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Audiology Online Webinar

2:00pm EST April 19, 2023

Minimally invasive surgical procedures for percutaneous bone conduction devices: A review of recent research

Nicole Amichetti, PhD, MS

NITC@oticonmedical.com



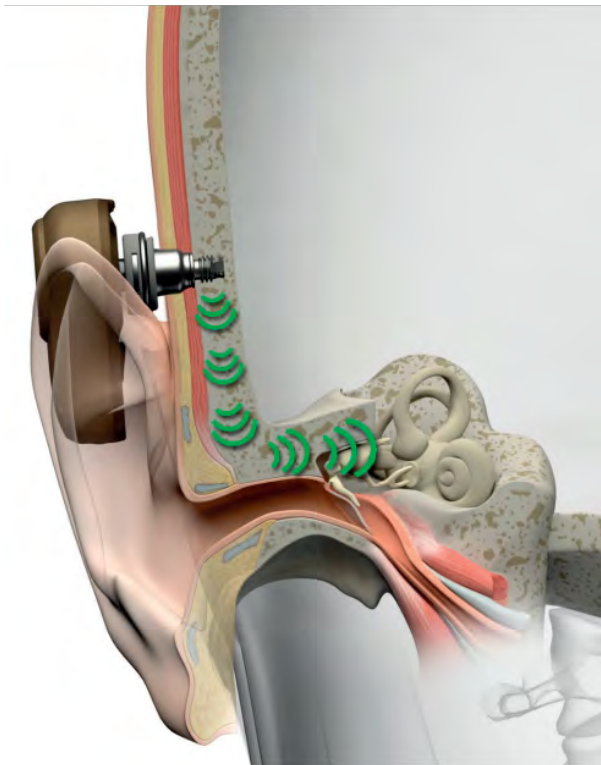
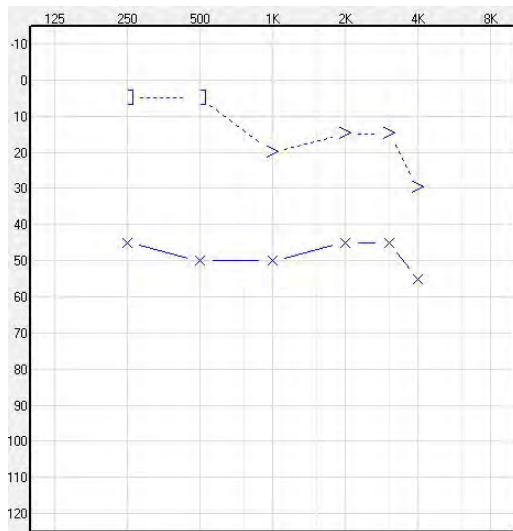
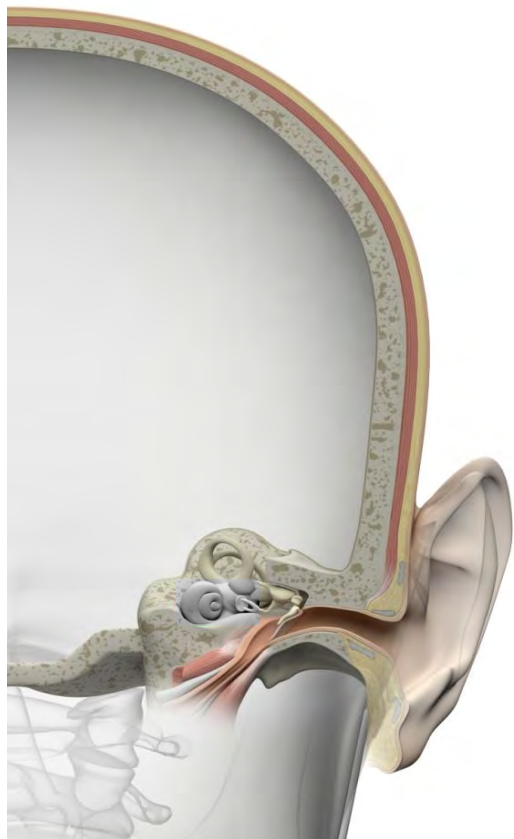
Learning Outcomes

Introductory level

- After this course, participants will be able to describe surgical outcomes in terms of skin reactions and appearance for minimally invasive percutaneous surgery (MIPS) and linear incision (LT) techniques.
- After this course, participants will be able to describe differences in cost between MIPS and LT techniques.
- After this course, participants will be able to describe the feasibility of safety of using the MIPS technique in an in-office setting.

