

## Short-term results from seventy-six patients receiving a bone-anchored hearing implant installed with a novel minimally invasive surgery technique

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The surgical installation of bone-anchored hearing systems (BAHS) has after decades finally undergone changes towards more minimally invasive techniques without soft tissue thinning.<sup>1–3</sup> Some surgeons are also performing the surgery and installation, using the classical drilling system, through a single punch entry.<sup>4–6</sup>

The minimally invasive Ponto surgery (MIPS) was suggested as a refinement of the tissue preservation techniques.<sup>1</sup> With a custom set of surgical components, the surgery is performed through only a 5-mm circular incision. This report presents the details of this method, the instruments used, key items to address and the short-term follow-up data from centres that evaluated this technique.

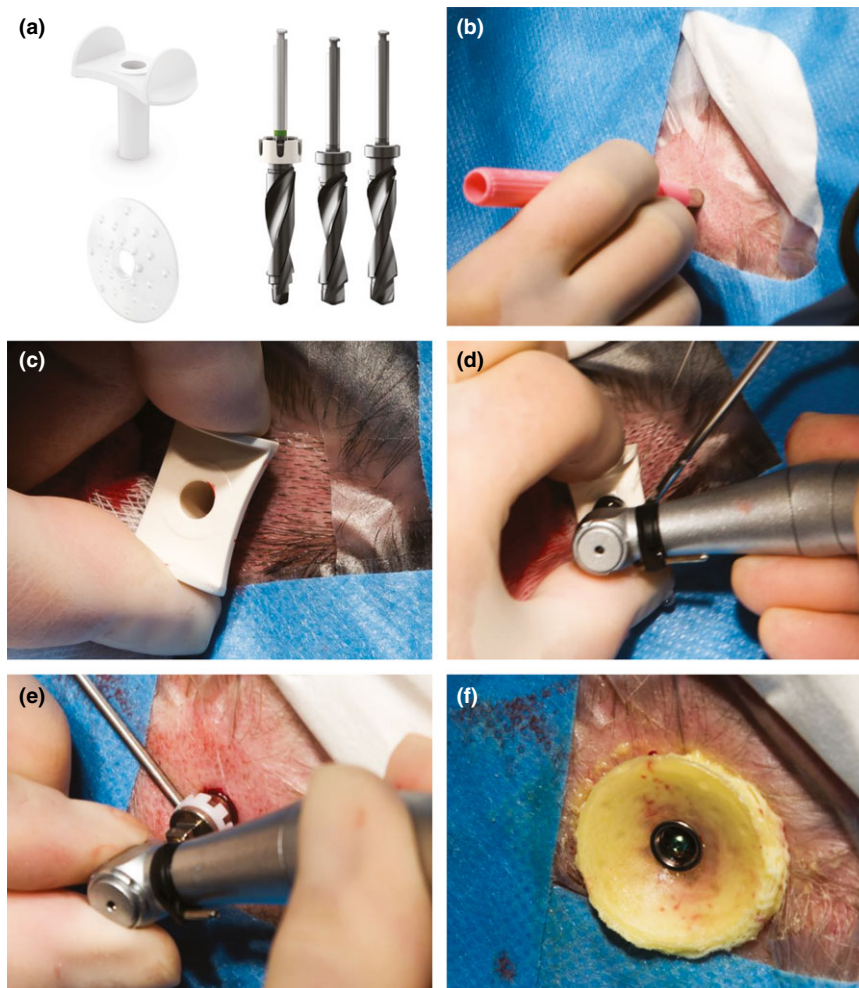
### Patients and methods

This multicentre service evaluation used the wide Ponto implants installed using first-generation MIPS components designed and made available by Oticon Medical AB (Askim, Sweden) (Fig. 1a) in combination with traditional instrumentation for BAHS. All participating surgeons (20

surgeons from 15 centres) were experienced in installing BAHS using classical methods and were provided MIPS training prior to the first surgery. Only adult patients eligible for single-stage bone-anchored surgery were included. Children below the age of 18 were excluded.

