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International Journal of Surgery Case Reports

journal homepage: www.casereports.com

Image-guided implantation of the Bonebridge™ with a surgical navigation: A feasibility study



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ARTICLE INFO

Article history:

Received 12 September 2016

Accepted 28 November 2016

Available online 30 November 2016

Keywords:

Bonebridge

Surgical navigation

3D simulation software program

Temporal bone

ABSTRACT

OBJECTIVE: To access a method of fitting a designated location on the patient's temporal bone by surgically navigating to the Bonebridge implantation.

STUDY DESIGN: A patient with unilateral profound hearing loss received early intervention with the Bonebridge implant for binaural hearing. The optimal implant site was determined from computed tomography (CT) images using a three-dimensional (3D) simulation software program before the surgery. The pre-calculated coordinates from the 3D simulation software program were moved to the Scopus Hybrid Navigation System. After using the surgical navigation system for the surgery, we evaluated the degree of mismatch of the center of the bone conduction-floating mass transducer (BC-FMT) between the computer simulation and the actual drilling.

RESULTS: The time required to determine the implant location on the surface of the patient's temporal bone was shortened, and the accuracy of the implantation was high. The coordinates on the 3D simulation system were comparable to the surgical navigation system. The predicted coordinates were replicated exactly upon actual drilling during the surgery, and we could confirm this in preoperative and postoperative images.

CONCLUSIONS: Using an image-guided surgical navigation system to aid in the placement of the BC-FMT on the simulated location is a simple procedure and is more effective than finding the exact coordinates. It also shortens the decision time for applying the implant.

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1. Introduction

The Bonebridge™ (Med-EL, Innsbruck, Austria) is an implantable bone conductive hearing device for patients with conductive, mixed or unilateral hearing loss [1–3]. It is semi-implantable and the bone conduction implant is positioned completely under the skin. However, it is difficult for the surgeon to decide on an appropriate location for the bone conduction-floating mass transducer (BC-FMT) in the narrowed surgical field because the transducer is large (8.7 mm in thickness, 15.8 mm in diameter) and requires a 3–4 cm minimal incision [4]. Since the Bonebridge must be embedded into a more dangerous structure such as sigmoid sinus or dura of the brain, a guide with high accuracy is required. The surgical workflow of the Bonebridge implantation procedure from Med-EL, Ltd., is not sufficient for finding the exact insertion location on the temporal bone in patients with congenital malformations in the middle and external

ear or in those with a history of multiple middle ear surgeries. Although there are a few simulation methods to calculate the best location for implantation [5–7], those are less successful in precisely replicating the simulation results in the actual surgery. Image-guided surgical navigation is currently the most reliable method to aid in placement of the BC-FMT on the simulated location.

We recently developed a successful preliminary experiment for applying surgical navigation to Bonebridge implantation in a patient with unilateral hearing loss. This is the first report to describe a method that fits only on the designated location on the bony surface of the patient's temporal bone. We were able to implant the Bonebridge safely and accurately into the targeted place when compared with 3D simulation software program [8].

2. Methods

2.1. Patient

A 51-year-old woman was suffering from profound unilateral hearing loss (90 dB at 0.5, 1, 2, and 4 kHz) in the right ear because

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of sudden idiopathic sensorineural hearing loss for six months. Despite using a hearing aid, she complained of an inability to perceive sounds in the deaf ear, difficulty comprehending speech and the presence of competing noise that negatively impacted her localization of sound. We decided on an early intervention with the

Bonebridge for binaural hearing with her agreement. She agreed upon the use of surgical navigation during the implantation to determine the exact location of the Bonebridge on the temporal bone.

