OPEN ACCESS ATLAS OF OTOLARYNGOLOGY, HEAD & NECK OPERATIVE SURGERY

BONE CONDUCTION DEVICE SURGERY – HIGHLIGHTING THE PERCUTANEOUS BCD

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Bone Conduction Devices (BCDs) utilise bone conducted sound to assist people with conductive hearing loss, mixed hearing loss and single sided deafness (SSD) who cannot use traditional hearing aids or prefer BCDs to conventional hearing aids.

Nomenclature of BCDs

This chapter focuses on the ***percutaneous BCD (percBCD)***.

There are today several types of BCDs. The major difference between BCDs is whether the skin is penetrated ***(percutaneous BCDs)*** or if the skin is intact ***(transcutaneous BCDs)***. The most recent BCDs on the market are ***active transcutaneous BCDs*** where the skin is intact, the transducer has direct contact with the skull bone and where the sound processor is attached to the skin surface with low magnetic force.

The 1st BCD using direct contact with the skull bone to transmit sound to the cochlea was a titanium fixture with a sound processor attached to it. This innovative way to transmit sound was based on osseointegration, which is the unique bond between titanium and living bone discovered by the Swedish professor of anatomy, Per-Ingvar Brånemark who implanted titanium dental fixtures in the jaw. He then proceeded in collaboration with Professor Anders Tjellström, a Swedish otolaryngologist [1], and an engineer Professor Bo Håkansson to develop a bone conduction hearing aid where a sound processor was attached to an osseointegrated titanium implant in the skull bone behind the ear.

The 1st ***Bone Anchored Hearing Aid (BAHA)*** was implanted in 1977. The system comprises an osseointegrated titanium implant (fixture), an abutment, and a sound processor including microphone and battery in one single housing *(Figures 1a, b).*

Figure 1a: Titanium fixture anchored in the bone with an abutment attached. The processsor is connected to the abutment with a snap coupling

Figure 1b: Titanium fixture with abutment

The fixture uses the characteristics of titanium to osseointegrate into bone. Bone cells (osteoblasts) adhere to the titanium surface of the implant without any other cells or connective tissue developing in-between. The biocompatibility of the metal is dependent on the titanium oxide layer on the surface of the implant and the lack of tissue interface between the bone and the titanium, all of which improve bone conduction of sound [2]. The surface and shape of the implant and its abutment have since been refined.

Surgical techniques continue to evolve. Historically there was a long tradition of a ***"skin thinning technique"***. The idea was to minimise the depth of the skin down to the periosteum and to remove all subcutaneous tissue. The ideal thickness of the skin was recommended to be 0.2-0.5mm. A full skin

transplant replaced the removed tissue, and the surgical procedure took up to 5 hours [3]. With new tools and new surgical flap techniques (semicircular flaps, dermatome, predrawn fixtures and abutments, one-step surgery *etc*.) the operating time was reduced further [4].

In 2007 the ***"non-skin thinning"*** or ***"tissue preserving"*** technique was introduced. Nowadays one simply makes a small opening in the skin without skin reduction by punching a hole through the skin where the abutment is externalised [5]. This requires longer abutments for different skin thicknesses. With commercially available abutments of required lengths, this technique has reduced the surgical time to only 10-15 minutes. Implantation is also now done in a single step in children [6].

Physiology of bone conduction

The BCD converts sound waves in the air to mechanical vibrations that are transmitted either through the skin and soft tissues to the skull bone, or directly to the skull bone, and then to both inner ears. With transcutaneous BCDs where the transducer is positioned on the skin, there is loss of sound transmission in the high frequency range (15-25 dB depending on the frequency). With percBCDs and active transcutaneous BCDs there is direct coupling to the skull bone. The latter is called ***hearing by direct bone conduction***. Direct bone conduction provides a sensitive input for vibrations to the skull, with high-quality transmission of sound and sufficient gain and power output with excellent patient comfort.

The cochlear function is important; if sensorineural hearing is adequate, then a bone conduction hearing aid can transmit enough sound to the cochlea for effective hearing rehabilitation. The degree of conductive hearing loss is of minor importance as the bone conducted sound bypasses the middle ear; the benefits of BCDs are therefore independent of the status of the external and middle ear [7].

When an acoustic stimulus is presented to one ear there is a reduction in intensity of the sound perceived by the opposite ear. This phenomenon is called ***interaural attenuation***. With air conduction, the reduction approximates 35dB, but for bone conduction it is $\leq$10dB depending on frequency and site of stimulation. Consequently, the sound delivered with a BCD is transmitted to the opposite cochlea without much loss.

Hearing with two ears ***(binaural hearing)*** makes it possible to localise a sound source and to improve hearing and speech perception in noisy environments. If one has only one hearing ear, *i.e.* single sided deafness (SSD) or ear canal atresia, there is absence of binaural stimulation, or a large intensity difference between the two inner ears (atresia), restricting the individual's ability to localise sound. BCDs have been shown to be of value when there is only one functioning cochlea as in SSD; sound waves from the processor on the deaf side can then be transmitted to the contralateral functioning cochlea *(Figure 2)*.

