

AudiologyOnline, Dec 15<sup>th</sup> 2015

## Minimally Invasive Ponto Surgery – A new perspective on bone-anchored surgery

Marcus Holmberg, PhD



Because sound matters

Not all products are available in all markets. Product availability is subject to regulatory approval in the respective markets.



---

---

---

---

---

---

---


---

### Outline

- Bone anchored hearing implants: Indications & benefits
- Background and the new MIPS surgical components
- MIPS video
- Pre-clinical results from MIPS development
- Clinical results from the first evaluation
- Q & A

### Learning Objectives

- After this course learners will be able to describe the advantages of the MIPS technique.
- After this course learners will be able to describe characteristics of the most suitable patients for the MIPS procedure.
- After this course learners will be able to list the steps of performing MIPS.



---

---

---

---

---

---

---

---

## Bone anchored hearing implants: Indications & benefits



Because sound matters



---

---

---

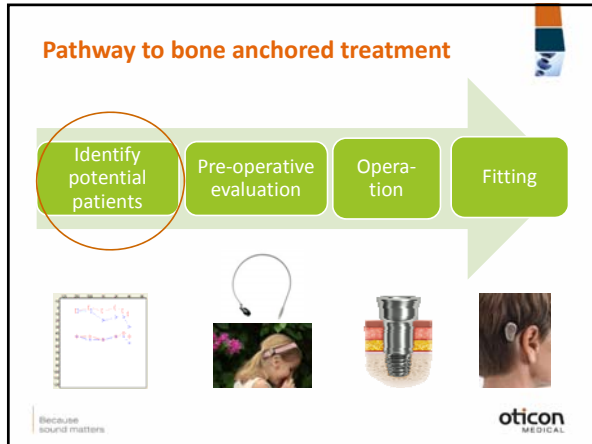
---

---

---

---

---



---

---

---

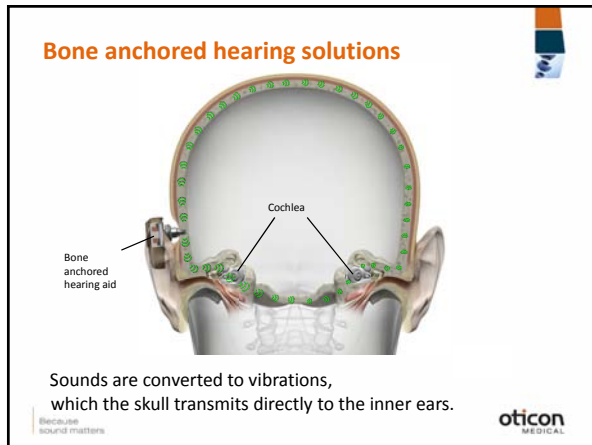
---

---

---

---

---



---

---

---

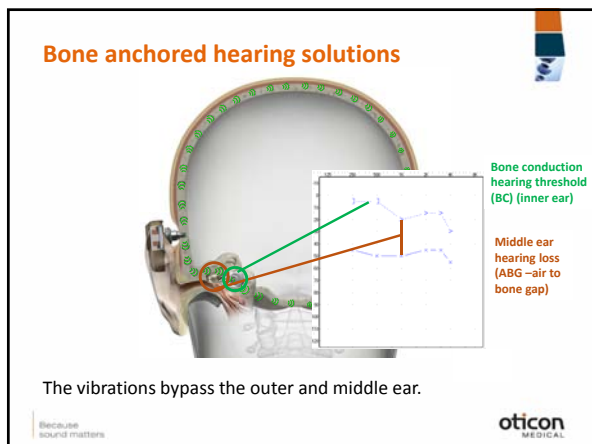
---

---

---

---

---



---

---

---

---

---


---

---

---

### Candidates for bone anchored hearing solutions

- Audiological indications
- Conductive & mixed hearing losses
- Single-sided deafness
- Other indications, medical



Because sound matters

oticon MEDICAL

---

---

---

---

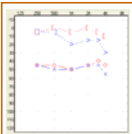
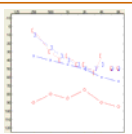
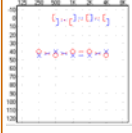
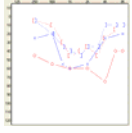
---

---

---

---

### Candidates

Conductive	Mixed HL
	
	

Typical diagnosis:

- Chronic otitis media
- Congenital malformation of outer ear (microtia)
- otosclerosis
- .....

without/with an inner ear hearing loss

Because sound matters

oticon MEDICAL

---

---

---

---



---

---

---

---

### Traditional HA versus bone anchored HA

Traditional HA	Bone anchored HA
	

Because sound matters

oticon MEDICAL

---

---

---

---

---

---

---

---

### Bone anchored sound processor

Inner ear hearing threshold (BC)

Bone anchored hearing aid

Because sound matters

oticon MEDICAL

---

---

---

---

---

---

---

---

### Bone anchored sound processor

Middle ear hearing loss (ABG - air to bone gap)

Bone anchored hearing aid

Ponto don't need to compensate for the Air-to-Bone Gap / the conductive component of the hearing loss.

