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ORIGINAL ARTICLE

Piezoelectric bone conduction hearing implant Osia® – audiological and quality of life benefits

Authors' Contribution:
A – Study Design
B – Data Collection
C – Statistical Analysis
D – Data Interpretation
E – Manuscript Preparation
F – Literature Search
G – Funds Collection

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ABSTRACT:

Introduction: Nowadays, there are many options to treat hearing-impaired patients: tympanoplastic surgery, hearing aids and a wide range of implantable devices.

Aim: The aim of this study is to present the mid-term audiological and quality of life benefits after the implantation of Osia®, an active piezoelectric bone conduction hearing implant.

Material and methods: The state of the tissues in the implanted area, as well as audiological and quality of life results were analyzed at six, nine and twelve months after implantation in a group of four adult patients with bilateral mixed hearing loss (1 after bilateral canal-wall-down mastoidectomy, 2 with chronic simple otitis media and after myringoplasty in the opposite ear, 1 with bilateral otosclerosis and after stapedotomy in the opposite ear).

Results: No postoperative complications were found in any of the cases. One year after surgery the mean audiological gain in FF PTA4 (pure tone average for 0.5, 1, 2, and 4 kHz) was 52.2 ± 3.5 dB in comparison to the unaided situation, the mean speech understanding with Osia® in quiet was 90 ± 8.2% for 50 dB SPL, 98.8 ± 2.5% for 65 dB SPL and 100 ± 0% for 80 dB SPL, and the mean speech understanding with Osia® in noise was 37.5% ± 23.6 for 50 dB SPL, 93.8 ± 4.8% for 65 dB SPL and 98.8 ± 2.5% for 80 dB SPL. There was also an evident improvement in the quality of hearing as well as in the quality of life, measured by APHAB (Abbreviated Profile of Hearing Aid Benefit) and SSQ (Speech, Spatial and Qualities of Hearing Scale).

Conclusions: The Osia® is an effective treatment option for patients with bilateral mixed hearing loss. The mid-term audiological and quality of life results are excellent, but further observations including bigger groups of patients and a longer follow-up are required.

KEYWORDS: bone conduction, bone-anchored prosthesis, hearing aids, hearing loss

ABBREVIATIONS

12M – twelve months after surgery
6M – six months after surgery
9M – nine months after surgery
AC – air conduction
APHAB – Abbreviated Profile of Hearing Aid Benefit
AV – aversiveness
BAHAs – bone-anchored hearing aids
BC – bone conduction
BCIs – bone conduction implants
BN – background noise
CE – European Conformity
EC – ease of communication
FF – free field
PreOp – preoperatively
PTA4 – pure tone average for 0.5, 1, 2 and 4 kHz
RV – reverberation
SSQ – Speech, Spatial and Qualities of Hearing Scale

INTRODUCTION

Nowadays, there are many options to treat hearing-impaired patients: tympanoplastic surgery, hearing aids and a wide range of implantable devices. The latter comprise: cochlear, bone conduction, middle ear and auditory brainstem implants [1–4].

Bone conduction implants (BCIs) or bone-anchored hearing aids (BAHAs) are used for treatment of patients with unilateral and bilateral, mixed and conductive hearing loss, as well as those with single-sided deafness and there is a variety of such devices on the market [5]. For many years, different passive bone conduction systems have been used, in which an external sound processor and a transducer are located behind the ear, and the vibrations produced by the transducer have to be transmitted to the implanted part, located inside the bone, through a percutaneous abutment (percutaneous devices) or through a system of magnets (transcutaneous devices). Unfortunately, both types of these passive devices have some disadvantages and limitations [5].

Tab. I. Inclusion and exclusion criteria.

INCLUSION CRITERIA	EXCLUSION CRITERIA
Adult patients (18 years of age or older at study entry).	Uncontrolled diabetes.
Women and men (no special requirements).	Progressive hearing loss.
Patients with mixed, unilateral or bilateral hearing loss, in whom a decision was made to use prosthetic hearing systems with bone conduction systems.	Diseases that may have a negative effect on osseointegration and wound healing (osteoporosis, psoriasis, long-term use of corticosteroids), or others diseases that disqualify the patient from surgery.
Bone conduction thresholds in pure tone audiometry for the frequencies of 0.5, 1, 2 and 4 kHz should be on average from 25–50 dB in the implanted ear.	Patients who received radiotherapy in the vicinity of the implantation site, or who have planned radiotherapy during the study.
Real expectations regarding the prosthesis.	Patients who take drugs that accelerate the growth of connective tissue, including: somatotropin, ibandronic acid, or organic compounds from the group of bisphosphonates.
	Insufficient quality, or insufficient bone thickness to insert the Cochlear BI300 implant.
	The use of ototoxic drugs during this study.
	The patient's inability to comply with the study protocol, eg, unable to comply self-completion of the quality of life questionnaires.

Tab. II. Patients' characteristics.

	PATIENT 1	PATIENT 2	PATIENT 3	PATIENT 4
Age (years)	53	76	38	65
Sex	Male	Male	Female	Male
Air conduction in the ear at the side of implantation – PTA4 (dB HL)	82.5	76.25	93.75	67.5
Bone conduction in the ear at the side of implantation – PTA4 (dB HL)	46.25	37.5	47.5	42.5
Etiology of hearing loss	bilateral chronic otitis media (both ears after canal wall down surgery)	bilateral chronic otitis media (right ear after myringoplasty, left ear – subtotal perforation of tympanic membrane)	otosclerosis (right ear after stapedotomy; left ear after explorative tympanotomy without stapedotomy due to difficult anatomical conditions)	bilateral chronic otitis media (right ear – subtotal perforation of tympanic membrane and adhesions, left ear after myringoplasty)
Side of implantation	left	left	left	right
Hearing devices used before Osia® implantation	air-conduction hearing aid right-sided	air-conduction hearing aid right-sided	air-conduction hearing aid right-sided	air-conduction hearing aid left-sided

PTA4 – Pure Tone Average for 0.5, 1, 2, and 4 kHz in decibels hearing level

The percutaneous bone anchored hearing aids (BAHAs) break the continuity of the skin barrier, require lifelong and daily hygiene, cause the risk of local skin complications and the aesthetic effect after surgery is not optimal [6–8]. Although the transcutaneous BAHAs were developed to overcome the aforementioned obstacles, the quality of sound can be limited due to sound attenuation caused by the skin between magnets [8, 9]. Also, permanent pressure on the skin can lead to redness or pain over a magnet [10], and sometimes even to soft tissue necrosis [11]. Therefore in the past, with a choice of only passive devices, getting a suitable audiological gain has usually been in opposition to good esthetic and hygienic results, and the choice of an optimal option was not often easy. An otological team and a patient had to choose between "better hearing" or „better wearing".