With a large conductive hearing loss on one or both sides, a unilateral or bilateral BCD will enable binaural cues, though less effective than with air conducted sound as bone conducted sound crosses over to the opposite cochlea and the difference in sound stimulation between the cochleae is therefore reduced.

percBCD

The percBCD has 3 parts *(Figure 3a and b)*:

1. Titanium fixture introduced into the skull behind and above the pinna
2. Skin-penetrating abutment attached (screwed) to the fixture

3. Microphone, sound processor and batteries in a single housing connected by a snap coupling to the abutment.

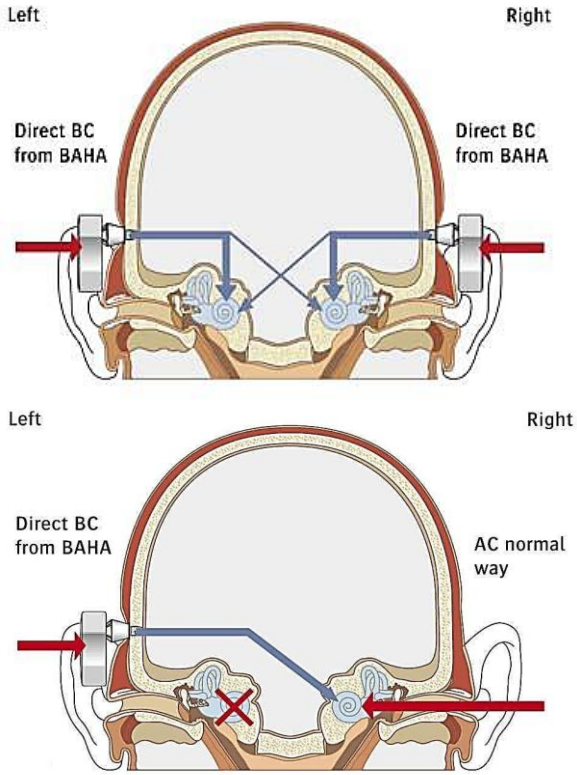

Figure 2: Sound conduction in the case of two normal cochleae (above) or with only one functioning left cochlea and right SSD

Figure 3a: Cochlear osseointegration system with coupling inside the abutment [8]

Figure 3b: Oticon system: Left-to-right: Sound processor; Coupling; Screw; Abutment; Implant. The coupling is on the outside of the abutment [9]

Patient selection

Patients who need a hearing aid but ***cannot use it or prefer not to use conventional hearing aids*** might benefit from a BCD.

A crucial factor for the decision to implant a BCD is ***how the patient perceives and appreciates BCD sound***. Therefore, a patient should try a BCD on a headband or a soft band before a decision is made.

There are ***no absolute hearing thresholds*** where BCDs are indicated, but it is rather ***decided by a trial period*** of using a headband/soft band. Thus, the decision to implant a BCD will be dependent on the patient, the hearing impairment, type of implant and the possible output of the sound processor.

To identify a suitable patient requires an audiogram and at least a ***3–4-week long trial with a BCD on a soft band*** at home and in working situations. If a patient is still interested to proceed after such a trial period, surgery can be planned. This selection process hopefully reduces the number of future non-users. The benefit is limited by the cochlear function. However, even if a pa-

tient does not fall within the domain of hearing loss recommended by the manufacturer, some patients note benefit during the try-out period and can still be suitable candidates for BCD rehabilitation.

Indications for BCD

- Unilateral or bilateral conductive or mixed hearing loss when reconstructive surgery is deemed not to benefit the patient
- When use of conventional hearing aids is impossible (ear canal problems, allergy to mould material)
- When hearing aids are contraindicated (ear must be kept dry)
- When hearing aids are ineffective
- In SSD when BCD is preferred instead of a CROS (Contralateral Routing of Signals) hearing aid

Examples of clinical indications

- Chronic suppurative otitis media (CSOM) with otorrhoea
- Congenital microtia or canal atresia (no ear canal for fitting).
- Chronic otitis externa (skin problems).
- Discomfort with conventional hearing aids e.g. pain, moisture, recurrent infections
- Ineffective conventional hearing aids due to considerable air-bone gap (not enough" gain", bad occlusion or feedback)
- Bilateral hearing problems or infections when surgery is planned for the two ears at different times to provide hearing while waiting for 2nd ear surgery
- Single sided deafness (SSD)

Selecting an appropriate BCD

Devices are recommended in accordance with hearing loss and individual preference.

General guidelines are

- Bone conduction average threshold (0.5, 1.0, 2.0, 4.0 kHz = PTA4) ≤55 dB HL
- Air-Bone gap PTA4 ≥30 dB
- SSD with PTA4 ≤35 dB HL in the functioning cochlea

Relative contraindications for percBCD

- Inability to manage a percBCD
- Inability to care for sufficient hygiene of the skin around the abutment to prevent skin infections
- General skin problems such as severe acne or psoriasis
- Lesions of the skin and skull bone from radiation therapy at the site for percBCD implantation

Surgical procedure

Older techniques that employ skin thinning (dermatome and variety of flap techniques is still used in many countries but will not be described here.

Newer ***skin preservation techniques*** have proven to be safer in the long term and have significant benefits [10] *(Figure 4)*.

