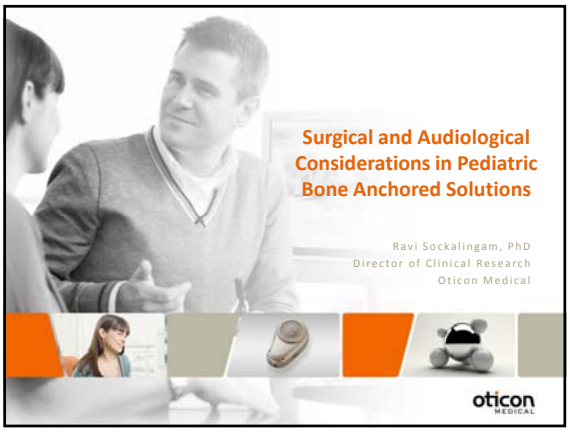


Outline

- Introduction to bone anchored hearing systems (BAHS)
- Sound processor considerations
- Surgical considerations
- Future Trends

Bone Anchored Hearing Systems

Proven

- to provide effective rehabilitation for conductive, mixed and unilateral sensorineural hearing losses (single sided deafness)
- To be safe in the long term

BAHS Candidate
Mixed and Conductive Hearing Loss

- ≥ 5 years of age
- ≤ 45 dB HL BC PTA
- ≥ or equal to 60% speech discrimination scores
- Symmetric bone conduction thresholds are defined as less than 10 dB difference in average or less than 15 dB at individual frequencies (0.5, 1, 2, and 4Khz)

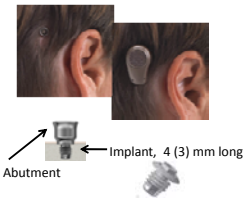
BAHS Candidate
Single sided deafness

- ≥ 5 years of age
- Profound sensorineural hearing loss in one year, normal hearing (average PTA thresholds better than 20 dB or better) in the contralateral year

Children under the age of 5 years

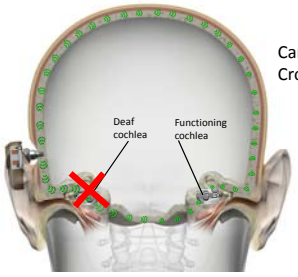
- the sound processor can still be used on a head or soft band

Bone-anchored hearing system



- Sound transmitted by bone conduction via the skull to the bony cochlea

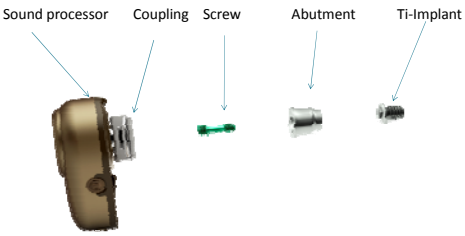
Ponto in single sided deafness



Can work as a Cross hearing aid

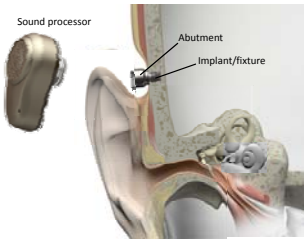
One cochlea is picking up sound from both sides.

Ponto bone anchored hearing system



composed of three main parts: (1) a titanium implant (2) an external abutment and (3) a sound processor

Direct Bone Conduction



Success of Bone Anchored Hearing System

- Retrospective review of 218 patients
- No major wound complications
- Implant extrusion rate: 1.8% (only children)
- Survey of patients revealed mean use of the device of 10h/day 5.6d/wk

Wazen J, Young D, Farragia M, Chandrasekhar S, Ghossaini S, Borik M, Soneru C, Spitzer J., Otology & Neurotology, 29:1115-1119, 2008

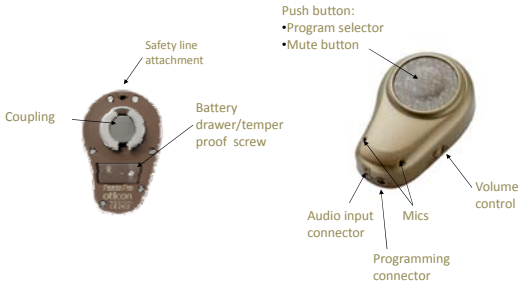
That was back in 2008!

