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ORIGINAL ARTICLE

The"symbiotic"regulation approach in bimodal hearing adults

Marco Carner[1] · **Luca Bianconi**[1] · **Luca Sacchetto**[1] · **Valerio Arietti**[1] · **Riccardo Nocini**[1] · **Maria Sofia Salvetta**[1] · **Giuditta Maulu**[1] · **Alessandro Diodati**[1] · **Luca Turchet**[2]

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Abstract

Purpose Patients with bimodal auditory stimulation represent an expanding group of cochlear implant users in many countries. The hearing results reported in the literature for subjects with bimodal hearing are controversial and often only evaluate hearing aids that are simply synchronized with their cochlear implant ("synchronized" regulation) and sometimes even adapted independently of the cochlear implant ("classic" regulation). This study aims to verify that the innovative "symbiotic" regulation of the cochlear implant with an integrated hearing aid and dedicated fitting formula allows to achieve adequate rehabilitative hearing levels.

Material and methods Thirty adult patients (12 females and 18 males; age range: 18–69 years) with bimodal hearing have been enrolled in a one-year study and divided into three groups of ten subjects for each of the regulation modes ("classic", "synchronized" and "symbiotic") applied to fit the cochlear implant and the hearing aid. Statistical analysis of the demographic characteristics and hearing outcomes observed in the three groups was conducted using the R statistical software.

Results For all subjects, the use of the "symbiotic" regulation approach with a dedicated bimodal regulation formula and integrated hearing aid allowed significantly better hearing performances ($p < 0.05$) compared to those obtained to either the "classic" or the "synchronized" regulations.

Conclusion The "symbiotic" bimodal fitting formula provides significant hearing benefits compared to "classic" and "synchronized" regulation and it proves to be the ideal adjustment and coupling modality between a cochlear implant and a contralateral integrated hearing aid in bimodal listeners.

Keywords Cochlear implant · Hearing aid · Bimodal hearing · Symbiotic regulation

Introduction

Subjects with bimodal auditory stimulation, with electrically aided hearing in one ear and acoustically aided hearing in the opposite ear, represent an expanding group of cochlear implant (CI) users in many countries, due to the well-known bimodal hearing potential benefits [1].

However, depending on the modalities used to regulate the CI and the contralateral hearing aid (HA), the hearing results reported in the literature for subjects with bimodal hearing are controversial [2–5] often revealing inadequate or worsening performance, compared to the previous hearing experiences (e.g., bilateral HAs). In most cases, standard HAs are not specifically designated to work together with a CI [6]. Moreover, CI and HA programming in the same bimodal listener is often completed by two different clinicians and is frequently performed in different centers, where each clinician has no knowledge of the other device settings [7–10].

The HA and CI in the same patient are today managed according to one of three different types of regulation: "classic", "synchronized" and "symbiotic".

In the "classic" regulation, CI sound processors and HAs are fitted independently by the audiologist in the Center for the CI and by the personal HA specialist, generally close to home, for the contralateral HA without alignment between the two devices [10].

In the "synchronized" regulation, to improve the sound localization, CI sound processor stimulation latency is

✉ Maria Sofia Salvetta
msofia.salvetta@gmail.com

1 ENT Department, Integrated University Hospital of Verona, P.Le L.A. Scuro, 10, 37100 Verona, Italy

2 Information Engineering and Computer Science, University of Trento, Trento, Italy

delayed by the CI specialist according to the delay of the individually worn HA, separately regulated by the HA specialist [5, 11], or the CI specialist reallocates the CI frequencies along the cochlea, without aligning the implant with the HA [12].

In the more recent "symbiotic" regulation the CI and the (new, integrated) HA are designed specifically to work together [13]. The dedicated HA is programmed using an innovative digital bimodal fitting formula, the Adaptive Phonak Digital Bimodal (APBD), different from the traditional Desired Sensation Level (DSL) and National Acoustics Laboratory (NAL) formulas used to regulate the HAs in the "classic" and "synchronized" bimodal hearing [4] The CI audiologist directly manages also the HA regulation.

