HNO 2023 · 71 (Suppl 1):S61–S66
https://doi.org/10.1007/s00106-023-01295-w
Accepted: 6 April 2023
Published online: 15 June 2023

A bone conduction implant using self-drilling screws

Self-drilling screws as a new fixation method of an active transcutaneous bone conduction hearing implant

Assen Koitschev[1] · Marcus Neudert[2] · Thomas Lenarz[3]

[1] Klinik für Hals-, Nasen-, Ohrenkrankheiten, Plastische Operationen, Klinikum Stuttgart—Olgahospital, Stuttgart, Germany

[2] Klinik für Hals-, Nasen-, Ohrenkrankheiten, Plastische Operationen, Universitätsklinikum Carl Gustav Carus an der TU Dresden, Dresden, Germany

[3] Klinik für Hals-, Nasen-, Ohrenkrankheiten, Plastische Operationen, Medizinische Hochschule Hannover, Hannover, Germany

Abstract

Background: The active transcutaneous bone conduction implant (tBCI; BONEBRIDGE™ BCI 601; MED-EL, Innsbruck, Austria) is fixed to the skull with two self-tapping screws in predrilled screw channels. The aim of this prospective study was to evaluate the safety and effectiveness of fixation with self-drilling screws instead of the self-tapping screws, in order to simplify the surgical procedure.

Materials and methods: Nine patients (mean age 37 ± 16 years, range 14–57 years) were examined pre- and 12 months postoperatively for word recognition scores (WRS) at 65 dB SPL, sound-field (SF) thresholds, bone conduction thresholds (BC), health-related quality of life (Assessment of Quality of Life, AQOL-8D questionnaire), and adverse events (AE).

Results: Due to avoidance of one surgical step, the surgical technique was simplified. Mean WRS in SF was 11.1 ± 22.2% (range 0–55%) pre- and 77.2 ± 19.9% (range 30–95%) postoperatively; mean SF threshold (pure tone audiometry, PTA_4) improved from 61.2 ± 14.3 dB HL (range 37.0–75.3 dB HL) to 31.9 ± 7.2 dB HL (range 22.8–45.0 dB HL); mean BC thresholds were constant at 16.7 ± 6.8 dB HL (range 6.3–27.5 dB HL) pre- and 14.2 ± 6.2 dB HL (range 5.8–23.8 dB HL) postoperatively. AQOL-8D mean utility score increased from 0.65 ± 0.18 preoperatively to 0.82 ± 0.17 postoperatively. No device-related adverse events occurred.

Conclusion: Implant fixation by means of self-drilling screws was safe and effective in all nine patients. There was significant audiological benefit 12 months after implantation.

Keywords
Bone screws · Hearing loss and implants · Bone-anchored hearing systems · Bone-hearing-implant interface · Hearing loss

The German version of this article can be found under https://doi.org/10.1007/s00106-023-01294-x

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New fixation method

Patients with conductive (CHL) or mixed hearing loss (MHL) may benefit from a bone conduction hearing aid. The active transcutaneous bone conduction implant (tBCI, BCI 601), which has been approved for this indication since 2012, consists of an active implantable transducer and an external audio processor. The audio processor transmits the signal via an inductive transcutaneous connection, which stimulates the electromagnetic implant to vibrate. The optimal fixation of the vibrating implant in the bone is ensured by two self-tapping screws that require pre-drilling. Since the screws facilitate the transmission of vibration to the cranial bone, optimal

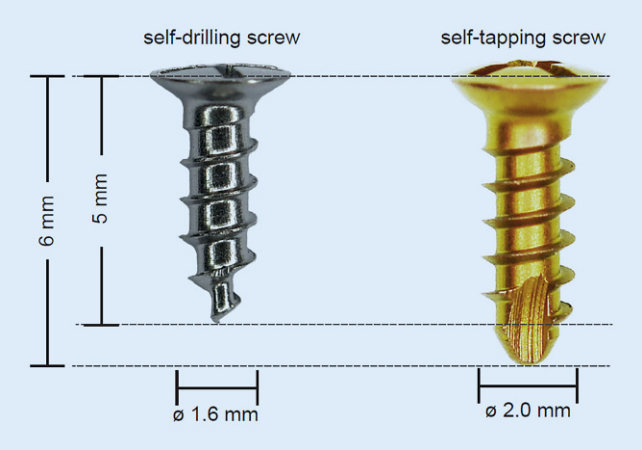

Fig. 1 ◀ Self-drilling and self-tapping screws in comparison. *Left* self-drilling screw, ∅ 1.6 mm, length 5 mm; *right* self-tapping screw, ∅ 2.0 mm, length 6 mm

