

# The Ponto System



## Abstract

The thirty-year history of bone anchored hearing systems has demonstrated safe, effective and highly beneficial results. Nonetheless, bone anchored hearing systems have previously been considered the “last resort.” However, a paradigm shift is underway. Bone anchored hearing systems for appropriate candidates have become the “first choice” solution to many medical and surgical problems. Oticon Medical’s all new Ponto Bone Anchored

Hearing System includes implants, abutments, surgical tools and state-of-the-art sound processors, intuitive fitting software and other innovative components. The Ponto processor is built on Oticon’s RISE platform, the most advanced digital sound processor platform available. Oticon Medical is proud to facilitate the paradigm shift, thus positioning the Ponto Bone Anchored Hearing System as the “first choice” solution for appropriate candidates.

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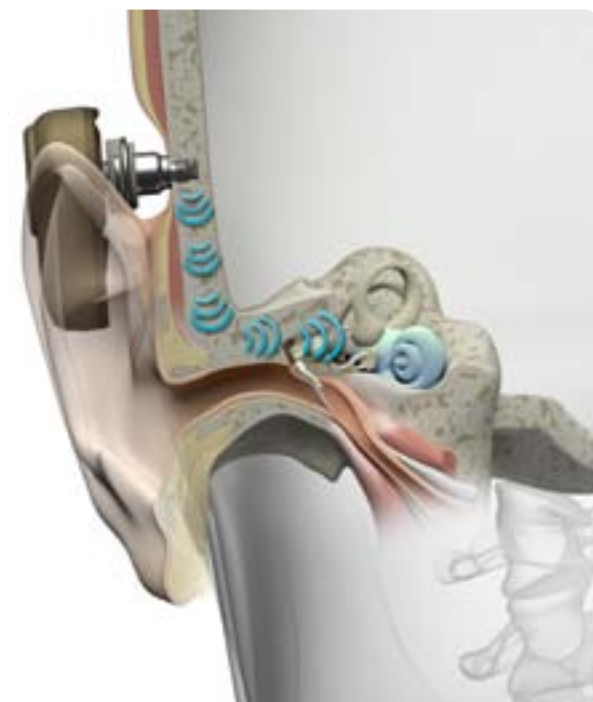
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## Overview

Based on a solid foundation of experience, amplification and innovation, Oticon Medical has introduced (2009) an advanced bone anchored hearing system. The Ponto System includes the implant, abutment, surgical tools and advanced audiology-based state-of-the-art sound processors, intuitive fitting software and other innovative components.

Long-term results from bone anchored hearing systems are well known and have been proven to be safe, effective and highly beneficial for appropriate patients (Snik, Mylanus, Proops, Wolfaardt, Hodgetts, Somers, Niparko, Wazen, Sterkers, Cremers, Tjellstrom, 2005). Experience with bone anchored hearing systems has been gathered for more than 30 years (Tjellstrom, Hakansson and Granstrom, 2001), yet innovative and beneficial applications continue to emerge.

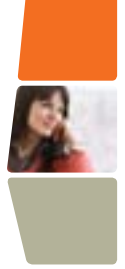


The Ponto processor is built on the most advanced digital sound processor platform available, the Oticon RISE platform. The processor creates finely tuned acoustic vibrations which are programmed to the individual patient, their hearing loss, their listening requirements and their needs. The sound is transferred from the processor through a tiny percutaneous penetrating abutment connected directly into the titanium implant. Thus, the outer and middle ear are bypassed as sound is directly transferred from the acoustic environment to the cochlea via the skull bones. High quality distortion-free sound is maintained through direct bone conduction, overcoming attenuation of sound via soft tissues as occurs with traditional bone conduction systems (Tharpe, Eiten and Gabbard, 2008). Bone anchored hearing systems represent innovative and pragmatic solutions for conductive hearing loss or mixed hearing loss and minimizes the negative effect of head shadow in specific cases (see below) of single sided deafness.

