Percutaneous bone-anchored hearing system implant survival after 550 primary implant surgeries

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1 | INTRODUCTION

The Bone-Anchored Hearing System (BAHS) has become an established option for rehabilitation of several type of hearing impairment such as conductive hearing loss, mixed hearing loss and single-sided deafness.[1] Overall good outcomes have been reported. Nevertheless, complications such as inflammation of the skin around the percutaneous abutment, pain and implant loss are related to BAHS.[2]

For implant loss stability, primary and secondary stability are important concepts. Primary stability is defined as implant stability immediately after surgery. Dental studies show that primary stability is influenced by implant design, surgical technique, bone quantity and bone quality.[3] Secondary stability is defined as stability over time and is determined by primary stability and osseointegration. In dental implants, osseointegration is influenced by surgical trauma, implant design, smoking status and other subject-related factors such as diabetes and hygiene.[4]

In BAHS, implant loss rates of 8.3%-18% have been reported.[5-8] 3-mm implants, young age, age of 60 or higher and male status have been described as risk factors for implant loss.[5-8] In this study, we aimed to analyse implant survival rates for BAHS surgery including risk factors for the population in Maastricht University Medical Centre+ (MUMC), the Netherlands.

2 | MATERIALS AND METHOD

2.1 | Ethics

Due to the retrospective nature of this study and anonymisation of data, ethical approval was not required according to the Medical Research Involving Human Subjects Act in the Netherlands.

2.2 | Study design

This is a retrospective case study of subjects receiving a BAHS implant between 1991 and January 2017 in MUMC. A database containing all subjects that have received a BAHS implant was used. Implant length, abutment length, manufacturer and if applicable extrusion or explant surgery are captured in this database. The database was checked by a second researcher for inconsistencies.

2.3 | Statistical analysis

Statistical analyses were performed using R version 3.3.2 (R Foundation for Statistical Computing, Vienna, Austria). Statistical significance was established at $P \leq .05$. Mean (*M*) age at implantation, standard deviation age (SD), mean follow-up time and SD for follow-up were calculated for all implants. Kaplan-Meier curves were created for overall survival. 1-year, 5-year, 10-year and 15-year implant survival rates were calculated for primary placed 4-mm implants, 3-mm implants and for 4-mm implants placed after implant loss. Based on previous reported possible risk factors,[5-8] the effect of 3-mm implants, second 4-mm implant, male sex, young age (<18) and age >60 at implantation was examined in a multivariable analysis using a Cox's proportional hazards regression model. An explorative analysis including new generation implants with a wide diameter (4,5 mm) as an additional factor was examined. Hazard ratios (HR) and 95% confidence intervals (CI) were determined for all factors.

3 | RESULTS

3.1 | Descriptives

From 1991 to January 2017, 536 subjects were implanted with 550 primary BAHS implants at MUMC. Five hundred and eleven 4-mm (92.9%) implants and 39 3-mm (7.1%) implants were inserted in 536 subjects of which 266 (49.6%) were males and 270 females (50.4%). Mean age was 49 years (SD = 18) with a mean follow-up time of 7.48 years (SD = 5.0). Five hundred and eleven 4-mm implants were inserted with a mean follow-up time of 7.5 years (SD = 5.1). Mean age at implantation for 4-mm implants was 51

(SD = 17). Thirty-nine 3-mm implants were placed with a mean follow-up time of 5.53 years (SD = 3.8). Mean age at implantation for 3-mm implants was 28 (SD = 24). In 29 subjects, a total of 36 sleeper screws were placed (*M* = 11.5 years of age, SD = 13.7). One hundred and eighty new generation wide implants were implanted as primary implant. Seven sleeper screws (19%) were mounted with an abutment after implant loss. None were extruded during follow-up.

3.2 | Implant loss

In total, 34 initial implants (6.2%) were lost during follow-up. For the primary placed implants, 28 4-mm implants (5.5%) were lost at a mean follow-up time of 3.8 years (SD = 3.9). Six primary placed 3-mm implants (15.4%) were lost at a mean follow-up time of 0.99 years (SD = 0.82). In 19 subjects, new implants were placed after loss of the primary implant of which 18 (95%) were 4-mm implants and 1 (5%) was 3-mm. Of the second implants, 4 (21%) were lost during follow-up. Reasons for implant loss are presented in Table 1.