At the best of our knowledge, to date, the hearing results obtained with the three methods of bimodal regulation have not yet compared and, in particular, it is unknown whether the innovative "symbiotic" regulation outperforms the classic and synchronized ones.

This study aims to verify that the "symbiotic"bimodal regulation of the CI and the integrated HA, using the dedicated fitting formula and/or other features (e.g., the coordinate beamforming across the two devices [4]), allows to achieve adequate rehabilitative hearing levels in bimodal listeners.

Methods

Subjects

Thirty post-lingually deafened adults (12 females and 18 males; age range: 18–69 years), with at least 15 years (15–26 years) of bilateral conventional HAs experience for profound hearing loss were included in this study. All subjects had discontinued use of their HA in one side from 10 to 16 months before undergoing CI surgery.

Before CIs surgery, the subjects were randomly divided into 3 groups and ten patients were assigned to each of the bimodal regulation hearing systems, labeled as "classic", "synchronized" and "symbiotic".

In "classic" and "synchronized" groups the latest "Cochlear" and "MED-EL" CI models were used indifferently and HAs were fitted with traditional formulas (NAL, DSL). In the "symbiotic" group "Advanced Bionics Marvel" CIs were used and at CI activation, the HA previously worn by the patient was upgraded to the integrated HA (Phonak Naida Link M) and fitted with the APDB formula.

All subjects wore both devices continuously for the whole day (per patient self-report) and were followed for one year after CI activation, with tests performed at 1 month, 3 to 6 months and 1 year. Follow-up was limited to one year based on literature reporting that after this interval of time most of CI users reach an adequate and stable aided hearing level [14–16].

The socioeconomic status (SES) of each subject was determined by Italian measures of educational and/or occupational level [17]. All participants passed the Italian version of the "Mini-Mental State Examination" (MMSE), used to evaluate their cognitive condition [18].

The main demographics, hearing characteristics and screening task performance details of the subjects are summarized in Table 1.

Table 2 reports the cause of deafness for all subjects.

The study was approved by the Research Ethics Committee of Verona University Hospital and conformed to the standards set in the latest version of the Declaration of Helsinki (except for registration in a database). Verbal and written informed consent were obtained from all subjects, prior to participation.

Table 1 Demographic hallmarks, hearing characteristics, screening task performance of the three groups with statistical analysis comparison. (CI = Cochlear Implant; HA = Hearing Aid; SD = Standard Deviation; MMSE = Mini-Mental State examination; SES = Socioeconomic status)

Characteristics	Classic group	Synchronized group	Symbiotic group	p value
SEX	5 female 5 male	3 female 7 male	6 female 4 male	
AGE (years)	20–67	18–65	21–69	0.9874
Unaided hearing threshold (CI side). Mean in dBHL (SD)	99.1 (6.22)	98.8 (6.49)	98.4 (5.92)	0.3356
Unaided hearing threshold (HA side). Mean in dBHL (SD)	59.08 (6.64)	59.52 (7.16)	60.13 (7.02)	0.9243
Bilateral HA time, before dismissing one HA (range in years)	15–22	13–20	15–20	0.7909
Dismissed HA time before CI (range in months)	10–15	11–15	11–15	0.7568
MMSE score. Mean (SD)	59.5 (2.9)	59.1(3.5)	59.3 (3)	0.9872
SES score. Mean (SD)	37.6 (2)	37.5 (2.5)	37.7 (2)	0.9052

Table 2 Cause of deafness observed in all subjects of the three groups

Cause of hearing loss	Classic group	Synchronized group	Symbiotic group
Genetic	1	0	0
Age-related/progressive	2	1	2
Viral infections	1	2	2
Trauma	1	0	0
Otosclerosis	1	0	0
Otitis media	1	2	1
Syndromic	0	1	1
Meniere's	1	2	1
Unknown	2	2	3

Test material

Phonetically balanced lists of 20 bisyllabic Italian words in quiet and in competing noise (babble noise) were used to test speech intelligibility. In the quiet condition, speech was presented at 65 dB SPL. In the noise condition, with speech presented at 65 dB SPL, babble noise (5 male and 5 female talkers) was presented at 65 dB SPL resulting in a signal-to-noise ratio (SNR) of 0 dB, or at 70 dB SPL, resulting in a SNR of—5 dB.

