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Outcomes after Bonebridge Implantation: Audiological Benefits and Health Related Quality of Life

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Abstract

Objective: Bone conduction implants (BCI) are medical devices for conductive and mixed hearing losses as well as for single side sensorineural deafness (SSD). All direct-drive BCI transmit vibrations directly to the skull bone and can be divided into percutaneous and active transcutaneous devices.

Method: We report a case series of 10 patients, suffered from mixed or conductive hearing loss, submitted to Bonebridge implantation. Audiological evaluation was conducted at six months to observe the functional impact of this device. Patients were asked to answer the Glasgow Benefit Inventory (GBI), a retrospective questionnaire, to measure the effect of the surgical intervention on the health-related quality of life.

Results: The functional gain was found to range from 25 dB to 40 dB. Speech perception in noise improves in all patients and no post-operative complications were observed. GBI questionnaire has reflected high device satisfaction rate.

Conclusion: Active transcutaneous BCI represent an effective and safety solution for people that cannot have adequate benefit from conventional hearing aids, to restore good audiological performance and life satisfaction.

Keywords: Bonebridge implantation; Audiological benefits; Health related quality of life

Introduction

The Bonebridge (BB) is an active transcutaneous bone conduction implant that has become a successful treatment modality for patients who suffer from conductive or mixed hearing loss or are affected by single sided sensorineural deafness, and cannot benefit from conventional hearing devices [1,2]. It consists of an external part, the audio processor (Amadèe BB), and an implanted part, the bone conduction implant (BCI). It uses a bone conduction floating mass transducer (BC-FMT) which is surgically fixed with two screws and is activated by an external Audio processor via a transmitter coil [3].

The BC-FMT has a diameter of 15.8 mm and a height of 10 mm, 8.7 mm of which is implanted into the bone. The weight is approximately 10 g. The implanted part is placed in the mastoid and temporal regions and it transmits the vibrations to the bone, by directly stimulating the inner ear, where they are processed like normal sound [2].

The underlying disease and the anatomical aspects of each patient help to evaluate the optimal surgical approach and also to decide where to fix the screws [4,5]. In a normal anatomy, the BC-FMT should be placed in the sinodural angle, avoiding any compression of the sigmoid sinus and the dura. The bone integration of the screws is not needed; the processor can be programmed as soon as the swelling of the skin has reduced [6].

Materials and Method

Ten adults (six females and four males) with hearing loss, that cannot have adequate benefit from conventional hearing aids, were recruited from the patient population referred to ENT Department of Reggio Emilia Hospital (Italy). The mean age was 53.2 years (range 31 to 71 years). All subjects gave their informed consent for the experimental study, which was approved by the Institutional Ethic Board.

The patients met the audiological indication for BB implant. Indication includes bone conduction thresholds better than or equal to 45 dB HL at 0.5; 1; 2; 4 kHz. The type of hearing loss was mixed in six patients and conductive in the others. Inclusion criteria were not restricted to a unique aetiology Preoperative mean average ABG on the ear to be implanted was 39.2 +/- 7 dB (Table 1).

Pre-operative CT scan, with a dedicated software, was performed to choice the correct position of the BC-FMT, basing of the anatomical and radiological aspects of each patients.

Audiometric assessment

Tone and speech audiometry were performed pre and post-operatively. Audiological measurements obtained were performed according to the standards of the "Committee on Hearing and Equilibrium guidelines for the evaluation of results of treatment of conductive hearing loss" (1995) [7]. The PTA_4 was performed at 0.5, 1, 2 and 4 kHz for air (AC) and bone (BC) conduction. The air-bone gap (ABG) was determined by subtracting the post-operative BC-PTA_4 from post-operative AC-PTA_4. Functional hearing gain, defined as the difference in dB between sound field thresholds with and without BB implant, was assessed for frequencies at 0.5, 1, 2, 4 kHz. Speech perception in noise was measured using a conventional test that includes twenty bisyllabic words that had been presented with a signal of 65 dB SPL and a background noise fluctuated (signal noise ratio [SNR] respectively of +10, +5, 0). It was tested in three condiction: unaided, with conventional hearing aids and with BB implant.

