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Research Article

Evaluation of Clinical Parameters in FMT-Application of a Vibrant Soundbridge® at the Short Incus Process Compared to Conventional FMT-Application

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ABSTRACT

Background: The application of the Floating Mass Transducer (FMT) of a Vibrant Soundbridge® (VSB®) to the short incus process is intended to reduce both the surgery time and the complication and revision rate compared to other forms of application. In addition to collecting these parameters, the aim of this study is to investigate the primary audiological outcome of patients with an FMT application to the short process compared to the conventional methods.

Methods: The present study retrospectively examined a total of n=36 patients who received a VSB® between 01/2015 and 08/2018 at the ENT University Hospital Leipzig. In n=12 patients (group 1) the FMT was coupled to the short process, in n=24 patients (group 2) to other ear structures. The audiological results were evaluated pre- and postoperatively in the pure tone audiogram according to the recommendations of the AAO-HNS (1995) and the intelligibility (Freiburger, monosyllabic) was measured at 65 dB in the speech audiogram. In addition, the revision and complication rates as well as the surgical time were evaluated.

Results: The audiological outcome of group 2 was significantly better postoperatively in both the pure tone ($p<.001$) and speech audiogram ($p=.012$). The surgery time of group 1 was significantly shorter ($p=.002$), but with a slightly increased revision rate ($p=.519$). The complication rate of group 2 was slightly higher, with no statistically significant difference to group 1 ($p=.185$).

Conclusions: The FMT application on the short ambos process does not seem to offer any advantage in terms of audiological outcome, but at the same time is associated with a significantly shorter surgery time. There are no statistically significant differences in revision and complication rates.

Introduction

The Vibrant Soundbridge® (VSB®) is a widely used, partially implantable active middle ear hearing system. Indications include mild to moderate, sensorineural or combined hearing loss, recurrent otitis externa, a failed conventional hearing aid fitting and also ear malformations [5, 3]. VSB® was introduced in 1996 and since then safety, efficacy and long-term data for audiological benefit were shown to be satisfying [4, 6, 12]. In addition, various coupling techniques were presented and compared, particularly in terms of audiological benefit. However, previous studies showed inconsistent results regarding these parameters. Some studies found no relevant difference in audiological outcome between different coupling techniques, others postulated that there might be a difference in audiological benefit between the different available coupling techniques [1, 10, 12].

The classic surgical approach for VSB® implantation is performed by mastoidectomy and subsequent posterior tympanotomy. The implantable part of the VSB®, mainly consisting of the Floating Mass Transducer (FMT), can be coupled to either the incus body, the long incus process (most commonly used), the stapes suprastructure, the round or the oval window. In 2006 Truy *et al.* were able to show in temporal bone models that FMT-coupling can also be performed through a transcanal approach using extended antrotomy [11]. Since 2014, an alternative approach of coupling the FMT to the short incus process (SP) has increasingly been performed and compared to classic FMT-coupling

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techniques. The main benefit of coupling the FMT to the short incus process (Figure 1) is the possibility of renouncing a posterior tympanotomy, which is always combined with mastoidectomy, making SP-coupling a more gentle surgical approach.

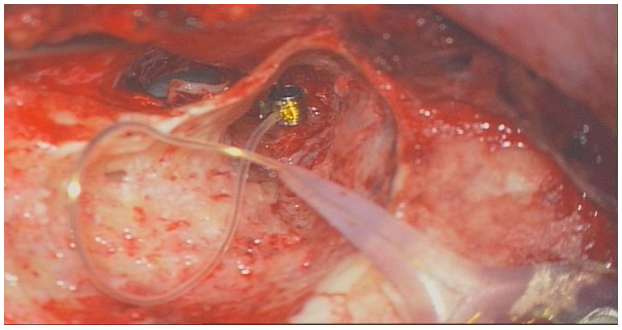

Figure 1: Intraoperative situs showing SP-coupling of the FMT.

SP-coupling has also been discussed to show better audiological results compared to standard FMT-coupling techniques (non-short process coupling = n-SP), as well as significantly shorter duration of surgery [10]. The aim of this study was to compare audiological results in pure tone and speech audiograms between patients who received FMT coupling at the middle ear structures SP and n-SP, implanted at the ENT department of the University Hospital Leipzig. In addition, the duration of the surgery, the complication and revision rates have been analyzed.

Materials and Methods

I Clinical Data

This retrospective study involved a total of n=29 patients (n=36 ears) (age 55.8 ± 20.3 years; n=14 male and n=15 female) who received a Vibrant Soundbridge® between January 2015 and December 2018. In n=12 ears the floating mass transducer was coupled to the short incus process, in n=24 ears FMT-coupling was performed at other possible middle-ear structures. The study was conducted at the ENT-Department of Leipzig University Hospital. Indications for VSB® implantation were middle to severe and severe mixed or sensorineural hearing loss, as well as recurrent otitis externa and failed permanent hearing aid fitting. The inclusion criteria specified maximum bone conduction thresholds of 65 dB [HL]. In addition, good potentials for assisted speech recognition, normal middle ear anatomy, and no evidence of retrocochlear or central auditory pathology were required. Patients receiving a combination of tympanoplasty and VSB® implantation were excluded. All surgeries were performed by experienced ear surgeons. Patients gave their informed consent and the study protocol was in accordance to the guidelines on human research.

