Clinical Experience Using the Active Transcutaneous Bone Conduction Implant (Bonebridge) in Children Under 5 Years Old

Running title: Bonebridge implantation under age 5

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Conflict of Interest and Source of Funding

The authors declare that there are no conflicts of interest.

This research was supported by the Basic Science Research Program through the National
Research Foundation of Korea (NRF) funded by the Ministry of Education (NRF-2020R1I1A1A01067241 to S.H. Bae).

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Acquisition, analysis, or interpretation of data: All authors.

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The Bonebridge active bone conduction implant (Med-El, Innsbruck, Austria) was developed to overcome skin and osteointegration complications of Bone anchored hearing aid (BAHA). Hearing outcomes are comparable between patients with conductive hearing loss receiving the Bonebridge device and those receiving BAHAs [1]. The Bonebridge device is permitted for use in children over 5 years old in Europe and in those over 12 years old in the USA. Such limitations are based on concerns regarding the size and thickness of the skull, which are relatively insufficient for the floating mass transducer (FMT). The thickness of cortical bone in the retro-sigmoid area in a 3-year-old child is approximately 3.5 mm [2,3]. The FMT of the BCI 601 model (Med-El, Innsbruck, Austria) is significantly thicker at 8.7 mm, and this discrepancy can theoretically result in intracranial complications. Nevertheless, hearing rehabilitation outcomes may be better when interventions are implemented early, as demonstrated in studies concerning cochlear implantation. Because early childhood is regarded as a critical period of language development [4], strategies for addressing these limitations may be necessary to improve patient outcomes.

In this report, we discuss six cases in which the Bonebridge implant was applied in Korean children under the age of 5 years. The feasibility of implantation in children younger than recommended ages is discussed in relation to our institutional experience. To the best of our knowledge, this is the first study to report Bonebridge outcomes and complications in children under the recommended age.

We identified six children under the age of 5 years who received the Bonebridge implant between 2015 and 2020. (Table 1) Skull thickness was calculated from an axial CT image of the temporal bone obtained at the level of the lateral semicircular canal. Skull thickness was defined as the average thickness of the thickest and thinnest parts of the retro-
sigmoid area. The institutional review board of the author’s affiliated hospital approved this retrospective study (4-2021-1157). The requirement for informed consent was waived due to the retrospective nature of the study. **Before surgery, sufficient information including the approved age of the device was given to parents. Surgery was decided after a deep discussion and agreement with the parents.**

All surgeries were conducted by one experienced ENT surgeon. The implanted model was the BCI 601 in all enrolled patients. The site of implantation was selected by the surgeon based on preoperative temporal CT and direct surgical findings. The surgery was performed in accordance with the procedure recommended by the manufacturer. Auditory brainstem responses (ABRs) or pure-tone audiometry (PTA) were used to confirm conductive hearing loss. The test selected (ABR or PTA) was based on the patient’s cooperation. If the patient was unable to understand conventional PTA, play PTA was conducted. Assessments of ABRs including bone conduction were performed if play PTA was also not possible.

The site of FMT implantation is determined mostly based on the status of the mastoid bone. For retro-sigmoid implantation, the skull was carefully drilled to create a thin island bony flap. After the dura was exposed, the skull and dura around the FMT well were gently dissected. Surgicel® was packed into the space between the dura and the skull. The sigmoid sinus was always identified and used as a landmark.

No intra-operative complications including cerebrospinal fluid leakage or bleeding were observed. However, patient #3 exhibited lethargy immediately after discharge and developed paralysis of the left abducens nerve (CN6) 1 week after surgery. After neurologic and ophthalmologic examination, the patient was diagnosed with increased intracranial pressure (IICP). After the Bonebridge device was removed, the patient recovered from the above-mentioned complications. No other patients experienced complications during the
follow-up period.

Four of six enrolled patients were examined using aided PTA. All patients experienced hearing gain using the Bonebridge device (Figure 1). The mean of the average PTA threshold (average thresholds of 0.5, 1, 2, and 4 kHz frequencies) decreased from 58.8 dB (unaided air conduction threshold) to 28.3 dB (aided threshold). The smallest difference between the aided and bone conduction thresholds was observed at frequency of 2 kHz.

