



Original Article

Two Different Percutaneous Bone-Anchored Hearing Aid Abutment Systems: Comparative Clinical Study

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OBJECTIVE: To compare two different percutaneous bone-anchored hearing aid (BAHA) abutment systems regarding operation time, scar healing, quality of life, implant stability, audiologic results, and complications.

MATERIALS and METHODS: The study involves a prospective multi-center clinical evaluation. Thirty-two consecutive patients who had undergone BAHA surgery from January 2011 to January 2013 in two tertiary centers were included in the study. The Glasgow Inventory Benefit Score was used to assess the patients at least 6 months after surgery. The operation time and complications were recorded. Implant stability quotient (ISQ) values were recorded using resonance frequency analysis. Holger's classification was used to evaluate skin reactions.

RESULTS: The mean length of the operation was 39.2 ± 4 min for standard abutment and 18.3 ± 5.7 min for hydroxyapatite-coated abutment. ISQ scores were significantly better for standard abutment in all tests. The mean total Glasgow Inventory Benefit Score was 39.3 ± 19 for the standard abutment and 46.3 ± 24.5 for the hydroxyapatite-coated abutment groups, but there was no statistical significance between the two groups. There was no difference in audiological improvement between the two groups after surgery.

CONCLUSION: Hydroxyapatite-coated abutment provided a shorter operation time that was significantly different from standard abutment. There were no significant differences between standard abutment and hydroxyapatite-coated abutment regarding audiologic improvement, quality of life, loading time, and complications.

KEYWORDS: BAHA, abutment, hydroxyapatite coated, hearing loss, bone conduction

INTRODUCTION

The bone-anchored hearing aid (BAHA) system was initially developed by Tjellström and Carlsson (Sweden) in 1977^[1]. Bone-anchored hearing devices have been commercially available in the market since 1988. BAHA has been used for patients who cannot benefit from conventional hearing aids, with conductive and mixed-type hearing loss. Recently, BAHA has also been used for rehabilitation in single-sided deafness to benefit from the head-shadow effect^[2].

The bone-anchored hearing aid surgery consists of two main parts: implantation of the manufactured piece and soft tissue reduction. The implantation technique has gradually been simplified. The original two-stage surgical procedure was replaced with a one-stage procedure in 1989 and is now accepted as a standard surgical procedure (Wolf 2008, Arnold 2011).

Different surgical techniques, including skin grafting with dermatome, a U-shaped incision, and a linear incision, have been described in the last quarter (Arnold 2011, Stalfors 2008, van de Berg 2009).

Skin reactions and local infections are the most common problems in BAHA surgery, in which different surgical techniques and implants are utilized (Arnold 2011, Mohamad 2014). Soft tissue reduction has been performed to avoid skin reactions in all surgical techniques.

The standard abutments, known as the Brånemark type Baha® fixture, were replaced in 2010 with BIA300 (Baha® BIA300 implant and abutment, Cochlear Ltd.; Lane Cove, Australia), which is wider, smaller in neck size, and has a moderately rough TiOblast™ surface on the intraosseous portion (Dun 2011). Soft tissue reduction is necessary for standard titanium abutment (STA) (Baha® BA300 Abutment, Cochlear Ltd.; Lane Cove, Australia) to maintain tight skin that holds the periosteum and reduces soft tissue move-

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ment, scar tissue, and infection around the implant. The hydroxyapatite-coated abutment (HCA) (Baha® BA400, Dermalock, Abutment, Cochlear Ltd.; Lane Cove, Australia) system, which is compatible with the Baha® BI300 implant, was released to the market in 2012. With this system, there is no need for soft tissue reduction. Therefore, it is an easy procedure with a decreased operation time.

The aim of present study was to compare STA and HCA BAHA abutment systems regarding operation time, quality of life (Glasgow Inventory Benefit), scar healing (Holger Index), implant stability quotient (ISQ), audiologic results, and complications.

MATERIALS and METHODS

Our study is a multi-center prospective clinical study. Thirty-two patients who had a history of implant surgery from January 2011 to January 2013 were included in the study. Two different tertiary centers participated in the study. The study was approved by the local ethics committee (Reference number: 2013/798), and informed consent was acquired from all the patients. Before the surgery, experienced surgeons examined all the patients, and the risks and benefits of the implantation and alternative treatments were discussed.

