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Bone anchored hearing implants without skin thinning: the Gruppo Otologico surgical and audiological experience

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Abstract To investigate the surgical and audiological outcomes of an installation of a bone-anchored hearing system (BAHS) procedure without tissue reduction using Ponto implants and abutments. Retrospective consecutive case series. Forty-nine patients, 18 years or older and eligible for treatment with a bone-anchored hearing system with tissue preservation surgery, were included in the study. Following a systematic scheme for medical outcomes, we collected the data regarding surgical intervention, quality of life (GBI), skin and soft tissue reactions (Holgers grading system), pain and numbness (VAS). Hearing performance (aided thresholds and speech recognition in noise) was recorded in 20 patients. No implants were lost, skin, and soft tissue reactions were mild in 96 % of the all visits. Quality of life (GBI) generally improved in the aided condition compared to prior to implantation. Audiologically, 100 % of the 20 patients examined showed improvement of speech reception and sound field thresholds comparing aided to unaided. An average improvement of 33 dB on PTA was recorded. The study, presenting data on a large population, treated with tissue preservation and modern titanium implants, shows that this treatment is a viable solution that results in fewer complications, high degree of predictability and good audiological results.

Keywords Ponto · Wide implant · Tissue preservation surgery · GBI · Pain and numbness · Skin reactions

Introduction

Bone-anchored hearing systems (BAHS) bypass the middle ear by conveying vibrations, generated by an external sound processor, to the inner ear via a percutaneous abutment and an implant osseointegrated in the mastoid bone [1]. BAHS was first introduced by Tjellström et al. [1] and has now been in clinical use for more than 35 years. Improved audiological and quality of life outcomes have been shown in many studies (for a summary, see [2]).

A successful clinical outcome is dependent on a firm fixation of the implant and good skin tolerance to the percutaneous abutment. The success rate with BAHS is high and long-term implant survival rate between 81.5 and 98.4 % has been reported [3–5]. The most common complications reported related to the skin, and soft-tissue surrounding the abutment is inflammation, infection, and soft-tissue overgrowth (e.g., [6]).

The implantation technique has evolved over time from the original technique involving removing subcutaneous tissue. The first clinical result of percutaneous BAHS implanted without tissue reduction was published by Hultcrantz [7] and since then the use of tissue preservation techniques has gained in popularity. Several reports discussing the details of the procedure as well as patient outcomes have been published, but this study accounts, to the best of our knowledge, for the largest patient population treated using this technique at the same clinic.

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The objective of this study was to investigate the surgical and audiological outcomes of a BAHS procedure without tissue reduction using Ponto implants and abutments with focus on the quality of life (GBI), post-operative complications, skin reactions, and hearing performance (aided thresholds and speech recognition in noise).

Materials and methods

The study was a retrospective case series of 49 consecutive adult patients treated at Gruppo Otologico, Piacenza, Italy in the period March 2013 to January 2015. A strict data collection scheme was adhered to, so that all visits were documented in the same fashion regarding medical outcomes. The systematic scheme for medical outcomes included a list of forms (see Fig. 1).

Audiological data were gathered retrospectively from medical records. To be included, the participants had to be 18 years or older and eligible for treatment with a bone anchored hearing system. Skin disease in the operation area (eczema, dermatitis) and/or inability to participate in follow-up were regarded as reasons for exclusion.

Implant and surgical procedure

The implant used was a Ponto Wide implant and abutment family developed by Oticon Medical AB (Gothenburg, Sweden). The implant (diameter 4.5 mm, length 4 or 3 mm) is self-tapping and has a traditional machined Brånemark titanium surface (see Fig. 2). The abutments are of non-coated titanium, available in length 6, 9, 12, and 14 mm.

After a skin incision of approximately 4 cm down to the bone, the periosteum was removed and a hole drilled and widened with a 3.8 mm countersink according to the manufacturer's instructions. An implant was placed using a 50-N cm torque. A biopsy punch was used to allow the abutment to penetrate the skin, and the incision was sutured.

A healing cap was fixed to the abutment at the end of surgery, and gauze with antibiotic-steroid ointment was circulated around the abutment under the healing cap. A pressure head dressing was applied overnight. The healing cap and gauze was removed after approximately 10 days.

The sound processor (Oticon Medical Ponto Pro, or Ponto Pro Power, Ponto Plus or Ponto Plus Power) was fitted from 6 weeks after surgery.

Follow-up examinations

Surgical outcome measurements

The patients were medically re-evaluated after 10 days, 6 weeks, and 1 year when possible. Due to the center being a major referral center, not all patients come back for all follow-up visits.

