

BONE ANCHORED APPLICATIONS

2/05

Launch of the Baha Divino™



Cochlear Limited acquires Entific Medical Systems AB

Latest technologies for Facial Rehabilitation



International News



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In Brief – product updates



The views expressed by the authors in this publication do not necessarily reflect those of Cochlear Limited.

Editorial

.....a personal experience

2005 has proved to be another momentous year! On March 4th, Cochlear Limited purchased Entific Medical Systems AB. The acquisition offers fresh possibilities and opens the door to further developments for the osseointegration-based Baha® and Vistafix™ product lines.

Following the acquisition, Cochlear announced the founding of its new division, **Bone Anchored Solutions (BAS)**, now headed by recently appointed President, David Morris. Cochlear's CEO, Chris Roberts, and David Morris talk about the acquisition and what it means from both a corporate and personal viewpoint, and how both customers and patients will gain from this business venture.

And 2005 has also seen the long-awaited launch of the latest Baha sound processor, the Baha Divino™. This edition of *Bone Anchored Applications* is largely dedicated to revealing what has been learnt about the Divino from extensive pre-launch testing. From Gothenburg, Sweden, the R&D team explain the background to its development and Mia Karlsson, in-house Audiologist, presents a paper detailing the results of the international pre-launch evaluation of the device.

We are also delighted to be able to publish the results from three of the Divino study clinics based in the USA, Canada and Switzerland. Bill Hodgetts of COMPRU, Edmonton, has carried out an objective study into the directional capabilities of this latest Baha sound processor. Jennifer Joy, from the Ear Institute of Chicago, reviews the subjective findings from the patient questionnaires, including three study participants suffering from single sided deafness. And from the University of Berne's Inselspital, Martin Kompis compares the Divino to the Baha® Compact in terms of speech understanding and sound quality.

In this issue we are also pleased to present a second article from the COMPRU group in Edmonton. Lisa Grotkowski reports on the introduction of 3D medical modeling and the future application of digital technologies in head & neck reconstruction.

We are extremely grateful to all the above-mentioned authors for their time and interest in presenting their work.

This edition also includes news items from Hong Kong, Australia, the USA and Germany as well as our regular product update, In Brief.

***Bone Anchored Applications* is published by Cochlear to keep you informed. Your contributions, comments and feedback are always welcome. If you have an article you would like to see published, please contact the editor, Nicola Walton, by email: nwalton@cochlear.com**

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*"Music now sounds
like music"*

Introducing the Baha Divino™

Baha Divino™ is the first device in a new generation of Baha® sound processors, developed to create a very personal listening experience for all of its wearers. The Divino introduces digital signal processing and adjustable AGCO combined with a built-in directional microphone to better meet the challenges of the endless variation of everyday hearing situations.

“ The views and expectations of our current Baha system wearers have been a driving force in the creation of our new sound processor,” says Marketing Director, Karin Andersson. “The Divino is built on a digital platform and combines the best features of previous devices, as well as incorporating the suggestions that have come from our customers over the years. We have striven to introduce an aesthetic, top of the line device that combines the advantages of digital signal processing with both technical and design based enhancements that have been in the pipeline for some time. We are delighted to introduce the Baha Divino™ to give our customers a new and improved solution for their patients!”

[Read more about the new Baha Divino™!](#)

Over the next pages you can find product facts and features and an interview with the development team based in Gothenburg, Sweden. The launch of Divino comes after extensive customer and patient testing that was designed to gauge market acceptance, wearer response and assess the quality of the new device. We are extremely grateful to three of our test clinics who have provided articles detailing both objective and subjective feedback from their patient assessment phase, as well as a comprehensive study by in-house audiologist, Mia Karlsson, presenting the overall results of the pre-launch patient evaluation.

Baha Divino™ – a personal experience

The Divino is suitable for people with bone conduction thresholds of the indicated ear better than or equal to 45 dB HL (measured at 0.5, 1, 2, 3 kHz), as well as patients with unilateral, profound sensorineural hearing loss of the indicated ear with normal contralateral hearing (as defined by 20 dB HL air conduction pure tone average). All current Baha® accessories can be used with the Divino and are easily connected via the sound processor's electrical input. The Divino is available as either a right or left-hand model and is delivered in a kit including the sound processor, abutment cover, battery, cleaning brush, safety line, User's Manual and a small test rod that allows wearers to 'share their Baha experience' with family and friends.



Design and aesthetics

The Divino is available in four new colours (black, silver-grey, blond and brown) that have been selected to allow the sound processor to blend in with the hair. The new design is both functional and aesthetic and takes into account feedback from our customers and our wearers. "We wanted a rounder and softer shape for the Divino," comments Product Manager, Helena Pruss-Cindric. "The square transducer puts limitations on how far we can go, but we are very pleased with the final design. A groove cuts through the middle of the housing which makes it look slimmer and the switches have been made more accessible. The improved colours blend in more naturally with the hair and we opted for specialised paint, which made our choice of shades much wider and allowed us to add lustre to the colour. People can also choose to make their sound processor a bit more individual if they want by using the stickers that come with the device!"

For more information, please contact your local representative.

*"we wanted a
rounder and softer
shape for the
Divino"*

The Baha Divino™ combines unique qualities to provide a truly personal listening experience:

- Adjustable AGCO control for individual setting. The AGCO limits distortion and the circuit has a dual time constant system, allowing for improved sound quality in loud environments. The compression keeps the sound at a comfortable level, so the wearer will not be startled by a sudden, unexpected noise.
- Adjustable tone control – an effective and powerful bass cut that can be adjusted depending on the wearer's hearing loss.
- Built-in, dual program, directional microphone for better sound comfort and ease of use.
- The dual programs allow the user to adapt to noisy or quiet surroundings depending on the current situation. Program 1 uses an omni directional microphone which means that the sound processor picks up sound regardless of the direction from which it comes. Program 2 uses a directional microphone to emphasize sounds that come from the front and reduces the background noise.
- New design, improved aesthetics and four new colours to blend in with the wearers' hair.
- An electrical input designed for connecting external equipment such as MP3, FM hearing systems and accessories such as the Audio adapter, Telecoil unit and MicroLink Baha FM-receiver.
- Improved protection against mobile phone interference. ■

Baha Divino™ – your questions answered

During the customer & patient testing phase for the new Baha® sound processor a variety of questions were raised, ranging from the background to its development to advice regarding fitting and general use. In this article, three key members of the development team provide answers to some of the most common questions.

Can you describe the key challenges faced during the development process and what is the outcome for the wearer?

Kristian Åsnes: “When developing a digital device that would suit all the requirements of our Baha users we really had to focus on three main areas: power, sound quality and optimisation of signal processing technology. Our first challenge was to get enough power out of the available digital circuitry, as it was not originally developed for high power applications. When conventional digital hearing aids were introduced they were aimed at mild to moderate sensorineural losses. The Baha system requires more power to aid a 45 dB loss via bone conduction than an AC (air conduction) aid does for a similar level of hearing loss. High power digital AC aids have only become available in the last couple of years, and Baha has the same demands on the circuitry that these most recent AC devices have had.

The demand for both power and performance also challenges the technology in terms of power supply for Baha sound processors. The need for power puts a higher demand on batteries – more recent circuitry development offers a solution by means of a volt-

age stabilisation circuit which stores power to keep the voltage to the DSP high enough, even when the device is delivering high output. This more recent technology also impacts on us being able to reach maximum output, as previous digital circuits were not equipped with a sufficiently powerful output stage to amplify the signal to the transducer.

In terms of sound quality the challenge was to achieve a high dynamic range, as well as a short time delay, using the available DSP circuits. Again, a question of making the most of the ‘hardware’ currently available. Some of our Baha wearers have very good cochlear function, making them very discriminating customers indeed, as they will detect any artefacts in the sound! This in itself puts great demands on the system and we didn’t want to compromise the success of the analogue devices with the introduction of a digital Baha. The analogue system has a high dynamic range and a short time delay and we had to achieve something similar with the digital device. In fact, the Divino has a 0.8 millisecond delay, which is a great result for a digital device.

Optimising the signal processing sets a

challenge at the ‘client interface’ – in other words, just how far to take the possibilities of signal processing but at the same time keeping the fitting process reasonably straightforward. We wanted to offer our fitting professionals more control over the overall performance of the new sound processor, but retain the simplicity of the Baha system as a whole.”

What can we expect in terms of overall quality from the new device?

Niklas Hofverberg: “We have introduced new quality testing controls and verification standards during the development of the Divino, especially with our outside suppliers. We have developed a new transducer and excluded the damping layer. Without this damping layer, the Divino’s sound quality will remain more consistent over time. The damping layer has become redundant because the damping of the frequency resonance peak is now processed digitally by a ‘so-called’ notch filter.

We have also improved the corrosion protection by gold plating sensitive parts like the transducer plate. Corrosion caused by sweat and other moisture, as well as humidity, can lead to a greater risk of distortion amongst other things.”



Niklas Hofverberg (Project Manager), Mia Karlsson (in-house Audiologist) and Kristian Åsnes (R&D Manager)

Can you give some advice about fitting especially regarding the built-in directional microphone?

Mia Karlsson: “With a built-in directional microphone, most people can improve their speech discrimination in challenging situations. Recent studies on the general benefits of directional microphones show a 2–3 dB improvement, but of course it depends on the listening environment. To get the best from the Divino’s built-in microphone it’s important to explain to the wearer exactly which situations the two programs (program 1 – omni directional microphone and program 2 – directional microphone) have been developed for. It may also be useful to give your patient instructions on how to try the programs at home so they are comfortable with this option – a bit like homework!”

One of our wearers in the pre-launch test complained about the sound when using the directional microphone program. Is program 2 softer?

Mia: “Due to the automatically reduced bass amplification, program 2 may be perceived as being weaker than program 1. When using program 2 in noisy surroundings the reduced bass amplification will not be noticed. It is very important to explain to your patients which situations the program has been developed for.”

Are there any specific recommendations for the AGCO depending on each patient’s hearing loss?

Mia: “Yes, although we can’t cover all possible hearing losses with an exact setting. Obviously the main purpose of the AGCO is to decrease the output to avoid distortion which should increase your patients’ listening comfort. In the past some people have described Baha as a ‘plug & play’ system, and the Divino continues to be a simple and effective solution, but at the same time also offers greater fitting flexibility! The Divino is delivered with the AGCO set at maximum, so it’s very important to make sure that it is adjusted for each patient so that

they get the greatest benefit. We suggest that you present speech and music at moderate levels and ask your patients to then adjust the volume to the most comfortable level after each alteration. People with normal inner ear function can be expected to prefer a decreased compression threshold – starting at the mid point is realistic. Patients with a sensorineural component, say around 40–45 dB, may prefer the higher ‘factory’ setting.”

Should we advise our wearers to adjust the AGCO and tone controls themselves?

