The Journal of Laryngology & Otology

cambridge.org/jlo

Is the use of a bone conduction hearing device on a softband a useful tool in the pre-operative assessment of suitability for other hearing implants?

P M Spielmann[1], R Roplekar[2], C Rae[3], F Ahmed[3] and S E M Jones[1]

[1]University Department of Otolaryngology, Ninewells Hospital and Medical School, Dundee, Scotland, [2]Department of Otolaryngology, Luton and Dunstable Hospital and [3]Department of Audiology, Kings Cross Hospital, Dundee, Scotland, UK

Main Article

Mr S E M Jones takes responsibility for the integrity of the content of the paper

Cite this article: Spielmann PM, Roplekar R, Rae C, Ahmed F, Jones SEM. Is the use of a bone conduction hearing device on a softband a useful tool in the pre-operative assessment of suitability for other hearing implants? *J Laryngol Otol* 2018;**132**:505–508. https://doi.org/10.1017/S0022215118000816

Accepted: 30 December 2017

Key words:
Hearing Loss; Bone Conduction Hearing; Implant; Middle Ear

Author for correspondence:
Mr Stephen E M Jones,
University Department of Otolaryngology,
Ninewells Hospital and Medical School,
Dundee DD1 9SY, Scotland, UK
E-mail: stephenemjones@nhs.net

Abstract

Objective. To assess whether pre-operative assessment with a bone conduction hearing device on a softband is an accurate predictor of performance with one of two transcutaneous hearing implants.

Study design. Cohort study comparing pre-and post-operative speech audiometry using correlation analysis.

Methods. Pre-operative pure tone audiometry and aided half optimum speech recognition thresholds were compared with post-operative aided results for each ear that had undergone implantation. Data were collected prospectively.

Results. Full data were available in 24 ears. In 19 out of 24 ears (79 per cent), the difference between pre- and post-operative speech scores was less than 10 dB, demonstrating a good clinical correlation. The Pearson correlation coefficient was calculated at 0.66 (95 per cent confidence interval = 0.357–0.842), indicating a strong statistical correlation.

Conclusion. Pre-operative softband testing shows good clinical correlation and strong statistical correlation with hearing implant performance. The findings suggest there is value in using the test to predict performance and guide patients' expectations.

Introduction

Implants for hearing loss, such as percutaneous bone conduction hearing devices, have been in use for more than 30 years. A number of newer transcutaneous devices have become available, which have increased patient choice of implantable hearing devices. Improvement in hearing thresholds, compared to both unaided and conventionally aided audiometry, when using an active middle-ear implant has been demonstrated previously.[1] A demonstrated improvement in pure tone thresholds does not necessarily translate into a useful pre-operative test to predict good functional outcomes for an individual patient.

The increased number of available devices has paradoxically made decision-making more difficult, as a patient may be a candidate for a number of suitable devices, each with relative advantages and disadvantages. As the cost of implantable hearing devices has restricted their use in many healthcare economies, it is important for physicians to be sure that a prospective patient will obtain adequate benefit from a particular device prior to its implantation. Audiometric candidacy criteria typically rely on bone conduction thresholds alone, but the ability to simulate the expected hearing thresholds and sound quality prior to surgery is desirable and useful for counselling patients. A bone conduction device worn on a headband can provide just that simulation.

It has previously been demonstrated that pre-operative pure tone audiometry and word recognition scores with a bone conduction hearing device on a soft headband correlate well with the post-operative results following implantation with the same bone conduction hearing device, either using a percutaneous attachment[2,3] or a magnetic attachment.[4] For obvious reasons, it is not possible to carry out tests using the transcutaneous devices pre-operatively.

Other studies have examined the outcomes of transcutaneous bone conducting devices and active middle-ear implants. Rainsbury *et al.* compared pre-operative softband bone conduction thresholds and speech discrimination scores with post-operative tests using their transcutaneous bone conducting aid in a small sample.[5] They demonstrated a correlation between pre-operative bone conduction thresholds and post-operative aided sound-field thresholds, but not between pre- and post-operative speech testing. Monini *et al.* compared pre-operative pure tone and speech audiometry in quiet and noise, and compared these to post-operative outcomes in patients who had undergone placement of an active middle-ear implant on the round window, again in a small sample of patients.[6] They demonstrated that 'statistically similar' results were achieved

in pre-operative word recognition scores in quiet and in noise with a bone conduction hearing device on a softband and in post-operative scores with an active middle-ear implant.

This study aimed to compare the results of pre-operative speech testing using a bone conduction hearing device on a softband with post-operative speech discrimination scores, in relation to both a transcutaneous active bone conducting implant and a transcutaneous active middle-ear implant.

