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Evaluation of Clinical Performance of Ponto Implantation Using a Minimally Invasive Surgical Technique—A Prospective Multicenter Study

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Objective: To investigate the clinical outcomes of bone-anchored hearing implant surgery using the MONO procedure.
Study Design: Multicenter, multinational, single-arm, prospective trial with a 12-month follow-up.
Setting: Seven European university hospitals from the United Kingdom, Sweden, Denmark, and The Netherlands.
Patients: Fifty-one adult patients requiring surgical intervention for bone conduction hearing.
Intervention: Bone-anchored hearing implant surgery using the MONO procedure.
Main Outcome Measures: The primary endpoint assessed implant usability 3 months after surgery. Implant status, soft tissue reactions, pain and numbness, postoperative events, and sound processor usage were assessed at all follow-up visits. Hearing-related quality of life was evaluated using the Glasgow Benefit Inventory (GBI).
Results: At 3 months, 94.2% of the implant/abutment complexes provided reliable anchorage for sound processor usage. No severe intraoperative complications occurred. Sixty-nine percent of surgeries were performed under local anesthesia, with surgery lasting 10 minutes on average. Four implants were lost due to trauma (n = 2), spontaneous loss of osseointegration (n = 1), or incomplete insertion (n = 1). Adverse soft tissue reactions occurred in 2.6% of visits, with a maximum Holgers grade of 3 (n = 1) and grade 2 (n = 5) across patients. Hearing-related quality of life at 3 months improved in 96% of patients.
Conclusion: The MONO procedure provides a safe and efficient surgical technique for inserting bone-anchored hearing implants with few and minor intra- and postoperative complications.
Key Words: BAHA—BAHI—Bone-anchored hearing aid—Bone-anchored hearing implant—Bone conduction—Implant loss—Minimal invasive—MONO—Soft tissue reactions.

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INTRODUCTION

Percutaneous bone-anchored hearing implants (BAHIs) were introduced in 1977 and have been used clinically for over 40 years (1). The BAHI itself, as well as their surgical techniques, have been in constant development. Historically, in adults, the two-stage surgery developed into a single-stage surgery, aiding faster hearing rehabilitation, less anesthetic exposure, and lower costs (2). Thereafter, the various surgical flap and graft techniques developed

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into the straightforward linear incision technique (3). This latter technique was first performed with tissue reduction (LIT-TR), but after the introduction of wider diameter implants and longer abutments, the tissue preservation technique was adopted, becoming the clinical gold standard (LIT-TP) (4). Shorter surgery times, less surgical invasiveness, faster healing, better cosmesis, and improved sensibility around the implant site were some of the advantages noted, in addition to fewer soft tissue complications (5,6).

To reduce postoperative complications and to shorten and simplify the surgical procedure even further, so-called punch-only techniques were introduced (7). However, even though the first standardized punch-only technique, the minimally invasive Ponto surgery (MIPS) (8), showed a shorter surgery time and better cosmetic outcomes, some studies reported increased implant loss rates compared with LIT-TP (8–13). The suggested underlying causes of the latter, mainly amounting to heat generation during drilling, resulted in the modified MIPS (m-MIPS). Using a new drill shape for the osteotomy, favorable intra- and postoperative clinical outcomes were demonstrated (14).

To further improve and simplify MIPS, the MONO surgical procedure (Oticon Medical AB, Gothenburg, Sweden) was developed. Here, the osteotomy is performed using one single drill step, in contrast to all other techniques that utilizes a three-step drilling sequence. The parabolic designed drill bit offers more effective bone removal, generates less heat, and eliminates the need for subsequent drill hole alignment (15). Additionally, since fewer drill steps are required, less discomfort for the patient is expected when operating under local anesthesia (16).

This prospective study investigates the clinical outcomes of bone-anchored hearing implant (BAHI) surgery using the MONO procedure.

