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New technology can beneft established middle ear implant users: Samba 2 vs previous models of audio processors for Vibrant Soundbridge

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Abstract

Introduction The Vibrant Soundbridge (VSB) is a semi-implantable hearing aid for patients with various types of hearing loss and has been available for over 25 years. Recently, new audio processors with advanced signal processing, noise reduction, and multi-microphone technology have appeared. The aim of this study is to compare the benefts of using the newest Samba 2 processor to the previous generation processors in a group of experienced VSB users.

Methods There were 22 experienced VSB users (mean time of using VSB was 9 years, SD=2) who had their processor (D404 or Amadé) upgraded to the newest model (Samba 2). The mean age of the subjects was 56 years (SD=20). Assessments were made by free-feld audiometry, speech reception in quiet and noise, and Patient-Reported Outcome Measures (PROMs).

Results Hearing tests in free feld showed statistically signifcant improvements in hearing sensitivity and speech discrimination in quiet and noise with the Samba 2 audio processor compared to the earlier technology. PROMs confrmed the benefts of using the newest audio processor and there was more satisfaction in terms of usability.

Conclusions Access to modern technology for VSB patients provides measurable benefts.

Keywords Middle ear implant · Vibrant Soundbridge · Semi-implantable hearing aid · Audio processor · Partial deafness

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Introduction

The Vibrant Soundbridge (VSB) is a partially implanted middle ear device (Med-El, Innsbruck, Austria) which was introduced in 1996 [[1](#page-8-0), [2\]](#page-8-1). It is intended for patients with acquired and congenital moderate to severe sensorineural, conductive, or mixed hearing loss who have contraindications to, or limitations with, the use of conventional hearing aids [[3](#page-8-2)[–5](#page-8-3)]. The approach of having the FMT attached to the long process of the incus was introduced to treat patients with SNHL. The newer coupling techniques using various types of couplers have been developed for treating conductive and mixed hearing loss. Currently, the FMT can also be placed on the round window, using direct or indirect coupling [\[6](#page-8-4)[–8](#page-8-5)]. The 25-year history of this solution has led to multiple reports of its safety, efectiveness, and improvement in the quality of life of patients $[9-12]$ $[9-12]$ $[9-12]$. During this time there have also been new developments in medical technology. In terms of middle ear implants, there have been several generations of audio processors (APs) with new functions.

The frst VSB was the D404 (transferred to Med-El in 2003), the Amadé processor introduced in 2009, and the Samba processor in 2015. The latest VSB processor is the Samba 2, launched in 2020. New functions include advanced signal processing, noise reduction, multi-microphone technology, speech tracking, and remote control. Signal processing and functionality have improved over the generations [[13\]](#page-8-8). The multi-microphone technique (on which we focus here) has been used for several years in both hearing aids and various types of implants [[14](#page-8-9)[–17\]](#page-8-10). It was presumed the technique would bring measurable benefts to our study group, although the improvements are difficult to measure objectively because of the built-in adaptive circuitry: measurements would need to simulate a rapidly changing acoustic scene to reproduce the conditions under which adaptive microphones operate. An easier alternative is to assess the benefts of using this technology by using Patient-Reported Outcome Measures (PROMs). The combination of both objective and subjective measures allows a reliable assessment to be made of the device's benefts—understood as the reduction in the user's limitations caused by hearing loss.

Thanks to the compatibility of newer APs with older implants, access to modern technology is even possible for long-term users. Patients can gain in two areas: they receive a new device that is more reliable than the old one, and they gain access to modern technology that was unavailable in their legacy processor. To the authors' knowledge, there has been only one previous study on upgrading the VSB technology—from Samba to Samba 2 [\[18](#page-8-11)].

The aim of this study was to assess the benefts to users from upgrading their previous generation processor to Samba 2 in terms of hearing sensitivity and speech discrimination outcomes as well as in terms of PROMs.