Most implants were lost during the first 18 months of follow-up. Spontaneous loss, trauma to the implant and inflammation were reported as reasons for implant loss. Spontaneous loss was reported for 15 male subjects compared to 10 female subjects. Trauma was observed as a reason for primary implant loss in 5 male subjects compared to 1 female subject. Elective removal was performed in two cases due to chronic pain in one case and recurrent irritation of the skin after abutment removal in the other case. After a second implantation, most implants were lost in the first 6 months.

3.3 | Survival

Kaplan-Meier survival curves are presented in Figure 1. Implants survival rates are described in Table 2. Due to the limited sample size, it was not possible to calculate 10-year survival rates for the second 4-mm implant and 15-year survival rates for 3-mm implants. For the primary 4-mm implant, 1-year, 5-year, 10-year and 15-year survival rates were 98%, 96%, 94% and 92%, respectively. For the primary 3-mm implant, survival rates were 92%, 84% and 84%. For the second 4-mm implant placed after initial implant loss, survival rates were 89% and 69%.

Cox proportional hazard models revealed that male sex (HR = 1.99, 95% CI = 1.00-3.95, $P < .05$), young age (HR = 3.43, 95% CI = 1.38-8.52, $P = .008$) and second implant (HR = 5.67, 95%CI = 1.94-16.54, $P < .002$) were associated with an increased risk for implant extrusion (Table 3). No significant risk of implant loss was observed for 3-mm implants ($P = .32$) or subjects older than 60 years of age ($P = .41$). The explorative analysis including implant diameter in the model showed similar results. No significant difference for survival was observed for the new generation implants (HR = 1.85, 95% CI = 0.83-4.14, $P = .13$).

Keypoints

- Overall BAHS Implant survival rate can be as high as 92% at 15-year follow-up for 4-mm implants
- Young age (<18) is associated with increased risk for implant loss
- 3-mm implants is not associated with increased risk for implant loss
- Second implants placed after implant loss are associated with increased risk for implant loss
- Male gender is associated with increased risk for implant loss

TABLE 1 Causes for implant loss

Reason	0-6 months n (%)	6 months-18 months n (%)	18 months-5 years n (%)	> 5 years n (%)	Total n (%)
Primary placed 3-mm (n = 6)					
Spontaneous	1 (16.6%)	1 (16.6%)	2 (33.3%)		4 (66.7%)
Trauma		1 (16.6%)			1 (16.6%)
Inflammation	1 (16.6%)				1 (16.6%)
Primary placed 4-mm (n = 28)					
Spontaneous	6 (21%)	4 (11.5%)	3 (10.7%)	6 (21%)	19 (67.9%)
Trauma	1 (3.6%)	1 (3.6%)	2 (7.1%)	1 (3.6%)	5 (17.9%)
Inflammation	2 (7.1%)	1 (3.6%)			3 (10.7%)
Elective removal				1 (3.6%)	1 (3.6%)
Second 4-mm after implant loss (n = 4)					
Spontaneous	2 (50%)				2 (50%)
Trauma	1 (25%)				1 (25%)
Elective removal			1 (25%)		1 (25%)

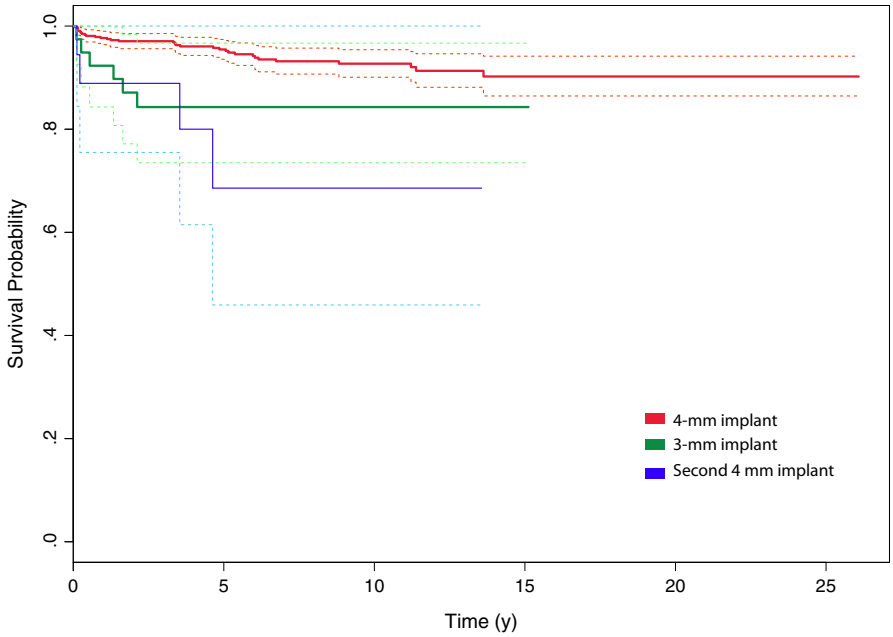

FIGURE 1 Kaplan-Meier Implant survival curve for 1-, 5-, 10- and 15-year implant survival for primary 3-mm implants, primary 4-mm implants and second 4-mm implants after loss of the primary implant. Dashes indicate 95% confidence interval

