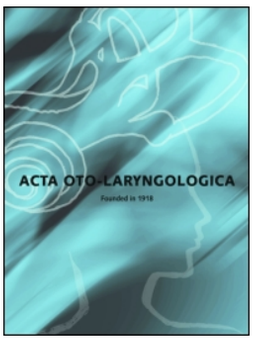

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RESEARCH ARTICLE

Patient satisfaction after auditory implant surgery: ten-year experience from a single implanting unit center

Simonetta Monini, Alessandra Bianchi, Rita Talamonti, Francesca Atturo, Chiara Filippi and Maurizio Barbara

NESMOS Department, ENT Clinic, Medicine and Psychology, Sapienza University, Rome, Italy

ABSTRACT

Conclusions: The satisfaction rate of the subjects with an auditory implant appears strictly related to the resulting auditory improvement, and the surgical variables would play a prevailing role in respect to the esthetic factors.

Objectives: To assess the rate of satisfaction in subjects who underwent the surgical application of an auditory device at a single Implanting Center Unit.

Method: A series of validated questionnaires has been administered to subjects who underwent the surgical application of different auditory devices. The Glasgow Benefit Inventory (GBI), the Visual Analog Scale (VAS), and the Abbreviated Profile of Hearing Aid Benefit (APHAB) have been used to compare the implanted situation with the hearing-aided one; a percutaneous bone conductive implant (pBCI) with an active middle ear implant (AMEI) on the round window in mixed hearing loss; and an invisible, fully-implantable device with a frankly and bulky semi-implantable device.

Results: The mean GBI scores were higher in Vibrant Soundbridge (VSB)® and Bonebridge® subjects, without significant differences among the various devices. The mean VAS score increased for all the devices in comparison with the conventional hearing aid. The mean APHAB score was similarly better in the implanted condition as total and partial scores.

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Auditory implants; Glasgow benefit inventory; visual analog scale; abbreviated profile of hearing aid benefit; bone conductive implants; active middle ear implants

Introduction

Hearing loss represents a condition that may certainly impair the quality-of-life. Although most of the subjects presenting with a moderate-to-severe hearing loss can usually benefit from a conventional hearing aid (cHA), a relevant number of them are shown to be poorly compliant to this type of solution due to various reasons that also include esthetic and cosmetic problems, social stigma, etc. In addition, cHA may also carry some important limitations, such as the impossibility to wear them during some physical activities, in cases of water contact, in the presence of ear pathology, and in subjects with inadequate manual skill. For the above-mentioned reasons, it has been reported that only 23% of potential users really benefit from cHA amplification and that only 58% of them regularly use it with satisfaction [1,2].

In order to avoid or minimize these adverse factors, especially when the ear is affected by an inflammatory pathology, different surgically implantable devices could be adopted in the form of percutaneous or transcutaneous Bone Conduction Implant (BCI), and partially- or totally-implantable Active Middle Ear Implant (AMEI) [3].

BCI have been proposed for the auditory rehabilitation of conductive and mixed hearing loss, with great benefit for the implanted subjects. The first validated study on BCI's quality-of-life has shown an overall improvement, in particular in the presence of ear malformations or open mastoid cavities [4]. Potential disadvantages for a percutaneous BCI (pBCI) application are a poor cochlear reserve, limitations during aquatic activity, and, mostly, the risk of skin infections, that has, however, been decreased by the adoption of new surgical modalities [5]. On the other hand, the pBCI is certainly one of the most visible among all the implantable auditory devices, due the presence of a screw behind the auricle and the still bulky design of the external component that is not easily hidden, for instance, on a male's head. In a recent survey among pBCI users, it has however been shown that the European population is likely to favorably accept the device when accurate pre-operative selection and counseling are carried out [6].

Apart from the post-operative audiological evaluation in terms of hearing improvement, many Implanting Centers are also implementing the overall assessment of their efficacy by administering standardized questionnaires, in order to get evidence of the effects that the implanted devices have on patients' quality-of-life. In this regard, most of the adopted questionnaires are the same as used for the evaluation of benefit with cHA, one of the main targets being the comparison of the performance between the auditory implant and the cHA.

The pBCI systems have undergone several investigations in this regard, counting on long-term follow-up evaluations due to their early introduction in the clinical practice, that

CONTACT Professor Maurizio Barbara, MD, PhD maurizio.barbara@uniroma1.it Head ENT Clinic, University Hospital Sant'Andrea, Via di Grottarossa 1035, 00189 Rome, Italy

Table 1. Demographics of the study sample.

Device	*n*	Males	Females	Hearing loss	Mean age, years
pBCI	27	10	17	21 CHL and MHL; 6 SSD	62.88 (36.92–80.03)
VIBRANT SOUNDBRIDGE	10	4	6	MHL	63.88 (43.83–72.06)
BONEBRIDGE	4	4	6	CHL	67.35 (62.78–77.49)
ESTEEM	26	16	10	SNHL	48.06 (24.39–88.69)

pBCI: percutaneous bone conductive implant; CHL: conductive hearing loss; MHL: mixed hearing loss; SNHL: sensorineural hearing loss; SSD: single-sided deafness.

have shown that, owing to its overall acceptance level, they remain the treatment of choice when indicated appropriate [7–9]. As far as AMEI are concerned, a few studies have been performed on one semi-implantable device, the VSB®, and on one fully implantable device, the Esteem®. The VSB is a partially-implantable electromagnetic device, whose actuator allows a prevalent amplification at the high frequencies, when applied either on the ossicular chain (sensorineural hearing loss) or on the round window membrane in case of mixed hearing loss (RW-VSB). For this type of implant, some studies have focused on the long-term functional outcome and showed a global satisfaction and positive benefits in the achievement of decreased difficulty in various listening environments [10,11]. Other reports have shown an improvement in performance and a large preference in respect to conventional hearing aids, along with an increased quality-of-life also for leaving the external ear canal non-occluded and the per-auricular region free [12].