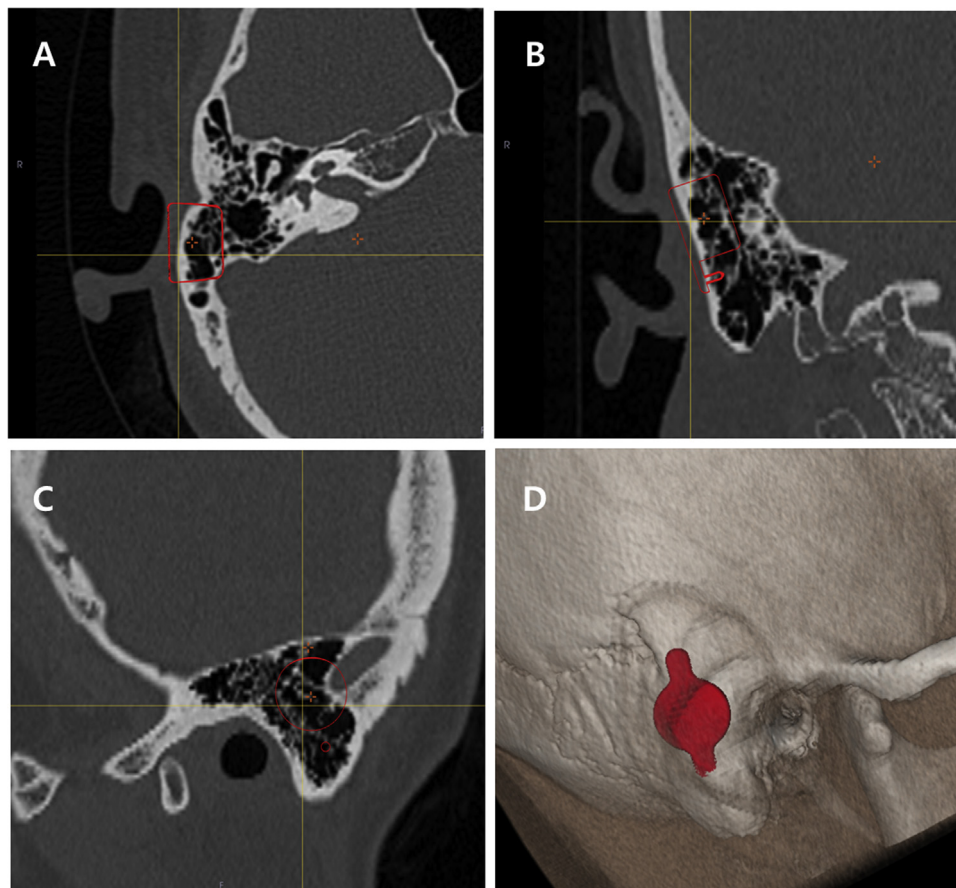


Fig. 1. Coordinates on the 3D simulation software program, i.e., BB fast view (CEIT, Guipuzcoa, Spain) show the recommended location of the BC-FMT (red lines) in the right mastoid. CT scan images show the axial (A), coronal (B), sagittal (C) views, and 3D reconstructed views (D) with a transducer position (red lines) that is located on the sigmoid sinus.

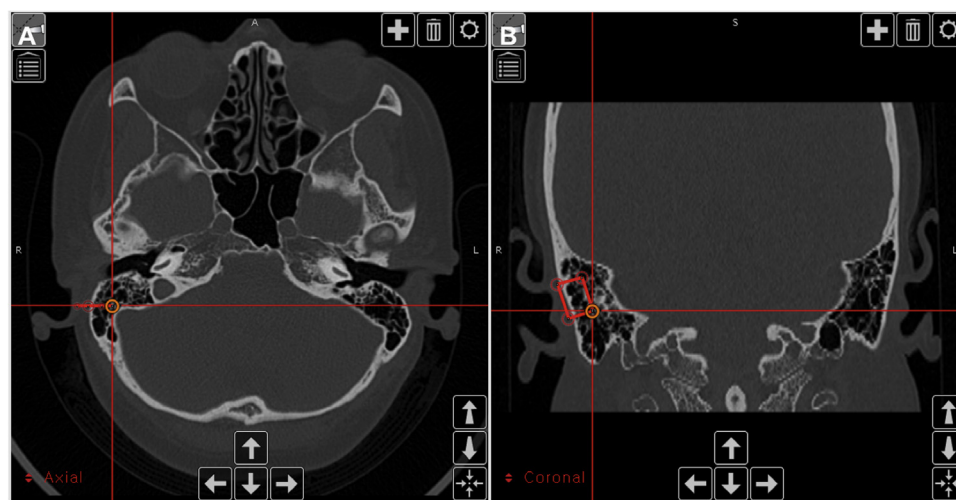


Fig. 2. The pre-calculated coordinates of 3D simulation software program were moved to the Scopis Hybrid Navigation System (Megamedical, Seoul, Korea). In the axial (A) and coronal (B) images, the orange and red spots represent the coordinates of the 3D simulation system. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

2.2. Preoperative imaging

Computed tomography (CT) datasets of the four temporal bones (768×768 pixels at a resolution of 0.129 mm/pixel and a slice thickness of 0.67 mm) were imported into the BB fast view (CEIT, Guipuzcoa, Spain) 3D simulation software program using the Digital Imaging and Communications in Medicine (DICOM) format. The location of the BC-FMT was determined as suggested in the surgical manual provided by the Bonebridge manufacturer. The optimal implant site was determined on CT images using the 3D simulation software program before the surgery (Fig. 1). The Scopis

Hybrid Navigation System (Megamedical, Seoul, Korea) was developed for use in ENT operations and helps doctors recognize the direction and structure of the operating area and the exact location of surgical equipment. The pre-calculated coordinates on the 3D simulation software were moved to the surgical navigation system (Fig. 2).