Mia: “The AGCO and tone controls should only be adjusted by the audiologist or fitting professional. But we do understand that some wearers are very interested and have a lot of knowledge about their hearing loss and sound. And in some cases, for practical reasons, you may find that a few wearers want to make adjustments themselves. If so, it’s very important that they have received good instructions and are competent to do so.”

Is the Divino as strong as the Compact and Classic models?

Kristian: “Yes, and it has the same audiological indications of 45 dB HL (PTA for 500 Hz, 1, 2 and 3 kHz). If you take a look at the output characteristic curves in the Audiological Manual, the Divino gives about 4 dB extra at around 500 Hz. So, depending on the wearer’s hearing loss, these extra dB can be important and some wearers have reported that the Divino is more powerful than their previous device.”

How long will the battery last compared to the Compact/Classic?

Niklas: “From the results of the patient test some wearers say that the Divino has a longer battery lifetime, while others say that the battery has a shorter lifetime. But in general we can say that the battery life varies depending on the volume setting and the background sound level.

High power batteries are recom-

mended for people who are dissatisfied with the sound quality when using their processor at high volumes or in loud environments.

If they are using an FM receiver, which is supplied from the sound processor, the battery life decreases so, again, patients may want to use a high power battery.”

What happens when the battery is losing power?

Kristian: “When the batteries run low, the sound will become weak and distorted as with previous analogue Baha devices. But the digital model may also shut down briefly at loud inputs, and then restart when the battery voltage has recovered. This is due to the different behaviour of analogue versus digital circuits. If your patients are using their Divino on max volume with the AGCO at the factory setting, which is at the highest level, then high power batteries should definitely be considered.”

When will the Compact and Classic be withdrawn?

Niklas: “The Divino is intended to replace the Classic and Compact sound processors over time. We anticipate that this will happen as soon as realistically possible in all markets according to local ‘medical device approval’ requirements.”

What is the biggest advantage with the Divino?

Kristian: “The built-in directional microphone and adjustable AGCO control & tone control mean that the Divino is a much more flexible sound processor. People who tried it during the pre-launch tests commented particularly on the improved sound quality. We are calling it a personal experience because we believe that the new sound processor really does offer a very individual listening experience for all of our users.”

If you have more questions about the Baha Divino™, please contact your local representative. ■



Baha Divino™ – Initial results from the pre-launch patient evaluation

by Mia Karlsson, Audiologist, BAS Division, Cochlear Limited

Introduction

For almost 30 years the Baha® system has been available as an alternative for patients in need of acoustic amplification but who for some reason cannot use an air conduction hearing aid (ACHA). Baha is now a standard treatment for patients with a hearing loss due to outer and middle ear problems, as well as for people with single sided deafness (SSD™). To date there are more than 25,000 Baha wearers worldwide.

Today most ACHAs are digital, offering wearers many advantages over analogue hearing aids; programmability, memory, flexible control of electro acoustic characteristics, advanced signal processing capabilities for noise reduction and speech enhancement, feedback cancellation etc. Patients and customers have asked about the possibility of a digital Baha sound processor for some time, but suitable digital circuitry has not been available until recently. And even current technology still does not allow the creation of a digital Baha device with all the advantages that can be found in digital ACHAs.

In this article we present a study based on the results of a pre-launch patient evaluation of the new digital Baha Divino™.

Aim of the study

The aim of the pre-launch test was to evaluate the benefits and reliability of a new digital Baha sound processor and to compare it to current Baha technology. The intention was to gather feedback over a three month period from a group

of experienced Baha users.

Material and methods

The Divino is a digital device with adjustable AGCO (Automatic Gain Control, output compression) and a bass cut for individual setting. It has a built-in directional microphone. The device is fitted as either a right or left version.

87 devices were sent out to clinics in Great Britain, France, Belgium, Holland, Switzerland, Sweden, Australia, China (Hong Kong), Germany and the USA. Test participation was limited to current Baha recipients, who were adults of 18 years of age and older, and who had used the Baha system for a minimum of 12 months. Their pure tone average bone conduction (BC) threshold of the indicated ear should be better than or equal to 45 dB HL (measured at 0.5, 1, 2, 3 kHz). For SSD participants, we recommended normal hearing in the good ear (20 dB HL AC threshold) and a hearing loss that cannot be aided properly with a traditional AC aid on the poor side.

The test participants were to wear the Divino sound processor for a 3 month period. (In this study the word 'previous' is used to describe the Baha device used by the participants prior to their being given the test Divino sound processor).

In order to evaluate the device we provided each wearer with two questionnaires. The questionnaire reported in this article has been developed by Entific (now Cochlear) and is intended to give specific information about the performance and

robustness of the new device. It consists of 17 questions grouped under the following headings: battery, handling, electrical input, GSM and other mobile phones, sound quality, directional microphone and other viewpoints.

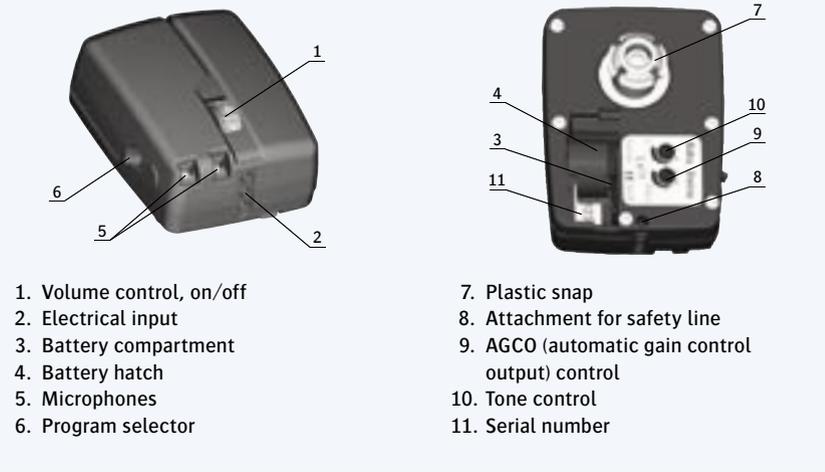
This questionnaire was filled in by the test participants on two occasions; 4 weeks after the Divino fitting and 12 weeks after the fitting. A second questionnaire, the Abbreviated Profile Hearing Aid Benefit (APHAB), was also distributed to the participating clinics but the results of the APHAB are not presented in this article. Basic background data about each patient has been documented using a Patient Test Data form.

Results

It can be called into question which is the best way to evaluate a new hearing device. Audiometric tests seldom show significant results even if the wearers report a notable difference regarding sound quality. Increasingly, questionnaires seem to be an acceptable measuring instrument for this type of evaluation. It should be observed that the optimum concept would be a mix of both. The placebo effect when presenting a new device in a non-blind test has to be taken into account as well.

The results from the company questionnaire are based on a total of 87 devices and 85 test participants – the difference due to the fitting of two bilateral users. Tight time schedules have meant that not all the results have been received within the deadline. 65 completed questionnaires

Fig. 1. Baha Divino™ showing overall design and positioning of controls



naires from the first test period (4 weeks) and 54 from the second test period (12 weeks) have been received so far and the results are summarised in this article.

The first heading in the questionnaire focuses on battery consumption. 42 out of 65 (65 %) test participants within the 1st test period said that they found the battery lifetime to be longer or the same as for their previous device. About 31 %, 20 test participants, found the battery lifetime to be shorter. Two months later ~30 % still found the battery lifetime shorter. These results are discussed later in this article.

The next question was designed to analyse the handling of the device. How easy/difficult was it to change the battery and locate the volume control and program selector? 56 of the 65 wearers found the battery as easy, or easier, to change than

their previous device after the first test period. For the volume control and the program selector the numbers finding it as easy or easier are 60/65 and 57/65 respectively.

Questions regarding the electrical input revealed only 8 Audio adapter, 4 Telecoil and 4 FM system users. Their judgement of the sound quality when using these accessories together with the Divino was noted as better/slightly better or no different.

46 out of 65 test participants (71 %) use a GSM or other mobile phone on a regular basis. 8 of this group reported some minor handling problems when using their phone together with the Divino. As expected, none of the participants experienced any interference when using their phones.

One third of the questions in the questionnaire are related to the users' judgement of the sound quality of the new device. Figs. 2-5 demonstrate how the test participants assessed the value in 4 different listening situations after their first test period: 37 out of 65 (57 %) found the new device more powerful or slightly more powerful than their previous device after the first test period. After another two months the numbers are 33 out of 54 (61 %).

Furthermore 47 (72 %) test participants found the sound quality of the Divino better or slightly better than their previous sound processor, 9 wearers (14 %) responded 'no difference', while 9 (14 %) said the sound quality was worse or slightly worse. After the second test period the percentage figures were 74 % for better or slightly better and 7 % for worse or slightly worse respectively.

26 out of 65 experienced less wind noise with the Divino, 31 said there was no difference to their previous device and 7 said they had more wind noise (results after the 1st test period).

Regarding occasional problems with feedback, 31 respondents experienced no feedback problems. 25 out of 65 users experienced some problems with feedback with their previous sound processor. Of these, 20 reported having had problems with feedback using the Divino as well. 9 respondents said they had no feedback problems with the Divino but they had experienced problems with their previous device.

Fig. 2. One person in quiet (in %)

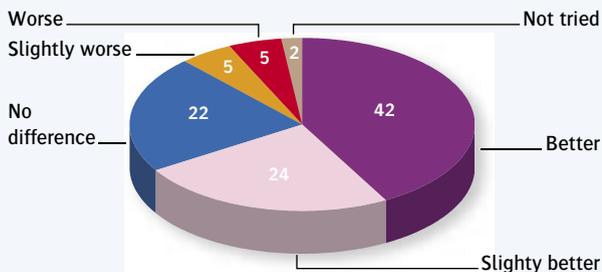
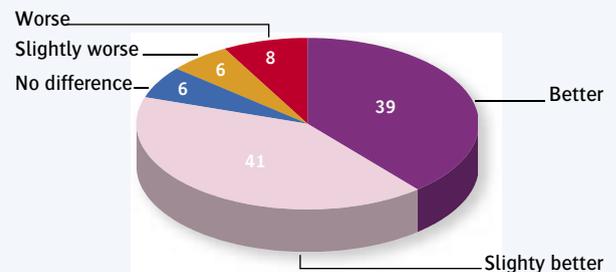


Fig. 3. One person in noise (in %)



These results are discussed in more detail in the next section.

17 of the test participants used a directional microphone with their previous device and of these 15 preferred the Divino's built-in directional microphone. The first test period showed that 45 out of 65 (69 %) used the Divino's directional microphone in specific situations. Finally, 11 participants noted that they had experienced some minor loss of function with the Divino in certain specific situations during the test period.

Discussion

The introduction of the Divino digital device opens up for new thinking when fitting direct bone conduction sound processors and allows for future developments in technology as we have seen for traditional ACHAs. With the Divino's two trim controls it is possible to influence the final fitting result a lot more than with previous models. In fact, failing to adjust the device can result in the wearer experiencing uncomfortable sound levels and higher battery consumption than necessary.