Materials and methods

Patients identified as candidates for a hearing implant were assessed according to the department's normal pre-operative testing regimen, including pure tone audiometry and speech audiometry without hearing aids, and then with a bone conduction hearing device mounted on a headband. Ponto Pro Power and Ponto Plus Power (Oticon, Smørum, Denmark), and BP110 (Cochlear, Sydney, Australia) sound processors were used.

All patients included in this study had conductive or mixed hearing loss. Patients with bone conduction thresholds greater than 50 dBHL were excluded from this study; these individuals would not be suitable candidates for implantation with the bone conduction hearing device used in the study and optimal hearing results would not be expected. Patients under 18 years old were also excluded. Patients with severe or profound unilateral sensorineural hearing loss (sometimes termed single-sided deafness) were analysed as a subgroup of the main cohort.

Speech audiometry was performed, with 'AB' phonetically balanced open-set word lists, using the Aurical hearing instrument fitting software system (Otometrics, Taastrup, Denmark) at 90° and 270° azimuth, with sound presented through both speakers at once. Half optimum speech recognition threshold in free field speech values were obtained pre-operatively, using the headband bone conduction hearing device. Pre-operative speech testing in the unilateral sensorineural hearing loss group was performed with the softband bone conduction hearing device applied to the non-hearing ear, with sufficient masking to the hearing ear.

Patients were then implanted with the appropriate transcutaneous device, either the Vibrant Soundbridge or the Bonebridge (Med-El, Innsbruck, Austria), according to audiometric testing, suitability of anatomy and patient choice. At three months post-operatively, the patients were re-tested using the device processor instead of the softband bone conduction hearing device. Results were recorded prospectively using the AuditBase audiology clinic management system (Auditdata, Taastrup, Denmark).

Data were collected prospectively at a single centre from consecutive patients. Ethical approval was not required, as this was the standard test battery applied to select implant candidates, and no additional tests were carried out pre- or post-operatively. Data were collated in Excel spreadsheet software (Microsoft, Redmond, Washington, USA) and statistical tests were carried out using R software, version 3.3.1.[7]

Results

Twenty-four ears met inclusion criteria and all underwent the full test battery, pre-and post-operatively. The cohort included 7 male and 17 female patients. Their ages ranged from 18 to 81 years (mean, 49.0 years). Seventeen ears received a Bonebridge implant, while seven received a Vibrant Soundbridge implant. Many of the Vibrant Soundbridge patients had bone conduction thresholds too poor for inclusion in the study, hence the relatively small numbers for this implant.

Table I summarises the assessment findings; negative values signify an improvement in the thresholds after implant surgery, compared with the assessment score.

Four patients (numbers 4, 5, 8 and 19) had single-sided deafness. This subgroup's thresholds were assessed separately. The mean difference between pre- and post-operative (implanted) half optimum speech recognition thresholds was −1.9 dBHL (range, −13 to 18 dBHL). The mean absolute difference (ignoring whether a positive or negative value) was 6.6 dB.

In 19 out of 24 ears (79 per cent), the difference was ± 10 dB, demonstrating a good clinical correlation. The Pearson correlation coefficient was calculated as 0.66 (95 per cent confidence interval (CI) = 0.357–0.842), indicating a strong statistical correlation (Figure 1).

The pre-operative bone conduction thresholds were averaged over 0.5, 1, 2 and 4 kHz, and compared with the post-operative half optimum speech recognition threshold. Bone conduction thresholds were only recordable in 20 ears as 4 patients were implanted for single-sided deafness.

Twelve ears had a pre-operative mean bone conduction of less than 25 dBHL; eight had a mean of more than 25 dBHL. In those ears with a mean pre-operative bone conduction of less than 25 dBHL, the mean absolute difference when compared to post-operative half optimum speech recognition threshold was 7.5 dB; when overestimates and underestimates were included as negative and positive values, the mean difference was just −3.2 dB. Seven of 12 ears (58 per cent) had a close clinical correlation, with a difference of less than 10 dB, and all were 15 dB or less. In those ears with a mean pre-operative bone conduction threshold of more than 25 dBHL, the mean difference when compared to post-operative half optimum speech recognition threshold was −20.4 dB; only two of eight ears (25 per cent) had a good clinical correlation with a difference of less than 10 dB.

In the single-sided deafness patients who underwent Bonebridge implantation, the average difference between pre- and post-operative half optimum speech recognition thresholds was −4 dB (range, −12 to 10 dB). In three patients, the half optimum speech recognition threshold was underestimated, but the mean was skewed by a single patient's data where it was overestimated.