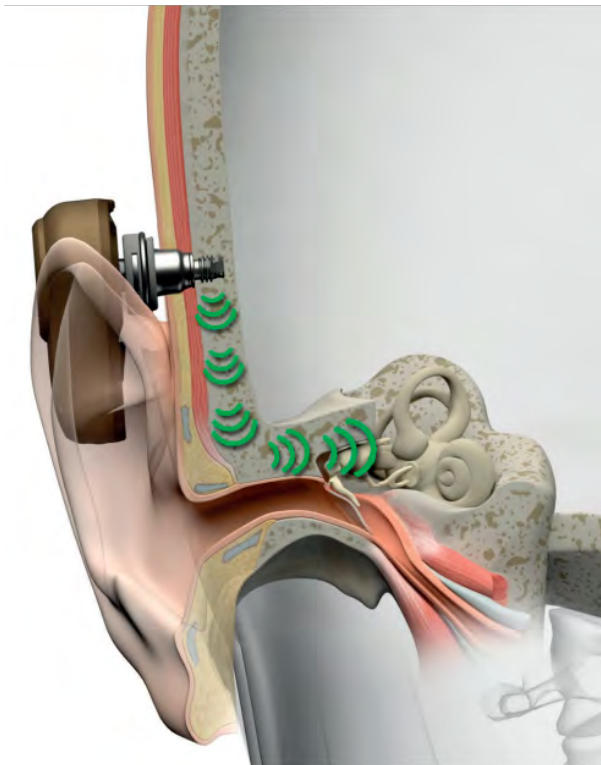
Bone Anchored Hearing Systems (BAHS)

A brief overview



Bone Anchored Hearing Systems (BAHS)

A brief overview



BAHS procedures

Linear incision

with tissue reduction/Skin flap technique



2010

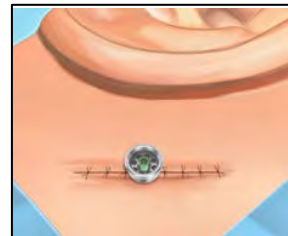
Linear incision

with tissue preservation

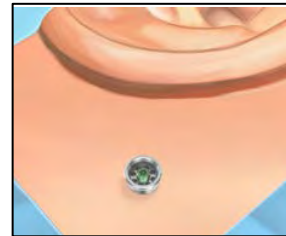
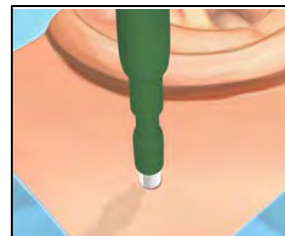


