Audiological Results and Quality of Life of Sophono Alpha 2 Transcutaneous Bone-Anchored Implant Users in Single-Sided Deafness

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AUDIOLOGICAL RESULTS AND QUALITY OF LIFE OF SOPHONO ALPHA 2 TRANSCUTANEOUS BONE-ANCHORED IMPLANT USERS IN SINGLE-SIDED DEAFNESS

RUNNING TITLE: SOPHONO ALPHA 2 IN SSD

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ABSTRACT

Single-sided deafness (SSD) represents one of the most difficult audiological condition to rehabilitate. The aim of this prospective study was to evaluate the audiological benefits and the quality of life when upgrading to Sophono Alpha 2® (Boulder, Colo., USA) external processor, patients affected by SSD previously users of Alpha 1®. Nine patients have been included. They underwent physical examination, free-field speech audiometry at 40dB and 60 dB, hearing in noise test (Hirsch's test and squelch test), Glasgow benefit inventory (GBI) questionnaire, and patient's satisfaction specific questionnaire with Alpha 1®. Afterwards, the Alpha 2® external processor was delivered to all patients and the above mentioned protocol was repeated after 1 month with the Alpha 2®. A statistically significant improvement was found in the speech discrimination score at 40 dB and in the squelch test when using the Alpha 2® external processor compared to the Alpha 1®. Concerning clinical tolerance, the specific questionnaire and the GBI, the differences were not significant. The new Alpha 2® external processor represents a safe and effective device for the rehabilitation of SSD and there is an audiological benefit from upgrading to Alpha 2® external processor patients previously users of the Alpha 1®. The improvement in the quality of life is similar to other bone-anchored hearing devices.

Keywords: single-sided deafness, transcutaneous bone-anchored hearing device, Hearing aids, bone conduction, implantable hearing aids, hearing loss

INTRODUCTION

Single sided deafness (SSD) affects the quality of life of the patients, since they experience discomfort in difficult situations such as hearing in noise or localizing the sound [Douglas et al., 2007]. The loss of hearing in one ear suppresses the interaural time and sound level differences that are responsible of localization [Kitterick et al., 2014]. Patient affected by SSD also show the effect of the acoustic shadow of the head [Carlile, 2006] which is the cause of these difficulties [Van Wanrooij, and Van Opstal, 2004]. Finally, listening to sounds coming from impaired side is also challenging for these patients.

Many studies have been carried out in order to define which was the optimal treatment for this pathological condition. Contralateral rerouting of signal (CROS) hearing aids [Finbow et al., 2015; Bosman et al., 2003; Hol et al., 2005; Wazen et al., 2003], and percutaneous bone-anchored hearing devices [Faber et al., 2013; Zeitler et al., 2012; Stewart et al., 2011; Martin et al., 2010] have been proposed for the rehabilitation of SSD with different results. More recently, cochlear implant has been suggested for the rehabilitation of SSD [van Zon et al., 2015; Erbele et al., 2015; Arndt et al., 2011; Vermeire, and Van de Heyning, 2009].

The Sophono Alpha® system (Sophono, Boulder, Colo., USA) is a transcutaneous bone conductive hearing device: the major advantage of this system, compared to the percutaneous ones, is the presence of the intact skin that dramatically reduced the skin related complications [Wazen et al., 2008]. The use of Alpha 1® system has already been described for conductive or mixed hearing loss, in adults and in children [Sylvester et al., 2013; Escorihuela-García et al., 2014; Siegert, and Kanderske, 2013; Hol et al., 2013; Magliulo et al., 2014; Denoyelle et al., 2013]. The first prospective clinical study comparing the Alpha 1® system and CROS hearing aids in SSD has been recently published [Leterme et al., 2015]. Authors showed that the Alpha 1® was preferred to CROS in 72% of patients and that the hearing performance were significantly improved when using the Alpha 1® system compared to unaided condition, whereas there were not statistically significant differences when comparing the audiological outcomes of the 2 devices.

Recently, the new Sophono Alpha 2® external processor has been released: the main differences between the Alpha 1 and the Alpha 2 are the following:

- A more square and little shape (Fig. 1A and 1B)
- The presence of 8 digital channels (instead of 4) with 8 programmable settings to facilitate program changing in different environments
- The presence of 2 microphones (instead of 1 omnidirectional); the first one is directional and the second is omnidirectional
- Transcutaneous energy transmission technology that should allow obtaining a functional gain of 30 dB by optimizing the mechanical impedance close to skin impedance. It uses an impedance adaptation achieved by a design of the device and the implemented force transducer that decreases the impedance over the relevant range for speech recognition to the impedance of the skin. This is achieved by two resonance frequencies close to each other in the relevant range flattening the transfer barriers through the skin and matching the resonance behaviors of the device and the skin.

