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Osseointegrated implants in children

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This study was undertaken on 86 children aged 15 years or lower scheduled for installation of osseointegrated implants. Of these, 64 had implants installed for bone-anchored hearing aids (BAHA) or epistheses. The main indication for implant installation was a bilateral ear malformation. Surgery was generally performed as a two-stage procedure with a healing time of 3–4 months in between. Available bone thickness averaged 2.5 mm, and lack of bone necessitated bone augmentation in 12 patients. Forty-five percent of the implants were installed in contact with the dura, sigmoid sinus or an air cell. Of 129 installed fixtures, 6.2% were implant failures. Adverse skin reactions appeared in 7.6% of patients over a 17-year follow-up period. Revision surgery was undertaken in 30% of patients due to appositional growth of the temporal bone. It is concluded that implant failures and skin reactions in this population are comparable to those in an adult group of implant patients, whereas revision surgery is more common in children. Nevertheless, osseointegrated implants can be used with good functional and aesthetic outcome in children. *Key words*: *bone-anchored epistheses*, *bone-anchored hearing aid*, *children*, *ear malformations*, *osseointegrated implants*, *syndromes*.

INTRODUCTION

Since the development of osseointegrated implants used for extraoral purposes in 1977, an increasing number of patients has been supplied with bone-anchored hearing aids (BAHA) or bone-anchored epistheses (BAE). The extraoral osseointegration concept was originally developed for adult patients (1), but has with time also been used in children below 16 years of age. Its main application has been to supply patients with bone conduction type of hearing loss with a BAHA. The second most common use of these implants has been in supplying patients with missing external ears with BAEs.

The present investigation was undertaken to study the outcome of BAHA and BAE implants in the age group below 16 years. The study was undertaken to get more information about what specific problems are seen in adolescents, who are known to have more soft and immature bone, appositional growth of the temporal bone, skin overgrowth of the abutments and cleaning problems. Closer follow-up and control of this patient category is especially important with respect to the long-term results.

MATERIALS AND METHODS

All children (aged below 16 years) that were supplied with osseointegrated implants at the ENT Clinic, Sahlgrenska University Hospital between 1978 and 1998 were studied. Age at surgery, age at follow-up, gender, type of malformation and syndromic grouping were investigated. Indications for insertion of osseointegrated implants, number of inserted implants, number of surgical procedures, bone thickness and specific surgical problems at the site of implantation were studied.

The surgical procedure was generally performed in two steps, as described by Tjellström (2), and involved gentle handling of the soft tissue and bone. At the first stage of the operation, the skin over the implant site (for the BAHA, in the temporal line 55 mm behind and 30 mm above the external ear canal, and for the BAE, 20 mm behind the ear canal) was incised, continuing through the subcutaneous tissue and periosteum. A hole was drilled under profuse irrigation with saline solution. Into this hole a 3.75-mm-diameter threaded flange fixture of 3 or 4 mm length (SEC 001, SEC 002; Nobel Biocare, Göteborg, Sweden) was inserted. The soft tissue was thereafter sutured and the implant allowed to integrate into the bone for a period of 3–4 months. At the second stage of the operation, standard titanium abutments for the BAHA or 4-mm abutments for the BAE (SHCB 179, SEC 007, SEC 008, SEC 010; Nobel Biocare) were adapted onto the fixtures and the skin penetration site prepared as described earlier (3). Two to three weeks after the second operation, the patients were either fitted with the hearing aid (HC 200, 300 or 360, Nobel Biocare) or an ear episthesis was fabricated individually.

The patients were followed during clinical follow-up periods at 3–6-month intervals, during which stability of the implants was checked and the skin penetration site cleaned and adjusted. Skin reactions around the implants were classified according to the clinical scoring system of Holgers et al. (4) as follows: 0 = no irritation, 1 = slight redness, 2 = red and moist, 3 = as in 2, but also granulation tissue formed and 4 = skin irritation of such a degree that the abutment has to be removed.

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RESULTS

There were altogether 86 patients included in the study. Of these, 50 were boys and 36 were girls. Sixty-four of them had been operated upon for installation of osseointegrated implants. Another 22 were under consideration for implant insertion.