All surgeries were performed according to instructions for the MIPS technique. In brief, the site for implant was estimated at 50–55 mm from the ear canal and skin thickness was determined prior to application of local or general anaesthetics. A 5-mm punch biopsy was used for making a circular incision (Fig. 1b). Using a raspatorium, the circularly incised periosteum was carefully removed from the implant site through the incision, before the cannula was inserted (Fig. 1c). Functionally, the cannula limits the depth of drilling, provides adequate cooling and protects the surrounding tissue at the site (Fig. 1d). Step-wise drilling was then performed in the same manner as in classical BAHS surgery. A guide drill was first used with a spacer in place. If careful probing confirmed bone, the spacer was removed and the guide hole deepened to allow implantation of a 4-mm implant. Care must be taken to correctly find the former drill hole with the tip of the drill. The relevant cannula widening drill (for 3- or 4-mm implant) was used to widen the hole. Prior to all drilling steps, the cannula has to be filled with saline, copious amount of saline used during and after drilling to facilitate cooling and removal of bone debris. The

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**Fig. 1.** Minimally invasive Ponto surgery (MIPS) instruments and step-by-step description. The MIPS instrument kit includes a cannula, a cannula guide drill with spacer, cannula widening drills for 3- and 4-mm-long implants, and a soft healing cap, all of which is single use (a). An incision is made using a 5-mm biopsy punch (b). A raspatorium is used to ensure that all soft tissue and periosteum are removed around the surgical site. The cannula is then inserted (c). The drilling steps are performed through the cannula (d). The cannula is removed, and the implant installation is performed through the circular incision (e). Finally, a soft healing cap is attached to the abutment and a suitable dressing applied (f).

cannula was held in place to prevent the skin from retracting while the implant was being prepared, and was removed immediately before implant installation (Fig. 1e). Finally, the soft healing cap was attached to the outside of the abutment with a suitable dressing (Fig. 1f). The healing cap was removed at the surgical follow-up visit (7–10 days post-surgery).

Details of the surgical procedure were collected and included surgery time, deviations from instructions and intra-operative events. Postoperative outcome from the first two follow-up visits were recorded using measures routinely collected for bone-anchored hearing implant, such as sensory outcome, complications, treatments and implant loss. Skin reactions were registered according to Holgers classification.<sup>7</sup>

### Ethics

Ethical committee approval was not required for this service evaluation.

### Results

Seventy-seven implants were installed in 76 adult patients. Baseline demographic information and implant configurations used are shown in Table 1.

### Intra-operative results

Majority of the surgeries, 75/77 (97.4%), followed the MIPS protocol with the exception of two cases, where conversion

**Table 1.** Patient demographics, baseline characteristics and devices used ( $n = 76$  patients,  $n = 77$  implants)

Parameter	Proportion
Gender, $n$ (%)	
Female	40 (52.6)
Male	36 (47.4)
Age, $n$ (%)	
18 < 50	19 (25.0)
50–75	50 (65.8)
>75	7 (9.2)
Skin thickness, mean (SD, Range)	6.3 mm (1.7, 3–12 mm)
Implant length, $n$ (%)	
3 mm	1 (1.3)
4 mm	76 (98.7)
Abutment length, $n$ (%)	
6 mm	3 (3.9)
9 mm	48 (62.3)
12 mm	23 (29.9)
14 mm	3 (3.9)

to a linear incision technique was necessary (Table 2). In 56/77 (72.2%) of the cases, local anaesthesia was used. The mean time for surgery, from skin punch to healing cap, was 16 min (median 13 min). There was a learning curve as there was a statistically significant reduction in surgical time per case with increased numbers of MIPS cases performed by the same surgeon. The average time taken per surgery per surgeon dropped from 21 to 12 min ( $P < 0.001$ ) after performing  $\geq 2$  surgeries.