MATERIALS AND METHODS

Ethical Considerations

This study was approved by the required ethical committees in the participating countries and performed in accordance with the guidelines for Good Clinical Practice, ISO 14155, and the Declaration of Helsinki.

Study Population

Seven European university hospitals from the United Kingdom, Sweden, Denmark, and The Netherlands participated in this study. The inclusion criteria for participants were adults (≥18 years) requiring surgical intervention for bone-anchored hearing, who provided signed consent, with adequate bone quality (>5-mm thickness) and ≤12-mm skin thickness at the implant site. Exclusion criteria included reimplantation cases, inability or unwillingness to comply with procedures, conditions jeopardizing skin or wound healing (such as prior radiotherapy and uncontrolled diabetes mellitus), contraindicating medical conditions, known or planned pregnancy during surgery, concurrent participation in conflicting clinical investigations, and other conditions hindering compliance or assessment. The study has been registered at clinicaltrials.gov (trial number: NCT04606823).

Surgical Technique and Follow-up

All surgeries were performed by ear, nose, and throat surgeons experienced in BAHI surgery, including MIPS. Before enrolment, all surgeons were trained in the procedure. The Ponto BHX or Ponto Wide implant (length 4 mm, Oticon Medical AB, Askim, Sweden) with abutment (length 6, 9, 12, or 14 mm) was inserted in a single-stage surgery. The abutment length was chosen based on the scalp thickness at the implant site, as measured prior to local infiltration of anesthetics.

The MONO procedure was performed using the MONO Surgery kit (Oticon Medical AB, Gothenburg, Sweden) (Fig. 1). This procedure involves a circular incision in the soft tissue and periosteum with a 4- or 5-mm biopsy punch, depending on the surgeon's preference, whereafter any residual periosteum is removed with a raspatory. A cannula is inserted in the punched hole and filled with saline, through which one-step drilling is performed during continuous irrigation. After removing the drill, the cannula is flushed to remove any remaining debris. The cannula is removed, and the implant with premounted abutment is inserted, counting the number of turns as visualized by an insertion indicator to confirm full implant insertion. If the implant engages ≤4 turns, careful manual tightening (up to 4.5–5 turns) is considered. The procedure is complete after placing a healing cap onto the abutment.

The healing cap was removed approximately 1 to 1.5 weeks after surgery. Follow-up visits were scheduled at 9 days (±3 d), 5 weeks (±2 wk), 3 months (±1 wk), 6 months (±2 wk), and 12 months (±1 mo) after surgery, with the sound processor (SP) fitting between 9 days and 3 months.

Outcome Measures

The primary outcome of this investigation was implant usability at 3 months after surgery. Implant usability was assessed based on five variables: implant survival, implant stability, and absence of adverse soft tissue reaction, skin overgrowth, and pain preventing use of the device.

Secondary outcomes included implant usability at 6 and 12 months after surgery, SP usage, skin condition, subjective pain and numbness, and patient-reported benefit. Intraoperative complications, duration of surgery, (serious) adverse events, unplanned visits, and additional treatments or interventions were recorded.

Soft tissue reactions were assessed using the Holgers classification and the IPS scale (17,18). The latter comprises inflammation, pain, and skin height variables, with higher scores indicating more severe complications, and offers standardized treatment advice (18). Holgers scores ≥2 or IPS scores indicating treatment were considered adverse soft tissue reactions. The skin around the abutment was assessed for dehiscence and overgrowth. Pain and numbness around the abutment were rated by the patient on a numeric rating scale (NRS), with 0 indicating no numbness/pain and 10 indicating complete numbness/most severe pain. Sound processor usage (h/d, d/wk) was assessed subjectively by the subjects. The patient-reported benefit was captured at 3 months using the Glasgow Benefit Inventory (GBI), a health-related quality of life measure that ranges from

