

A new transcutaneous bone anchored hearing device - the Baha® Attract System: the first experience in Turkey

İşitme cihazına bağlanmış yeni transkütanöz kemik - Baha® Attract Sistemi: Türkiye’de ilk deneyim

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Objectives: In this study, we reported our experience with a new transcutaneous bone conduction hearing device, the Baha® Attract System.

Patients and Methods: This multi-center clinical study included the first 12 patients (8 females, 4 males; mean age 27.6 years; range 5 to 65 years) in whom a new transcutaneous bone conduction system was implanted in Turkey.

Results: The mean air-bone gap was 41 dB. Bone smoothing around the implant was needed in five patients. We placed a sound processor in the fourth postoperative week for all patients.

Conclusion: Our study results suggest that the new bone conduction implant is promising for the patients with conductive or mixed hearing loss who are unable to wear conventional air conduction hearing aid and comparable to percutaneous systems.

Key Words: Baha; implantation; magnet; transcutaneous.

Amaç: Bu çalışmada yeni bir transkütan kemik iletimli işitme cihazı Baha® Attract Sistemine ilişkin deneyimlerimiz sunuldu.

Hastalar ve Yöntemler: Bu çok merkezli klinik çalışmaya Türkiye’de yeni bir transkütan kemik iletimli cihazı implante edilen ilk 12 hasta (8 kadın, 4 erkek; ort. yaş 27.6 yıl; dağılım 5-65 yıl) dahil edildi.

Bulgular: Ortalama hava-kemik yolu farkı 41 dB idi. Beş hastada implant çevresinde kemik düzeltme işlemi gerekti. Ses işlemcileri tüm hastalara ameliyat sonrası dördüncü haftada yerleştirildi.

Sonuç: Çalışma bulgularımız, yeni kemik iletimli implantın konvansiyonel hava-yolu işitme cihazı kullanamayan iletim veya mikst tip işitme kayıplı hastalar için ümit verici ve perkütan sistemler ile kıyaslanabilir olduğunu göstermektedir.

Anahtar Sözcükler: Baha; implantasyon; magnet; transkütan.

Bone conduction implants (BCI) were first described in 1977 by Tjellström and Granström^[1] and Mudry and Tjellström^[2] Since then, over 100,000 patients have been treated with this implants.^[3] Patients with conductive and mixed

hearing loss who are unable to wear a conventional air conduction hearing aid are the main target of BCIs. More recently, BCIs have also been used by patients with single sided deafness to solve the head shadow effect, especially in noise.^[4]



Direct transmission of sound vibrations to an abutment provides high quality sound transmission and with this feature, percutaneous bone anchored hearing aids (Baha®) are accepted as the gold standard therapy for bone conduction hearing loss.^[5] Main disadvantages of the Baha® are related to its percutaneous abutment. Due to the characteristics of percutaneous systems, it needs lifelong daily hygienic care. Nevertheless, it may cause some skin complications around the abutment, such as relapsing infections, skin overgrowth, wound dehiscence, and eventually, implant removal.^[6,7] Additionally, some of the patients may not be pleased with the aesthetics of the percutaneous Baha®. The percutaneous abutment of these devices and its related complications have led the manufacturers to work on the development of transcutaneous bone conduction hearing aids with intact skin. Today, there are only three companies that have subcutaneous bone conduction implants to rehabilitate patients with conductive and mixed hearing loss. With this study, we aimed to share the first impressions of the new subcutaneous BCI of Cochlear™ Company.

PATIENTS AND METHODS

The research protocol was submitted and approved by the Kocaeli University Ethics Committee and was conducted in accordance with the ethical regulations of the Declaration of Helsinki and in adherence to Turkish law and regulations. Kocaeli University Medical Faculty and Istanbul University, Istanbul Medical Faculty participated the study. In total, 12 patients (8 females, 4 males; mean age 27.6 years; range 5 to 65 years) were enrolled in this study. In this article, we present the first seven patients implanted in Turkey with Cochlear™ Baha® Attract System (Cochlear Ltd, Gothenburg, Sweden). Personal surgical and clinical experience with this semi-implantable system are described. All of the patients met the following inclusion criteria: (i) Patients >5 years of age; (ii) eligible for the Baha® system; (iii) no history of uncontrolled diabetes mellitus; (iv) no history of conditions that could jeopardize osseointegration and/or wound healing such as radiotherapy or Paget's disease. All of the patients were informed about the alternative treatments, risks and benefits of this surgery and signed informed consent. Data on sex, current concomitant disease, clinical signs, symptoms, surgical and postoperative features were recorded.

