Osseointegrated device placement with minimally invasive surgery. *Experience and audiological outcome*

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ABSTRACT

Objectives: To evaluate the clinical and audiological outcomes of percutaneous bone conduction device placement by minimally invasive Ponto surgery (MIPS).

Methods: This was a retrospective descriptive study of patients who underwent MIPS from March-November 2019 at King Abdullah Ear Specialist Center, Collage of Medicine, King Saud University, Riyadh, Saudi Arabia. We reviewed all the clinical data of patients, including preoperative data, postoperative surgical results, and audiological performance (aided and unaided pure tone audiometry and aided and unaided speech tests).

Results: A total of 9 patients with 10 implants were enrolled in this study. One patient underwent revision surgery because of infection and loss of the abutment. We followed the patients from 1-2 years, with a mean of 16.8 months. A significant difference was found between the unaided air conduction pure tone average, with a mean of 72.6±28.4 decibel (dB), and the postoperative aided threshold, with a mean of 20.8±12.2 dB/hectoliter (p=0.008), indicating a functional gain of 51.8 dB. The mean unaided speech discrimination at 65 dB sound pressure level was 34.7±24.8, which was significantly improved to 88.4±11.7 after implantation (p=0.007).

Conclusion: minimally invasive Ponto surgery is a suitable minimally invasive surgical method for bone-anchored implant placement. This technique has an advantage in terms of skin sensitivity, cosmetic outcomes, and operative duration.

Keywords: Ponto, minimal invasive surgery, bone conduction, hearing loss

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Minimal invasive Ponto surgery (MIPS) is different from the classical surgical technique. There is no skin incision with a knife to place the implant. We use a 5-mm dermal punch biopsy to place a 4-mm implant, which leaves the surgical site with no suture needed. The bone conduction hearing level reflects the actual hearing function of the human cochlea with no effects of another conduction pathways.[1] This idea can explain why bone conduction devices (BCDs) work when a problem with the outer or middle ear exists, as in aural atresia and chronic otitis media. Since BCDs vibrate the skull to stimulate both cochleae, they have become an option for the management of single-sided deafness (SSD).[1] Many different types of BCDs are available, such as percutaneous BCDs, active transcutaneous BCDs, and passive transcutaneous BCDs.[2] The direct delivery of sound to the skull by a percutaneous BCD after surgical implantation has a better effect on hearing rehabilitation than provided by other transcutaneous BCD options.[1,2] In the last few years, a different technique was developed by Oticon (Copenhagen, Denmark), involving the use of a 5-mm punch biopsy with no incision to place the implant for osseointegration.

Two kinds of percutaneous BCDs are currently being manufactured and are available on the market to deliver sound by osseointegration with the skull: the BAHA™ system (Cochlear Co., Gothenburg, Sweden) and the Ponto™ system (Oticon Medical, Askim, Sweden). Reports analyzing MIPS are limited. Therefore, in this report, we present our experience with MIPS and a literature review to evaluate and discuss many aspects of this technique and these devices.

Methods. A comprehensive file review was carried out to collect preoperative and postoperative data for all patients. Patients with incomplete data or patients not treated with percutaneous BCD MIPS were excluded. The study was reviewed and approved by the Institutional Review Board of the University College of Medicine, King Saud University Medical City, Riyadh, Saudi Arabia.

The preoperative data included audiological assessment results and the etiology and duration of hearing loss. Generally, audiological assessments consisted of pure tone audiometry for a frequency range between 250-8000 Hz for air conduction and for frequencies between 500-4000 Hz for bone conduction threshold. The pure tone average (PTA4) for the frequency range of 500-4000 Hz was calculated and used for data analysis. Speech audiometry measurements were reviewed, including the speech reception threshold (SRT) using Arabic spondee words and speech discrimination score (SDS) using Arabic phonetically balanced monosyllabic words lists where each list has 25 words.

The primary outcome was the postoperative auditory gain achieved using the Ponto device. Six months after

implantation, aided hearing thresholds with the Ponto 3 super power audio processor in the sound field using a warble tone for a frequency range of 500-4000 Hz were measured and used for data analysis. A loudspeaker was placed at a distance of one meter at a 45-degree azimuth to the side of the implant for each patient. The aided SRT and SDS at 65 dB HL were also included. In all conditions, clinical masking was applied when required. In sound field measurements in cases of SSD, the contralateral ear was occluded using a specific ear plug and covered with a telephonics dynamic headphone headphone to minimize its participation during testing.

The secondary outcomes of the current study were related to MIPS. Surgical steps as recommended by the company were followed for all patients.[3] Figure 1 illustrates the surgical steps. The type of anesthesia, operative duration, hospitalization duration, and occurrence of postoperative complications were determined by reviewing the patients' files.