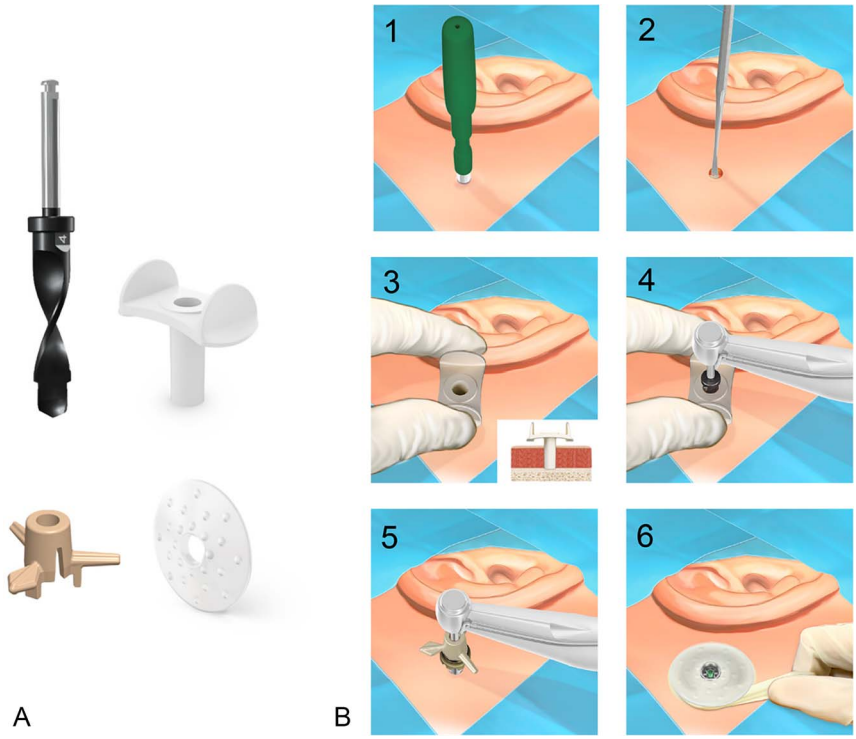

FIG. 1. *A*, The items included in the MONO surgery kit: MONO drill, cannula, insertion indicator, and healing cap. *B*, The MONO procedure presented stepwise: 1) skin incision using punch, 2) removal of the periosteum from the site, 3) insertion of the cannula, 4) drilling using the MONO drill, 5) insertion of the implant while counting the turns using the insertion indicator, 6) application of suitable dressing and attachment of the healing cap. Images were provided by Oticon Medical™. Reprinted with permission.

−100 to +100, with positive scores indicating improved quality of life (QoL) (19).

Statistical Analysis

All data were analyzed using descriptive statistics and are presented for the intention-to-treat (ITT) population (i.e., all implanted subjects). Data are presented using the mean (standard deviation), median, and range, with 95% confidence intervals where applicable, or by using numbers and percentages.

RESULTS

Study Population

Fifty-two patients (54 implants) with a mixture of indications were enrolled in the study between November 2020 and April 2022. One patient planned for bilateral surgery was postponed due to a positive COVID-19 test and withdrawn from the study, leaving 51 patients (52 implants) in the ITT population. Patient demographics and surgical characteristics are reported in Table 1.

Surgery

All surgeries were performed without major intraoperative complications (Table 1). In one case, the surgery was converted to a linear incision because of a spinning implant due to an insufficient drilling depth. After conversion, the MONO drill was used to generate a new osteotomy and the implant was successfully repositioned. Veins and air pockets were encountered in four and two surgeries, respectively, in all cases without further complications.

Implant Survival and Stability

Forty-nine implants (94.2%; CI: 84.4–98.0) were confirmed stable in situ and without any problems hindering the use of an SP at 3 months after surgery. At the 6- and 12-month follow-up visit, 48 implants remained in situ, resulting in an implant survival of 92.3%. The first implant loss occurred 33 days after surgery, possibly due to repeated light trauma while dressing. This implant was reported to have been incompletely inserted (3.75 turns) during implantation and had a long leverage arm with a skin thickness and abutment length of 6 and 12 mm, respectively. The second loss occurred spontaneously at 36 days after surgery. The third and fourth losses occurred due to head trauma 7 weeks (51 d) and 3.5 months (114 d) after surgery.