Over the last years, a few active bone conduction systems have become available [5, 12], with the aim of addressing the problems of skin discontinuity, poor aesthetic effect, soft tissue attenuation and skin pressure. In these devices, a processor is still located outside the body but a transducer is positioned directly in/on a patient's bone. The first such an electromagnetic device – the Bonebridge® (Medel, Austria) was introduced to the market in 2012, and there is a significant amount of information about its outcomes and reliability [12–14]. Another one, an electromagnetic system – the Sentio (Oticon, Denmark) is currently in the regulatory process for European Conformity (CE) marking. Furthermore, in 2019, a new active piezoelectric bone conduction system – the Osia® (Cochlear Ltd) received CE, and was available, as an early market release, for 8 selected European clinics, including our department. The audiological indications for this device are unilateral and bilateral, mixed and conductive hearing loss, as well as single-sided deafness. In cases with mixed hearing loss the bone conduction pure tone average in the implanted ear must not exceed 55 dB HL. The details of the surgery and early surgical and functional results (3 months after surgery) of our patients were published in our previous paper [15].

The aim of this study is to present the mid-term audiological and quality of life benefits after the implantation of the Cochlear™ Osia® System.

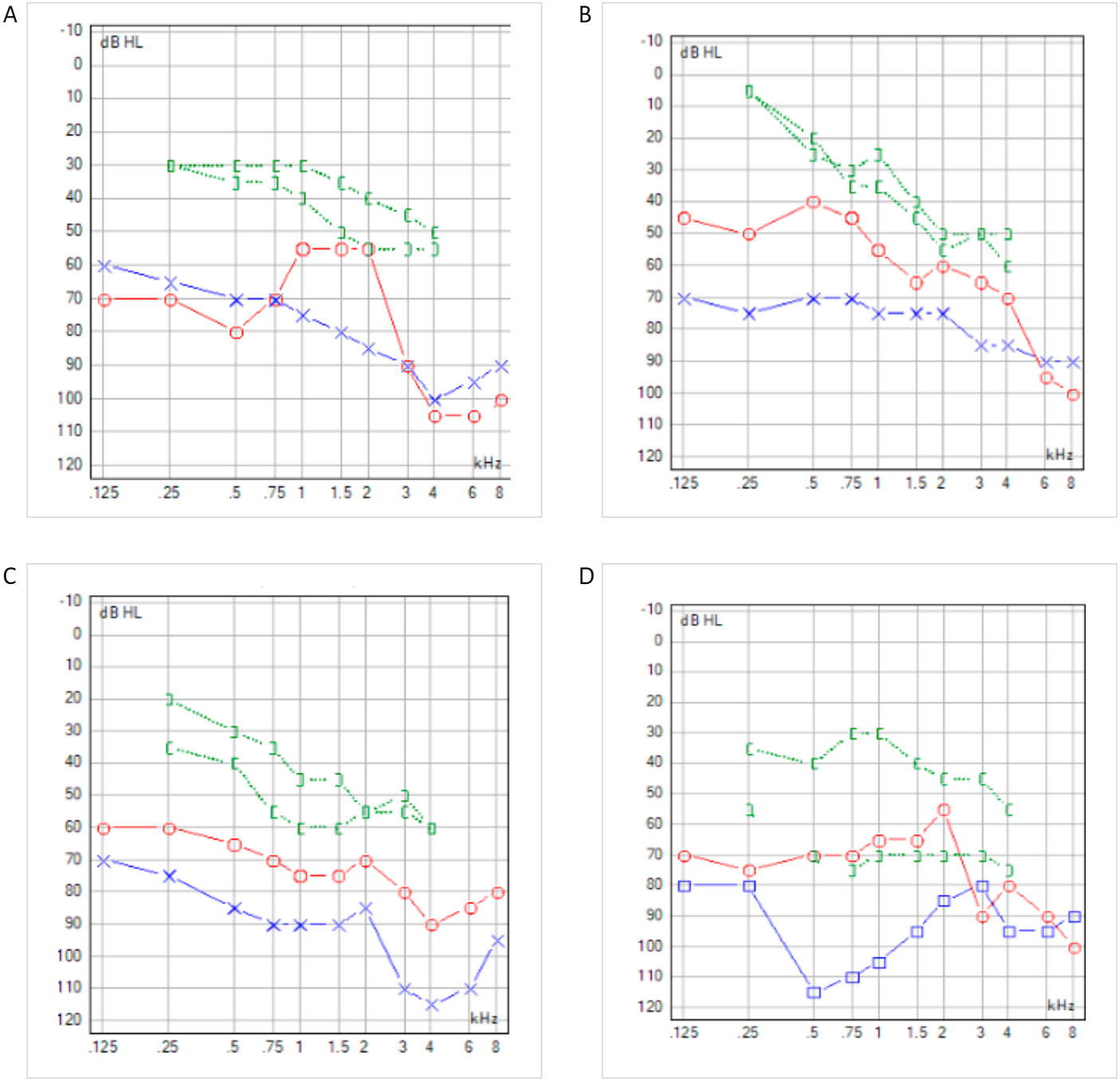

Fig. 1. Preoperative audiograms of the patients (A – patient 1, B – patient 2, C – patient 3, D – patient 4).

MATERIALS AND METHODS

Study design and patients' characteristics

The described study was conducted between June 2019 and October 2020. The study protocol was prepared in cooperation with Cochlear company. The inclusion and exclusion criteria are presented in Tab. I. Ultimately, four adults were randomly selected from the group of patients who met these criteria, and they were implanted with the Osia® 1st generation system and prospectively evaluated. The analyzed group consisted of 3 males and 1 female, aged 38–76 years (mean 58), all with bilateral mixed hearing loss. In the ear at the side of implantation the mean AC (air conduction) PTA4 (pure tone average for 0.5, 1, 2 and 4 kHz) was 80 ± 11.1 dB HL and the mean BC (bone conduction) PTA4 was 43.5 ± 2.5 dB HL. No one of the patients used an air-conduction hearing aid in the ear selected to implantation of Osia® due to otological conditions (1 case after canal-wall-down surgery and 2 cases with subtotal tympanic membrane perforation, who had not been qualified for myringoplasty due to the patient's age and patient's decision [case 2] or hearing condition in the opposite ear [case 4]) and/or audiological state (large air-bone gap and no significant gain of hearing aid). However, all the patients used air-conduction hearing aids in the contralateral ear. The details concerning the patients are presented in Tab. II. and the individual audiograms of the patients are presented in Fig. 1. The evaluation was performed before surgery, and

Tab. III. Individual results of free field pure tone audiometry of implanted patients.

