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First Generation Osseointegrated Steady State Implant Benefits in Children With Hearing Loss

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Objective: To assess outcomes of a new Osseointegrated Steady State Implant (OSSI) for bone conduction in adolescents.

Method: In an initial trial, 14 adolescents (14.5 years of age, SD = 2.22) were provided with an OSSI; unilateral OSSI (n = 13), bilateral OSSI in sequential surgeries (n = 1). Outcomes measured were surgical duration, complications, hearing thresholds, speech perception and self-reported hearing benefits using the Speech and Spatial Quality of Hearing Questionnaire.

Results: The surgical times were mean 93.6 minutes (SD = 33.3). Surgery was slightly longer in three adolescents who required skin flap reduction (n = 1) or significant bone polishing (n = 2) (121.33 minutes, SD = 8.14). Adverse events occurred in two adolescents post-implant poor external device retention in one child requiring revision flap reduction and inflammation at the incision site due to magnet overuse in another. The ''Digital Link Calibration'' measure was a good proxy predictor of the strength of magnet required for external device adherence (p = 0.002). The OSSI increased audibility in the implanted ear by mean 31.48 dB HL (SE = 1.58). Aided thresholds were best at 1 kHz (mean 25.33 dB HL, SD = 22.60) and only slightly poorer at 3000 and 4000 Hz (estimate decrease = 8.33 dB HL, SE = 3.54), reflecting good auditory sensitivity even at high frequencies. Speech perception when using the new device alone was good (89.67%, SD = 7.84%) and self-reported hearing by participants and parents improved in all domains assessed by the Speech and Spatial Quality of Hearing Questionnaire (estimate = 1.90 points, SE = 0.25, p < 0.0001).

Conclusion: The OSSI provides hearing benefits with surgical safety in a carefully selected cohort of adolescents.

Key Words: Auditory—Bone conduction hearing aid—Conductive hearing loss—Piezo-electric vibration—Single sided deafness.

A new osseointegrated steady state implant (OSSI) for bone conduction (BC), has been developed to provide effective BC hearing in a nonskin penetrating system to decrease complications compared to percutaneous devices (1). An additional goal was to reduce attenuation of high frequency vibrations to achieve better gain and access to high frequency sounds than available in previous devices. Good outcomes of this device have recently been shown in adults (2). The aim of the present study was to assess the outcomes of this new BC device in adolescents.

BC devices have provided improved hearing in adolescents with conductive and mixed hearing loss who are unable to wear a conventional hearing aid (3). These devices range from external vibrators which are adhered and/or secured to the head (4) to implantable devices in which an internal component is implanted, some with and some without osseointegration, in order to vibrate the skull. Surgical devices are either percutaneous, penetrating the skin, or transcutaneous without skin penetration. Percutaneous devices provide efficient directly driven skull vibration by physically coupling vibrations generated by the external equipment to the internal components; they can be used for mixed hearing loss of moderately severe

degree (5) and in young children (6) but are prone to infection in children (1,7,8). The first transcutaneous devices generated vibrations from the external component that transferred across the skin to the internal component (passive). Passive transcutaneous devices reduce the incidence of complications but do not eliminate them (9) and can provide less efficient transduction of high frequencies (10). More recent technology aims to improve transcutaneous devices by using a stationary external device to communicate with the internal osseointegrated vibrator (active transcutaneous system) (3). One such device, the Med-El Bonebridge (Innsbruck, Austria), uses a bone-conduction floating mass transducer fixed to the temporal bone (11). The size of the device, particularly in its original form, can make it challenging to implant in young children (12). Early reports in a carefully selected group (n = 11) of children 10 years and older show improved hearing thresholds and speech perception (13).

As described, previously used devices are mechanically driven which may result in decreases in performance over time and eventual fatigue of the device leading to failure. The OSSI is a more recent active transcutaneous system and provides an alternate method of BC. Specifically external vibrations are captured by the external microphone, converted into an electrical signal, which is in turn converted into vibrations via reverse-piezoelectricity by the osseointegrated internal device. These vibrations then travel to the cochlea [Cochlear Ltd. (Fig. 1)].
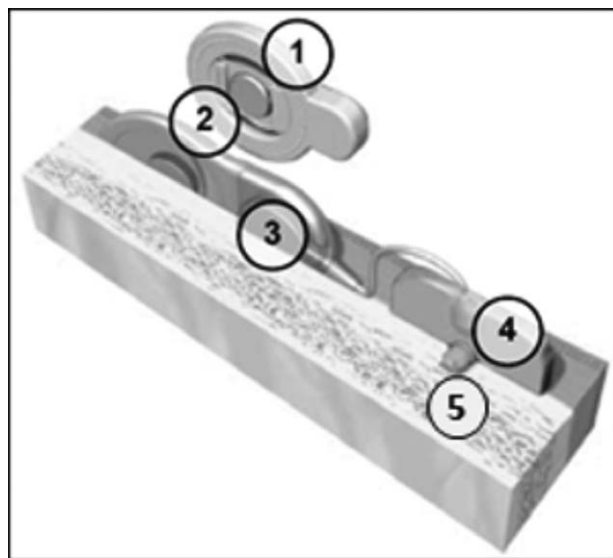