The aim of this prospective clinical study was to analyze the audiological performance and quality of life (QOL) of patients affected by SSD previously users of Alpha 1® external processor, when upgrading them to the new Alpha 2® external processor.

MATERIALS AND METHODS

This prospective clinical study was authorized by the hospital ethical committee and all patients gave the written consent for the use of their clinical data. Collin® Ltd. (Bagneux, France), local distributor of Alpha system, supported this study by providing the Alpha 2® external processor to all patients.

The Sophono Alpha ® system consists in one external processor and one implantable twin magnet (Fig. 1C). The external processor contains a bone conductive oscillator which is mounted on two external magnets. The implantable twin magnets are encapsulated in a titanium case which is fixed to the skull with five little arms.

Nine patients were included in this protocol (Tab. 1). All patients had been using the Alpha 1® system for at least 1 year. ~~There were 5 males and 4 females. The mean age was 50 ± 9.9 years (mean ± SD, range 40/65 years); the right side was involved in 5 cases, the left side in 4 cases. The etiology of unilateral hearing loss was vestibular schwannoma surgery (22%), sudden sensorineural hearing loss (22%), chronic otitis (11.2%) with ipsilateral profound hearing loss, head trauma (11.2%), ototoxicity (11.2%), mumps (11.2%), congenital (11.2%). The mean air conduction threshold (mean of the frequencies 500, 1000, 2000 and 4000 Hz) of the contralateral ear was 21± 9 dB and the bone conduction threshold was 14 ± 8.6 dB (Tab. 1).~~

At the first visit, a physical examination of the skin over the implant was performed (normal or hyperemic). The strength of the magnet, ranging from 0 to 7 was noted. The strength of the magnet was the lowest strength that allowed the uncoupling of the external device when a strength ranging from 1 and 1.5 N was applied with a specific tool. The total hour of wearing the external processor per day was analyzed, as well as the regularity of wearing the external processor (everyday or occasionally in particular situation as in noisy environment, in social activities etc.).

Audiological tests

All tests were performed in an audiometric insonorized room. The mean air conduction (AC) and bone conduction (BC) thresholds were calculated using headphone (mean of the frequencies 500, 1000, 2000 and 4000 Hz). In the free-field test as well as in noise, 3 speakers were used placed at 1 m from the patient (in front, left and right ear)

Free-field speech audiometry in quiet using French Lafon's monosyllabic words delivered at 40 and 60 dB to the deaf side was performed in unaided (UA) condition and without Alpha 1® device. The percentage of correct responses was noted.

In noise, two tests were performed depending of the respective presentation of the noise and stimulation: The Hirsch's test [Hirsch, and Anderson, 1980] (white 65 dB noise presented frontally and French Lafon's monosyllabic words of increasing intensity delivered to the deaf side) was performed in UA condition and without Alpha 1® and the speech reception threshold (SRT) was noted. The squelch test using white noise at 65 dB delivered to the deaf side and monosyllabic words of increasing intensity presented frontally was performed in UA condition and with Alpha 1®, recording the SRT. Both tests aimed to measure the efficacy of the system for the transfer of sound information to the contralateral side.

Questionnaires

Patient satisfaction with Alpha 1® was evaluated by Glasgow Benefit Inventory (GBI) [Robinson et al., 1996] and by a specific questionnaire. The GBI was divided in 3 subgroups (general, social support and physical health) and the results were reported from -100 to +100 for each subgroup and for the global score. The specific questionnaire investigated the satisfaction of wearing the device through a Likert scale ranging from 0 to 4 (0= very dissatisfied; 1= somewhat dissatisfied; 2 = neither satisfied nor dissatisfied; 3 = satisfied; 4 = very satisfied).

Afterwards, the Alpha 2® external processor was delivered to all patients, and all the test and questionnaires described above were repeated after 30 days with the Alpha 2® processor. The same method of fitting was used across the patients and this fitting was normalized with air conduction pure-tone average, as well as the same magnetic strength was maintained between Alpha 1 and Alpha 2.

Statistical analysis

Values were expressed as means ± SD. The results obtained with the two external processors were analyzed by a paired t-test or by non-parametric Wilcoxon test because of the small number of patients. Qualitative data were compared using Mc Nemar test. A p value < 0.05 was considered significant.