The Divino is equipped with an adjustable AGCO function, its main purpose being to decrease the output to avoid distortion at high output levels, and to increase listening comfort – but there is always a trade-off between loudness and distortion. With the AGCO trim control set at its maximum, in an environment with high background noise, and with the volume control above 2, the battery consumption can be expected to be high.

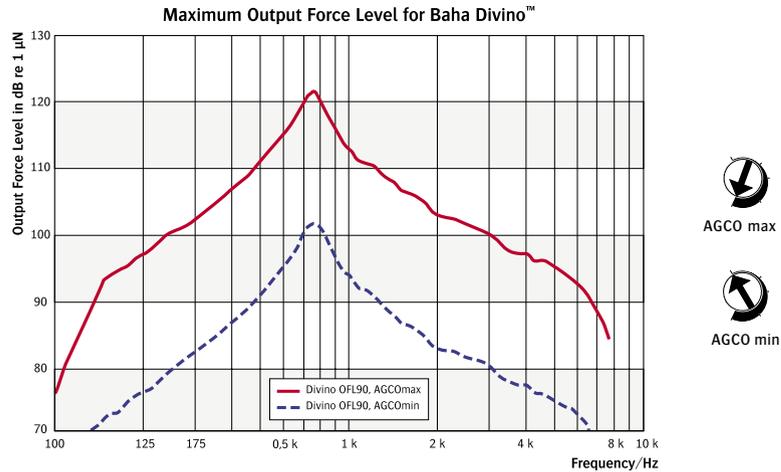


Fig. 6. Divino output force levels and relevant positioning of the AGCO control

20 test participants found the Divino battery lifetime shorter compared to their previous device. 3 of them had thresholds below 45–50 dB HL (borderline cases for the Cordelle II) and the sound processor could therefore be expected to be set on its maximum. 7 of them had bone conduction thresholds between 35–45 dB HL and we can assume they preferred the AGCO setting to be somewhere between maximum and 1/4 reduced. These 10 wearers were all in the region where you can expect high battery consumption and where it can be suitable for the wearer to use power batteries. But 3 test participants were found with almost normal inner ear function, though the AGCO trim control was set very close to its maximum. In general, the fitting instructions recommend that the AGCO is positioned halfway down from the maximum setting for a wearer with normal or almost normal inner ear func-

tion, and for hearing losses around 40–45 dB HL the factory (maximum) setting will probably be the most appropriate.

Regarding handling, the new positioning of the volume control and the battery compartment was well accepted by a big majority. The program selector was also well accepted even though it can be difficult for some older wearers to learn new dexterity.

8 test participants reported some inconvenience when using a GSM or other mobile phone with the Divino. However, from the associated comments, it is apparent that none of the respondents detected any form of actual interference between the sound processor and the cell phone itself. 2 respondents had feedback problems when holding the phone towards the ear/sound processor, 3 suggested 'technical' solutions

Fig. 4. Several people in noise (in %)

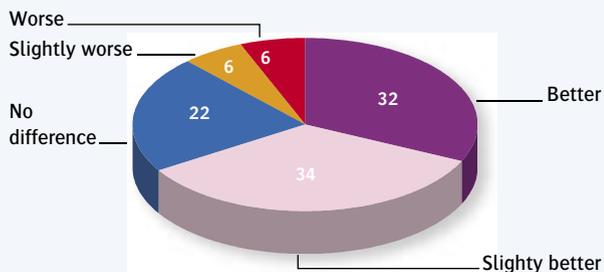
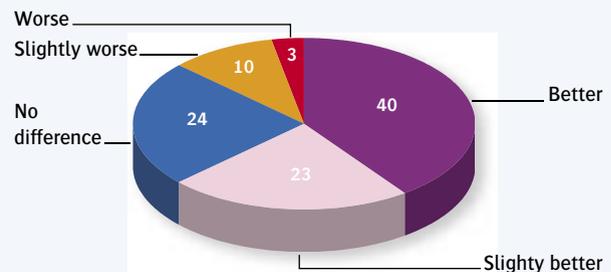


Fig. 5. Listening to TV/radio (in %)



for simplifying phone use (finding the correct position, using mute for surrounding sounds etc.), and 3 did not specify what the difficulty was.

Feedback problems are associated with all hearing devices, although recent technology has allowed for the introduction of Automatic Feedback Control to new digital ACHAs. Hopefully, assuming further developments in digital technology, we will be able to incorporate this feature in Baha devices in the future. But until then we have to accept a certain amount of feedback problems for our wearers due to the specific issues of Baha treatment e.g. individual differences in bone and soft tissue thickness, size of the head etc.

When analysing the results of the sound quality questions we must express our delight to find that more than 80 % of the participants experienced better or slightly better sound quality when listening to 1 person in noise, a situation we know most hearing impaired people find very stressful. About 65 % answered better or slightly better when listening to one person in quiet, several people in noise and when listening to TV/radio. It is difficult to pinpoint a specific reason why the sound quality has been reported to be so much better with the Divino compared to previous models. But one of our test participants expressed it this way: “Sound quality is a feeling and this is a good feeling.” In addition, 57 % of participants considered the Divino to be more powerful than their previous device.

Of course we should also bear in mind that it can be a big challenge for the wearer to change from a well-known ‘sound picture’ to that provided by a new device. In a test situation there will always be Baha wearers who prefer their own/previous sound processor. This goes for traditional AC hearing aids as well. Even if it can be proved that the wearer has better speech understanding with a new device, it is not unusual that they choose to keep their old device. We can only try to encourage them to swap their ‘sound picture’ by offering support, either in the form of relevant accessories

or simply by listening to their opinions and explaining what is happening. It is hard to find a common denominator amongst the relatively small number of participants who answered negatively when assessing the value of the Divino in different listening situations.

Under ‘other viewpoints’ we received some comments about a metallic sound when chewing or when the teeth ‘close together’. The Divino uses a highly efficient transducer featuring minimized internal losses. In combination with the very efficient titanium coupling, this may result in a slightly changed perceived sound when chewing, even when the device is not switched on. This has been reported from 3 test participants who all have normal inner ear function.

Regarding the use of the built-in directional microphone, 69 % of the test participants declared they had used the directional microphone in specific situations (1st test period). Amongst those who answered that they had not used it, there were explanatory comments such as; “the sound is too weak”, “tried it but it was of no benefit for me”. For borderline cases (45–50 dB HL) these are quite understandable comments. But some test participants with hearing losses within the range, where you would have expected a benefit in terms of better speech recognition in noisy surroundings, also said they had not used the directional microphone. This highlights the need to explain to the wearer exactly which situations the two programs (Program 1 – omni directional microphone and Program 2 – directional microphone) have been developed for. It should also be stressed that if the directional microphone is used in quiet surroundings, the device may be perceived as being weaker. The weaker sound arises due to the inevitable reduced bass amplification in Program 2 compared to Program 1.

Finally, during the 1st test phase, 11 participants remarked that they had experienced occasional, temporary loss in sound when there was a significant change in the background noise or environment. Some of the comments explained that the Divino had cut out

‘in case of loud noises’ or ‘cuts out in very noisy environments’ and ‘when there are loud wind noises’. However, in most cases the wearers commented that the loss was only for a few seconds and that they had been able to deal with the situation by simply switching the device off and on again. On inspection we found that 7 of the devices had the AGCO control at factory (maximum) setting. Our conclusion is that it is either the AGCO function that cuts the sound in situations where the background noise suddenly changes to a very high volume, or that the battery was not able to give the extra current needed for very loud sounds. In this situation the battery should be changed or a power battery used instead. From the feedback we have received so far we advise that the AGCO at factory setting (maximum) is only used when absolutely necessary. If this high setting is necessary then the wearer should be advised to use power batteries.

2 test participants reported that the Divino ‘shuts down’ when it is very cold. It is a well known phenomenon that batteries work worse and worse the colder it gets. Only 1 device was returned for repair due to a sound ‘cut out’ and for which there could be no fault found.

Conclusion

This evaluation of the results of the pre-launch patient test of the Baha Divino™ confirms that we have developed a device in line with the requirements of both our customers and patients. The built-in directional microphone offers a great benefit for most users in noisy and difficult hearing situations. The adjustable AGCO and bass trim control give many more options when adjusting and fitting the device for each individual’s need. While at the same time these options raise the demand on the audiologist when fitting the device! The results from our pre-launch test clearly show how important it is to adjust the device properly and to give the wearer the correct information on how to use the directional microphone.

We thank all the clinics involved in this pre-launch test for their help in collecting the data and bringing it to us in time. ■



Bill Hodgetts is an audiologist and member of the COMPRU Baha Program. He is currently completing his PhD dissertation in the areas of assessment and verification of Baha at the University of Alberta.

Directional Capabilities of the Baha Divino™: Preliminary Objective Results

By: Bill Hodgetts
COMPRU, Caritas Health Group, Misericordia Community Hospital
and
Department of Speech Pathology and Audiology, University of Alberta,
Edmonton, Alberta, Canada

Introduction

As reported in other articles in this volume, much has been learned about the subjective impressions of patient performance with the Divino. Although important, patient satisfaction taken in isolation does little to inform the clinician, researcher or manufacturer about what specific aspects of the device lead to these subjective improvements. Moreover, as Bentler et al (2003) discovered, something as seemingly insignificant as “labeling” a device as “digital” can have profound effects on the subjective impressions obtained from hearing aid users.

When COMPRU was invited to par-

ticipate in the trial of the Divino, we felt that it was important to keep these considerations in mind. That is, to test the objective benefit of the device, it would be important to use as much “blinding” as possible. Consequently, our subjects were not told the device was “digital.” Moreover, objective results might help to augment what has been reported by the patients on the subjective scales in other articles in this volume (as well as those of our own subjects).

Device Improvements

The Divino received several upgrades from its Baha brethren including: digital processing, multichannel capabilities and

variable output limiting. Perhaps the most important improvement made on the Divino is the inclusion of a “built-in” directional microphone. As Killion (2004) points out, there is abundant evidence that every hearing aid dispensed should feature a directional microphone. Given the difficulties patients have in background noise, the lack of a directional microphone may partially explain why 40 % of those who buy hearing aids do not consider themselves “satisfied” (Kochkin, 2004).

For this brief report, we sought to investigate the performance of the directional microphone on the Divino with the following 2 questions in mind:

1. How much electromechanical directionality is there at 0, 90, 180 and 270 degrees?
2. Were clinically significant improvements achievable with the directional microphone using the Hearing in Noise Test (HINT)?

Methods

Subjects

5 adult male Baha users with bilateral conductive or mixed hearing loss were selected. Bone conduction hearing thresholds for all 5 subjects are shown in *Table 1*.