Statistical analysis

Statistical analysis was performed using the R (4.4.1 version) statistical software. The Kruskal–Wallis test was used to assess differences among the three groups across the main demographic characteristics and as well as the observed screening task performances. An ANOVA was performed on generalized linear mixed-effects models for the comparison of the hearing results obtained in the bimodal listeners of the three groups of regulation, for each of the three dimensions (Quiet, SNR 0 dB, SNR −5 dB). Each model had the rating of the three conditions ("classic", "synchronized" and "symbiotic" regulation) as fixed factors, and the subject as a random factor. For each model, the assumption on the normality of residuals was verified. Post-hoc tests were performed on the fitted model using pairwise comparisons adjusted with the Tukey correction. It has been considered as statistically significant a value of $p < 0.05$.

Results

The three subject groups did not differ significantly ($p > 0.05$) regarding age, duration of deafness, unaided hearing threshold in each ear (CI and HA side), bilateral HA period of use, before abandoning one, HA dismission time before CI surgery, SES and MMSE outcomes (see Table 1).

After one year of bimodal hearing, in both the "classic" and the "synchronized" groups, nine out ten of subjects had discontinued using their HAs. In the two groups, ten patients perceived no additional benefit from the HA use and eight subjects reported interference between the CI and the contralateral HA with degraded acoustic signal in bimodal listening. In these two groups, eighteen subjects reported remarkable superior sound quality when they wore only the CI and eleven CI users affirmed that also the additional HA costs and hassles influenced the decision to dismiss their HA (unfavorable cost/benefit balance).

In the "symbiotic" group all the subjects retained their HAs, with significantly ($p < 0.05$) better bimodal hearing performances compared to those obtained with the "classic" or "synchronized" regulation (see next paragraph). Three out ten subjects in this group, already at the activation, were able to use the telephone with improved ease of speech understanding even in noisy environment.

An example of speech perception performances, obtained in the same subject in quite condition, with "classic" conventional (NAL-NL1) regulation and with "symbiotic" (APDB) regulation, is reported in Fig. 1. The subject, with "symbiotic" regulation, reaches a speech intelligibility score of 100% at 50 dBHL with a normal morphological vocal curve, without any trial or adaptation period, already at the CI activation.

Statistical analysis of speech perception outcomes

In Fig. 2 the mean speech intelligibility scores in percentage correct for quiet, noise (SNR 0 dB, SNR −5 dB) dimensions. Regarding dimension quiet, a significant main effect was found ($F(2,18) = 448.18$, $p < 0.001$). A post-hoc test showed that regulation "symbiotic" was rated significantly higher than conditions "classic" and "synchronized" (both $p < 0.001$). Concerning dimension SNR 0 dB, a significant main effect was found ($F(2,18) = 126.55$, $p < 0.001$). A post-hoc test showed that group "symbiotic" was rated significantly higher than groups "classic" and "synchronized" (both $p < 0.001$), as well as that condition "synchronized" was rated significantly higher than condition "classic" ($p < 0.001$). Dimension SNR −5 dB

