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The Birmingham bone anchored hearing aid programme: surgical methods and complications

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Abstract

Since 1988, 309 patients have been referred to the Birmingham bone anchored hearing aid programme for assessment. One hundred and eighty-eight have been fitted with bone anchored hearing aids (BAHA). Of these 169 have been fitted with a BAHA alone and 20 with a BAHA and auricular prosthesis(es).

Only four (2.1 per cent) are not wearing their BAHAs. Three cases because the hearing had continued to deteriorate and in one case because of repeated failure to integrate. Nineteen patients (10.1 per cent) have lost fixtures but all but one of these have been successfully reimplanted. Of these 19 patients 10 (52.6 per cent) were syndromal and 10 (52.6 per cent) were under 16 years of age.

A surgical method has been evolved both to cope with predictable failure of integration and soft tissue control.

Key words: Hearing aids, bone anchored; Surgery, complications

Introduction

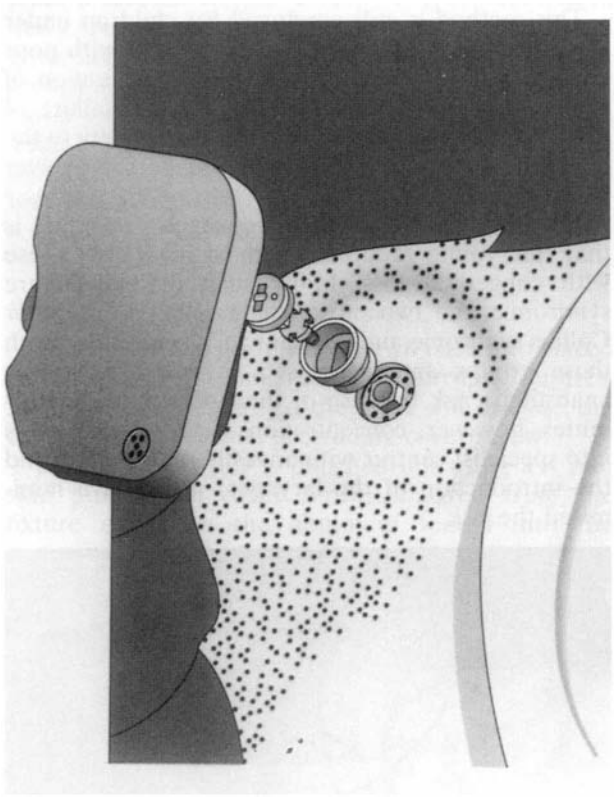
Understanding of the mechanism of bone conduction has developed over the last century and many ingenious methods of applying it clinically have been devised (Tondorf, 1966; Mylanus, 1994).

The concept of direct bone conduction was introduced by Tjëllström *et al.* (1980) and is achieved by using a skin penetrating coupling from an osseointegrated implant in the mastoid bone to an impedance matched transducer that the patients can apply and remove at will (Figure 1). The absence of interposed soft tissues (direct bone conduction) gives better quality sound, requires less energy and offers much greater comfort (Tjëllström and Ganstrom, 1994).

Although this technology has been marketed by the "Nobel Biocare Company" for more than a decade the only reports of long-term results have been published from two centres (Cremers *et al.*, 1992; Mylanus *et al.*, 1994; Tjëllström and Ganstrom, 1994). This paper will report on the surgical results obtained in Birmingham, the complications encountered and the evolution of surgical techniques to minimise difficulties.

Referrals

The Birmingham programme started in 1988 as part of a multi-disciplinary team approach to the management of congenital ear defects (Proops, 1992). After the initial referral letter patients are either seen in a full multi-disciplinary clinic or a



The components of the BAHA

FIG. 1
The components of the BAHA: Fixture, abutment, insert, hearing aid.

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specific bone anchored hearing aid clinic which is attended by an audiologist, a specialist speech therapist and an otologist. Three hundred and two patients have been assessed, and 188 have received bone anchored hearing aids.

Specific information about the criteria for selection, the adult results (Cooper *et al.*, 1996), the paediatric results (Powell *et al.*, 1996), the results with otosclerosis (Burrell *et al.*, 1996) and with patients with significant sensorineural hearing loss (Hartland and Proops, 1996) and the effect on ear discharge in chronic suppurative otitis media patients (Macnamara *et al.*, 1996) are presented in separate papers.

Surgical methods

For the first 60 cases the two stage technique described by Tjëllström *et al.* (1989) was employed. The first stage procedure involves choosing the site and placing the titanium fixture into the temporal bone. Three months later, at the second procedure, the fixture is uncovered, checked for integration, then the soft tissue reduction, attention to the skin flap and placement of the abutment undertaken. Approximately, one month later the patient is sufficiently healed to have the transduction aid fitted (Figure 2).