Methods

Subjects

There were 22 VSB users who were enrolled in this study (13 female, 9 male). The subjects were implanted between 2009 and 2015 with a VSB (either a VORP 502 or VORP 503) and were provided with a D404 or Amadé audio processor. The mean age of the subjects was 56 years $(SD=20, \text{range})$ 14–79 years) at the time of the upgrade visit. The mean time of VSB use was 9 years (SD = 2, range $5-12$ years). Details are given in Table [1.](#page-2-0)

Audio processors

In 6 cases a D404 audio processor was used and in 16 cases Amadé, all with the omni-directional microphone switched on in the universal program setting. They were all ftted at standard follow-up visits. All processors were replaced with Samba 2 (in 12 cases on the right, in 10 on the left). The Samba 2 AP was individually ftted to the patient based on a Vibrogram (in situ measurement of hearing thresholds) with SYMFIT, version 8.0.1, following a frst ftting session using DSL version 5 for Samba 2. Samba 2 was set with directionality, surround sound, and voice tracking on in the universal program. An overview of the diferences between processors of diferent generations is shown in Table [2.](#page-2-1)

Outcome measures

Pure-tone audiometry Pure-tone audiometry was performed in an anechoic chamber with an Otometrics Madsen Itera II diagnostic audiometer. Air conduction thresholds were measured with TDH39 on-ear headphones at 0.125, 0.25, 0.5, 1, 2, 4, and 8 kHz; bone conduction was measured using a B-71 calibrated bone transducer at 0.25, 0.5, 1, 2, and 4 kHz. If there was no response to sound during the test, the maximum value available in the audiometer for the given stimulus was taken to be the threshold value.

Sound feld tests Sound feld thresholds were tested using warble tones from a loudspeaker 1 m in front of the subject at 0.25, 0.5, 1, 2, 4, and 6 kHz under unaided and aided conditions (in both the old and new APs). Word recognition score in quiet (WRS) was measured using the Polish Monosyllabic Word Test at 65 dB SPL from the front under unaided and aided conditions (in the old and new AP). The speech perception threshold in noise, at which the subject can correctly repeat 50% of the words in a presented sentence (SRT_{50}) , was measured with the Polish Matrix Sentence Test under two conditions: with signal and noise presented from the front (S0-N0); and with signal presented from the front and noise from the back (S0-N180). The noise level was fxed at 65 dB SPL, and the speech presentation level was adapted according to the measuring protocol; measurements were conducted under the aided condition (in old and new AP).

Patient-Reported Outcome Measures (PROMs) Subjective beneft was determined using the Speech, Spatial, and Qualities of Hearing Scale Questionnaire (SSQ12), and the Audio Processor Satisfaction Questionnaire (APSQ) for both aided conditions (Samba 2 and the previous generation AP). The Speech, Spatial, and Qualities of Hearing Scale Questionnaire (SSQ12) consists of 12 items divided into 3 dimensions (speech hearing, spatial hearing, and qualities) and uses a scale from 0 to 10 [[19](#page-8-12)]. Higher scores indicate less disability. The APSQ consists of 15 items divided into 3 dimensions (comfort, social life, and usability) and is scored between 0 and 10 [\[20](#page-8-13)].

Higher scores indicate more satisfaction with the AP. The questionnaires were completed twice before the upgrade and after 5–10 weeks of new AP use, either electronically or in hard copy sent by post.

Table 1 Demographic and audiometric details

F female, *M* male, *R* right, *L* left, *AC* air conduction, *BC* bone conduction, *PTA4* pure tone average for 0.5, 1, 2, 4 kHz, *CHL* conductive hearing loss, *MHL* mixed hearing loss, *SNHL* sensorineural hearing loss

Statistical analyses

A Student's *t* test was used to make pair-wise comparisons of patients' outcomes between the old AP and the new AP in terms of sound feld thresholds, speech outcomes (word recognition scores in quiet and speech discrimination in noise), and PROMs. The hypothesis of normal distribution of the data was evaluated using a Shapiro–Wilk test. The relationships between speech outcomes and PROM results were analyzed by means of Pearson correlations. The level of significance was set at α = 0.05.