## Patient Selection & Candidacy

In general, patients for whom bone anchored systems are appropriate include those with conductive hearing losses, mixed hearing losses and those with single sided deafness. Specifically patients implanted with bone anchored systems include people with therapy-resistant, draining or chronic otitis media, congenital ear malformations, aural atresia, mastoidectomy patients with ongoing hearing loss, ossicular disease not amenable to surgical correction, cholesteatoma, post-operative acoustic neuroma patients with one remaining normal hearing ear, other single sided deafness etiologies (trauma, sudden sensorineural hearing loss etc.), patients with conductive hearing loss in their only remaining ear, inoperable otosclerosis, tympanosclerosis, cranio-facial anomalies, syndromes and more.

Although no one knows the actual number of people for whom bone anchored hearing solutions are indicated, estimates across the USA and the EU indicate a potential patient population of some two million candidates.

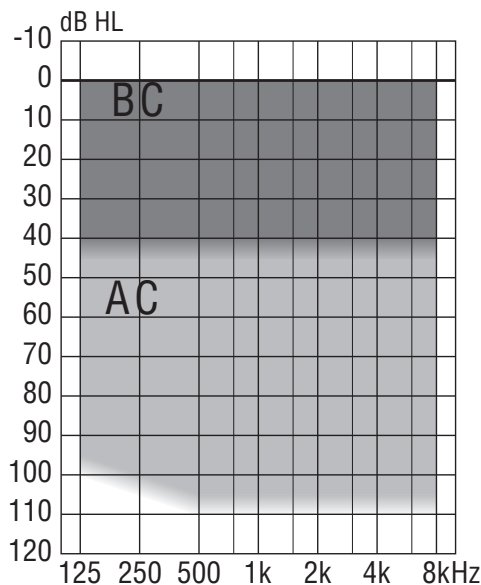


## Audiograms & Pure Tone Thresholds

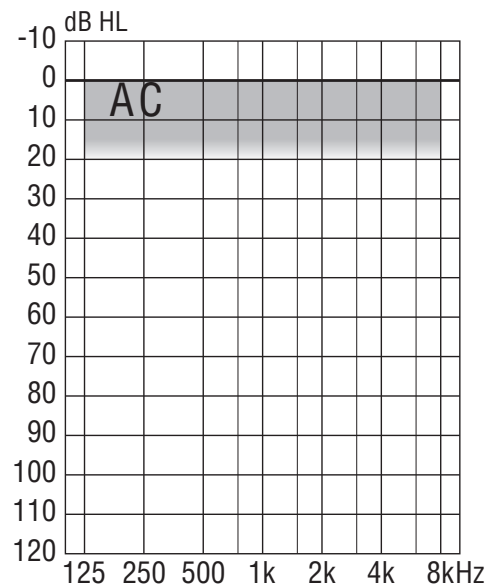
In many respects, the traditional view of the audiogram is “modified” when bone anchored hearing systems are considered. Rather than focusing on traditional pure tone air conduction thresholds, the primary concern for bone anchored hearing systems are bone conduction thresholds. Appropriate patients with bone conducted pure tone averages (based on 500, 1000, 2000 and 3000 Hz) better than 45 dB HL may be considered candidates for a Ponto sound processor. With regard to word recognition scores (i.e., speech discrimination scores) candidacy inclusion requires scores of 60 percent or better. Additionally, the magnitude of the air-bone gap is of little consequence. Indeed, when the air-bone gap exceeds 30 dB, bone conduction performance is apt to be better than traditional air conduction amplification (see Snik, Mylanus, Proops et al., p. 4, 2005).

In the case of single sided deafness, the remaining ear should have an air conduction pure tone average better than 20 dB HL to effectively minimize head shadow effects.

When considering bilateral bone anchored hearing system fittings for patients with bilateral conductive or mixed hearing losses, “bilaterally symmetric” bone conduction scores are important to help assure benefits associated with bilateral fittings, such as: improved speech thresholds, better speech recognition in noise and better localization ability. Bilaterally symmetric bone conduction scores are present when the difference between the left and right ear bone conduction thresholds are within 10 dB of each other with regard to pure tone average, or less than 15 dB differences at individual frequencies.



