Survival rate of self-tapping implants for bone-anchored hearing aids

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Abstract
Objective: The purpose of this study was to investigate whether a new self-tapping implant for a bone-anchored hearing aid (BAHA) had the same high frequency of osseointegration as previous implants requiring pre-tapping.

Method: Over a three-year period, 144 consecutive implants were placed in the mastoid for BAHA and evaluated.

Results: Two implants were lost; both were of the self-tapping type. One was in an 11-year-old boy, who lost his implant six weeks after surgery when the BAHA was fitted. The other was in an elderly man, a heavy smoker with diabetes. Using Fisher's exact test, there was no significant difference between the two groups ($p > 0.30$).

Conclusion: Self-tapping implants facilitate surgery and shorten operating time. Over a short follow up, we did not find any significant difference; however, it is important to follow these implants over a longer time period.

Key words: Hearing Aids; Implants and Prostheses; Osseointegration; Titanium; Otologic Surgical Procedures
Material and methods

Over a three-year period (2002 to 2004), 144 patients received BAHA-related surgery in our institution. The charts of all these patients were tabulated. Patients’ ages varied from two to 85 years. There were 65 men and 79 women. We excluded from the analyses those who, during the study period, underwent only the second stage procedure (mainly in early 2002). Relevant data were not available in two cases, and one patient was lost to follow up. One other patient was excluded: a 46-year-old woman whose implant was placed at the same time as a successful trial of ossicular reconstruction. At the time of writing, this patient had no need for a BAHA. A total of 138 patients were included.

Two different lengths of implant were used. Thirty of these were 3 mm long and 108 were 4 mm. Standard implants (placed in the bone after tapping the implant site) and self-tapping implants of each length were used. Seventy-four standard implants and 64 self-tapping implants were placed. A one stage procedure was used in 106 patients and a two stage procedure in 32. Most of the latter group were younger patients aged two to 15 years, with a mean age of 8.2 years. Follow-up time varied from five to 41 months, with mean value of 22.3 months.

Figure 5 presents in detail the structure of the study group.

Results

Of the 138 implants placed in the study, two were lost. Both were of the self-tapping type. One was in an 11-year-old boy who had received a 4 mm implant during one stage surgery. Six weeks after insertion, the boy experienced pain during the fitting of the BAHA. Over the following days, the implant area became tender and the coupling was painful to touch. After another seven days, the implant was lost. The other lost implant occurred in a 78-year-old man with chronic ear disease, who was a heavy smoker and a diabetic. A 4 mm long self-tapping implant was inserted during one stage surgery, with BAHA fitting six weeks later. The BAHA worked very well for almost three months; then, with only minor discomfort, the implant was lost.

Fisher’s exact test was used to evaluate whether there was a statistically significant difference, regarding loss of integration, between the self-tapping and standard implants. The difference between the loss of implants – two losses out of 64 self-tapping implants, compared with no losses out of 74 standard implants – was not statistically significant ($p > 0.30$).

Two other patients were not satisfied with their implant sound, and their couplings were removed but the fixtures left in place. One patient, aged 69 years, suffered a direct hit to the implant, which became loose. However, reintegration took place and the patient was wearing his BAHA at the time of writing. One patient suffered repeated infections around the implant site; conservative treatment was unsuccessful so the coupling was removed but the infection continued, and the 4 mm self-tapping implant was therefore removed.

Discussion

The success rate for standard BAHA implants is high. Over a one to eight year follow up, one study reported that 6.0 per cent of adult implants were lost. In children, an even lower frequency of loss, 5.6 per cent, has been reported. It should be noted that adults generally undergo a one stage surgical procedure, whereas a two stage procedure is still standard practice for children, with three to six months between the two stages. Using resonance frequency analysis, it is possible to evaluate implant stability, not only during follow up but also during the surgery itself. One study found no difference between the stability of standard and self-tapping implant types (M. Ödersjö, unpublished data from an ongoing study). Implant stability was found to be
even better than that reported for intra-oral implants of the Bränemark type. Interestingly, this study also found that the stability of implants in the child mastoid process was as good or even better than that of dental implants in adults (M. Odersjö, unpublished data from an ongoing study).

When the self-tapping implant was introduced, one concern was that the insertion torque would be too great and would cause more trauma to the bone tissue. However, when the torque for the traditional tap was compared to that of the self-tapping implant, no difference was detected (M. Odersjö, unpublished data from an ongoing study).

Out of the 138 implants inserted in this study, two were lost, both of them 4 mm long, self-tapping and inserted in a one stage procedure. The younger of these patients was only 11 years old and, in retrospect, a two stage procedure might have prevented this loss. The older patient was a heavy smoker. In the field of dental implants, there is evidence that smoking has a negative influence on clinical results. However, the impact of smoking on the survival rate of osseointegration in the mastoid process is not known.

Two patients were not satisfied with the function of their BAHA and requested that the coupling be
removed. The bone implants were left and healing was uneventful.

In our experience, re-integration in adults is not common. However, it has been seen in children, probably due to the high level of bone regeneration in the growing child.

Adverse skin reactions are often caused by inadequate surgical subcutaneous tissue reduction, but can also be due to poor personal hygiene. The latter was probably the reason for the foul infection around the implant experienced by one of our patients. The standard treatment in such cases is to try to improve the cleaning routine. In our patient, the coupling was temporarily removed but the infection continued. When we attempted to remove the implant it was not possible to unscrew it (indicating good osseointegration), and it had to be drilled out. Following removal, healing was uneventful and the infection resolved.

The total frequency of loss of integration was 1.4 per cent (2/138). The frequency of known implant failure was zero in the standard implant group and 3.1 per cent in the self-tapping implant group; however, this difference was not statistically significant \( (p > 0.30) \).

In a ‘worst case scenario’, five of the cases discussed above should also have been counted as failures, together with the patient lost to follow up. However, even with such a calculation, the success rate was still high, at 95.7 per cent.

**Conclusion**

The introduction of self-tapping implants for BAHA has made the surgical procedure more streamlined for the surgeon, the assistant and, most importantly, the patient. Time spent in surgery is reduced. Implant losses will always occur; however, in our study, the frequency of loss was low and there was no statistically significant difference between the two techniques. One of the implants lost in this study was in an 11-year-old boy who had undergone a one stage procedure; this supports our philosophy that two stage procedures are still to be recommended in children. It should be pointed out that the follow-up period in this preliminary study was for a maximum of three years. However, the patients in this study will be followed carefully in order to evaluate long term results.

**References**


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