We aimed to share our experience with Bonebridge® implantation in children under 5 years old. Obvious hearing gains were observed following implantation in all patients. Furthermore, surgical findings were unremarkable, and no long-term complications were identified. However, one of the six patients experienced serious complications associated with IICP shortly after surgery. Given that the FMT is thicker and larger relative to the skull in young children, IICP is a major concern. IICP has never been reported as a complication for adults and children after cochlear implantation, BAHA, or Bonebridge surgery [5-10]. In this regard, the IICP observed in this patient seems to be associated with his young age.

Except for a risk of IICP, our findings indicate that the Bonebridge implant may be safe and beneficial for children under 5 years of age, as we observed no complications over a follow-up period of at least 2 years. In this study, the mean of the aided average PTA threshold was 28.3 dB (functional gain of 30.5 dB), and the most effective frequency was 2 kHz. Functional gain was consistent with previously reported results for the Bonebridge implant [9].

The BCI 602 device has recently been commercialized and exhibits an FMT thickness of 4.5 mm from the surface of the skull, which is remarkably thinner than that of the BCI 601. This advance may significantly reduce the risk of complications resulting from compression of brain structures including the dural venous sinus. Our findings highlight the need for future
prospective studies to investigate implantation of the BCI 602 device in younger children.

In conclusion, our findings indicate that the Bonebridge device can be implanted in children under 5 years old when extreme care is taken to avoid compression of the sigmoid sinus. Furthermore, functional gain was comparable to that observed in older patients, and no intra-operative or long-term complications were observed.
References


Figure Legends

Figure 1. The audiogram findings after the Bonebridge implant in younger children. AC, air conduction; BC, bone conduction. Error bar = SD.
Table 1. Patient characteristics

<table>
<thead>
<tr>
<th>Patient number</th>
<th>Sex</th>
<th>Operative age (months)</th>
<th>Skull thickness (mm)</th>
<th>Follow-up duration (months)</th>
<th>Side</th>
<th>Contralateral hearing threshold</th>
<th>Model/Sound processor</th>
<th>CHL etiology</th>
<th>Syndromic disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>Female</td>
<td>49</td>
<td>5.03</td>
<td>62</td>
<td>Left</td>
<td>No response</td>
<td>BCI601/ Amadé</td>
<td>Ossicle anomaly (L)</td>
<td>CHARGE SD</td>
</tr>
<tr>
<td>#2</td>
<td>Male</td>
<td>41</td>
<td>3.32</td>
<td>62</td>
<td>Right</td>
<td>No response</td>
<td>BCI601/ Amadé</td>
<td>Ossicle anomaly (B)</td>
<td>Cornellia de Lange SD</td>
</tr>
<tr>
<td>#3</td>
<td>Male</td>
<td>52</td>
<td>3.62</td>
<td>59</td>
<td>Right</td>
<td>15 dB</td>
<td>BCI601/ Amadé</td>
<td>Microtia (R)</td>
<td>None</td>
</tr>
<tr>
<td>#4</td>
<td>Male</td>
<td>54</td>
<td>6.63</td>
<td>57</td>
<td>Left</td>
<td>64 dB</td>
<td>BCI601/ Amadé</td>
<td>EAC narrowing (R)</td>
<td>None</td>
</tr>
<tr>
<td>#5</td>
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<td>43</td>
<td>3.96</td>
<td>54</td>
<td>Right</td>
<td>70 dB</td>
<td>BCI601/ Amadé</td>
<td>EAC atresia (L)</td>
<td>Cornellia de Lange SD</td>
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<td>#6</td>
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<td>54</td>
<td>4.05</td>
<td>29</td>
<td>Left</td>
<td>55 dB</td>
<td>BCI601/ Samba</td>
<td>Ossicle anomaly (B)</td>
<td>None</td>
</tr>
</tbody>
</table>

CHL: conductive hearing loss; EAC: external auditory canal; L: left; R: right; B: bilateral; SD: syndrome