A novel Cochlear™ Baha® abutment to enable surgery without soft tissue reduction

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Currently, the protocol for bone conduction surgery involves soft tissue reduction in order to stabilise the skin around the abutment and reduce the risk of skin-related complications in the area. The new Cochlear™ Baha® BA400 Abutment features a hydroxyapatite surface and a pronounced concavity to enhance soft tissue stability by establishing tight adherence between the soft tissue and abutment. These improvements facilitate a simpler and shorter surgical procedure with improved patient outcomes. This paper suggests that the Cochlear™ Baha® BA400 Abutment with no soft tissue reduction may become a standard for the bone conduction treatment.

Introduction

The benefits of the Cochlear Baha BI300 Implant design in terms of stability and reduced time to loading, have been demonstrated in numerous studies. With the improvements made, the treatment schedule has shifted from waiting for osseointegration to occur, to waiting for the soft tissue to heal before loading the implant with the Baha sound processor. Also, the improvements of the abutment shape and tight seal have significantly reduced soft tissue complications using the BA300 Abutment with the current surgical protocol.

Currently, the protocol for bone conduction surgery involves soft tissue reduction in order to stabilise the skin around the abutment and reduce the risk of skin-related complications in the area. The reduction of soft tissue adds complexity to the surgical procedure that is otherwise a routine type of skin incision. A less invasive surgical technique that avoids soft tissue reduction would result in a simpler and shorter procedure and would be aesthetically more appealing to patients, since it removes the need for permanent tissue and hair removal in the area around the abutment. Faster healing may also be expected if the soft tissue is left intact.

This paper summarises the design innovations and experiences of the next-generation Cochlear Baha abutments.

Background

Recently, there have been reports of the use of surgical techniques involving little or no soft tissue removal. Promising results have been published in a clinical study by Professor Hultcrantz. In this study a series of patients (n=7) receiving implants and abutments without skin reduction experienced less numbness and faster healing compared to patients who underwent traditional Baha surgery. No increase in the frequency of adverse skin reactions was reported. However, the number of patients were limited, and the study lacked randomisation. In these studies standard titanium abutments were used. Titanium has never been shown to integrate well with soft tissue, instead findings in the literature suggest that soft tissue stability may be significantly improved if materials and designs are used to support a tight adherence between the abutment and surrounding skin.

Next-generation Cochlear Baha abutments.

The new Cochlear™ Baha® BA400 Abutment (Figure 1) was designed to enhance soft tissue stability compared with conventional titanium abutments and facilitate surgery with limited or no soft tissue reduction. The BA400 Abutment has been shaped with a pronounced concavity at its lower section and the surface intended to come into contact with the tissue is coated with a hydroxyapatite layer.

Hydroxyapatite is a naturally occurring mineral and one of the main constituents of bone. It has been used in several medical applications ranging from orthopaedic and dental implants to dermal fillers as well as some percutaneous applications. Numerous pre-clinical and clinical studies report excellent outcomes with hydroxyapatite in different percutaneous applications such as external fixators and catheters. With hydroxyapatite coated implants, most authors report significantly improved dermal adherence, a substantial reduction in epidermal migration and little or no inflammation. Epidermal migration is believed to be a key contributing factor in adverse reactions and can, in severe cases, result in failure of percutaneous implants. A tight connection between the abutment and the surrounding soft tissue reduces interfacial stresses and limits pocket formation, thus improving the barrier against bacteria.

Figure 1. Cochlear Baha BA400 Abutment with pronounced concavity and a hydroxyapatite coating.
The hydroxyapatite coating on the BA400 Abutment is applied with a plasma-spray technique. Factors such as surface roughness, thickness and surface texture have been carefully selected to optimise the mechanical properties and durability of the coating. The thickness of the coating is approx. 80µm and before plasma-spraying takes place, the abutment surface is blasted to optimise the fixation. As the surface of the hydroxyapatite-coated part of the BA400 Abutment is rougher compared to a titanium abutment, cleaning tests were conducted to verify that any bacteria on the hydroxyapatite surface can be effectively removed using the existing cleaning guidelines for the Cochlear Baha abutments. The result of the cleaning tests confirm that there were no differences in cleaning effectiveness compared to the BA300 Abutment.