Procedure

ELECTROMECHANICAL DIRECTIONALITY TEST

Directional microphones suppress sounds coming from some directions (usually the sides and back) of the listener, while retaining good sensitivity to the front of the listener. To test the directionality of the Divino, the sensitivity needed to be determined when an input signal source arrived from different directions (azimuths). To accomplish this, a Divino sound processor was attached to a skull simulator and placed on a stand in the middle of an anechoic chamber (see *Figure 1*). An Audioscan Verifit produced a broadband spectrum of 1024 tones that were delivered via 2 soundfield speakers. The 1024 tones were split into 512 tones that were individually controlled in real time to produce a precise spectrum from each speaker at the reference microphone of the Verifit. These 512 tones were then separated in the measured coupler output force level (OFL; ref: 1µN) and displayed as two real-time response curves (Audioscan, 2005). This allowed for a comparison of the sensitivity of the Divino to sounds arriving from different directions. The conditions reported here are 0, 90, 180 and 270 degrees. Three of these conditions allow for a direct comparison to the results of the Hearing in Noise Test (HINT).

HINT

The HINT (Nilsson, Soli, & Sullivan, 1994; Soli & Nilsson, 1994) was used to measure the signal-to-noise ratio (SNR) for 50 % correct sentence performance. There were 4 conditions for the test: (1) quiet, (2) speech and noise at 0 degrees

Table 1

SUBJECT	250	500	1000	2000	4000	PTA
1 (PN)	15	20	45	30	40	27.5
2 (MS)	0	15	55	55	50	31.25
3 (DE)	15	45	50	45	45	38.75
4 (JD)	30	20	30	25	20	26.25
5 (BB)	15	30	30	15	30	22.5

Figure 1. Electromechanical set-up for the directional testing of the Divino

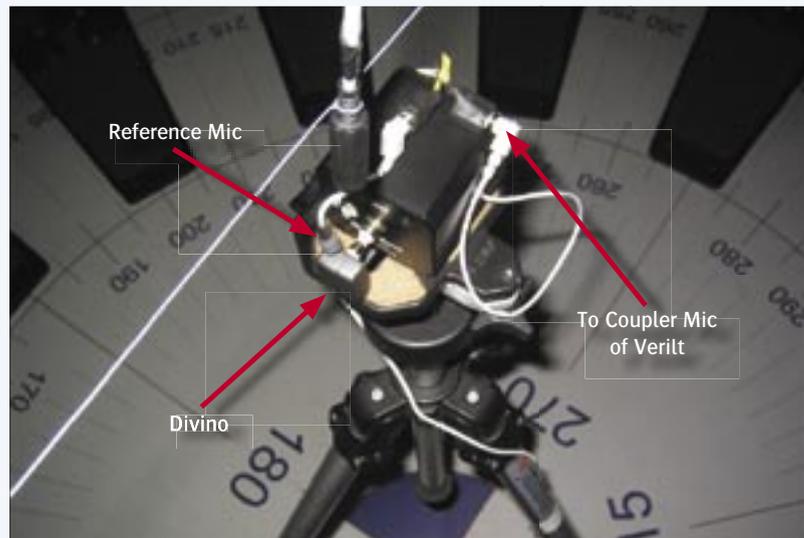
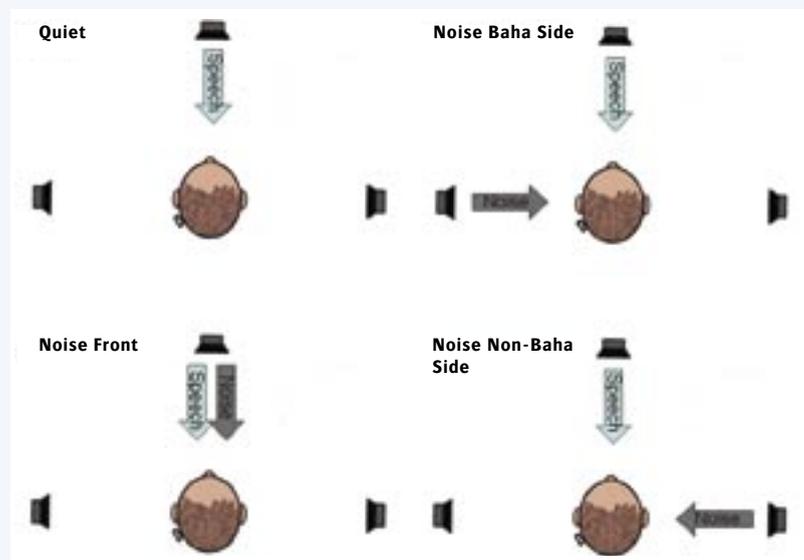


Figure 2. The four Hearing in Noise Test (HINT) conditions



azimuth, (3) speech at 0 degrees, noise at 90 degrees, and (4) speech at 0 degrees and noise at 270 (–90) degrees (see Figure 2). For each condition, 20 sentences of a male talker were presented to the subject. The subject's task was to repeat the sentence. The noise has a spectrum matched to the speech spectrum of the sentences. The level of the noise was fixed at 65 dBA and the level of the sentences was varied adaptively (up or down in 2 dB steps) depending on the correctness of the subject's responses. The entire sentence needed to be repeated accurately for it to be considered correct. Calculation of the SNR for 50 % correct performance was accomplished by averaging the presentation level of sentences 5 through 20 and relating that value to the 65 dBA noise. For example, if the average level for sentences 5 to 20 was 68 dBA, the SNR 50 % would be 3 dB. Each of the 5 test subjects performed the HINT under 3 aided conditions: 1) with their current Classic device, 2) with the Divino in omni-directional mode, and 3) with the Divino in directional mode. A skull simulator connected to the Verifit hearing aid analyzer was used to ensure that the Divino omni-directional setting for each subject matched the output of that user's Classic setting. This allowed for a better isolation of the effects of the directional microphone.

Results & Discussion

ELECTROMECHANICAL DIRECTIONALITY TEST

The frequency response spectra for the various directional testing conditions are shown in Figure 3 (a–d). When both spectra arrive from the front of the Divino, there is virtually no difference in OFL measured at the coupler (a). When one of the speakers is to the right (90 degrees) or left (270 degrees) of the Divino, there is separation between the sensitivity to the front speaker and the sensitivity to the lateral speaker (b & c).

This indicates that noise to the right and left of the user would be attenuated in the directional mode. There is also a separation in spectra when the speakers are at the front and back of the Divino (d). This separation is less pronounced (especially for low frequencies) indicating the directional microphone appears to be less effective when the noise is directly behind the device than when it is at the sides. This data agrees with the polar plot data supplied by the manufacturer of the directional microphone used in the Divino. There should be greater attenuation from the sides than from the back with this microphone (Sonion, 2005).

HINT

It was important to know whether the benefits obtained in the directionality tests lead to objective benefit on each of the 4 HINT conditions. There were no meaningful differences in quiet for the 5 subjects, so these data are not presented. Figure 4 shows the average scores (error bars represent ± 1 SD) for the SNR required to obtain 50 % in the 3 noise conditions (as well as a composite score). The more negative the score the better the performance in noise. As expected, there were no differences between the 3 conditions when the speech and noise arrived from the front of the subject. When the noise arrived from the Baha side, there appears to be no advantage for the Divino omni over the Classic. However, when switched to directional the difference was much greater. Each 1 dB improvement on this test equates to approximately 10 % improvement in sentence intelligibility. Therefore, with the noise at the Baha side, there was an average improvement of approximately 70 % with the Divino in directional mode over the Classic. When the noise is at the non-Baha side, there should be improved performance for all aided conditions, even without a directional microphone. This can be seen quite clearly in Figure 4. This improved

Figure 3(a)

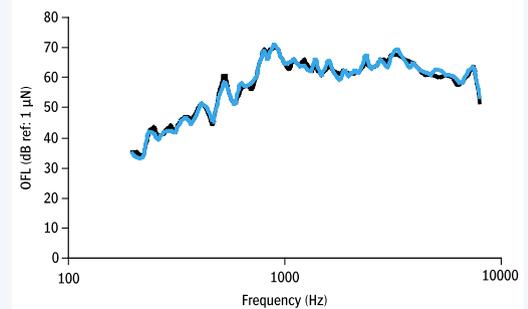


Figure 3(b)

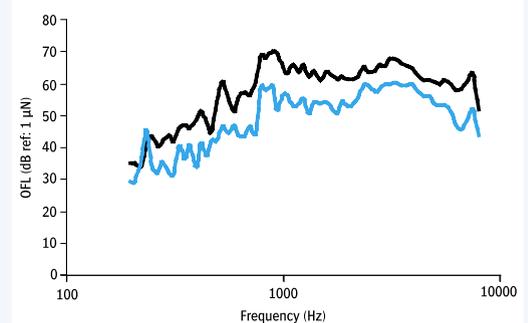


Figure 3(c)

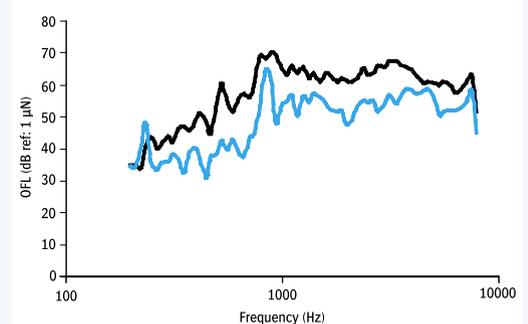
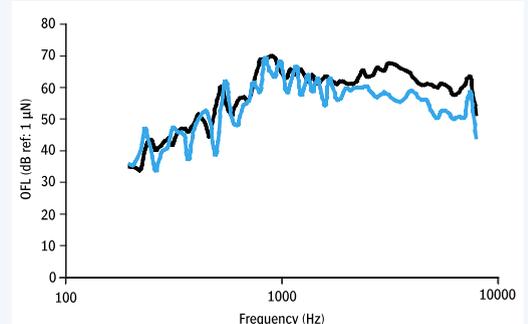


Figure 3(d)

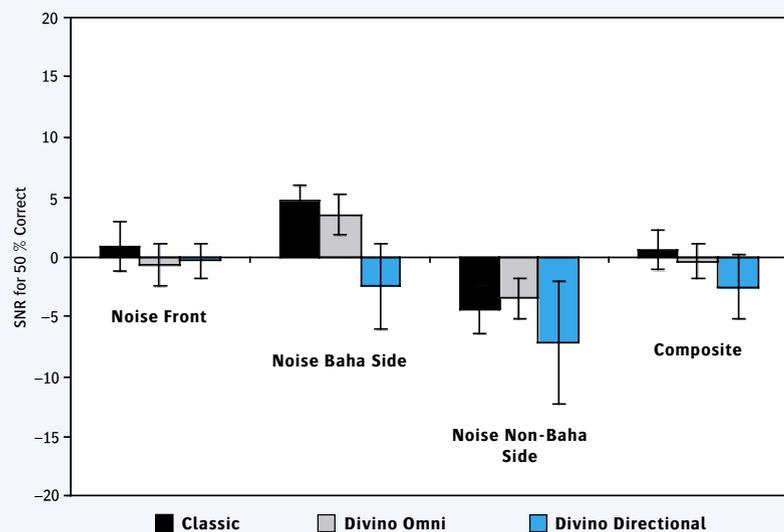


performance is a result of the head attenuating the noise path from the speaker to the Baha device. Interestingly, it appears that these 5 subjects still obtained a directional advantage in this condition (~30 %). It is likely that the low frequencies in the noise bend around the head and still interfere with the listener's ability to hear speech. In the directional mode, these low frequencies are attenuated enough to result in improved performance (see Figures 3 b & c).