As far as the totally implantable middle ear device Esteem® is concerned, only a few reports have regarded the outcome for quality-of-life. The Esteem®, an invisible piezoelectric middle ear implant, has been proposed as a possible rehabilitative procedure for moderate and severe SNHL, especially in patients who are unsatisfied cHA-wearers such as in the young population that suffers from the negative symbolic image associated to a HA [13]. With the Esteem®, one of the most important factors for patient satisfaction is surely the possibility to use it every day and without interruptions (overnight use) [14,15].

The Bonebridge® implant is a semi-implantable, transcutaneous BCI device, recently introduced in clinical practice, that is composed of an internal, implantable part, completely under the skin, coupled to an external audio-processor. Its use has been associated to an improvement of quality-of-life regarding social and physical health in patients with conductive and mixed hearing loss [16,17].

To our knowledge, no study has previously reported on the satisfaction outcome after implantation of different implantable devices taken altogether. The present study has been designed for this purpose by using standardized questionnaires on a cohort of subjects affected by different type of hearing loss and who, accordingly, have received the most appropriate auditory device. Despite the heterogeneity of the sample and different numbers for each device, that certainly could represent an objective limitation of the study, some interesting remarks could be drawn, in particular when comparing:

- cHA-aided vs the implant-aided situations;
- pBCI vs an AMEI in mixed hearing loss; and
- the two potentially extreme aesthetic situations, such as a percutaneous BCI against an invisible, totally implantable device, such as the Esteem®.

Materials and methods

From January 2005 to November 2015, 130 subjects underwent an auditory surgical rehabilitation with different types and modalities of implantable devices at a tertiary care University Hospital and were planned to be included in a satisfaction survey. Sixty-three of them were, however, excluded for the following reasons: deceased ($n = 3$), lost to follow-up ($n = 21$), short, less than 1 year follow-up ($n = 5$), unavailable at the question time ($n = 16$), explant of the device ($n = 11$), processors temporarily on repair ($n = 2$), or insufficient number of cases for single device (Maxum®, Ototronix, Saint Paul, MN; Retro-X®, Auric, Rheine, Germany; and Codacs®, Cochlear, Melbourne, Australia). Therefore, the present evaluation has taken into account 67 implanted patients (33 males and 34 females, age ranging from 24–88 years, mean = 60.54 years) that were further distinguished in: 27 percutaneous Bone Conduction Implants or pBCI (either BAHA®, Cochlear, Melbourne, Australia; or PONTO®, Oticonmedical, Askim, Sweden), 21 presenting with a conductive or mixed hearing loss and six with single sided deafness; four transcutaneous BCI (Bonebridge®, Medel, Innsbruck, Austria) with a conductive or mixed hearing loss, 10 Vibrant Soundbridge® (Medel) with mixed hearing loss and 26 Esteem® (Envoymedical, Minneapolis, MN) with sensorineural hearing loss (Table 1). All the patients had previously been rehabilitated with different types of cHA for a minimum of 6 months. The study has taken into consideration patients that had been implanted at least 1 year before the present survey, in order to allow several fitting sessions for an optimal individual adaptation of each device.

Different questionnaires were administered to each implanted subject to obtain information on their subjective perception of sound, on health status, esthetic impact, and overall quality-of-life. Each questionnaire has been administered during a check-up visit after all the subjects signed a specific informed consent, and the study was performed in accordance with the Helsinki Declaration principles.

The standardized questionnaires were:

1. General Glasgow Benefit Inventory (Italian standardized version) [18]. This is a general questionnaire that aims to evaluate post-surgical quality-of-life. It is based on 18 questions that assess health changes after surgery (12 on

general health, three on physical health, three on social health). To each question, five answers are possible, with a score ranging from 1–5, so that the total score will be allocated between −100 to +100 (from the worst to the best one), calculated through a simple mathematical formula (the total score is divided by the number of questions, subtracting 3 and multiplying by 50).

2. Visual Analog Scale (VAS). The VAS scale (from 0–10) has been used to measure subjective judgment in relation to both quality of perceived sound and to quality-of-life, by comparing the pre-implant (conventional hearing aided: cHA-aided) with the post-implant (activated implant: I-aided) situation. In order to increase the sensitivity of the test, the results have also been distinguished according to the rate value, considering a score >6 as good, and >8 as excellent.
3. Abbreviated Profile of Hearing Aid Benefit (APHAB) (Italian standardized version) [19]. This questionnaire is generally used to quantify everyday life problems associated with hearing loss and to evaluate the reduction of disability that can be achieved with a hearing aid. In the present study, the APHAB questionnaire has been used to compare the I-aided situation with the cHA-aided one, giving the patients the possibility to describe the frequency of auditory problems with or without the device.
   The questionnaire comprises 24 items divided into four sub-domains:

   - Ease of Communication (EC): communication skills under relatively favorable conditions.
   - Background Noise (BN): communication in settings with high background noise levels.
   - Reverberation (RV): speech understanding in moderately reverberant rooms.
   - Aversiveness (AV): the negative reactions to the environmental sound.