2012

Linear incision with tissue preservation



Biopsy punch technique

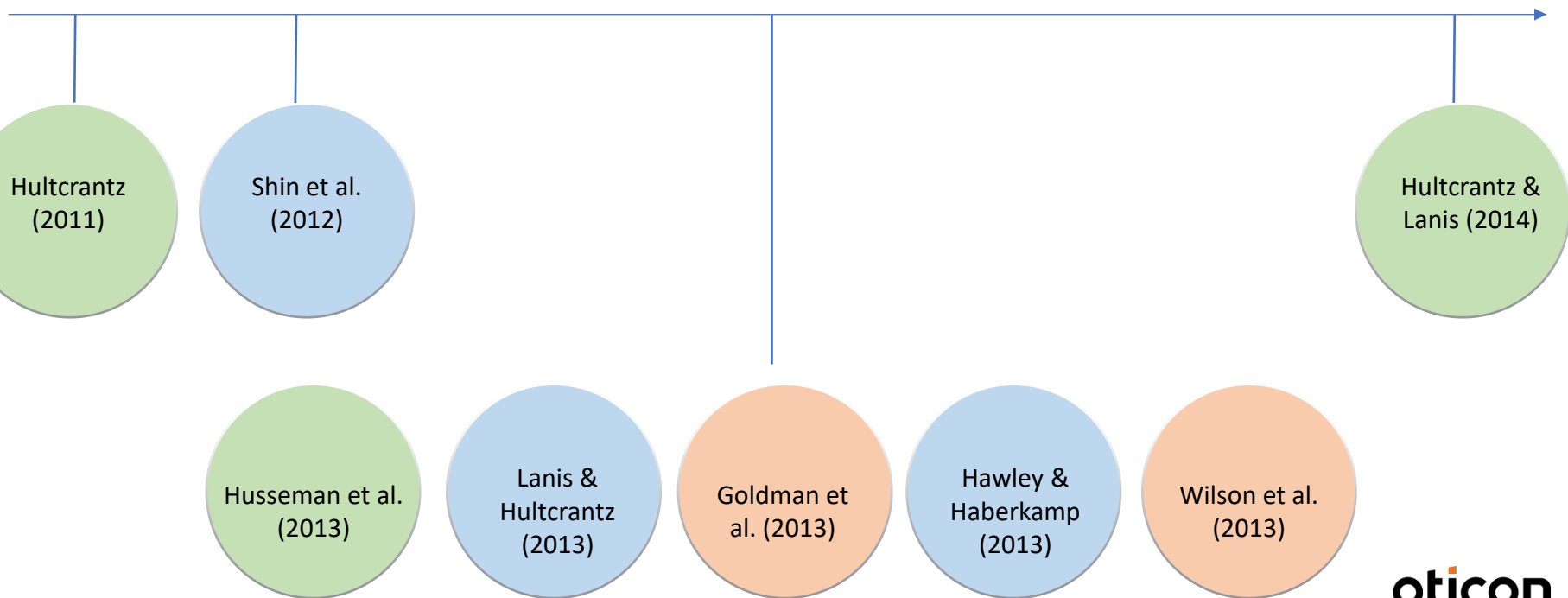


Linear Incision with tissue preservation and biopsy punch techniques – 2011-2014

Adult patients, linear incision

Adult patients, punch technique

Pediatric patients



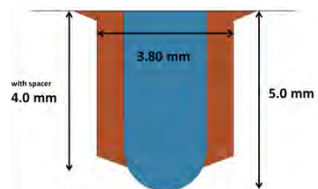
Reinventing BAHS procedures

2015 and onwards

Linear incision
with tissue reduction/Skin flap
technique



2010



Linear incision
with tissue preservation

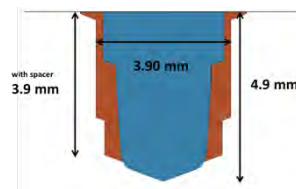


2012

MIPS procedure



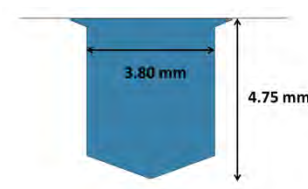
2015



MONO procedure



2021



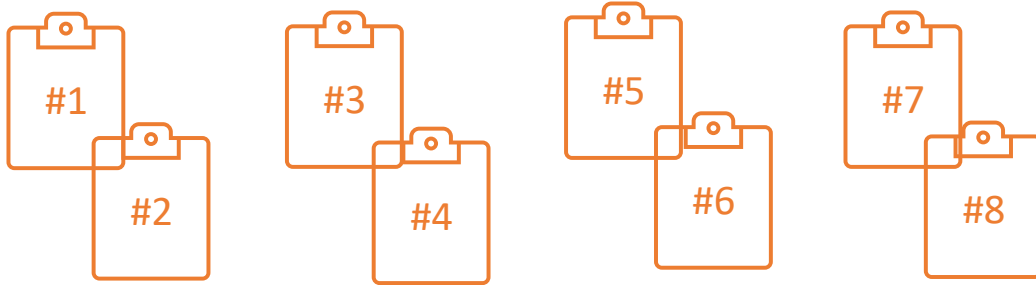
Guide hole



Widening hole

oticon
MEDICAL

Recent investigations



<u>Grade</u>	<u>Description</u>
--------------	--------------------

- | | |
|---|--|
| 0 | Normal skin around the abutment |
| 1 | Redness around the abutment |
| 2 | Redness, moistness and moderate swelling |
| 3 | Redness, moistness and moderate swelling with tissue granulation around the abutment |
| 4 | Signs of infection resulting in removal of the implant |

Surgical and audiological outcomes of BAHS surgery performed by the *same surgeon* using either the punch technique or tissue-preserving linear incision technique

Study Design:

- Retrospective cohort, BAHS placement between 2012-2019

Patient Population:

- 22 adult and pediatric patients
- 13 punch technique, 9 Linear Incision

Outcome Measures:

- Perioperative and postoperative complications, surgical time, postoperative audiological results, and patient reported satisfaction

Surgical and audiological outcomes of BAHS surgery performed by the *same surgeon* using either the punch technique or tissue-preserving linear incision technique