Statistical analysis. Statistical Package for the Social Sciences, version 24.0 (IBM Corp., Armonk, NY, USA) was used for data analysis. Quantitative variables are presented as the mean, standard deviation (SD), median, quartiles, and range. The Kolmogorov test was carried out to test the normality of quantitative variables. The data were found to be non-parametric. Non-parametric variables were compared within groups using the Wilcoxon signed-rank test. Usually, *p*-values of <0.05 were considered significant.

Results. All 9 patients received unilateral implants except for one patient who received bilateral implants. Ponto 3 Superpower sound processors (Oticon Medical, Askim, Sweden) were fitted for all patients 4-6 weeks after surgery. One patient developed an infection at the implant site, and the abutment was lost. The infection was treated, and 3 months later, revision surgery was carried out. The follow-up of the patients ranged from 12-24 months, with a mean follow-up of 16.8 months. Overall results are summarized in Tables 1 & 2.

Primary outcome. A significant difference was found between the unaided air conduction PTA4, with a mean of 72.6±28.4 dB, and the postoperative aided threshold, with a mean of 20.8±12.2 dB HL (p=0.008). The overall average functional gain was 51.8 dB. The mean unaided SRT was 72.8±27.5 dB HL, which was significantly improved to 13.9±9.9 dB HL after implantation (p=0.008). The mean unaided SDS at 65 dB/SPL was 34.7±24.8, which was significantly improved to 88.4±11.7 after implantation (p=0.007).

Secondary outcomes. The operative duration among all patients ranged from 15-30 minutes, with a mean of 22.2 minutes. Three patients underwent surgery under local anesthesia with a mean operative duration of 15 minuntes and 6 patients underwent surgery under general anesthesia with mean operative duration of 25.83 minutes. All patients underwent a same-day surgical procedure. While no intraoperative complications were observed, postoperative follow-up

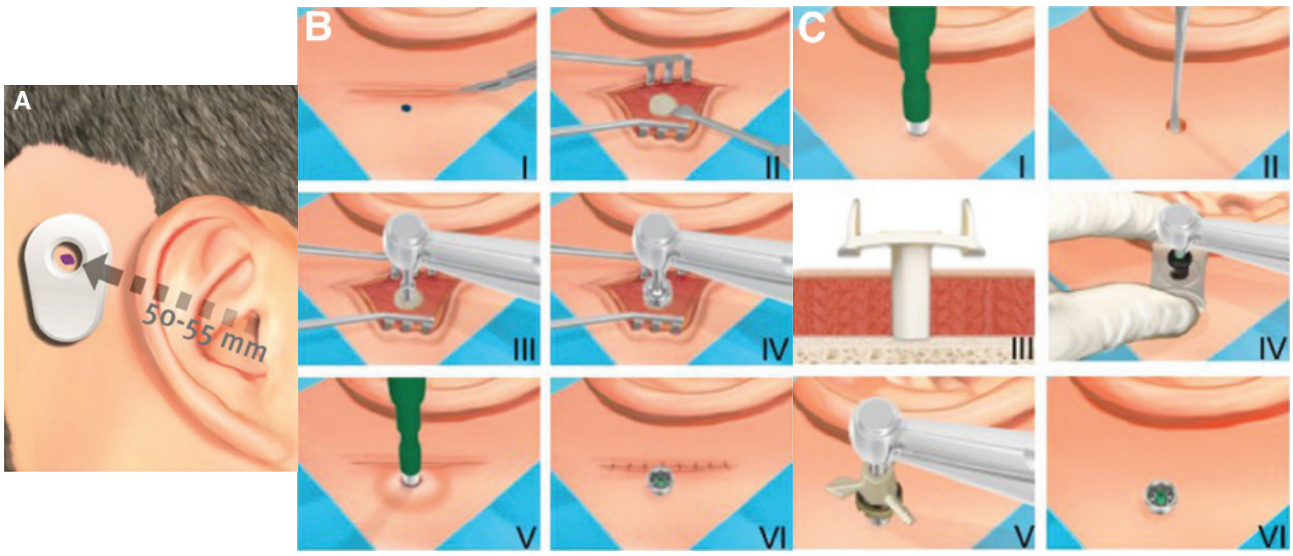

Figure 1 - Surgical implantation techniques. **A)** Implant positioning. **B)** Schematic presentation of the linear incision technique with soft tissue preservation: **I)** linear incision; **II)** opening of skin; **III)** initial hole drilling; **IV)** countersink drilling; **V)** eccentric skin punch to uncover abutment; **VI)** result. **C)** Schematic presentation of minimally invasive Ponto surgery technique: **I)** incision hole; **II)** removal of preiost and soft tissue; **III)** placement of cannula; **IV)** drilling procedure (cannula guide drill and cannula widening drill); **V)** implant placement with the insertion indicator; **VI)** result.