Soft Tissue Reaction and Treatment

All wounds except one (98%) were confirmed to be completely healed 3 months after surgery (Table 2). Skin dehiscence around the abutment was reported in 13 subjects (25.0%) at the first follow-up visit (9 ± 3 d postoperatively), with sizes ranging between 1 and 3 mm at the widest point. In one case, dehiscence occurred after initial healing and remained until the 6-month visit. At 6 months, another patient presented with skin dehiscence as part of an adverse soft tissue reaction that resolved with topical

medication. Partial skin overgrowth over the abutment was reported at one unplanned visit, 11 months after surgery, in conjunction with an adverse soft tissue reaction. Sound processor usage was not hindered, and the condition was resolved within 1 week after topical treatment.

TABLE 1. *Baseline and surgical characteristics for the patient population*

Baseline Characteristics	n = 51 Patients
Gender, n (%)	
Male	26 (51.0%)
Female	25 (49.0%)
Age in years, mean (SD)	56.2 (15.6)
Range	19–82
Ethnicity, n (%)	
Caucasian	46 (90.2%)
Asian	2 (3.9%)
Hispanic	1 (2.0%)
Other	2 (3.9%)
Body mass index, mean (SD)	27.0 (4.2)
Smoking, n (%)	
Never	22 (43.1%)
History	21 (41.2%)
Current	8 (15.7%)
Relevant surgical history, n (%)	
Yes[a]	21 (41.2%)
No	30 (58.8%)
Concomitant medication, n (%)	
Yes[a]	35 (68.6%)
No	16 (31.4%)
Indication, n (%)	
Conductive hearing loss	15 (27.2%)
Mixed hearing loss	28 (50.9%)
Single-sided deafness	8 (14.5%)
Sensorineural hearing loss	4 (7.3%)
Bilateral hearing loss, n (%)	32 (62.7%)
Surgical (implant) characteristics	n = 52
Duration of surgery in minutes, mean (SD)	10.0 (5.5)
Range	3.0–27.3
Type of anesthesia, n (%)	
Local	35 (68.6%)
General	16 (31.4.%)
Skin thickness in millimeters, mean (SD)	6.1 mm (1.4)
Range	4–9 mm
Punch size, n (%)	
4 mm	12 (23.1%)
5 mm	40 (76.9%)
Implants, n (%)	
Ponto Wide 4 mm	20 (38.5%)
Ponto BHX 4 mm	32 (61.5%)
Abutment lengths, n (%)	
9 mm	25 (48.1%)
12 mm	26 (50.0%)
14 mm	1 (1.9%)
Manual tightening, n (%)[b]	20 (38.5%)
Intraoperative events, n (%)	8 (15.4%)
Drilling into vein	4 (7.7%)
Drilling into air pockets	2 (3.8%)
Repositioning of the implant (drilling at more than one site)	1 (1.9%)
Faltering drill	1 (1.9%)
Malfunctioning handpiece prior to implant insertion	1 (1.9%)

[a]Most common concurrent diseases (based on medical history and medications) were hypertension (39%) and high cholesterol (33%). Diabetes, psoriasis, and osteoporosis were reported by 12%, 8%, and 6%, respectively.
[b]Manual tightening using the counter torque wrench was for one center used as a routine to confirm full implant seating. In these cases (n = 6), the implant was turned 0 to 0.1 turns.
SD indicates standard deviation.