Results:

- Surgery duration
 - Punch technique, mean 9.7 ± 2.9 minutes
 - Linear technique, mean 47.7 ± 6.1 minutes $P < 0.001$
- Complications
 - No significant difference between groups
- Audiological results
 - No significant differences between groups pre-op or post operative thresholds. Post-operative thresholds significantly higher post-operative for both groups.
- Patient satisfaction
 - No significant differences between groups on GBI scores



Punch technique



Tissue-preserving linear incision

A retrospective review, comparing MIPS and linear incision with tissue preservation

Study Design:

- Retrospective review, BAHS placement between 2014-2019
- Follow-up timepoints: 15 days post procedure, between 1 -2 months post (SP loaded), distant follow-up point:
- LT group average follow-up time 42 months, MIPS group average 14 months

Patient Population:

- 48 Adult patients (19 – 81 years of age)
- 35 MIPS procedure, 13 Linear Incision

Outcome Measures:

- Surgical duration, intraoperative complications, implant survival, and incidence of skin reactions

A retrospective review, comparing MIPS and linear incision with tissue preservation

Results:

- Surgery duration
 - MIPS group, mean 15 $\pm$ 6 minutes (range: 7-25) P<0.001
 - Linear group, mean 36 $\pm$ 10 minutes (range: 27-62)
- Intraoperative complications and implant survival
 - No surgical complications reported in either group
 - No implant losses in either group
- Soft tissue reactions
 - 7.7% for Linear group (1 patient with Holger's score of 3), 0% MIPS at first follow-up
 - No reactions reported on subsequent follow-ups

A multi-center randomized control study: comparing surgical outcomes between MIPS and Linear Incision with tissue preservation



Study Design:

- Randomized control trial
- 22-month follow-up period

Patient Population:

- 64 patients, 1:1 randomization to each group

Outcome Measures:

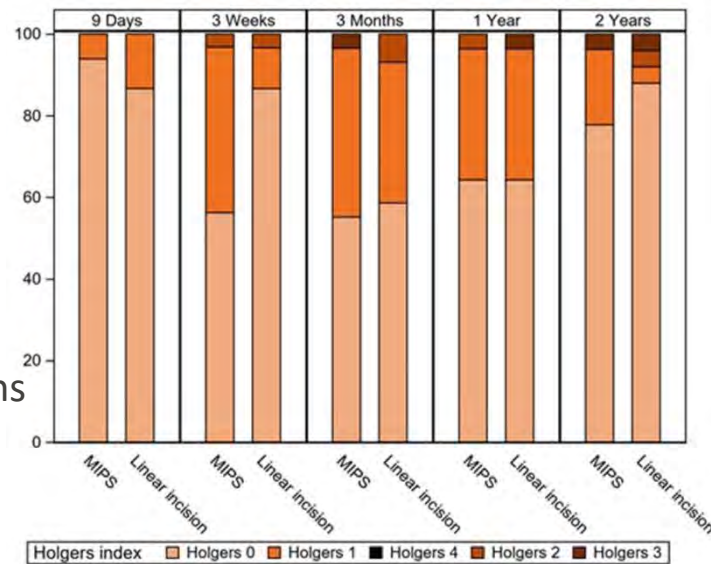
- incidence of soft tissue reactions, reported pain, numbness, cosmetic outcomes, and implant survival

A multi-center randomized control study: comparing surgical outcomes between MIPS and Linear Incision with tissue preservation

#3

Results:

- Soft tissue reactions
 - no difference in adverse reactions (Holger's ≥ 2)
- Reported pain / numbness
 - No difference in reported pain
 - Significantly less numbness in MIPS group first three months
- Cosmetics
 - Significantly better in MIPS group at 3 months and 1 year
- Implant loss
 - 5 extrusions MIPS, 1 Linear (n.s.)



Comparing intra- and postoperative outcomes between the standard linear incision with tissue preservation and the Minimally Invasive Ponto Surgery (MIPS)



Study Design:

- Retrospective cohort study, BAHS placement 2013-2018

Patient Population:

- Adult and pediatric patients
- 21 MIPS, 31 Linear Incision (same surgeon)

Outcome Measures:

- implant survival, operative time, anesthesia use, intra and postoperative complications, soft tissue tolerability, and implant stability.