Surgical outcome measurements were skin reactions, abutment replacement, implant loss, and revision surgery. Skin reactions were assessed according to Holgers [6] (grade 0 = normal skin; grade 1 = slight redness, no

Fig. 1 Case report forms

LIST OF FORMS:

Form 1: Screening/Baseline characteristics

Form 2: Surgery, single stage surgery

Form 2A: Surgery, 2-stage surgery, 1st stage

Form 2B: Surgery, 2-stage surgery, 2nd stage

Form 3: Follow-up 1, surgical follow-up, 10 days

Form 4: Follow-up 2, implant loading/sound processor fitting

Form 5: Patient questionnaire, 12 months, Glasgow Benefit Inventory (Italian version)

Form 6: Follow-up 3, 12 months

Form 7: Implant loss (Form to be filled out in case of implant loss)

Form 8: Revision surgery (Form to be filled out in case of revision surgery)

Form 9: Adverse Events (AEs) / Adverse Device Effects (ADEs)

Form 10: Medication/Treatment during the investigation

Form 11: Serious Adverse Events (SAE) / Serious Adverse Device Effect/Unanticipated Serious Device Effect (USADE)

Form 12: Study termination (Form to be filled when the patients is no longer part of the investigation)

Form 13: Follow-up, unplanned visit

Fig. 2 Ponto wide implant and abutment. Copyright Oticon Medical, printed with permission

treatment needed, grade 2 = redness and moist, requires local treatment, grade 3 = formation of granulation tissue, requiring treatment; grade 4 = extensive soft tissue reaction, requiring implant removal). All skin reactions assessed as Holgers ≥2 are considered clinically relevant, i.e., requiring medical treatment.

Numbness and pain were investigated with a ten-grade visual analog scale (VAS).

Quality of life was assessed using the Glasgow benefit inventory (GBI) [8] approximately a year after surgery. The patients were asked to complete a questionnaire adjusted for patients with a BAHS. The questionnaire provided scores for general satisfaction, social benefit, physical benefit, and a total score. Scores were measured on a 5-point Likert scale and could range from −100 (total deterioration) to 100 (total benefit) after surgery.

Audiological outcome measurements

Twenty-nine patients were omitted in the audiological analysis. For 17 patients, SRT and aided thresholds were not performed. Patients with single-sided deafness ($n = 9$) and patients where masking were showed not to be sufficient ($n = 3$). In connection with fitting the sound processor, the audiological assessment was carried out and compared to measurements on unaided condition before implantation. Outcome measures for the audiological assessment were audibility and speech reception. Audibility was assessed by obtaining aided thresholds in sound field using variable tones to prevent standing waves. Speech reception in quiet was evaluated by measuring the speech recognition thresholds (SRT) for 50 % correct for unaided and aided condition using disyllabic words. Both sound field thresholds and SRT were measured in a sound proof booth with loudspeaker 0° azimuth at 1-m distance from the patient. During measurements, the non-test ear was adequately masked using white noise through headphones.

Ethical approval

The study was conducted in accordance with the ethical guidelines promulgated by the Declaration of Helsinki.

Results

Patient characteristics

Forty-nine patients were recruited, 18 (37 %) men and 31 (63 %) women. Their average age at implantation was 51 years (range 21–74 years). The most common reason for implantation was acquired conductive or mixed hearing loss. Patient characteristics are shown in Table 1. Average time since surgery at the time of data analysis was 22.8 months.

The number of patients attending each visit together with the average time since surgery is summarized in Table 2. Thirty-seven patients attended follow-up 9–20 months after surgery (mean 13.6 months).

The sound processor fitting was done on average 9 weeks (4–17 weeks) after surgery.

Clinical observations

Forty-five patients received 4-mm implants and the remaining four received 3-mm implants, all of the wide 4.5-mm diameter type. Abutment length was chosen with

Table 1 Patients characteristics

Patients	49
Gender	37 % men, 63 % women
Age	51 years (21–74 years)
Indication	Cond/mixed: 82 %
	SSD: 18 %
Implant	4 mm: 92 %, 3 mm: 8 %
Abutments	6 mm: 2 %, 9 mm: 80 %, 12 mm: 18 %
Hearing threshold, pure tone average, PTA for 500 Hz, 1, 2 kHz (standard deviation)	Cond/mixed, fitted ear: AC 68 (1) dBHL, BC 28 (6) dBHL
	Cond/mixed, non-fitted ear, AC: 55 (2) dBHL, BC 25 (3) dBHL
	SSD, bes eart: AC 48 (5) dBHL, BC 21 (1) dBHL
	SSD, deaf ear: AC 104 (8) dBHL

Table 2 Overview of follow-up visits with Holgers and pain and numbness (VAS) scores