This method is still employed for children under the age of 12 years and older individuals with poor cognitive skills. The reason for this continuation of the staged method is the higher level of failure of primary integration; the greater risk of trauma to the abutment, plus the fixture tends to be the shorter 3 mm type within the thinner skulls of the young.

The disadvantage of this two-staged procedure is that this young group are almost invariably those with congenital loss. Many such individuals are syndromic, the two most common being Treacher Collins syndrome and Goldenhaar's syndrome. Both these groups are recognised as being of higher anaesthetic risk because of their mandibular deformities, however, concentration of these individuals into specialist centres with anaesthetic expertise and the introduction of the laryngeal mask have minimised the risk.

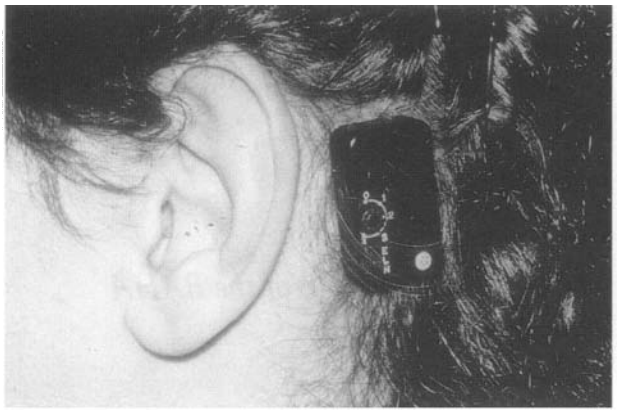

FIG. 2
The BAHA in position.

The single stage technique was first suggested by Tjëllström, (1989) and Tjëllström and Ganstrom (1993). Shortly thereafter the Nijmegen group (Mylanus and Cremers, 1994) developed their own single stage technique. Simultaneously a single stage technique has evolved in Birmingham which continues to develop (Proops and Wake, 1993).

The surgical techniques can be divided into five components:

(1) Anaesthesia and preparation.
(2) Soft tissue reduction.
(3) Placement of fixtures.
(4) Skin graft and abutment placement.
(5) Dressings and after care.

As in all good surgery the best results are obtained by meticulous attention to detail. This is not challenging surgery but good long-term results are obtained only if certain principles are followed.

The first principle is minimal trauma to the bone and a "no touch" technique with the titanium fixtures. The second principle is widespread and adequate soft tissue reduction. The third principle is to surround the fixture and abutment with an adequate split thickness skin graft.

Anaesthesia and skin preparation

Children and the very nervous undergo general anaesthesia but the vast majority of adults tolerate this procedure well under local anaesthesia with minor sedation. In Birmingham adult patients receive intravenous Midazolam (0.1 mg per kg). A small area of the scalp (3–4 cms in diameter) is shaved. Three to four cartridges of two per cent lignocaine 1:80,000 adrenaline are placed subcutaneously and then subperiosteally 3–4 cms behind the auricle on an imaginary line, extending backwards from the zygomatic arch. This has the effect of raising a platform of tissue. The skin is prepared with an aqueous antiseptic solution; the hair is secured away from the operation site with gel, and head towels applied.

Soft tissue reduction

Management of the soft tissue is vital to achieve the immobility of the skin around the skin penetrating abutment which is so vital for long-term maintenance by the patient. A systematic approach to the soft tissues should be used: A circle 4 cms in diameter is drawn on the skin in ink centred on the planned site for the fixture. There are five options available for the management of the skin graft:

a) The Tjëllström method (Tjëllström, 1989). Free post-auricular skin graft (Figure 3).
b) The Browning method (Browning 1990). Transpositional flaps (Figure 4).
c) The Cremers method (Mylanus and Cremers, 1994). Straight-line incision (Figure 5).
d) The Proops method. Thinned pedicle flap (Figure 6).

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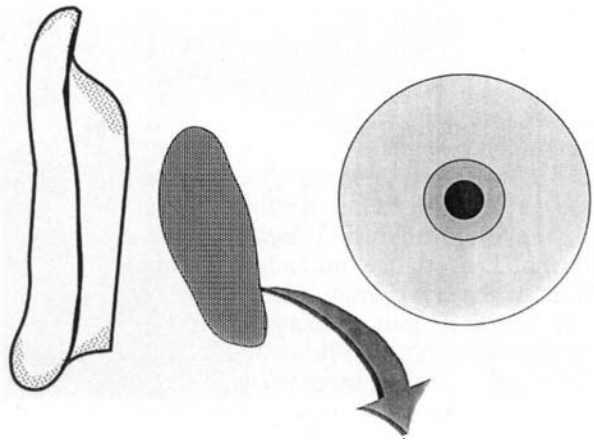

FIG. 3
Tjëllström method.

e) The Rothera method (personal communication). Free local skin graft (Figure 7).