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N°	Age	Sex	Pathology	Hearing device used	Pre-AC-PTA4 (implanted side)	Pre BC-PTA4 (implanted side)	Pre-ABG (implanted side)
1	31	F	Atresia auris	BC-device	66.25 dB	23 dB	43.25
2	66	F	otosclerosis	AC-device	60 dB	23 dB	37
3	53	F	otosclerosis	AC-device	65	25 dB	40
4	49	M	Chronic otitis with cholesteatoma	BC-device	75 dB	30 dB	45
5	51	M	Simple chronic otitis	BC-device	70 dB	33 dB	37
6	65	F	otosclerosis	AC-device	65 dB	25 dB	40
7	49	M	Chronic otitis with cholesteatoma	BC-device	75.25 dB	35 dB	40.25
8	43	F	Chronic otitis with cholesteatoma	BC-device	80 dB	40 dB	40
9	54	M	Chronic otitis with cholesteatoma	BC-device	75 dB	35 dB	40
10	71	F	Chronic otitis with cholesteatoma	BC-device	65 dB	34 dB	31

BC: Bone-Conduction; AC: Air-Conduction; Pre AC-PTA4: Preoperative Air-Conduction Pure Tone Average; Pre BC-PTA4: Preoperative Bone-Conduction Pure Tone Average; Pre-ABG: Preoperative Air-Bone Gap

Table 1: Subjects demographics and clinical factor of patient operated.

Degree of satisfaction's assessment

The Glasgow Benefit Inventory (GBI) was used to measure the quality of life and the change in health status produced by the surgical intervention [8]. This questionnaire, which can complete by interview or self-completed by patients, consists of 18 questions. Responses can be given on a 5-point Likert scale, with a score range from -100 (maximum lack of benefit) to +100 (maximum benefit). There are three distinct subscales. Twelve questions focused on general changes in health status, as well as change in psychosocial health (general subscale). A further three questions were related to the amount of social support needed in relation to the patient's condition (social subscale). The remaining three questions addressed changes in physical health status (physical subscale).

Results

In our case series no intra-operative complications were observed. None of the patients submitted to BB implant, presented complications in the postoperative period. No skin reactions, wound infections or implant extrusions were observed locally in all the patients.

The Table 2 shows the postoperative outcomes after six months from Bonebridge implantation. The unaided bone conduction and air conduction thresholds were unchanged in all patients. After activation and fitting of the implant, mean average ABG was reduced to 1.5 +/- 5.3 dB. The questionnaires (GBI) prove the degree of satisfaction of the patients. Speech recognition in noise showed a very good performance with BB implant as shown in Table 3.

Functional gain in free field after BB implantation	Decibel (dB)	Standard deviation
	32.42	6.37
GBI questionnaire	Patient group score	Standard deviation
Total Glasgow score	63	18.12
General subscale	71.6	16.29
Social subscale	66 .6	16.1
Physical subscale	51.6	25.1

Table 2: Functional gain (in free field) and GBI score mean.

Speech recognition in noise	Unaided condiction	With conventional hearing aid	With BB implant
SNR +10	69.00%	75.00%	100.00%
SNR +5	36.00%	68.00%	87.00%
SNR 0	8.00%	20.00%	68.00%

Table 3: Speech recognition in noise for BB group – average percentage of word recognition in all ten patients.

Discussion

In general BCI are used for conductive and mixed hearing loss not treatable by surgery and by traditional air\bone conduction hearing aids or in the patients with bilateral middle ear agenesis or in patients with SSD [1,2]. Direct-drive BCI offers acoustic and aesthetic benefits compare to other bone conduction devices [9]. The BB avoids the most common problems presented by traditional hearing aid as local irritation, itching and headaches caused by the pressure that must be necessarily applied by the transducer behind the ear [10,11]. The position of BB was determined under the evaluation of a preoperative CT images in relation to the anatomical structures and their possible anomalies. The implant was activated four weeks after surgery. The questionnaire was done when the free field test and speech in noise were performed.

We evaluate the satisfaction and the health benefit produced through the Glasgow Benefit Inventory questionnaires (GBI). The total score GBI demonstrated the improvement of life´s quality regarding the Social Support and Physical Health for all patients. The three subscales were used in order to elicit the profile of improvement across GBI scores and interventions.

The study shows a substantial improvement in both tonal and speech audiometry in all patients, better than conventional hearing aids, especially in noise condition. This is due to the fact that direct drive BCI transmits vibrations directly to the skull bone and show a better performance than traditional hearing devices, which the attenuation of the signal is up to 10-15 dB [12]. With the test speech in noise at 65 dB SPL, a very good performance with the BB is noted. This study shows the improvement compared to an unaided condition and the benefit for the patient to be able to participate in a fully active social life. The candidates were satisfied and it was noticed that the binaural performance was restored and the capacity in understanding was improving.

Conclusion

In our opinion, BCI implants represent a safe and effective solution for people with mixed or conductive hearing loss that cannot be aided with conventional hearing aids.

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