A pure tone audiogram (preoperative), free field thresholds (with and without device) and speech recognition thresholds [pre- and postoperative] were performed and they were tested with a Baha® soft band before the operation. Audiologic tests were performed by audiologist with AC 40 clinical audiometer (Interacoustics A/S, Assens, Denmark). The audiometer was calibrated according to the ISO standards. Air conduction hearing thresholds in 0.25- of 8 kHz and bone conduction hearing thresholds in 0.5, 1, 2, 3 and 4 kHz were found with TDH 39 "Telephonics" "Radioear" and B-17 brand bone vibrator, respectively.

The investigational devices are CE marked in the European Union. Cochlear™ Baha® Attract System is a new non-skin penetrating device that uses magnet retention instead of an abutment to connect the Baha® sound processor with the BI300 implant. It is a semi implantable system in which the BCI is positioned completely under the skin. The subcutaneous part of the system is comprised with an osseointegrated implant (BI300) and a magnet which is screwed to the implant. The visible part of the system include a sound processor and a magnet with a soft pad to connect with the subcutaneous part. The internal magnet is made with polished titanium casing and has rounded edges to minimize soft tissue interference that can prevent osseointegration and to made the implant removable (Figure 1).

The surgeries were performed under general anesthesia. We identified the implant site using the indicator for Baha® Attract, generally 50-70 mm from the ear canal and the superior edge of the processor in line with the top of the pinna. We planned the incision anterior or posterior to the position of the magnet, at least 15 mm from the edge of the magnet (Figure 2). Before local anesthesia skin thickness was measured with a needle on three different regions prior to incision (Figure 3a). If the soft tissue was thicker than 6 mm, soft tissue reduction was performed later in the procedure. The proposed incision line was then infiltrated with local anesthesia with adrenalin and than a 'C' or 'S' shaped skin incision of approximately 8 cm was made. After reaching the periosteum, the anteriorly or posteriorly based flap was elevated. Once hemostasis was obtained, the flap thickness was measured again using a measuring probe (Figure 3b). If it was necessary, a soft tissue reduction was performed (Figure 3c). After finding the implantation point, a plus like



Figure 1. Cochlear™ Baha® Attract System.

incision on the periosteum was made (Figure 4a). Subsequent to elevation of the periosteum, the guide drill was used to establish the skull depth, and either a 3 mm or 4 mm counter-sink was used to drill the recipient side for the implant. Then the implant was placed. After this implantation, the surface of the skull around the implant was determined for a possible irregularity with bone bad indicator (Figure 4b). If it was necessary, the bone irregularity was smoothed with a diamond burr. To achieve this, an extra incision in the periosteum was made and sutured back at the end of the procedure. Two perpendicular measurements of Implant Stability Quotient (ISQ) values were performed. Finally the magnet was screwed onto the implant and the skin incision was closed primarily (Figure 4c).

RESULTS

Table 1 documents the characteristics of the patients and main surgical features. None of them had concomitant disease. Seven patients

were implanted on the right side and the other five on the left. Four millimeter implants were used in 11 cases and 3 mm implant used in only one patient whose age was five. Bone smoothing around the implant was needed in five of the patients. The mean skin thickness with the highest values of three measurements was 6.2 mm with a range in 4 to 9 mm, and soft tissue reduction was performed in four patients whose soft tissue thickness were 7, 8, and 9 mm. The mean surgical time was 48 minutes with a range of 35 to 65 minutes, and it was especially associated with bone smoothing and soft tissue reduction.