	Surgery	Surgical follow-up	Follow-up 2	Follow-up 3
Number of patients	49	38	46	37
Average time after surgery (standard deviation)	NA	9.3 (5.5) days	9.3 (2.6) weeks	14.7 (2.4) months
Holgers				
0		19	41	34
1		16	3	3
2		1	2	0
3		2	0	0
4		0	0	0
Numbness (VAS)				
None (0)				
0		22	34	24
Limited				
1		7	1	4
2		3	3	0
3		2	0	0
Moderate				
4		3	1	1
5		1	4	0
6		0	0	0
7		0	2	0
Extensive				
8		0	0	0
9		0	0	0
10		0	0	0
Pain (VAS)				
None				
0		24	34	24
Limited				
1		8	6	3
2		2	1	2
3		3	5	0
Moderate				
4		1	0	0
5		0	0	1
6		0	0	0
7		0	0	0
Extensive				
8		0	0	0
9		0	0	0
10		0	0	0

regard to tissue thickness; 80 % of the patients ($n = 39$) received 9-mm abutments, 2 % ($n = 1$) received a 6-mm abutment, and 18 % ($n = 9$) received 12-mm abutments.

All surgical procedures were performed under local anesthesia. Fifteen complications were noted [exposure of dura mater ($n = 13$) and drilling into vein ($n = 2$)]. The surgical time was on average 20.3 min (range 10–30 min).

The skin reactions according to Holgers grading system are summarized in Table 2. In 96 % of the all visits ($n = 116$), the skin reaction were mild (Holgers grade 0 or 1). Five adverse skin reactions (Holgers ≥ 2) were reported across all visits corresponding to 4 %. At the 12-month follow-up, Holger 0 was reported in 92 % of the cases, Holgers 1 in 8 %, and there were no reports of Holgers ≥ 2.

No abutments were removed or changed and no implants were lost. One implant was electively removed 8 months after surgery for other reasons than complications related to the implant.

Numbness and pain was investigated with Visual Analog Scale (VAS), the results are shown in Table 2. No cases of extensive numbness or pain (VAS 8–10) were reported across all visits. Moderate pain (VAS 4–7) was reported in two cases across all visits ($n = 121$), and moderate numbness (VAS 4–7) was reported in thirteen cases across all visits ($n = 120$) corresponding to 2 and 11 %, respectively. Two patients, 5 % of ($n = 37$), reported remaining moderate pain and numbness at the end of the study.

Thirty-eight patients completed the Glasgow benefit inventory (GBI) on average 14 months post-surgery (9–26 months). Figure 3 shows the mean and range of individual answers on the total scale, as well as on the individual subscales. Mean scores were positive on all subscales, with a total score of 39.5. Two patients reported negative GBI scores on individual subscales, one for physical benefit and one for social. However, the total benefit score was positive also for these two patients.

Speech reception thresholds and sound field thresholds were measured on 20 of the patients, all with conductive and mixed hearing losses. All patients showed an improvement comparing aided to unaided. For five of the 20 patients, unaided speech reception thresholds of 50 % could not be obtained. For the patients for whom unaided SRTs could be measured, unaided SRT was 74 dB SPL compared with aided SRT 51-dB SPL. The difference was highly significant ($p < 0.01$) using a two-tailed paired student's t test.

Aided threshold compared with unaided showed improvement for all measured frequencies for all 20 patients (Fig. 4). On average, the improvement was between 12 and 36 dB across the whole frequency range, with a PTA improvement of an average of 33 dB. For frequencies 250 Hz–8000 kHz, the improvement was highly significant ($p < 0.01$) and the improvement on 125 Hz was significant ($p < 0.05$) according to a repeated measures ANOVA with post hoc Tukey HSD analysis.

Discussion

The bone anchored hearing implant and sound processors, as well as the surgical technique for implanting them, have evolved in the recent years. This study reports results for

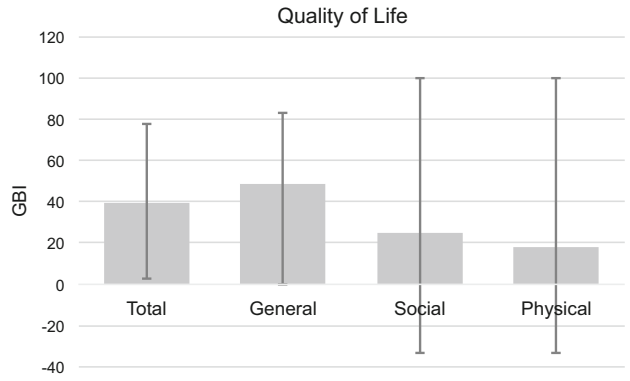

Fig. 3 Quality of life (GBI)