TABLE 2. *Soft tissue outcomes across the 12-month study period (per implant)*

	n (%)	Average NRS (SD)[a]
Wounds healed		
9 d	37 (71.2%)	
3 mo	48 (98.0%)	
Skin dehiscence around the abutment		
9 d	13 (25.0%)	
3 mo	1 (2.0%)	
12 mo	0 (0.0%)	
Skin overgrowth 0–12 mo[b], n (%)	0 (100.0%)	
Pain presence around abutment site		
9 d	21 (40.4%)	3.2 (2.1)
3 mo	13 (26.5%)	1.5 (1.1)
12 mo	10 (20.8%)	4.3 (3.0)
Unscheduled	4 (17.4%)	4.4 (4.6)
Numbness presence around abutment site		
9 d	4 (7.7%)	4.0 (2.2)
3 mo	3 (6.1)	7.3 (4.6)
12 mo	0 (0.0%)	-
Unscheduled	1 (4.3%)	4.0 (0.0)
Holgers score across all visits (n = 265) 0–12 mo		
Holgers 0	205 (77.4%)	
Holgers 1	53 (20.0%)	
Holgers 2	6 (2.3%)	
Holgers 3	1 (0.4%)	
Maximum Holgers score per implant 0–12 mo		
Holgers 0	17 (32.7%)	
Holgers 1	29 (55.8%)	
Holgers 2	5 (9.6%)	
Holgers 3	1 (1.9%)	
IPS scores indicating treatment per visit		
9 d	17 (32.7%)	
5 wk	6 (12.2%)	
3 mo	9 (18.4%)	
12 mo	6 (12.5%)	

[a]Numerical rating scale (NRS) average based on patients experiencing pain/numbness.
[b]Skin overgrowth hindering sound processor usage.
SD indicates standard deviation.

Over the entire study period, a Holgers score of 0 was reported in 205 visits (77.4%) compared to an IPS score of $I_0P_0S_0$ reported in 162 visits (61.1%). Adverse skin reactions (Holgers ***≥2***) were observed at seven visits (2.6%) in six patients (Table 2, Fig. 2). In contrast, adverse IPS scores were reported at 46 visits (17.4%) in 26 patients (27 implants) distributed across the entire study period.

Topical ointment with antimicrobial and/or anti-inflammatory was prescribed to 72.5% of the patients, most often in conjunction with removal of the healing cap according to local practice (58.8% of patients) or adverse soft tissue reactions. Adverse skin reactions, according to Holgers, were more likely to be treated medically compared with adverse IPS scores, particularly in cases were pain contributed to the adverse IPS score. One patient was prescribed oral antibiotics 14 days after surgery because of redness and a minor skin dehiscence around the abutment (Holgers 1, $I_1P_0S_0$). In addition, three prescriptions of oral antibiotics were made by general practitioners for (presumed) implant site-related infections approximately 2 (n = 2) and 4 (n = 1)

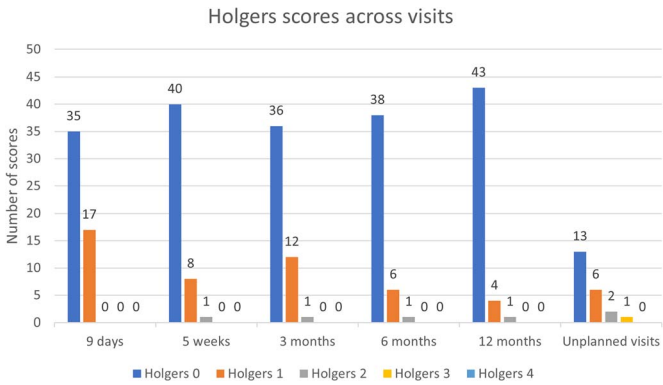

FIG. 2. Soft tissue reactions across all visits according to the Holgers classification. [a]Adverse skin reactions at unplanned visits seen 1.5 week, 1 month, and 11 months postsurgery.

months after surgery. No soft tissue revision surgeries were performed.

