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Subtemporalis Muscle Middle Cranial Fossa Bone-Island Craniotomy Technique for Placement of an Active Transcutaneous Bone-Conduction Implant

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Objective: Placement of an active transcutaneous bone-conduction implant (BCI) requires drilling of a precise bone bed to accommodate the device and allow for fixation points to make appropriate contact with bone, which can be difficult even when lifts are used. We describe a subtemporalis muscle middle cranial fossa bone-island craniotomy technique that simplifies the procedure and obviates the need for lifts in securing the device.
Study Design: Prospective case series.
Setting: Tertiary academic medical center.
Patients: Seventeen patients underwent surgery for placement of 18 transcutaneous BCIs, 14 for conductive or mixed hearing loss, and 4 for single-sided deafness.
Interventions: Surgical placement of a transcutaneous BCI with a bone-island craniotomy technique.
Main Outcome Measures: Functional gain in air-conduction thresholds, aided air-bone gap, frequency of need for lifts, and minor and major complications.
Results: For the conductive or mixed hearing loss cohort, with the transcutaneous BCI in place, there was a highly statistically significant mean functional gain of 35.4 dB hearing level (HL) (range, 16.7–50.25 dB HL; standard deviation, 12.4 dB HL) compared with the unaided condition ($p < 0.0001$; 95% confidence interval, 36.6–51.6 dB HL). Lifts were not needed in any case. There was one minor complication requiring a second procedure in a patient who had previously received radiation and no major complications. There was no device loss or failure.
Conclusions: A subtemporalis muscle middle cranial fossa bone-island craniotomy technique eliminates the need for lifts and is a safe and effective method for placement of a transcutaneous BCI.
Key Words: BAHA—Bone-anchored hearing aid—BONEBRIDGE—Bone conduction—Bone conductive—Bone conductive implant—Implant—Single-sided deafness.

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INTRODUCTION

Bone-conduction implants (BCIs) are useful in the rehabilitation of hearing loss in both children (1–5) and adults (6–9). BCIs transmit sound by vibration of the skull, transmitting sound energy directly into to the cochlea. They do not require any device in the ear canal and are particularly helpful for patients with conductive or mixed hearing loss (CMHL) that cannot wear conventional hearing aids because of otorrhea, altered ear canal anatomy due previous surgery, malformation, recurrent infections, or cannot tolerate a device in the canal for other reasons (7,10,11). They are also useful for patients with single-sided deafness (SSD), as they can stimulate the cochlea of the opposite (best hearing) ear (12–14).

BCIs are classified as percutaneous if the device passes through a defect in the skin and soft tissue, or transcutaneous if they transmit through intact skin. Percutaneous devices have the disadvantage of more frequent skin complications such as infection due to the opening in the skin, whereas transcutaneous devices benefit from a much lower incidence of skin complications (9–11). Transcutaneous BCIs are further classified as passive if they transmit vibrations through the skin, or active if the vibrating component is beneath the skin. Passive transcutaneous devices are typically smaller because there are less components under the skin, but some of the energy is dissipated as it passed through the skin, especially in the higher speech frequencies, limiting performance (10,11). Active transcutaneous devices have a larger component under the skin but do not suffer from the high rate of skin issues of percutaneous devices or the energy loss of passive transcutaneous devices, and

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thus may be ideal device for rehabilitation of certain cases of CMHL and SSD (15,16).