Because sound matters

oticon MEDICAL

---

---

---

---

---

---

---

---

### Traditional HA versus bone anchored HA

<p><b>Traditional HA</b></p> <ul style="list-style-type: none"> <li>• Need <u>high</u> gain.</li> </ul> <p>[gain(BC) + gain(ABG)]</p>	<p><b>Bone anchored HA</b></p> <ul style="list-style-type: none"> <li>• Need <u>little</u> gain.</li> </ul> <p>[gain(BC)]</p>
---	---

Because sound matters

oticon MEDICAL

---

---

---

---

---


---

---

---


### Traditional hearing aid versus bone anchored HA

**Traditional HA**



- Need high gain
- Likely problems with feedback
- Tight ear mould
- Advanced technology

**Bone anchored HA**



- Low gain
- Better sound quality
- Ear canal is open
- Just as advanced technology as in modern traditional HA

**oticon**  
MEDICAL

---

---

---

---

---

---

---

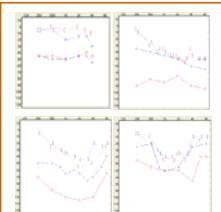
---

---

---

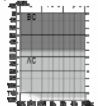
### Potential candidates for Ponto

**Conductive and mixed HL**



- Chronic otitis media
- Congenital malformation
- .....

- If ABG >30 dB, speech recognition is likely to be better with a bone anchored sound processor than with a traditional hearing aid.<sup>1,2</sup>
- Bone Conduction (BC) threshold up to av. 55 dB HL



1) Mykhus et al. Intraindividual comparison of the bone-anchored hearing aid and air-conduction hearing aids. Otolaryngology-Head & Neck surgery. 1998; 124(3): 271-6  
2) Hoyle et al. Better performance with bone-anchored hearing aid than acoustic devices in patients with severe air-bone gap. The Laryngoscope 121:613-616, 2010.

**oticon**  
MEDICAL

---

---

---

---

---

---

---


---

---

---

### Candidates for bone anchored hearing solution

- Conductive & mixed hearing losses
- Single-sided deafness



**oticon**  
MEDICAL

---

---

---

---

---

---

---

---

---

---

### Bone anchored sound processor

works as a  
Cross device

The only functioning cochlea is 'receiving' sounds from both sides.

Because sound matters

oticon MEDICAL

---

---

---

---

---

---

---

---

### Candidates

Single-sided deafness

- Patients with Single-sided deafness (SSD)
  - they have a profound sensorineural hearing loss in one ear, and close to normal hearing in best ear.
- Diagnosis
  - Acoustic neuroma
  - Sudden deafness
  - Congenital
  - ...

Because sound matters

oticon MEDICAL

---

---

---

---

---

---

---

---

### Candidates for Ponto sound processors

Single-sided deafness

- Average hearing threshold better than 20 dB HL

- Sudden deafness  
- Acoustic neuroma  
.....

Av. AC < 20 dB HL

---

---

---

---

---

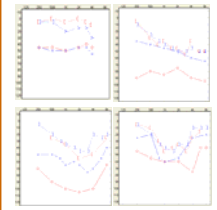
---

---

---

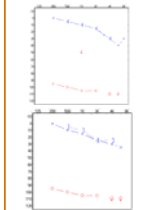
### Summary: Candidates

Conductive and mixed HL

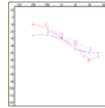


- 1) BC up to av. 55 dB HL
- 2) if ABG >30 dB, speech recognition is likely to be better with a bone anchored sound processor compared to a HA

Single-sided deafness



Close to normal hearing in best ear



Other medical background:  
-Skin allergies  
in ear canal

---

---

---

---

---

---

---

---

### Background and the MIPS surgical components

Because sound matters

oticon MEDICAL

---

---

---

---

---

---

---

---

### Guiding Star

The aim with the MIPS method is to provide a **truly minimally invasive technique** because we strongly believe in that **less surgical trauma** leads to **better outcome**