In 57/77 (74.0%) of the surgeries, no intra-operative events were reported (Table 2). There was an intra-operative CSF leak in one of the cases with exposed dura. The leak

**Table 2.** Intra-operative events reported for 77 minimally invasive Ponto surgery procedures

Intra-operative events	$n$ (%)
None	57 (74.0%)
Dura mater exposed	3 (3.9%)
CSF leak	1 (1.3%)
Temporarily some bleeding from the bone	11 (14.3%)
Punching over suture line visually confirmed*	4 (5.2%)
Low ISQ <sup>†</sup>	1 (1.3%)

\*Suture line was detected at the planned implant site in four surgeries. In three of these cases, a new implant position was chosen either by repositioning the cannula and drilling site (one case) or by exposing the bone with an incision (two cases). In the fourth case, the implant was successfully installed in the suture line.

<sup>†</sup>ISQ at surgery was measured in 32 of the 77 cases. The case with low primary ISQ value was lost within a week after surgery.

occurred while assessing the bone at the bottom of the surgical hole by palpation using a dissector and was sealed by installing the implant.

### Post-surgical results

Postoperative results were collected from a total of 160 follow-up visits. At the time of analysis, median time following surgery was 34 weeks (range 20–49 weeks).

Patients received their first follow-up at a median time of 7 days (range 2–12 days) after surgery. At this visit, 61/76 (80.3%) of the wounds were healed with no swelling, moistness nor crusting around the abutment (Fig. 2). The timing of the second visits varied and was recorded at a median of 5 weeks postoperatively (range 1.0–19.7 weeks) with excellent cosmetic results (Fig. 2).

Implant survival was 74/77 (96.1%) with three implant losses recorded. One loss occurred within the first week after surgery and was related to low primary stability (determined by implant stability quotient, ISQ (Osstell, Göteborg, Sweden)) presumably caused by an incorrect drilling procedure where the widening of the hole was performed offset to the guide hole resulting in an oversized osteotomy. One implant was lost spontaneously 8 weeks after surgery. This was the same patient that experienced a mild CSF leak. The potential relation between implant loss and CSF leak remains unclear. The third implant loss occurred after 15 weeks following prolonged inflammation around the implant site.

The rate of adverse soft tissue reactions (Holgers  $\geq 2$ ) was 5.0% (eight of 160 visits) and 9.2% (seven of 76 implants) per visit and per implant, respectively (Table 3). These data include the two cases of Holgers 3 which were resolved with local treatment. At the first follow-up and second consultation, sensation of numbness was reported by the patient in two of 74 (2.6%) and three of 74 (4.1%) of the cases, respectively. For the same follow-up visits, patients reported sensation of pain in six of 76 (7.9%) and eight of 74 (10.8%) of the cases, respectively. Overall, from 160 follow-up visits, numbness and general sensation of pain were found in 3.1% and 9.4%, respectively.

### Discussion

Minimally invasive Ponto surgery is a refinement of tissue preservation and punch-only surgeries previously described.<sup>1,4</sup> In the MIPS technique, the drilling procedure is performed through a cannula and the implant installation is completed through the incision created by a 5-mm biopsy punch.

Tissue preservation surgery has reported shorter surgical time, as well as faster healing compared to classical techniques.<sup>1,3,8</sup> Due to instrumentation and pre-defined





**Fig. 2.** Typical skin status and cosmetic outcome after minimally invasive Ponto surgery. (a) After surgery, (b) at 1st follow-up, 1 week, (c) at 2nd follow-up 3 weeks post-surgery. Images kindly provided by Maastricht UMC+, the Netherlands.