The most common reason for osseointegrated implantation was the combination of microtia and ear canal atresia in 57 patients, whereas another 12 were considered for isolated microtia, 9 had ear canal atresia, 4 had chronic otitis media, 2 had middle ear malformation, 1 had a traumatic ablatio auris and 1 had the pinna removed because of a juvenile rhabdomyosarcoma. Forty-four of the patients had ear malformation as part of a syndrome, the most common of which was mandibulofacial dysostosis (Treacher-Collins syndrome; $n = 14$), and hemifacial microsomia (or Goldenhar syndrome; $n = 12$). Other syndromes were occulo-auriculo-vertebral dysplasia, Pfeiffer syndrome, Möbius syndrome, CATCH 22, Crouzon syndrome and diabetic embryopathia. Several patients had ear malformations combined with other malformations, such as oesophagus atresia, facial clefts, vertebral fusion, syndactylia and anal atresia. Forty-five of the patients had unilateral symptoms, whereas the other 41 had bilateral ear symptoms.

Patients' age at the onset of the study ranged from 1–15 years, with a mean ($\pm$ SD) of 7.7 ± 3.8 years. Age at follow-up ranged from 1–34 years (14.0 ± 7.9 years). Age at the time of osseointegration surgery ranged from 1–15 years for BAHA (7.4 ± 4.1 years, $n = 39$) and from 5–15 years for BAE (9.5 ± 2.8 years, $n = 32$). Three patients were supplied with bilateral BAHA, another three had a combination of BAHA and unilateral BAE and another five had BAHA and bilateral BAE. Follow-up time ranged from 1–21 years (8.0 ± 5.1 years, $n = 64$).

Altogether 129 implants were inserted. All implants were of the Brånemark type (Nobel Biocare), of which 92 were 4 mm long and 37 were 3 mm long. All implants were inserted in the temporal bone. In 26 patients, the thickness of the bone was measured during surgery and was found to range from 1–4 mm (2.5 ± 0.8; Fig. 1). Of 129 implants, 34 (26%) were inserted in contact with the dura, 14 (11%) were inserted in contact with a mastoid cell and 11 (8.5%) were inserted in contact with the sigmoid sinus. The other implants were inserted in compact temporal bone.

Fifty-seven of the operations were performed as a two-stage procedure. The time from first to second stage ranged from 3–20 months, with a mean ($\pm$ SD) of 6.3 ± 4.0. Three operations were performed as a one-stage procedure. During the observation time, eight implants were lost ($8/129 = 6.2\%$). Implant failure over time is presented in Fig. 2. As can be seen from this figure, only early losses were observed among children, and no implant was lost later than 3 years after surgery.

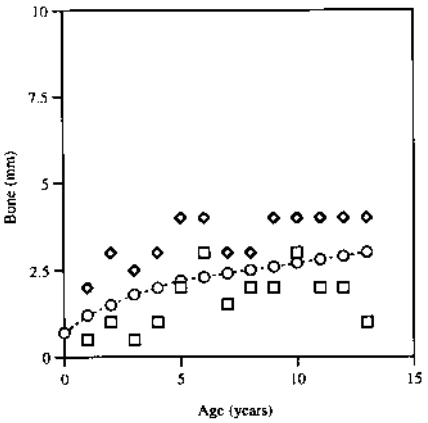

Fig. 1. Bone thickness in mm from 26 patients in relation to age. Minimum (□), maximum (◇) and mean (-○-) thickness is expressed.

Skin reactions were followed from 1–17 years. Of 539 observations, 92.4% were completely reaction-free. Adverse reactions were seen in 41 instances, of which 4.0% were of grade 1, 1.8% grade 2 and 1.6% grade 3. Skin reactions over time are shown in Fig. 3. As can be seen from this graph, the incidence of adverse reactions is distributed evenly over the follow-up period. Subcutaneous tissue reduction was undertaken in 19 patients, of whom 16 were BAE wearers and another 3 BAHA wearers. Two patients had their implants replaced more distally in the temporal bone because of growth of the bone.

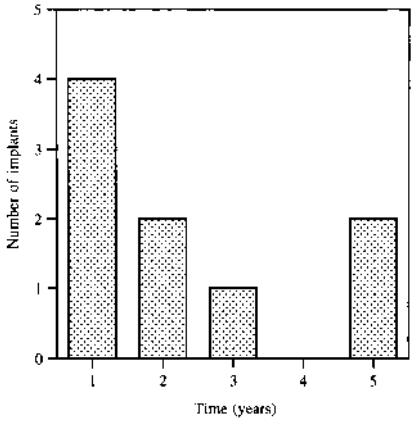

Fig. 2. Implant failures over time. Two implants were surgically removed after 5 years because of lack of space. No implants were spontaneously lost in the group after 3 years of follow-up.