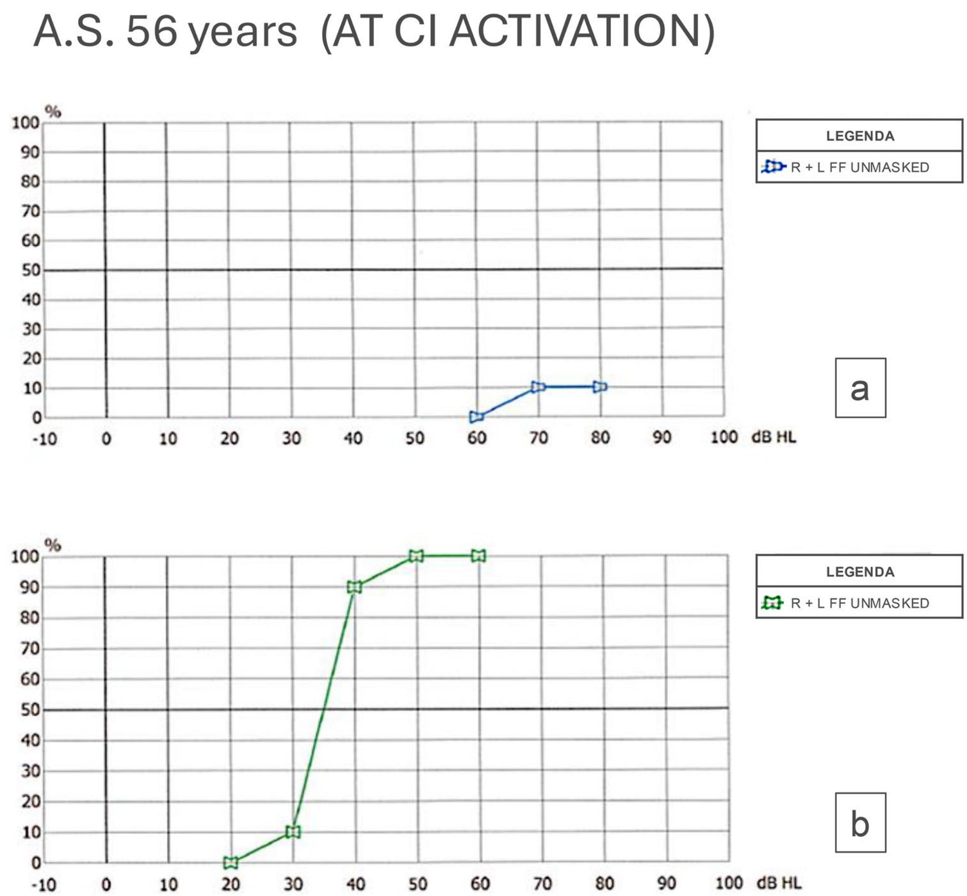


Fig. 1 Speech understanding performances at CI activation in the same subject with classic (**a**) and symbiotic (**b**) bimodal regulation

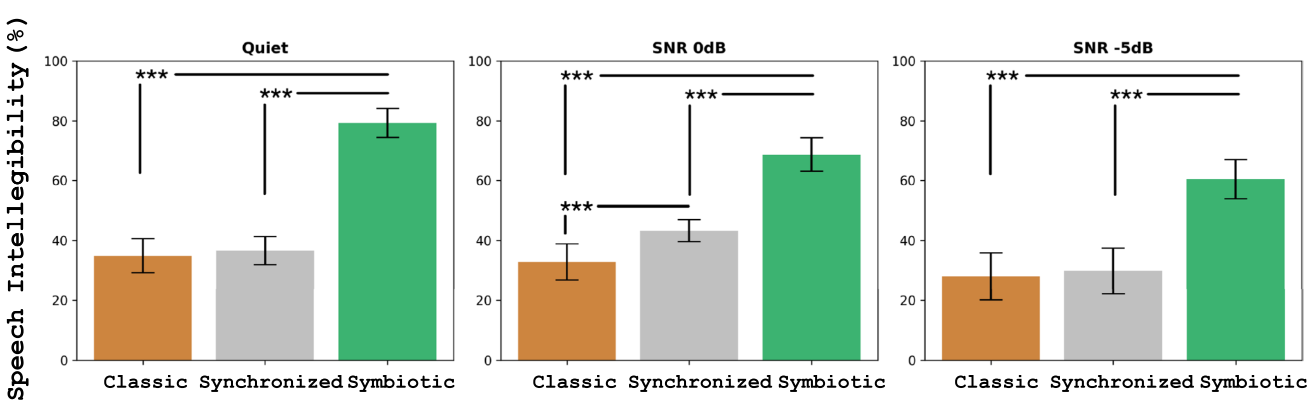


Fig. 2 Speech intelligibility scores (% correct) for quiet, noise (SNR 0, − 5 dB) conditions and different bimodal regulations. Asterisks indicate statistical significance, boxes mean values, bars standard error. (CI = Cochlear Implant; HA = Hearing Aid)