*Fitting range for conductive or mixed hearing loss*



*Fitting range for single sided deafness*

## Literature Review

Bosman, Snik, van der Pouw, Mylanus and Cremers (2001) reported bilateral fittings of bone conduction hearing systems on 25 patients: 19 had recurrent otorrhoea or otitis externa and 6 presented with congenital atresia. All patients had symmetric bone conduction thresholds. Bosman et al. reported correct localization judgments essentially doubled for these patients while using bilateral bone anchored hearing systems as compared to their previous unilateral-based scores. Specifically, scores increased from 22% and 24% (with 500 and 2000 Hz noise bursts, respectively) with unilateral fittings to 42% and 45% with bilateral fittings. Bilateral speech reception thresholds (SRTs) for sentences significantly improved in quiet, too, going from 41.7 dB in unilateral fittings to 37.5 dB in bilateral fittings (a 4.2 dB decrease).



Bosman et al. noted that in patients with symmetric bone conduction scores who had been bilaterally fitted with bone anchored hearing systems, directional hearing as well as speech recognition in noise improved significantly with the addition of the second unit. Thus, bilaterally fitted bone anchored hearing devices in appropriate patients results in binaural hearing.

Lustig, Arts, Brackmann, Francis, Molony, Megerian, Moore, Moore, Morrow, Potsic, Rubenstein, Srieddy, Syms, Takahashi, Vernick, Wackym and Niparko (2001) reported their multicenter experience with the first 40

USA-based patients. Their report was a retrospective review and analysis of findings from 12 participating medical centers. The authors implanted people with pre-operative bone conduction pure tone averages of 60 dB HL or less. The most common reason for implantation was chronic otitis media or draining ears (n=18), followed by external auditory canal stenosis or aural atresia (n=7). The average improvement across all patients was noted as 32 dB (+/- 19 dB). Closure of the pre-operative air-bone gap occurred (within 10 dB) in 32 patients, closure within 5 dB occurred in 24 patients and “over-closure” occurred in 12 patients. The authors stated the bone anchored hearing system was reliable and predictable in appropriate patients with conductive or mixed hearing loss who were otherwise unable to benefit from air conduction amplification.

Niparko, Cox and Lustig (2003) compared traditional contralateral routing of signal (CROS) hearing aid fittings to bone anchored hearing systems in nine patients with one remaining, normal hearing ear. Patients included 9 adults: 7 post-operative acoustic neuroma patients, 1 patient unilaterally deafened from meningitis and 1 patient with unilateral deafness from sudden sensorineural hearing loss. The authors reported poor acceptance of traditional CROS amplification system, versus consistent satisfaction with the bone anchored hearing system. Additionally, Niparko, Cox and Lustig noted the bone anchored hearing system allowed significantly improved speech recognition in quiet and in certain noisy situations. The authors concluded the bone anchored hearing system overcomes some head shadow effects associated with unilateral deafness, and the bone anchored hearing system provided greater benefits than the CROS system.

Snik, Mylanus, Proops, Wolfaardt, Hodgetts, Somers, Niparko, Wazen, Sterkers, Cremers and Tjellstrom (2005) published outcomes from their scientific roundtable discussions held in 2004. They noted that adults can undergo a one-stage surgical procedure in the operating room under local anesthesia while children require a two-stage procedure under general anesthesia.