The magnetic resonance imaging–compatible transcutaneous BCI used in this study does not require osseointegration, thus allowing for activation and device use as soon as postoperative swelling has resolved. Outcomes from multiple series have shown favorable audiologic outcomes and satisfaction with the device (15). It consists of an external processor worn on the skin and internal device containing a corresponding magnet and floating mass transducer (FMT). The FMT is secured via self-drilling screws placed into the bone on either side through "wings" of the FMT, which transmit the sound energy through the bone to the cochlea. Contact of the wings of the FMT with the underlying bone is critical to proper device function and requires a precisely drilled bone bed (17). The device can be placed in a presigmoid, retrosigmoid, or middle fossa location (18). Candidates for the device have often undergone previous mastoid surgery or an exteriorized mastoid cavity that makes the presigmoid location undesirable in these patients. For those without previous surgery, presigmoid placement also places the sigmoid sinus at risk of injury (19). Previous studies have noted the difficulty of a retrosigmoid location where the transverse sinus is at risk of injury, and the increase curvature of the skull in this region makes it difficult to contour the bone bed such that appropriate contact is made for these, even when spacers called "lifts" are used to bridge the gap that may be present between the device and the bone. These difficulties have prompted the development of techniques that use a craniotomy in the temporal squama to accommodate the device. Several previous studies have examined these approaches with promising results (19–22). However, in the authors' opinion, further study and technique refinement are needed. Several authors required complex preoperative three-dimensional modeling to plan the craniotomy site, and their techniques often required lifts to create the appropriate fit of the device (20–22). Carnevale et al. (19) restricted the approach to patients with previous mastoid surgery and did not report audiometric outcomes. There are no studies that describe a surgical technique and report audiometric outcomes that precludes the need for lifts, which was the goal of this study. In this article, we describe detailed safety and audiometric outcomes and the surgical technique of a modified middle fossa craniotomy technique that uses a subtemporalis muscle middle cranial fossa bone-island craniotomy for simple, rapid, and safe placement of a transcutaneous BCI in a variety of clinical scenarios, which eliminates sizing and fixation issues and precludes the need for lifts in securing the device.

PATIENTS AND METHODS

Study Design

The study protocol was approved by the institutional review board of our institution (protocol number 2021001732). The inclusion criteria were all patients who underwent bone-conduction device placement surgery with the MED-EL BONEBRIDGE BCI602 active transcutaneous BCI (MED-EL; Medical Electronics, Innsbruck, Austria) from 2020 to 2021 at our tertiary care academic medical center and have consistent follow-up for at least 4 months postoperatively. All operations were performed with a subtemporalis muscle middle cranial fossa bone-island craniotomy technique. Informed consent was obtained either from patients or from their parents/guardians for those younger than 18 years. There were two cohorts of patients, those with CMHL and those with SSD. Inclusion criteria for the CMHL cohort consisted of patients with a CMHL, who were unable to fit or tolerate a conventional hearing aid, and had a maximum bone-conduction threshold on the affected side of 45 dB hearing level (HL) between 500 and 3000 Hz. Inclusion criteria for the SSD cohort consisted of patients with ipsilateral profound unilateral sensorineural hearing loss with a contralateral maximum air-conduction threshold meeting the Food and Drug Administration–approved criteria for the use of the transcutaneous BCI for SSD, which is approved for the maximum air-conduction threshold in the best hearing ear to be as poor as 60 dB HL.

A comprehensive preoperative audiogram was performed on all patients measuring air and bone thresholds across the frequency spectrum of 250 to 8000 Hz. At approximately 3 months postoperatively, bone-conduction thresholds were measured with the active device across the frequency spectrum. The four-frequency pure-tone average (PTA) was calculated as the average threshold at 0.5, 1-, 2, and 3 kHz. In a few cases the 3-kHz threshold was missing, a 3-kHz threshold was interpolated by averaging the thresholds at 2 and 4 kHz (23). The need for lifts intraoperatively as well as any intraoperative and postoperative complications were recorded. Adult patients completed the Speech, Spatial, and Qualities of Hearing Scale (SSQ) questionnaire preoperatively and postoperatively (24). Summary statistics for the study population were expressed in means and ranges. Functional gain was calculated as the difference in PTA of preoperative air-conduction thresholds and postoperative hearing thresholds with the device in place on the operated ear. Speech discrimination was tested via different methods depending on the patient's age, most commonly via NU-6 word lists at a fixed sensation level based on speech reception threshold (n = 14). Student *t* test was used to complete the statistical comparisons. Statistical analysis was performed using SPSS Statistics (IBM Corporation, Armonk, NY).

Subtemporalis Muscle Middle Cranial Fossa Bone-Island Craniotomy Surgical Technique

A lazy "S" incision was designed and created just posterior to the postauricular crease. The incision contoured the crease and then turned posteriorly at its superior apex where it extended about 4 cm superior to the auricle (Fig. 1A). Dissection was carried down to the level of the temporalis muscle, and a pericranium-temporalis flap was raised to expose the cortex over the planned site of the device implantation. Sizing templates provided by the manufacturer were used to outline the location, and that there was adequate exposure of the cortical bone. A subperiosteal pocket was developed for the internal receiver-stimulator portion of the device, and the outline of the FMT location was marked (Fig. 1B). A high-speed drill, using a 3-mm cutting bur followed by a 4-mm extra coarse diamond bur, was