anchoring is an essential prerequisite for the acoustic effect of the implant.

Many studies have described the effectiveness of the implant, with the aforementioned bone fixation method [1, 2, 5, 6, 12, 13, 16, 17, 23]. In this study, the safety and effectiveness of using self-drilling screws, which do not require pre-drilling for implant fixation, were reviewed after an observation period of at least 12 months.

Materials and methods

Study design and surgical procedure

In this multicenter, prospective study, 5- or 6-mm self-drilling screws were used (**Fig. 1**); the 6-mm screw could be implanted in combination with a 1-mm BCI lift [3].

Cranial screws such as those used in craniofacial surgery, e.g., in trauma cases, were used.

The initial stability of the implant was checked intraoperatively using palpation, and the audiological results over the subsequent 12 months supported this.

The indications were CHL or MHL, with the bone conduction threshold (BC-$PTA_4 \leq 30$ dB HL) corresponding to the manufacturer's specifications (MED-EL, Innsbruck, Austria). Audiological assessments were performed preoperatively and 12 months postoperatively, and study participants filled out a quality-of-life questionnaire (Assessment of Quality of Life, AQoL-8D).

Participants were included in accordance with the Declaration of Helsinki 2008, with the approval of the ethics committees (Stuttgart: 392/2017BO1; Hannover: 7596; Dresden: EK233062017), and after obtaining informed consent.

Since a control group was not planned, the data from the current study were compared with the patient group from the publication by Sprinzl et al. [17].

Audiometric methods

The audiological evaluation was carried out using pure-tone audiometry, hearing thresholds in free field (FF), and the Freiburger monosyllable test at 65 dB in FF. All patients wore the Samba BB audio processor (MED-EL). The contralateral ear, which did not have an implant, was audiologically masked, if possible. Masking was not possible in two patients because of a malformation in the untreated ear.

All FF measurements were carried out after optimizing the patient's audio processor settings, taking into consideration individual tolerances in volume and sound quality.

Bone conduction thresholds

The mean bone conduction threshold (PTA_4) was calculated from the sum of the measured values of the frequencies 0.5, 1, 2, and 4 kHz, divided by 4.

Changes in a patient's bone conduction PTA_4 value of ≤ 10 dB HL were not considered to be clinically relevant.

Hearing thresholds in free field

The evaluation of the FF hearing threshold was carried out with a warble tone stimulus, and an individual PTA_4 improvement of ≥ 15 dB HL with the implant was defined as the secondary target criterion of the study.

Freiburger monosyllable test in free field

The Freiburger monosyllable test was performed in FF at 65 dB SPL, in which an improvement of ≥ 15% with the implant considered to be significant.

Speech intelligibility improvement of ≥ 15% on the Freiburger monosyllable test with the implant was the primary target criterion of the study.

Adverse events

Adverse events (AEs) were recorded from the beginning of the patient's enrollment in the study until the 12-month postoperative follow-up.

Quality of life

The AQoL-8D questionnaire was used to evaluate the patients' quality of life [10]. The AQoL-8D is a generic health-related questionnaire consisting of 35 questions. These 35 questions are divided into two dimensions (physical and mental), which in turn are divided into eight further domains. This results in an index of the patient's quality of life—the "utility score." The pre- and postoperative AQoL-8D results were compared with a weighted algorithm using version 25 of IBM SPSS (IBM, Armonk, NY, USA). The maximum and minimum of the weighted algorithm range between 0 and 1.

Statistical analysis

Statistical significance was set at $p \leq 0.05$. A per-protocol analysis was carried out. The software IBM SPSS Statistics, Version 25 was used for statistical analysis.