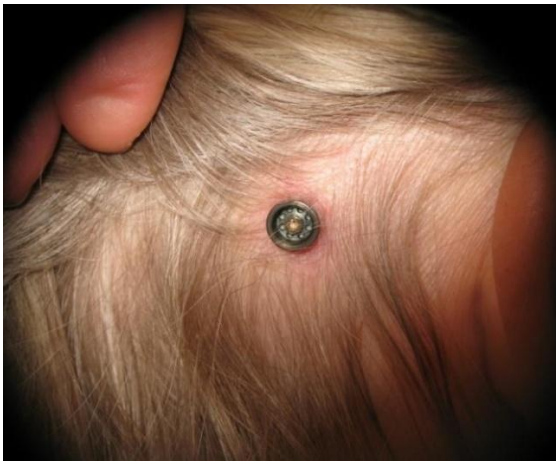

Figure 4: Normal hair cover 5 years after surgery

Benefits include shorter surgical time; quicker healing; earlier loading of the processor; less peri-implant infections; limited or no numbness around the implant site; and normal hair cover.

Two approaches will be described below

- Linear incision with tissue preservation
- Minimal Invasive Punch Technique (MIPS)

Linear incision with tissue preservation

- Most adult cases are done under local anaesthesia as an outpatient procedure with the head turned to the side; general anaesthesia can be used with a laryngeal mask, more commonly with children *(Figure 5)*
- Clean the skin and drape the surgical area *(Figure 6)*
- Shave a small part of the surgical area if necessary
- Mark the position of the implant with dye *e.g*. methylene blue, approximately 5.5cm behind and above the opening of the external ear canal *(Figure 7)*
- Take care to choose the right position if a patient wears glasses so that the processor will not interfere with the earpiece of the spectacles; if an otoplasty is to be done in the future, place the skin incision more posteriorly *(Figure 41)*

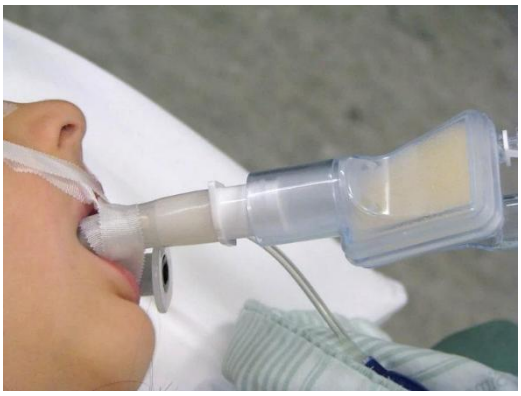

Figure 5: A child anaesthetised with head in lateral position

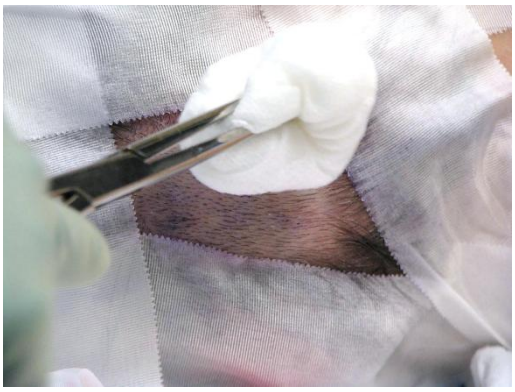

Figure 6: Mark the position spot of the implant on skin. Wash and then redraw so that the designated spot is visible

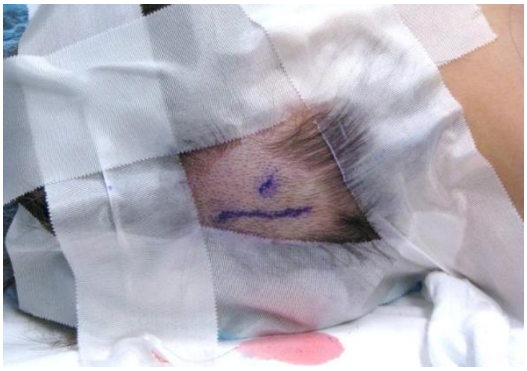

Figure 7: Blue mark indicates position of implant (spot) and surgical incision (line)

- Before giving local anaesthetics, measure the skin depth with a needle and note the number of mm to choose the correct abutment length
- Drape the patient *(Figures 8-12)*

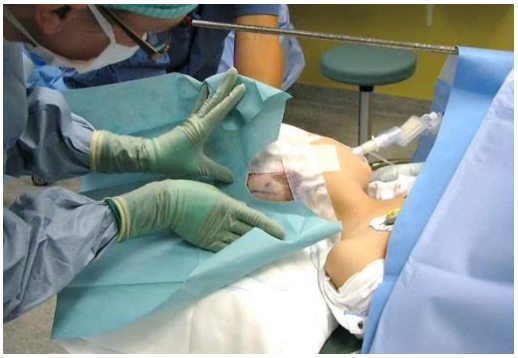

Figure 8: Cut a hole in the superior and inferior drape for the ear and surgical field