Eleven of them were with bilateral mastoidectomy due to chronic suppurative otitis media and one of them had bilateral aural atresia. Nine of the patients had conductive hearing loss, and the remaining three had primarily conductive hearing loss. Mean air bone gap was 41 decibels (dB). Three patients had not had enough time with Baha® for audiological evaluation so we only presented the other nine patients' audiological measurements. The mean of free field hearing thresholds (0.5 kHz, 1 kHz, 2 kHz, 4 kHz frequencies mean) was 45 dB without Baha® hearing aid and 26 dB with Baha®. The mean of free field speech recognizing thresholds was 56 dB without Baha® and 37 dB with Baha® hearing aid (Figure 5). These values were statistically evaluated by Wilcoxon signed-ranks test and found to be significantly different ($p < 0.001$). We observed an average gain of 19 dB in the speech reception threshold with the Baha® compared with unaided speech.

All patients received the Baha® monaurally. One of the patients had a hematoma on the first postoperative day and was treated with aspiration. Suture removal was performed in the

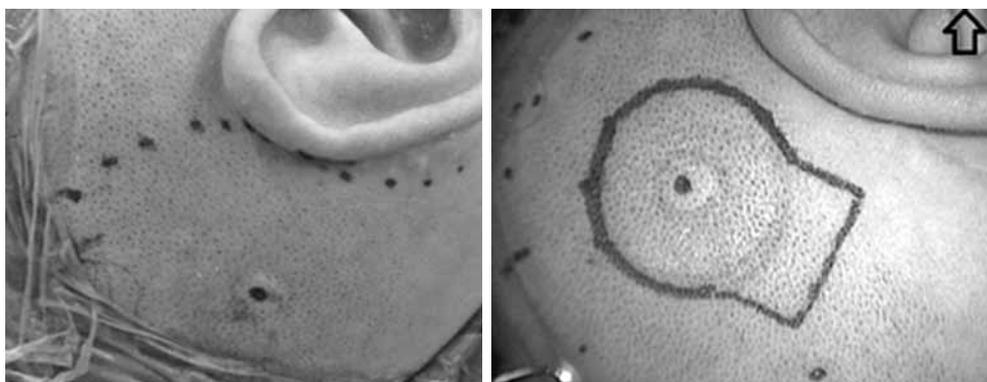


Figure 2. Planning of the incision line; at least 15 mm from the edge of the magnet.

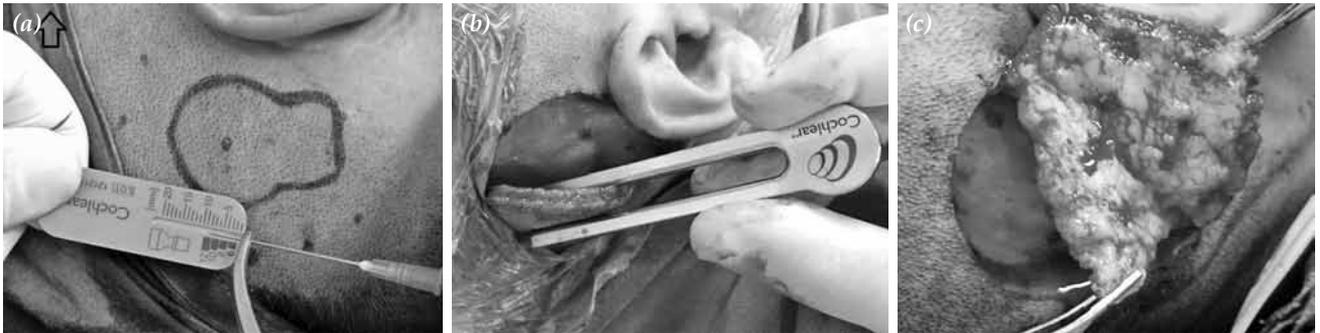


Figure 3. (a) Measuring the soft tissue thickness in several positions over the planned implant site. (b) Measuring the flap thickness with a measuring probe. (c) Reduction of the soft tissue.

first postoperative week for all patients. The mean ISQ value was determined as 75.9 in the operating room and we placed the sound processors in the fourth postoperative week for all of the patients (Figure 6). One of the patients had temporary skin erythema with pain and three had pain around the implant. This problem was solved by decreasing the magnet strength.