Subjective Pain and Numbness

Three patients (four implants) reported pain preoperatively; two of these did not report pain at any follow-up visit. Thirty-one patients (32 implants) reported pain during at least one visit after surgery (Fig. 3). At the end of the study, four patients graded their pain ≥4. One patient had temporary pain related to an adverse soft tissue reaction, and another experienced varying pain around the abutment since approximately 7 months after surgery. In the remaining two patients, pain prevented SP usage at the 12-month visit. Three patients with pain were considering abutment or implant removal at the end of the study, of which one implant/abutment complex and one abutment were removed after study completion.

Six patients (seven implants) reported numbness on at least one visit, of whom two patients (three implants) experienced numbness preoperatively. At the first follow-up visit, three patients (four implants) reported numbness, a number that gradually decreased. At the end of the study, no numbness was reported. Subjective pain and numbness scores are summarized in Table 2.

Sound Processor Usage

The implant was loaded with an SP 38 ± 20 days after surgery (range: 6–118). One patient was loaded after the 3-month follow-up visit due to a delayed audiology visit. At 12 months, 45 patients (45 implants of the 48 implants in situ) used the SP daily with an average of 13.0 ± 3.3 hours per day (median 14.0; range 4–17). One patient was a non-user, while another used the device 1 day per week for an hour (both having pain and considering abutment/implant removal). The third patient used the device 16 hours a day, although it is unknown how many days per week.

Patient-Reported Benefit

At the 3-month visit, 46 patients (94%) completed the GBI questionnaire. Most patients (96%) experienced an improvement in quality of life. One patient with sensorineural hearing loss reported no change. In contrast, another patient with mixed hearing loss reported a slight deterioration (total score: −2.8) despite high SP usage and the absence of severe complications. Patients with SSD had a lower total score (3.61 units; n = 6) compared to non-SSD patients, with the social support subscale showing the largest difference (2.78 vs 10.00). Total scores, as well as subscale scores for the entire patient cohort, are presented in Table 3.

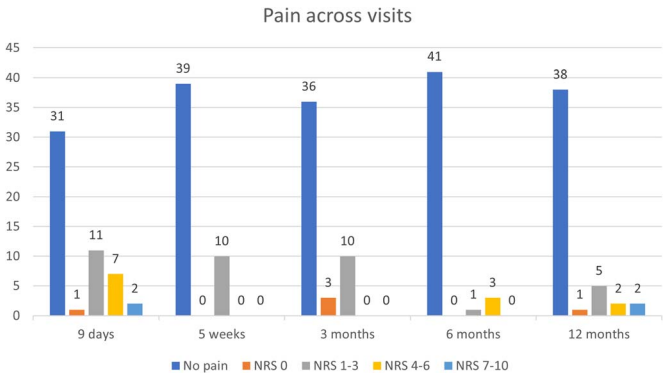

FIG. 3. Pain across visits as subjectively judged on an NRS-scale from 0 to 10. Patients only experiencing pain upon touch were reported as NRS 0 (four patients/five implants across visits) and are included in *orange bars*.

TABLE 3. *Glasgow benefit inventory data 3 months postoperatively*

GBI	Total	General	Social Support	Physical Support
Score	26.8 ± 18.0 (−2.8 to 83.3)	37.7 ± 24.7 (−4.2 to 100.0)	9.1 ± 19.5 (−33.3 to 66.7)	1.45 ± 24.3 (−66.7 to 100.0)
>0 (improvement)	44 (95.6%)	43 (93.5%)	17 (37.0%)	5 (10.9%)
0 (no change)	1 (2.2%)	2 (4.3%)	27 (58.7%)	34 (73.9%)
<0 (deterioration)	1 (2.2%)	1 (2.2%)	2 (4.3%)	7 (15.2%)
Total	*46*	*46*	*46*	*46*

For categorical variables, n (%) is presented.
For numerical variables, average ± SD (range) is presented.