Because sound matters

oticon MEDICAL

---

---

---

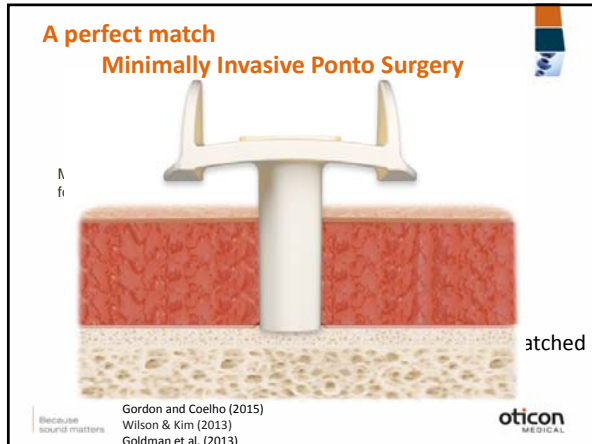
---

---

---

---

---



---

---

---

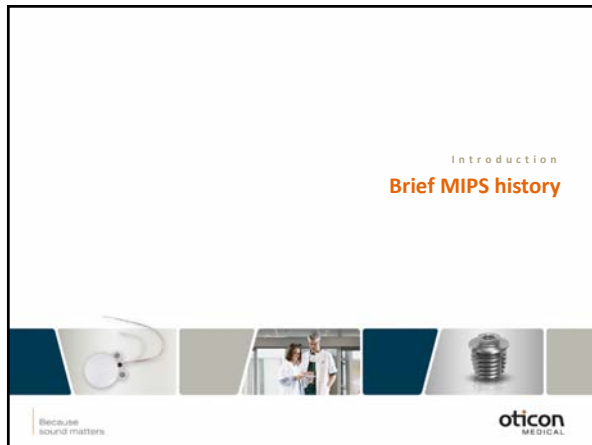
---

---

---

---

---



---

---

---

---

---

---

---

---



---

---

---

---

---

---

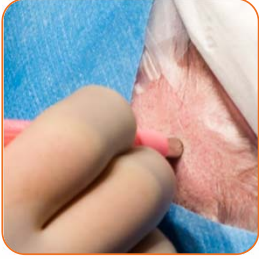
---

---



**MIPS – Minimally Invasive Ponto Surgery**

1. Punch hole with 5mm punch



Because sound matters

oticon MEDICAL

---

---

---

---

---



---

---

---

**MIPS – Minimally Invasive Ponto Surgery**

2. Insert cannula



Because sound matters

oticon MEDICAL

---

---

---

---

---



---

---

---

**MIPS – Minimally Invasive Ponto Surgery**

3. Drill through cannula



Because sound matters

oticon MEDICAL

---

---

---

---

---



---

---

---

**MIPS – Minimally Invasive Ponto Surgery**

4. Remove cannula and insert implant



Because sound matters

oticon MEDICAL

---

---

---

---

---

---

---

---

**MIPS – Minimally Invasive Ponto Surgery**

5. Healing cap & dressing



Because sound matters

oticon MEDICAL

---

---

---

---

---

---

---

---