**Table 3.** Distribution of Holgers classification<sup>7</sup> at post-surgery follow-ups ( $n = 160$  visits)

Holgers grade	Follow-up 1 Median 7 days	Follow-up 2 Median 5 weeks	Unplanned visits	Total (%)
0 No irritation	62	60	7	129 (80.6%)
1 Slight redness	14	8	1	23 (14.4%)
2 Red and slightly moist tissue; no granuloma formation	0	4	2	6 (3.8%)
3 Reddish and moist; sometimes granulation tissue	0	2	0	2 (1.3%)
4 Removal of skin-penetrating implant necessary due to infection	0	0	0	0 (0%)

steps, MIPS requires short surgical time, and naturally lends itself to be performed under local anaesthesia. This technique is conducive to fast healing due to minimal soft tissue trauma. Perceived peri-abutment numbness and pain were a subjective dichotomous evaluation made by the patient and therefore subject to a high degree of variability. Nevertheless, the outcomes regarding sensibility were good with few reports of numbness and pain, comparable with short-term data reported previously.<sup>3,8–10</sup> Moreover, no sutures are required and the early cosmetic outcome is promising.

An obvious weakness of the current evaluation is the lack of long-term follow-up on skin reactions and other complications. However, the skin reactions from the short-term follow-up presented here are similar to the results obtained with other tissue preservation techniques.<sup>8,10</sup> Results from randomised controlled MIPS studies with longer follow-up are needed for definitive conclusion.

Overall, implant survival was 96.1% at 20 weeks. The only complication during this evaluation was the occurrence of a CSF leak. This implant was later spontaneously lost. CSF leak is a complication that is considered to occur rarely. However, during MIPS, great care should always be exercised, both for patient selection and during the procedure. It should be noted that conversion to linear incision is strongly recommended in MIPS if complications are encountered or if increased access to the bone bed is warranted. Surgeons should have experience with this classical technique before using MIPS.

The current evaluation also impresses that although MIPS appears to be a simple, safe and straightforward procedure, use of this approach requires advanced clinical experience and surgical judgement. The current evaluation has highlighted a number of steps that need to be followed for the success of the technique. It is important to avoid offsetting the cannula prior to drilling, which may cause tension in the tissue and potential slight dehiscence around the abutment. Movement of the cannula was a major concern for the surgeons as it made step-wise drilling at the same location challenging. This was also identified as the root cause for the implant lost within 1 week after surgery in one of the patients.

We used the results to construct new cannula drills with tactile feedback so that it is easier to find the guide hole to ensure that successive drill steps are performed in perfect alignment and prevent an offset widening. Also, less pressure is required when drilling. Generous flushing of the cannula with saline solution between drill steps improves visibility and ensures proper irrigation, as well as removal of bone debris. Finally, confirmation of the full installation of the implant is advised, either visually or by counting the number of turns the implant engages in the bone.

Comparing techniques that incorporated reduction in the soft tissue, van de Berg et al. concluded that a linear incision technique led to fewer complications compared to the Dermotome and skin graft techniques.<sup>11</sup> The hypothesis is that less invasive techniques lead to better long-term outcomes. Tissue preservation surgery, where the soft tissue

is kept intact around the implant, was first reported in 2011.<sup>12</sup> Overall, the medium-to-long-term results of tissue preservation surgery are promising with skin reactions at least similar to control groups, and benefits including less numbness and more cosmetically pleasing outcomes being commonly reported.<sup>1,3,9,10</sup> This multicentre evaluation reported here demonstrates, short-term, similar positive outcomes for MIPS.

## Conclusion

MIPS is a minimally invasive surgery to place Ponto bone-anchored hearing implants. The first evaluation of the system is encouraging with few intra-operative complications, short surgery time, excellent healing and good short-term results regarding soft tissue reactions and implant survival. Cosmetically, this technique leaves the soft tissue and hair around the implant intact. Based on the preliminary results, the MIPS instruments have been further improved and a further evaluation is in progress. Long-term follow-up will be needed to compare the outcomes of this technique to other surgical techniques with tissue preservation.