II Audiological Measurements

All audiological measurements were performed with calibrated instruments in a sound booth room (DIN EN ISO 8253). The audiological testing included standard pure-tone audiometry (air conduction (AC): 0.25 to 8 kHz; bone conduction (BC): 0.5 to 6 kHz), performed with a clinical audiometer, in 5 dB steps; pure-tone averages of the BC thresholds were measured at 0.5, 1, 2 and 3 kHz (AAO-HNS 1995 guidelines after tympanoplasty) and speech audiometry in quiet (‘‘Freiburger monosyllables speech test’’ at 65 dB SPL) was performed. Preoperatively unaided thresholds were compared to postoperative thresholds. Audiological testing was conducted preoperatively and 3-9 months postoperatively by audio-engineers.

III Statistical Analysis

Statistical analysis for thresholds, speech audiometry (unaided vs. aided) and significance of the duration of surgery was performed by Man-Whitney-U-Test. Interpretation of complication and revision-rates was performed by fisher’s exact test. Statistical significance is assigned at the 95% confidence level and above ($p<0.05$). Error bars are given as standard deviations (SD).

Results

I Audiological Outcome

Figure 2A shows the results for audiological outcome pre- and post-surgery between the n=2 groups. Preoperatively no statistically significant difference between thresholds was found (U=117.0, Z= -1.07, p=.296, d=.363). Postoperatively the data of n=7 ears for thresholds remained missing. The audiological outcome was significantly better in patients with n-SP-coupling postoperatively in pure tone audiometry (U=30.5, Z=-3.09, p=.001, d=1.394).

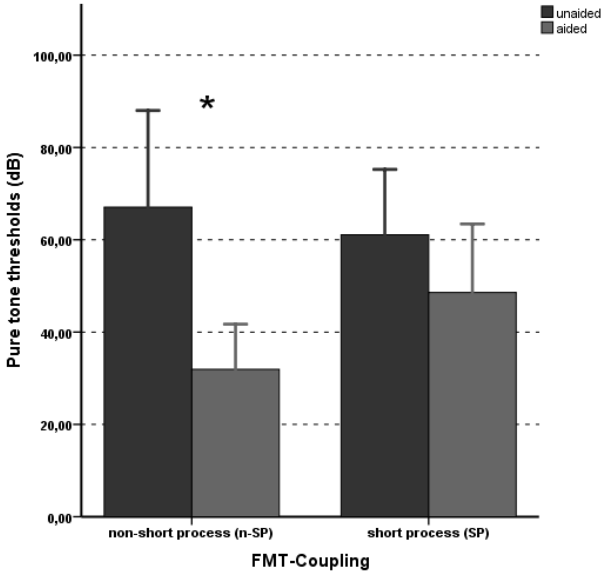

Figure 2A: Results for mean pure tone audiometry thresholds preoperatively (unaided) and after coupling the FMT to either SP or n-SP structures (aided). For n-SP-coupling a statistically significant benefit regarding mean pure tone thresholds was found (*p=.001).

Figure 2B shows the results for speech recognition in Freiburger monosyllabels at 65 dB pre- and post-operatively between the n=2 groups. Pre-surgery the data of n=5 ears for speech recognition in Freiburger monosyllabels at 65 dB remained missing, no statistically significant difference between the n=2 groups was found (U=107.5, Z=-.33, p=.795, d=.095). Post-surgery the data of n=9 ears for speech recognition in Freiburger monosyllabels at 65 dB remained missing. A statistically significant benefit regarding speech recognition for n-SP-coupling was found (U=38.5, Z=-2.47, p=.013, d=1.065).

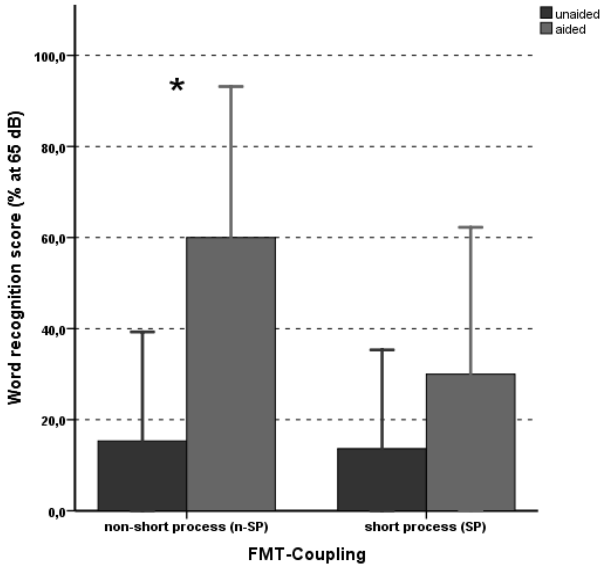

Figure 2B: Results for speech recognition in Freiburger monosyllabels at 65 dB before (unaided) and after (aided) coupling the FMT to either SP or n-SP structures (aided). For n-SP-coupling a statistically significant benefit regarding speech recognition was found (*p=.013).