DISCUSSION

Bone anchored hearing aids are effective and well established hearing solutions for patients with mild to moderate conductive and mixed hearing loss. Indications of these devices are chronic suppurative otitis media, congenital aural atresia, chronic otitis externa, unilateral profound hearing loss, and unilateral mixed hearing loss. The principles of these devices are different from the traditional air conducted hearing aids. While the traditional hearing aids amplify sounds and then present them to the middle ear via the

external ear canal, bone conducted hearing aids by pass the external ear canal and middle ear to directly vibrate the cochlea. Therefore, these devices solve some of the problems of conventional air conducted hearing aids, especially in the patients with radical mastoidectomy or external ear pathologies. Nowadays, there are many different devices that use the bone conduction path. These devices can be used by adapting them to a headband, glasses, tooth or bone anchored titanium implants.^[2] Among these devices, the Baha® directly transmits sound vibrations to the temporal bone via a titanium abutment. Thereby, it can provide a high quality sound transmission and with this feature, percutaneous Baha® implants are accepted as the gold standard therapy for bone conduction hearing loss.^[5]

Despite the success of the Baha®, it has some potential limitations because of the nature of the percutaneous system. It needs a daily hygienic care

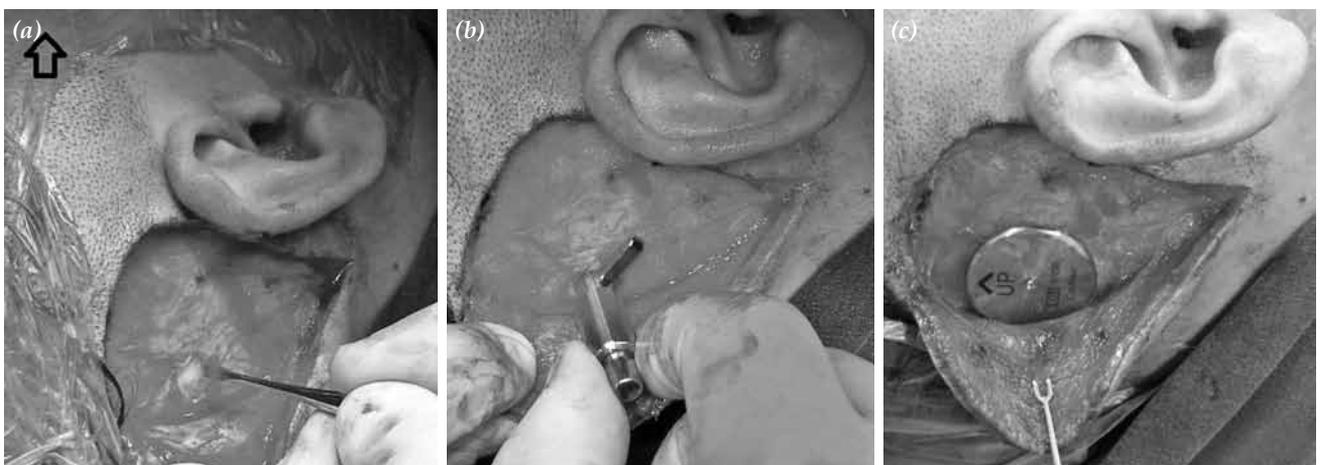


Figure 4. (a) Plus like incision on the periosteum. (b) Determination of a possible irregularity with bone bad indicator. (c) The magnet over the implant.

Table 1. The characteristics of the patients and main surgical features

| Patients | Indication | Age (years) | AC mean | BC mean | Implant used (mm) | Skin thickness | Soft tissue reduction | Bone smoothing | Preoperative ISQ |
|----------|-------------------------|-------------|---------|---------|-------------------|----------------|-----------------------|----------------|------------------|
| 1 | Bilateral mastoidectomy | 12 | 55 | 3 | 4 | 4 | X | X | 70 |
| 2 | Bilateral mastoidectomy | 33 | 53 | 16 | 4 | 7 | √ | √ | 86 |
| 3 | Bilateral mastoidectomy | 27 | 51 | 6 | 4 | 5 | X | √ | 85 |
| 4 | Bilateral mastoidectomy | 11 | 30 | 3 | 4 | 6 | X | √ | 81 |
| 5 | Bilateral mastoidectomy | 35 | 56 | 11 | 4 | 6 | X | X | 80 |
| 6 | Bilateral mastoidectomy | 16 | 43 | 11 | 4 | 9 | √ | X | 70 |
| 7 | Bilateral mastoidectomy | 16 | 66 | 13 | 4 | 8 | √ | √ | 70 |
| 8 | Bilateral mastoidectomy | 41 | 56 | 20 | 4 | 6 | √ | √ | 82 |
| 9 | Bilateral mastoidectomy | 65 | 63 | 20 | 4 | 9 | √ | X | 81 |
| 10 | Bilateral aural Atresia | 5 | 50 | 6 | 3 | 4 | X | X | 53 |
| 11 | Bilateral mastoidectomy | 22 | 33 | 4 | 4 | 5 | X | X | 74 |
| 12 | Bilateral mastoidectomy | 49 | 53 | 26 | 4 | 6 | X | X | 79 |