TABLE 2 Implant survival rate

Implant survival	Mean	95% confidence interval	
1-year			
3-mm implant (n = 36)	0.92	0.84	1.00
4-mm implant (n = 467)	0.98	0.97	0.99
2nd 4-mm implant (n = 13)	0.89	0.76	1.00
5-years			
3-mm implant (n = 21)	0.84	0.74	0.97
4-mm implant (n = 310)	0.96	0.95	0.98
2nd 4-mm implant (n = 6)	0.69	0.46	1.00
10-years			
3-mm implant (n = 5)	0.84	0.71	0.97
4-mm implant (n = 172)	0.94	0.91	0.96
15-years			
4-mm implant (n = 37)	0.92	0.87	0.95

TABLE 3 Cox regression analysis of risk factors for implant loss. 3-mm implant is compared to 4-mm implant. Male gender is compared to female gender. Age > 60 is compared to age ≤ 60 years. Age < 18 years is compared to Age ≥ 18 years. Second implant after implant loss is compared to the first 4-mm implant

Implant loss	Hazard ratio	95% confidence interval	*P*-value
3-mm implant	1.68	0.61-4.67	.32
Male gender	1.99	1.00-3.95	<.05
Age < 18 y	3.43	1.38-8.52	.008
Age > 60 y	0.59	0.31-1.61	.41
Second 4-mm implant	5.67	1.94-16.54	<.002

4 | DISCUSSION

4.1 | Synopsis of key/new findings

This study shows an overall survival rate of 93.8% for first implants, which is high compared to previous studies.[5-7] Implant survival rates at 1-year, 5-years, 10-years and 15-years were 98%, 96%, 94%, 92% for 4-mm implants, respectively. Young age, male sex and the second 4-mm implant were significantly associated with implant loss. 3-mm implants, old age and implant diameter were not associated with implant loss. The observed higher rates of implant loss in 3-mm implants are most likely attributed to young age. Sleeper screws are often placed in young children. After implant loss, a second sleeper screw was placed in several subjects upon abutment placement on the original sleeper screw. None of these implants were lost during follow-up possibly indicating that placement of a second sleeper screw might not have been necessary in these cases.

4.2 | Strengths and limitations

In this study, long-term implant survival is described for 550 primary placed implants and 19 implants placed after loss making it one of the largest case series published to date for BAHS.[5-7] Moreover, here, we specifically describe the use of sleeper screws. The methods used in this study provide a statistical model for risk factors related to implant loss. This study suffers from some limitations. Due to the limited number of implant losses, we were unable to include factors such as very young age (<6 years), surgeon, learning curve, implant type and abutment length. Some subjects might not report an implant loss. Unfortunately, non-usage is not reported in our

database. Possible relevant factors such as smoking status, body mass index, medication use and medical history were not structurally reported. The sample sizes of 3-mm implants, sleeper screws and second implants are relatively small warranting some caution when interpreting the data.

4.3 | Comparison with other studies

Compared to other studies, the implant survival rates are high. Especially, long-term follow-up results show higher survival rates. Larssen et al[6] showed 10-year survival rates for 4-mm implants was 74% and overall cohort survival rate of 91.2%. Dun et al. described an overall cohort survival rate of 91.7%.[5] Both centres were early adopters of the BAHS system.[5,6] During the early years of development, implant loss rates may have been higher. In recent years, wider implants have been introduced[9,10] which increased stability and facilitated the use of longer abutments and possibly early loading. These wider implants may have improved 5-year survival rates. However, we did not observe this effect in our sample. Here, we mainly observed trauma in male subjects. In addition to risk factors such as smoking, male subjects may potentially exhibit more active behaviour, potentially explaining the increased risk for implant loss. In contrast to previous studies, we observed no increased risk for 3-mm implants. In young subjects, 3-mm implants are often placed. The risk for implant loss might be increasesd by the combination of younger subjects and the placement of 3 mm implants. The sample size of very young children is limited in our database and pooling data of several centres might be necessary to achieve an adequate sample size to identify whether very young age (<6) itself is an additional risk factor. We found no evidence for an increased susceptibility for implant loss in older subjects. Osseointegration is insufficient in cases of spontaneous loss and loss due to recurrent infection. In normal healthy bone, osseointegration should be sufficient after approximately 3 weeks to facilitate loading of the BAHS.[5,10] Often spontaneous loss is raported after this period indicating that some amount of osseointegration did take place. Future studies may clarify the reasons for spontaneous implant loss and their respective relation to known risk factors.