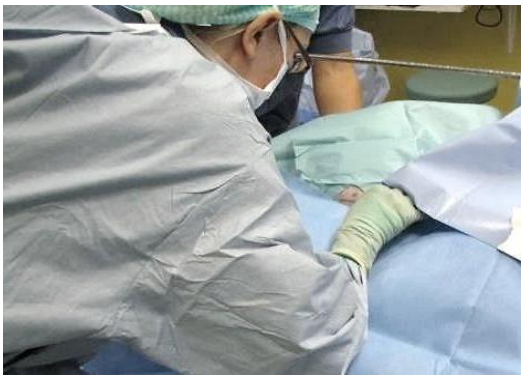

Figure 9: U-shaped sheets taped……

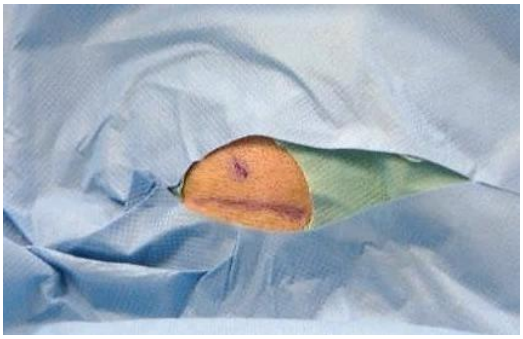

Figure 10: ….and pasted to the skin

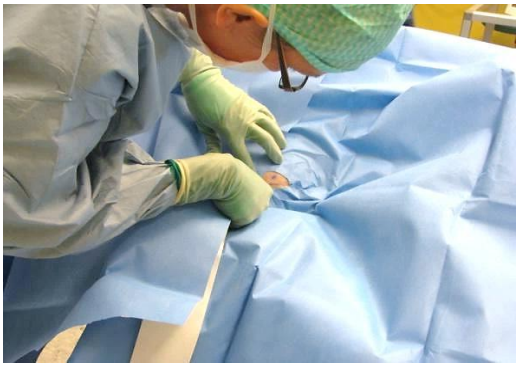

Figure 11: Apply adhesive transparent plastic sheet (optional)

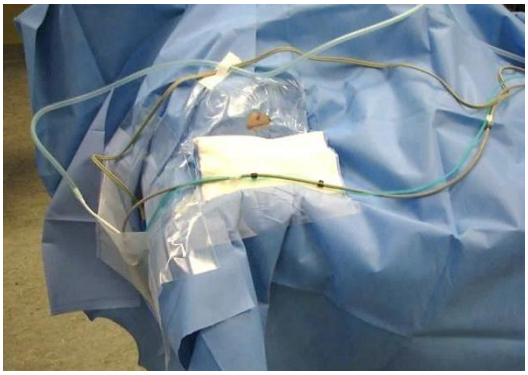

Figure 12: Final view of draped field

- Prepare the drill system *(Figures 13-17)*

Figure 13: Mount the drill irrigation tubing to the drilling machine (if such system is not available irrigate with a syringe filled with NaCl to cool the drilling of the bone

Figure 14: Attach the irrigation solution

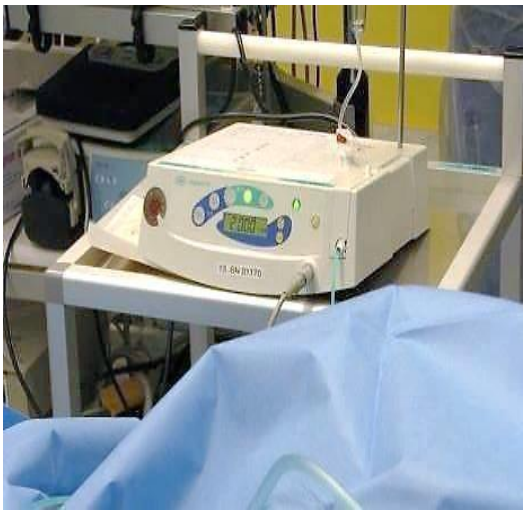

Figure 15: Set the drill speed

Figure 16: Check drill and integrated irrigation system

Figure 17: Drill heads

- Set out the required instruments *(Figure 18)*

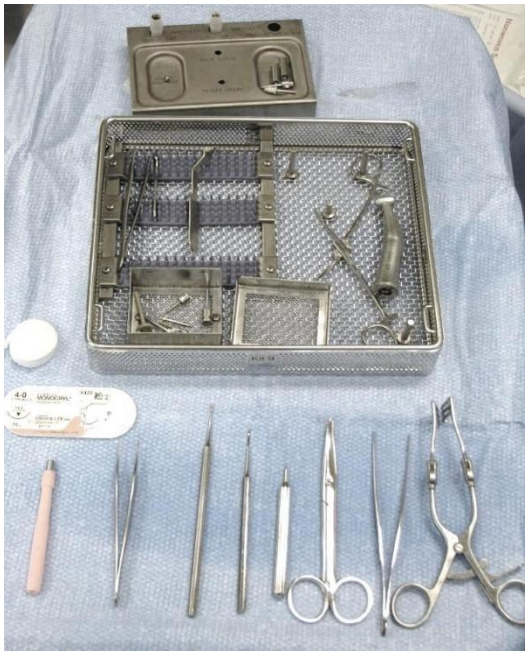

Figure 18: Instruments required

- Measure skin thickness either now (or later) as in *Figure 22* with a needle through the blue marked spot, mark the depth and measure with a ruler
- Make a straight 30-40mm linear incision down to periosteum in front of the spot as indicated in *Figures 19, 20*
- Obtain haemostasis *(Figure 21)*
- Incise the periosteum