The favoured method in Birmingham for the single stage technique is the Rothera method using a free split skin graft. A 'Silver's' dermatome is used to take a skin graft free of adnexal structures conforming to the 4 mm diameter circle previously marked. The four cartridges of local anaesthetic heap the skin to a flat topped mound which makes this simpler. The free skin graft is then stored in saline and all the remaining soft tissues radically removed leaving only the periosteum free of loose areolar tissue. A Swan Morton 15 blade is used to back-cut and to under-cut the free skin edge for at least the length of the blade. This should be especially thorough superiorly into the substance of the temporalis muscle. If this is not undertaken adequately then with age the soft tissues, especially the temporalis muscle, tend to prolapse onto the abutment (Figure 8). When haemostasis has been achieved it is time to place the fixture.

Placement of the fixture

The method recommended by the manufacturer should be followed scrupulously with the longest

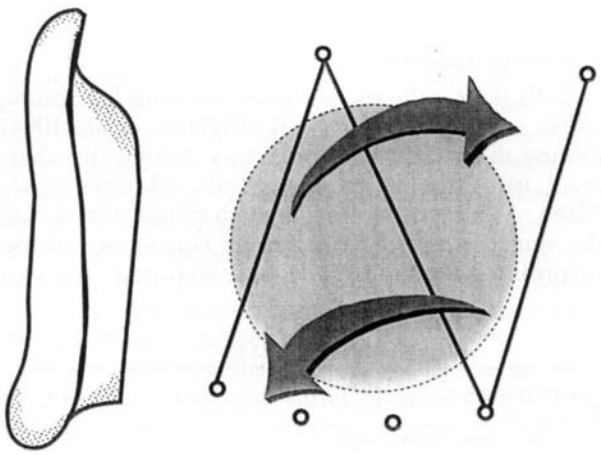

FIG. 4
Browning method.

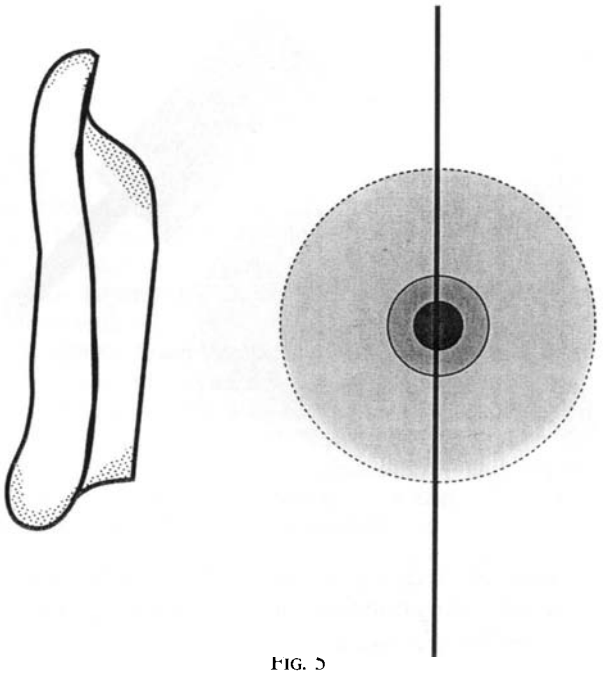

FIG. 5
Cremers method.

fixture (always place a 4 mm fixture whenever possible) being placed. If there is any doubt about the long-term viability of the fixture it is safer to place a second 'sleeper fixture'. It is recommended that a spare fixture be placed in all children and in all syndromal patients as, in our experience, these groups account for the vast majority of lost fixtures. Cover screws are placed in the fixture to protect the inner thread but, in the favoured fixture, it should be left half protruding to signal which fixture will receive the abutment.

Skin graft and abutment placement

The stored skin graft is now sewn back into placed over the fixture(s) using multiple interrupted sutures. Then, digital pressure to the graft will disclose the chosen fixture with its protruding cover screw.