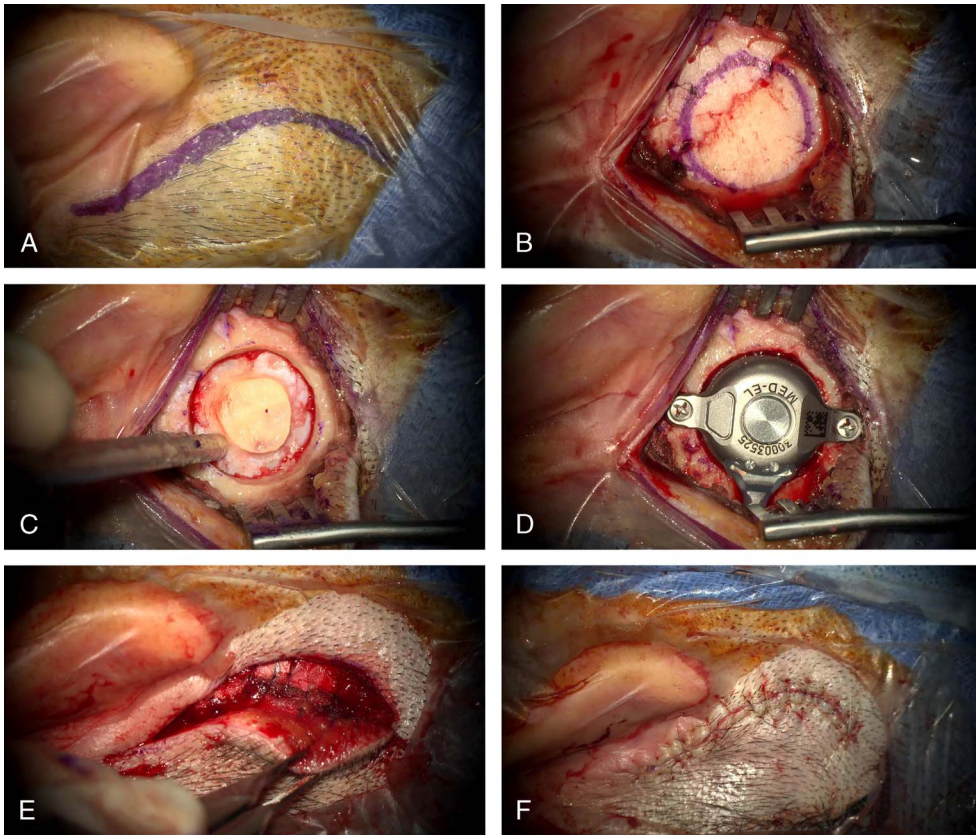

FIG. 1. Surgical steps for the subtemporalis muscle middle cranial fossa bone-island craniotomy technique for the implantation of the transcutaneous bone-conduction device. *A*, Lazy "S" postauricular incision extending approximately 4 cm above auricle, shown relative to this left ear. *B*, Planned location of the floating mass transducer after completion of soft tissue dissection. *C*, Bone-island craniotomy with exposure of the dura at the edges of the craniotomy. *D*, Device is placed, and the floating mass transducer is secured with the self-drilling screws provided with the active transcutaneous bone-conduction implant. *E*, Temporalis muscle closed primarily over the floating mass transducer and previous to closing the scalp and postauricular incision. *F*, Galeal and subcutaneous tissue closure followed by skin closure.

used to perform a circular craniotomy with the edges of craniotomy lowered to the level of the dura. The thickness of the bone island was reduced to limit the degree of dural compression necessary to fully inset the FMT without needing lifts. The dura was not deliberately exposed in the center, creating a mobile "island" of bone with dura exposed at the edges (Fig. 1C). The craniotomy was sized so that the FMT can sit in the defect on the mobile island of bone, whereas the wings of the FMT and the fixation holes were seated at the craniotomy edges in intact bone (Fig. 1D). The mobile bone island was gently depressed allowing the FMT to sit at whatever depth is needed for direct contact of the fixation wings and holes with the undrilled bone at the edge of the craniotomy defect. The active transcutaneous bone-conduction device was secured with the self-drilling fixation screws provided by the manufacturer, and the wound was closed in layers (Fig. 1, E and F). The temporalis muscle was closed as a separate layer over the FMT (Fig. 1E). A Glasscock dressing (Grace Medical, Memphis, TN) was placed after wound closure and removed on postoperative day 1. The device was activated after the wound healed and edema resolved, which was typically 3 weeks.