2.3. Navigation assisted demarcations on the temporal bone

Before the patient's entry into the room, the patient's radiological data were transferred to the surgical navigation system



Fig. 3. An actual surgery with image-guided surgical navigation to aid in the placement of the BC-FMT at the simulated location. We drew the location coordinates on the skin of the temporal bone during the perioperative period (C).

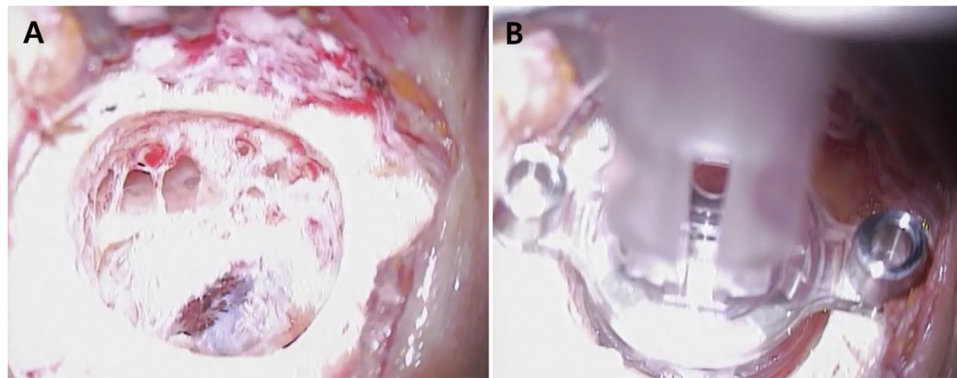


Fig. 4. To determine the depth of the BC-FMT, we exposed a part of the sigmoid sinus with the help of the surgical navigation system (A). The BC-FMT size gauge fit exactly on the temporal bone (B).

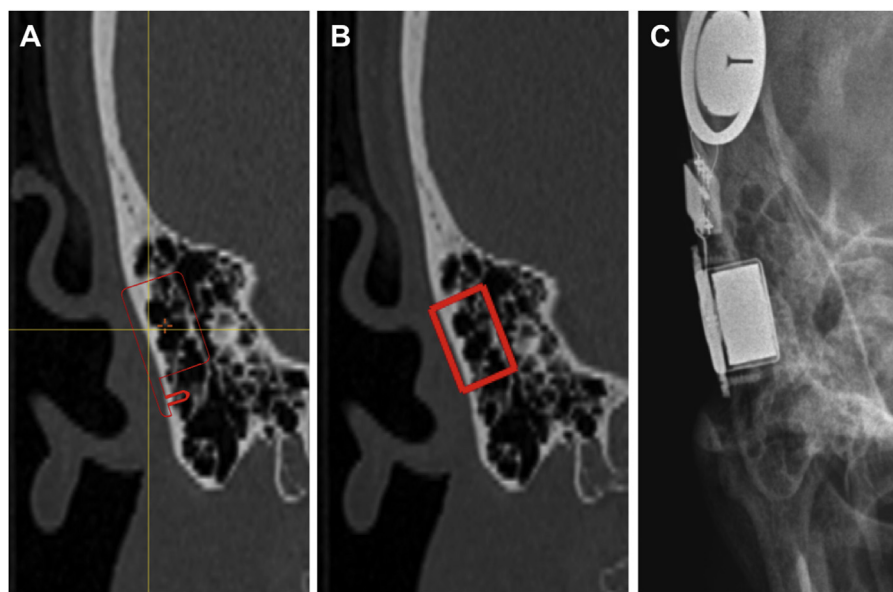


Fig. 5. We confirmed the accuracy of the image-guided surgical navigation method by determining the degree of mismatch between the computer simulation location and the actual drilling location by comparing X-ray images (transocular view, C) with the images from preoperative 3D simulation (A) or perioperative navigation (B).

workstation. After anesthesia, the patient electromagnetic tracker enabled the coordinates measuring on the temporal bone during surgery. This was attached with a non-invasive head band on the patient's forehead. The tracker came with a remote control, an instrument verification functionally and a calibration area for the instrument adapter system. The anatomic reference points used during the calibration included the tragus, antihelix, nasion, lateral canthus of both eyes, the groove of the incisors, nasal labial angle, and the lateral process of the malleus. To complete the preoperative tasks, the 3D model was edited as needed and our desired anatomical landmarks and fiducials were registered on the workstation using on the three 2D view (axial, coronal, and sagittal views). We confirmed that the previously selected, computer registered points were correlated with their actual physical coordinates using the blunt tip pointer (probe) to identify fiducials and anatomical landmarks on the temporal bone of the patient.