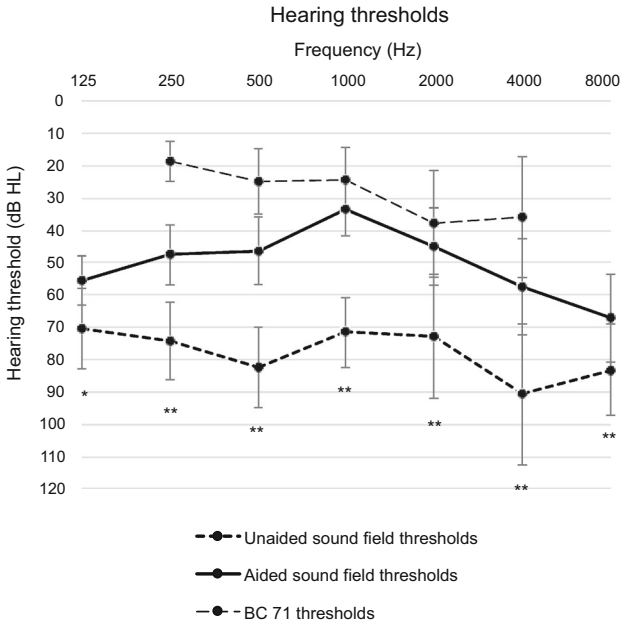

Fig. 4 Hearing thresholds unaided and aided hearing thresholds and conventional bone conduction thresholds measured with BC71. *Asterisk*, *double asterisk* denotes highly significant differences between the two sound field conditions repeated measures ANOVA with post hoc Tukey HSD analysis

the latest type of wide bone-anchored implants (as [9]), installed with tissue preserving techniques (as [7]). Modern sound processors (as [10]) were used by all patients. The study followed the standard care in a private referral center, and thus, represents real-life outcomes with the state-of-the-art bone-anchored treatment. The inherent limitations of retrospective studies were leveraged by a systematic follow-up scheme for all medical outcomes.

All surgical procedures were performed under local anesthesia, without major intraoperative complications and with an average surgery time of 20.3 min. No revision surgery or change of abutment was needed within the 12-month follow-up. No implant was lost; one implant was electively removed, because the patient did not accept for esthetic reasons. This supports the growing literature on the higher stability and, in the longer perspective, potentially lower loss rates of the wide-diameter implants (e.g., [9, 11, 12]). The 12-month data show excellent preliminary result with good skin tolerance to the percutaneous abutment; only three patients showed a slight redness around the abutment (Holger = 1). At the time of writing, the patients first included in this study are now 33 month post-op and are continuously reporting satisfaction. This is in line with other studies with long follow-up on tissue preservation technique and titanium-surface abutments, e.g., [13, 14].

The original tissue reduction surgery causes extensive trauma to tissue and subsequent postoperative pain and persisting numbness. It has been shown that tissue preservation reduces postoperative pain and numbness [15]. The result of the current study is in line with these findings. At 12 months, two patients, 5.4 % of 37, reported moderate pain and numbness, and the remaining patients reported no or limited pain or numbness.

Aided thresholds improved between 12 and 36 dB across the frequency range 125–8000 Hz with a PTA improvement of 33 dB. These results compare favorably with results from Lustig et al. [16] where an improvement in aided thresholds was also shown. We do not see a complete closure of the air bone gap (as [17]) which could be explained by the masking with white noise. Speech reception in quiet was significantly better as compared unaided; on average, an improvement of 23 dB was found as expected from unaided and aided thresholds. These results concur with other studies ([17, 18]) where improvements in SRT have also been found. Altogether, audiological results are consistent with previous studies in the area, demonstrating that bone-anchored hearing systems are an effective solution for patients with conductive hearing losses (e.g., [17]).

Quality of life generally improved in the aided condition when compared to before implantation. The GBI scores are comparable to those of another recent study of bone-anchored implants by Nelisssen et al. [19]. It should be remembered that comparing GBI scores between studies should be made with caution, since indications and patient characteristics are influencing factors. However, the total score of on average 39.6 on the GBI is high, when comparing to the early studies on GBI results for bone anchored hearing systems [20–22].

Conclusion

The study, presenting data on a large population ($n = 49$) treated with tissue preservation, wide implants and an abutment family for facilitating modern surgical

techniques, shows that this treatment is a viable solution that results in a few of complications, high degree of predictability and good audiological and quality-of-life outcomes.

Compliance with ethical standards

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of interest The authors have no conflict of interest.

Informed consent Informed consent was obtained from all individual participants included in the study.

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