showed a significant main effect ($F(2,18) = 136.42$, $p < 0.001$). A post-hoc test showed that group "symbiotic" was rated significantly higher than conditions "classic" and "synchronized" (both $p < 0.001$).

In Fig. 3 the mean speech intelligibility scores in percentage correct obtained in quiet with only CIs worn are presented for the different groups of regulation ("classic", "synchronized" and "symbiotic"): no significant main effect was found.

Mean speech intelligibility scores in percentage correct for the different groups of regulation ("classic", "synchronized" and "symbiotic") in quiet, with only CIs worn or with CI and HA used bimodally, are showed in Fig. 4. Concerning the interaction between CI and HA in quite vs only CI in

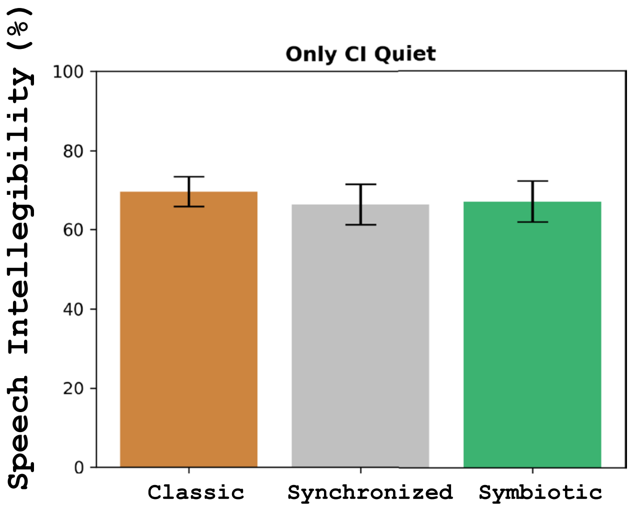


Fig. 3 Speech intelligibility scores (% correct) in quiet with only CIs for different bimodal regulations: no statistical significance was observed. Boxes indicate mean values, bars standard error. (CI = Cochlear Implant; HA = Hearing Aid)

quiet, a significant main effect was found ($F(2,45) = 145.57$, $p < 0.001$). A post-hoc test showed that CI and HA in quiet was rated significantly lower than only CI in quiet for group "classic" and "syncronized" (both $p < 0.001$), and that CI and HA in quiet was rated significantly higher than only CI in quiet for group "symbiotic" ($p < 0.001$).

Discussion

The use of multiple varying methodologies, inconsistent or independent employment of HA fitting approaches in bimodal hearing regulation with a wide range of fitting formulae (DSL, NAL-NL1, NAL-NL2), a lot of different manufacturer recommendations for bimodal programming devices and rarely real-ear HA verification measures used, might explain why, until today, only from 32 to 64% of adult CI patients wear a contralateral HA in addition to their CI, despite the known benefits of the bimodal hearing [4, 7, 10, 19, 26, 29, 30].

These considerations motivated the present study and to the best of our knowledge, this is the first work in literature that compares the three different devices regulations, i.e., "classic", "synchronized" and "symbiotic" approaches, used today in bimodal listeners.

This study has been performed in homogeneous bimodal hearing population (no statistically significant difference in the three groups, as detailed in Table 1) to overcome the bias reported in literature, where typically the same subject is tested with different regulation approaches and different HAs and, therefore, he is not blind to the type of regulation and HAs utilized [4, 10, 19, 20].