The inclusion criteria were at least 5 years of age, convenient for the BAHA system, and no history of diabetes mellitus or conditions that could endanger osseointegration and/or wound healing, such as Paget's disease or radiotherapy. Patients with single-sided deafness and unilateral conductive hearing loss were not approved by our social security service; thus, these patients were not included in the study.

The first 17 of 32 cases were the STA group and last 15 cases were the HCA group. Experienced audiologists from each center performed audiologic tests, including pure tone audiogram (preoperatively obtained) by using an Interacoustic Clinical Audiometer (model AC40; Assens, Denmark) and the B71 from Radioear (Radioear Corporation; Pennsylvania, USA), free-field thresholds (FFT) (with and without device), and speech recognition thresholds (SRT) (preoperatively and postoperatively obtained). Masking was applied during audiological workups when needed.

Experienced surgeons (YG, MI, KSO) performed the operations. We used the same implant (Baha® BI300 implant, Cochlear Ltd.; Lane Cove, Australia) in both groups, although, different abutments were inserted. For STA, an implantation point, which was 55–60 mm postero-superior to the tragus, was marked on the skin. The anticipated processor area, which was 4×6 cm elliptical-shaped and centered on the implantation point, was also marked where the soft tissue reduction would take place. We performed a 3-cm vertical skin incision approximately 1 cm behind the implantation point (Figure 1). After skin elevation, the implant was placed on the temporal bone after drilling. Soft tissue reduction was performed without using electrocautery. For HCA, a skin point was marked using the same method as described above. Skin thickness was measured before making the incision using a needle and then a 2-cm vertical skin incision approximately 1 cm behind the implantation was made (Figure 2). After the placement of the implant, unlike standard techniques, soft tissue reduction was not performed.

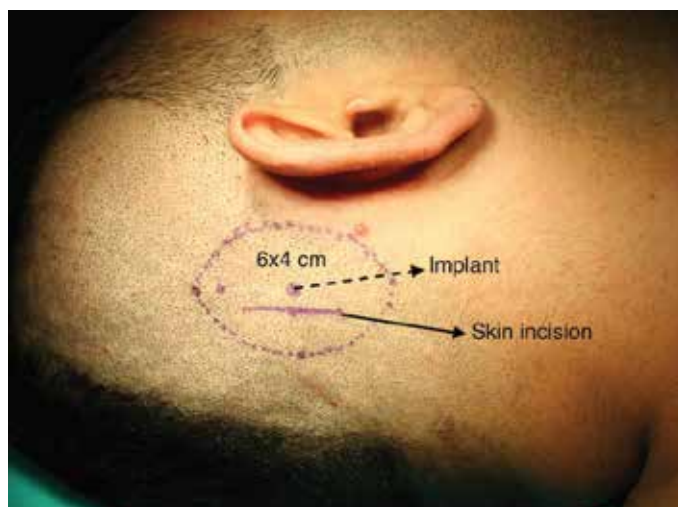


Figure 1. Surgical procedure with standard titanium abutment

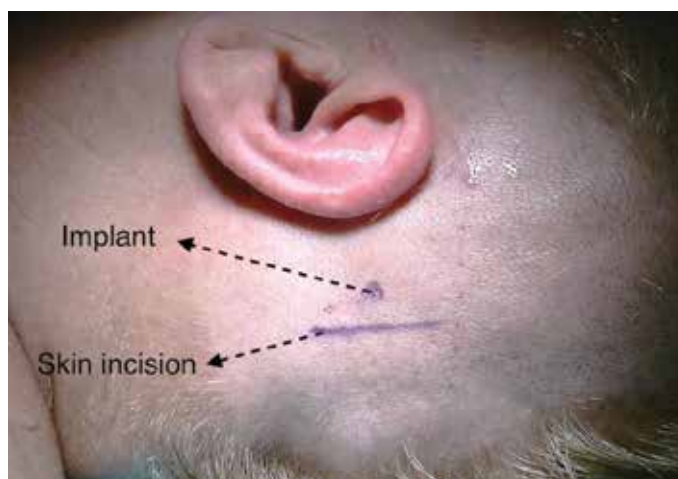


Figure 2. Surgical procedure with hydroxyapatite-coated abutment

The implant stability quotient (ISQ) was measured using resonance frequency analysis with an Osstell ISQ recording meter (Osstell; Gothenburg, Sweden). The Osstell device emits a magnetic field that vibrates the abutment of BAHA, and the same part of the device also detects any vibration of the abutment. The device was programmed to display resonance as a score from 1 to 100, where 100 is the maximal stability. ISQ measurements were performed at the time of the implantation and at the 1st, 2nd, 3rd, 4th, and 12th week after the surgery. If the abutment length was longer than 6 mm, 3 ISQ values were added for each 1 mm. At the 4th week after surgery, the same sound processors (BP 110® Sound Processor, Cochlear Ltd.; Lane Cove, Australia) were loaded in both groups [3].