RESULTS

Seventeen patients underwent surgery for placement of 18 transcutaneous BCIs over the study interval, with 14 in the CMHL cohort and 4 in the SSD cohort. The age range was 7 to 68 years, with eight patients younger than 18 years (47%). Eleven devices were placed in male and 7 in female patients. Thirteen of 14 patients in the CMHL underwent previous surgery for middle ear pathology, and 1 had congenital aural atresia. One CMHL patient who received bilateral devices in two separate operations had previous bilateral Sophono 2 Alpha MPO devices, which had failed and were removed at the time of each transcutaneous BCI bone-island craniotomy surgery.

Averaged preoperative and postoperative hearing data are summarized in Table 1 and shown in Figure 2. For the CMHL cohort, the mean preoperative unaided air-conduction threshold PTA on the operated ear was 65.6 dB HL (range, 40.0–78.1 dB HL; standard deviation [SD], 11.3 dB HL), mean bone-conduction threshold PTA was 15.5 dB HL (range, 3.8–23.8 dB HL; SD, 8.81 dB HL), and mean air-bone gap PTA was 46.8 dB HL (range, 25.0–60.6 dB HL; SD, 11.5 dB HL). The mean postoperative threshold PTA aided by the transcutaneous BCI was 24.4 dB HL

TABLE 1. *Patient hearing characteristics*

Patient (Age at Implantation in Years)	Preop PTA A-C Threshold (dB HL)	Preop PTA B-C Threshold (dB HL)	Preop A-B PTA Gap (dB HL)	Postop Aided PTA Threshold (dB HL)	Postop PTA Aided A-B Gap (dB HL)	PTA Functional Gain (dB HL)
1 (7)	62.5	1.9	60.6	19.5	17.1	43.7
2 (11)	40.0	3.8	36.3	18.0	14.3	22.8
3 (11)	SSD[a]			21.3		
4 (12)	67.5	23.8	43.8	27.0	3.3	40.6
5 (13)	50.5	5.6	45.0	24.1	18.4	26.6
6 (16)	SSD[a]			25.0		
7 (16)	45.0	7.0	38.0	14.2	7.0	31.0
8 (18)	SSD[a]			19.8		
9 R (23)	40.0	3.8	36.3	18.0	14.3	22.8
9 L (23)	65.6	8.8	56.9	20.0	11.3	45.6
10 (30)	62.5	14.4	48.1	17.0	2.6	45.4
11 (27)	60.0	22.5	37.5	30.1	7.6	30.4
12 (30)	51.0	21.9	29.1	28.8	6.1	23.0
13 (42)	75.0	25.0	50.0	27.0	2.0	48.4
14 (42)	76.3	20.0	56.3	26.0	6.2	50.3
15 (52)	78.1	17.5	60.6	25.0	7.5	53.1
16 (62)	SSD[a]			21.8		
17 (68)	52.5	27.5	25.0	35.8	7.6	16.7
Average	65.6	15.5	46.8	24.4[b]	8.55	35.4
SD	11.3	8.81	11.5	6.39	5.10	12.6

[a]Single-sided deafness denoted to show the ages of patients implanted with the active transcutaneous bone conduction device for this indication.
[b]Excluded single-sided deafness patients from the average.
A-B indicates air-bone; A-C, air-conduction; B-C, bone-conduction; dB HL, decibels hearing level; L, left; Postop, postoperative; Preop, preoperative; PTA, four-frequency pure-tone average; R, right; SD, standard deviation; SSD, single-sided deafness.

(range, 17.7–35.0 dB HL; SD, 6.39 dB HL), and the mean functional gain was 35.4 dB HL (range, 16.7–50.25 dB HL; SD, 12.6 dB HL); this result was highly statistically significant ($p < 0.0001$). Patient 17 was the oldest patient in the study who had the lowest preoperative air-bone gap. Their final air bone gap was 8.55 resulting in a functional gain of 16.7 dB HL. The unaided and aided thresholds for each patient are displayed in Figure 3. Mean aided speech discrimination score (word recognition score [WRS]) for those tested via NU-6 word lists was 90.7% postoperatively while wearing the device. Mean SSQ scores among adult patients improved from 3.71 preoperatively to 5.42 postoperatively. Two patients did not complete either preoperative or postoperative SSQ questionnaires.