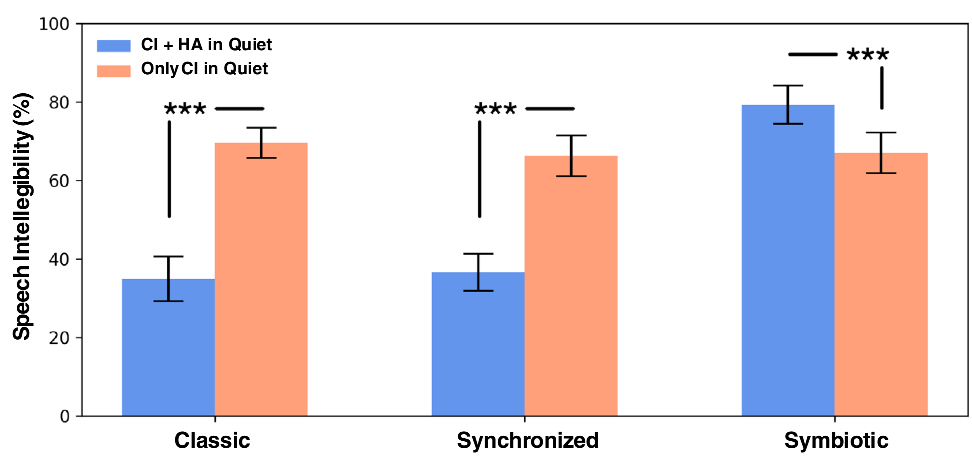
An important advantage of this study is that the outcome measures are related to a long-term follow-up (one year), going well beyond the limitations of short term (weeks or some months) results [9, 21]. A further element of novelty is that the three different bimodal regulations have been performed in to date real-world bimodal common listening scenarios, overcoming the limitations of the clinical laboratory studies [4, 10, 22–24].

Results from multiple international surveys indicate that most CI audiologists, to exploit the bimodal hearing benefits, advise CI recipients to wear a contralateral HA if indicated, and recommend to use CI manufacturer's partner HA when available [10, 25].

However, to date only two CI manufacturers (Cochlear Ltd. and Advanced Bionics LLC) have partnered with HA companies (Resound Ltd. and Phonak LLC, respectively) to optimize bimodal benefits [4].

Resound's bimodal fitting formula provides additional gain in the low frequencies in the case of severe hearing losses, but does not address the mismatch in loudness growth and automatic gain control (AGC) between the CI and HA [4].

Fig. 4 Speech intelligibility scores (% correct) for different regulation groups in quiet, with only CIs vs. CI + HA conditions. Asterisks indicate statistical significance, boxes mean values, bars standard error (CI = Cochlear Implant; HA = Hearing Aid)



The APDB formula developed by Advanced Bionics manufacter [26–28] permits a perfect alignment in frequency, loudness and dynamic compression behavior (AGC) of the HA to the CI sound processor, considered the primary contribute to speech understanding, and the shared software platform between HA and CI can wirelessly communicate with each other to allow for additional features [4].

Furthermore, only a few CI audiologists are also specialized in HA regulation and handle bimodal fittings of both devices. More commonly, in the "classic" and "synchronized" approaches, the HA is programmed by a different audiologist in the clinic or is referred to an outside specialist (e.g., hearing aid acoustician), that have no knowledge of the other device's setting [8] and with the two devices not aligned to each other for bandwidth frequencies, loudness growth, dynamic behavior, etc. [4].

Therefore, it is not surprising that in this study, in both the "classic" and the "synchronized" groups, nine out ten subjects dismissed their HAs, despite a hearing level (see Table 1) successfully (on the basis of the literature data [3, 30] and self-reported patient's opinion) fitted with a HA, before the contralateral CI application. Considering that the CIs alone provide similar (no statistically significant differences) hearing levels in all three groups (see Fig. 3), it is evident that the dismission of HAs in "classic" and "synchronized" groups is due to the lack of alignment between the two devices with negative acoustic interferences, degraded acoustic signal and reduced sound quality.