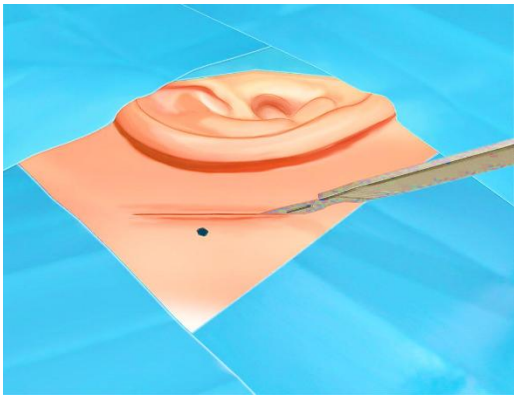

Figure 19: Straight 30-40mm linear incision down to periosteum

Figure 20: Vertical 4 cm incision down to bone

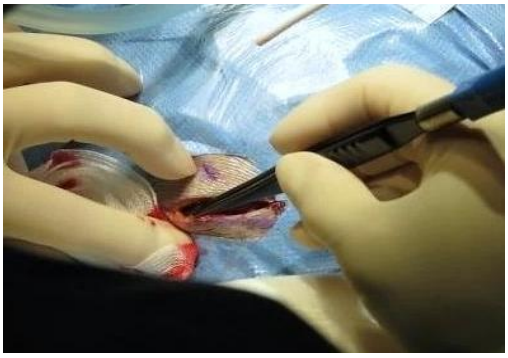

Figure 21: Use electrocautery for haemostasis

- Measure the skin thickness with a ruler *(Figure 22)*
- Set the drill at 2000 rpm *(Figure 23)*

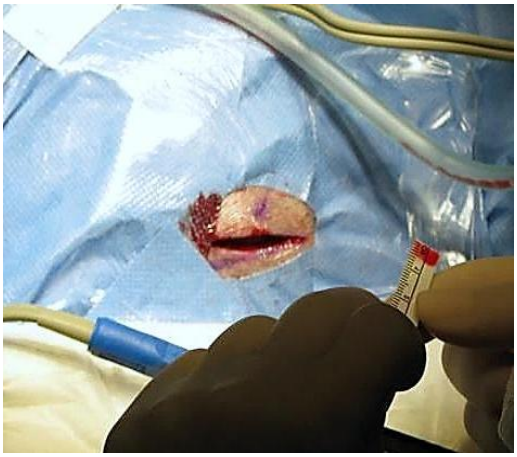

Figure 22: Measure the skin thickness

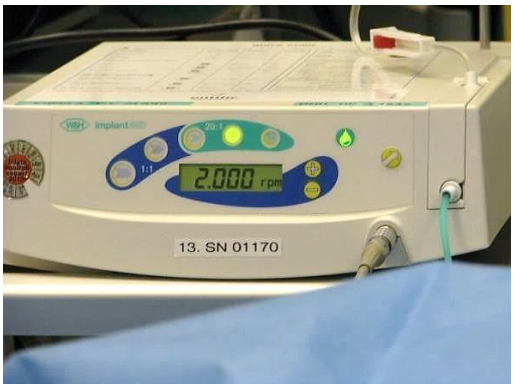

Figure 23: Drill setting for initial drill holes

- Drill a 3 mm deep hole in the bone in the selected place with a high-speed drill (2000rpm) with a plastic "stopper" attached *(Figure 24)*
- If there is still bone in the bottom of the hole, remove the plastic stopper on the drill piece and continue drilling until the next stop is reached and a 4mm depth is achieved. This allows a 4mm fixture to fit into the hole with good stability for the abutment especially in adults, where only one hole is drilled. In children an extra hole is drilled to allow for a "sleeper" fixture *(Figures 25 and 29)*

Figure 24: 3 mm drill bit with plastic "stopper"

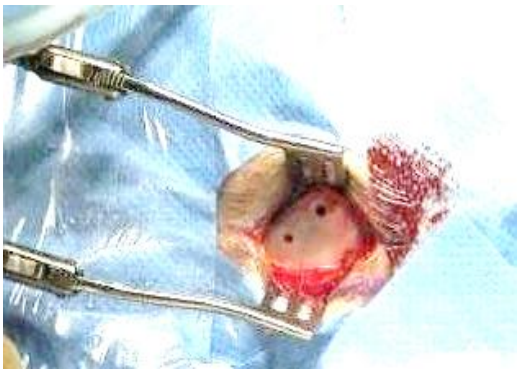

Figure 25: Note: 2nd hole is drilled in children for a "sleeping fixture"

- Widen the drill hole with a "countersink" burr, still at 2000 rpm drill speed (choose a 3- or 4-mm countersink depending on the depth of the burr hole) *(Figures 26, 27)*

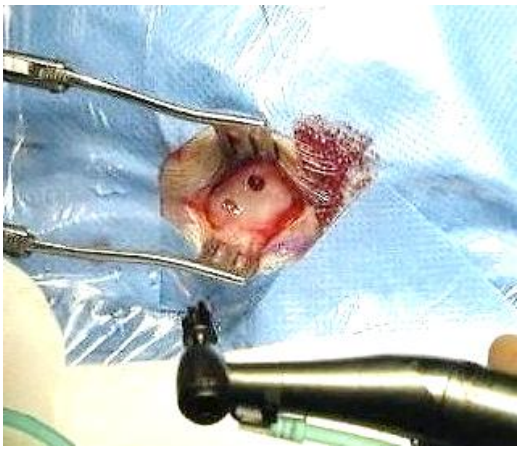

Figure 26: One hole has been enlarged with the countersink drill. (A second hole for a rescue fixture is performed in a child)