RESULTS

~~All patients completed the protocol.~~

Population

There were 5 males and 4 females. The mean age was 50 ± 9.9 years (mean ± SD, range 40/65 years); the right side was involved in 5 cases, the left side in 4 cases. The etiology of unilateral hearing loss was vestibular schwannoma surgery (22%), sudden sensorineural hearing loss (22%), chronic otitis (11.2%) with ipsilateral profound hearing loss, head trauma (11.2%), ototoxicity (11.2%), mumps (11.2%), congenital (11.2%).

At the first visit with the Alpha 1®, the local skin over the implant was evaluated normal in 8 cases and hyperemic in 1 case. The mean strength of the external magnet was 5 ± 1.7 N. The mean wearing time per day was 5 ± 4.5 hours and the patients had a regular daily use of the Alpha 1® in 5 cases, and an occasional use in 4 cases.

With the Alpha 2®, the local skin was evaluated normal in 7 cases and hyperemic in 2 cases. The strength of the external magnet was 5 ± 1.9, and the wearing time was 7 ± 4.3 hours, values that were similar to those obtained with Alpha 1®. One more patient used the Alpha 2® regularly (6 instead of 5 for Alpha 1®).

Audiological tests

The mean air conduction threshold (mean of the frequencies 500, 1000, 2000 and 4000 Hz) of the contralateral ear was 21± 9 dB and the bone conduction threshold was 14 ± 8.6 dB (Tab. 1).

The mean speech discrimination score (Fig. 2A) using monosyllabic words delivered at 40 dB (73%) and at 60 dB (98%) was similar in UA condition and with Alpha 1® . Similarly, no difference in SRT in both Hirsch's test (58dB) and squelch test (54 dB) was observed between the UA condition and with the Alpha 1® (Fig. 2B).

At the 1 month audiological tests with Alpha 2®, using monosyllabic words at 40 dB, the speech discrimination score was 82 ± 19.7%: the mean gain was 8 ± 8% and this difference was significant (paired t-test; $p < 0.005$) (Fig. 2A).

At 60 dB, the speech discrimination score was 100 ± 0.7% with Alpha 2® , a value not different to that observed with Alpha 1®.

Regarding the Hirsch's test (Fig. 2B), the SRT with Alpha 2® was similar to that observed with Alpha 1® but it was improved by 4 ± 4 dB ($p<0.02$, paired t-test) compared to UA condition.

For the squelch test, the SRT with Alpha 2® improved of 1.4 ± 1 dB ($p<0.02$, paired t-test) compared to that measured with Alpha 1®.

Questionnaires

The GBI global score with Alpha 1® was 11 ± 12.9, and the scores for the subscales were 12 ± 15.6, 15 ± 22.7 and 6 ± 22.6 for the general, social support and physical health respectively; Fig. 5). Patient's satisfaction stood at 2 ± 1.2 using the specific questionnaire.

Regarding the GBI score, with the use of Alpha 2® device we obtained a value of 14 ± 11.0 for the global score and 18 ± 18.3, 18 ± 22.7, -4 ± 11.1 for the general, social support and physical health subscales respectively. There was no significance when comparing these data to the results with the Alpha 1® processor (Fig. 3, Wilcoxon test).

The specific questionnaire revealed a score of 3 ± 0.3 with the Alpha 2® and the difference with the score obtained with the Alpha 1® was <u>not significant</u> (Wilcoxon test).

DISCUSSION

The SSD certainly represents one of the most difficult clinical condition for hearing rehabilitation: Studies analyzing the results of BAHA showed that the hearing outcomes and the patient's satisfaction were significantly poorer in patients affected by SSD than in those affected by conductive of mixed hearing loss [Tringali et al., 2008; Martin et al., 2010]. Furthermore, when using a trans-cutaneous bone conductive hearing device, the presence of an intact skin, although beneficial from a clinical point of view, attenuates sound transmission especially in high frequencies [Verstraeten et al., 2009; Kurz et al., 2014], and this could decrease the efficiency of this device when used in SSD.

Sophono Alpha system is a bone conductive transcutaneous implant that transmits the vibrations of the external processor thought an intact skin, by means of a magnetic coupling. It has been described firstly by Siegert et al. [Siegert, 2011] and since, other papers have been published concerning the use of this device in different pathological condition [Denoyelle et al., 2013; Hol et al., 2013; Sylvester et al., 2013; Magliulo et al., 2014; Escorihuela-García et al., 2014; Leterme et al., 2015; Siegert, and Kanderske, 2013].