The skin over this is punched out using a 4 mm skin punch, the cover screw removed from the fixture and then the abutment seated into the

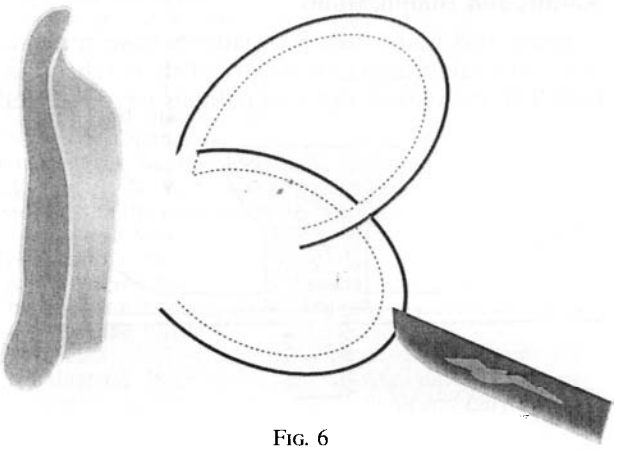

FIG. 6
Proops method.

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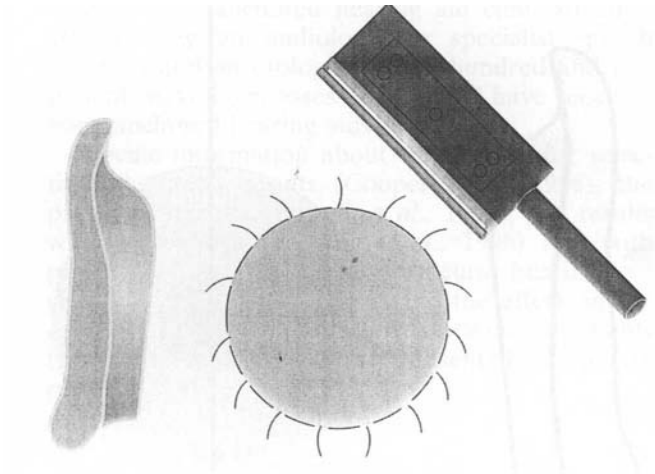

FIG. 7
Rothera method.

hexagon and securely screwed down with the slot in the head of the abutment pointing caudal to cephalic in direction.

Dressing and after care

The plastic healing cap is now placed upon the abutment and 1/2" ribbon gauze soaked in 'Terra-Cortril' ointment wound around to compress the split skin graft onto the periosteum. This is left for 10 days when the dressing and the sutures are removed and new dressings applied. Small areas of necrosis or even complete loss of the graft are not disastrous as they will heal well within the three months that need to elapse before osseointegration has occurred sufficiently for fitting of the aid.

The patient and an 'important other' should be instructed by both surgeon and competent nurse in the cleaning and long-term management of the skin around the penetrating abutment as hygiene is the key to long-term comfort and success (Figure 9).

In Birmingham a specialised out-patient nurse has taken particular interest and pride in the osseointegrated patients and she is the primary open access point of call of all patients who might experience difficulty.

Results and complications

Since 1988 more than 300 patients have received osseointegrated implants as part of their rehabilitation. Three hundred and nine patients were referred

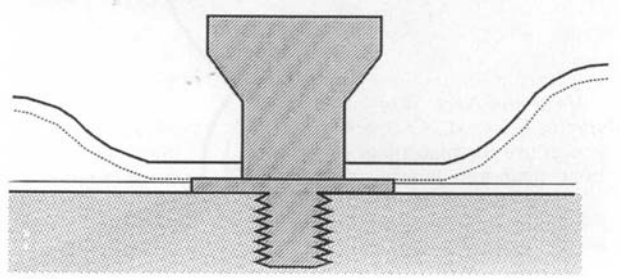

FIG. 8
Idea BAHA.

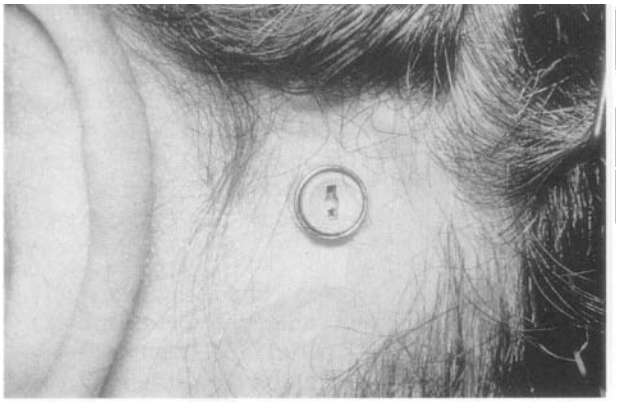

FIG. 9
The skin penetrating abutment; note the reaction free hairless skin surrounding it.

specifically to the bone anchored hearing aid programme for assessment. To date, 188 of those have been assessed and found suitable and fitted with a bone anchored hearing aid. Of those, 168 have been fitted with a bone anchored hearing aid alone and 20 with a bone anchored aid and auricular prosthesis (es).