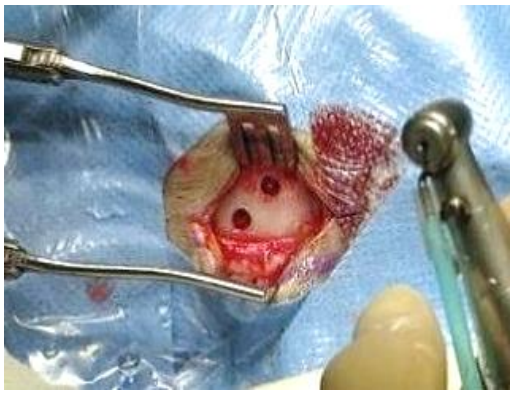

Figure 27: Both holes have been enlarged (child)

- Select the correct fixture according to the drill hole (3 or 4 mm) and the predrawn correct abutment according to the skin thickness (6-12 mm long)
- Set the drill at a low speed and at a power setting of 40-50 Ncm *(in adults, and approximately 25* Ncm *for children)*
- Screw the fixture into place *(Figure 28)*

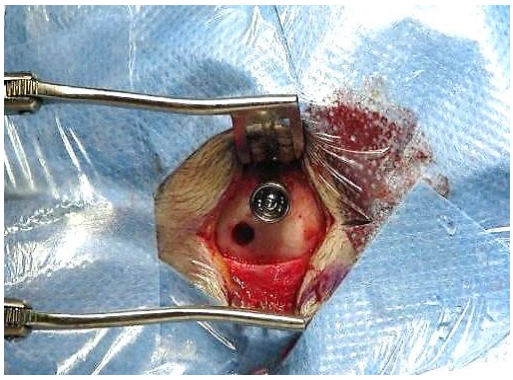

Figure 28: Fixture screwed into bone

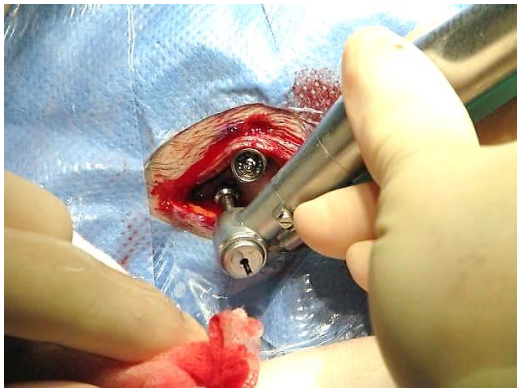

Figure 29: 2nd fixture (sleeper) being inserted (child)

- Punch a hole in the skin at the marked place with a 5mm diameter skin punch *(Figures 30, 31)*
- Externalise the abutment through the hole and close the skin with resorbable intracutaneous sutures *(Figure 32)*
- Tape the incision *(Figure 33)*

Figure 30: Punching a hole in the skin

Figure 31: Punch a hole through the skin and apply a cover screw to the 2nd fixture in children

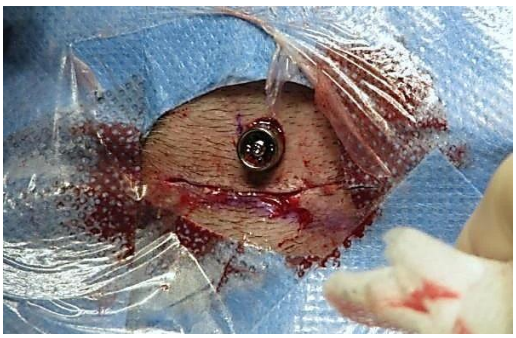

Figure 32: Pass the abutment through the hole in the skin and close the wound with intracutaneous sutures

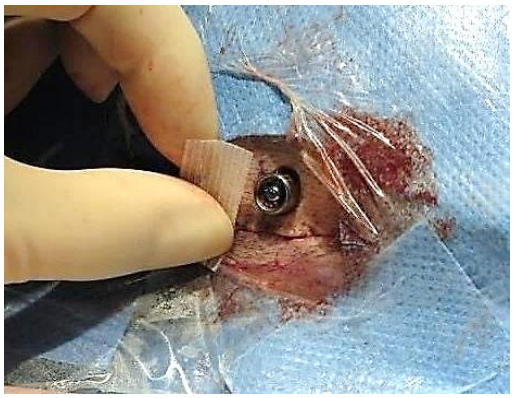

Figure 33: Taping the incision

- Attach a healing cap to the abutment *(Figure 34)*

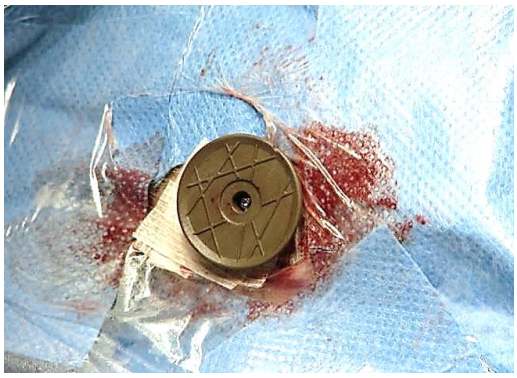

Figure 34: A healing cap is applied

- Gently wind gauze impregnated with antibiotic ointment around the abutment and under the cap *(Figure 35)*