FIG. 1. The OSSI system consists of an external sound processor (1) that captures and digitally processes sound. The sound processor then transmits power and digital information to the internal implant (2). Digital information in the internal implant converts the analog sound into an electric signal which is then transmitted to the actuator (4). The actuator converts the electric signal to vibrations that are transmitted to the mastoid bone through the osseointegrated implant (5). The osseointegrated Implant for anchorage in the bone is the same as in existing Baha Connect and Baha Attract (Cochlear Bone Anchored Solutions AB). OSSI indicates osseointegrated steady state implant.

In the present study, a group of 14 adolescents were provided with OSSIs through a clinical trial sponsored by Cochlear Americas. Ten of the 15 devices used were provided by the manufacture and the remaining 5 were purchased by our Institution. Since that time the OSSI has been approved for use in the United States by the Food and Drug Administration, and in Canada by Health Canada.

METHODS AND MATERIALS

The study protocol was approved as an Investigational Device Trial by Health Canada and the Research Ethics Board at the Hospital for Sick Children (REB: # 1000058120, ITA: # 272423). The focus of the study was to assess outcomes of the first generation Osia® (Cochlear Ltd, Sydney, Australia).

Participant Recruitment
Inclusion criteria for participation in the study were: children 5–18 years of age who had no benefit or perceived usefulness from conventional or non-surgical BC hearing aids. Exclusion criteria were: uncontrolled diabetes as judged by the investigator; radiotherapy in the area of implantation; use of ototoxic drugs; medical condition that could jeopardize osseointegration and/or wound healing or that may have an impact on the outcome of the investigation as judged by the investigator; insufficient bone quality and quantity for implantation of a BI300 Implant, as determined by the surgeon; inability to follow investigational procedures; and/or participation in another clinical investigation with pharmaceutical and/or device.

Masked BC thresholds were obtained for both ears when possible in response to 500, 1000, 2000, 3000, and 4000 Hz pure tones. In many cases of bilateral conductive hearing loss this was not possible due to a ''masking dilemma''. Analyses were conducted on masked BC from the implanted ear where possible in the participants with conductive or mixed hearing loss or unmasked responses, reflecting the better ear at each frequency. Air conduction (AC) thresholds to narrowband noise centred at 500, 1000, 2000, 3000, and 4000 Hz were obtained in the soundfield from 0° azimuth both prior to OSSI implantation (unaided) and after activation of the OSSI (aided). The non-implant ear was plugged and muffed at both test times.

Surgical Procedure
The actuator is ideally placed ≤2 cm posterior to the external auditory canal and oriented with a line drawn through outer canthus to the pinna's superior attachment which approximates the vertical position of the cochlea. As shown in Figure 2, the incision is anteriorly based (postauricular) for a typical pinna and posteriorly based (scalp) for microtia with aural atresia. Methylene blue denotes the implant and receiver-stimulator locations. Skin thickness overlying the receiver-stimulator was measured with thicknesses >9 mm requiring reduction. Photos taken over the course of the procedure, shown in Figure 2, provide further details.
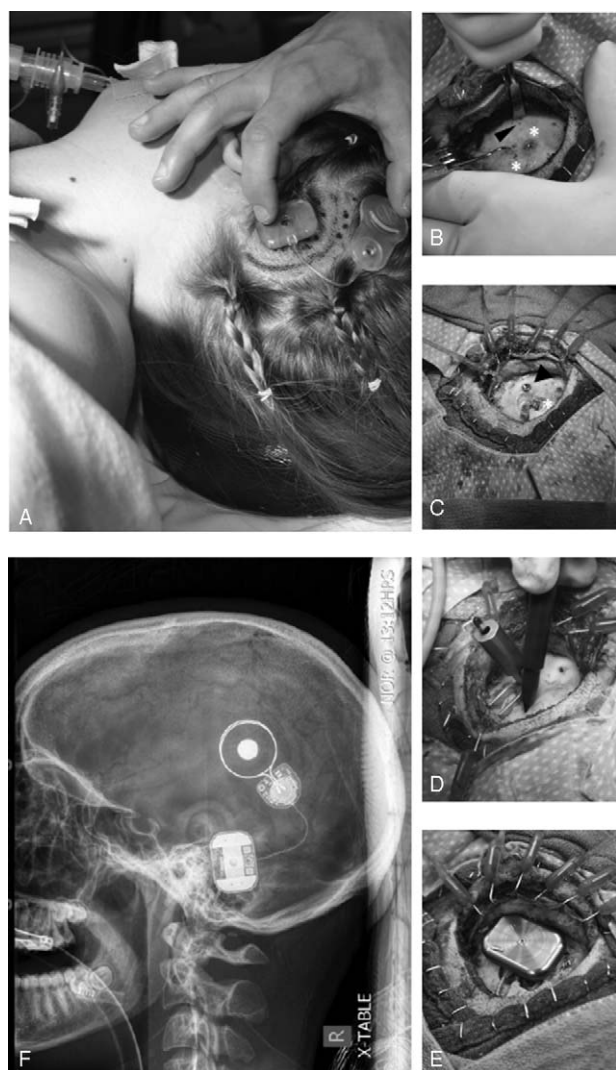
FIG. 2. Intraoperative photos show incision placement relative to device allowing for a minimum of 1 cm of clearance from the actuator itself while minimizing area of the head shaved (A), periosteum is elevated exposing Methylene blue mark denoting eventual new implant placement. Two prior percutaneous device implants are visible (white *) (B). New OSSI implant in place () with one prior implant (white*) remaining to be removed (C). Clearance indicator in place to verify bony clearance prior to placement of actuator. Bone polishing was performed using an otologic drill if bony clearance was not achieved (D). Actuator seated and fixed to the osseointegrated implant (E) Postoperative radiograph of device placement (F). OSSI indicates osseointegrated steady state implant.