The study was approved by the Institutional Review Board of the Institute of Physiology and Pathology of Hearing (KB.IFPS: 3/2022) and was conducted in accordance with the Helsinki Declaration.

Results

Pure‑tone audiometry

The unaided mean AC PTA4 in the implanted ear (average air conduction thresholds for 0.5, 1, 2, and 4 kHz) was 69.3 dB ($SD = 14.7$). The BC PTA4 (bone conduction for the same frequencies) was 38.1 dB (SD = 17.8). Audiometric details for individual patients are shown in Table [1.](#page-2-0)

Sound feld tests

Sound feld thresholds improved considerably with both devices over unaided conditions. The mean unaided free-field PTA4 was 69.9 dB (SD = 12.6), whereas with Samba 2 it was 38.1 dB (SD = 7.4) and with the old AP it was 42.1 dB ($SD = 11.6$). The 4 dB improvement with the new AP compared to the old was significant $(t(21)=2.47;$ $p = 0.022$).

The mean word recognition score in the unaided condition was 13.2% (SD = 25.4). The mean aided word recognition scores in quiet for old AP was 61.8% (SD = 33.4) whereas for new AP was 75.0% (SD=24.3) (Fig. [1](#page-3-0)a). The diference of 13.2 percentage points in favor of the new AP was significant $(t(21) = 3.92; p = 0.0008)$. A similar signifcant improvement of speech discrimination in noise was observed; mean results of the Polish Matrix Sentence Test using diferent loudspeaker confgurations (S0-N0 and S0-N180) for the old and new AP are shown in Fig. [1](#page-3-0)b. In the S0-N0 confguration, SRT improved by 1.98 dB SNR $(SD = 2.89; t(21) = 3.21; p = 0.004)$ when the new AP was compared to the old. In the S0-N180 confguration, the advantage of the new AP over the previous one was 3.52 dB SNR (SD=3.83; *t*(21)=4.30; *p*=0.0003).

Patient‑Reported Outcome Measures

Evaluation with the SSQ questionnaire revealed that the post-upgrade Total score increased by 1.47 points over the pre-upgrade outcomes and this diference was signifcant. Similarly, signifcant increases were observed for Speech hearing (1.47), Spatial hearing (1.23), and Qualities of hearing (1.66). The mean results for the SSQ questionnaire and the results of pairwise comparisons are provided in Table [3.](#page-4-0)

Fig. 1 a Mean word recognition scores (WRS) in quiet in old and new AP; the bars are mean scores; the error bars represent standard deviation, **p*<*0.05*. **b** Results of the Polish Matrix Sentence Test, Speech Recognition Thresholds (SRT) in old and new AP for difer-

ent loudspeaker confgurations, *S* signal, *N* noise, *0, 180* angles of incidence of sound; the bars are mean scores; the error bars represent standard deviation, **p*<0.05

SD standard deviation

For the APSQ questionnaire, the mean post-upgrade score, compared to pre-upgrade, increased by 0.41 points for Total score, 0.02 for Comfort, 0.53 for Social life, and 0.63 for Usability. The increase in the Usability dimension was found signifcant. Mean pre- and post-upgrade APSQ results and pairwise comparisons are presented in Table [3.](#page-4-0)

PROMs and outcomes relationships

The investigation of relationships between speech outcomes and PROM results revealed a negative correlation between speech discrimination in noise in the S0-N0 condition and the Speech hearing dimension of the SSQ questionnaire (*r*=−0.48, *p*=0.03). A similar relation (*r*=−0.38), although not signifcant, was observed for speech discrimination in noise in the S0-N180 condition and the Speech hearing dimension. However, there was no correlation between speech discrimination in quiet and this dimension of SSQ (Fig. [2](#page-4-1)). In addition, we did not fnd any correlations between speech outcomes and SSQ or APSQ total score, or any other dimensions of those questionnaires.