### Keypoints

- Several studies have reported encouraging outcomes with bone-anchored hearing implants and tissue preservation techniques, where no or limited subcutaneous tissue is removed around the implant.
- Minimally invasive Ponto surgery (MIPS) is a modification of the punch-only surgical technique, presently trialled and advocated in adults only.
- A new custom set of surgical components have been developed to protect the soft tissue during drilling and facilitate cooling.
- Surgery is performed through only a 5-mm circular incision with minimal soft tissue trauma.
- This first multicentre evaluation reveals few intra-operative events and excellent healing.

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## Conflict of interest

Johansson, ML. and Jonhede, S. are under the employment of Oticon Medical AB. Holmberg, M. was previously under

the employment of Oticon Medical AB. Hultcrantz, M. and Cremers, CW are consultants for Oticon Medical AB. Mylanus, E. and Hol, M. report financial support to their authors' institution for conducting two clinical studies from Oticon Medical AB (Askim, Sweden) and from Cochlear Bone Anchored Solutions AB (Mölnlycke, Sweden), outside the submitted work. Remaining authors declare no conflict of interest.

## References

- 1 Hultcrantz M. & Lanis A. (2014) A five-year follow-up on the osseointegration of bone-anchored hearing device implantation without tissue reduction. *Otol. Neurotol.* **35**, 1480–1485
- 2 Singam S., Williams R., Saxby C. *et al.* (2014) Percutaneous bone-anchored hearing implant surgery without soft-tissue reduction: up to 42 months of follow-up. *Otol. Neurotol.* **35**, 1596–1600
- 3 den Besten C.A., Bosman A.J., Nelissen R.C. *et al.* (2016) Controlled clinical trial on bone-anchored hearing implants and a surgical technique with soft-tissue preservation. *Otol. Neurotol.* **37**, 504–512
- 4 Wilson D.F. & Kim H.H. (2013) A minimally invasive technique for the implantation of bone-anchored hearing devices. *Otolaryngol. Head Neck Surg.* **149**, 473–477
- 5 Gordon S.A. & Coelho D.H. (2015) Minimally invasive surgery for osseointegrated auditory implants: a comparison of linear versus punch techniques. *Otolaryngol. Head Neck Surg.* **152**, 1089–1093
- 6 Dumon T., Medina M. & Sperling N.M. (2016) Punch and drill: implantation of bone anchored hearing device through a minimal skin punch incision versus implantation with dermatome and soft tissue reduction. *Ann. Otol. Rhinol. Laryngol.* **125**, 199–206
- 7 Holgers K.M., Tjellstrom A., Bjursten L.M. *et al.* (1988) Soft-tissue reactions around percutaneous implants – a clinical-study of soft-tissue conditions around skin-penetrating titanium implants for bone-anchored hearing-aids. *Am. J. Otol.* **9**, 56–59
- 8 Johansson L.M., Holmberg M. & Hultcrantz M. (2014) *White paper: bone anchored hearing implant surgery with tissue preservation – a systematic literature review (M52107, Oticon Medical, Sweden)*. Retrieved from Research Gate. doi:10.13140/RG.2.1.1205.5761
- 9 Hogsbro M., Agger A. & Johansen L.V. (2015) Bone-anchored hearing implant surgery: randomized trial of dermatome versus linear incision without soft tissue reduction-clinical measures. *Otol. Neurotol.* **36**, 805–811
- 10 Mowinckel M.S., Moller M.N., Wielandt K.N. *et al.* (2016) Clinical outcome of a wide-diameter bone-anchored hearing implant and a surgical technique with tissue preservation. *Otol. Neurotol.* **37**, 374–379
- 11 van de Berg R., Stokroos R.J., Hof J.R. *et al.* (2010) Bone-anchored hearing aid: a comparison of surgical techniques. *Otol. Neurotol.* **31**, 129–135
- 12 Hultcrantz M. (2011) Outcome of the bone-anchored hearing aid procedure without skin thinning: a prospective clinical trial. *Otol. Neurotol.* **32**, 1134–1139