Conclusions

There are many possible contributors to why patients might prefer the Divino over their current Baha model. Some of these may include: better sound quality, greater flexibility, variable compression characteristics or simply the label "digital." However, the directional microphone on the Divino appears to be effective both in terms of an electromechanical test and a speech in noise test. This brief report provides preliminary evidence that the directional microphone is likely a significant contributor to positive subjective reports and patient opinion of the Divino (noted in other articles in this issue). This is not a surprising result given that the "number 1" complaint of hearing aid users is "difficulty in background noise." While this report provides a starting point for how much benefit one might expect with the Divino in directional mode, these results need to be replicated with a greater number of subjects to ensure there is sufficient statistical power before these claims can be considered completely valid. The Divino represents the culmination of many years of widely expressed need to introduce a digital processor to osseointegration mediated bone conduction hearing. The unbridled enthusiasm that typically accompanies the introduction of new technology needs to be tempered

Figure 4. HINT test results by condition



with well designed scientific scrutiny. Failure to conduct this scrutiny all too often robs biotechnology of its true credibility and hence value in the eyes of regulators, professionals and users. It

is hoped that future research with the Divino will keep these considerations in mind so that the full potential of this new technology can be truly understood. ■

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Baha Divino™

– Our Pre-launch Results

By: Jennifer Joy
Director of Audiology, Ear Institute of Chicago, Chicago, USA

Jennifer Joy, MA, CCC-A, FAAA, joined the Ear Institute of Chicago in December 2004 as the Director of Audiology. Prior to joining the group, she was the Supervising Audiologist for the Division of Audiology as well as the Dizziness and Balance Center at the University of Miami Ear Institute in Miami, FL. Jennifer Joy has a significant background in diagnostic and vestibular evaluation in addition to rehabilitation with the Baha system.

Over forty Baha® surgeries have been performed by the physicians at the Ear Institute of Chicago, LLC, since 2002 and have included both pediatric and adult populations. Neurotologist, Robert Battista has performed the majority of the Baha surgeries at the Ear Institute of Chicago and has been instrumental in campaigning for Baha devices at both local and regional levels. As Director of Audiology, Jennifer Joy has been involved in the evaluation and fitting of patients with Baha devices since 2000. Together, Dr. Battista and Ms. Joy lead the Baha clinic at the Ear Institute of Chicago, LLC, with the help of an excellent support staff.

About the digital device

Having experienced such positive results with Baha in the past, we were anxious to take part in the company-sponsored clinical trial of the new digital device, Baha Divino™. Being able to try out and offer digital technology has been a long awaited addition to the Baha system. The goal of digital technology in hearing devices is generally to provide cleaner sound quality and volume without distortion. Therefore, many changes to the internal components have been made to improve the overall reliability of the sound processor. In the new Divino, the developers have designed a sound processor with output compression that mimics the original Baha® Classic sound processor without reintroducing the sound distortion that is often associ-

ated with linear hearing instruments. The AGCo is now adjustable and, unlike the Compact, the Divino can be adjusted to sound more like the Classic – depending upon the recipient's preferences. As mentioned, the AGCo is an adjustable trimmer that helps limit distortion to the Divino wearer upon loud sound input. This feature is also especially helpful for anyone who has an unusually low level of tolerance for loud sounds (i.e. hyperacusis).

In addition to the AGCo output trimmer, there is still a tone control trimmer that is generally adjusted to accommodate the user's neural level as well as their personal listening preference. The tone control trimmer allows the audiologist or fitting professional to adjust the amount

of high or low frequency emphasis. In my experience in the past, soundfield testing tended to show little audiometric change with various adjustments to the tone control. Therefore, most of my tone control adjustments came from patient feedback. This same approach was utilized for the Divino clinical trial.

When you look at the new Divino, the first thing you'll notice is a slight size variation and the lack of a directional microphone plugged into the bottom. While the Divino is slightly shorter in height, it is also slightly deeper. The directional microphone has been integrated into the device and thus makes the accessory port more accessible for other uses. A switch has been added to the side of the device that activates the directional microphone when the user feels it is necessary. The integration of the directional microphone also allows for easier access to the battery compartment.

Study design

To be included in the Divino clinical trial, participants were to be at least 18 years of age and have worn their Baha device (Compact, Classic, or Cordelle II) for at least 12 months. The hearing experience and satisfaction with the Divino was evaluated by having the participants



Baha® Compact with Directional Microphone



Baha Divino™ with built-in Directional Microphone

complete two sets of questionnaires over the course of three months. Prior to being fit with the Divino, the participants were asked to complete the APHAB (Abbreviated Profile of Hearing Aid Benefit) to qualify their hearing experience with their current Baha device. The Divino device was then fit with the appropriate adjustments to their tone control and output trimmers.

Since the tone control adjusts for high and low frequency emphasis, most of the participants preferred the tone control to be set at the midpoint. This setting allowed for a fairly even distribution of the high and low frequency sound input, which created a more natural sound according to the wearers. Additionally, it is best to make any fine tuning adjustments based on subjective reports, while in a moderately noisy situation, so that you're not only adjusting for the best sound quality, but also for speech clarity in noise. (My favorite method is to take a walk outside while having a casual conversation with the wearer, positioning myself on the same side as the device). You can also make any adjustments to the output trimmer, if necessary, in this same environment.

The participants were then given the two sets of questionnaires, the APHAB as well as a specially designed user questionnaire, to complete and send in, after wearing the

Divino, at 4 and 12 weeks respectively.

Four patients met the study criteria from our clinic. The cause of hearing loss of these four patients included one patient with bilateral chronic ear infections resulting in a bilateral conductive hearing loss and three single sided deafness (SSD™) individuals. Of the three SSD patients, two lost hearing after acoustic neuroma removal and one from a sudden sensorineural hearing loss. The length of hearing loss prior to Baha implantation ranged from one to ten years, with an average of just over four years. Prior to enrolling in the Divino study, the average length of Baha use (all previous Compact users) ranged from 12 to 17 months, with an average of 13.5 months.

Study results from our clinic

The results given by the study participants from our clinic revealed some interesting aspects. The specially designed user questionnaire showed no significant change in device usability from the 4 to 12 week interval. Our participants reported performance of the new digital device to equal the performance of their current Compact device in the following three areas:

1. Changing the battery
2. Wind noise
3. Talking to several people in noise

The five areas where the Divino outperformed their current device were:

1. Listening to the TV/radio
2. Device power
3. Better sound quality
4. Better directional microphone
5. Easier to handle

The APHAB questionnaire was completed immediately prior to the Divino fitting and then again at the 4 and 12 week intervals for direct comparison of the new digital device to their current device in terms of hearing performance. Prior to the Divino fitting, the percentage of hearing problems our participants reported with their Compact device ranged from 16 % to 44 %. At the 4 and 12 week intervals, three participants reported greater hearing benefit with the Divino for all aspects of the APHAB. While some variations were noted in their perception of hearing performance with their Compact device, over the 12 weeks the percentage of increased hearing benefit with the Divino ranged from 6 % to 35 %.

Most of the study participants had difficulty returning the Divino at the conclusion of the study. In fact, all Ear Institute of Chicago, LLC, study participants have chosen to purchase the new digital device. Such positive feedback thus far with the Divino is very encouraging for those individuals who are contemplating Baha implantation. The device size/color changes, as well as the integration of the directional microphone, make the Divino more aesthetically appealing. The integration of the directional microphone may also aid in troubleshooting any functional problems by eliminating the external connection. The straightforward fitting formula of the Baha system continues with the Divino and makes this device a pleasure to fit and work with. ■

Improved speech understanding in noise and better sound quality with the Baha Divino™

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Inselspital, University of Berne, Switzerland*

Martin Kompis has been working with Baha in Berne since 1996, although the system has been in use at the clinic since 1992 with more than 170 patients treated to date. Previously, Prof. Häusler had also been treating Baha patients in Geneva since 1987.

Background

In a study comparing the new Baha Divino™ and the Baha® Compact in seven adult, unilaterally fitted Baha® users, statistically significant advantages of the Divino regarding speech understanding in noise and overall sound quality were found. This article summarises selected results from a larger study performed at the University-ENT clinic of Berne, Switzerland.¹

The Baha system is used increasingly in the treatment of conductive or mixed hearing losses.² Its success is based on a number of well documented, unique advantages over both conventional air conduction and bone conduction aids, such as leaving the external auditory canal open and providing a stable acoustical coupling without static pressure.

The only ear-level Baha sound processors that have been available until recently, the Baha® Compact³ and the older Baha® Classic, are basically linear aids using analogue technology. While such simple signal processing is adequate for the treatment of purely conductive hearing losses with preserved binaural hearing, there are users who suffer from

an additional sensorineural hearing loss or who use only one Baha device and might therefore benefit from more complex signal processing technology. Recently, a new device, the Baha Divino™ (see Fig. 1), featuring more sophisticated signal processing, has been developed. We report on first experiences and the results of a study comparing the Divino with the Compact in seven unilaterally implanted patients.¹



Fig. 1. The Baha Divino™

Materials and methods

Two types of Baha sound processors, the Baha® Compact³ and the Baha Divino™, were compared. In contrast to the Compact, the Divino features straightforward

digital signal processing with audiologist-adjustable compression in addition to a low frequency gain adjustment. For noisy environments, a built-in two-microphone directional noise reduction system can be activated by the user.

Seven adult subjects, aged between 19 and 66, who had previously been fitted with the Baha system at our clinic participated in the study. All participants had been using their sound processor unilaterally on a daily basis for at least two years. All had a substantial conductive hearing loss in both ears, some combined with a moderate sensorineural component.

All subjects participated in two sessions 3 months apart, with the option of additional visits for fine-tuning of the new device's settings between these sessions. During the first session, air and bone conduction thresholds were measured for each ear. Then free-field measurements in the unaided condition and in an aided condition using a Baha® Compact device were conducted. Measurements included free-field thresholds using narrow-band noise and speech audiometry in quiet (Freiburger monosyllabic words) and in noise (Basler sentence test). All tests were



performed in German. For the Freiburger monosyllabic words, the percentage of correctly repeated words at 50, 65 and 80 dB SPL was measured. For the Basler sentence test, the signal-to-noise ratio (SNR) in dB, at which 50 % of the key words were understood correctly, was measured. The speech signal was emitted from a loudspeaker in front of the listener whilst noise was emitted either from the same direction or from behind. After these tests, but still within the first session, a Baha Divino™ was fitted and the subjects were asked to use this new device for the next 3 months. Our study group were also given a questionnaire inquiring about their experience with the new device which was to be returned after 3 months.