In the SSD cohort, three of four had idiopathic sudden sensorineural hearing loss, and 1 had a cochlear malformation.

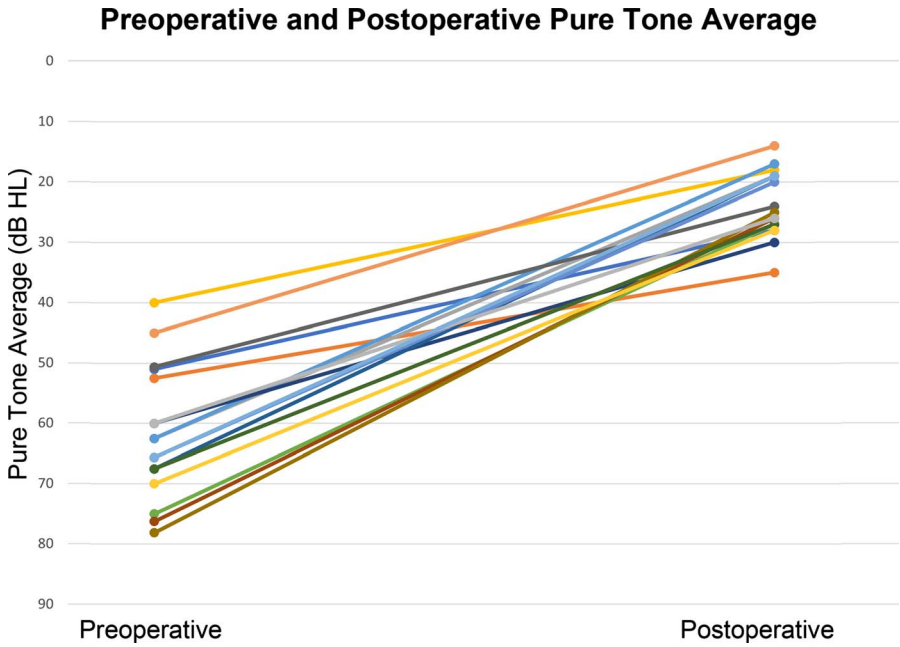

FIG. 2. Scattergrams of pure-tone average and air-bone gap. Preoperative (*A*) and (*B*) postoperative change in outcomes after implantation and use of the transcutaneous bone-conduction device. Single-sided deafness patients are denoted to show the age of the patients receiving the transcutaneous bone-conduction device in that cohort.

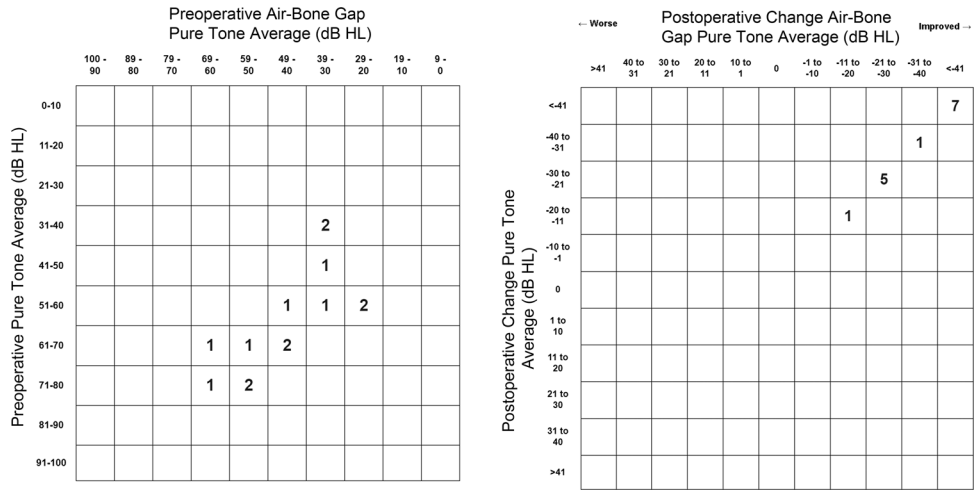

FIG. 3. Preoperative and postoperative pure-tone average values for individuals in the conductive/mixed hearing loss cohort.