To date only four patients (2.1 per cent) are non-wearers of their bone anchored hearing aids. In three cases because their bone conduction thresholds had continued to deteriorate to a level where no benefit was obtained even from the body-worn superbass BAHA and in one case of unexplained repeated failure to integrate.

The most serious complication is loss of the osseointegrated fixture from its placement in the skull. Nineteen patients (10.1 per cent) have lost fixtures, all but one of these have been successfully re-implanted. Of these 19 fixture failure patients 10 (52.6 per cent) were congenital auricular problems in syndromic patients and 10 (52.6 per cent) were in patients under 16 years. Two of these failed fixtures were directly the result of trauma and not surprisingly were both children. Three failures were associated with poor hygiene. Of the remaining 14 failures five were primary failure to integrate and nine were unexplained late failures (see Table I).

Soft tissue reaction

Both the Gothenborg (Tjëllström and Ganstrom, 1994) and Nijmegen reports (Mylanus *et al.*, 1994) discuss the detailed skin reaction around the abutment using the Gothenborg scale (Holgers *et al.*, 1988). Although the Birmingham patients have had the same assessments made, the consistency of the recording has not been adequate to report. The vast

TABLE I
FIXTURE FAILURE

Direct trauma	2
Poor hygiene	3
Primary failure to integrate	5
Late unexplained failure	9
Total	19

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majority of the patients do not have an adverse skin reaction and the majority 79 per cent have grade 0 reactions.

Six patients have required soft-tissue revisions necessitating further surgery. Inadequate surgical excision plus poor hygiene from the patient were the cause in all cases probably in equal part.

It has been observed in child patients however that the initially good skin reduction tends to thicken with time and that this becomes more apparent around puberty. It is now anticipated that some of the children may well require soft-tissue reductions and adjustments as they pass into adult life.

Intra-operative surgical complications have been few. Inadvertent penetration of the lateral venous sinus occurs but is easily controllable by the insertion of muscle and re-drilling another nearby site for the fixture placement. The greatest problem encountered is inadequate thickness of bone and this is especially so in young children. In most cases the guide drills are used to find bone thick enough to accept 4 mm fixtures. There are, however, occasions where only 2 mm of useable thickness are available. In this situation a 3 mm fixture will be used and the flange will stand proud. Two solutions are available, bone chips and dust can be packed under the flange of the fixture, and/or 'Gortex'® membrane placed over to secure it. In both methods this is obviously the first stage of a two-stage procedure. As this problem has only been encountered in children this was always designed as a staged procedure in advance.

Obviously, in these thin-skulled young children a second sleeper fixture should also be placed if possible. It has also been the practice in Birmingham to wait an extra month so that four months elapse between the stages when there is any anxiety about an adequate length of fixture and completeness of osseointegration. To date the limited experience of three cases where 'Gortex'® has been used is positive.

At the second stage good osseoneogenesis up to and including the flange on the fixture was observed and the three children are successful wearers.

Conclusions

Osseointegration is now firmly established in the surgical armamentarium of otologists. It has two major roles at the moment, firstly for the fixation of bone anchored hearing aids and for the provision of auricular prostheses and/or bone anchored hearing aids in the management of congenital ear abnormalities. Bone anchored hearing aids are likely to become much more widely used outside the fixed number congenital cases for which it has become the first treatment of choice.

The greatest beneficiaries are likely to be the legion of individuals who suffer bilateral conductive deafness secondary to chronic suppurative otitis media and who cannot be satisfactorily aided because of persistent or recurrent otorrhoea despite the best efforts of their otologist. The second group are those otosclerotics for whom, by virtue of their age, occupation or personal choice do not wish or cannot be advised to undergo stapedectomy and will not, or cannot, use conventional aids. The advantages of the BAHA as rehabilitation for both these groups are binaural hearing gain from one aid and the predictability of improvement. Some otologists may perceive this development as a threat to conventional otosurgery. On the contrary, it is not; it is an adjunct for those who were not previously well served.

Neophyte teams would do well to develop their experience only on adults. Cases requiring prosthetic help should be referred to teams with established prosthetic and craniofacial links.

The set up costs are considerable and multi-disciplinary clinicas are expensive in time. To justify the investment a business plan of at least twelve cases per year would seem essential with long-term maintenance contracts for continuing care and replacement aids. Working within a multi-disciplinary team does not suit all personality types but the shared clinical responsibility conveys itself to patients and purchases a sense of purpose and long-term commitment.

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