**MIPS**  
**Tailor-made Surgical Components**



Because sound matters

oticon MEDICAL

---

---

---

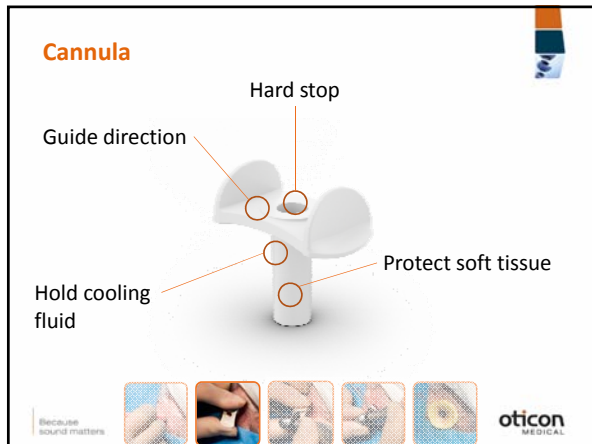
---

---

---

---

---



---

---

---

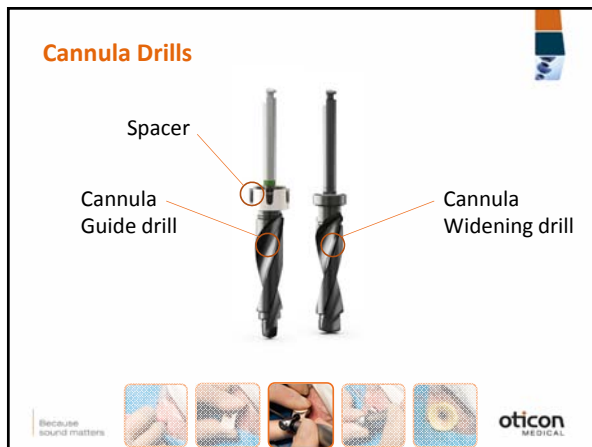
---

---

---

---

---



---

---

---

---

---

---

---

---



---

---

---

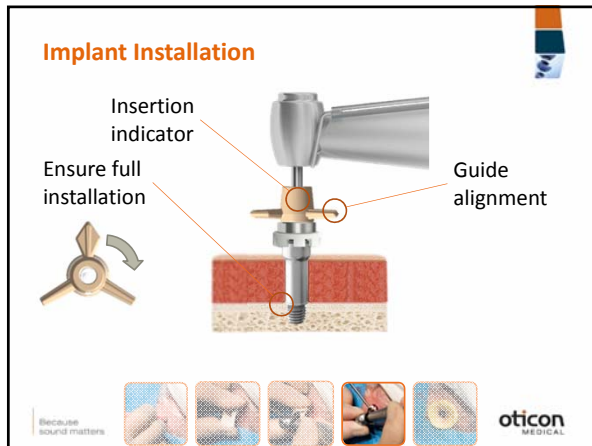
---

---

---

---

---



---

---

---

---

---

---

---

---



---

---

---

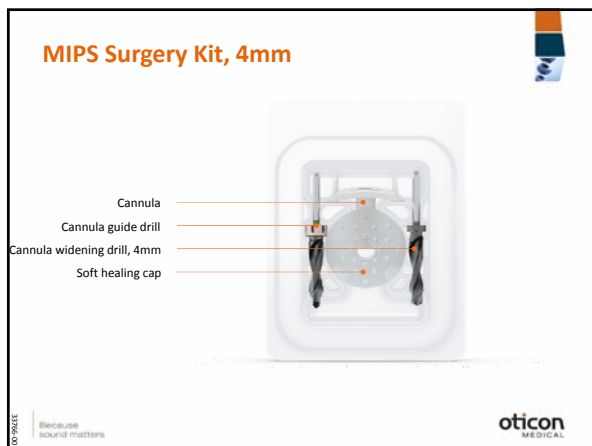
---

---

---

---

---



---

---

---

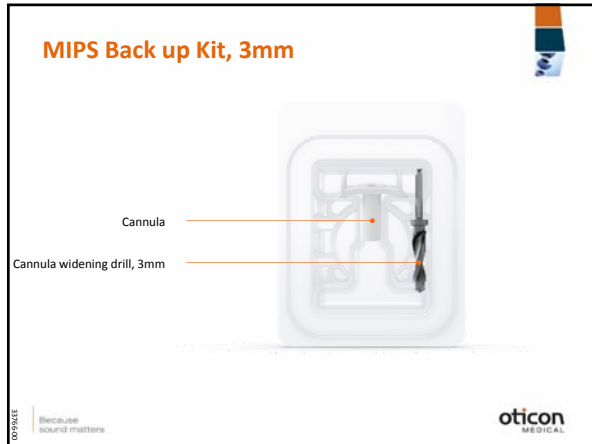
---

---

---

---

---



---

---

---

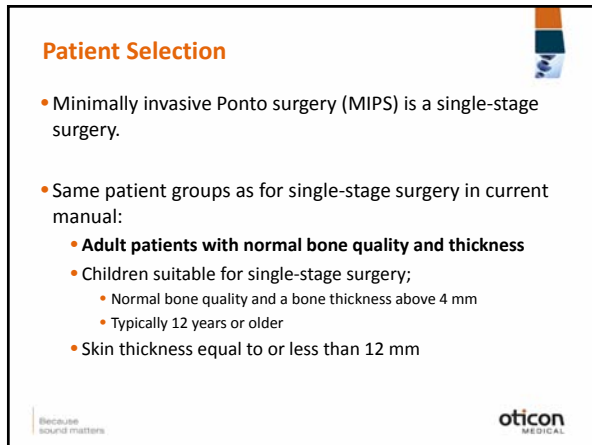
---

---

---

---

---



---

---

---

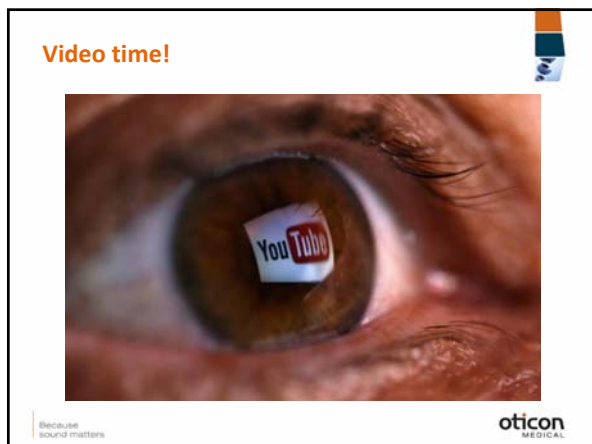
---

---

---

---

---



---

---

---

---

---

---

---

---



**MIPS**  
**Pre-clinical Results**

Because sound matters

oticon MEDICAL

This slide features a background image of a surgeon in a white cap and mask. Below the main text, there is a horizontal strip of four small images: a stethoscope, a person in a lab coat, a person in a lab coat, and a metal drill bit. The Oticon Medical logo is in the bottom right corner.

---

---

---

---

---

---

---

---

**White paper available**



Design and clinical evaluation of MIPS –  
A new perspective on tissue preservation

Because sound matters

oticon MEDICAL

The slide shows a white paper cover with the title "Design and clinical evaluation of MIPS – A new perspective on tissue preservation". The cover has a blue and orange header and a small image of a drill bit. The Oticon Medical logo is in the bottom right corner.

---

---

---

---

---


---

---

---

**New drill system**

- Heat-induced trauma
- Quality of bone-to-implant interface
- As atraumatic as possible



Twist drill design

Low-friction coating

"Feel the drop" tip

Countersinking

Because sound matters

oticon MEDICAL

The slide features a diagram of two drill bits. The left bit is labeled "Twist drill design" and the right bit is labeled "Low-friction coating". A circular inset shows a close-up of the tip of the new drill bit, labeled "Feel the drop" tip. The bottom of the diagram is labeled "Countersinking". The Oticon Medical logo is in the bottom right corner.