The patients were examined for possible soft tissue problems around the implant. They were classified using Holger's scale (0-4).

Quality of life (QoL) was assessed by using the Glasgow Inventory Benefit Score for adults and the Glasgow Children's Benefit Inventory for pediatric patients. The patients were assessed using these tests at least 6 months after surgery.

The time of the operation and any complications were recorded.

Statistical Analysis

Statistical of the data was performed using the Statistical Package for the Social Sciences for Windows (SPSS), version 21.0 (SPSS Inc.; an IBM Company, Chicago, IL, USA). Mann–Whitney U tests were used to compare the results of the two groups. P values below 0.05 were regarded as statistically significant.

RESULTS

Thirty-two patients aged 6 to 67 years, mean±SD 32.8±17.1 years, were included in the study. Of these patients, 19 were male and 13 were female. The reasons for hearing loss were chronic otitis media in 23 patients (71.9%), who had bilateral modified or radical mastoidectomy cavities, and bilateral congenital aural atresia in 9 patients (28.1%), who had a Jahrsdoerfer score of 6 or lower [4]. Two centers participated in the study. Of these patients, 17 were from Kocaeli University and 15 were from İstanbul University. The implants were placed on the right side in 21 patients and on the left side in 11 patients (Table 1).

The mean operation time was 39.2±4 minutes for STA and 18.3±5.7 minutes for HCA. This difference was statistically significant with the Mann–Whitney U test ($p<0.001$) (Figure 3).

The mean preoperative air conduction thresholds were 62.7±20.1 dB HL for STA and 58.5±14.3 dB HL for HCA. The mean preoperative bone conduction thresholds were 25.1±14.1 for STA and 17.5±14.7 dB HL for HCA. There were no statistically significant differences in air and bone conduction thresholds between the STA and HCA groups ($p=0.18$ and $p=0.11$, respectively). Therefore, the two groups were homogenous regarding preoperative audiologic data. Free-field thresholds (FFT) with and without BAHA were measured. The mean FFT at 0.5, 1, 2, and 4 KHz with and without BAHA of the two groups are presented in Figure 4. Postoperative values were found to be significantly improved compared with preoperative values in each group, but there was no significant difference between the two groups ($p>0.05$). The mean SRT without BAHA was 66.9±12.2 dB for BA 300 and 61.3±12.6 dB for HCA. The mean SRT with BAHA was 27.9±6.7 dB for BA 300 and 28.6±10.5 dB for HCA. The mean improvement in SRT with BAHA was 36±18.5 dB for STA and 30.5±15.4 dB for HCA. However, no statistically significant difference was found between the two groups when analyzed with the Mann–Whitney U test ($p>0.05$) (Figure 5).

There was no statistically significant difference of the mean intraoperative, at the 1st, 2nd, 3rd, 4th, or 12th week for the ISQ values in between the two groups (Mann–Whitney U test $p>0.05$) (Figure 6).

Soft tissue reaction was graded using Holger's index. In the STA group, 14 patients had a Holger Index score of 0, 2 patients had Holger 1, and 1 patient had Holger 2. There were no patients with Holger 3 or 4. In the HCA group, 11 patients had Holger 0, 3 patients had Holger 1, and 1 patient had Holger 2. There were no patients with Holger 3 or 4. All the patients with skin reactions in both groups were treated with local medication.