Post-Operative Device Fitting and Outcome Measures

Following implantation, the device was activated using the Cochlear fitting software (OFS). The OFS measures a ''Digital Link Calibration'' (DLC) between the external speech processor and internal receiver-stimulator. The DLC is a calibration protocol that takes the distance between external and internal coils into account to ensure correct linking between the two and to optimize power requirements. It also allows for a setting of a notch filter that assist with sound quality as it relates to the resonance peak of the coupled actuator to the installed BI 300 implant fixture (4 mm fixture used in all cases).

Thresholds to OSSI stimulation were measured at 250, 500, 750, 1000, 1500, 2000, 3000, 4000, and 6000 Hz. The OFS then determined a modifiable gain for comfortable audibility. Hearing outcomes were measured using a standard paediatric speech perception test (Phonetically Balanced Kindergarden Word List (PBK)—prerecorded) presented at 65 dB SPL from a loudspeaker at 0° azimuth in a soundbooth. Speech perception was measured prior to implantation and after 6 months of device use. The Speech, Spatial and Qualities of Hearing (SSQ) Questionnaire was used to monitor self-perceived changes in hearing by parents/caregivers and the child version of the SSQ was used to measure the participant's perception of their hearing. These were administered prior to implantation and again after 6 and 12 months of OSSI use.

Analyses

Analyses were completed using R-studio (version 1.0.153). Individual ear information (n = 15 in 14 participants) were analysed for surgical time, skin flap thickness, audiometric thresholds, speech perception results, and the SSQ. Linear mixed effects regressions using the lmer4 package (14) were conducted to account for the repeated measures in participant #14. Age, sex, and hearing loss type were included as fixed effects in all models. Model effects were described by Type III Analysis of Variance Tables using Satterthwaite's method. Least-squares means were used for post-hoc comparisons of factors in the mixed models with Satterthwaite method for correcting degrees of freedom.

RESULTS

Participants

A total of 14 adolescents received OSSI devices through this initial clinical trial (mean (SD) age 14.5 (2.22) years, 95%CI = 13.3–15.8 years). Demographic details are provided in Table 1. As shown in Table 1, 13 adolescents received a unilateral device (10 right:3 left) and 1 (participant 14) received an OSSI on both sides in sequential surgical procedures. Four adolescents had congenital single sided deafness (SSD) (2 right:2 left). Ten had previous experience with a BC device. In four, the OSSI was implanted in a previously implanted ear (participants 1, 5, 8, and 14). From these, the percutaneous device had either failed (n = 1) or been removed (n = 2) and in one child, the abutment was still in place at the time of receiving the OSSI. In two adolescents, the non-implanted ear was aided with a percutaneous Baha (participants 1, 14) and four had used softband Bahas. Four adolescents had never experienced prior amplification (three unilateral atresia and one SSD).

Surgical Results

Surgical times were mean (SD) = 93.6 (33.3) minutes (95%CI = 75.1–112.0 min). Soft tissue reduction was required in 1 of the 14 participants. Soft tissue thickness