PATIENT	BEFORE SURGERY UNAIDED [dB SPL]					BEFORE SURGERY WITH BAHA® 5 POWER ON SOFTBAND [dB SPL]					AFTER SURGERY 6 MONTHS WITH OSIA® [dB SPL]					AFTER SURGERY 9 MONTHS WITH OSIA® [dB SPL]					AFTER SURGERY 12 MONTHS WITH OSIA® [dB SPL]				
[kHz]	0.5	1	2	4	mean	0.5	1	2	4	mean	0.5	1	2	4	mean	0.5	1	2	4	mean	0.5	1	2	4	mean
1	85	85	95	110	93.8	35	25	25	50	40.0	40	30	40	55	38.8	35	30	40	55	40.0	40	25	40	55	36.3
2	80	80	80	95	83.8	35	30	35	50	36.3	25	25	25	40	27.1	35	25	30	50	28.8	25	25	25	45	26.3
3	95	95	95	120	101.3	55	55	55	90	38.8	45	30	40	60	33.8	45	35	45	70	36.3	35	30	35	55	32.5
4	80	70	60	95	76.3	35	35	40	55	61.3	45	25	30	50	51.3	45	25	30	50	56.3	45	25	30	50	51.3

at six, nine and twelve months after surgery. The investigation was approved by the local Ethics Committee (decision number 42/19).

Cochlear™ Osia® System

The new bone conduction system evaluated in this study is composed of implantable parts (a BI300 bone conduction implant, a piezoelectric transducer attached to an implant and a receiver-stimulator module, similar to that in a cochlear implant) and an external sound processor (Fig. 2.).

Surgery

Surgery was performed in general anesthesia between 5 and 11 September 2019. The surgical technique was as described in the Cochlear surgical guide. In all the cases, a typical C-shaped incision was performed, a hole for a bone conduction implant, BI300, was drilled and the implant was inserted. Then, the bone around the implant was polished, a subperiosteal pocket and a bone bed for a receiver-stimulator module was created, the rest of the device was inserted and, after measurements, connected to the implant. In one case, soft tissue had to be reduced. The details of surgery were described in our previous study [15].

Evaluated parameters

The state of the soft tissues

The skin integrity, as well as pain and numbness in the implanted area were evaluated by an ENT specialist.

Audiological assessment

The following audiological tests were performed:

- pure tone audiometry: (1) with headphones – AC and BC – before surgery, (2) in free field (FF): first, before surgery, unaided and with the Baha® 5 Power sound processor on the Softband, and then, after surgery, with the implanted Osia® device; free field thresholds were measured using warble tones presented from the loudspeaker which was situated 1 m in front of a patient,
- speech audiometry (Polish Monosyllabic Word Test): (1) with headphones – in quiet, (2) in free field – both in quiet and in noise (the speech of 50 dB, 65 dB and 80 dB SPL was presented from the loudspeaker which was situated 1 m in front of a patient; the noise of 55 dB SPL was presented from the loudspeaker placed behind a patient) – first, before surgery, unaided and with the Baha® 5 Power sound processor on the Softband, and then, after surgery, with the implanted Osia® device,
- direct bone conduction measured through the implanted device (BC *in situ*),
- subjective patients' evaluation of the quality of sounds with the implanted device – 4 parameters were evaluated using a scale ranging from 1 (the worst) to 5 points (the best): sound loudness, sound distinction, hearing of one's voice and reverberation.

Fig. 2. The Cochlear™ Osia® System. 1 – sound processor, 2 – receiver-stimulator module, 3 – connecting cable, 4 – piezoelectric transducer, 5 – BI300 implant. Image by Cochlear Bone Anchored Solutions, Gothenburg, Sweden © Cochlear Limited 2020. All rights reserved.

The audiological tests were performed with the Otometrics Madsen Astera in a soundproof room. During all free field tests, the contralateral ear was blocked with an earplug. Performing pure tone audiometry and speech audiometry in free field allowed to compare the results obtained with the Osia® device with: 1) the results obtained in unaided situation, thus measuring audiological gain of this new device, and 2) the results obtained with the Baha® 5 Power sound processor on the Softband, which, according to literature data, indicate a potential benefit of Baha® Attract implantation [16].

The quality of life benefits

The impact of implantation on the quality of life was evaluated by the comparison of preoperative and postoperative results of APHAB (Abbreviated Profile of Hearing Aid Benefit) and SSQ (Speech, Spatial and Qualities of Hearing Scale) questionnaires.