Figure 35: Antibiotic ointment on a ribbon gauze rolled under the healing cap

- Place fluffed gauze over the wound and apply a head bandage *(Figures 36, 37)*

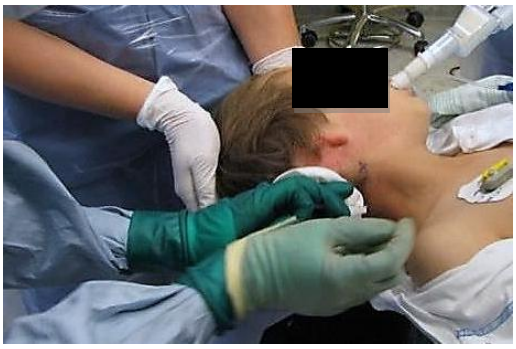

Figure 36: Fluffed gauze is placed over the wound

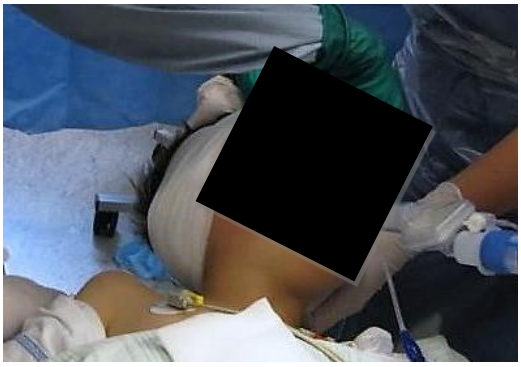

Figure 37: Apply a head bandage

- Remove the healing cap after 7-10 days together with the gauze
- The processor can be loaded to the abutment after another 2-4 weeks [5]

Video of surgical technique of linear incision with tissue preservation:
https://www.youtube.com/watch?v=7lQsaV6GTA8 [11]

The Minimal Invasive Punch Technique (MIPS) *(Figures 38 a, b)*

- Mark the implant site
- Measure the skin thickness with a needle before local anaesthesia
- Injection of local anaesthesia
- Remove the skin and soft tissue with a wide punch down to periosteum
- Insert the specified cannula
- Drill a hole in the bone through the cannula in the punch hole to an appropriate length (3 or 4 mm)

- Remove the cannula
- Introduce the pre-drawn fixture with an abutment of the correct length
- No suturing is required unless a very wide punch, has been used [12]
- Note: The emissary veins in the bone can bleed briskly when drilled through, so always be prepared for this event *e.g.* open the skin wider and have bone wax ready *etc*

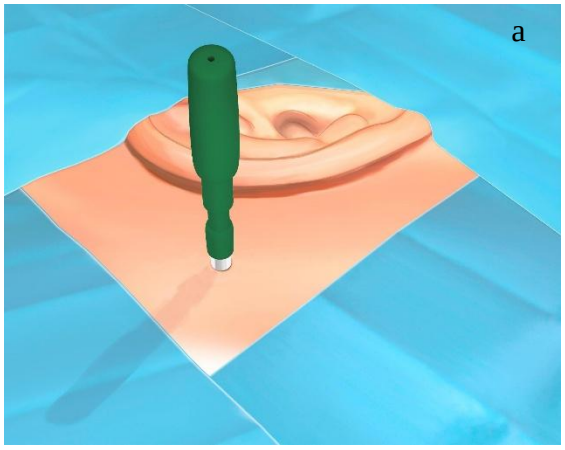

Figure 38a: Removing skin and soft tissue (also the periosteum) with a wide punch

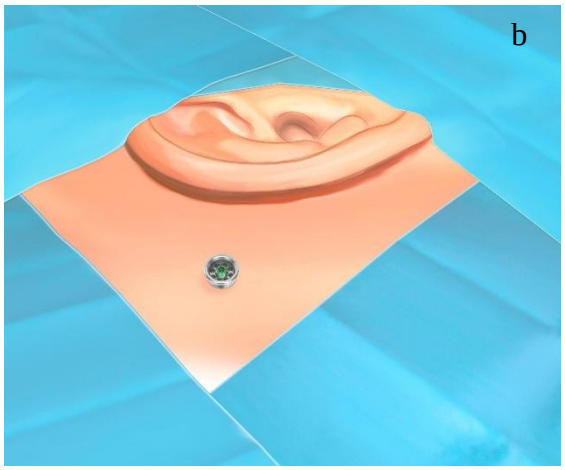

Figure 38b: Abutment in place (With permission from Oticon Medical)

Surgical procedures in children

If a child is born with severe hearing loss, single or double-sided atresia or SSD, it is recommended to refer the child to an audiological centre early. Testing with a BCD on a soft band can then be done and a BCD fitted later *(Figure 39)*.

Figure 39: BCD on a soft band

With atresia, outer ear reconstruction is recommended when enough rib cartilage has developed at the age of 5-10 years. Outer ear canal reconstruction can be considered when children are able to decide for themselves (14-16 years of age). If a new ear canal has been surgically constructed the patient needs to see an ENT specialist every 6-12 months for the rest of his/her life to clean the ear canal to avoid retention of debris and development of cholesteatoma.

The trend today is to avoid the difficult surgery to reconstruct the ear canal, as the results have not been good enough, and instead to reconstruct the pinna in a cosmetically acceptable way and to use a BCD for hearing.