- Since 2009, the bone anchored world had changed dramatically
- Advances in the design and signal processing of Ponto sound processor
- Advances in implant and abutment design, and in surgical techniques

Child friendly Bone Anchored Hearing System

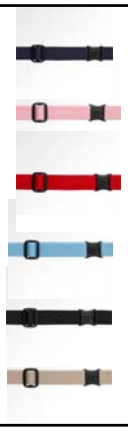
- Aesthetically appealing
- Easy to use and handle
- Perform well in difficult listening situations
- Safe, robust and reliable
- Provide communication possibilities
- East to fit and handle by Audiologists

Design is not just how it looks – it is how it works



Designed for children - Aesthetics

- Shaped to blend in
- Left and right versions
- Stickers to make Ponto more personal
- Softband comes in 6 different colours



2 styles 4 colours

Ponto
and Ponto Pro

Ponto Pro Power

White Silver | Chroma Beige | Mocca Brown | Diamond Black

Designed for Children – Ease of Use

- Child friendly softband: Elastic and adjustable or any head size

- Fully automatic advanced features
- Big and easy to find program and mute button

Designed for Children – Performance

- **Processing features in Ponto**
  - Automatic Multiband Adaptive Directionality
  - Wind Noise Management
  - Speech Guard Amplification Scheme
  - 2-stage Feedback Management

Designed for Children – Safety, Robustness and Reliability

- Transducer Impact Protection
- Temper Proof Battery Drawer
- Safety Line
- Nano Coating : protects from moisture and dirt

Designed for the Audiologist

- Dedicated Soft band fitting mode in Genie Medical
- In situ bone conduction thresholds
- Individualised feedback management
- Adapt Ponto to the children's needs – for example special programs and deactivate controls

Expanded Communication Possibilities

Audio adapter

FM Receiver

Telecoil

Pediatric Anchored Surgery

- Surgery generally done in children aged 5 and older
- Typically done in **2 stages** in children under 10 years of age :
  - insert implant first and wait for osseointegration before inserting abutment.
  - Requires two surgeries
- Typically done in **1 stage** using a 4mm implant in children 10 years of age and older
  - implant and abutment inserted in one surgery.
- Complications are greater in the pediatric population due to issues relating to wound care compliance and susceptibility to trauma

Osseintegration Failure

The Birmingham Pediatric Bone-Anchored Hearing Aid Program: A 15-Year Experience

Otology & Neurotology
30:178–183 © 2009, Otology & Neurotology, Inc.

Ann-Louise McDermott, Jo Williams, Michael Kuo, Andrew Reid, and David Proops

TABLE 4. *Age and fixture failure*

Age, yr	No. cases	Loaded fixtures	Fixtures lost	Fixture failure rate, %
<3	14	23	9	40
3–5	25	40	15	38
5–10	75	88	7	8
>10	68	79	1	1

Revolutionary Implant and Abutment Design

- "OptiGrip" implant design for improved stability
  - Universal hexagon implant interface
  - Based on proven surface
  - Minimized bone intervention*

- Widened abutment range
  - Maintained design concept
  - Respond to more patient needs
  - Respond to new surgical techniques
  - Compatibility

- Simplicity for clinics and patients

*) In relation to the implant diameter

Ponto Bone Anchored System

- **Wide diameter implant**
  - 4.5 mm diameter
  - OptiGrip design – maximizes bone contact
  - Well proven implant safety - the Brånemark implant has long term clinical documentation in the temporal bone

Universal hexagon I

Ponto Bone Anchored System

+ 10 % bone contact surface*
+ 72% bone contact surface vs. 3.75mm diameter implant

Wide (∅ 4.5mm) Ponto implant
Cutting grooves along entire implant surface

BI300 by Cochlear (4.5 mm)

Ponto (∅ 3.75 mm) implant

* Compared to any other available bone anchored hearing implant

Shift in staging surgeries in Children

- Roland and colleagues from UT South Western Medical School, Dallas, USA
- Retrospective review of 65 children
- 75 bone anchored devices
- 60 single stage, and 15 two stage surgeries

Question: Will single stage surgery result in a greater incidence of complications and especially failure of osseointegration?

Peter Roland. Single-staged Bone Anchored Hearing Aid in The Pediatric Population. Oticon Medical Scientific Meeting, Copenhagen, March 18 2013.