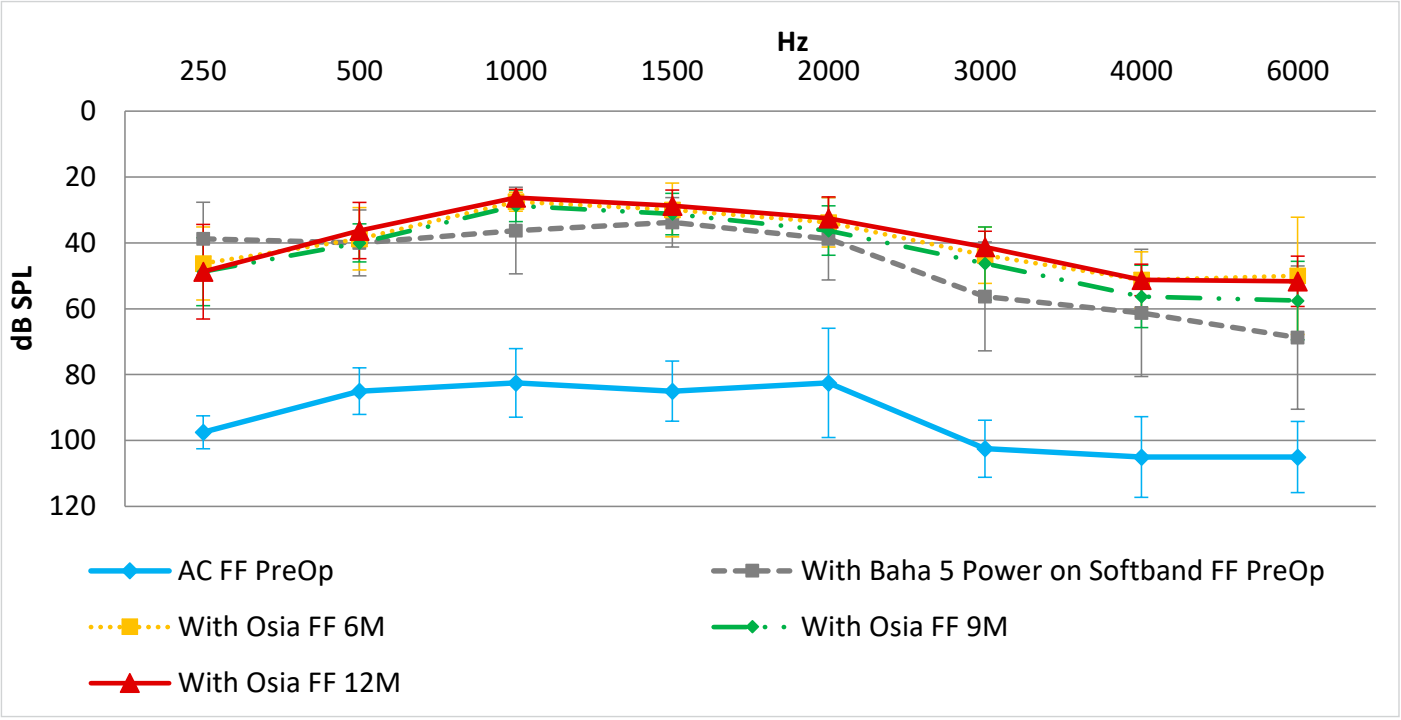

Fig. 3. The results of pure tone audiometry in free field (mean value with a standard deviation) with the implanted Osia® device in comparison to the preoperative results – unaided and with the Baha® 5 Power processor on the Softband; PreOp – before surgery, 6M – six months after surgery, 9M – nine months after surgery, 12M – twelve months after surgery.

RESULTS

The state of the soft tissues in the implanted area

In all the cases, no postoperative complications were found. Six, nine and twelve months after surgery, the skin integrity was preserved, the operated area was free of pain, and the skin sensitivity was normal in all the cases.

Audiological benefits

Pure tone audiometry

In all the patients, a significant improvement was observed in pure tone audiometry in free field with the implanted device, in comparison to unaided hearing. The mean results of FF PTA4 at six, nine and twelve months after surgery were 38 ± 10, 40 ± 12 and 37 ± 10 dB SPL respectively. The audiological gain, calculated as a difference between the postoperative FF PTA4 results with Osia® and preoperative FF PTA4 unaided results, was 51 ± 4, 48 ± 4 and 52 ± 3 dB at six, nine and twelve months after surgery respectively. The obtained results were also better than those with the Baha® 5 Power processor on the Softband. The difference between the postoperative FF PTA4 results with Osia® and preoperative FF PTA4 results with Baha® 5 Power processor on the Softband, was 6 ± 4, 4 ± 3 and 7 ± 3 dB six, at nine and twelve months after implantation respectively. The improvement was observed especially in high frequencies – for 6 kHz, the difference at six, nine and twelve months after surgery was 19 ± 8, 11 ± 8 and 17 ± 8 dB, respectively. The details are presented in Fig. 3. and in Tab.III.

Speech audiometry

A significant improvement was observed in speech understanding in free field, both in quiet and in noise, with the implanted device in comparison to the unaided situation. Before surgery, a mean of 23.8 ± 27.5% of speech understanding was achieved only at 80 dB SPL in quiet. One year after surgery the mean speech understanding with Osia® in quiet was 90.0 ± 8.2% for 50 dB SPL, 98.8 ± 2.5% for 65 dB SPL and 100 ± 0.0% for 80 dB SPL, and the mean speech understanding with Osia® in noise was 37.5 ± 23.6% for 50 dB SPL, 93.8 ± 4.8% for 65 dB SPL and 98.8 ± 2.5% for 80 dB SPL. Generally, the results after surgery were much better in comparison to those before surgery with the Baha® 5 Power processor on the Softband, with which our group of patients obtained a mean of 27.5 ± 15.0% for 65 dB SPL and 73.8 ± 11.1% for 80 dB SPL in quiet, and 8.8 ± 6.3% for 65 dB SPL and 71.3 ± 6.3% for 80 dB SPL in noise. The details are presented in Fig. 4. and in Tab. IV.

Direct bone conduction

For most frequencies, the results of bone conduction in the in situ measurements with the implanted device were better in comparison to the preoperative levels. The mean BC PTA measured with the implanted device was 35 ± 9, 34 ± 9 and 33 ± 8 dB HL at six, nine and twelve months after surgery, respectively. The mean preoperative BC PTA measured with bone conduction headphones was 43 ± 6 dB HL. The details are presented in Fig. 5.

Subjective quality of hearing

The patients evaluated the quality of hearing very high, considering all four aspects (sound loudness, sound distinctness, hearing of

Tab. IV. Individual results of free field pure tone audiometry of implanted patients.

IN QUIET															
PATIENT	BEFORE SURGERY UNAIDED [%]			BEFORE SURGERY WITH BAHA® 5 POWER ON SOFTBAND [%]			AFTER SURGERY 6 MONTHS WITH OSIA® [%]			AFTER SURGERY 9 MONTHS WITH OSIA® [%]			AFTER SURGERY 12 MONTHS WITH OSIA® [%]		
[dB SPL]	50	65	80	50	65	80	50	65	80	50	65	80	50	65	80
1	0	0	50	0	50	90	0	90	100	0	60	100	90	100	100
2	0	0	0	0	20	70	0	90	100	10	90	100	100	100	100
3	0	0	0	0	20	65	0	80	100	0	50	100	80	100	100
4	0	0	45	0	20	70	0	80	100	0	80	100	90	95	100
IN NOISE															
PATIENT	BEFORE SURGERY UNAIDED [%]			BEFORE SURGERY WITH BAHA® 5 POWER ON SOFTBAND [%]			AFTER SURGERY 6 MONTHS WITH OSIA® [%]			AFTER SURGERY 9 MONTHS WITH OSIA® [%]			AFTER SURGERY 12 MONTHS WITH OSIA® [%]		
[dB SPL]	50	65	80	50	65	80	50	65	80	50	65	80	50	65	80
1	0	0	0	0	15	80	0	70	100	0	60	90	20	90	100
2	0	0	0	0	10	70	0	90	100	0	90	100	70	100	100
3	0	0	0	0	0	65	0	80	100	0	50	90	40	95	95
4	0	0	0	0	10	70	0	40	100	0	40	100	20	90	100

their own voice, and reverberation). The mean results of all these aspects were 4.75 to 5.00 in a five-point scale. The details are presented in Fig. 6.