---

---

---

---

---

---

---

---



---

---

---

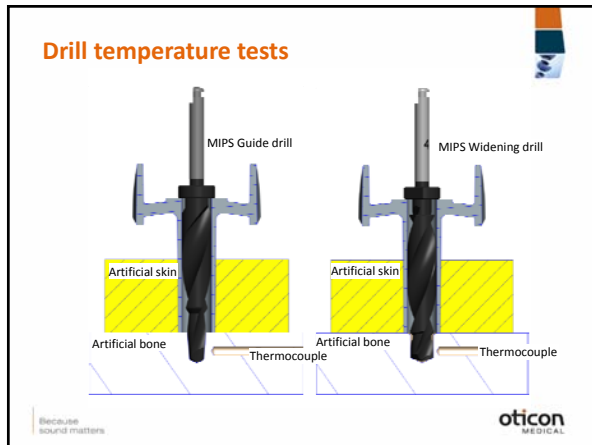
---

---

---

---

---



---

---

---

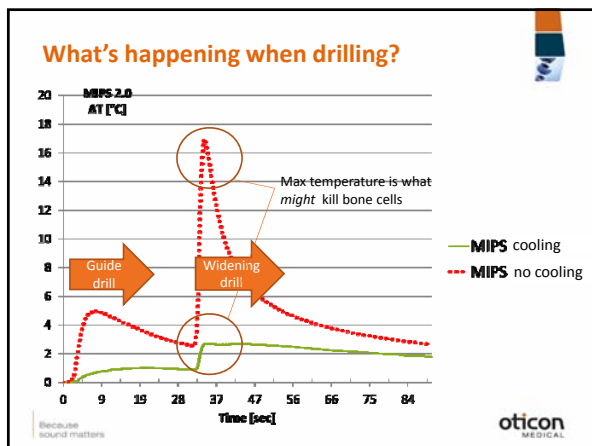
---

---

---

---

---



---

---

---

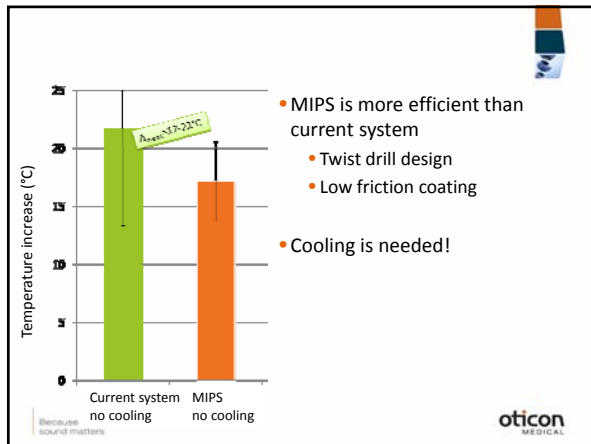
---

---

---

---

---




---

---

---

---

---

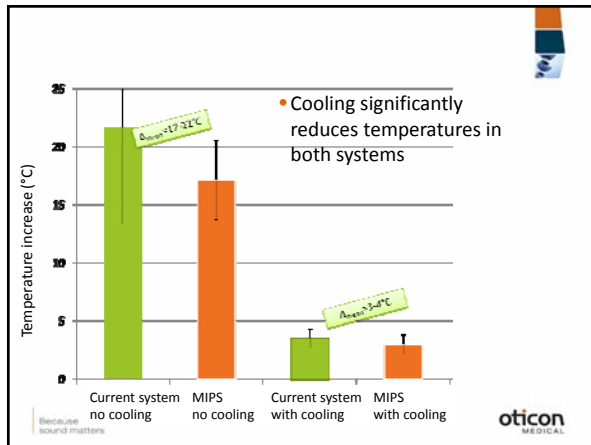
---

---

---

---

---




---

---

---

---

---

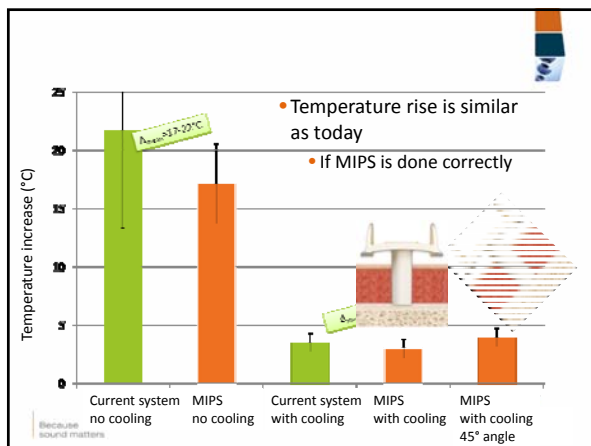
---

---

---

---

---




---

---

---

---

---

---

---

---

---

---



### Drill temperature tests

#### Conclusion

- MIPS with cooling is comparable to today's situation
- Take away for "how to do it"
  - Consider angle of patient's head
  - Fill cannula prior to each drill step
  - Continue flushing – there is no such thing as too much
  - Stop drilling immediately when reaching stop
  - Flush it directly after drilling

Because sound matters **oticon** MEDICAL

---

---

---

---

---

---

---

---

### Drill efficiency



Because sound matters **oticon** MEDICAL

---

---

---

---

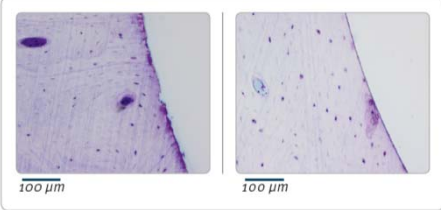
---

---

---

---

### Bone-to-implant interface



Because sound matters **oticon** MEDICAL

Figure 7. Histological slides of drill sites from bovine compact bone (tibia) using the classic drill system (left panel) compared to the cannula drills (right panel). An uneven edge with micro-fractures was present with the classic Ponto drills. In comparison, the MIPS drilling protocol provided a clean cut edge of the bone.