On the contrary, in the "symbiotic" group all the subjects retained their HAs, confirming the utility of an integrated HA and CI bimodal system. For all conditions (quiet, SNR 0 dB and SNR −5 dB) subjects of the "symbiotic" group achieved significantly better outcomes than the patients included in the "classic" and "synchronized" groups (see Fig. 2 and 4).

Bimodal hearing is one of the most complex audiological challenges and the linking of HA and CI is only one of the steps in avoiding HA dismission, in newly implanted CI users, consequently avoiding the loss of the advantages of bimodal hearing. This study demonstrates that "symbiotic" regulation can optimize bimodal hearing outcomes and subjective benefit, so that the patient does not dismiss the HA.

To maximize the benefit for bimodal users, specific guidelines (APBD algorithm formula) must be established for a CI integrated with a partner HA, used together for an adequate time lapse and with both devices regulated by the same specialized audiologist.

While CI directly stimulates the acoustic nerve through the electrodes inserted in the cochlea (electrical stimulation), the HA is subject to the natural transduction of sound (mechanical stimulation) into neural impulses and this generates a delay at the cortical level of the information which affects both the subject's audiological performance and on the directionality of sound [5]. To the neural delay, the delays introduced by the processing times of the two systems (HA and CI) must be added.

It is known that the performance of bimodal hearing strategy is independent of the severity of the contralateral CI hearing loss [10, 19] but is greatly affected by the different types of stimulation of the two ears [9, 10, 20].

In literature is reported that in absence of such a correlation HA should be always considered and bimodal hearing trained with severe to profound hearing loss [8, 30].

Currently, the different types of bimodal regulation considered in this study try to optimize the sound processing system in different ways.

"Classic" regulation does not attempt in any way to align the neural signal of the HA and the CI, the acoustic systems are treated individually as two separate entities.

The "synchronized" system, by introducing a delay in the electrical stimulation, depending on the type of contralateral HA device, attempts to align the processing delays of the individual devices (CI and HA). With both devices acting independently and the processing times of the HA depending on the frequency of the input signal, it is not possible to have a complete frequency alignment.

The "symbiotic" system, using matched sound processing strategies on the CI and HA sides has demonstrated to be the only regulation approach that allows to have exactly the same processing times on both sides regardless of the sound signal frequency, with perfect frequency alignment. Using the same AGC in both devices also achieves a similar loudness increase.

The results presented in this study show that the "symbiotic" regulation approach performs better both in quiet and in a competitive environment compared to the "classic" and "synchronized" regulation approaches, indicating therefore that the perfect alignment of the input sound signal between the CI and integrated HA with bandwidth optimization (bandwidth as wide as possible [31], frequencies between 250 and 750 audible [32] and amplification not extended into dead regions [33]) allows to improve the acoustic bimodal performances.

A second CI in "motivated" bimodal users should always consider the loss of residual acoustic hearing [30, 34] and consequently the advantages provided with a HA, of course when correctly aligned with the contralateral CI [30].

However, it should also be underlined that at the present, no regulation approach to bimodal hearing takes into account neural delays and, therefore, to further improve the bimodal system in addition to the alignment of the input system, it would be necessary to perfectly coordinate the output, at the neural level, of the individual systems.

Last but not least, it is important to implement a favorable purchase reimbursement policy, as it is in our experience, to sustain the HAs upgrade.

Conclusion

Our results suggest that the audiologists, expert in bionic hearing rehabilitation, should have the competences to regulate and to align both devices (HA and CI) in bimodal users. The “symbiotic"bimodal formula, in our hands, has provided significant hearing benefits and it has been confirmed as the ideal adjustment and coupling modality between the CI and the contralateral integrated HA.

Author Contributions Marco Carner: conceptualization, design, data collection, data analysis, writing; Luca Bianconi: data collection; Valerio Arietti: data collection; Luca Sacchetto: data collection; Riccardo Nocini: writing revision; Maria Sofia Salvetta: data collection; Giuditta Maulu: data collection; Alessandro Diodati: data collection, writing revision; Luca Turchet: statistical data analysis, writing revision.

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Declarations

Conflict of interest None.

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