The mean total Glasgow Inventory Benefit score was 39.3±19 for the STA and 46.3±24.5 for the HCA group. This difference was not statistically significant with the Mann–Whitney U test ($p=0.3$)

Table 1. Demographic data

	STA	HCA
No. of patients	17	15
Age (mean±SD)	32.1±18.3	33.7±16.7
Diagnosis (No. of patients)		
Chronic Otitis Media	10	13
Congenital Auricular Dysplasia	7	2
Implant Side (No. of patients)		
Right side	12	9
Left side	5	6
Gender (No. of patients)		
Male	8	11
Female	9	4

STA: standard titanium abutment; HCA: hydroxyapatite-coated abutment

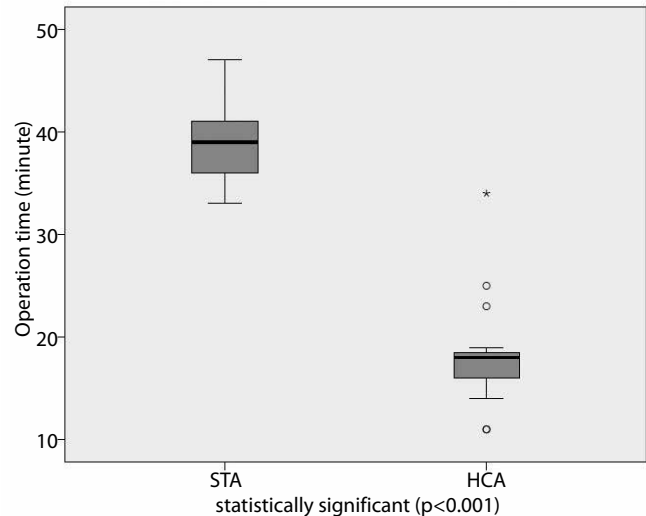


Figure 3. Operation time. This difference was statistically significant (Mann–Whitney U test $p<0.001$).

STA: standard titanium abutment; HCA: hydroxyapatite-coated abutment

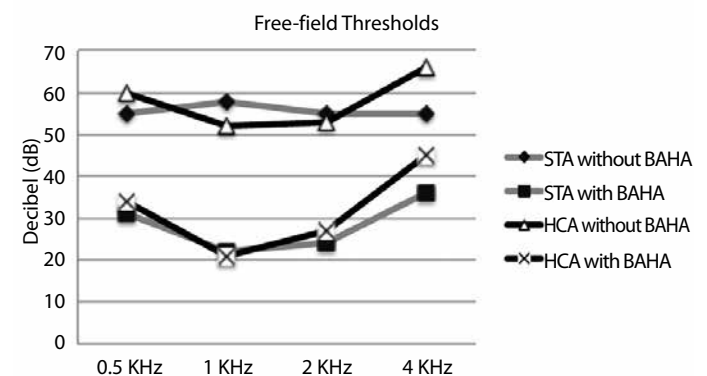


Figure 4. Free-field thresholds with and without BAHA. No statistically significant difference was found with the Mann–Whitney U test.

STA: standard titanium abutment; HCA: hydroxyapatite-coated abutment

There was no implant loss. In the 32 operations performed, complications were reported in five cases. Skin overgrowth occurred in three patients, one patient from the STA group and two patients from the HCA group. Those who required revision, were managed in the office

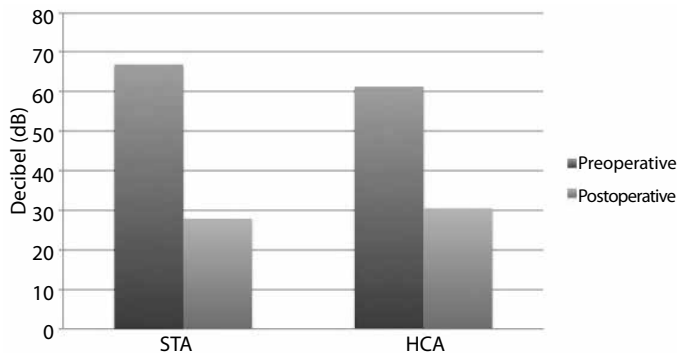


Figure 5. Speech recognition thresholds (SRT). No statistical significant was found with the Mann-Whitney U test.

STA: standard titanium abutment; HCA: hydroxyapatite-coated abutment

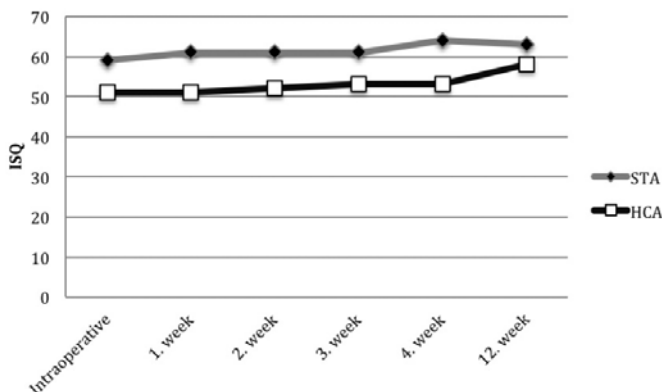


Figure 6. Implant stability quotient (ISQ) levels (all comparisons were statistically significant with the Mann-Whitney U test $p < 0.05$). STA: standard titanium abutment, HCA: hydroxyapatite-coated abutment