The quality of life results

The number of hearing problems evaluated by the APHAB scale in different acoustical situations was significantly reduced after implantation. The reduction of problems in a global score after six, nine and twelve months was 67.1 ± 9.2%, 65.6 ± 6.3% and 66.1 ± 10% respectively. An evident improvement was observed in three subscales: EC (ease of communication), BN (background noise), RV (reverberation). In the AV (aversiveness) subscale there was a deterioration (which is typical for the use of hearing prosthetic devices). The details are presented in Fig. 7.

Similarly, an evident improvement in the quality of hearing, speech hearing and spatial hearing measured by the SSQ scale was observed after implantation. The results for "speech" subscale increased from 4.5 ± 0.8 before surgery to 9.2 ± 0.5, 9.3 ± 0.4 and 9.3 ± 0.4 at six, nine and twelve months after surgery, respectively. The results for "spatial" subscale also increased from 3.5 ± 1.6 before implantation to 8.7 ± 0.7, 8.8 ± 0.7 and 8.9 ± 0.6 after surgery. Similarly, there was an improvement of the "quality" subscale from 5.1 ± 0.6 before intervention to 9.5 ± 0.2, 9.6 ± 0.4 and 9.4 ± 0.5 afterwards. The details are presented in Fig. 8.

DISCUSSION

In this study, the mid-term results of the new Osia® system are presented. This device differs from the previous bone conduction systems in a position of a transducer (active system) but also in its construction (piezoelectric instead of electromagnetic). The efficiency of a piezoelectric transducer was proven in cadaver studies [17, 18]. To the best of our knowledge, there are only four published studies concerning surgery and benefits of the above-mentioned Osia® device; three single-center, with a follow-up no longer than 6 months and a limited number of patients [15, 19, 20], and one multicenter [21]. The results of all these studies showed safety of surgery, an evident audiological gain and functional benefits of this device. Our present study confirms these excellent audiological and functional results. One can ask if this device has any audiological or functional advantage over other non-skin penetrating systems with similar hygienic and esthetic benefits. Thus, further discussion concerns the mid-term results obtained in our group in comparison to those reported for the Baha® Attract and the Bonebridge®.

Our study showed no complications in the implanted area in a mid-term observation. Initially observed postoperative pain disappeared quickly, and numbness in the operated area was not observed at six, nine and twelve months after surgery. Similarly, generally good healing and low rate of complications after implantation, both for the Baha® Attract and the Bonebridge®, were reported [10, 12–14, 16]. Moreover, gradual reduction of local complaints over time had been previously described for the cases implanted with the Baha® Attract in big cohorts of patients [10, 16], however, even 6 months after surgery some degree of discomfort or pain was still observed in nearly 38% of the cases [16]. On the other hand, most of the minor adverse events reported after implantation of Bonebridge® were not observed at 6-month follow-up [14].

Furthermore, we found that there was an evident audiological benefit after the Osia® implantation, when compared to the unaided conditions. In our group of patients, a significant improvement was observed in pure tone audiometry and speech audiometry, both in quiet and in noise. Six, nine and twelve months after surgery, the mean audiological gain in pure tone audiometry (51, 48 and 52 dB) was really impressive, and exceeded that reported for both the Baha® Attract [16] and the Bonebrige® [12–14]. The mean improvement in pure tone audiometry after the Baha® Attract implantation in

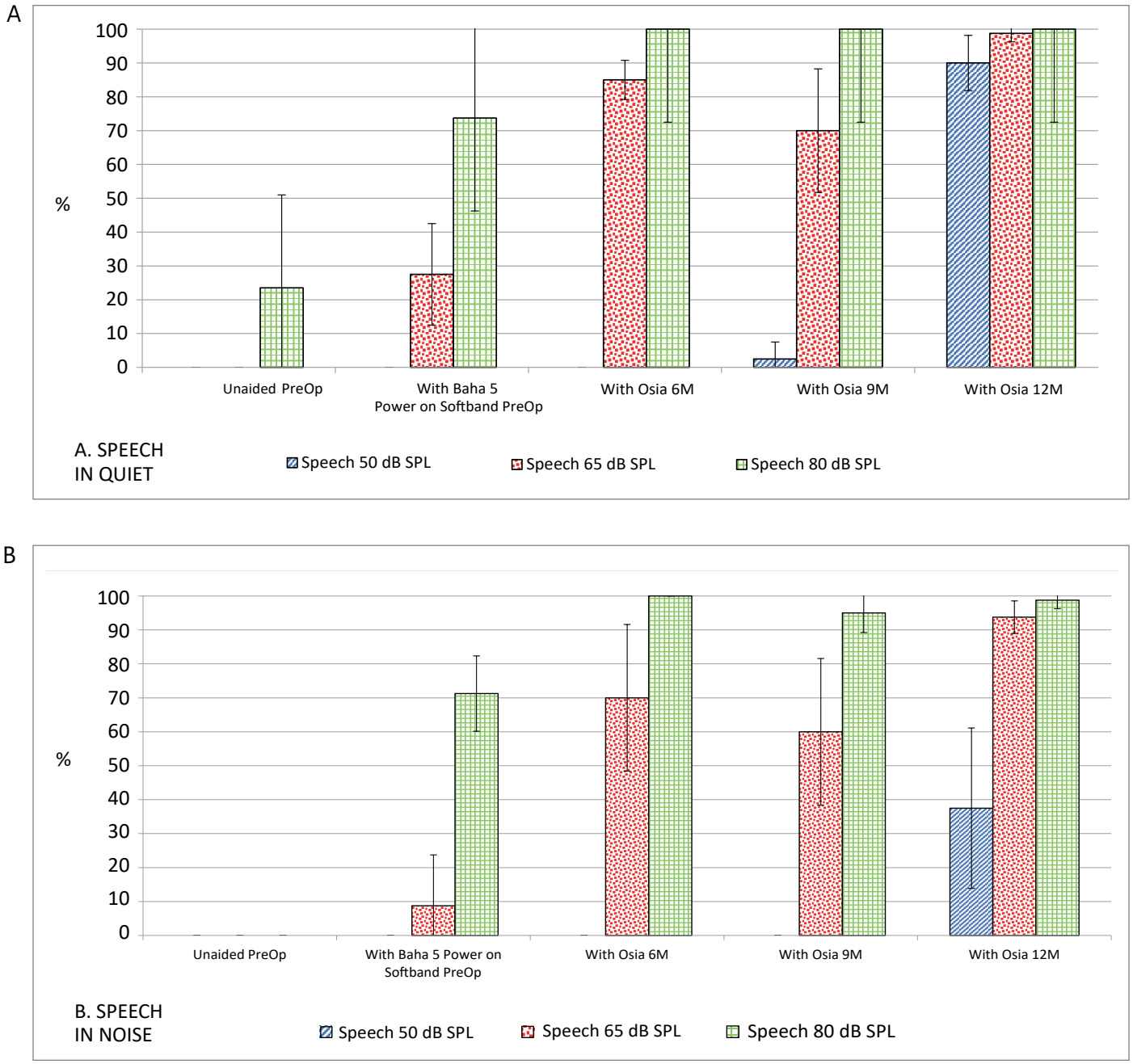

Fig. 4. The results of speech audiometry in free field (mean value with a standard deviation) in quiet (A) and in noise (B); PreOp – before surgery, 6M – six months after surgery, 9M – nine months after surgery, 12M – twelve months after surgery.