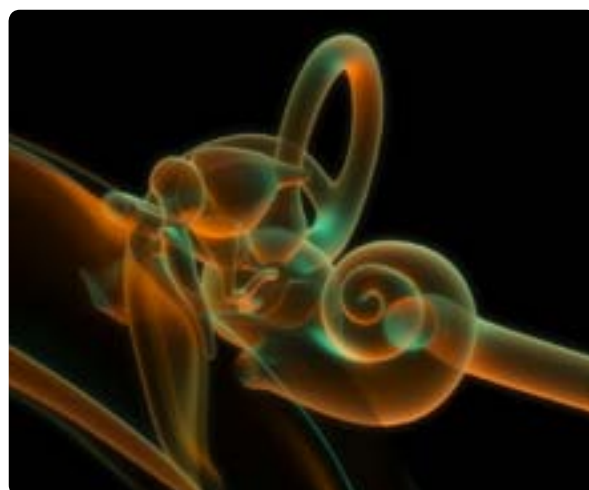


They stated the implant team should minimally consist of an otolaryngologist surgeon and an audiologist. Snik, Mylanus, Proops et al. noted bone anchored systems provided audiologic results superior to traditional bone conduction systems. With regard to bilateral bone anchored implants in patients with bilateral conductive hearing loss and symmetric bone conduction thresholds, binaural hearing (such as improved directional hearing, diotic summation and improvements regarding speech-in-noise) was apparent. With regard to single sided deafness, the authors noted bone anchored hearing systems act as a “transcranial CROS” (contralateral routing of signal). However, although stereophonic hearing will not occur, negative effects from head shadow will be minimized. With regard to patients with significant unilateral air-bone gaps, bone anchored hearing devices applied to the conductive side allow the perception of binaural cues.

Wazen, Young, Farrugia, Chandrasekhar, Ghossaini, Borik, Soneru and Spitzer (2008) reviewed their patients with conductive and mixed hearing loss and single sided deafness, all of whom were implanted with bone anchored hearing systems. Of the 218 patients evaluated no major complications were reported. The authors reported 4.5% of patients required revision due to soft tissue issues and 1.3% needed revision due to failure to osseointegrate. Additionally, 106 of their patients completed a questionnaire. Of those, 92% use their bone anchored hearing system regularly (on average 10.1 hours per day). The authors concluded the device is safe and effective for patients with conductive and mixed hearing loss, and for patients with single sided deafness. Wazen et al. noted the high success rate and the high satisfaction rate – combined with the predictable outcome – render bone anchored hearing systems among the leading choices for auditory (re)habilitation.

Yuen, Bodmer, Smilsky et al. (2009) reported 21 consecutively implanted patients with single sided deafness. All patients demonstrated significant speech reception threshold improvements as measured with the Hearing-In-Noise Test (HINT) as well as improvements noted on

two questionnaires (Abbreviated Profile of Hearing Aid Benefit, APHAB and Glasgow Hearing Aid Benefit Profile, GHABP). The authors concluded the bone anchored hearing system provided significant benefits and improved speech understanding in noise.



### Status Quo

Bone anchored hearing systems have performed admirably while providing outstanding safety, alternatives and efficacy in appropriate patients with conductive and mixed hearing loss, and for patients with single sided deafness.

Importantly, titanium bone anchored implants are CT and MRI compatible.

Therefore, Oticon Medical has recently synthesized more than a century of advanced sound processing innovation and technology with modern ergonomic considerations, intuitive audiology-based and familiar Genie programming software, with advanced implants, abutments and surgical tools. The status quo is indeed excellent. Nonetheless, patients, surgeons and audiologists will continue to experience advances and improvements in efficacy, reliability and clinical outcomes.

## Paradigm Shift

To some physicians, audiologists and patients, bone anchored systems have previously been considered the “last resort.” That is, in recent years, bone anchored hearing solutions were generally only availed to patients after more traditional solutions (i.e., surgery, air-conduction hearing aids etc.) had failed.

At this time (2010), a paradigm shift is underway. Bone anchored hearing systems for appropriate candidates have become the “first choice” solution for many medical and surgical problems. (Beck, 2010).

## Pre-Op Trial

Bone anchored hearing systems are unlike other surgical solutions as the patient can literally “try it before they buy it.” For many years, bone conduction hearing systems have offered pre-operative evaluations using traditional head bands, test bands and test rods. These simple devices allow the patient to wear the device in their own acoustic environments (home, school, work, recreation etc.) for days or weeks at a time so as to personally evaluate the benefits of bone conducted sound.



*Test band*

*Head band*

*Test rod*

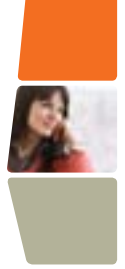
Additionally, as children under the age of five years are not eligible for bone conduction hearing systems in the USA, pediatric “soft bands” are available to allow bone conducted speech and other sounds to be delivered to children prior to the age of five years.