Each domain is composed of six questions. The answer to each item considers seven possibilities of changing, in percent from 1% to 99%, with intermediate scores of 12%, 25%, 50%, 75%, and 87%. The partial domain score has been derived from the average percentage of the six questions in the single domain, while the total score has been derived from the mean of the total questions of all the sub-domains. The eventual partial or total score reduction, from the cHA-aided to the I-aided situation, would show the possible and probable gain and displays the benefit of the implanted device.

A Student's *t*-test ($p < .05$) has been used for statistical analysis to evaluate the difference among the questionnaire scores recorded in different devices, and between the unaided and the aided situations in each device, only in the APHAB and VAS for quality of sound.

Results

Demographic data relative to the study sample are described in Table 1.

General Glasgow benefit inventory (GBI)

The mean total GBI score recorded for each device is shown in Figure 1(A) and was 22.92 for pBCI; 19.93 for Esteem®; 36.47 for VSB, and 35.21 for Bonebridge®. A significant difference was found only between VSB and Esteem®, in favor of the former ($p = .028$).

The mean partial scores recorded for each device is shown in Figure 1(B). For 'social health', it was 40 in Bonebridge® 47 in VSB; 18 in pBCI; and 24 in Esteem®. For 'general health', it was 30 in Bonebridge®, 8 in VSB, 9 in pBCI, and −2 in Esteem®. For 'physical health', it was 22 in Bonebridge®, 28 in VSB; 50 in pBCI; and 34 in Esteem®. For 'social health', a significantly better score has been recorded for pBCI over the other implants ($p < .05$); for 'general health', a significantly better score has been recorded for VSB vs Esteem® ($p < .05$); for 'physical health', a significantly better score has been recorded for the pBCI vs the Esteem® ($p < .05$).

Visual analog scale (VAS)

Quality of sound

The mean VAS score in the different devices, in comparison with the conventionally-hearing aided (cHA-aided) condition, is presented in Figure 2. In pBCI, it has increased from 5.3 to 7.9; in the Esteem® from 4.9 to 7.1; in VSB from 5.8 to 8.4; and in Bonebridge® from 5.5 to 8.1.

For all the devices, the comparison between cHA-aided and I-aided scores showed a significant difference in favor of the former ($p < .05$), whilst no statistical differences ($p > .05$) in the gain for the perceived quality of sound had been assessed among them.

When considering the VAS score >8, a significant difference was only found in favor of the VBS vs the Esteem® ($p = .0128$).

Quality-of-life

The mean VAS score in the different devices is reported in Figure 2. When considering VAS >6, values were 10 for the Esteem® and Bonebridge®, 9 for VSB, and 8 for pBCI. When considering VAS >8, values were 10 for the Esteem®, 3 for VSB, 2.5 for Bonebridge®, and 1 for pBCI.

Abbreviated profile of hearing aid benefit (APHAB)

The APHAB score in conventionally aided (cHA-aided) and I-aided situation is presented in Figure 3. The mean total percentage score was 58% in the cHA-aided condition and 24% in the pBCI-aided; 60% in the cHA-aided condition and 31% in the Esteem-aided; 64% in cHA-aided condition and 29% in the VSB-aided; and 58% in the cHA-aided condition and 23% in the Bonebridge-aided. The comparison between the cHA-aided and the I-aided condition showed significant differences for each device ($p < .05$). The APHAB scores for single sub-domain, in the cHA-aided and I-aided situations are summarized in Figure 3. For all the devices,