Three months after the first session, pure tone audiometry and unaided and aided free-field thresholds with the Compact as well as speech audiometry in quiet were repeated to ensure that no significant change in the hearing of the subjects had occurred. Speech audiometry in quiet and in noise was then performed using the Divino. For measurements in quiet, the Divino was set to its omnidirectional mode. To test the effect of the directional two-microphone noise reduction system, speech tests in noise were performed both with the directional two-microphone system switched on and off respectively.

Results

Pure tone audiometry and speech audiometry using the Baha® Compact yielded essentially the same results at 0 months and at 3 months. The aided free-field thresholds were also very similar for the Compact and the Baha Divino™. Speech understanding in quiet using monosyllabic words (*Fig. 2*) improved substantially at all tested sound pressures between 50 and 80 dB with both of the Baha devices when compared

to the unaided conditions. There was no statistically significant difference between the Compact and the Divino in these tests.

Fig. 3 shows the results from the speech reception thresholds (SRT) in noise, presented at a level of 70 dB. For noise arriving from the front, the difference between the three aided conditions was small (0.4–0.9 dB) and not statistically significant. Comparing test situations with noise from the front and from the rear, a statistically significant difference ($p=0.03$) was found for the Baha Divino™, when using the directional two-microphone noise reduction mode, with an average improvement of 1.9 dB. For noise coming from behind, the Divino in its directional two-microphone noise reduction mode was found to be clearly better than the Compact (average SNR improvement 2.3 dB, $p=0.04$).

Table 1 shows the answers to the most pertinent questions from the questionnaire after the 3 month evaluation. In all aspects covered by these questions, the Baha Divino™ was rated more favourably than the wearers' own (previous)

Baha device. This advantage is statistically significant for overall sound quality and for listening to a single speaker in quiet (Wilcoxon signed rank test, $p<0.047$).

Discussion and summary

Speech tests in quiet did not reveal any statistically significant advantage of the Baha Divino™ when compared to the Baha® Compact. However, it is possible that some individuals do benefit from the new device even in these situations. Although the group as a whole did not, one subject showed a small but reproducible improvement in terms of free-field thresholds and speech recognition in quiet. We think that this improvement is due to the compression limiting the output, which enabled her to use a louder setting at low levels than with her previous sound processor.

When the two-microphone noise-reduction system was activated, a statistically significant improvement in speech understanding in noise of approximately 2 dB was found when the speech signal was presented from the front and noise from

Fig 2. Monosyllabic word recognition scores

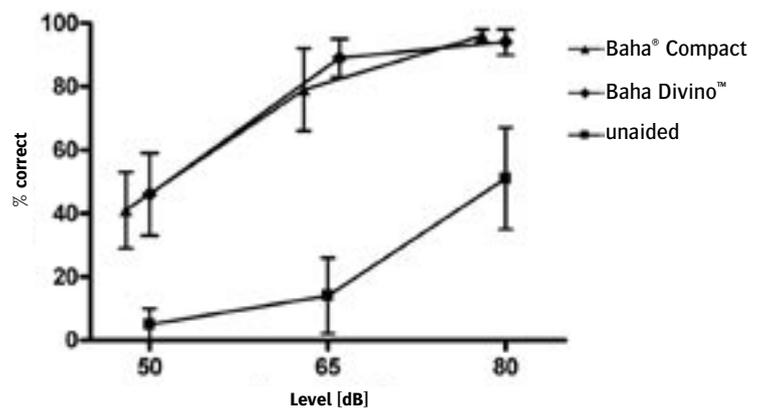


Fig. 2. Monosyllabic word recognition scores in quiet at three different presentation levels in aided and unaided conditions. Average values and standard deviations of the mean are shown.

Cochlear acquire Entific Medical Systems

On March 4th 2005, Cochlear Limited acquired Entific Medical Systems AB. In this report from Cochlear's HQ in Sydney, Australia, we look at the background to the transaction and CEO, Chris Roberts, explains why the acquisition will benefit customers, patients and employees alike.

“ From Cochlear's point of view this is a strategic acquisition,” Chris Roberts comments. “As a high quality company operating in the implantable hearing device market, Entific is an ideal purchase for Cochlear. The fit between the two companies is perfect in terms of patient base as well as from a technological and a geographical point of view. By joining forces, the possibilities to broaden and refine the offer will benefit an increasing number of people, not least our customers and patients.

Entific is known for the Baha® bone conduction implant treating conductive/mixed hearing losses and Single Sided Deafness (SSD™), whereas Cochlear's cochlear implant range, Nucleus®, is designed to treat bilateral severe to profound sensorineural hearing loss. The product systems complement each other, without any unnecessary competition. From a technological standpoint there are many synergies and it will be

beneficial to share experience in both implant technology and in sound processing. These joint efforts will allow for continued strong development and the possibilities arising from the combination of technological know how will ensure long term product innovation.”

What about Entific and its customers attracted you to the purchase?

“It was difficult not to be impressed by the clinical results of the patients who have received the Baha system, as well as the enthusiasm of the implanting surgeons. In many cases, our cochlear implant surgeons are also Baha surgeons, so it was our own customers telling us how Baha was changing the lives of so many people.”

What are the synergies between the companies and how will these benefit customers and patients?

“There are synergies at many levels. For example, there is a significant

overlap between the surgeons doing cochlear implants and Baha. We are attending the same congresses, reading the same medical literature. We both have a lifetime commitment to the patients. There are also many potential areas of technology synergy. The opportunity for customers and patients is to create scale whereby we can develop better products, faster and distribute these products wider and with improved support. It is a true win-win situation.”

Why is the acquisition good news for customers?

“The acquisition is good news for customers as Cochlear is totally committed to maintaining its global leadership in innovative implantable solutions for the hearing impaired. The Baha system is a strategically important addition to the portfolio of products we wish to offer to our customers so they have a wide array of solutions suitable for the entire range of hearing problems they



on being truly global in outlook.”

Cochlear’s organisation is based on three distinct sales regions – how do you anticipate this will affect customers?

“I believe strongly in the need to drive most aspects of the business from the regions rather than corporate headquarters. For truly global businesses to succeed in the fast changing world decisions must be made at the appropriate level. The integration of the Entific sales activities into the regional structure is all about ensuring fast response time for our customers. The combined efforts will therefore strengthen the global presence and help to bring the appropriate treatment closer to patients.”

And what lies in the immediate future for the Baha and Vistafix product lines?

“To maintain the appropriate focus on the Baha and Vistafix product lines we are establishing the **Bone Anchored**

Solutions (BAS) Division, which will continue to be based in Gothenburg, Sweden. But it is with sincere regret that I say that Dan Pitulia has decided to leave Cochlear to pursue other opportunities. Dan has made a great contribution since Entific was formed more than 6 years ago, building a strong business foundation from which we will create our future. Dan has been instrumental in ensuring a smooth transition in the integration of our two companies and we truly wish Dan all the very best for the future.

David Morris is now the President of the **Bone Anchored Solutions (BAS) Division**. David has broad knowledge of our Cochlear implant business, and has strong capabilities and extensive experience in all aspects of business management, operations, and finance. David will lead the **BAS Division** with enthusiasm and, together with the BAS Executive team, will achieve great success!”

encounter with their patients. The issue of scale in terms of research and development right through to clinical support is also an important benefit for our customers.”

How do Cochlear employees feel about the new products lines?

“There is a genuine excitement and thirst for knowledge within the Cochlear employee base as well as within our distributor markets across the world.”

How do the cultures of the two companies compare?

“There are more similarities than differences between the two companies. The similarities include a commitment to the customer and a pride in being involved with products and technology that make such a difference to people’s lives. Also the international flavour of both companies is similar; the domestic market (Sweden for Entific and Australia for Cochlear) is a relatively small market for both companies and both have focussed

“The product systems complement each other...”



Dr. Chris Roberts was appointed as CEO/President of Cochlear Ltd on 1 February 2004. Prior to his appointment he had worked in the global medical device industry for more than 28 years in a number of senior management positions.

David Morris joined Cochlear Limited in December 2002 as Senior Vice President of Strategy and Business Development. Previously, David has had extensive experience in strategic and operational consulting with a global technology and management consulting company working in the medical device, pharmaceutical, consumer products and financial services industries throughout Asia Pacific, the United States and Europe. In September 2005, David was appointed as President of the newly formed Bone Anchored Solutions Division, a role about which he feels extremely positive. Here he shares his thoughts about the future of the BAS Division.



David Morris

“ When I commenced work with Cochlear in December 2002, I had a basic understanding of what deafness was, but had little appreciation of what life would be like without sound. During the past few years, I have been fortunate to meet many CI recipients and hear their stories of how Cochlear Implants have allowed them to interact more fully with the world around them.

More recently I have had the opportunity to meet with Baha users and have found that they too have had similar experiences. It is wonderful to know that what you do really does make a difference to someone's life.

When the opportunity to purchase Entific Medical Systems arose, I felt strongly that

this was a very positive move that would benefit all those involved, and particularly the patients themselves. From the company's viewpoint it will expand our footprint and enhance our global leadership position in innovative implantable solutions for the hearing impaired. But, importantly, this in turn will allow us to continue to offer pioneering solutions to hearing impairment for our customers and their patients, as well as the ongoing support that is essential to the success of hearing rehabilitation.

The **BAS Division** will be the champion for the Baha and Vistafix product lines. We will make substantial investments in developing innovative and commercial products and services that not only meet the needs of our existing customers, but also enable us to support new customers

with different indications.

This new Cochlear Division is collaborating with our Regional Operations in the Americas, Asia Pacific and Europe. These regional operations market and sell the Baha and Vistafix product lines and will continue to build and manage customer relationships. The **BAS Division** and the Regional Operations are working closely together, to ensure that customer needs are met.

This is a great company, with remarkable technology and committed employees. Our people have deep knowledge, strong capabilities and great relationships with customers and it is through these capabilities that Cochlear has become the world leader in innovative implantable solutions for the hearing impaired.” ■

About Cochlear Limited

Delivering more than two decades of implant innovation to over 67,000 people, Cochlear is built upon a foundation of success and is the international leader in cochlear implant technology. The company was formed in 1982 to build on the unique work of Australian Professor Graeme Clark, founder of the multi-channel implant of the University of Melbourne, and was the first company in the world to bring multi-channel cochlear implants to the market in general. Foremost known for their Nucleus® implant, Cochlear listed on the Australian Stock Exchange in 1995 and employs about 800 people worldwide (BAS Division not included). The company has regional offices in the USA, UK, Switzerland, Germany, Belgium, China and Japan and is represented in more than 80 countries in over 1,000 clinics.



Cochlear HQ in Sydney



How I hear the difference

– a Divino wearer's story!