Examining the Bonebridge group alone, the correlation coefficient for pre- versus post-operative half optimum speech recognition thresholds was 0.52 (95 per cent CI = 0.05–0.80). In the Vibrant Soundbridge group, which had a sample size of only seven, the correlation coefficient was 0.82 (95 per cent CI = 0.18–0.97). The wider CIs are unsurprising, given the smaller sample size; nevertheless, a moderate correlation was still observed in the Bonebridge group, and there was a strong correlation in the Vibrant Soundbridge group. The wide CIs mean that it is not possible to make any firm conclusions; larger sample sizes are required for a definitive answer. In the Bonebridge group, only one patient showed an overestimation of greater than 10 dB (number 7, who only achieved a half optimum speech recognition threshold of 28 dB post-operatively, compared to 10 dB with the softband bone conduction hearing device). In the Vibrant Soundbridge group, no patients' outcome was overestimated by more than 10 dB.

https://doi.org/10.1017/S0022215118000816 Published online by Cambridge University Press

TABLE I. PRE- AND POST-OPERATIVE HALF OPTIMUM SPEECH RECOGNITION THRESHOLDS

Patient number	Implant type	Pre-op HOSRT (dBHL)	Post-op HOSRT (dBHL)	Difference (dBHL)*†	Pre-op mean bone conduction threshold (dBHL)‡
1	BB	10	10	0	9
2	BB	12	10	−2	22.5
3	BB	16	10	−6	19
4	BB	17	5	−12	Not recordable
5	BB	15	10	−5	Not recordable
6	BB	15	24	9	17.5
7	BB	10	28	18	24
8	BB	5	15	10	Not recordable
9	BB	5	5	0	7.5
10	BB	26	15	−11	17.5
11	BB	15	22	7	21
12	BB	40	34	−6	21
13	VSB	16	15	−1	32.5
14	VSB	10	10	0	34
15	VSB	35	40	5	39
16	VSB	23	30	7	38
17	BB	7	0	−7	11
18	BB	19	6	−13	17.5
19	BB	19	10	−9	Not recordable
20	VSB	15	4	−11	31
21	VSB	22	13	−9	43
22	VSB	5	5	0	20
23	BB	13	5	−8	30
24	BB	10	8	−2	41

*A negative score implies better hearing with the implant compared to the predicted level. †Mean difference = −1.9 dBHL. ‡Averaged over 0.5, 1, 2 and 4 kHz. Pre-op = pre-operative; HOSRT = half optimum speech recognition threshold; post-op = post-operative; BB = Bonebridge; VSB = Vibrant Soundbridge

Discussion

Our results for 24 operated ears indicate a strong correlation between the results of pre-operative speech audiometry using the headband bone conduction hearing device and the results after implantation. These findings are in keeping with a series from Dalhousie University, Canada, where Rainsbury *et al.* assessed a series of seven implants (Bonebridge only) and found that the headband assessment underestimated the implanted device.[5] Rainsbury *et al.* advise caution using the headband testing because of this underestimation. This might be expected, given what is already known regarding sound attenuation, particularly in the high frequencies, by soft tissues when the softband or magnetic systems (such as Baha® Attract) are used.[4,8]

- Aided pure tone and speech audiograms using a bone conduction hearing device on a soft headband are used to assess hearing implantation suitability
- Few studies have examined the correlation between pre- and post-operative speech audiometry for a softband bone conduction hearing device versus Bonebridge or Vibrant Soundbridge
- The results suggest good correlation between pre-operative bone conduction hearing device aided speech audiometry and post-operative device aided speech

This study demonstrated that, when the mean bone conduction thresholds were less than 25 dBHL, bone conduction was a particularly good predictor of post-operative half optimum speech recognition threshold. In patients with mixed hearing loss, with a mean bone conduction of more than 25 dBHL, bone conduction was a poor predictor of performance, and the pre-operative softband half optimum speech recognition threshold was a much better predictor of subsequent performance.

We also noted that the bone conduction hearing device on the softband was a good predictor of subsequent implant performance in patients with single-sided deafness; however, with only four patients in this group, further statistical analysis was not possible. An additional study with a larger number of single-sided deafness patients would help to confirm its usefulness in this group.

Overall, 19 out of 24 ears (79 per cent) had 10 dB or less difference between pre- and post-operative half optimum speech recognition thresholds, and the mean difference between pre- and post-operative results was less than 10 dB.

In this study, the results obtained using the softband with a bone conduction hearing device correlated strongly with hearing implant performance, indicating that it is useful for anticipating the degree of benefit. Use of the bone conduction hearing device on a softband in patients' assessment not only allows prediction of implant performance, as assessed

https://doi.org/10.1017/S0022215118000816 Published online by Cambridge University Press