patients with conductive and mixed hearing loss six months after surgery reported in a recent multicenter study was 20.8 dB [16]. In a systemic review of the literature concerning the Bonebrige® device, the gain in pure tone audiometry after implantation of patients with conductive and mixed hearing loss was found to range from 24 to 37 dB (results of seven studies in a total of 58 subjects) [12]. According to other recent studies concerning the Bonebridge® device, it was 24 dB (patients with mixed hearing loss) [13] and 28 dB (cases with conductive and mixed hearing loss) [14]. Our results were also better than those reported for Osia® in the previous studies [19–21]. The mean gain in pure tone audiometry observed two months after implantation of the Osia® in a group of nine patients with conductive hearing loss was 36.88 dB [19], four months after surgery in a group of five cases with mixed hearing loss it was 31 dB [20] and twelve months after surgery in a group of 32 cases with mixed and conductive hearing loss it was 30.9 dB [21].

Moreover, in our Osia® patients, a significant improvement was observed in a percentage of correctly perceived words in speech audiometry, both in quiet and in noise. In quiet, six months after surgery the mean improvement of 85% and 76.2% for 65 and 80 dB SPL respectively, was much better than that obtained for the Baha® Attract reported in the multicenter study (44.5% for 65 dB and 13.8% for 80 dB) at the same time of observation [16]. Furthermore, our results in quiet for 65 dB were better than those reported for patients with mixed hearing loss implanted with Bonebridge® (improvement of 44.4%) [13].

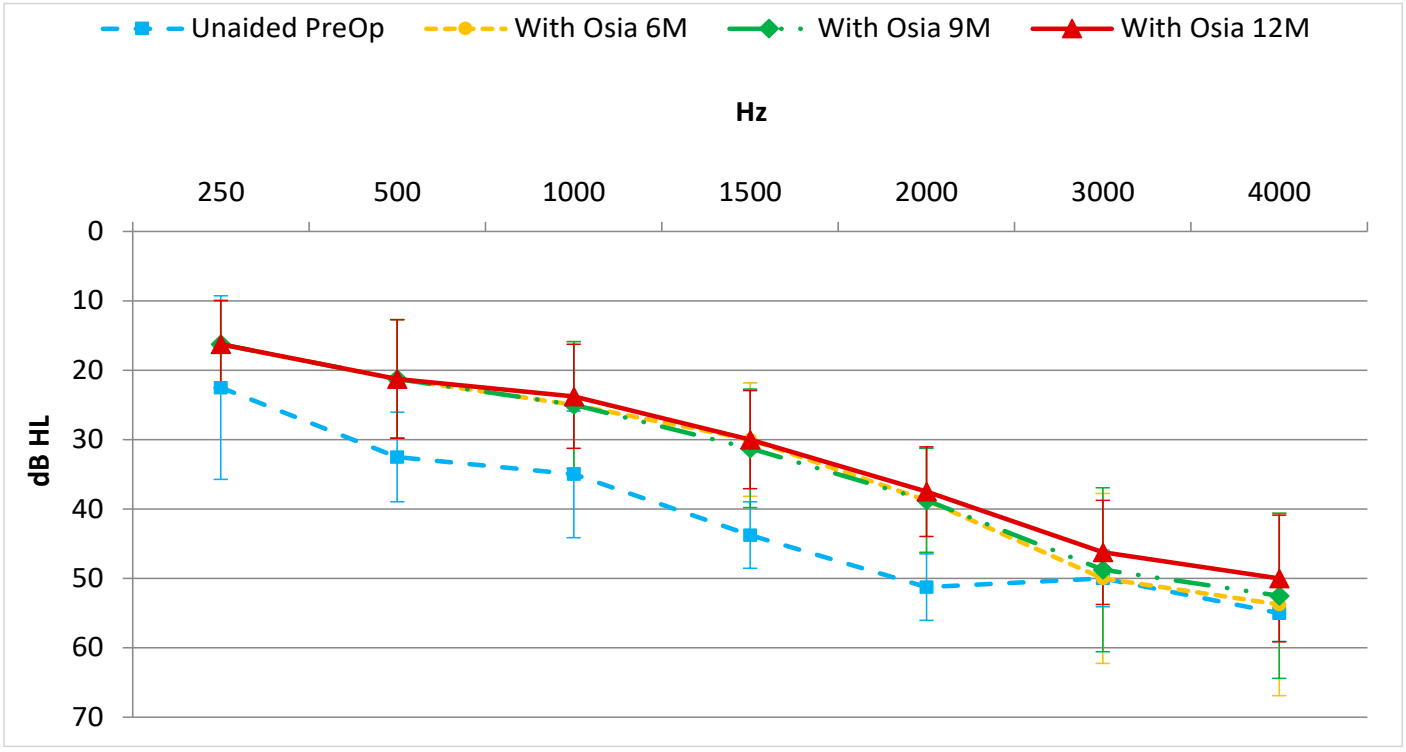

Fig. 5. The difference in bone conduction between the in-situ measurements with the implanted device (6M – six months after surgery and 9M – nine months after surgery, 12M – twelve months after surgery) and those performed preoperatively (PreOp) by using pure tone audiometry with bone conduction headphones (mean value with a standard deviation).