TABLE 1. *Participant details*

Participant	Age (yr)	Sex	Configuration and Type of Hearing Loss	Etiology of Hearing Loss	Prior Device Use	Ear Implanted
1	16.3	F	SSD	Enlarged vestibular acqueduct	Right percutaneous device (Baha)	Right
2	16.3	M	Bilateral conductive	Aural atresia	Left percutaneous device (Baha)	Right
3	15.6	F	Bilateral conductive	Acquired stenosis of the EAC	Baha softband	Right
4	17.7	F	Unilateral conductive	Aural atresia	None	Right
5	12.9	M	SSD	Absent VIII nerve	Right percutaneous device (Baha)	Right
6	15.4	F	Bilateral mixed	Acquired stenosis of the external auditory canal	Conventional Hearing aid & Baha on softband	Left
7	16.3	M	Unilateral conductive	Aural atresia	Right Baha-softband	Right
8	16	F	SSD	Absent VIII nerve	Left percutaneous device (Baha)	Left
9	13.4	M	Unilateral conductive	Aural atresia	None	Right
10	11.3	M	Unilateral conductive	Aural atresia	Right Baha softband	Right
11	10.3	M	SSD	Absent VIII nerve	None	Left
12	13.2	F	Unilateral conductive	Aural atresia	None	Right
13	16.2	M	Bilateral conductive	Aural atresia	Left percutaneous device (Baha)	Right
14	12.8	F	Bilateral conductive	Aural atresia	Left percutaneous device (Baha)	Right
14	13.2	F	Bilateral conductive	Aural atresia	Left percutaneous device (Baha)	Left

SSD indicates single sided deafness.

was mean (SD) = 6.5 (2.4) mm (95%CI = 5.2–7.8 mm) prior to reduction.

Surgical complications occurred in 2 of the 14 participants. One (participant #2) required reduction of the skin flap on three occasions in order to achieve secure connection of the external speech processor to the internal device. This was noted at the first device activation (4 weeks after surgery) and likely related to morbid obesity in this child. The first reduction occurred at the time of the initial surgery through the same incision used to implant the device. The extent of this reduction was primarily limited by the exposure through the incision provided limited ability to substantially reduce at the site of the internal magnet while maintaining adequate access to control bleeding should this occur. The following two reductions in this child occurred through a separate incision superior to the receiver stimulator similar to what would be used to remove or replace a magnet in a cochlear implant. The first revision occurred 2.5 months following the initial surgery and the second revision occurred a year after the 1st revision. Another participant (#5) reported irritation at the magnet and incision site roughly 2 months after activation and 3 months after surgery. This participant was using the device continuously through the day and night. Magnet strength was reduced and the patient was advised to use a comfort pad if a stronger magnet was needed for better retention. Resolution came from a combination of these measures as well as removal of the device prior to sleep. The soft tissue irritation and mild skin breakdown resolved with decreased magnet strength and removal of the external processor during the night.

Device Fitting and Programming

Device activation occurred mean (SD) 30.86 (5.70) days (95%CI = 27.57–34.15 days) following surgery and proceeded without complication in all participants bar participant 2. As discussed above, participant 2 required skin flap reduction to achieve connection between the external and internal components. In the group, magnet strength required for a physically secure and effective connection with the internal component could not be predicted by the skin thickness measured at surgery (Fig. 3A; model ANOVA: $F(1,9) = 2.33$, $p = 0.16$, $\eta^2 = 0.28$) but was better predicted by the DLC measure when accounting for age and sex (Fig. 3B; model ANOVA: $F(1,10) = 16.17$, $p = 0.002$, $\eta^2 = 0.81$). The #4 magnet strength was most commonly used (6/15 ears) and a range in magnet strength from #2 to #6 was required in this group.

Initial settings were adjusted slightly in 11/15 ears in follow-up appointments; there was a slight reduction in gain in 10 ears and increase in gain in 1 ear.

Two candidates experienced a prolonged period of non-use (reports of <1 h per day for over 1 mo) following implantation. One child had unilateral microtia and the other had bilateral microtia and had a percutaneous BC aid on the contralateral side. Both reported a preference for their first/better hearing ear and, despite excellent speech perception accuracy with the OSSI, reported challenges with bilateral hearing. Eventually with counselling, reprogramming and an upgrade to the latest external processor more consistent use was reported.