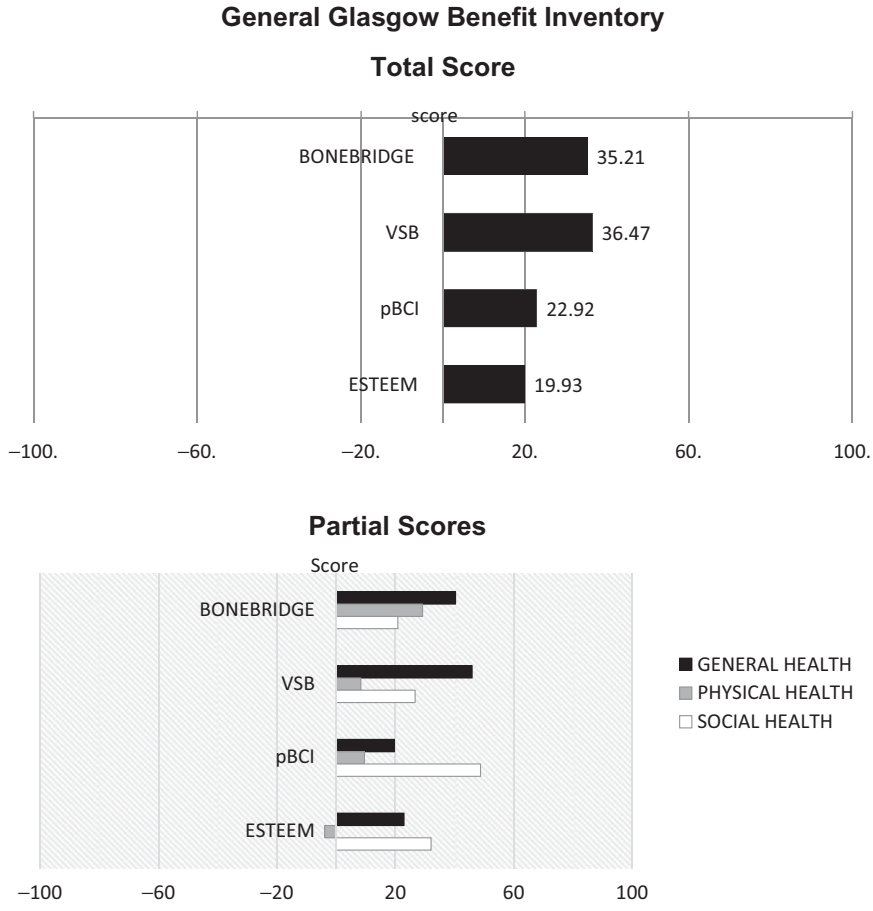


Figure 1. Glasgow Benefit Inventory (GBI) score, which explores the surgical impact on life. (A) Total score. A significant difference between VSB and Esteem has been shown ($p = .028$). (B) Evaluation of the GBI partial scores (social health, general health, and physical health). For 'social health', a significantly better score has been recorded for pBCI over the other implants ($p < .05$); for 'general health', a significantly better score has been recorded for Vibrant Soundbridge (VSB) vs Esteem. ($p < .05$); for 'physical health', a significantly better score has been recorded for the pBCI vs the Esteem ($p < .05$). General health (black bar); Physical health (grey bar); Social health (white bar). VSB, Vibrant Soundbridge; pBCI, percutaneous bone conductive Implants.

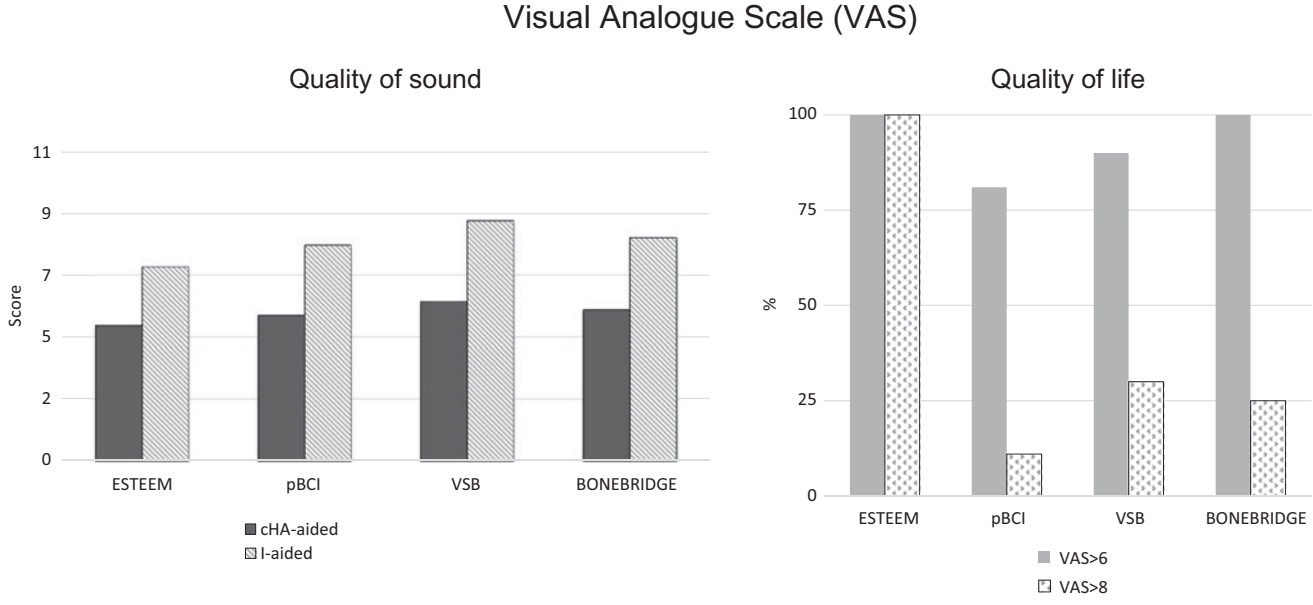
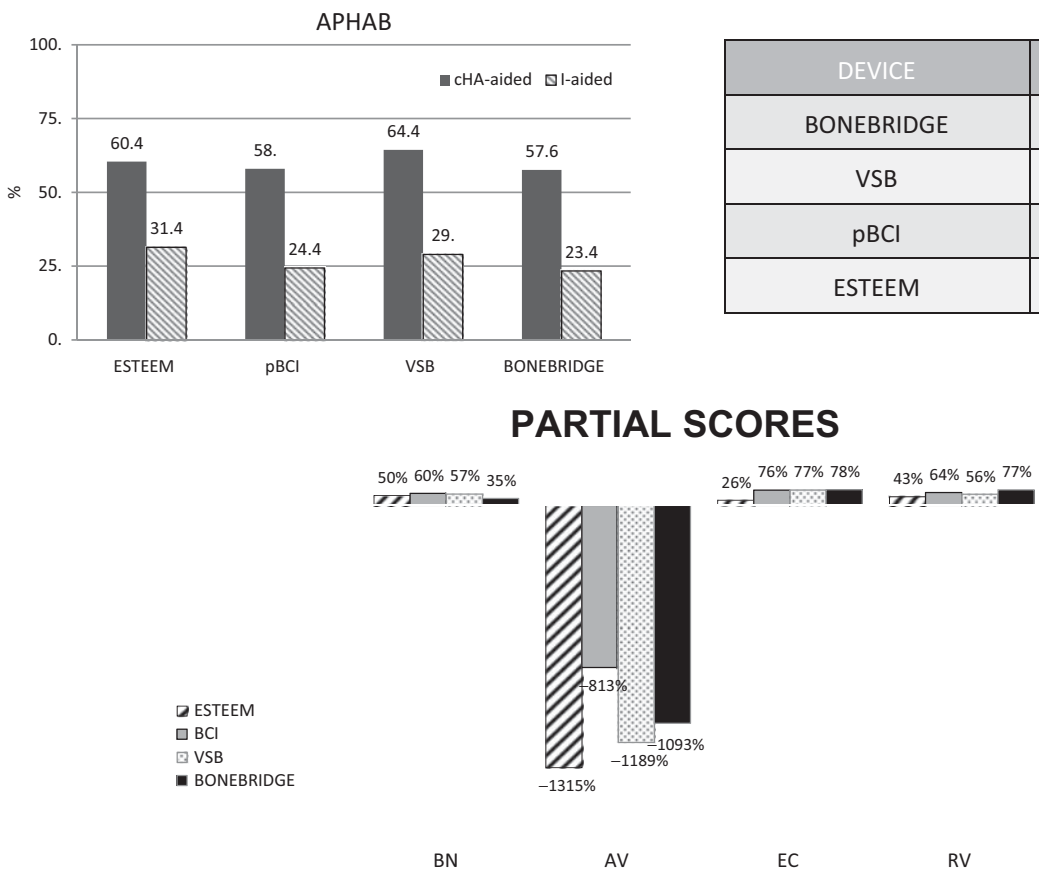