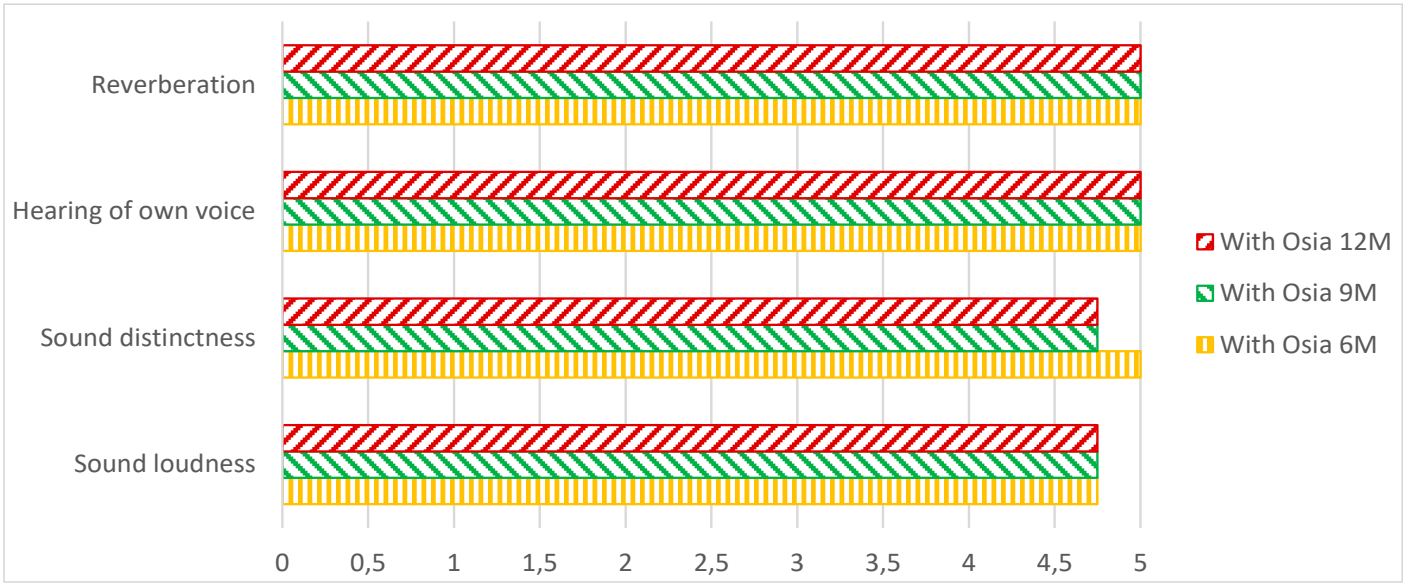

Fig. 6. The quality of hearing (mean results) – patients' subjective opinion at six, nine and twelve months after surgery – every parameter evaluated from 1 (the worst) to 5 points (the best) (6M – six months after surgery, 9M – nine months after surgery, 12M – twelve months after surgery).

We are conscious that all these audiological comparisons with other studies should be evaluated critically and in relation to preoperative hearing results. Detailed analysis shows that our patients had much worse preoperative audiograms (both BC and AC) than those analyzed in the multicenter Baha® Attract study [16], in the recent Bonebridge® studies [13, 14] and in two previous Osia® studies [19, 21]. BC PTA4 was 12–32 dB worse, and AC PTA4 was 14–24 dB worse compared to the above-mentioned studies.

In turn, there is no doubt that the audiological benefit after the Osia® implantation was higher than that with the Baha® 5 Power processor on the Softband before surgery, and the difference is especially evident in speech audiometry, both in quiet and in noise. This is in contrast to the results of the Baha® Attract obtained in the above-mentioned multicenter study, which showed no significant difference between the postoperative results and preoperative results with the Softband [16]. This observation confirms that the Osia® is a more powerful device.

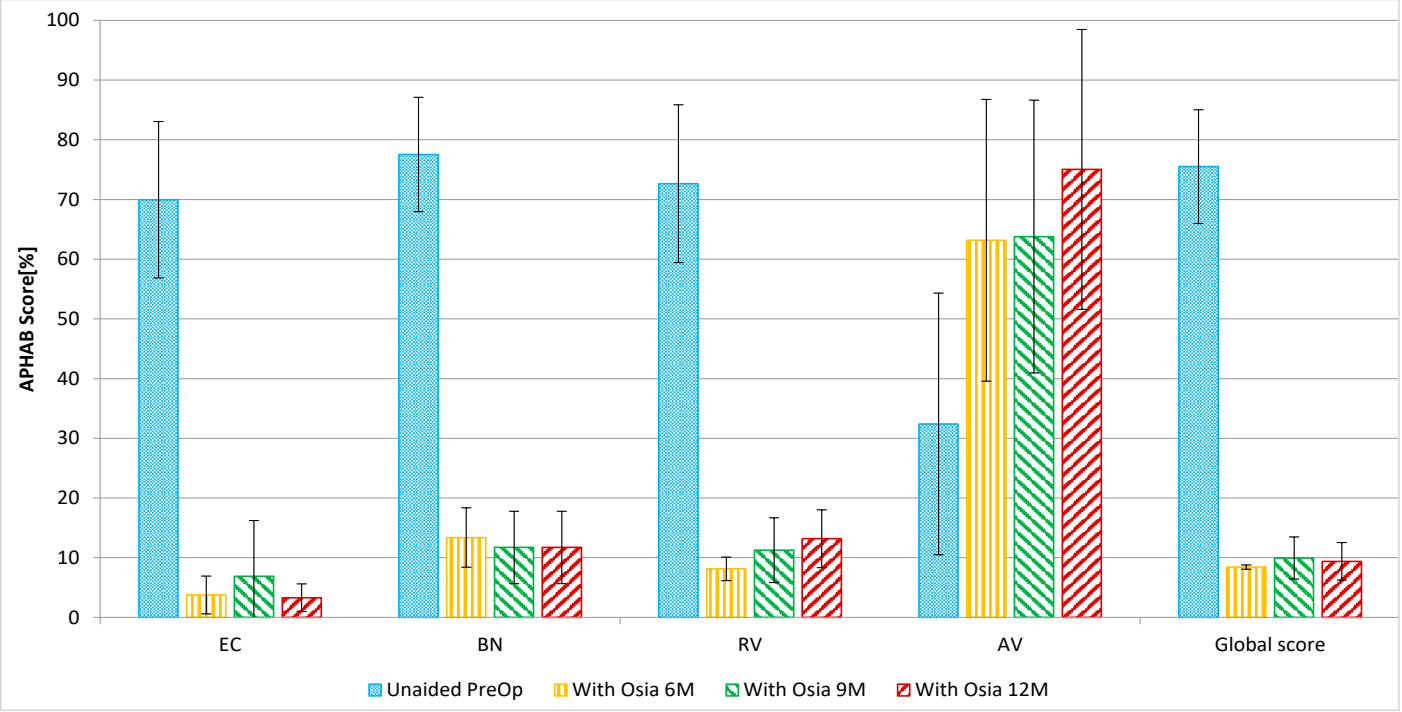

Fig. 7. The benefits of the Osia® implantation – the APHAB scale (mean value with a standard deviation); PreOp – before surgery, 6M – six months after surgery, 9M – nine months after surgery, 12M – twelve months after surgery; EC – ease of communication, BN – background noise, RV – reverberation, AV – aversiveness, Global score – mean of EC, BN and RV.