Importantly, despite the advantages of a pre-operative trial, Snik, Mylanus, Proops et al. (2005) reported (p. 7) “the overall conclusion is that the vast majority of patients benefited significantly” when they changed from their traditional bone conduction system to their bone-anchored hearing system. Snik et al. noted the bone anchored hearing system is “superior to conventional bone conductors.” Therefore, although the pre-operative trial is very important and is not to be minimized, the majority of patients report their bone anchored implant system has a better quality of sound and is louder than the trial equipment.



## New Professional Opportunities and Challenges

Now that advanced processing has been incorporated into programmable bone anchored hearing systems, the audiologist has three new challenges. The first is to become familiar with bone anchored hearing systems as an option or recommendation for appropriate candidates. The second is to counsel patients with regard to realistic expectations, benefits and limitations of bone anchored hearing systems. The third is to maximally program the sound processor to meet the unique, ongoing and changing needs of the individual.



### Ponto and Ponto Pro Sound Processors

Ponto and Ponto Pro sound processors incorporate the most advanced sound processing platform (the Oticon RISE platform) available into a bone anchored hearing

system. The Ponto and Ponto Pro build upon decades of bone anchored hearing system success while adding advanced sound processing, ergonomics, durability and maximal cosmetic appeal.

### Ponto Pro and Ponto Features

The features offered by Ponto Pro and Ponto are listed below.

Features	Ponto Pro	Ponto
10 channel frequency response shaping	✓	✓
Multiband Adaptive Directionality	Automatic	Manual
Tri-state Noise Reduction	✓	
Data Logging	✓	
Learning Volume Control	✓	
Wind Noise Reduction	✓	✓
Output AGC	✓	✓
Up to 4 programs	✓	✓
Volume Control	✓	✓
Start-up delay	✓	✓
Mute/stand-by function	✓	✓
Low battery warning	✓	✓
Telecoil/DAI/FM input	✓	✓
Fitting software, Genie Medical	✓	✓
Styles available	Left and right	Left and right
Color palette	Chroma Beige Mocca Brown Diamond Black	Chroma Beige Mocca Brown Diamond Black

*Ponto sound processors are ergonomically designed and are available in left and right versions and multiple colors.*



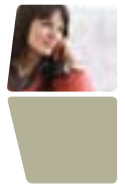
### Ponto and Ponto Pro Coupling

The Ponto and Ponto Pro coupling is the key to durability and the ability to withstand extensive wear and tear. The Ponto coupling has been designed for maximal long-term reliability and end-user ease-of-use. This robust design is patented and includes separate contact and spring materials. The metal spring ensures long-term spring function and the optimized polymer contact material is

designed with generous contact surfaces to ensure long-term durability, high performance sound transmission and user-friendly handling while connecting and disconnecting the device. Additionally, the built-in vibrator protection system ensures that the connection forces on the coupling are not transferred to the vital parts (vibrator) inside the sound processor – a key component of the device.



*The Ponto coupling is designed for long-lasting durability and to withstand the rigors of daily connect/disconnect of the sound processor. The Ponto coupling design is user-friendly and transmits excellent sound quality to the implant.*



