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

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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.
Pathway to bone anchored treatment

Identify potential patients
Pre-operative evaluation
Operation
Fitting

Bone anchored hearing solutions

Sounds are converted to vibrations, which the skull transmits directly to the inner ears.

Bone anchored hearing solutions

Bone conduction hearing threshold (BC) (inner ear)

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

The vibrations bypass the outer and middle ear.
Candidates for bone anchored hearing solutions

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

Candidates

Conductive
Mixed HL

Typical diagnosis:
- Chronic otitis media
- Congenital malformation of outer ear (microtia)
- Otosclerosis
- ....

without/with an inner ear hearing loss

Traditional HA versus bone anchored HA

Traditional HA
Bone anchored HA
Bone anchored sound processor

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

Traditional HA versus bone anchored HA

Traditional HA

• Need high gain.
  \[\text{gain(BC) + gain(ABG)}\]

Bone anchored HA

• Need little gain.
  \[\text{gain(BC)}\]
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

Potential candidates for Ponto

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

Candidates for bone anchored hearing solution

- Conductive & mixed hearing losses
- Single-sided deafness
The only functioning cochlea is ‘receiving’ sounds from both sides.

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
  - …

Candidates for Ponto sound processors

Single-sided deafness

- Average hearing threshold better than 20 dB HL
  - Sudden deafness
  - Acoustic neuroma
  - …
Summary: Candidates

Conductive and mixed HL

Single-sided deafness

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

Other medical background:
- Skin allergies in ear canal

Close to normal hearing in best ear

Background and the MIPS surgical components

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
Introduction

Brief MIPS history

How Is MIPS Performed?
MIPS – Minimally Invasive Ponto Surgery

1. Punch hole with 5mm punch

MIPS – Minimally Invasive Ponto Surgery

2. Insert cannula

MIPS – Minimally Invasive Ponto Surgery

3. Drill through cannula
MIPS – Minimally Invasive Ponto Surgery

4. Remove cannula and insert implant

MIPS – Minimally Invasive Ponto Surgery

5. Healing cap & dressing

MIPS Tailor-made Surgical Components
Cannula

- Hard stop
- Guide direction
- Hold cooling fluid
- Protect soft tissue

Cannula Drills

- Spacer
- Cannula Guide drill
- Cannula Widening drill

Cannula Drills

- Bone chip removal & Cooling
- Tactile guidance
- Countersinking
- Twist drills & Low-friction coating
Implant Installation
Ensure full installation
Guide alignment
Insertion indicator

Soft healing cap
Open interface
Soft material
Resilient design

MIPS Surgery Kit, 4mm
Cannula
Cannula guide drill
Cannula widening drill, 4mm
Soft healing cap
Patient Selection

• Minimally invasive Ponto surgery (MIPS) is a single-stage surgery.

• Same patient groups as for single-stage surgery in current manual:
  • Adult patients with normal bone quality and thickness
  • Children suitable for single-stage surgery;
    • Normal bone quality and a bone thickness above 4 mm
    • Typically 12 years or older
  • Skin thickness equal to or less than 12 mm

Video time!
MIPS
Pre-clinical Results

White paper available

New drill system

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

Drill temperature tests

What’s happening when drilling?

Max temperature is what might kill bone cells.
MIPS is more efficient than current system
- Twist drill design
- Low friction coating
- Cooling is needed!

Cooling significantly reduces temperatures in both systems

Temperature rise is similar as today
- If MIPS is done correctly
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

Drill efficiency

Bone-to-implant interface

Figure 1. Histological slides of drill sites from bovine compact bone (tibia) using the classic drill system (left panel) compared to the console drills (right panel). An uneven edge with micro-fractures was present with the classic Panta drills. In comparison, the MIPS drilling protocol provided a clean cut edge of the bone.
Drill efficiency test

Feel the drop! – 4 mm implant

1. [Image]
2. [Image]
3. [Image]
Bone!

As atraumatic as possible

Figure 9. Dura in a porcine model after drilling for 5 seconds with the drill tip positioned 4 mm beneath the inferior bone surface. Drilling was performed at the position of the white arrow with the cannula guide drill. Impression on the dura could be seen, however there was no penetration of the dura.
MIPS Clinical Results

Clinical pre-launch activities MIPS

- MIPS evaluation across 15 centers
- A multi-center randomized control trial
  - Maastricht UMC+ (Prof. Stokroos)

Jan 2015  OSSEO  Jul 2015  MUMC+  Jan 2016
MIPS evaluation  OSSEO  MUMC+  MIPS 500 evaluation  Commercial release

MIPS Evaluation
MIPS Evaluation
15 centers across 6 countries

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

Intra-operative Results
Intra-operative results

Intra-surgical complications

Surgical time

Comments to procedure/instruments
The Surgeons’ View

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

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
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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 placed at once
    • Typically adult patients with normal bone quality
    • New instruments designed for minimal trauma
    • Suture-free and scar-less surgery!