Audibility Measured by Audiometric Thresholds

Audiometric thresholds are plotted in Figure 4A by type of hearing loss but this grouping had no significant effect on the thresholds in mixed model regression analyses ($F(3,8) = 1.78$, $p = 0.23$, $\eta^2 = 0.01$). Most of the adolescents had normal BC thresholds; BC thresholds were mean (SD) = 10.21(9.80) dB HL (95%CI = 7.41–13.01 dB HL) across test frequencies. Unaided AC thresholds measured
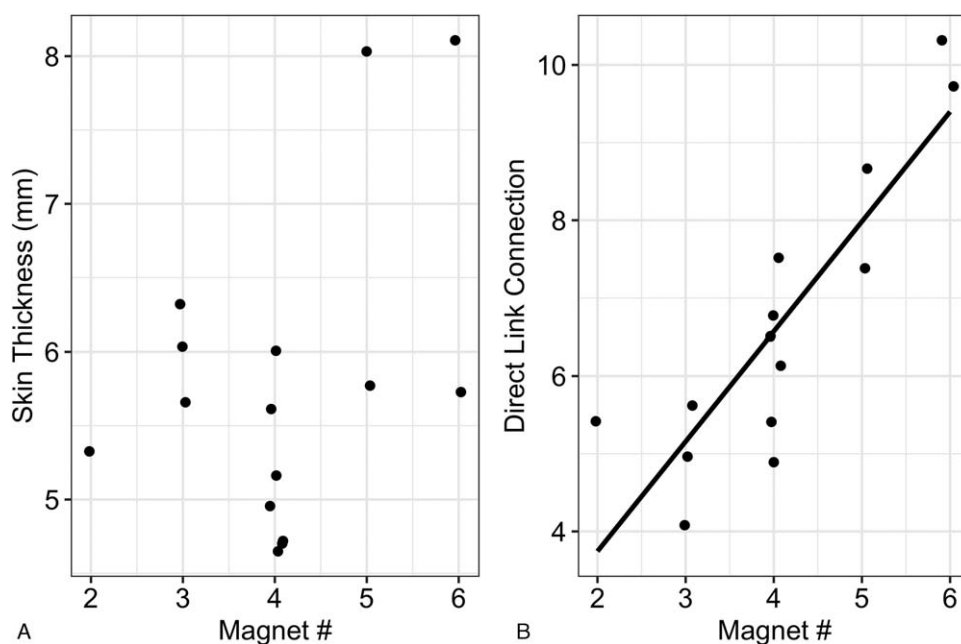
FIG. 3. *A*, The magnet # (indicating increasing magnet strength) required for device retention and communication is: (A) not predictable by the skin thickness measures but *B*, is better predicted by the Digital Link Calibration measure ($p = 0.004$, $\eta^2 = 0.73$).

in the soundfield prior to OSSI implantation reflected the hearing loss in the implanted ear in participants with bilateral hearing loss and maximum audibility for participants with unilateral hearing loss when the better ear was plugged and muffed. These unaided soundfield thresholds were mean (SD) = 54.75(15.40) dB HL (95%CI = 51.18–58.32 dB HL) across frequencies, indicating poor access to speech at typical conversational levels. Aided soundfield thresholds show significantly improved thresholds across frequencies [$t(194) = 19.82$, $p < 0.0001$, $\eta^2 = 0.78$] and
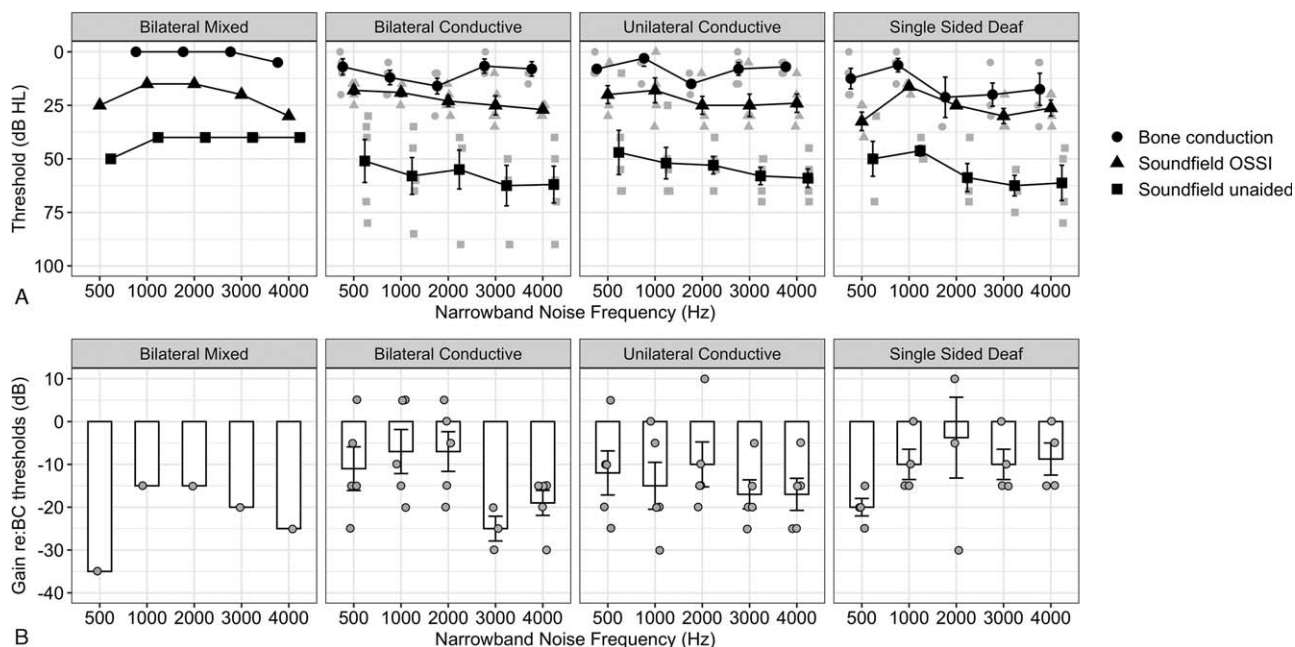