Fig. 2 Correlation between Speech Hearing Score (SSQ) and results of speech tests with a new AP: **a** in noise S0-N0; **b** in noise S0-N180; **c** in quiet

Study		Subject Audio processors	Speech in quiet	Speech in noise	Free-field thresholds	PROMs
Mühlmeier et al. [17]	$N = 14$ adults	Amadé \rightarrow Samba	WRS65 WRS Amadé = 65% WRS Samba $=63.6\%$ - Difference not significant	1. OLSA S0 N180 SRT Amadé = 5.9 dB SNR SRT Samba = 2.3 dB SNR - Significant differ- ence 2. OLSA S180 N0 SRT Amadé=2.9 dB SNR SRT Samba = 1.1 dB SNR - Significant differ- ence	Mean aided Amadé FF thresh- olds = 41.3 dB Mean aided Samba FF thresh- olds = 40.4 dB - Difference not significant	APHAB - Difference not significant HDSS - Difference not significant
Zimmermann et al. $[19]$	$N = 20$ adults	Amadé \rightarrow Samba	WRS65 WRS Amadé = 76% WRS Samba = 59% - Significant differ- ence	1. OLSA S0 Ncon- tra Samba vs Amadé - Omni: significant advantage of 3.8 dB SNR for Samba - Directional: differ- ence not significant 2. OLSA S0 NVSB Samba vs Amadé - Omni: significant advantage of 2.5 dB SNR for Samba - Directional: 1.1 dB SNR better with Samba, not signifi- cant	Mean aided Amadé FF thresh- $olds = 38 dB$ Mean aided Samba FF thresh- $olds = 38 dB$ - Difference not significant	APHAB $-$ Significant difference in Background Noise subscale SSQ-C - Significant differ- ence
Rahne et al. [12]	$N = 15$ adults	$Samba \rightarrow Samba 2$	WRS65 WRS Samba $=66\%$ WRS Samba $2 = 74\%$ - Significant differ- ence	1. OLSA Olnoise (S0, N120, 180, 240) SRT $Samba = -5.4 dB$ SNR SRT Samba $2 = -7.7$ dB SNR - Significant differ- ence 2. OLSA ISTS (S0, N120, ISTS180, N240 SRT $Samba = -4.8 dB$ SNR SRT Samba $2 = -7.1$ dB SNR - Significant differ- ence	Mean aided Samba FF thresh- $olds = 36.9 dB$ Mean aided Samba 2 FF thresh- $olds = 36.7 dB$ - Difference not significant	APSQ Social life, Usability and Total Score $-$ Significant differ- ence SSQ - Significant differ- ence

Table 4 Recent studies that included assessment of the new technology in the Vibrant Soundbridge

Discussion

To the authors' knowledge, there are few studies on upgrading the VSB audio processor. Older works compare the benefts of the 3-channel processor to the 8-channel, showing an auditory beneft [\[21](#page-8-14), [22](#page-8-15)]. In the study of Todt et al. in 2005, the D-type audio processor was replaced by a Signia-type processor in three patients [[22\]](#page-8-15). Due to the small number and markedly older technology of processors, the results are not comparable with those obtained here.

Table [4](#page-5-0) gives an overview of recent studies. These studies cover speech discrimination in quiet and in noise, free-feld thresholds, and PROMs. In all three studies there were no statistically signifcant diferences between the old and the newer APs in terms of hearing thresholds in free-feld. By way of contrast, in the study here there were statistically signifcant diferences in mean hearing thresholds: in the old processor the mean PTA4 value was 42 dB HL, whereas in the new it was 38 dB HL.

In terms of speech discrimination in quiet, only Rahne et al. showed a statistically signifcant diference in WRS in favor of the new processor, with an improvement from 66 to 74% when the Samba processor was changed to the Samba 2. These WRS scores are in line with the results of our study, where the WRS in the old processor (D404 or Amadé) was 61% compared to 75% with the new Samba 2.