II Duration of Surgery

Figure 3 shows the results for the duration of surgery. The data of n=4 VSB®-implantations were excluded of statistical analysis due to being combined with other otosurgical procedures. Surgery time (transection-suture-time) within SP-coupling was significantly shorter (95.15 min ± 24.53 min, U=51.5, Z=-2.764, p=.005, d=1.119).

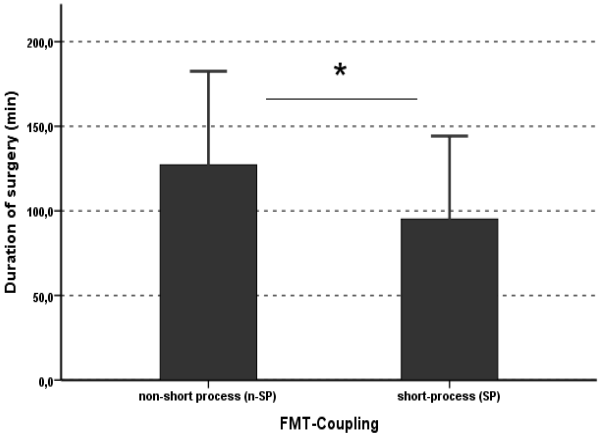

Figure 3: Results for duration of surgery between n-SP- and SP-Coupling. For SP-coupling a statistically significant shorter duration of surgery was found (*p=.005).

III Revision- and Complication-Rates

The revision-rate within SP-coupling was 14.3 % and therefore slightly elevated compared to n-SP-coupling (11.4 %). However, there was no significant difference (p=.243) between the n=2 groups. The complication rate within n-SP-coupling was 5.7 % and therefore slightly elevated compared to SP-coupling (0.0 %) but showed no significant difference (p=.519) compared to SP-coupling.

Discussion

In the present study, patients who received SP-coupling of a VSB® showed no advantage regarding the audiological outcome in pure tone or speech audiometry. Statistically significant differences can only be found in patients aided with n-SP-coupling for pure tone thresholds ($p_{aided\ pure\ tone}$ = .001, $d_{aided\ pure\ tone}$ =1.394) and speech perception ($p_{aided\ speech}$=.013, $d_{aided\ speech}$=1.065). Considering the small sample sizes in the present study, however, this audiological effect size must be viewed critically for a realistic statistically significant difference. These audiological results therefore contrast with other recent studies, that found SP-coupling leads to better audiological results than conventional FMT-coupling [8, 10]. Better audiological outcome after SP-coupling may for example be explained by the lower risk of cochlear damage during surgery, which can either be caused by fewer acoustic trauma as a result of shorter surgery time, or the longer anatomic distance of the short incus process to the inner ear.

On the other hand, there are several reasons that might explain worse audiological outcome after SP-coupling. One approach may be the lack of surgical experience using this relatively new coupler technology, compared to conventional FMT-coupling [9]. It is also possible that the coupler design and technology itself still has room for improvement in order to optimally conduct the required forces to the inner ear. Other reasons may be the relatively tight anatomic space created after antrotomy, possibly making it difficult for the SP-coupler to swing correctly. The comparatively longer distance of the short incus process to the inner ear may be another important handicap, making higher forces necessary for sound conduction than in conventional FMT-coupling. This in turn contrasts with a cadaveric study which showed that that SP-coupling leads to similar electromechanical velocity responses as for fixation on the long incus process [11]. In the course of the discussion of the audiological results between SP-coupling and n-SP coupling it has to be noted that this study did not perform a subgroup analysis to verify the specific indications of the different coupling strategies.

The lack of significant differences between revision- and complication rates in both coupling techniques may indicate the surgical safety of SP-coupling. These results stand in opposite to other studies that found adhesive processes after SP-coupling to be the most common reason for surgical revision [7]. In terms of surgical safety, the SP- coupling has several advantages compared to the conventional FMT coupling. This is mainly due to the absence of the posterior tympanotomy, which can lead to damage to the facial nerve and/or dizziness symptoms. Another advantage is the reduced surgical trauma to tissue and middle ear structures, which may lead to faster recovery, reduced pain after surgery and shorter surgery times [10]. Especially shortened surgery times in SP-coupling could play an important role for the choice of FMT-coupling techniques in the future as rising costs and economic pressure become more important [2].

Conclusion

Especially considering the lack of differences between revision- and complication rates, as well as significantly shorter surgery-time, SP-coupling may be a method worth to be more focused on at the implanting centers, taking the preoperative audiological indications and anatomical conditions of the patient into account. However, the good audiological

results of conventional FMT-coupling must also be reproducibly achieved by SP-coupling in the future in order to become the method of first choice for FMT-coupling in clinical routine.

Compliance with Ethical Standards

All procedures performed 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.

Funding

Not applicable.

Conflicts of Interest

None.

Ethical approval

Not Applicable. No ethical approval necessary for this study.

Consent

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

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