Constance Runyon was born with a bilateral conductive hearing loss due to Treacher Collins Syndrome. Having worn a bone conductor and modified BTE aid for many years, Connie learned about the Baha® system several years ago on a mailing list for Treacher Collins patients and, after a consultation with her doctor, underwent bilateral implantation surgery in April 2001. She received her sound processors in July 2001 and can't believe the difference the system has made in her life.

In early 2005, Connie was invited to participate in the clinical study of the Baha Divino™, the newest sound processor. For 12 weeks, she wore only the Divino sound processors, rather than her Compacts. She says the differences between the Compact and Divino are noticeable.

“A key difference is that the directional microphone is now incorporated into the Divino, as opposed to being an accessory plugged into the sound processor. I find this to be a very good new feature, as it makes using the directional microphones

much less obtrusive and more cosmetically appealing. It also makes access to the ‘three-in’ contact points in the base of the sound processor more convenient for when I want to plug in my audio adapter. Because the directional microphone is now integrated into the sound processor, the volume control is positioned slightly differently than on the Compact and there is now a

switch for the directional microphone. I find the directional microphone switch to be much sturdier and easier to handle than the accessory directional microphones at the bottom of the Compact sound processor.”

As for the directional microphone settings, Connie notices a significant difference in crowded, noisy rooms and restaurants when using program two. She says this setting is an even bigger improve-



Connie Runyon

ment over the original directional microphone accessory. Connie also says the Divino's battery compartment is positioned differently and more conveniently than on the Compact.

“There is a definite difference in the sound quality,” says Connie. “The sound with the Divino is fuller, richer, smoother. There seems to be more resonance. I am a bit more aware of the compression effect and also realize that the Divino seems to be a bit more powerful than the Compact. It seems as if I'm hearing better without being bothered by a lot of extraneous background noise, either with or without the directional microphones adjusted. As far as physical wearing comfort, the Divinos snap nicely into place and stay put. Just as with my Compacts, I don't feel them in place. And only when I've got them turned on do I know they're on my head. I reluctantly turned the Divino sound processors in at the conclusion of the 12 week study. I can't wait to get a pair of my very own soon!” ■

News from COMPRU

Medical Modeling Research Laboratory (MMRL) at COMPRU provides new hope for Canadians through 3D digital modeling technologies.

Byline: Lisa Grotkowski

Capital Health, Edmonton, Alberta, CANADA

Brenda Frederick was relieved when her doctor told her that it would be possible to remove the large cancerous tumor in her upper palate. What Brenda didn't know was that removing the cancer would also mean removing a large portion of her upper jaw and that she would require multiple surgeries to reconstruct the area.

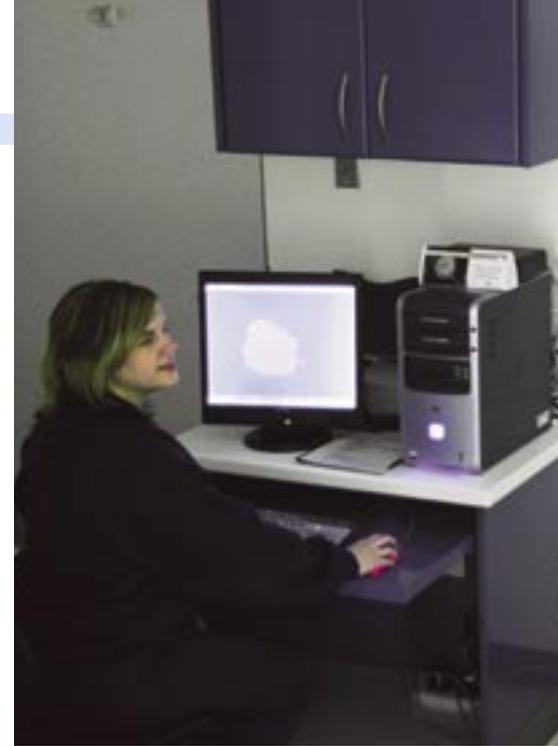
On April 27, 2005 the Caritas Health Group's Craniofacial Osseointegration and Maxillofacial Rehabilitation Unit (COMPRU) at the Misericordia Community Hospital in Edmonton, Alberta, Canada opened a first of its kind research facility, the Medical Modeling Research Laboratory (MMRL), which will provide hope for patients like Brenda Frederick. The research laboratory will allow clinical experts to explore the future of digital three-dimensional modeling technologies in advancing patient care.

COMPRU, established in 1993 as Canada's first centre dedicated to reconstruction of the head and neck with a specific interest in osseointegration, provides

care to individuals with absent or missing structures of the head and neck that have resulted from birth defects, cancer, infections, trauma or other conditions. With a founding mandate committed to creating excellence in clinical care and research, COMPRU's MMRL is another step forward towards reducing uncertainty in treatment and improving quality of life for patients.

"My surgical reconstruction has been a long and difficult process," says Brenda. "The surgeons are working to replace bone and place implants to create a stable dental prosthesis. With each new surgery, I am facing a new unknown." The unknown results of a surgical procedure can be unsettling for any patient but the MMRL offers research opportunities into digital modeling technologies that could translate into better known surgical outcomes and less time in the operating room.

"It can be speculated that the evolution and convergence of advanced digital technologies is, as never before, becoming the



fundamental driver that is transforming patient care," said Dr. John Wolfaardt, Co-director of COMPRU. "While there are other facilities in the world that build medical models, the MMRL is unique because clinical specialists themselves can access the technology to build these patient specific models."

Medical modeling is the process of using anatomical data, such as images captured in CT scans or MRI scans, to create three-dimensional virtual or physical models of a patient's anatomy. Virtual images, maintained on a computer, have the potential to eliminate much of the current guesswork in surgery.

"Virtual medical modeling has incredible potential for clinical specialists," says Dr. Wolfaardt. "With digital images, surgeons are able to pre-plan surgical procedures on the computer. This technique reverses the standard surgical practice of cutting to view patient anatomy and instead allows the surgeon to view the anatomy and virtually navigate the surgery before even entering the operating room."

Once images have been created on the computer, the computer can translate the digital image into a physical model using three-dimensional prototyping technolo-





gies. The virtual model is sent from the computer to a device that has the ability to “print” three-dimensional wax or plastic models that can be held in the hand.

Both virtual and physical medical models aid in visualizing, planning and designing patient treatment. They are used in diagnosis, surgical planning, patient education and as intra-operative navigation aids. Although COMPRU will rely on medical modeling to advance care for head and neck reconstruction patients, the potential with using these technologies spans the full spectrum of health care, including cardiac surgery, orthopedics, neurosurgery, diagnostic imaging, biomedical engineering and many other disciplines.

“The MMRL is a cutting-edge facility that will provide dedicated space for developing innovative basic and applied research and assembling world class talent dedicated to advancing all areas of patient care,” said Dr. Gordon Wilkes, Co-Director of COMPRU. “Use of medical modeling technologies has the potential to improve treatment outcomes for patients, save time and costs in the operating rooms, and greatly improve teaching and information sharing capabilities for clinicians.”

International Conference for Advanced Digital Technology in Head and Neck Reconstruction

Byline: Lisa Grotkowski

On March 10, 2005 delegates from 22 countries arrived at the Fairmont Banff Springs Hotel and Conference Centre in Banff, Alberta, Canada for a four day conference set to explore the future application of advanced digital technology in head and neck reconstruction. The conference was co-hosted by Caritas Health Group’s Craniofacial Osseointegration & Maxillofacial Prosthetic Rehabilitation Unit at the Misericordia Community Hospital in Edmonton, Alberta and The Maxillofacial Unit, Morryston Hospital in Wales, United Kingdom.

Bringing together researchers, clinicians, industry partners and institutions, this conference provided a forum crossing many professional disciplines to share and develop ideas around technologies or patterns of convergence important for improving the future of health care.

“Much of our future diagnosis, treatment planning and understanding treatment outcomes lies in the digital and hence virtual world,” says Dr. Mark Urken, Honorary Conference Chair for the conference. “The power of digital technologies lies in their ability to converge. This conference provided an invaluable opportunity to begin the development of an international network of researchers, clinicians and industry partners with a shared vision for the role of advanced digital technologies in medicine.”

Over the four days, delegates were invited to attend lectures, workshops and an evening of poster presentations outlining current research applications involving advanced digital technologies in head and neck reconstruction.

“With over three hundred participants, this was an extremely successful conference in a world class environment,” said Dr. John Wolfaardt, one of four conference chairs. “We were pleased to host experts across multiple disciplines who shared a wealth of knowledge related to new technologies, current practices and ongoing research work. Collaboratively, there is endless opportunity to advance diagnosis, treatment planning and patient outcomes through a shared vision of the future of advanced digital technologies.”

With the success of the conference and the growing interest in the clinical use of digital technologies a third international conference will be considered for three years time. For more information on this conference or additional upcoming events in the field of head and reconstruction, visit: www.caritas.ab.ca/compru

The opening of the MMRL positions Alberta and Canada as leaders for multidimensional technology research. Attending the formal opening, and announcing Western Economic Diversification Canada’s contribution of nearly one million dollars to establish the labora-

tory, was Deputy Prime Minister Anne McLellan, on behalf of the Honourable Stephen Owen, Minister of Western Economic Development and Minister of State (Sport). Additional funding was provided by Caritas Health Group to support construction of the laboratory. ■



1st Baha[®] Course held in Hong Kong

The Chinese University of Hong Kong conducted its inaugural CUHK Baha[®] Course at the end of April which covered the repertoire of osseointegration concepts and surgical techniques with an in-depth purview of current and forthcoming indications for the Baha system.



The whole day course started with an entertaining morning of lectures that included the instruction of the surgical technique with a unique 3D graphic animation teaching tool, Baha for single sided deafness (SSD[™]), paediatric issues as well as the latest developments on



Baha's indication for nasopharyngeal cancer hearing rehabilitation.

The early afternoon programme provided the twenty-eight participants with the opportunity to meet four very different Baha clients and to learn first-hand about their unique experiences. Unbeknownst to the course audience, these users had been “embedded” within the audience both during the course lunch and post-lunch talks, demonstrating how the Baha device can empower the user to hear and not be noticed! Mr Michael Mercer, of Cochlear, was also to hand to make his very own cameo debut in Hong Kong, demonstrating the available Baha accessories!

After tea, it was onto the high energy hands-on workshop where participants

learnt how to elegantly perform Baha surgery on freshly prepared pig's skulls. Prosthetic crafting of the pinna was also demonstrated to delegates in between their drilling pit stops.

The CUHK local faculty of Professor Michael Tong, Dr. Gordon Soo, Dr. Willis Tsang, Ms Wong Yim Mui and Mr Johnnes Mak played host to their guest faculty of Mr David Proops from the Queen Elizabeth Hospital, Birmingham, UK and Dr. Sigfrid Soli of the House Ear Institute, Los Angeles, USA.