with debridement under local anesthesia. Two patients (1 patient from the STA group, 1 patient from the HCA group) required topical and systemic antibiotherapy for local infection around the implant. All the complications were managed successfully. There were no major complications.

DISCUSSION

Standard titanium abutment has been widely used for several years. This abutment needs soft tissue reduction; consequently, the skin flap and skin graft technique has been performed for a long time. The new BAHA HCA abutment system, which is covered with hydroxyapatite, allows for an easy and safe surgical procedure without soft tissue reduction.

With the STA abutment system, there is a need for subcutaneous soft tissue reduction. The possibility of bleeding increases the operation time and creates technical difficulty. In our study, operation times with HCA were halved compared with those of STA. Similarly, Gawęcki et al. [5] showed that HCA abutment decreased the operation time compared with STA abutment. This decreases the cost of operation and may enable an easier surgical technique, even under local anesthesia.

The original protocols recommend waiting for 3–6 months before loading the abutment to allow osseointegration [6]. Snik et al. [7] reported a consensus recommending a loading time of between 4 and 6 weeks in adult patients. Wazen et al. [8] also showed that reducing the loading time from 3 months to 6 weeks did not result in the fail-

ure of osseointegration of the titanium implants. The earlier activation resulted in improved patient satisfaction. The Cochlear BAHA B1300 implant has been designed with a wider diameter, small-sized threads at the implant neck, and a moderately rough TiOblast (Astra Tech; Mo'ndal, Sweden) surface on the intraosseous portion of the implant. Dun et al. [9] reported that the B1300 implant system has better osseointegration than the previous version of the implant. We used the B1300 BAHA implant in both groups. We did not wait for 3 months to load the implant.

According to the standing rules of our social security service, BAHA is indicated for conductive and mixed-type hearing loss in patients with bilateral mastoidectomy cavity and bilateral atresia. We have not performed BAHA in any patients with single-sided deafness. We found similar mean postoperative FFTs at 0.5, 1, 2, and 4 KHz frequency and SRT values in both groups because the same implant and sound processor were used in all patients.

In the literature, many studies show that there is a significant benefit to the quality of life with BAHA surgical intervention, as measured using the Glasgow Benefit Inventory [10–13]. Arunachalam et al. [10] reported that BAHA produces a greater improvement in quality of life than middle ear surgery for discharging ears. In our study, we found that there was no statistical difference between the two groups at the 6th postoperative month using the Glasgow Benefit Inventory.

Skin problems, such as local infection and skin overgrowth, are common complications in BAHA surgery. In the literature, the rate of skin overgrowth was observed in 4%–7.4% of patients [13–15]. The implant extrusion rate is around 3% [13, 14]. In our study, we encountered 3 patients with skin overgrowth (2 patients from HCA, 1 patient from STA) and 2 patients with local infection (1 patient from HCA, 1 patient from STA). We had no cases with implant extrusion.

The limitations of the study are the few number of patients and the short follow-up period. There is a need for new studies with a large case series and longer follow-up periods.

The hydroxyapatite-coated abutment is a safe and easy implantable device that provides for short operation and loading time because there is no need for soft tissue reduction. There was no significant difference between STA and HCA regarding the audiologic results, quality of life scores, and complication rates.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of İstanbul University School of Medicine (Reference number: 2013/798).

Informed Consent: Written informed consent was obtained from patients and patients' parents who participated in this study.

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Author Contributions: Concept - B.P., M.İ., K.S.O.; Design - B.P., M.İ., K.S.O.; Supervision - B.P., M.İ., K.S.O.; Resources - B.P.; Materials - M.İ., K.S.O.; Data Collection and/or Processing - A.B.Y., N.E., D.Y., A.K.; Analysis and/or Interpretation - K.S.O., N.E.; Literature Search - B.P., K.S.O.; Writing Manuscript - B.P., K.S.O., Ş.Ç.; Critical Review - Y.G., Ş.Ç.

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