FIG. 4. *A*, Bone conduction (BC) (masked from implanted ear where possible and unmasked in children with single sided deafness) and soundfield air conduction (AC) thresholds with unimplanted ear plugged and muffed (mean data and SE error bars in black, individual data in grey). Plots are divided by the type of hearing loss in the group: bilateral mixed (n = 1); bilateral conductive (n = 5); unilateral conductive (n = 5); single sided deaf (n = 4). Improved AC thresholds post-OSSI reveal increased audibility. *B*, Gap between AC and BC thresholds reduced with OSSI use (mean, SE, individual data shown by bars, error bars, and symbols, respectively). OSSI indicates osseointegrated steady state implant.
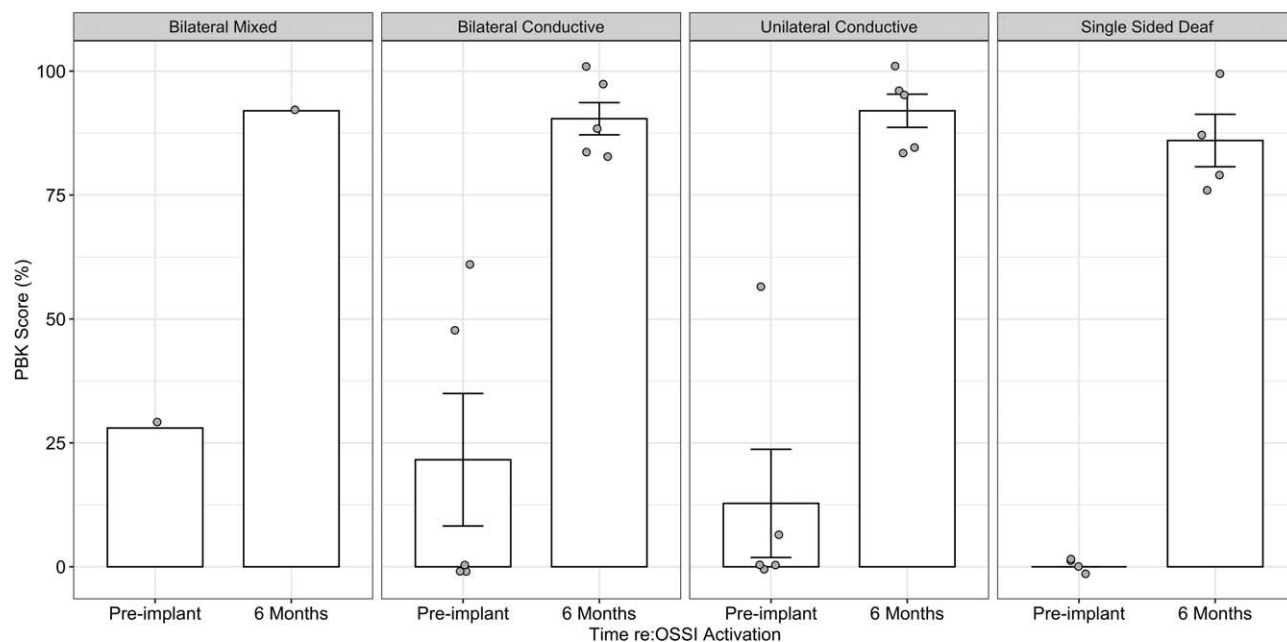
FIG. 5. Monosyllabic works in the PBK test presented at 65 dB SPL at 0° azimuth, grouped by hearing loss type: bilateral mixed (n = 1); bilateral conductive (n = 5); unilateral conductive (n = 5); single sided deaf (n = 4), were inaudible for most participants in the unaided soundfield condition prior to OSSI implantation but could be repeated at very high accuracy with the OSSI when tested at 6 months after activation. OSSI indicates osseointegrated steady state implant; PKB, phonetically balanced kindergarden.

good access to conversational speech [mean (SD) thresholds = 23.67(8.28) dB HL, 95%CI = 21.36–25.18 dB HL]. Aided thresholds are best (lowest dB HL) at 1 kHz [mean (SD) = 17.67 dB HL, 95% CI = 13.50–21.84] with only slightly poorer thresholds than this best frequency hearing at 3000 and 4000 Hz [estimate decrease (SE) = 8.33(3.54) dB HL]. The gap in thresholds between the BC and AC thresholds are shown in Figure 4B. A slight remaining gap between BC and aided soundfield thresholds remains [estimate (SE) = 13.22(1.60) dB, $t(194) = 8.28$, $p < 0.0001$].

Speech Perception

Speech perception scores are shown, grouped by type of hearing loss, in Figure 5. There was no significant effect of type of hearing loss in mixed model regression analyses [$F(3,8) = 1.75$, $p = 0.23$, $\eta^2 = 0.20$]. Without aids, most adolescents did not have sufficient access to the words presented in the soundfield at 65 dB SPL which accounts for their very poor ability to accurately repeat the words prior to OSSI implantation; 10 participants could not repeat any of the words and only 1 participant with bilateral conductive loss and 1 participant with unilateral conductive loss (n = 3 ears, reflecting good scores from both ears in participant #14) scored over 30% [mean(SE) = 54.67(6.11)%, 95%CI = 39.49–69.85%]. With the OSSI, speech understanding improved with all adolescents achieving highly accurate scores [mean(-SD) = 89.87(7.84)%, 95%CI = 85.53–94.21%].