Unplanned Visits and Adverse Events

In total, 29 unscheduled visits (for 19 patients) were registered. Ten were due to complications related to the implant/abutment complex, seven for complication review (of which two were remote appointments), five for change of wound dressing and/or wound review, which was routine for one of the surgeons, one to complement a remote 3-month follow-up visit, three due to SP-related device deficiencies, and three due to unrelated ear treatments.

DISCUSSION

Key Findings

The current study is the first to report the clinical outcome and performance data of the new MONO surgical procedure to install bone-anchored hearing implants. Implant usability, i.e., a stable implant and absence of soft tissue reaction, skin overgrowth, and pain preventing sound processor usage, was confirmed in 94.2% (CI: 84.4–98.0), 91.8%, and 88.5% of cases at 3, 6, and 12 months after surgery, respectively. Eight minor intraoperative complications were reported. Postoperative complications were mainly soft tissue related and resolved spontaneously or with topical ointment. At the end of the study, 45 patients (86.5%) used their SPs daily. Most patients (96%) reported improved quality of life 3 months after the MONO procedure.

Interpretation of Findings

At 12 months, 4 of 52 implants (7.7%) had been lost, and 2 implants were not used due to pain at the implant site. Therefore, 88.5% were providing reliable anchorage and usability at 12 months. Two implant losses were due to head trauma, one loss possibly due to repetitive mild trauma in combination with an incomplete inserted implant, and one loss occurred spontaneously 36 days after surgery, most likely due to lack of osseointegration. Traumatic cases excluded, the implant survival rate was 96.2%, aligning with results from MIPS or conventional surgical techniques (14,20,21).

More than half of the MONO procedures (>60%) were specified as "easy" by the surgeons. Similar to other minimally invasive techniques, a steep learning curve is expected. For less experienced surgeons or residents, the MONO procedure can be more challenging because no visual information is available, only tactile information. Like MIPS, the MONO procedure is performed using a drill guide, i.e., the cannula. In contrast, one single drill step is needed to generate the osteotomy using MONO, whereas a three-step sequence is used in MIPS, eliminating the possibility of misalignment between the drill steps. The specific burr design of the MONO drill offers effective bone dust removal and cooling fluid exchange, with less heat generation compared with three-step procedures, decreasing the risk of overheating the bone (15). Moreover, less discomfort can be expected under local anesthesia since only one short drilling sequence is used. Consequently, more than two-thirds of the surgeries were performed under local anesthesia. Using MONO, the complete osteotomy required for housing a 4-mm fixture is performed in one step to a depth of 4.75 mm (15). This depth is less than the average skull thickness for adult patients (22,23) and less than for other surgical techniques when drilling for a 4-mm implant. If the skull thickness is 1 mm less than the maximum drilling depth (i.e., 3.75 mm), minimal to no dural damage can be expected when using the MONO drill (24). In the present study, no dural exposure or cerebrospinal fluid leaks were reported, and no severe intraoperative complications occurred, underlining the MONO procedure's safety.

The surgery duration averaged 10 minutes, similar to the range of 6.2 to 21.8 minutes reported for MIPS (9,10,14,20,25,26). The combination of local anesthesia and short surgery duration makes this surgery particularly suitable for outpatient procedures, improving efficiency and reducing surgical waiting lists (27).

Adverse soft tissue reactions were seen in 2.6% of the visits, as graded by Holgers, and spread across the entire study period. All adverse soft tissue reactions resolved within 1 to 2 weeks after topical treatment. These results are comparable and even better than other results in the BAHI literature (9,14,28). The same applies to soft tissue reactions classified using the IPS score (14). Only one wound (2.0%) was considered incompletely healed 3 months after surgery, possibly due to vigorous cleaning around the abutment. Skin dehiscence around the abutment was reported in 6.7% of the visits, most frequently at the first visit after surgery, and affected 15 patients. This is lower than what has been reported for MIPS (48.5–72.0%) (9,14). All dehiscences were successfully treated with antimicrobial and/or anti-inflammatory ointment. Interestingly, the reports regarding skin dehiscences (defined as a tiny space between the abutment and adjacent skin) seemed site dependent, likely due to differences in interpretations of skin dehiscence in relation to wound healing. Moreover, using a 4-mm biopsy punch for the incision, preferred among some surgeons, provides for a snugger fit of the skin around the abutment, possibly reducing the risk of skin dehiscence. In agreement, no skin dehiscence was reported in the 4-mm