Mean PTA in the better ear was 13.9 dB HL (range, 8–18 dB HL; SD, 5.54 dB HL), and the aided PTA on the implanted side postoperatively was 22.0 dB HL (range, 19.8–25.0 dB HL; SD, 7.7 dB HL). Mean SSQ scores for the two adult recipients in the SSD cohort improved from 3.26 preoperatively to 4.76 postoperatively.

There were no intraoperative complications such as dural injury, temporal lobe injury, epidural hematoma, or cerebrospinal fluid leak. Lifts were not needed in any case to secure the device. One patient who had previous radiation developed a wound infection and skin breakdown around the device; this required a local flap operation for it to heal. There were no major complications. There was no device loss or device failure during the study interval.

The subtemporalis muscle middle cranial fossa bone-island craniotomy technique obviates the need for a precisely contoured bone bed, where it is often the case that the immobile bone at the depth of the well often contacts the bottom or side of the FMT and does not allow the edges and fixations holes to make good contact with the bone, which is why lifts are often needed to fill this space. In our experience, even with lifts, achieving the precisely contoured bone bed can be challenging and tedious. This "bone-island" craniotomy technique was performed rapidly and safely without the need for lifts.

DISCUSSION

The transcutaneous BCI has the advantages of fewer skin complications than percutaneous devices, while not suffering from the audiologic disadvantages of passive devices. It does not require osseointegration, allowing for activation soon after surgery. These attributes make it potentially an ideal BCI for the rehabilitation of certain cases of CMHL, as well as SSD. Several case series have demonstrated that it is both safe and effective for rehabilitating certain cases of hearing loss (15).

According to manufacturer recommendations, placement of the device requires a precisely contoured bone to accommodate the FMT of the internal device and allow the edges or wings to make good contact with the cortical bone (17). In the authors' opinion, it is challenging and tedious to size and contour the bone bed to achieve this tight fit, even if lifts are used as spacers to fill gaps between the device and the bone. This issue has also been highlighted by previous studies (19,20). The primary limiting factor to achieve the fit required is the bone at the depth of the bed does not allow the edges of the device (which are more superficial) to sit close enough to the bone. Surgeons may also be reticent to drill a deep enough bed for fear of exposing or injuring underlying dura. Our technique, developed by the senior author and examined in this study, mobilizes an island of bone by performing a craniotomy, creating an island of bone with exposed dura at the edges. The dura and overlying bone island can be gently depressed to whatever depth is required to allow the FMT to make excellent contact with the bone at margins of the craniotomy. Anecdotally, with bone-island craniotomies to inset larger ceramic encased cochlear implants, for example, the Clarion 1.2 device (Advanced Bionics, Sylmar, CA), the bone regrows along the exposed dura reconstituting an intact skull as observed in reimplantation after device failure. We are not the first to report a craniotomy technique for the placement of the transcutaneous BCI (19,20). However, several authors used a complex three-dimensional modeling to plan the craniotomy site, which we hypothesized as unnecessary (20–22). You et al. (20) frequently required lifts because they were hesitant to compress the dura, which we have found to be safe when a bone island is left in place rather than removing the bone down to the level of the dura across the entire well. The technique described by You et al. (20) required a 90-degree bend in the device. Although manufacturer guidelines allow for this, we believe that minimizing or eliminating any bend is safer for maintaining device integrity. Carnevale et al. (19) did not report audiometric outcomes and restricted the technique to those who have a previous mastoidectomy, whereas we applied to the technique to all patients including those without previous surgery, although most of our patients in our series did have previous otologic surgery. We also included eight patients younger than 18 years

(47% [8 of 17]). Our study is the first to use a craniotomy technique that precludes lifts and report audiologic outcomes in addition to surgical complications.