The results of speech-in-noise discrimination from previous studies are more difficult to compare with our results. The reasons are methodological. Although all authors used adaptive tests, diferences in loudspeaker confguration, sound direction, word material, processor settings, and other details were employed. In the work of Mühlmeier et al., the measurement conditions largely corresponded to those used in our study, although a constant noise of 70 dB SPL was used instead of the 65 dB SPL used in our work [\[23\]](#page-8-16). The SRT obtained for the S0-N180 condition was 5.9 dB SNR for the Amadé and 2.3 dB SNR for the Samba processor, a difference which was statistically significant $[14]$ $[14]$). For similar measurement conditions in our work, the SRT was 7.0 and 3.5 dB SNR for the old and new processors, respectively. In the case of replacing the processors with the latest Samba 2, Rahne et al. observed a statistically signifcant improvement in speech-in-noise discrimination after the use of a newer processor for multiple confgurations of speech and noise sources. However, the types of stimuli and noise, as well as the spatial confgurations of the loudspeakers, were diferent from what we used here. Nevertheless, the conditions used (S0-N120, N180, N240) are roughly similar to the one (S0-N180) used in our paper (since in both studies speech was presented from the front and noise from the back). Thus, we can broadly compare the improvement of 2.3 dB identifed by Rahne et al. for S0-N120, N180, and N240 to the 3.5 dB improvement for the S0-N180 condition in our study. The slightly larger improvement reported by us could stem from the extra noise sources used by Rahne et al. (N120, N240) which could reduce the beneft from the directional microphone in the new processors.

Because speech and noise signals were spatially separated in our work, the diferences in speech reception threshold in noise between the old and new processors may be due to a markedly diference in the way the microphones in the older and newer processors operate. The previous generation processors used an omnidirectional mode microphone,

whereas the Samba 2 processor uses an advanced directional microphone system that is automatically adaptive.

In our study, a statistically signifcant diference was observed for the S0-N0 condition. A better result was obtained for the newer processor (Samba 2), with an SRT of 5.0 dB SNR compared to the 7.0 dB SNR for the older ones. The diference in SRT between APs was smaller when signal and noise were spatially separated.

There are certain difficulties in determining the most appropriate measurement setup for assessing modern technologies—for example, directional microphones, speech tracking, acoustic scene analysis, and others. The results of tests for hearing sensitivity and speech discrimination obtained in a clinical setup may not correspond with patients' needs and expectations in everyday life. This is the reason questionnaire tools (PROMs) were also used.

There are two other reasons for using PROMs. First, it is not easy to test new front-end processing features. During a single test session, simulating multiple environments is difficult, and so the user's self-report (the PROM) becomes an important measure of how well this new technology works under diferent common situations. Second, there are many real-life situations—such as activity limitations and participation restrictions—which cannot be gauged by a speech discrimination test. These problems are unique and depend on personal circumstances, family situation, life-style, and so on, making PROMs necessary to quantify performance [[24–](#page-8-17)[26\]](#page-8-18).

In the current study, the PROM results pointed to an appreciable subjective improvement when the speech processor was upgraded to the new technology. According to SSQ, patients reported less hearing disability and more satisfaction with the new AP, particularly in terms of its usability (APSQ).

Patients indicated that, compared to the legacy processor, the Samba 2 gave better spatial hearing, speech hearing, and better other qualities of hearing. Spatial hearing involves judgements of direction, distance, and movement. Speech hearing relates to diverse situations: noisy background conditions, reverberation, multiple voices, and the ability to ignore one voice while attending to another, following a conversation that switches quickly from one person to another, or following two speakers simultaneously. Other qualities of hearing refer to signal segregation, identifcation/recognition, clarity, naturalness, and ease of listening [[27\]](#page-8-19). Improvements in spatial hearing and in speech hearing due to the upgrade is especially encouraging, as it indicates clear advantages of the new technologies, particularly automatic scene analysis when listening in difficult acoustic conditions.

In two previous studies in which the processor was replaced with a newer one, the SSQ questionnaire was used, after which a statistically signifcant improvement

was noticed on all three dimensions: speech hearing, spatial hearing, and qualities of hearing [\[18](#page-8-11), [28\]](#page-8-20).