---

---

---

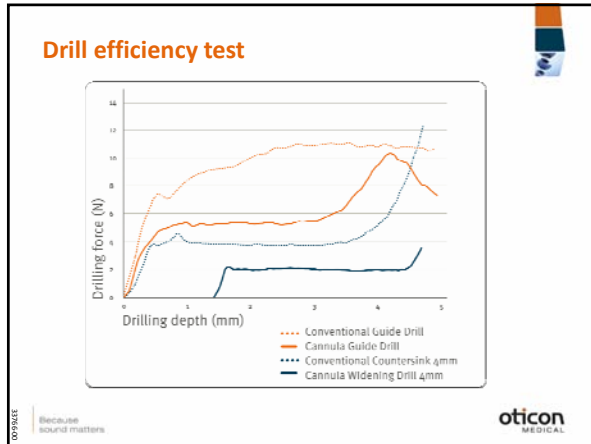
---

---

---

---

---




---

---

---

---

---

---

---

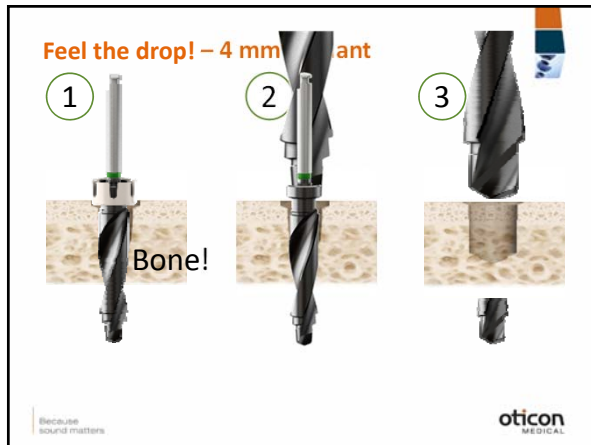
---

---

---

---

---




---

---

---

---

---

---

---

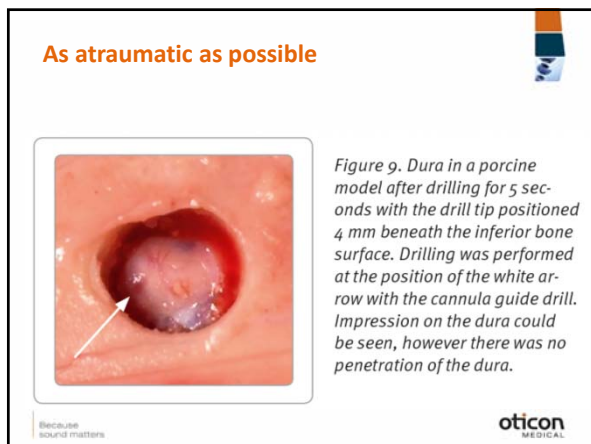
---

---

---

---

---




---

---

---

---

---

---

---

---

---

---

---

---



---

---

---

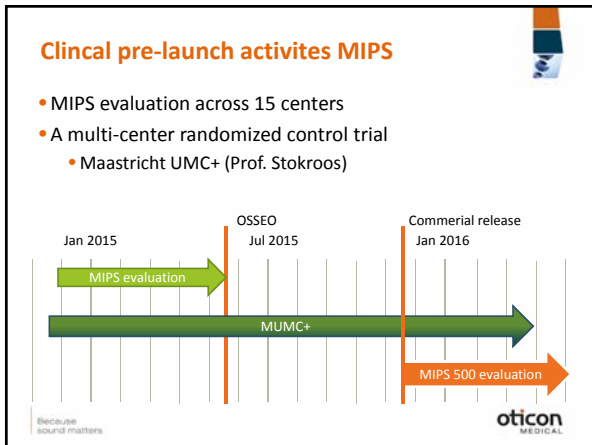
---

---

---

---

---



---

---

---

---

---

---

---

---



---

---

---

---

---

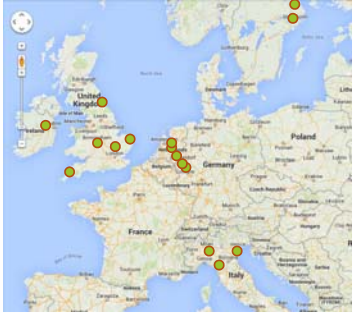
---

---

---

### MIPS Evaluation

15 centers across 6 countries



Because sound matters

oticon MEDICAL

---

---

---

---

---

---

---

---

### Design & Patients

- Case series design
  - Adult patients eligible for single-stage surgery
  - Follow-up scheme according to local clinical practice
- 21 surgeons across 15 centers

BAHS surgeries per Year

Category	Percentage
< 5	5%
5 - 10	16%
10 - 20	32%
> 20	47%

Surgical technique used

Category	Percentage
Linear incision with tissue reduction	10%
Punch only	5%
Linear incision with tissue preservation	74%
Other	11%