The most salient findings reported in this study were the few complications, lack of lifts being required in any case, secondary coverage by the temporalis muscle, and excellent audiologic outcomes. The lack of complications beyond a wound infection in a patient who had previous radiation to the area suggests that the technique is safe. The fact that lifts were not required in any case indicates that the subtemporalis muscle middle cranial fossa bone-island craniotomy technique performed its intended purpose of achieving an excellent fit of the device with the lowest possible profile. The temporalis muscle coverage of the FMT further limits a noticeable contour beneath the skin or scalp. The time from skin incision to completion of implantation was typically less than 15 minutes. We did not have a control group to compare the length of the operation, but we believe that the technique is much faster than contouring the bone bed, in which incremental drilling and frequent checking for device fit are often required. We acknowledge that surgeons may be reticent to use the technique because it technically includes performing a craniotomy, which gives the impression that the technique is more invasive than "simply" drilling a bed in the cortical bone for the device. However, we believe that a controlled and deliberate exposure of the dura around the bone island is much safer than the less deliberate (or possibly accidental) dural exposure that can occur when lowering the depth of the bed to achieve the adequate fit. Another advantage of our technique is that it gives the device a lower profile on the skull and scalp, which is safer in the case of accidental trauma to the head and results in a better cosmetic outcome.

Overall, the audiologic outcomes were excellent. Patients in the CMHL group had highly statistically significant functional gain with the device (mean, 35.3 dB HL; $p < 0.0001$), which was consistent with previous studies (5,25–27). Aided air-bone gaps were also similar to a study that used a related middle fossa technique but with an older version of the device (the BCI601) (22). One limitation was that there was no control group of patients for comparison, who ideally would have been composed of patients who underwent surgery with a conventional technique. Unfortunately, heterogeneity in the study populations and significant differences in the reporting of audiologic outcomes of existing studies make direct statistical comparison difficult; but in general, similar or better audiologic outcomes were seen in our cohort, compared with comparable studies that are shown in Table 2. Speech discrimination with the device was also very positive (mean, 90.7% word recognition score). Aided postoperative thresholds of the SSD cohort were in the range of mild hearing loss. Although our analysis was limited to adult patients for this metric, improvement in SSQ scores indicates that patients were satisfied with the device in real-world situations. For the CMHL group, the mean SSQ scores among adult patients improved from 3.71 preoperatively to 5.42 postoperatively. Although the mean SSQ scores for the two adult recipients in the SSD cohort improved from 3.26 preoperatively to 4.76 postoperatively, statistical comparison cannot be made because the cohort is too small.

Our study was not without limitations. Our sample size was not large enough to power any meaningful subgroup analysis. Limiting SSQ surveys to adult patients also reduced the power of our analysis of patient satisfaction, especially in the smaller SSD cohort. There were two patients in the CMHL cohort who had missing SSQ data. Although recent otology and audiology visits indicate otherwise, it is possible that these two patients were unhappy with or even not wearing the device, which introduces the potential for bias. There was significant clinical heterogeneity of our study population with a wide range of ages and indications with multiple different previous operations performed for ear disease. This may limit the ability to extrapolate our results to very specific clinical scenarios. Conversely, the positive outcomes despite this clinical heterogeneity suggest that the techniques are versatile, and there were no issues performing it in situations where a previously created mastoid cavity was present. There were no issues in children or older adults.

SUMMARY

The subtemporalis muscle middle cranial fossa bone-island craniotomy technique is a simple and effective way of placing the transcutaneous BCI in a variety of clinical scenarios. Our study demonstrates a lack of major complications, with the single minor complication resulting from the previous irradiated field, and excellent audiologic outcomes in a heterogeneous population managed with this technique. Future studies may include metrics such as length of surgery and patient satisfaction with comparison to other techniques and implantable devices.

TABLE 2. *Summary audiologic outcomes reported in previous studies*

	Device Location	Active Transcutaneous Bone-Conduction Implant Device Model	Postop PTA Aided A-B Gap, Mean dB HL (SD)	PTA Functional Gain, Mean dB HL (SD)
Our cohort (n = 14[a])	Subtemporalis Muscle middle fossa	602	8.55 (5.10)	35.4 (12.6)
Schmerber et al. (23)	Variable, predominantly presigmoid	601	NR	26.1 (13.7)
Cywka et al. (3)	Presigmoid	602	NR	27.0 (10.7)
Siegel et al. (22)	Middle fossa	601	4.6 (17.9)	40.3 (19.0)

[a]Conductive or mixed hearing loss patients only, 18 total in the series with 4 patients with single-sided deafness.

A-B indicates air-bone; A-C, air-conduction; Aided, active transcutaneous bone conduction implant; B-C, bone conduction; dB HL, hearing level in decibels; Middle fossa, middle cranial fossa craniotomy; Postop, postoperative; NR, not reported; PTA, our-frequency pure-tone average; SD, standard deviation.

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