In the work of Zimmermann et al., the improvements with the new processor in the speech hearing dimension were on average 1.1 points, in the work of Rahne et al. they were 2.0 points, and in our study 1.5. In the spatial hearing dimension, the improvements were 0.8 points in Zimmermann's work, 1.7 in Rahne's, and 1.2 in ours. In the qualities of hearing dimension, the improvement reported by Zimmermann was 1.7 points, by Rahne et al. 1.5, and in our study 1.7. The average SSQ total score calculated in Rahne et al.'s work was 5.2 in the old processor and 7.0 in the new, while in our work it was 4.8 in the old and 6.3 in the new. In general, the diferences between SSQ scores obtained with the old and new processors were statistically signifcant, both for the total score and for the individual dimensions, and consistent with the ones reported in the literature.

In the APSQ, the results obtained for both the new and old AP for each of the three dimensions exceeded 8 points. A statistically signifcant diference between the results for the new and old processors was obtained only for the usability dimension (9.4 for the new vs. 8.8 for the old). This dimension consists of questions about the ease of placing the AP properly on the head, ease of changing the battery, ease of switching on and off, proper functioning of the AP, and ease of care. For the APSQ total score, the diference was not statistically signifcant. In the work of Rahne et al., the mean total score was 8.2 for the older and 9.0 points for newer processors. They observed statistically signifcant improvements in total score, social life, and usability. In the usability dimension, the diference between the older and newer processor was 0.8 points, compared to 0.6 in our study.

As already stated, in the patient-centered care model, it is important not only for clinicians to obtain objective, measurable benefts under experimental conditions, but also that patients themselves report benefts in everyday functioning. The rationale is that numerous publications have shown that audiological measures generally correlate poorly with PROMs [\[29](#page-9-0)[–32](#page-9-1)]. Dornhofer et al., in a group of 95 hearing aid users, correlated aided audiological measures (PTA, Nu-6, SPIN) with aided APHAB subscales and global score; they saw no signifcant relationship. Absent or low correlations between patient self-reported scores and speech recognition have also been reported among cochlear implant users [\[33](#page-9-2)[–35](#page-9-3)]. Mertens et al. reported that self-assessment tools, like SSQ, ofer insights into dynamic hearing capacities that cannot be easily measured in the laboratory and provide useful information about the hearing status of CI users [\[33](#page-9-2)]. The results obtained in this study are consistent with the conclusions from other work, confrming the lack of correlation (or weak correlation) between the results of speech discrimination in quiet and noise and the results of PROMs. When testing the relationship between speech hearing dimension in the SSQ and the result of speech tests with the new AP, a signifcant negative correlation was obtained for S0-N0; a smaller (also negative) but not signifcant correlation for S0-N180, and no correlation for WRS obtained in quiet. A similar relationship was noted by Remakers et al., who found, using SSQ, a signifcant (but weak to moderate) negative correlation between the subjective test results of the speech hearing dimension and the related objective speech perception in noise test [[35](#page-9-3)]. In the recently published 'Consensus Statement on Bone Conduction Devices and Active Middle Ear Implants in Conductive and Mixed Hearing Loss', the authors address an important issue, noting that companies introducing new processors should enable patients with older implants to reap the benefts of new features and signal processing developments [\[36](#page-9-4)]. We see the opportunity here for long-term users of implantable devices: they do not need surgical intervention to gain access to modern technologies (ignoring, of course, issues relating to cost and insurance). Upgrades offer a way of reducing the impact of hearing impairment in everyday life and offering better functional performance.

Conclusion

By replacing the processor, modern technology can bring measurable benefts, particularly in terms of speech discrimination. PROMs confrm the obtained benefts: a reduced impact of hearing impairment on everyday functioning. Patients also notice the practical, functional benefts of the newer solutions. This study has shown that the use of the latest solutions—adaptive microphone directionality, speech tracking, and environmental sound classifcation—can provide signifcant benefts to patients.

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Declarations

Conflict of interest The authors declare no conficts of interest in conducting this study.

Ethical statement The study was approved by Bioethics Committee of the Institute of Physiology and Pathology of Hearing (No.IFPS. KB:3/2022).

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