Figure 2. Visual Analog Scale (VAS) for quality of sound, by comparing the conventionally-aided (cHA-aided) vs the activated implant (I-aided) conditions. A better score is recorded in the I-aided setting, with score for BCI statistically better than for Esteem ($p < .05$). VAS for quality-of-life. Percentage of distribution of patients who reported VAS values over 6 and over 8. When considering a good appreciation, no significant differences are seen among all the devices; when considering an optimal appreciation, the Esteem device's values appear significantly much better than the other devices.



DEVICE	% OF BENEFIT
BONEBRIDGE	54,34%
VSB	54,30%
pBCI	54,86%
ESTEEM	46,18%

Figure 3. Upper row: Total APHAB score for the assessment of benefit of the implanted device in cHA-aided vs I-aided conditions. For all the devices a statistically significant improvement has been recorded in comparison with the cHA-aided situation, without any significance among the devices themselves ($p > .05$). A high percentage of benefit is shown in all the devices. Lower row: APHAB gain for each device in the different sub-domains. In all the devices, 'aversiveness' gave negative values. Bonebridge reached the highest value for reverberation and percutaneous BCI for background noise. BN: background noise; AV: aversiveness; EC: ease of communication; RV: reverberation.

an APHAB positive gain has been recorded between the cHA and I-aided situation, in all the domains except for the aversiveness domain in which a negative gain was always found. The largest improvement was reached in pBCI patients for the BN domain and in Bonebridge® patients for the RV domain. In all the devices the same gain was observed for the EC domain. The comparison between I-aided and cHA-aided situations for each domain showed a significant difference ($p < .05$), except for AV in VSB and BN in Bonebridge®.

pBCI vs round window vibrant soundbridge (RW-VSB) in mixed hearing loss

VAS quality of sound

A significant improvement was found when comparing the cHA-aided vs the I-aided conditions, both for BCI ($p = .013$) and for RW-VSB ($p = .000\ 039$) (Figure 4). No statistically significant difference between the two devices was found.

Aphab The total and partial scores recorded for pBCI and RW-VSB were similar, without significant differences (Figure 5).

Fully-implantable esteem vs pBCI

VAS quality of sound

In both Esteem® and pBCI, a significant better score was found in comparison with the cHA-aided condition, without significant differences between them (Figure 6).

VAS quality-of-life

For values over 6, a better score was found in both situations (Esteem® = 10; pBCI = 8). For values over 8, the Esteem® maintained the same value, i.e. 10, whilst the score for pBCI dropped to 1.5 (Figure 6).

APHAB The total score showed a statistically significant improvement, both for the Esteem® ($p = .000\ 000\ 000\ 58$) and the pBCI ($p = .000\ 000\ 010$). The partial scores recorded an improvement in all the sub-domains but for aversiveness. A statistically significant higher score was recorded for pBCI in the reverberation sub-domain (Figure 7).