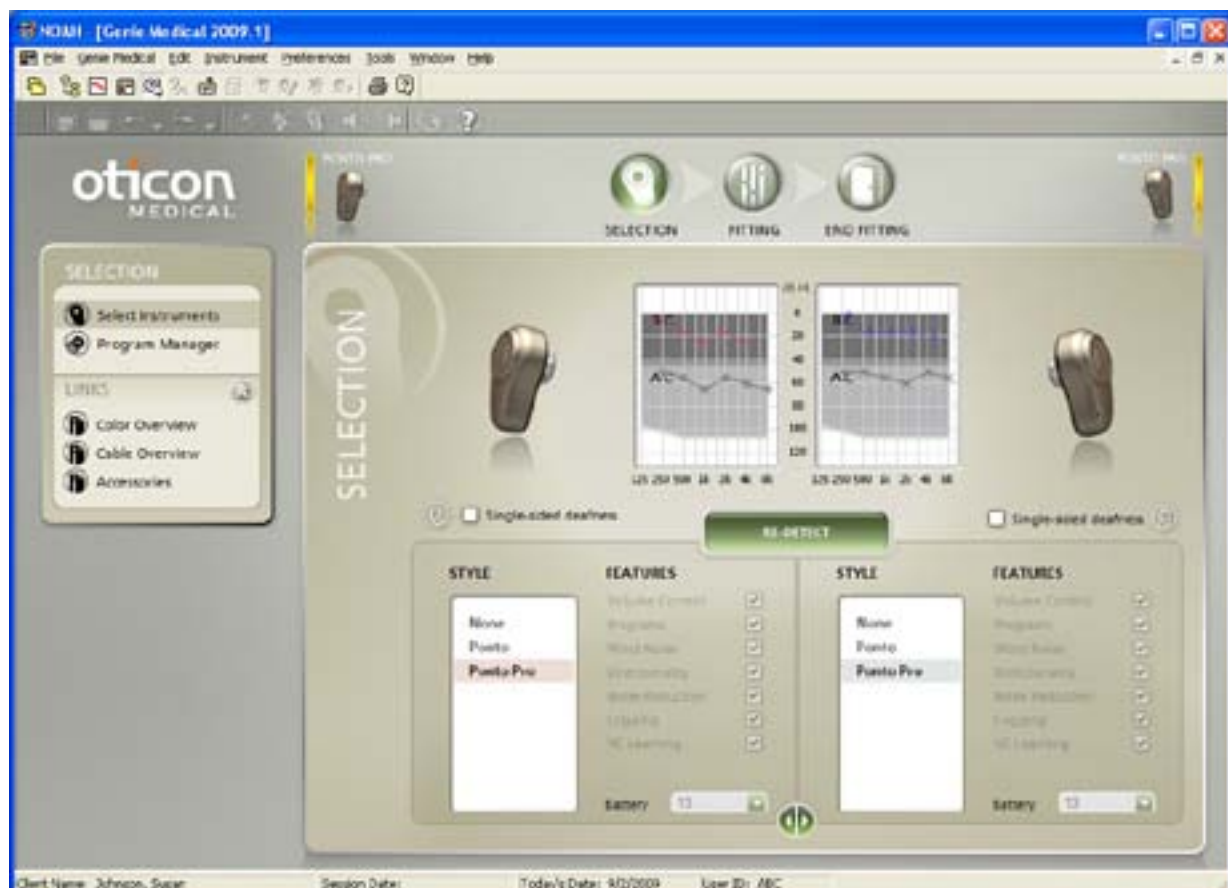
## Programming Software

Genie Medical Software has been built on the well-known Oticon Genie platform, thus assuring an intuitive and easy-to-operate programming and management experience. Prescription-based fittings serve as an excellent starting point for initial programming and fine tuning. Prescriptions are derived from the entered left and right bone conduction (BC) thresholds.

In cases of single sided deafness, the prescription is based on the BC threshold measured on the good ear

side. In these cases the software automatically incorporates compensation for the transcranial attenuation as well as less low frequency amplification – compared to conductive or mixed hearing losses – because there is almost no head shadow effect for very low frequencies.

The look and feel of Genie Medical is the same as Oticon Genie. However, Genie Medical contains tools specifically developed for the Ponto system, such as a loudness control to quickly and efficiently manage the patient's initial reactions to their bone anchored hearing system.

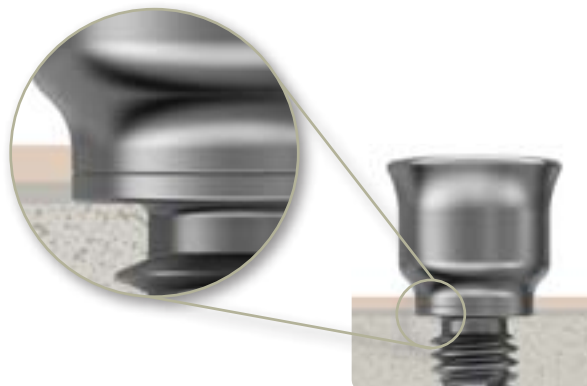


## Oticon Medical Bone Anchored Titanium Implant

The Oticon Medical bone anchored implant is based on the known and proven Branemark osseointegration implant concept. The implant is self-tapping and uses additional micro-size threads at the flange to assure maximal contact surface between the implant and bone. This feature is designed to discourage bone resorption. The implant diameter is 3.75 mm and the standard length is 4 mm (also available in 3 mm).