Results - Complications

Complication	Single stage (60 sides)	Two stage (15 sides)
Skin overgrowth requiring revision surgery (%)	8 (13.2)	2 (13.3)
Failure to osseointegrate	4 (6.7)	1 (6.7)
Infection requiring explant	1 (1.6)[1]	0

[1] Occurred during first postoperative week

Peter Roland . Single-staged Bone Anchored Hearing Aid in The Pediatric Population. Oticon Medical Scientific Meeting, Copenhagen, March 18 2013.

Conclusions

- Single stage BAHA procedure is a safe and effective procedure for all ages
- This minimizes the need for a planned second surgery and allows the device to be placed sooner.
- Consideration should be given to staging children with craniofacial abnormalities due to a higher extrusion rate.

Roland, P . Single-staged Bone Anchored Hearing Aid in The Pediatric Population. Oticon Medical Scientific Meeting, Copenhagen, March 18 2013.

Shifts in Surgical technique

- **Surgical Procedure**
  - **Transitioning to less invasive approach(s)**
    - Semicircular Flap
    - Dermatome – larger wound with more soft tissue reduction, removal of hair follicles
    - Linear – approximately 4 cm incision with minimal soft tissue reduction
    - Punch – biopsy punch procedure used to remove skin and no soft tissue reduction

Shifts in Surgical technique

- **Surgical Procedure**
  - **Less invasive considerations**
    - Extended abutment lengths

    - Less skin thinning ➡ decrease incidence of post-operative complications

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Percutaneous Osseointegrated Implant Surgery Without Skin Thinning in Children: A Retrospective Case Review

*†Aviya Lanis and †Malou Hultcrantz

*Washington University, St. Louis, Missouri, U.S.A.; and †Department of Otorhinolaryngology, Karolinska University Hospital, Stockholm, Sweden

Objective: To determine the follow-up status of osseointegration in children and to see if the omission of skin thinning in percutaneous osseointegrated implant surgery can be beneficial for children, 2 groups of children who underwent surgery with and without skin thinning were compared.
Study Design: This was a single-center, retrospective case review at a university hospital designed to assess the outcome of a new technique for percutaneous osseointegrated implantation in children.
Material: Thirty-four children who had undergone implantation from 2001 to 2012 were included in the study. The 2 groups were divided according to whether skin thinning was used.
Methods: Percutaneous osseointegrated implantation was performed in 1- or 2-stop surgeries on patients under general anesthesia. Twenty-three patients were operated with traditional skin thinning and with a 3.5- mm long abutment, 10 patients were operated without thinning and with a 6-, 8.5-, or 9-mm-long abutment, and 1 patient was lost. Primary points of interest were clinical signs and symptoms of inflammation or infection at the site of skin penetration, time required for surgery, healing time, and any additional complications experienced by the patients.
Results: The group of children who underwent surgery without thinning and with shorter follow-up time experienced fewer complications, shorter time for surgery, minimized healing time, no numbness, and improved cosmetic appeal in comparison with the group that underwent the traditional skin thinning procedure.
Conclusion: The percutaneous osseointegrated implantation technique without skin thinning that has recently been implemented in adults is also beneficial for children. **Key Words:** Children—Direct implantation—No skin thinning—Percutaneous osseointegrated implant—Skin reduction.
Otol Neurotol 00:00–00, 2013.

TABLE 3. *Complications for operations performed with and without skin thinning*

Complication	Thinning	No thinning
Pain (persistent)	1	—
Peri-implant infection	9	1
Loss of abutment	4	1
Removal of abutment	3	—
Skin overgrowth	6	—
Fixture loss because of lack of integration primarily at 3 mo	5	1
Numbness after 12 mo	12	—

Early postoperative infections were excluded from peri-implant infections for both thinning and nonthinning groups. The 4 lost abutments for the thinning group included 1 traumatic loss.

No skin thinning technique

1.5 – 2 cm incision
Close with vicryl and 5-0 fast absorbing
Simple procedure

Peter Roland . Single-staged Bone Anchored Hearing Aid in The Pediatric Population. Oticon Medical Scientific Meeting, Copenhagen, March 18 2013.

Outcome

✓3 months post-op
✓ No divot
✓Hair bearing skin

Advances in Bone Anchored Hearing and the Ponto System

What about the future?

- Design
- signal processing
- transducer technology
- verification
- wireless connectivity
- implant and abutment design
- surgical technique
- transcutaneous solution

The Interacoustics SKS10 Skull Simulator

- Can be used for the same purpose as a 2cc coupler is used for hearing aids
- Simulates the behaviour of the skull when a bone anchored hearing device is attached to it