Table 1 - Clinical and audiological data of overall treated patients.

Patients	Side	Age at implantation	Follow-up duration	SRT		Hearing loss threshold		Speech discrimination SDS @ 65 dB		Surgical data	
				Unaided	Aided	Pre	Post	Preoperative	Postoperative	Type of anesthesia	Operative duration
1	L	13 years	15 months	60	10	55	13.7	40	100	GA	25 min
2	R	15 years	16 months	0	5	120	21.4	0	80	LA	15 min
3	R	7 years	16 months	60	15	57.5	21.2	68	96	GA	25 min
4	L	70 years	24 months	70	35	76.2	45	20	80	LA	15 min
5	R	62 years	22 months	0	10	120	25	0	64	LA	15 min
6	R&L	25 years	16 months	60	5	71.2	12.5	32	92	GA	20 min
7	L	8 years	12 months	50	20	48.7	0	52	92	GA	30 min
8	R	10 years	17 months	65	5	50	23.7	64	92	GA	30 min
9	L	36 years	14 months	50	20	55	25	36	100	GA	25 min
Mean		27.3	16.8	72.8	13.9	72.6	20.8	34.7	88.4		22.22
25th p				55.0	5.0	52.5	13.1	10.0	80.0		
75th p				95.0	20.0	98.1	25.0	58.0	98.0		

SRT: speech reception threshold, SDS: speech discrimination score, dB: decibel, L: left, R: right, GA: general anesthesia, LA: local anesthesia, p: percentile, min: minutes

Table 2 - Clinical and audiological data of the treated SSD patients.

Patients	Side	Age at implantation	Follow-up duration	SRT		Hearing loss threshold		Speech discrimination SDS @ 65 dB		Surgical data	
				Unaided	Aided	Pre	Post	Preoperative	Postoperative	Type of anesthesia	Operative duration
1	R	15 years	16 months	NR	5	120	21.4	0	80	LA	15 min
2	R	62 years	22 months	NR	10	120	25	0	64	LA	15 min
Mean		46 years	19 months	NR	7.5	120	23.2	0	72		15 min

SRT: speech reception threshold, SDS: speech discrimination score, dB: decibel, R: right, NR: no response, LA: local anesthesia, min: minutes

records showed that one patient developed an infection and lost his abutment.

Discussion. The goals of any given hearing loss management program are to maximize the auditory system's access to sounds and to minimize the resulting difficulties associated with this access. The implantation of a bone-anchored hearing device is considered a hearing intervention method that has been used effectively since 1977 to restore hearing.[4] In the present study, the primary aim was to analyze the performance of patients who received Ponto implants. Our Ponto cohort included 9 patients who had hearing loss due to different etiologies and were candidates for BCD implantation. All patients underwent implantation using the MIPS approach.

The patients' hearing threshold was improved to 20.8 dB HL after implantation, yielding a functional gain of 51.8 dB. Similarly, the postoperative aided SRT was improved to approximately 14 dB HL. This postoperative improvement has been documented by other centers using the same device in their patients. Wang et al[5] reported an aided threshold of 17.5±5.2 dB HL in their group of 6 patients who underwent Ponto implantation. In an another multicenter study, the average aided PTA threshold of 12 patients using the same device was 37.9±11.3 dB HL.[4]

Different reports from other centers described the use of different osseointegrated devices that have shown significant hearing improvement.[6,7] Of note, hearing restoration, even in cases of unilateral hearing loss or conductive hearing loss, has been proven to improve quality of life (QoL) and scholastic achievement in the pediatric population.[8] Moreover, restoration of hearing during the critical time window in children will prevent any auditory perception distortion due to long standing auditory deprivation.[9] In the 2 cases of SSD in this series, an improvement from no response to a mean hearing threshold of 23.2 dB occurred. One systemic review published in 2017 also showed the efficacy of bone-anchored devices in treating SSD, concluding that BCD implantation was a good rehabilitative method to restore some hearing in cases of SSD.[10] In different types of hearing loss, the current study confirmed the efficacy of the Ponto device as a successful intervention to restore hearing when indicated. Binaural hearing rehabilitation with BCDs for patients with hearing loss has a good impact on their QoL.[11]