Discussion

Particular attention has recently been focused on the necessity to evaluate any type of auditory rehabilitation, not only

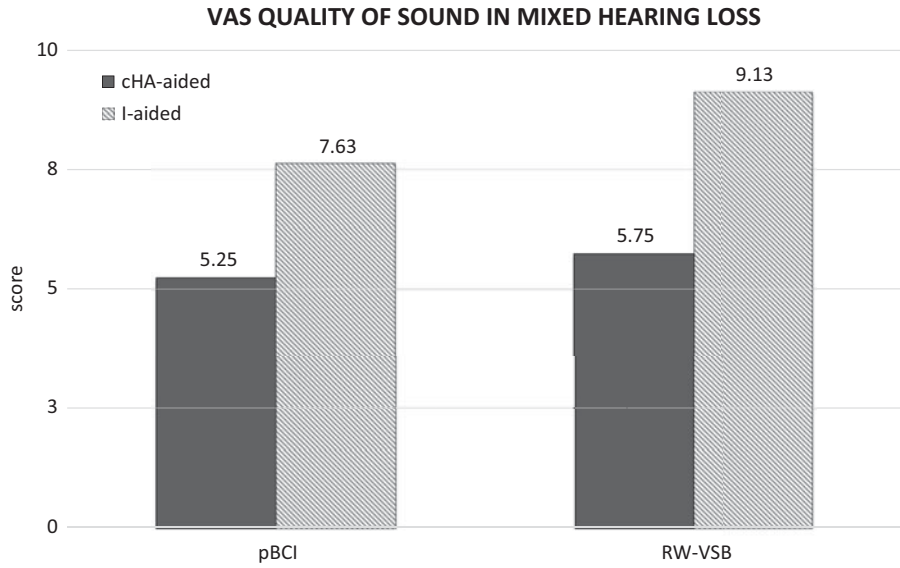


Figure 4. VAS for quality of sound in mixed hearing loss (mean bone conduction threshold <40 dB), comparing percutaneous BCI (eight subjects) vs round window vibroplasty (eight subjects). A significant improvement was recorded when comparing the cHA-aided vs the I-aided situations (pBCI: $p = .013$; RW-VSB: $p = .000\ 039$).

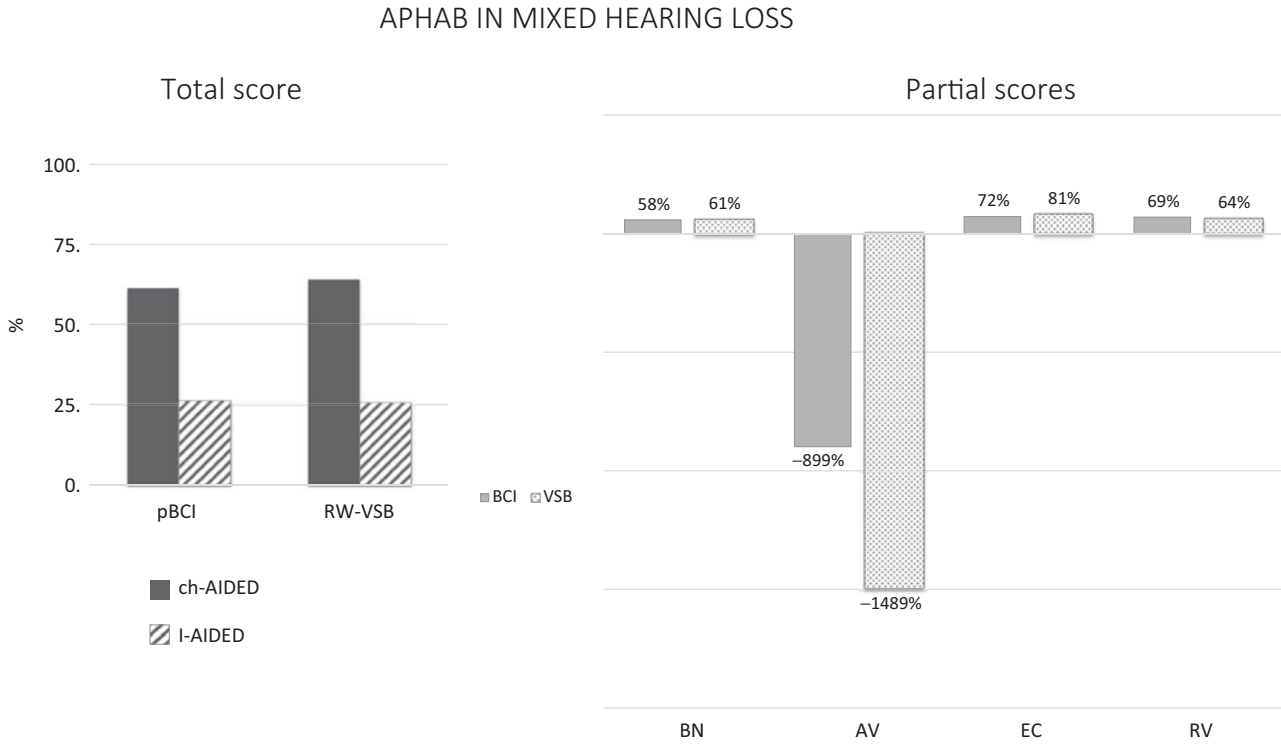


Figure 5. APHAB in mixed hearing loss (BC threshold <40 dB), comparing pBCI (eight patients) vs RW-VSB (eight patients). The I-aided condition allowed a significant improvement of the score, whilst no difference was found between the two implanting procedures. pBCI: percutaneous Bone Conduction Implants; RW-VSB: Round window Vibrant Soundbridge.

in terms of auditory improvement, but also as patients' compliance to wear, for instance, a conventional hearing aid (cHA), with their subjective judgment on benefit and satisfaction. For this purpose, specific questionnaires have been available for scoring the different stages of cHA rehabilitation, from selection, candidature, hearing aid fitting, and adaptation.