Because sound matters

oticon MEDICAL

---

---

---

---

---

---

---

---

### Intra-operative Results



Because sound matters

oticon MEDICAL

---

---

---

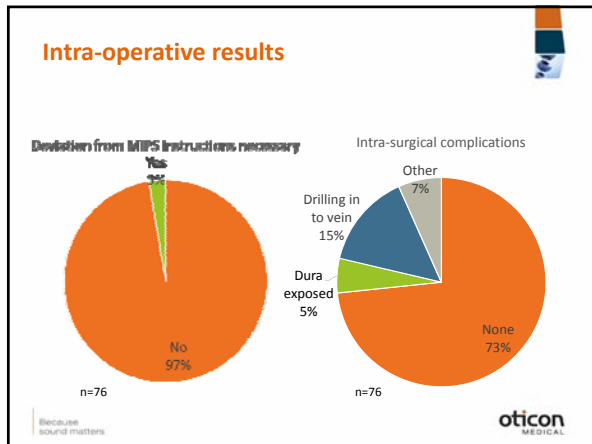
---

---

---

---

---




---

---

---

---

---

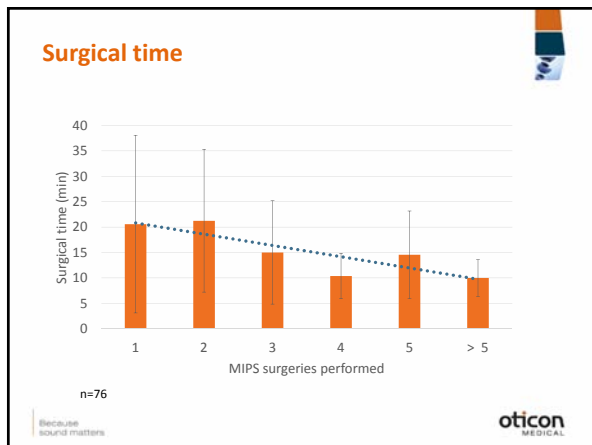
---

---

---

---

---




---

---

---

---

---

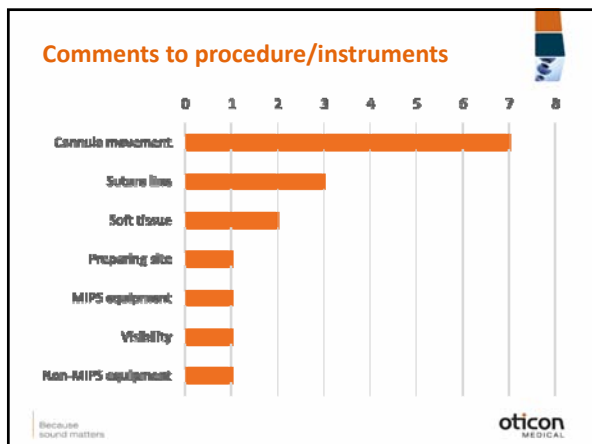
---

---

---

---

---




---

---

---

---

---

---

---

---

---

---

**The Surgeons' View**



Because sound matters oticon MEDICAL

---

---

---

---

---

---

---

---

**First 5 Patients in Multi-center RCT  
1 week post-op results**



Because sound matters oticon MEDICAL

Calon et al. (Osseo, 2015)

---

---

---

---

---

---

---

---

**Summary**  
**Result of first 77 surgeries**

- There is a learning curve
  - From a visual...
  - ... to a primarily tactile surgery
- Results are very encouraging
  - Few intra-operative complications
  - Excellent healing
  - Good starting point for long-term success
- Surgeons are happy...
  - ... and feel they help the patients is a better way

Because sound matters oticon MEDICAL

---

---

---

---

---

---

---

---

### Acknowledgements



Addenbrook's Hospital	Cambridge, UK	Mr. James Tysome
Akademiska Sjukhuset	Uppsala, Sweden	Karin Strömbeck
Careggi University Hospital	Florence, Italy	Dr. Vannucchi
Dominikus Krankenhaus	Düsseldorf, Germany	Dr. med. Claus Cantus,
Gruppo Otologico	Piacenza, Italy	Dr. Caruso; Dr. Giannuzzi
Isala Klinieken	Zwolle, The Netherlands	Dr. Rik Lutgert
James Cook University Hospital	Middlesborough, UK	Mr. Anirvan Banerjee
Karolinska University Hospital	Stockholm, Sweden	Prof. Malou Hultcrantz
Krankenhaus Maria Hilf	Mönchengladbach, Germany	Prof. Dr. med. Jochen Windfuhr
Ospedale Civile	Venice, Italy	Dr. Bordin
MUMC+	Maastricht, The Netherlands	Prof. Robert Stokroos
		Janny Hof; Jan Wouter Brunings; Joost van Tongeren
		Marc van Hoof; Tim Calon
Norfolk and Norwich University Hospital	Norwich, UK	Mr. Junaid Hanif
Queen Elizabeth Hospital	Birmingham, UK	Ms. Rupan Banga
Radboud University Medical Centre	Nijmegen, The Netherlands	Dr. Myrthe Hol; Dr. Emmanuel Mylanus
		Chrisje den Besten
Torbay Hospital	Devon, UK	Mr. Shyam Singam
Tullamore General Hospital	Tullamore, Ireland	Mr. Savage Jones; Ms. Theresa Frawley

Because sound matters



---

---

---

---

---

---

---

---

---

---

### Summary



- Bone anchored implants indicated for
  - Mixed/conductive losses
  - Single-sided deafness
  - Some medical conditions
- MIPS: *Minimally Invasive Ponto Surgery*
  - Single-stage patients, i.e. where the implant and abutment are place at once
    - Typically adult patients with normal bone quality
  - New instruments designed for minimal trauma
  - Suturefree and scar-less surgery!

Because sound matters



---

---

---

---

---

---

---

---

---

---