Self-Reported Hearing

The results of the child and parent versions of the SSQ questionnaire, grouped by type of hearing loss, are plotted in Figure 6. Mixed model regression analyses showed a potential trend for slightly higher scores in the Unilateral conductive group [$F(3,8) = 3.51$, $p = 0.07$, $\eta^2 = 0.06$] than Bilateral conductive but there were no significant interactions between hearing loss type and either child or parent reporter [$F(3,56) = 1.74$, $p = 0.03$] or time [$F(6,56) = 1.53$, $p = 0.05$]. Results show that both participants and their parents indicated significantly improved self-reported hearing after 6 months of OSSI use [$F(2,51) = 40.62$, $p < 0.0001$, $\eta^2 = 0.43$]. Scores improved by estimate(SE) = 2.11(0.30) points across participants and parents/caregivers during this time, remaining stable after 12 months of OSSI use [$t(56) = 1.36$, $p = 0.18$]. Parents/caregivers at all test times consistently rate their child's hearing higher than children's rating of their own hearing abilities by an estimate(SE) of 0.96(0.24) points across test time [$F(1,56) = 15.43$, $p < 0.00001$, $\eta^2 = 0.08$]; no interaction with test time: $F(2,56) = 0.51$, $p0.60$, $\eta^2 = 0.00$.

DISCUSSION

The present clinical trial of the OSSI in 14 participants (n = 15 ears) reveals no complications and good outcomes in our group of adolescents with conductive and mixed hearing loss and SSD. Demonstrable hearing benefits in the implanted ear occurred soon after activation.

Considerations of Skin Flap Thickness

Surgical data reveals that the time needed for implantation is fairly short [mean(SD) = 93.6(33.3) min] but may be lengthened if there is a need for soft tissue
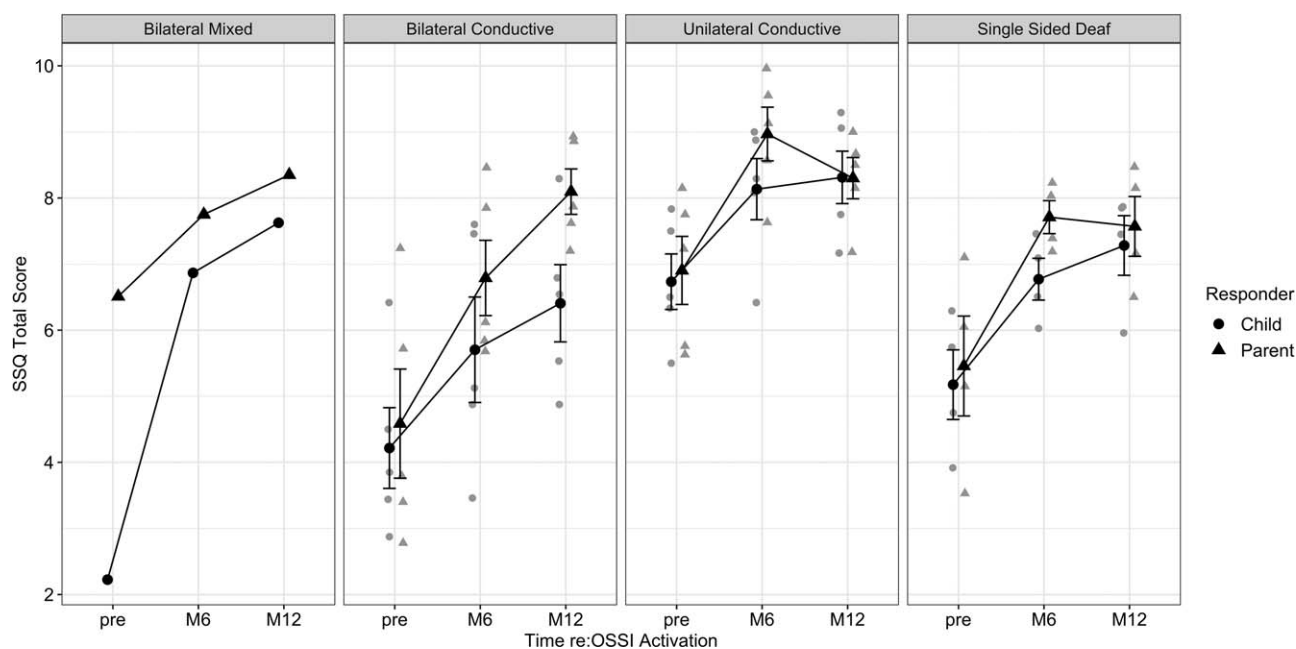
FIG. 6. Self-reported hearing measured by SSQ, grouped by hearing loss type: bilateral mixed (n = 1); bilateral conductive (n = 5); unilateral conductive (n = 5); single sided deaf (n = 4), revealed significant improvement after 6 months of OSSI use and retained benefits after 12 months of OSSI use. SSQ scores by parents/caregivers were slightly better than from the children themselves. OSSI indicates osseointegrated steady state implant; SSQ, speech, spatial and qualities of hearing.