When the semi- and totally implantable hearing devices have become available and started to be applied in properly selected cases, a similar approach has been followed, by adopting new questionnaires that would specifically take into consideration the surgical issues.

The present study has considered a cohort of implanted subjects taken from a larger group that has undergone different types of procedures at the same Implanting Center. The study group was eventually composed of 67 subjects, while the rest of the subjects were not included for different reasons. While some of these reasons, such as death

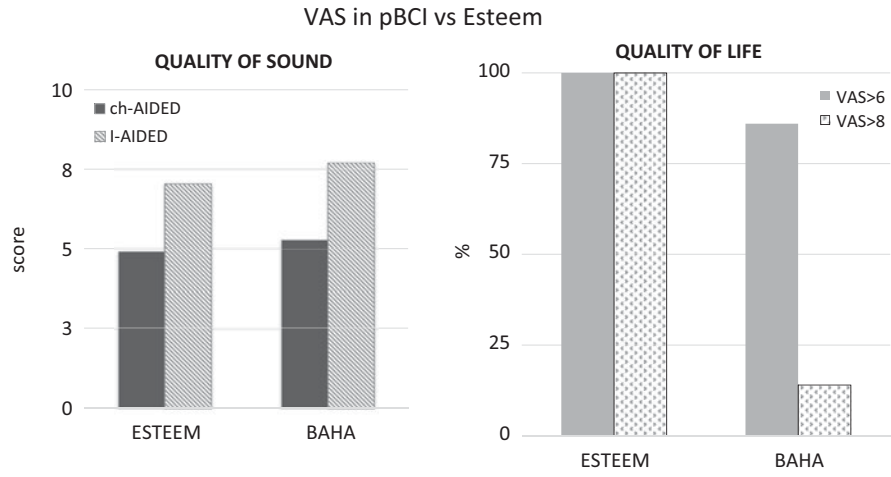


Figure 6. VAS comparison in quality of sound and life between non-SSD percutaneous BCI; pBCI (21 patients) and Esteem (26 patients). The improvement of quality of sound in respect to the c-HA condition is highly significant with both devices ($p = .000\ 040\ 7$ for pBCI; $p = .000\ 000\ 035$ for Esteem) without differences between the two. A higher improvement of the quality-of-life was found for the Esteem subjects in comparison to the pBCI ones, when considering VAS scores >8 ($p = .000\ 074\ 04$).

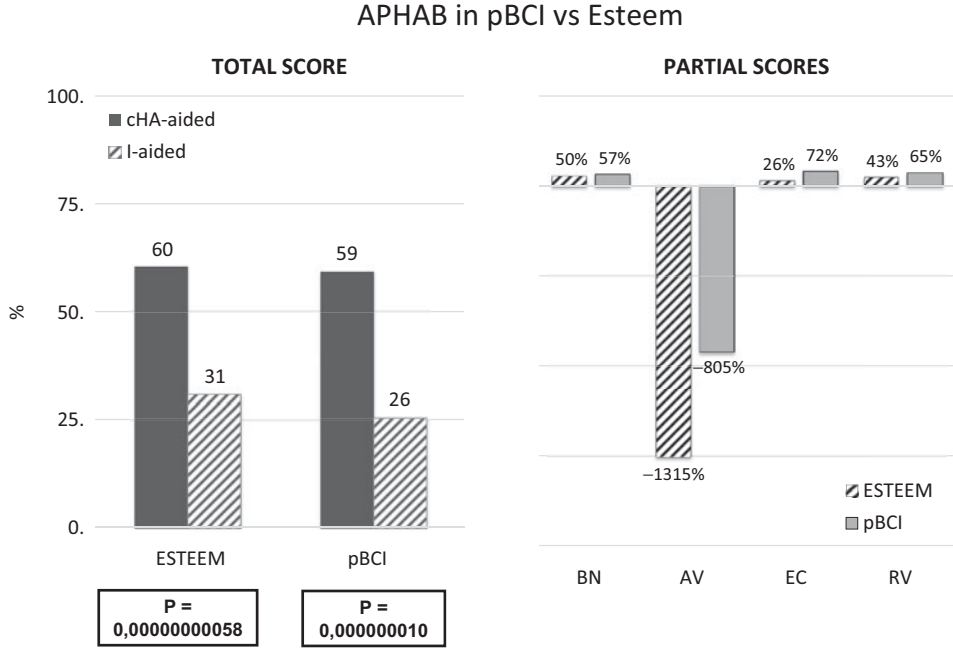


Figure 7. APHAB total and partial scores between non-SSD percutaneous BCI; pBCI (21 patients) and Esteem (26 patients). Both aided conditions were found significantly improved in respect to the cHA situation (Esteem, $p = 0.000\ 000\ 000\ 58$; pBCI, $p = 0.000\ 000\ 010$). Partial APHAB scores showed an improvement for all the sub-domains, except for 'aversiveness'. A statistical difference in favor of the pBCI was found in the sub-domain 'reverberation'. pBCI: percutaneous bone conductive implant; BN: background noise; AV: aversiveness; EC: ease of communication; RV: reverberation.