AC: Air Conduction; BC: Bone Conduction; ISQ: Implant Stability Quotient.

to prevent the soft tissue complications around the implant. Furthermore, the cosmetic problem is the other limitation of these devices, especially for teenagers. The mentioned limitations have led the manufacturers to work on the development of transcutaneous bone conduction hearing aids with intact skin to solve these problems.

The Cochlear™ Baha® Attract System was presented as a new solution for the patients with conductive or mixed hearing loss if bone conduction hearing thresholds are better than 30 dB or for single sided deafness when the hearing ear has bone conduction hearing thresholds better than 20 dB. As it is mentioned before, it is a semi-implantable, transcutaneous system. It is more acceptable for cosmetic reasons. However, because of the nature of the transcutaneous systems, there is a skin interposition between the external and internal magnet. Due to this reason, we may think that the hearing performance may be worse than the percutaneous systems. However, the single point sound transmission with BI300 implant and the soft pad between the magnet and skin

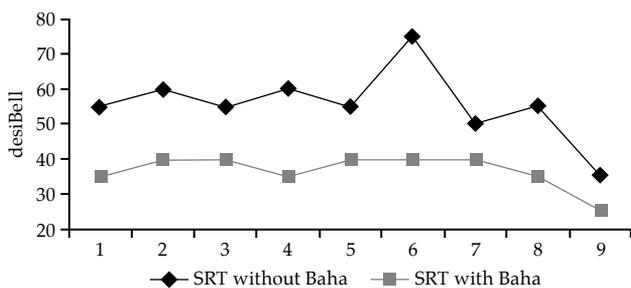


Figure 5. The mean of free field speech reception threshold (SRT) with and without Baha.

was designed for this purpose. And also, some of the primarily results of the other studies with another transcutaneous system shows satisfactory functional gain, cutaneous tolerance with the new transcutaneous bone conduction devices.^[8-10]

The operation procedure is a routine and straightforward procedure. However, because of irregularities around the implant side, it may need some bone smoothing and sometimes soft tissue reduction. Bone smoothing around the implant was needed in three of our patients, and this has an important reason of the long surgery times when compared with the percutaneous Baha®.



Figure 6. Four weeks after surgery.

We did not reposition the implants due to these irregularities but it may be needed. If there is a necessity to reposition of the implant, care must be taken not to position the implant close to the incision. Optimum thickness of the skin recommended is 3 to 6 mm. If it is thicker than 6 mm, the flap must be reduced to avoid the sound transmission loss. Conversely, if it is thinner than 3 mm there may be a possible risk for flap necrosis because of the pressure. After the soft tissue reduction, hemostasis must be ensured to avoid postoperative hematoma. The loading time of the sound processor is recommended as two weeks later from implantation to wait the osseointegration period. However, this period may change for some patients due to bone quality and the first ISQ measurements.

The system has no complications associated with skin penetration and does not need lifelong daily hygienic care. However, there may be some skin irritation due to the pressure of the magnets like pain, erythema and skin necrosis of the skin covering the implant. As mentioned before, four of our patients had this problem and the problem was managed by a temporary reduction of the intensity of the external magnets as recommended in the literature.^[8]

In conclusion, we can say the new BCI described in this article shows promise in this regard. Due to limited studies, conclusions about the possible undesirable complications like skin irritations cannot be made. However preliminary information on hearing gain is satisfactory and comparable to percutaneous systems.

Declaration of conflicting interests

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