reduction (particularly when skin thickness exceeds 10 mm) or extensive bone polishing. This step is important both for the external device to be retained in place on the head as well as to ensure consistent communication with the internal component. In one of the three cases requiring skin thickness reduction, the child's morbid obesity likely played a role. Initially, steroid injection was used in an attempt to thin the tissue although this did not yield any reduction in skin thickness as measured ultrasonographically after three injections. Given the distance between the internal magnet and the incision initially created to insert the device, a separate incision was required to adequately access the area in need of soft tissue reduction in a fashion that allowed for adequate control of hemostasis. The reach from the original incision was too far away from the area in need of reduction and provided limited access to control bleeding should this occur. This issue is specific to the design of this first-generation device as it allows the receiver stimulator to be placed at a significance distance from the actuator which is the landmark for the incision. In most cases, surgical reduction can be avoided and, as shown in Figure 3, an appropriate strength magnet strength can be used to effectively accomplish both device retention and communication. A prior study measuring skin thickness at this site revealed that adolescents under 7 years of age rarely have skin thickness in this region of greater than 3 to 4 mm (15). After age 7, skin thickness increases with age (15). Increased skin thickness can also affect percutaneous BC devices. For example, the affected participant (#2) in this study also required skin thickness reduction for the percutaneous device used on the side

contralateral to the OSSI. In statistical models which accounted for this change with age, the DLC measurement available from the software was able to predict needed magnet strength whereas magnet strength could not be predicted the skin thickness measure made in the operating room (Figs. 3A and B). This was an unexpected finding as the DLC in this first generation of the OSSI was not intended to predict needed magnet strength but, rather, to ensure optimal signaling between the external and internal components. Thus, there may be an unintended potential use of the DLC to support the choice of initial magnet strength for individual users.

Low Rates of Skin Infection

One of the main goals of OSSI use was to provide adolescents with an implantable BC device with reduced risk of complication. Only 1 of the 14 adolescents (and 1 of 15 ears) experienced inflammation of the incision. This occurred at the surgical incision site many months following surgery and was resolved by reducing the numbers of hours of daily use. That this participant elected to use the OSSI during both waking and sleeping hours is a testament to the benefits experienced; however, this also highlights the potential for deterioration of the skin with extended use. Similar findings have been shown in cochlear implant users who can experience deterioration of skin between the magnets (16). Removal of the external processors for daily periods (commonly during night-time sleep) effectively resolve or avoid this problem in cochlear implant users (16). The same solution was effective in resolving the skin infection in the one participant who experienced this problem in this

study. By contrast, infections and inflammation around percutaneous BC devices can persist and recur in roughly 50% of pediatric users even with typical durations of daily use (1,7,8).

Hearing Benefits

The OSSI provided measurable benefits in hearing. Audiometric thresholds, shown in Figure 4A reveal increased audibility of mean (SD) hearing thresholds across frequencies from 54.72(15.39) dB HL to 23.67(8.28) dB HL. This gain of estimate(SE) = 31.48(1.59) dB HL was consistent across frequencies, indicating the effectiveness of the OSSI even in the high frequencies. This is a clear benefit of the OSSI given the reduction of high frequency gain by previous transcutaneous BC devices (10). Less effective high frequency hearing can compromise speech perception (10,17). Perhaps the good audibility of sounds across the test frequency range explains the high speech perception scores shown in Figure 5 after only 6 months of OSSI use [mean(SD) = 89.87(7.84)% accuracy] and the improvement of self-reported hearing measured by the SSQ at this same time point of OSSI use. SSQ results shown in Figure 6 reveal increased scores of almost 2 points out of a total of 10 [estimate(SE) = 1.90(0.25)]. This large improvement was indicated by both participants and their parents although parents tended to be more optimistic about their children's hearing than the participants themselves. Importantly, self-reported hearing improvement remained stable to 12 months post-OSSI activation.

Study Caveats

This study cohort were carefully chosen candidates who should not be considered wholly representative of the population of children who may benefit from the OSSI technology. Future candidacy in children should be based on multi-disciplinary assessment, further miniaturization of the device, use in bilateral fittings, and increased evidence of complication rates.

CONCLUSION

The OSSI in a selected group of adolescents 10 years and older demonstrated low rates of complication and significant hearing benefits. Continued studies should assess potential benefits of early and bilateral implantation to diminish the developmental consequences of hearing loss.

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