Postoperative follow-up records showed that one (11%) patient developed an infection and lost his abutment. Steps recommended by the manufacturer in drilling for the implant was to use a copious amount of irrigation to prevent osteocyte injury from heat and avoid implant from contamination to decrease the risk of infection.[3] The rate of implant infection varies in the literature from 1.0-21.4%.[12] This recent MIPS approach has advantages over the old linear incision approach in terms of a reduced operative duration and reduced surgical trauma to the bone and soft tissue.[13,14] We found the MIPS technique to be easier, faster, and less invasive than the linear incision method carried out in previous cases. Moreover, it can be carried out under local anesthesia. A total of 3 patients underwent MIPS under local anesthesia. The patients were subjectively observed to be comfortable, with uneventful procedures. Minimally invasive surgery facilitates rapid recovery and reduces the hospitalization duration. In the current study, all patients were discharged from the hospital on the same day. A multicenter randomized controlled study, comparing MIPS versus linear incision techniques reported a statistically significant reduction in the operative duration and better cosmetic results with the MIPS technique.[15] The mean operative duration in this review was 22.2 minutes, and the operative duration was shorter in the treatment of patients under local anesthesia (mean: 15 minutes) than for those under general anesthesia.

Study limitation. The small sample size. Larger numbers of recipients are recommended in future research projects. Subjective evaluation by certain questionnaires should increase the amount of information on the effect of this type of intervention on QoL.

In conclusion, the MIPS can be carried out under local anesthesia as a same-day surgical procedure. This cohort study shows that the Ponto implant is a safe and effective device for the treatment of a variety of types of hearing loss. All Ponto users gained significant audiological benefits.

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References

1. Tjellström A, Håkansson B, Granström G. Bone-anchored hearing aids: current status in adults and children. *Otolaryngol Clin North Am* 2001; 34: 337-364.
2. Reinfeldt S, Håkansson B, Taghavi H, Eeg-Olofsson M. New developments in bone-conduction hearing implants: a review. *Med Devices (Auckl)* 2015; 8: 79-93.
3. Johansson M, Holmberg M. Design and clinical evaluation of MIPS - a new perspective on tissue preservation. ResearchGate. [Updated 2015; 2019 Mar 3]. Available from: https://www.researchgate.net/profile/Martin-Johansson/publication/283015072_Design_and_clinical_evaluation_of_MIPS_-_A_new_perspective_on_tissue_preservation/links/56265c7908aed3d3f13838b2/Design-and-clinical-evaluation-of-MIPS-A-new-perspective-on-tissue-preservation.pdf
4. Kara A, Guven M, Sinan Yilmaz M, Demir D, Adigul Ç, Durgut M, et al. Comparison of 2 different bone anchored hearing instruments: Baha-5 vs Ponto-plus. *Acta Otolaryngol* 2019; 139: 517-521.
5. Wang Y, Fan X, Wang P, Fan Y, Chen X. Hearing improvement with softband and implanted bone-anchored hearing devices and modified implantation surgery in patients with bilateral microtia-atresia. *Int J Pediatr Otorhinolaryngol* 2018; 104: 120-125.
6. Lippmann E, Pritchett C, Ittner C, Hoff SR. Transcutaneous osseointegrated implants for pediatric patients with aural atresia. *JAMA Otolaryngol Head Neck Surg* 2018; 144: 704-709.
7. Baker S, Centric A, Chennupati SK. Innovation in abutment-free bone-anchored hearing devices in children: updated results and experience. *Int J Pediatr Otorhinolaryngol* 2015; 79: 1667-1672.
8. Borton SA, Mauze E, Lieu JE. Quality of life in children with unilateral hearing loss: a pilot study. *Am J Audiol* 2010; 19: 61-72.
9. Popescu MV, Polley DB. Monaural deprivation disrupts development of binaural selectivity in auditory midbrain and cortex. *Neuron* 2010; 65: 718-731.
10. Kim G, Ju HM, Lee SH, Kim HS, Kwon JA, Seo YJ. Efficacy of bone-anchored hearing aids in single-sided deafness: a systematic review. *Otol Neurotol* 2017; 38: 473-483.
11. Celikgun B, Kalcioglu MT. Assessment of discrimination ability in ipsilateral and contralateral ears with a unilateral bone-anchored hearing system. *Ear Nose Throat J* 2017; 96: 297-310.
12. Kiringoda R, Lustig LR. A meta-analysis of the complications associated with osseointegrated hearing aids. *Otol Neurotol* 2013; 34: 790-794.
13. Dumon T, Medina M, Sperling NM. 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* 2016; 125: 199-206.
14. Gordon SA, Coelho DH. Minimally invasive surgery for osseointegrated auditory implants: a comparison of linear versus punch techniques. *Otolaryngol Head Neck Surg* 2015; 152: 1089-1093.
15. Calon TGA, Johansson ML, de Bruijn AJG, van den Berge H, Wagenaar M, Eichhorn E, et al. Minimally invasive Ponto surgery versus the linear incision technique with soft tissue preservation for bone conduction hearing implants: a multicenter randomized controlled trial. *Otol Neurotol* 2018; 39: 882-893.