The use of Alpha 1$^{®}$ system has already been described in conductive or mixed hearing loss in adults and in children [Sylvester et al., 2013; Escorihuela-García et al., 2014; Siegert, and Kanderske, 2013; Hol et al., 2013; Magliulo et al., 2014; Denoyelle et al., 2013]. No studies have been yet published in the English literature with the use of Alpha 2$^{®}$.

After the release of the new external processor Alpha 2$^{®}$, we aimed to study if, regardless the technological improvements of this new external processor, there were audiological improvements with the use of this new device compared to the previous Alpha 1$^{®}$.

First of all, the new external processor is safe: no increase in adverse skin reactions was observed ~~and the patient's satisfaction improved, even if this was not significant in the specific questionnaire and in the GBI due to the limited number of patient~~. Nevertheless the results of the GBI questionnaires are similar to those obtained with the use of other bone anchored hearing devices [Faber et al., 2013; Saroul et al., 2013] in SSD.

From an audiological point of view, as expected, the benefits of Alpha 2® are significant at 40 dB stimulation and this could be useful in improving speech perception of the deaf side. At 65 dB this difference is not significant probably because, at this level of stimulation, the normal hearing ear is stimulated as well. Regarding hearing-in-noise tests, we observed a significant differences for the squelch test: this test reflects the reduced masking of the speech by the noise [Snik et al., 2015] and the improvement is probably due to the presence of the 2 microphones in the Alpha 2® external processor. For the Hirsch's test, even if there was an improvement in the scores, this was not significant probably because of the low number of cases. Anyway, if compared to unaided condition, the improvement with Alpha 2® was significant.

In conclusion, the new external processor Alpha 2® improves the hearing performance in patients with SSD compared to the previous Alpha 1® external processor; since this pathological condition is one of the most challenging to rehabilitate, the upgrade revealed beneficial for the patients.

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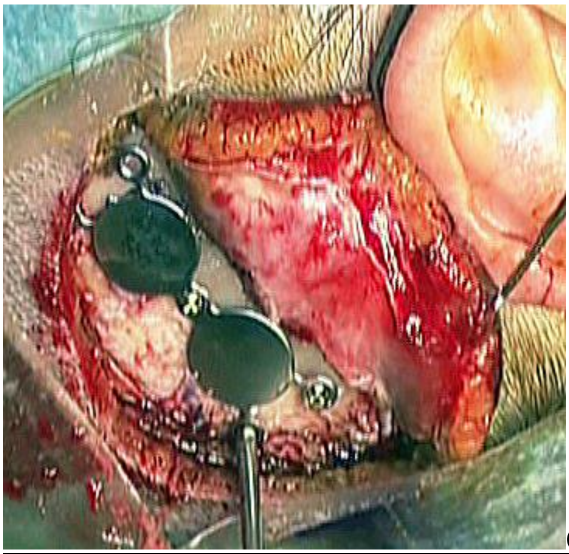
Fig. 1. A: Comparison between Alpha 1® (on the left) and Alpha 2® (on the right) external processor . and after placement in the retroauricular region of the Alpha 2® (B). Surgical view of internal magnet in place in a right ear (C)