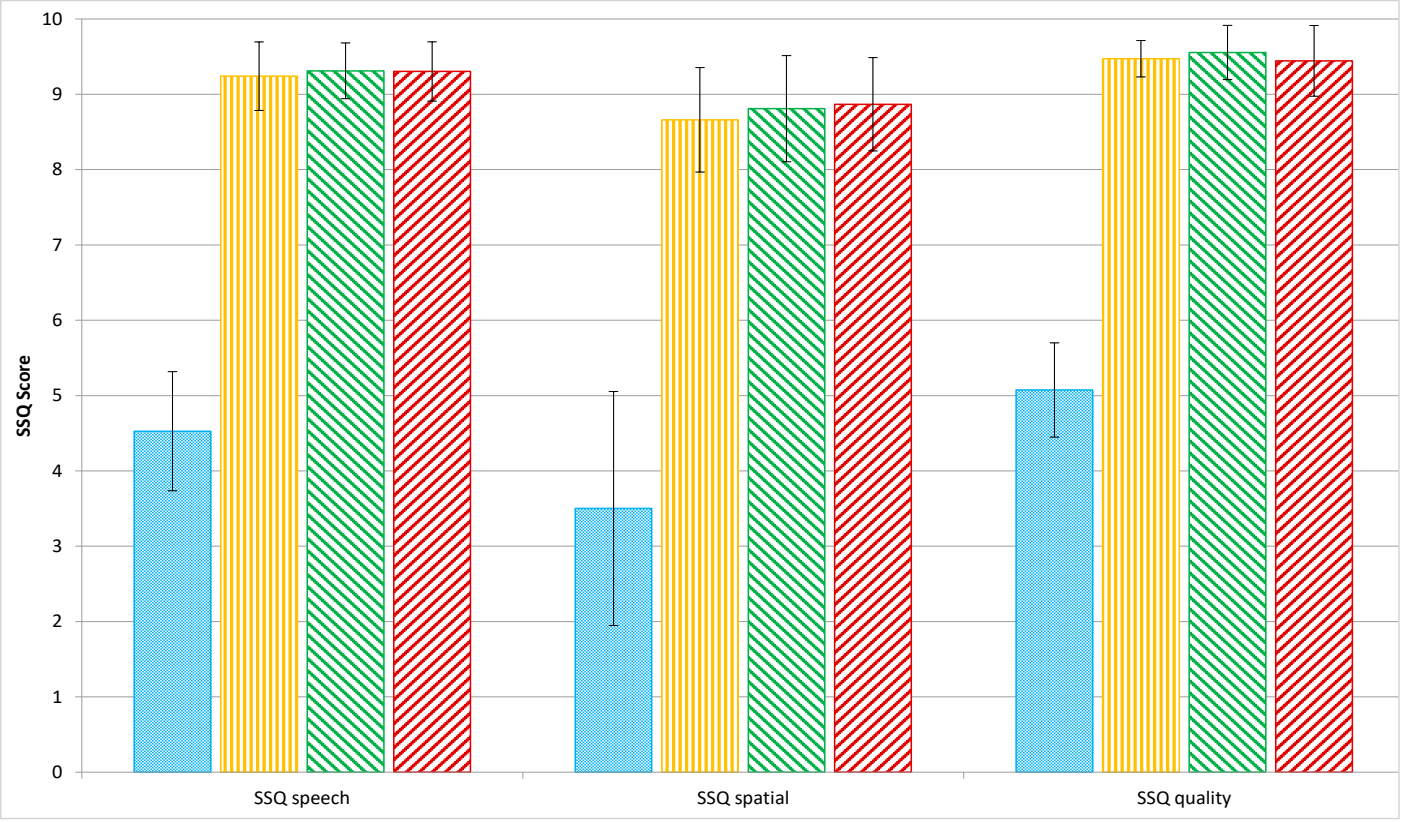

Fig. 8. The benefits of the Osia® implantation – the SSQ scale (mean value with standard devation); PreOp – before surgery, 6M – six months after surgery, 9M – nine months after surgery, 12M – twelve months after surgery; SSQ speech – speech hearing, SSQ spatial – spatial hearing, SSQ quality – qualities of hearing.

Additional audiological evaluation of our patients showed better results of bone conduction measured with the Osia® device (BC in situ) than the ones measured preoperatively with bone conduction headphones, which is the result of a direct stimulation of a bone without attenuation by the skin when measuring with Osia®. Moreover, the subjective evaluation of four aspects of the quality of hearing in our study indicated that the Osia® is a very good solution.

We have also observed an evident improvement in the quality of life after the Osia® implantation measured by both the APHAB and the SSQ scale. The gain in the reduction of hearing problems in different acoustical situations evaluated by the APHAB questionnaire was evident at six, nine and twelve months after surgery, as well as the benefits measured by the SSQ scale.

Six months after surgery, the mean improvement in the APHAB global score was 67.1% and was much higher than 26.5% reported by den Besten et al. in Baha® Attract patients after the same time of follow-up [16]. Similarly, the improvement for Osia®, six months after surgery, was higher in all SSQ subscales than that reported for Baha® Attract [16] (speech 4.7 *vs* 2.7, spatial 5.2 *vs* 2.1, quality 4.4 *vs* 1.8). The results of APHAB for the Bonebridge® device have been reported in a recent study [14]. The percentage of hearing problems in a global score decreased from 48.5% before surgery to 29.6% after a 6-month follow-up (improvement of 18.9%).

Another observation from our study is that most of the above-mentioned mid-term audiological and quality of life benefits were much more evident than those observed three months after surgery published in our previous study [15], which suggests that some time is required for experiencing optimal benefits of an implanted device. This is in agreement with the observations made by Goycoolea et al. [19]. We are conscious that our study has some limitations, especially a small number of implanted patients, so the power of our observations is limited. However, we believe that the benefits of this new device are evident and worth being published without a delay.

In conclusion, the Osia®, a new active bone conduction implant, is an effective option to treat patients with bilateral mixed hearing loss. The mid-term audiological and quality of life results are excellent, but further observations in bigger groups of patients followed by a longer follow-up are required.

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