Comparing intra- and postoperative outcomes between the standard linear incision with tissue preservation and the Minimally Invasive Ponto Surgery (MIPS)

Results:

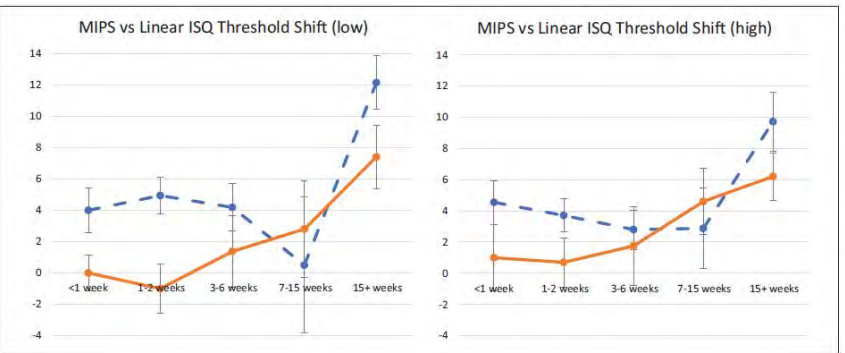
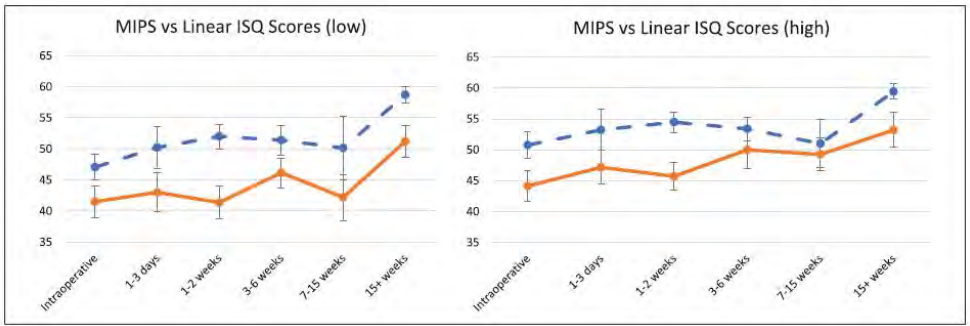
- Implant survival
 - no losses reported
- Intra and postoperative complications
 - none reported
- Anesthesia use
 - local anesthesia 67% MIPS, 16% Linear Incision
- Operative time
 - mean 29min MIPS, 69min Linear $p=0.007$
- Soft tissue reactions

Holgers Classification	MIPS (n)	Linear (n)
Grade 1: light redness and slight swelling	26	23
Grade 2: redness and swelling	9	9
Grade 3: redness, swelling, moistness, and slight granulation tissue	1	5
Grade 4: redness, swelling, moistness, granulation tissue, and infection	0	1

Comparing intra- and postoperative outcomes between the standard linear incision with tissue preservation and the Minimally Invasive Ponto Surgery (MIPS)

Results:

- implant stability
 (Resonance Frequency Analysis)
 17 MIPS
 8 linear



5 Year outcomes of the linear incision technique with soft tissue reduction (LIT-TR) compared with a linear incision technique with soft tissue preservation (LIT-TP) technique

Study Design:

- Prospective single follow-up visit, 5 years after BAHS implantation for patients (n=39) who had completed the follow-up of two previously published studies^{1,2}

Patient Population:

- Adults (mean age 51.5 LIT-TP, 53.9 LIT-TP)
- 25 LIT-TP, 25 LIT-TR

Outcome Measures:

- implant survival, soft tissue status, skin height, skin sensitivity around the abutment, and subjective numbness were assessed.

5 Year outcomes of the linear incision technique with soft tissue reduction (LIT-TR) compared with a linear incision technique with soft tissue preservation (LIT-TP) technique

#5

Results (at 5 years):

- Implant survival
 - Not significantly different
- Soft tissue reactions
 - Not significantly different
- Skin height and sensitivity
 - Not significantly different
- Subjective numbness
 - Not significantly different

Comparing outcomes of MIPS and Linear incision with no soft tissue removal



Study Design:

- Retrospective cohort study
- EMR review of BAHS placement August 2015 and April 2018
- Follow-up period: visits at 7 days, 30 days, 12 months and 18 months post surgery

Patient Population:

- Adult (17 MIPS, 19 Linear) and pediatric (5 MIPS, 5 Linear) patients
- 22 MIPS, 24 Linear Incision with no soft tissue removal

Outcome Measures:

- The presence/severity of localized skin reaction, cosmetic outcomes, number of revision surgeries needed, incidence of adverse events, device utilization and postoperative SRTs