Results

Patients

A total of 12 patients (12 ears) from three ENT clinics (Klinikum Stuttgart—Olgahospital; Carl Gustav Carus University Clinic at TU Dresden; Hannover Medical School) were included in the study between December 2017 and January 2019. Three

Table 1 Patients ($n = 9$)

Patient ID	Etiology	Gender	Side	Type of hearing loss	Age (year)	Age at onset of hearing loss (years)
1	COM	m	R	Mixed	43	37
2	COM	f	R	Mixed	39	17
3	Glomus tumor	m	L	Mixed	39	34
4	COM	f	R	Mixed	49	38
5	Atresia	f	L	Mixed	16	0
6	COM	f	R	Mixed	54	9
7	Atresia	m	R	Mixed	57	0
8	COM	m	L	Conductive	22	14
9	COM	f	L	Conductive	14	1
Mean ± SD					***37 ± 16***	***17 ± 16***

COM chronic otitis media, *m* male, *f* female, *r* right, *l* left, *SD* standard deviation

patients had to be excluded due to various reasons (insufficient explanation of the informed consent, incorrect screws). Thus, nine out of 12 patients were included in the analysis.

The mean age of the patients (5 women, 4 men) was 37 ± 16 years (14–57 years). Five patients underwent implantation on the right and four patients on the left ear. Seven patients suffered from MHL, while two patients suffered from purely CHL. The cause of hearing loss was chronic otitis media in six patients, congenital bilateral atresia in two, and glomus tumor in one patient (**Table 1**).

Self-drilling screws

The bone structure surrounding the implants was compact/cortical and at least 2 mm thick in all nine patients. In all patients, the implant was secured primarily in the mastoid without the use of emergency screws or change of position and was stable on palpation.

Audiological results

All patients used the Samba BB audio processor. The setting was individually adjusted so that the best subjective improvement in speech understanding could be achieved during the 12-month postoperative period.

Bone conduction threshold

The mean bone conduction PTA_4 hearing threshold ($n = 9$) was 16.7 ± 6.8 dB HL (6.3–27.5 dB HL) before surgery and 14.2 ± 6.2 dB HL (5.8–23.8 dB HL) 12 months postoperatively (**Fig. 2**). All nine patients showed stable individual BC PTA_4 mean values.

Hearing thresholds in free field

The mean FF PTA_4 hearing threshold ($n = 9$) in the unaided state was 61.2 ± 14.3 dB HL (37.0–75.3 dB HL). This improved to 31.9 ± 7.2 dB HL (22.8–45.0 dB HL; **Fig. 3**) with the Bonebridge 12 months postoperatively.

Overall, eight out of nine patients achieved or exceeded the specified target criterion of individual improvement in FF PTA_4 of ≥ 15 dB HL (16.3–45.0 dB HL) 12 months postoperatively. One patient took an additional 8 months to show an improvement in the FF hearing threshold (PTA_4) from 38.8 dB HL to 26.3 dB HL, i.e., 20 months after the implantation. This prolonged course also corresponded to the delayed improvement in monosyllabic speech understanding. This delayed improvement in speech understanding was due to volume intolerance, which resulted in the patient being unable to fully use the amplification power of the system after 12 months.

Freiburger monosyllable test in free field

The implant treatment resulted in a clear improvement in speech understanding in all patients 12 months after the implantation. The mean monosyllabic speech recognition score increased by 66.1%, from 11.1 ± 22.2% (0–55%) to 77.2 ± 19.9% (30–95%; **Fig. 4**). One of the patients had a relatively low speech recognition score of 30% (preoperative 0%) 12 months postoperatively, and therefore the tests were repeated 8 months later (20 months after the implantation), with an improvement from 30% to 55%. The bone conduction threshold was stable. All nine patients exceeded the study's primary endpoint of at least 15% improvement in speech recognition score at 12 months, and the results showed statistical significance on the Wilcoxon signed-rank test ($p = 0.008$).

Adverse events

One patient reported fluctuating vertigo and otalgia, presumably due to a previous radical cavity development with damage to the vestibular organ on the implanted side. These symptoms were found to be unrelated to the implantation.