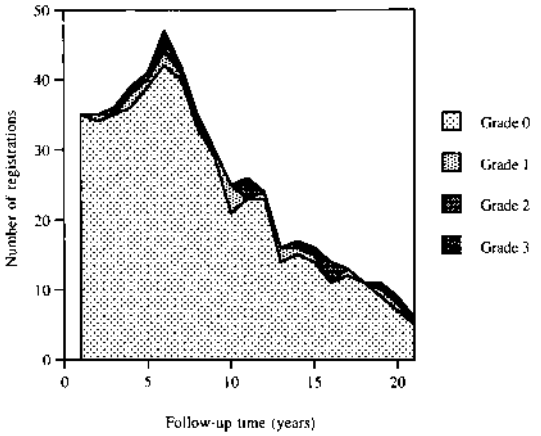

Fig. 3. Skin reactions over time. A clinical scoring system was used where Grade 0 = no irritation, Grade 1 = slight redness, Grade 2 = red and moist and Grade 3 = granulation tissue. No Grade 4 reactions occurred.

Patients who were BAE wearers were supplied with a mean of 6 new prostheses per 10 years. BAHA users were supplied with a mean of 3 new hearing aids per 10 years.

Of the 22 patients who were not supplied with osseointegrated implants, 14 had microtia combined with ear canal atresia, 7 had isolated microtia and 1 had isolated ear canal atresia. In 6, ear malformation was part of a syndrome. Mean age ($\pm$ SD) at the time of the study was 7.0 ± 3.8 years. Sixteen were boys and six were girls. The reasons these patients were not considered for osseointegration surgery were as follows: awaiting further growth ($n = 5$), referred to plastic surgery ($n = 5$), normal hearing despite microtia ($n = 4$), patient/parents not yet made their decision ($n = 3$), serious brain or inner ear damage ($n = 2$), not interested in osseointegration surgery ($n = 2$) and waiting for ear canal atresia surgery ($n = 1$).

DISCUSSION

In earlier studies, we have shown that the BAHA is a good alternative to both reconstructive middle ear surgery and conventional types of bone conduction hearing aids (5, 6). Especially in children with bilateral ear malformations, the BAHA has been useful. The fixture for the BAHA can be installed distally to the ear canal, which means that the options for future plastic surgery will not be limited. Future reconstructive middle ear surgery can also be postponed, and the child can wear the BAHA during the postoperative healing time without disturbances. Syndromatic patients with severe malformations of the sound transmission system might not even need surgery because of the good hearing results with and comfort of the BAHA.

The BAE is also a good alternative to plastic surgery. Several techniques exist to create a new external ear surgically (7, 8). They are generally difficult to handle, and failures occur. In cases of failure, the BAE can be used (5, 9). Patients who are supplied with a BAE will often accept the prosthesis as their own ear. With new materials, the prosthesis can be made to look almost like a normal ear.

In an earlier report, implant survival was reported for the child group of patients of the ENT Clinic at Sahlgrenska University Hospital (10). It was found that implant failures were slightly higher than in the adult population. There was also a tendency for adolescent patients to neglect skin care, resulting in higher grading scores (10). We could not confirm these results in the present study. Instead, implant survival seemed to be equal to that in the older patient group. Skin reactions were also of the same magnitude as in the older group.

More important, however, is that there was a high (30%) rate of revision surgery due to appositional growth of the temporal bone. This growth results in a shorter distance between the bar and the skin, or the BAHA abutment may be buried deeper in the skin, making cleaning more difficult. Revision included removal of subcutaneous tissue and excess bone. In some patients, this revision was done up to four times over a decade. In two patients, the growth of the temporal bone was asymmetric, necessitating distal replacement of new fixtures.

Whenever lack of bone was a problem, a bone augmentation technique was used (11). With e-PTFE membranes, appositional bone can be directed to grow under the flange of the fixture. The technique seems promising, since it can be combined with standard fixture and abutment placement and does not alter therapy planning. Further studies are, however, needed before this technique can be generally recommended.

In summary, osseointegrated implants can be placed in children for use with the BAHA or BAE. Surgery is performed in thinner temporal bone, but with bone augmentation techniques, it is possible to find space for 3-mm implants even in 1-year-old children. The distances to the dura, sigmoid sinus and air cells are shorter, which must be recognized as a surgical risk. Implant survival and adverse skin reactions are comparable to those in an adult implant group.

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