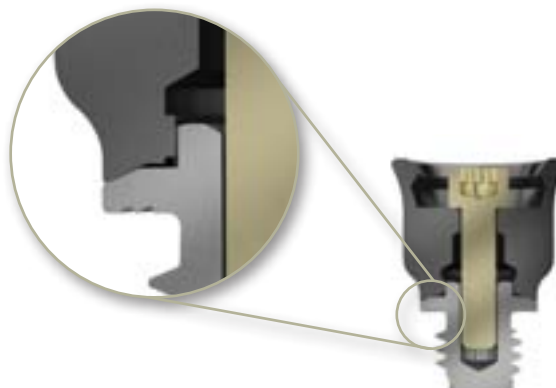


The bone supports the skin through the underlying periosteum all the way to the abutment. Because the interface between the abutment and the implant has the same outer diameter, there is no unsupported skin movement on top of the implant flange. Therefore, this feature supports the skin and the soft tissue and minimizes the movement as this design aims to minimize post-operative local infection and irritation.

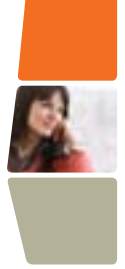


*The design supports the skin and soft tissue, thus minimizing skin movement.*

The conical fit between the abutment and the implant offers a true and tight seal to prevent bacterial leakage across the interface between the components. The advanced conical design has been verified to be micro-leak-proof to a depth of 80 meters (pressure = 8 bar)



*Illustration demonstrating the interface between the Ponto implant and abutment.*



### Realistic Expectations & Counseling Issues

Assessing and managing patients with regard to realistic and achievable bone anchored hearing systems outcomes is of paramount importance. Unfortunately, there is no “one size fits all” counseling protocol. A multiplicity of factors impact the specific counseling protocol, as does the type and degree of hearing loss, diagnosis, listening needs, acoustic environments and personal expectations unique to each patient.

Nonetheless, there are a few “core counseling issues” which should be addressed with each bone anchored hearing system candidate, including keeping the abutment clean and dry, the physical appearance of the device, the abutment protruding from the head, surgical issues and possible negative outcomes (see Snik, Mylanus, Proops et al., 2005).

### Contraindications

The primary contraindication to bone anchored hearing systems are psychiatric issues, immature personality, drug and alcohol abuse and inability to maintain a hygienic abutment and surrounding skin. Indeed, poor hygiene is the chief reason for skin reactions (Tjellstrom, Hakansson and Granstrom, 2001).

In the USA, implantation in children below the age of five years is contraindicated.

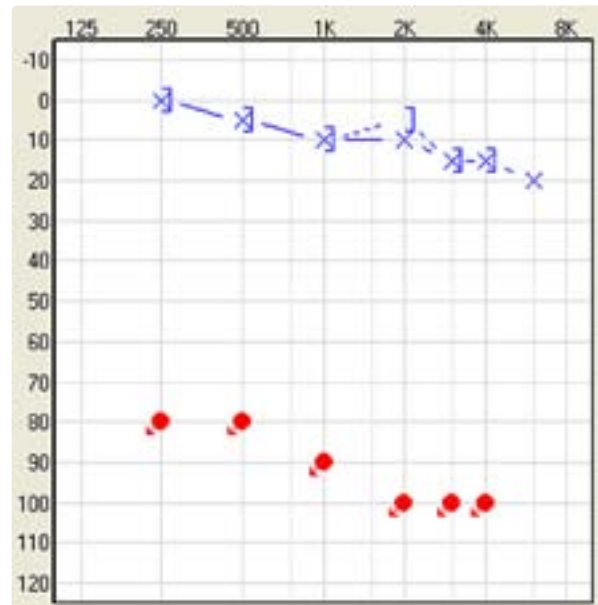


## Case Studies

### *Pia Cramer: Single Sided Deafness*

Pia is a 40-year-old post-operative acoustic neuroma patient with normal hearing in her remaining ear. She has previously worn bone anchored hearing systems for 3.5 years. She reports the Ponto Pro sound processor provides a very different sound from her previous device and she says it is strikingly more clear. Pia reports the Ponto Pro allows her more flexibility with regard to her head position and the origin of speech sounds.