5 | CONCLUSION

This study shows an overall survival rate of 93.8% for first implants. Survival rates of 98% and 92% after 1-year and 15-years follow-up, respectively, were found for 4-mm implants. Age <18, male gender and second implantation were found to be significantly associated with implant loss.

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CONFLICT OF INTEREST

T.C is involved in a multicenter randomized controlled study comparing bone-anchored hearing implants sponsored by Oticon Medical AB (Askim, Sweden). The other co-authors have no conflict of interests in connexion with this article.

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Contralateral neck metastases in lateralised, resectable advanced stage oropharyngeal squamous cell carcinoma—Results of 57 patients undergoing bilateral selective neck dissection

1 | INTRODUCTION

Management of the clinically N0 contralateral neck has long been a contentious issue in the management of oropharyngeal squamous cell carcinoma (OPSCC). The work of Lim *et al*[1] established the value of electively treating the N0 contralateral neck in patients with OPSCC, particularly to include levels II-IV, rather than I-III. There is also good evidence to support the accurate staging of contralateral disease in these patients, with current literature suggesting a rate of 9%[2] and even up to 26% in the HPV-positive population.[3] However, studies have shown no survival benefit of surgical versus oncological treatment.[4] The issue remains controversial, with staging and treatment of the neck being determined largely by local protocol.

It is well recognised that the incidence of OPSCC is increasing, largely due to the epidemic rise in human papilloma virus (HPV)-related disease. The HPV-positive population of patients is distinct from the HPV-negative subgroup as they are generally younger patients with fewer co-morbidities, who present with more advanced disease (75% being AJCC stage III and IV). Options for treatment of advanced OPSCC include chemoradiotherapy or transoral surgery with neck dissection(s) and adjuvant oncological treatment. We are aware that HPV-positive patients' survival is generally high, irrespective of the primary treatment modality. Therefore, functional considerations (such as swallow, voice and quality of life) are of the utmost importance when deciding on a treatment rationale. There is a trend reported in the literature towards improved swallowing outcomes with transoral surgery versus chemoradiotherapy.[5] Whilst surgical data are heterogeneous in terms of adjuvant therapy in this setting, the possible benefit of transoral surgery on swallowing is likely to be due to the reduction in radiotherapy field sizes and the omission of chemotherapy where appropriate. There is also published evidence to support decreased morbidity and improved long-term functional outcomes with unilateral irradiation compared to bilateral.[6,7] Local analysis (unpublished) showed a significant reduction in hospital admissions and a reduction in acute toxicity when unilateral neck irradiation (with or without chemotherapy) was compared to bilateral neck radiotherapy treatment fields. Function is also high on the current research agenda, with a number of current trials in the UK, and worldwide, considering de-intensification of treatment in HPV-positive patients with OPSCC, with the aim of ascertaining functional benefits.

2 | METHODS

Between March 2014 and April 2017, the head and neck multidisciplinary teams in Newcastle, Carlisle and Sunderland have considered a policy of performing a contralateral, staging, selective neck dissection (principally levels IIa and III) in patients undergoing primary transoral surgery and therapeutic neck dissection for lateralised advanced stage OPSCC. Tumours were at least 1 cm lateral to the midline of the base on tongue. All patients were clinically N+ with no evidence of contralateral nodal disease, according to standard clinical examination and radiological staging (all patients underwent computed tomography [CT] with positron emission tomography—CT utilised in the work up of the unknown primary cases). Patients in whom a primary site was not found following thorough investigations, which often included transoral robotic tongue base mucosectomies, were excluded. Data were collected prospectively. Primary tumour specimens were assessed for P16 immunohistochemistry followed by high-risk HPV in situ hybridisation, as per current best practice guidelines.[8] Postoperative RT was administered at a dose of 60–65 Gy for 2 or more pathologically involved neck nodes, and postoperative concurrent CRT (weekly cisplatin at 30–40 mg/m^2) was initiated in patients with pathologically involved primary site margins or ECS within the resected lymph nodes.

3 | RESULTS

We performed contralateral neck dissections on 57 patients with lateralised OPSCC, 52 of whom had HPV-positive disease. Forty