Codacs™ patients are needed to monitor BC thresholds and the performance of the device to predict the possible time of successful use and to provide evidence based indication criteria.

In addition to audiological advantages in noisy environments, our experience with the Codacs™ showed that the time and effort for rehabilitation is significantly reduced compared to cochlea implants. Although not quantified here, patients adapted quickly to the more natural acoustic stimuli and required significant less aftercare. To this promising findings may have contributed that patients with acoustic stimulation probably have a comparable frequency resolution to hearing aid patients with similar residual hearing and a better presentation of temporal acoustic fine structure in speech. Additionally, the Codacs™ better supports low frequencies transmission than it is common in CIs and the usable dynamic range can be assumed higher than in electric stimulation. The more natural presentation of the acoustic input permitted a fast and effortless adaptation to the direct acoustic stimulation and possible factors contributing to this result needs to be investigated in future studies.

Overall, the advantage of direct acoustical stimulation of the inner ear over cochlear implantation is particularly noticeable in difficult hearing situations.

6. Conclusion

Our results indicate that for patients with sufficient cochlear reserve, speech intelligibility in noise with the Codacs™ hearing implant is significantly better than with a CI. In quiet, the advantage of acoustical amplification was significant only for patients with pre-operative BC above 60 dB PTA. Nevertheless, the performance of the Codacs™ in quiet was ≥50% for all patients that were implanted with Codacs™ up to date. Further, results in Codacs™ patients were more predictable, encouraging the extension of the indication to less cochlear reserve than reported in the current study.

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