Intraoperatively, the blunt probe was used to identify structures and to outline the extent of the drilling. Accuracy was accessed simultaneously on the screen with the alarm, which a special landing and alarm system ensured safe and quick navigation to

anatomic targets during the operation to prevent the surgical errors (Fig. 3).

2.4. Evaluation of postoperative CT

We obtained a transocular X-ray to identify the location of the BC-FMT and the anchor screws after implantation. We evaluated the degree of mismatch between the computer simulation and the actual drilling based on the distance between the center of the outer circle of the BC-FMT and the mastoid tip on X-ray compared with the preoperative 3D simulation or perioperative navigation images (Fig. 5).

3. Results

The time required for the procedures consisted of marking the surface, performing the surgical navigation, and using the drill. The average navigation processing time was 98.2 min. Considering that setting up for the navigation procedures took 21.8 min, we thought that the time required to determine the implant location on the

surface of the patient's temporal bone was shortened and more easily performed. The coordinates on the BB fast view were comparable to the surgical navigation system. Through simulating with the BB fast view, we predicted that exposure of the sigmoid sinus was inevitable before the implantation. We could determine the exact coordinates of the sigmoid sinus in the surgical field by using the navigation system, and we could expose part of the sigmoid sinus as much as we needed (Fig. 4). With the navigation system, the locations of screws could also be predicted. These expected coordinates were exactly replicated upon actual drilling (Fig. 5).

4. Discussion

The Bonebridge is an active bone conduction implant (BCI) that is primarily indicated in patients with conductive and combined hearing loss. It requires precise identification of the sigmoid sinus, which cannot be achieved accurately by using external anatomical landmarks. In this study, we showed an effective approach for Bonebridge implantation using surgical navigation to determine the exact coordinates of implantation on the patient's temporal bone. This observation highlights the necessity for surgical preplanning and neuronavigation in procedures involving the Bonebridge.

The 3D simulation software for Bonebridge has been developed to enable safe implantation. Lassaletta et al. [9] used the 3D slicer 4.1 software for surgical planning. According to this program, the implant transducer should be positioned in the retrosigmoid area. According to Wilmmer's study [10], using Amira[®] visualization software (VSG, Burlington, MA, USA), they showed the feasibility of using topographic bone thickness maps in a standard presigmoid Bonebridge implantation. However, the 3D simulation software is not enough to be applicable to implantation in the patient's temporal bone. Since there is no landmark in the actual surgery, the sigmoid sinus and dura are sometimes inadvertently exposed. By using the 3D simulation software in conjunction with a navigation system we increased the implant location accuracy. We exposed part of sigmoid sinus on the surgical field with assistance from the navigation system, as was expected in the 3D simulation program before the surgery.

The first report on image-guided surgical navigation being applied in otolaryngology for sinus surgery was in 1985 by Schlondorff et al. [10]. Many potential benefits existed in applying these systems to otology and neurotology, and they suggested that accuracy with a margin of error less than 1 mm would be needed to successfully utilize navigational systems in the temporal bone [11,12]. Using intraoperative anatomic landmarks in combination with fiducial markers, they found the accuracy within the temporal bone region to be between 0.9–1.5 mm. Furthermore, they found that the system decreased operating time and increased safety in a series of 11 patients [13]. Another study group recently provided insight into a new navigator-guided approach for modiolar implantation through the cochlear apex in auditory nerve implantation [14]. There was a CT-assisted Bonebridge implantation trial using a retrosigmoidal approach [15], but the navigation was invasively fixed in the skull and just showed the location of the dura and sigmoid. In our study, we used the attached reference on the forehead by a bandage, and we showed the correlation of coordinates between a preoperative 3D simulation program and an intraoperative navigation program. We thought that this method would be more effective in finding the exact coordinates for implantation and in shortening the time for applying the implant.

Image-guided surgical navigation to aid in the placement of the BC-FMT at the simulated location is a simple procedure. If surgeons can input the coordinates into a 3D simulation and navigation program, they could apply a probe into the surface of the temporal

bone during surgery and drill the BC-FMT without any prior training. This preoperative simulation method is feasible, but this study suggests that applied neuronavigation is essential for Bonebridge implantation.

Conflict of interest

None.

Financial disclosure information

This material is based upon work supported by the National Research Foundation of Korea (NRF) grant funded by the Korea government (MSIP) (2015R1C1A1A02036354) and by the Ministry of Trade, Industry & Energy (MOTIE, Korea) under Industrial Strategic Technology Development Program (10051518).

Ethical approval

No ethical approval needed.

Consent section

Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

Authors contribution

THK: writing in journal.
YAP: assistant of surgery and help the surgery.
YJS: did the surgery.

Guarantor

Young Joon Seo.

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