(three cases), unavailability at the question time (16 cases), processor under repair (three cases), short follow-up (six-cases), inadequate amount of single implant (five cases), and lost to follow-up (21 cases) would not have represented a biasing factor for the analysis, those who were explanted (11 cases) could certainly represent a group with an at least not favorable attitude towards the received surgical auditory rehabilitation, although the explantation was not always ensuing a totally negative experience. For instance, four of the five subjects who had received a RetroX® device, before the advent of the open fitting hearing aids, preferred to shift to this latter conventional system after removal of the implanted device, that was carried out in an outpatient setting, under local anesthesia, and no further annoyance for them. Even the four subjects who had their invisible device Esteem® explanted were not regretting their previous implanting surgery that had allowed—although temporarily—to improve their quality-of-life and were, after the explant, returning to a favorable hearing condition either with an ossicular reconstruction (two cases) or with a cochlear implant (two cases).

For all the implanted devices, a significantly better hearing performance has been shown in comparison with the unaided condition. From this finding, one would have expected a homogenous positive trend in the patient's satisfaction rate, but the results from the different questionnaires

have clearly shown that many differences do exist among the devices taken into consideration, presumably related to the specificity of each surgical procedure. Modality of anesthesia, duration of hospitalization, and post-operative course with the complication rate are surely of considerable importance in this regard. The GBI questionnaire used in the present study is specifically related to the health changes generated by a surgical procedure, by measuring them as a whole as well as partial scores (general, physical, and social health changes). The total GBI score showed a greater improvement of the VSB, which resulted as significant only in respect to the Esteem®, but not to the other devices taken into consideration (percutaneous and transcutaneous BCI). Coming to the partial GBI scores, the greatest score for social health was registered in pBCI, while for physical health and general health, the transcutaneous BCI Bonebridge® and VSB and Bonebridge® were shown to prevail, respectively. From these findings it is possible to assume that the effect on health is not related to esthetic or functional features, but mainly to some surgical aspects (duration and post-operative course, for example).

A deeper insight within the overall results of the present study has been targeting specific issues that regarded the comparison between:

a. cHA-aided vs I-aided situations;
b. pBCI vs AMEI in mixed hearing loss; and
c. an invisible device (Esteem®) vs the most unesthetic device (percutaneous BCI).

cHA-aided vs I-aided situations

Although the study group was composed of subjects who were glad to be enrolled, whilst other subjects, including some with negative features (explanted, not available, etc.) were not part of it, all the devices implanted recorded—via the VAS scale for quality of hearing—a statistically better auditory condition in comparison with that achieved by cHA. For AMEI, the higher score was found to be for the VSB in respect to the Esteem®, which can be explained with the prevalent gain at high frequencies that can be provided by the VSB actuator [20]. When considering the quality-of-life, it has been arbitrarily decided to distinguish two different score ranges of positivity: one limited to 6, indicative of a good achievement, the other extended up to 8, that should regard an optimal outcome. So, while VAS data up to 6 were reached by all the devices, when considering those reaching 8, the advantage of having an invisible, fully-implantable device, such as the Esteem®, has clearly emerged.

For each device, the comparison between the activated implant and the conventionally-aided situation showed a significant improvement of the total APHAB score, with the worst score gain obtained by the Esteem®. For reverberation, in addition, a better score was found in pBCI than in the Esteem®, presumably due to the lack of alternative, reliable rehabilitation means for the mixed hearing loss cases that eventually received a pBCI. Similar findings were also obtained from the APHAB questionnaire in which the sub-domain aversiveness was the only one that did not show an improvement.

pBCI vs round-window vibrant soundbridge in mixed hearing loss

The rehabilitation of mixed hearing loss, in presence of a BC threshold <40 dB, still represents a challenge for the otologists that may theoretically choose between a BCI, either percutaneous or transcutaneous, and an AMEI coupled to the ossicular remnants or to the round window membrane. Part of our study group was actually formed by several individuals with this type of hearing loss, who received either of the implants and could, therefore, be compared. At APHAB questionnaire, very similar and better results were found in both situations in comparison with a cHA, as total and partial scores. However, as shown by the VAS on quality of sound, the outcome with the RW-VSB device was much higher and more appreciated, presumably due to the selective amplification that this device may provide at the high frequency level.

pBCI vs esteem

The last issue that it was decided to explore was the comparison of patient's appreciation between two theoretically extreme situations in implanting surgery: one that ends up with an invisible device (Esteem®) against another one that retains a visible component anchored to a penetrating skin trough (percutaneous or pBCI). When assessed by questionnaires, somewhat surprising results were observed. It was, in fact, shown that the quality of sound at VAS was pretty similar between the two devices, although the starting auditory level was obviously different, being mostly conductive for the BCI and sensorineural for the Esteem®. Also, the changes of health status occurring after the surgical application (GBI score) indicated to give preference to the pBCI with statistical significance, although the sub-domain of physical health was prevailing for the Esteem®, presumably owing to the absence of any external component. When applying the APHAB questionnaire to this comparison, instead, no differences were shown between the two devices, even though the reverberation gain was statistically better for the pBCI.

The present survey has provided some insight into the role played by auditory implantable devices for improving quality-of-life in all subjects who have benefited of this surgical solution in terms of hearing improvement. All the devices provided a better quality-of-life in respect to conventional hearing aids, but the esthetic factor was not the most important role for it. In fact, when experiencing less invasive and shorter surgical procedures, such as is the case for a percutaneous BCI, the patients would retain a more positive experience and, therefore, receive a greater improvement in quality-of-life.

Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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