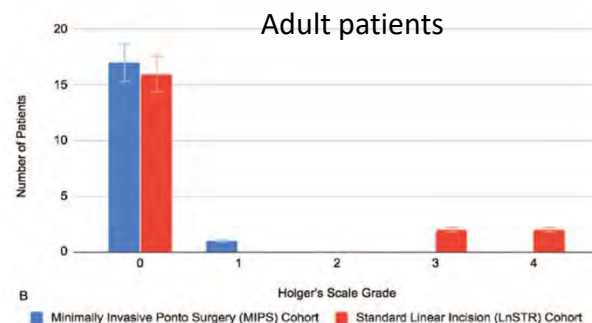
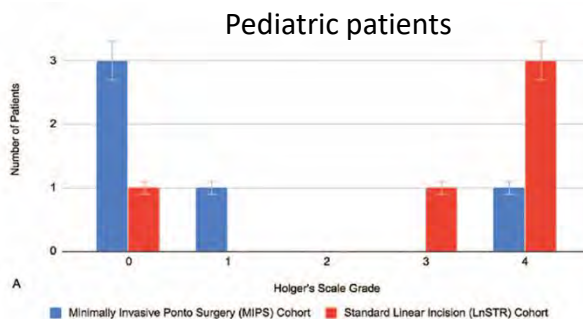
Comparing outcomes of MIPS and Linear incision with no soft tissue removal



Results:

p=0.026

- Skin reactions
 - MIPS group, 4.5%
 - Linear group, 33.3%



- Cosmetic Outcome
 - Poorer outcomes less in MIPS group (9.1%) than linear (20.8%) p=0.005
- Revision surgery
 - Fewer revisions in MIPS (13.6%) than linear (21%) p=0.008
- Adverse events, device usage, and SRTs
 - All were comparable between groups

minimally invasive procedures

Surgery → Procedure

- Looking ahead to reduce financial and resource costs
- Looking ahead to expand access to procedure for BAHS

The hospital factor

- We only have so much OR time

The economic factor

- The costs related to the surgery are the largest of the treatment costs

Direct cost comparison of minimally invasive punch technique versus traditional approaches for percutaneous bone anchored hearing device



Study Design:

- A retrospective direct cost comparison of MIPS and open approaches in Canada

Patient Population:

- 12 adult patients operated on by the same surgeon as day case procedures
- MIPS procedures done out of OR; open approaches done in OR

Outcome Measures:

- Direct costs considering time, staff and equipment needs

Direct cost comparison of minimally invasive punch technique versus traditional approaches for percutaneous bone anchored hearing device

#7

Results:

- The mean time for the MIPS procedure was 5min55s and 1 hour7 min for the open approaches
- The MIPS technique produced a \$456.83 total cost saving when compared to open approaches

Procedure type	HCP	Number of HCP	Hourly wage (\$/h)	Hours	Total cost (\$)
MIPS	Nurse	1	44.72	0.10	4.41
	Surgeon	1	140.00	0.10	13.81
	Total Provider Cost				18.22
Open/Incision	Nurse	3	44.72	1.13	151.60
	Surgeon	1	140.00	1.13	158.20
	Anaesthesiologist	1	125.00	1.13	141.25
	Total Provider Cost				451.05

Feasibility and safety of minimally invasive technique in the in-office setting



Study Design:

- Single institution case series
- Veterans Affairs Northern California Healthcare System
- 11-month follow-up period

Patient Population:

- 20 patients in-office BAHS placement with MIPS from 2018 to 2021

Outcome Measures:

- Total procedure time and patient reported satisfaction with procedure

Feasibility and safety of minimally invasive technique in the in-office setting



Results:

- 5-minute reduction in procedural time in the clinic vs the OR
- Intraoperative complication rates were similar to/ better than those described in the literature
- No adverse skin reactions; 2 patients experienced a mild skin reaction
- Four (4) implant losses, all due to trauma
- 14/20 patients completed the questionnaire, and all indicated that they would be willing to undergo the procedure again and would recommend it to someone else

Conclusions: Overall trends and future directions

- Minimally invasive procedures → better outcomes
- Primary outcome measures of implant survival and skin assessments
- Feasibility of in-office procedures and associated financial and resource savings (shift from surgery to procedure)
- Increase knowledge of challenging patient populations (e.g., pediatric populations, older adults, and syndromic patients)

Thank you