The CUHK Baha Course was jointly organized by the Division of Otorhinolaryngology of the Chinese University of Hong Kong and the Institute of Human Communicative Research with the generous support of Cochlear Ltd. ■



Information on future Baha courses is available on request via email to Ms Christine Tse at ent@surgery.cuhk.edu.hk or please visit <http://www.surgery.cuhk.edu.hk/baha>

In the heart of Australia!

By Michael Mercer

Ayers Rock, an icon for Australia and the indigenous people, provided the backcloth and hotel venue for a Baha® Workshop held over a long weekend in April this year. It also proved to be the first such meeting under the Cochlear banner focusing on Baha.

The weekend saw the culmination of an idea from Professor Bill Gibson to bring together all those Baha (and planning to be) surgeons from around Australia following the original meeting with Professor Anders Tjellström some two years ago. Over 30 attended, many with their families taking advantage of the holiday weekend and some of the activities offered at this unique venue.

The main guest speaker was Mr David Proops from The Queen Elizabeth Hospital, Birmingham, UK, whose extensive experience was shared with the mainly Australian team. He spoke about global results in adults and children, Single Sided Deafness (SSD™) and children with

syndromes. Adding an international flavour, Professor Andrew van Hasselt and Dr. Gordon Soo from Hong Kong presented their results to date studying Nasopharyngeal Cancer (NPC).

Australian surgeons demonstrated their experience of several hundred patients with Professor Marcus Atlas from Perth presenting his SSD study findings, Professor Gibson from Sydney presenting his group and Dr. Phil Chang offered his experience of surgical techniques and post-operative care, including an outstanding video covering patient selection and counselling from his large group of patients. Also under discussion were the changes in the rebate system and Michael Mercer from Cochlear provided some insight into the future of Baha digital devices.

The value of such a meeting is often in the ensuing discussions and there was no shortage of stimulating debate

*“no
shortage of
stimulating
debate”*



reflecting the energetic adoption of Baha in Australia and results which match those found in other parts of the world. The workshop followed on from the acquisition of Baha by Cochlear Ltd. and Dr. Chris Roberts, CEO of Cochlear, attended the meeting. Many of the delegates, being CI surgeons, recognised the synergistic opportunities of the merger.

Held over two days the programme allowed time for delegates to make the most of some of the fascinations of the venue, such as seeing the sunrise and sunset over the rock. Our thanks go to all those who helped in the organisation of this very successful workshop. ■



Baha® Courses for Operating Theatre Staff prove very popular

Previous years have shown that the training courses for Operating Theatre Staff are always booked up very quickly, so in 2006 we are planning to expand our offer on courses for customers in Germany and Austria.

A special 'thank you' goes to all employees who are involved in the clinics and universities where we have been welcomed as guests for past courses. On each occasion we experienced great facilities provided by the clinics that directly benefited the participants in both local and nationwide events.

Very often the speakers and tutors had travelled a long way in order to make their presentations and they have always been awarded with an interested and enthusiastic audience. "One of the best training events we have ever attended," remarked one delegate recently. Comments such as this certainly motivate us to ensure that the quality of future courses also becomes a tradition!

Please contact us by email at info@cochlear.de if you are interested in arranging a course in your clinic.



Teilnahme bei den Baha-Kursen für OP – Personal sehr begehrt

Seit Jahren sind die Plätze bei den Kursen für das OP – Personal immer sehr schnell ausgebucht. Aus dieser Erfahrung werden wir das Kursangebot in Deutschland und Österreich im Jahr 2006 noch erweitern.

Besonders danke sagen wir den beteiligten Mitarbeiterinnen und Mitarbeitern in den Kliniken und Universitäten, in denen wir zu Gast sein durften. Wir konnten immer wieder feststellen, dass sowohl bei den überregionalen wie auch regionalen Veranstaltungen in den Kliniken optimale Bedingungen für die optimale Durchführung geschaffen wurden.

Die teilweise von weit her angereisten Referenten konnten durch die Inhalte ihrer Vorträge die Teilnehmer begeistern. „Eine der besten Fortbildungsveranstaltungen, die wir je besucht haben“, waren Kommentare, die wir oft hörten. Diese Qualität wollen wir gern in der Tradition fortsetzen. Bitte nehmen Sie mit uns Kontakt auf, wenn Sie an der Durchführung eines solchen Kurses in Ihrer Klinik interessiert sind.





Innovation Award to be presented at MÜNSTER/WESTFALEN SYMPOSIUM

It has almost become a tradition that Entific Medical Systems Deutschland GmbH (now Cochlear GmbH) sponsors the 'Innovation-Prize' at the annual symposium of the renowned 'International Association for Surgical Prosthetics and Epithetics'. As its name suggests, the focus of this association is the scientific and practical promotion of surgical prosthetics and epithetics – more information can be found at www.iaspe.com

In 2004, on the occasion of the 16th International Symposium in Linz, Austria, Prof. Dr. Bernd Reitemeier from Dresden was awarded with the prize for his publication 'Experimental examinations in combining epithetics and silicone'. The award was presented to him by Prof. Dr.

Karin Wieselmann-Penkner.

In previous years the prize was given to Mr. Norbert Schilling from Neubrunn and Prof. Dr. Alexander Berghaus from Munich. Mr. Schilling received his award for presenting a complex epithetic treatment of a patient who had a large defect in his mid face and solving associated functional problems. Prof. Berghaus was awarded for his presentation of 'Surgical Outer-Ear Reconstruction with an Artificial Frame-Work'.

This year the 17th International Symposium will be held during 7–9 October 2005 and the incumbent president of the Association, Priv. Doz. Dr. Dr. Volker Schwipper, is inviting his professional audience to Münster/Westfalen. The



Prof. Dr. Bernd Reitemeier receiving his award at the 2004 symposium

topic will be the surgical and epithetic reconstruction of major eye and lid defects.

All of us at Cochlear GmbH are excitedly anticipating who we may honour with the Innovation-Prize for the best presentation this year. ■

US Update

Baha[®] System Reimbursement Services Now Available

Cochlear Americas is proud to announce that new reimbursement preauthorization services are now available for the Baha[®] system.

This program is a significant advancement as we work to secure consistent reimbursement for this unique implant system. Baha system preauthorization services and case activity have now been fully integrated into Cochlear Americas existing preauthorization service, Otologic Management Services (OMS). Upon request, OMS will assist centers, physicians, and candidates in obtaining predetermi-

nation of health plan coverage including payer education, benefit investigation, submission of predetermination requests and appeals (if necessary) for auditory bone conduction implant components, and related professional services.

OMS is a no-charge service. For each case, OMS will make initial contact with and educate the candidate's health plan, investigate existing benefits and

pursue coverage to the fullest extent possible. To move forward with obtaining preauthorization assistance, contact OMS and request an introductory packet, which includes a letter, a center information form, a patient release form and a patient information form.

For more information or to enroll in OMS, contact Cheryl Anderson, or Christy Davis at 800-633-4667, 8:00 a.m.–5:00 p.m. (MT), Monday through Friday. ■



In Brief

Keeping you informed – ‘In Brief’ brings you the latest news of all changes within the Baha® and Vistafix™ systems.

Discontinued Baha® sound processors

360 and Cordelle I

As it is five years since these Baha models were discontinued these devices will no longer be repaired.

Classic 300 with bayonet coupling

The Classic 300 with bayonet coupling was discontinued at the end of 2004. Repairs will be possible for five years from this date for devices less than five years old.

Classic 300 in blue and yellow

Classic 300 is no longer available in blue and yellow due to lack of demand.

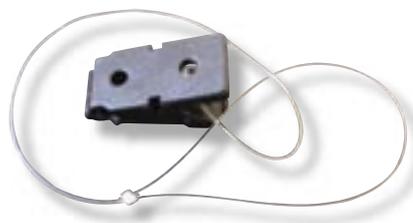
New article number for Raspatorium

The AS 43-245-36 Raspatorium has been replaced by **PI 010/36 Raspatorium**. The Raspatorium is included in the Baha® Pick’n Place instrument set and in the Basic Vistafix™ instrument set, but can also be ordered separately. It is delivered non-sterile in a plastic bag.

Old article number	Denomination	New article number
AS 43-245-36	Raspatorium	PI 010/36

Safety line for Baha® sound processors

A new safety line has been introduced for the Divino, Compact and Classic 300 models. It is comprised of a plastic clip and a transparent elastic polyester line. It is used for attaching the sound processor firmly to clothing when taking part in sports or active play. The safety line forms part of each Divino/Compact/Classic 300 kit but can also be ordered as a separate item.



Article number	Denomination
90711	Safety line

Baha® Softband – latex caution

As a manufacturer of medical devices we have an obligation to inform about latex contents in any of our products. Baha® Softband contains small amounts of latex and therefore a caution text as follows has been included in the User’s Manual, Audiological Manual, Operating Theatre Manual and Product Catalogue;

“Caution: This product contains natural rubber latex which may cause allergic reactions.”

Denomination change to Baha® accessories

The name of the 90065 Audio adapter for the Compact and Classic 300 has been changed to ‘**Audio adapter head worn devices**’. The Audio adapter is also compatible with the Baha Divino™. The article number remains the same.

Implantmed

The manufacturer of the Implantmed drilling equipment, W&H Dentalwerk Bürmos GmbH, has implemented the following changes;

- The Sterile goods packaging has been discontinued and will no longer be delivered with each new Implantmed kit. The demand for this article has been very low, which is why it has been removed from the product range.
- The Y-spray tube (delivered with each WS-75 E/KM contra-angle handpiece) has been altered, and is now available as a plastic version. This new Y-manifold is approved for medical applications and may be sterilized. It is smaller and will thus interfere less during surgery.



Y-spray tube



Face to Face™ becomes Vistafix™

Face to Face™ has now been re-named Vistafix™, a name that reflects the product system more closely. Vistafix is a combination of face and fixation, a perfect description of our craniofacial rehabilitation system.

To coincide with the name change we have produced a new Patient Brochure which has been redesigned with updated treatment information, aftercare questions and some new testimonials from patients who have implant retained prostheses.

We are also in the process of updating the Operating Theatre Manual (OTM). When complete, this new OTM will introduce the Vistafix™ self-tapping implant for one-stage auricular cases in good bone. The self-tapping implant is used with a pre-mounted fixture mount, cutting out both the tapping phase and manual mounting of the implant. This will help reduce surgery time and make the procedure easier.

The surgical protocol will also include the use of healing abutments which are placed during the osseointegration period thus allowing the tissue to heal before the final length of abutment is chosen. Healing abutments are also suggested for second stage surgery during the tissue healing period to enable the tissue to be fully healed before the choice of abutment is made. It is well known that the tissue around the implant site can change over the healing period and, if a standard abutment is placed at the time of surgery, it may have to be changed to a different size once the tissue has settled down. So using a healing abutment will prevent the wastage of incorrectly sized abutments.

As well as including new sterilization guidelines, the OTM



will also detail the use of all the relevant components and the patient preparation information has been made easier to follow.

There are more developments underway for Vistafix during the upcoming year, demonstrating our continued commitment to the product range and to simplifying the system. ■

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