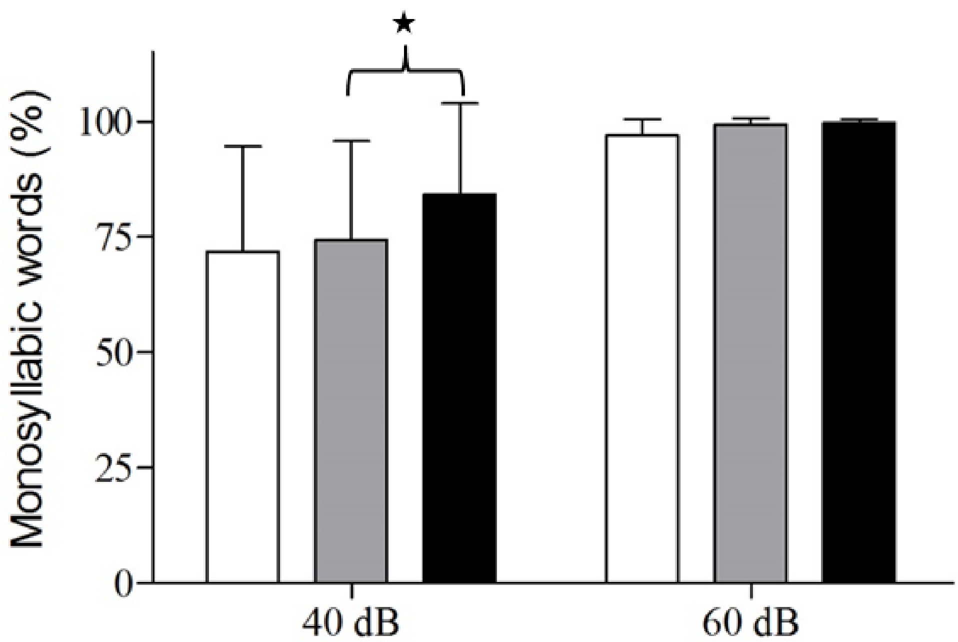
A

B

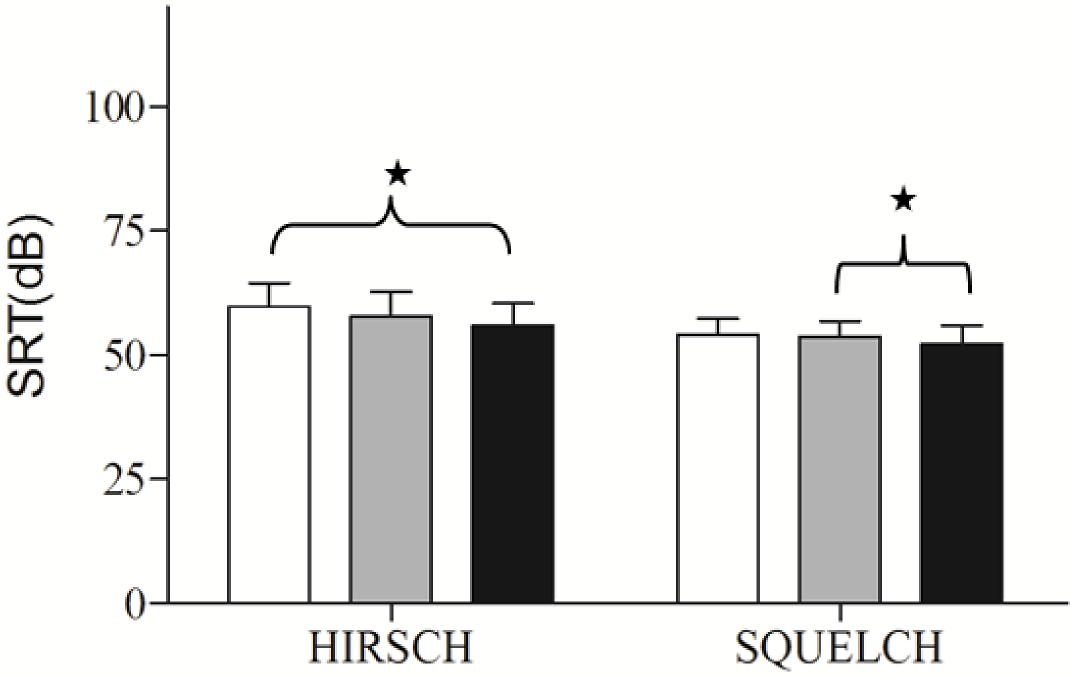


C

Fig. 2. (A) Free-field speech audiometry in quiet using monosyllabic words to the deaf side at 40 dB and 60 dB. The improvement of the speech discrimination score is significant with the Alpha 2® compared to the Alpha 1® at 40 dB ($p=0.023$; paired t-test) white bars are test performed in unaided condition, grey bars with Alpha 1® and black bars with Alpha 2® external processor). (B) Speech discrimination in noise; Results of the Hirsch (left column) and squelch tests (right column) in unaided (white bars), with Alpha 1® (gray bars) and with Alpha 2® (black bars). For the Hirsch test, the improvement between unaided condition and Alpha 2 is significant ($p<0.02$, paired t-test). For the squelch test, the improvement in the speech reception threshold (SRT) is significant ($p=0.016$; paired t-test) .



A



B

~~Fig. 4. Results of the Hirsch (left column) and squelch tests (right column) in unaided (white bars), with Alpha 1® (gray bars) and with Alpha 2® (black bars). For the squelch test, the difference between the 2 test is significant (p=0.016; SRT: speech reception threshold)~~

Fig. 3. Glasgow Benefit Inventory (GBI) questionnaire showed no statistically significant differences between the 2 devices (Wilcoxon non parametric test). Grey bars: with Alpha 1®; black bars: with Alpha 2®.