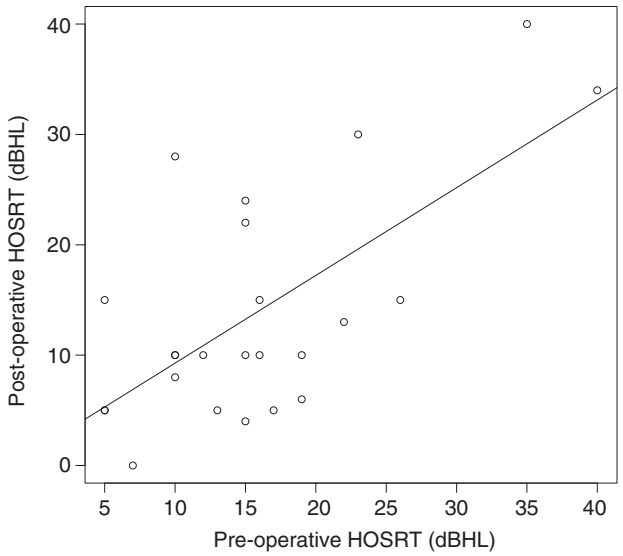

Fig. 1. Scatterplot of pre- and post-operative half optimum speech recognition threshold ('HOSRT') scores. Individual patients represented by dots, with a line of best fit.

by Rainsbury *et al.*; it can also be used to guide patients' expectations regarding the outcome of hearing benefit.

Patients whose hearing is outside the fitting range for a bone conduction hearing device undergo testing with a softband bone conduction hearing device in our unit. We do not believe that it is a good predictive indicator of their final hearing outcome; nevertheless, it may still be beneficial to give patients some time with the device as it may help to manage their expectations.

The main limitation of this study is the small number of patients in the series, hence the 95 per cent CI ranging between 0.357 and 0.842. Despite this, it remains the largest published UK series assessing pre- and post-operative audiological outcomes of middle-ear and transcutaneous bone conduction hearing implants, as far as we are aware, and perhaps reflects the recent introduction of this technology. We feel that a larger series would be valuable in order to gain a better insight into the predictive value of this pre-operative assessment tool and to improve the accuracy of the calculated correlation, narrowing the rather wide CI.

Conclusion

In this series of 24 patients, the mean difference between aided half optimum speech recognition thresholds using a headband bone conduction hearing device and actual values after hearing implant surgery was −1.9 dB, indicating slightly better outcomes than predicted by the pre-operative assessment. This study has shown that, in the majority of cases (79 per cent, 19 out of 24), the difference between the simulated and actual post-implant half optimum speech recognition threshold is less than or equal to 10 dB. In addition, in most cases (18 out of 24), the simulated half optimum speech recognition threshold underestimated or matched the post-operative outcome. There was also a strong statistical correlation between the simulated and actual results (Pearson's coefficient = 0.66).

This early series indicates a role for the use of a headband bone conduction hearing device for simulating the expected minimal improvement in speech audiometry for a patient. Larger studies may confirm the predictive value of speech audiometry with a softband bone conduction hearing device, prior to the use of Bonebridge or Vibrant Soundbridge implants in suitable patients. We believe that it also plays an important role in patients' counselling and expectation management, and thus contributes to both the patient's and surgeon's decision-making.

Competing interests. None declared.

References

1 Ihler F, Bewarder J, Blum J, Matthias C, Canis M. Long-term functional outcome and satisfaction of patients with an active middle ear implant for sensorineural hearing loss compared to a matched population with conventional hearing aids. *Eur Arch Otorhinolaryngol* 2014;**271**:3161–9
2 Monini S, Filippi C, Atturo F, Biagini M, Lazzarino AI, Barbara M. Individualised headband simulation test for predicting outcome after percutaneous bone conductive implantation. *Acta Otorhinolaryngol Ital* 2015;**35**:258–64
3 Pfiffner F, Kompis M, Stieger C. Bone-anchored hearing aids: correlation between pure-tone thresholds and outcome in three user groups. *Otol Neurotol* 2009;**30**:884–90
4 Kara A, Iseri M, Durgut M, Topdag M, Ozturk M. Comparing audiological test results obtained from a sound processor attached to a softband with direct and magnetic passive bone conduction hearing implant systems. *Eur Arch Otorhinolaryngol* 2016;**273**:4193–8
5 Rainsbury JW, Williams BA, Gulliver M, Morris DP. Preoperative headband assessment for semi-implantable bone conduction hearing devices in conductive hearing loss: is it useful or misleading? *Otol Neurotol* 2015;**36**:e58–62
6 Monini S, Filippi C, Atturo F, Barbara M. Is the bone-conduction headband test useful for predicting the functional outcome of a round window active middle ear implant? *Otol Neurotol* 2013;**34**:1329–35
7 R Core Team. *R: A Language and Environment for Statistical Computing* [computer program]. Vienna: R Foundation for Statistical Computing, 2016
8 Heywood RL, Patel PM, Jonathan DA. Comparison of hearing thresholds obtained with Baha preoperative assessment tools and those obtained with the osseointegrated implant. *Ear Nose Throat J* 2011;**90**:E21–7

https://doi.org/10.1017/S0022215118000816 Published online by Cambridge University Press