A few weeks after the implantation, another patient, who had previously undergone pinna reconstruction and implantation of an osseointegrated bone anchor, which resulted in scars and aggressive skin thinning in the mastoid area at the edge of the implant housing, presented with skin dehiscence approximately 5 cm from the implantation scar. Two follow-up surgeries were required to cover the implant housing using local plastic skin flaps (**Table 2**). A total of two AEs (2/9 = 22.2%), none of which were device- or procedure-related, occurred in the study.

Quality of life

The AQoL-8D questionnaire was used to evaluate the patients' quality of life [8]. The values of the individual dimensions were compared before and after the implantation. Overall, quality of life in these nine patients showed a significant improvement, increasing from a mean score of 0.65 ± 0.18 preoperatively to 0.82 ± 0.17 at 12 months postoperatively (**Table 3**). Since the questionnaire is generic and not related to symptoms, improvements in quality of life can only be expected in certain subdomains. These are particularly evident in the fields of communication/self-esteem.

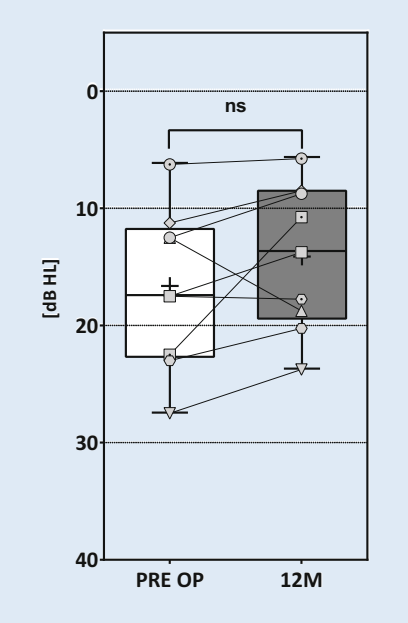

Fig. 2 ▲ Bone conduction thresholds ($n = 9$). Preoperative results were compared with 12-month postoperative data. + mean; *horizontal lines* median; *circles, squares, triangles pointing up, triangles pointing down, hexagon, diamond* these symbols represent the distribution of the individual patient values; *whiskers* represent the maximum and minimum; *ns* not statistically significant

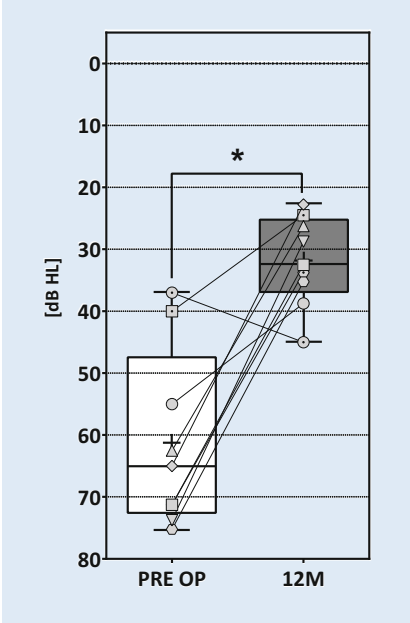

Fig. 3 ▲ Free-field audiometric thresholds ($n = 9$). Mean hearing threshold at the tested frequencies for the implanted ear in the free field. The opposite ear was audiologically masked. Preoperative (unaided) hearing thresholds compared to aided hearing thresholds 12 months postoperatively. + mean; *horizontal lines* median; *circles, squares, triangles pointing up, triangles pointing down, hexagon, diamond* these symbols represent the distribution of the individual patient values; *whiskers* represent the maximum and minimum; * statistical significance