Previously, she had to turn her head sideways to maximally perceive speech sounds. With Ponto Pro, she is able to maintain more of a natural head position while listening to speech from all angles. Another benefit reported by Pia is her newly developed ability to “multi-task.” Specifically, while she is using the phone on her good ear, she maintains an appreciation of sounds occurring around her through her Ponto Pro processor.



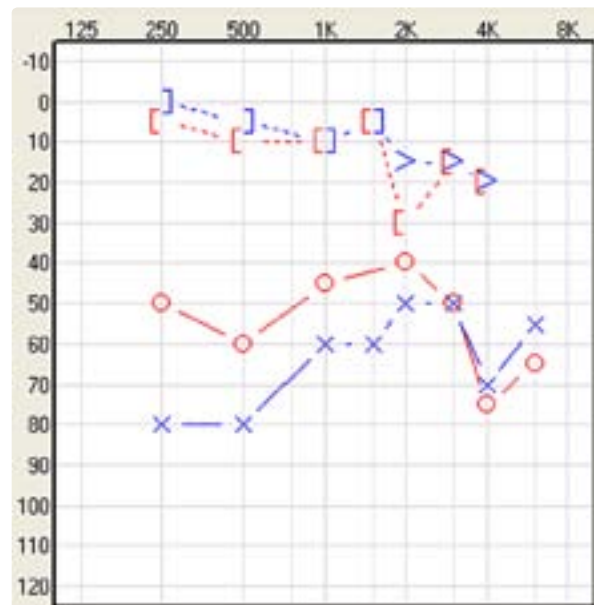
*Pia Cramer Audiogram*



### ***Britt Vangsbaek: Chronic Bilateral Otitis Media***

Britt is a 50-year-old female. She has had chronic otitis media since age 3 years. She has had four operations on her left ear and three operations on her right ear. She has worn bilateral bone anchored hearing systems for a number of years. She is currently fitted with the Ponto Pro system.

Her audiometric scores indicate improvements in speech understanding of approximately 25%. Britt reports speech sounds perceived via the Ponto Pro are “nice, detailed, comprehensive and speech is clean – all the frequencies are included.” She noted the sound quality of the Ponto Pro is comparable to a high quality stereo system (Bang & Olufsen).



***Britt Vangsbaek Audiogram***

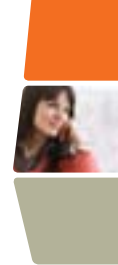
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## Conclusion & Discussion

Oticon Medical's bone anchored hearing system offers the most advanced sound processing technology and newly engineered bone anchored surgical solutions. Oticon Medical's new hardware and software solutions provide the next step in advanced bone anchored hearing systems, thereby positioning Oticon Medical's Bone Anchored Hearing System among the "first choice" options for appropriate new candidates.

Bone anchored hearing systems have been available for almost three decades. Bone anchored hearing system technologies have made strong and steady progress, built upon a solid foundation of scientific and clinical outcomes, demonstrating undeniable benefit for patients with conductive hearing loss, mixed hearing loss and patients with single sided deafness. Indeed, candidates with equal bone conduction thresholds and bilateral conductive hearing loss have repeatedly demonstrated binaural hearing benefits. Beyond the primary goal of improved hearing, bone anchored systems have contributed to improvements in behavior, concentration, learning and development in children (McDermott, Williams, Kuo et al., 2009).

Therefore, Oticon Medical is proud to offer advanced bone anchored hearing systems for appropriate candidates with conductive and mixed hearing loss and for patients with single sided deafness. Oticon Medical is committed to the patients, surgeons and audiologists and will continue to explore and develop advances and improvements in hardware and software, as well as efficacy, reliability and clinical outcomes for the benefit of patients using bone anchored hearing systems. Oticon Medical is proud to lead and facilitate the paradigm shift, thus positioning bone anchored hearing systems as the "first choice" solution for appropriate candidates.



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