punch group. Four patients were prescribed oral antibiotics, usually (75%) by the general practitioner (GP) because of a (suspected) implant site infection. Comparing the prescription of local ointment with skin conditions as assessed by Holgers and the IPS scale, overtreatment of these local skin reactions is often indicated. Therefore, to prevent overtreatment and antibiotic resistance, our advice is to draw (GPs') attention to the IPS score and accompanying treatment advice. It may also be advisable to consider its incorporation within the national antibiotic guidelines.

Chronic or recurrent pain after BAHI surgery has a reported incidence between 1.2% and 4.2% and is the leading cause of elective implant removal (29–33). Although the underlying mechanisms for pain in relation to BAHIs are not fully understood, it may be associated with a chronic bacterial infection and raised inflammatory response despite the absence of macroscopic signs of infection (32,33). In this study, reported pain decreased at the subsequent visits in all but three patients (5.9%), for whom the pain (combined with other factors) led to consideration of implant and/or abutment removal. One patient with multiple comorbidities and dementia regarded abutment problems and risks (abutment hooking onto things) higher than the benefits. The second patient experienced minor chronic pain since loading, resulting in implant explanation after study completion. The third, bilaterally fitted, patient judged the pain as disproportional to the audiological benefit of his second device despite the high usage of 17 hours a day. The relatively high rate of idiopathic pain in this study compared to the literature is unclear.

The three patients experiencing pain and the two patients experiencing numbness before surgery all had previous otologic surgeries (mastoidectomy, tympanoplasty, middle ear surgery). It is suspected that these previous surgeries likely caused the (referred) pain or numbness.

Five patients reported postoperative numbness of varying degrees, but no numbness was recorded at 12 months. Interestingly, one patient experiencing complete numbness before surgery reported none after surgery. Overall, these results are comparable to reports from other studies using minimally invasive approaches and indicate that numbness after surgery is no longer an issue following BAHI surgery (8,9,14,34).

Strengths and Limitations

The strength of this study is the prospective, multinational, multicenter design. The results may therefore be considered to reliably reflect expected clinical outcomes of BAHI following the introduction of the MONO procedure into clinical practice. However, the clinical introduction of a new surgical technique such as MONO may be associated with a learning curve. Since all participating surgeons were new to the MONO procedure, aspects of learning curve may be visible in the presented data. An additional limitation is that some surgeons performed a limited number of procedures. (In total, 11 different surgeons performed between 1 and 8 [median: 5] procedures.)

The study comprised a sample of 51 patients, followed-up for 12 months, all adhering to an identical follow-up schedule in line with the clinical investigation plan. Some site-dependent differences could be discerned in the dataset, likely because of local differences in the standard practice associated with BAHI treatment. This could be seen as a limitation, but on the other hand, it also reflects variations seen in clinical practice. Given the single-arm nature of the study, comparisons with established surgical techniques, such as the commonly used linear incision technique (with tissue preservation) and MIPS, were absent. Moreover, despite use of inclusion and exclusion criteria, patient groups remained heterogeneous in terms of surgical indication and hearing loss, potentially impacting patient satisfaction and device usage. Indeed, the range of SP usage was large (4–17 h/d) and may be affected by recall bias or social desirability bias due to being self-reported.

CONCLUSION

Using the MONO surgical procedure for bone-anchored hearing implantation provided adequate anchorage for sound processor usage, and few minor intra- and postoperative events were reported. The results demonstrate that the procedure is safe to perform in adults indicated for bone-anchored hearing implantation.

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