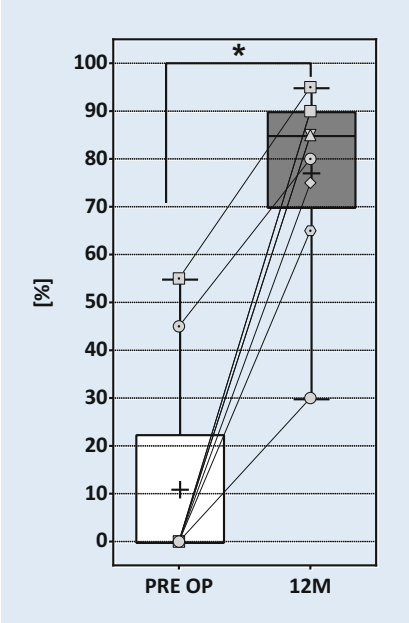

Fig. 4 ▲ Freiburger monosyllable test at 65 dB SPL. Monosyllabic speech understanding was compared preoperatively (unaided) and 12 months postoperatively (aided). + mean; *horizontal lines* median; *different symbols* represent the distribution of the individual patient values; *whiskers* maximum and minimum, * statistical significance

Discussion

The data of this study show that the BCI 601, with simplified fixation to the cranial bone using self-drilling screws, significantly improves speech understanding in FF. At 12 months after the implantation, the mean FF hearing threshold improved from 61.2 ± 14.3 dB HL to 31.9 ± 7.2 dB HL with the implant, resulting in a significant functional gain of 30.3 dB HL ($p = 0.001$). The mean monosyllabic word recognition score improved from 11.1 ± 22.2% preoperatively to 77.2 ± 19.9% postoperatively, resulting in a mean improvement in speech understanding of 66.1%. It was assumed that the hearing threshold in FF with the implant switched on was sufficient to assess the quality of the acoustic coupling, so that no vibrogram was necessary.

In the meantime, the BCI 601 has been replaced by a new model, BCI 602, which now uses identical self-drilling screws to those used in this study, as standard tools for fixation.

Sprinzl et al. in 2021 [17] and in 2023 [18] reported similar improvements, from a mean FF PTA_4 hearing threshold of 57.66 and 55.71 dB HL before the implantation to 28.4 dB HL and 26.16 dB HL after the implantation, using self-tapping screws in combination with the BCI 601 and BCI 602. The monosyllabic word recognition score improvement was 64.8% and 68.0%, from 17.6% and 8.48% preoperatively to 83.46% and 76.5% at 12 and 3 months post-implantation, respectively.

Comparable audiological results were achieved in further studies using the classic fixation method [1, 4, 6, 9, 12, 14, 16, 19, 20].

Sprinzl et al. reported 15 adverse device effects (ADE) in 14 patients (24.6%) and three patients (5.3%) with serious device-related adverse effects [17]; a subsequent study had two ADEs in two (8.69%) out of 23 patients [18].

A total of two AEs (2/9 = 22.2%) occurred in our study, neither of which were device- or procedure-related. The AEs were attributed to pre-existing medical conditions.

Cywka et al. [7] reported a pre- and postoperative mean FF PTA_4 hearing threshold of 64.4 dB HL and 37.4 dB HL with the BCI 602; the monosyllabic word recognition score increased from 13.5% to 87.6% at 12 months after the implantation. Cywka et al. also observed that the duration of the surgery with the BCI 602 was shorter than with its predecessor, and the effectiveness and safety remained constant compared to the BCI 601.

Skarzynski et al. [15] also compared results between the BCI 601 and the BCI 602, with the BCI 601 achieving a mean FF PTA_4 hearing threshold of 68.6 dB HL before and 38.6 dB HL 6 months after the implanta-

Table 2 Adverse events

Patient ID	Event	Event description	Event outcome
4	AE	Chronic imbalance with fluctuating vertigo and intermittent otalgia	Ongoing
5	SAE	Skin dehiscence over the implant caused by scarring from previous percutaneous screw	Resolved
5	FU	Recurrent skin dehiscence at the implanted ear	Resolved