**Summary of experiences with the Cochlear Baha BA400 Abutment**

**Data from the initial in vitro investigations**

The development of the Cochlear Baha BA400 Abutment started in 2008 by studying hydroxyapatite in vitro. Circular sections (Ø=12 mm) of human skin from breast reduction procedures were used with the adipose tissue removed. One hundred twenty cylindrical tubes (Ø=5 mm) were inserted in a hole punched in the centre of the skin. Two different tubes were used: (A) hydroxyapatite-coated and (B) uncoated titanium controls. After 8 days of incubation, the samples with surrounding skin were processed for histology. Histomorphometric measurements demonstrated a reduction in mean pocket depth for the hydroxyapatite-coated tubes compared to the titanium tubes: 354µm vs. 759µm. Although the difference was not statistically significant, the results were encouraging and a pre-clinical investigation was then planned in collaboration with independent investigators to histologically investigate soft tissue healing and integration of differing abutment designs and/or surfaces. For this purpose a sheep model was used as sheep are deemed to present soft tissue characteristics, including thickness and mobility, similar to human skin.

**Pre-clinical data**

Results from the pre-clinical investigation were reported at the 12th International Conference on Cochlear Implants and Other Implantable Auditory Technologies (Baltimore, USA, 3-5 May 2012) by researchers at the University of Gothenburg (Sweden) and have been published in a peer-reviewed journal. The study included 6 adult sheep receiving a total of 36 Cochlear Baha BI300 4 mm implants with pre-mounted 9 mm abutments of 4 different types: (A) Cochlear Baha BA300 Abutment, (B) BA300 Abutment coated with hydroxyapatite, (C) concave titanium abutment, and (D) concave titanium abutment coated with hydroxyapatite. The implants and abutments were inserted into the skull without performing soft tissue reduction. The sites were left to heal for 1, 2 and 4 weeks respectively (2 animals per time period) before samples were analysed by descriptive histology and morphometric measurements of pocket depth and epidermal downgrowth. Statistical analysis was performed by an independent bio-statistician. Wilcoxon's signed-rank test was used.

The histological samples showed tight contact between hydroxyapatite coated abutments and surrounding soft tissues with minimal epidermal downgrowth and absence of inflammation, while weaker adherence often associated with significant epidermal downgrowth and pocket formation was noted for uncoated titanium abutments (Figure 2). The smallest pocket depth and epidermal downgrowth was recorded for the hydroxyapatite coated concave abutment (abutment type D) which had the same design as the new BA400 Abutment. The mean pocket depth for abutment types A, B, C and D was 1.38 mm (SD 1.22), 0.42 mm (SD 0.75), 1.51 mm (SD 0.69) and 0.24 (SD 0.39), respectively; the difference between C and D was statistically significant (p=0.031) (Figure 3).
Evaluation of samples with different healing times showed stable and possibly decreasing pocket depth for hydroxyapatite coated abutments between 2 and 4 weeks of healing, while a trend towards increasing pocket depths was noted for uncoated titanium abutments (Figure 4).

The presence of a blood clot was noted after 1 week of healing within the concavity of a number of concave shaped abutments; for the longer time periods, the concavity became filled with soft tissue. This observation is in line with data from dental literature, which suggests that the concave shape may further stabilise the soft tissue by creating a void space where new tissue regeneration can take place, resulting in localised thickening and improved stability of the soft tissue.16

In conclusion, the results from the pre-clinical study showed improved soft tissue adherence and significantly reduced pocket depth for hydroxyapatite coated Baha abutments compared to uncoated titanium abutments placed without soft tissue reduction.

Abutments in various heights

The Cochlear Baha BA400 Abutment has the same concave design and same type of hydroxyapatite coating as the abutment that showed the best result in the pre-clinical investigation. The BA400 Abutment is available in four different heights for the varying thickness of individual patient’s soft tissue (Figure 5). Mechanical tests have been performed to verify that the use of abutments longer than the 6 and 9 mm, currently available in the Baha systems does not increase the risk of osseointegration failure during normal use. The test show that the 12 mm Cochlear Baha BA400 Abutment does not significantly increase the torque applied to the implant when snapping the sound processor on and off and that the forces are mainly directed along the long axis of the implant (Figure 6).

Summary

The current trend in bone conduction surgery is moving towards performing less, if any, soft tissue reduction. The Cochlear Baha BA400 Abutment is specifically designed for this purpose. It has proven to enhance soft tissue stability by establishing tight adherence between the dermis and abutment surface, thereby minimising epidermal migration and pocket formation, which are believed to be key factors in obtaining a stable skin to abutment interface and creating an effective barrier against bacteria.

The Baha BA400 Abutment’s key clinical benefit is the tight soft tissue adherence that allows for good soft tissue stability without soft tissue reduction. This can facilitate a simpler and shorter surgical procedure, and the outcome can be more aesthetically appealing to patients, since it removes the need for permanent tissue and hair removal in the area around the abutment. Faster healing may also be expected if the soft tissue is left intact.

Figure 5. Cochlear Baha BA400 abutments.

Figure 6. Torque measured for the 6, 9 and 12 mm abutment while snapping on and off the sound processor.
References


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