AE adverse event, *SAE* serious adverse event, *FU* follow-up

Table 3 Quality of life questionnaire

	Preoperative mean ± SD	12 Months postoperative mean ± SD	*p*
Independent living	0.91 ± 0.08	0.96 ± 0.06	0.089
Happiness	0.85 ± 0.06	0.88 ± 0.07	0.092
Mental health	0.62 ± 0.15	0.69 ± 0.15	0.66
Ability to cope	0.78 ± 0.12	0.89 ± 0.07	0.018
Relationships	0.66 ± 0.14	0.81 ± 0.18	0.008
Self-worth	0.74 ± 0.14	0.89 ± 0.09	0.012
Pain	0.89 ± 0.16	0.87 ± 0.18	0.068
Senses	0.55 ± 0.12	0.78 ± 0.15	0.012
Physical	0.16 ± 0.15	0.76 ± 0.19	0.011
Mental	0.36 ± 0.16	0.55 ± 0.21	0.008
Utility—utility score	0.65 ± 0.18	0.82 ± 0.17	0.008

Weighted AQoL-8D data, preoperative and 12 months postoperative ($n = 9$), ordered by domain
SD standard deviation
The *p* value was calculated using the Wilcoxon signed-rank test. Statistical significance was set at $p \leq 0.05$

tion; the monosyllabic word recognition score increased from 9.3% to 85.0%. The BCI 602 demonstrated a mean FF PTA_4 hearing threshold of 60.6 dB HL preoperatively and 36.4 dB HL postoperatively; the monosyllabic word recognition score improved from 33.9% to 87.2%. Skarzynski et al. based the decision to implant a BCI 601 or BCI 602 on individual patient anatomy.

The reliability of self-drilling screws in traumatology [21] is well known [11]), but to date it has been rarely studied in vibrating implants. You et al. [22] successfully implanted the same tBCI in 37 patients, cranially to the mastoid, in contact with the dura of the middle fossa, using 6-mm-long self-drilling screws. Audiological results were stable over a reporting period of up to 6 years [14].

The measured hearing improvement in our study was confirmed by an increase in the subjective quality of life. Maxwell et al. defined the lower limit of the normal state for the weighted index of quality of life ("utility score") to be 0.792 ± 0.185 [10]. In our study, the mean weighted AQoL-8D score increased from 0.65 ± 0.18 preoperatively to 0.82 ± 0.17 12 months postoperatively, with an improvement reported both in mental and in physical dimensions. In the domains "self-esteem" and "relationship" the increases were clearly significant. These domains correlate best with improvements in communication.

In summary, based on the data of this study, it can be stated that the simplified fixation of the tBCI (BCI 601) in the mastoid, using self-drilling screws, represents a problem-free and safe implantation while maintaining the known advantages of the system in terms of hearing gain. The hearing improvement remained stable for a period of at least 1 year, despite the fact that it is a vibrating implant. A long-term statement regarding its stability can only be made with the help of further studies with more patients; more minors should be included in the study population and several postoperative measurements should be made.

Practical conclusion

- **Since its approval in 2012, the active tBCI (Bonebridge BCI 601) implant has been attached to the cranial bone using two self-tapping screws that require a pre-drilled channel.**
- **This study shows that the direct fixation of the tBCI in the mastoid with self-drilling screws represents a simplification of the implantation with comparable improvement in hearing and quality of life over a period of at least 1 year.**
- **The use of self-drilling screws did not pose any additional risks or complications and was just as reliable as the original method of implantation.**
- **The study provides a central argument for this type of implant fixation with the current version (BCI 602) of the tBCI.**

Corresponding address

Prof. Dr. med. Assen Koitschev
Klinik für Hals-, Nasen-, Ohrenkrankheiten, Plastische Operationen, Klinikum Stuttgart—Olgahospital
Kriegsbergstraße 62, 70174 Stuttgart, Germany
a.koitschev@klinikum-stuttgart.de

Funding. The supplement containing this article is not sponsored by industry.

Declarations

Conflict of interest. A. Koitschev, M. Neudert and T. Lenarz declare that they have no competing interests. The participating clinics and principal investigators had no financial or professional relationship with the sponsor that could have influenced the study. MED-EL (Innsbruck, Austria) sponsored the study (Ethics Committee fees, study conducting fees, travel expenses for the patients). Aylin Zengin and Noelani Peet (both MED-EL) edited a version of the manuscript.

For this article no studies with human participants or animals were performed by any of the authors. All studies mentioned were in accordance with the ethical standards indicated in each case.

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