Children with double-sided atresia must use a BCD on a soft band from a young age (3 months or earlier) for language acquisition, whereas others should start as soon as possible, and always 3-4 weeks before a decision is made to operate.

Children with single-sided atresia benefit from training the hearing pathways early on the atretic side. Previously no rehabilitation was given to these children since they developed speech normally. However, it has been shown that these children will have problems later in life and that the earlier they are fitted with a BCD the better.

A soft band at an early age gives the child the possibility to get used to binaural hearing. Reports show that as many as 1/3 of children with a unilateral hearing loss need to repeat one year at school and that every other child needs extra resources during schooling. Some children with single-sided atresia, even if they do not have other syndromes, will never develop strategies to cope with their hearing handicap [13].

A permanent fixture and abutment for a BCD is easier to utilise for a child than a soft band and gives better hearing. The timing to introduce a permanent fixture can be decided when the skull bone thickness is ≥2.5mm, which is usually around the age of 2,5 - 3 years.

BCD surgery in children is usually done under general anaesthesia. It can be performed as a 1-stage or a 2-stage procedure depending on how thick the skull bone appears to be at surgery. If the bone is ≥2.5-3mm thick, then surgery can be performed as a 1-stage procedure in the same manner as described previously for adults. If the skull is thinner, a 2-stage procedure should be considered. For this reason, it can be wise to wait until the child is 4 years of age before implanting the fixture, to facilitate a possible 1-stage procedure.

Two fixtures are usually placed in the bone in children; one to be used with the abutment and the second as a rescue fixture ("sleeper"), to be used if the first implant is lost following trauma or infection *(Figure 40)*. In such cases one simply needs to punch through the skin overlying the sleeping fixture as the implant is already osseointegrated.

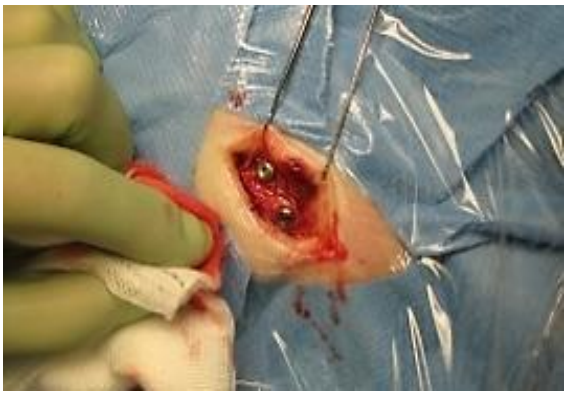

Figure 40: Two fixtures placed in the skull of a child

With 2-stage surgery, the two fixtures are introduced and the skin is closed. The system is left undisturbed for 2-3 months for osseointegration to occur. The 2nd surgical stage is performed under general anaesthesia. At the 2nd surgery, the skin over the selected fixture is punched out and the abutment is introduced.

Loading the sound processor

The processor can be loaded quite soon after surgery [6] *(Figure 41)*.

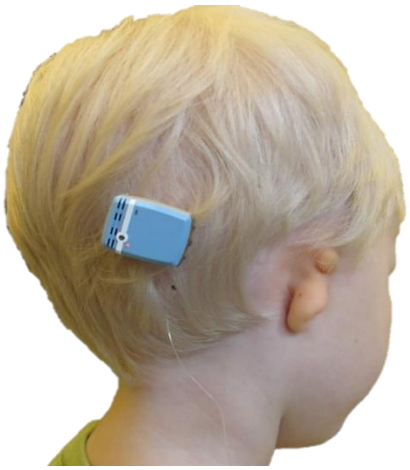

Figure 41: Processor placed a bit further back due to pending outer ear reconstruction

Two manufacturers currently produce percBCD fixtures and abutments, which are compatible with both manufacturers' sound processors.

Once the fixture has osseointegrated after 2-3 weeks, the audiologist or audiology technician fits the processor according to the individual audiogram using the corresponding software program. Usually, 2-3 appointments with the audiologist are required to adjust and finetune the processor to optimise the sound perception.

Note that for children the loading time may be postponed for up to 3 months as osseointegration requires longer time in thin and soft skull bones.

It is recommended that the child uses a "safety line" to attach the processor to his/her clothes to avoid losing the processor during activity.

Complications

Problems encountered with percBCD systems include peri-implant infection, loss of the abutment (infection or trauma) and skin numbness. Skin infections are less troublesome and recurrent if skin preservation surgical techniques are used.

Peri-implant infection

Peri-implant infections occur commonly around the abutment *(Figure 42)*.

The *Holgers classification system* grades soft tissue reactions at the implant site from Grade 1 to Grade 4 [14]:

- *Grade 1:* Redness with slight swelling around abutment
- *Grade 2:* Redness, moistness and moderate swelling
- *Grade 3:* Redness, moistness and moderate swelling with tissue granulation around abutment
- *Grade 4:* Overt signs of infection resulting in removal of implant

Risk of infection can be reduced if the correct skin care is applied daily. Cleaning the skin around the abutment is an important task for the patient who must learn the signs and properties of their skin. Recommended tools for skincare are a soft toothbrush to gently clean the abutment site, water and soap, the correct type of hair shampoo and a softening ointment if the skin is dry.

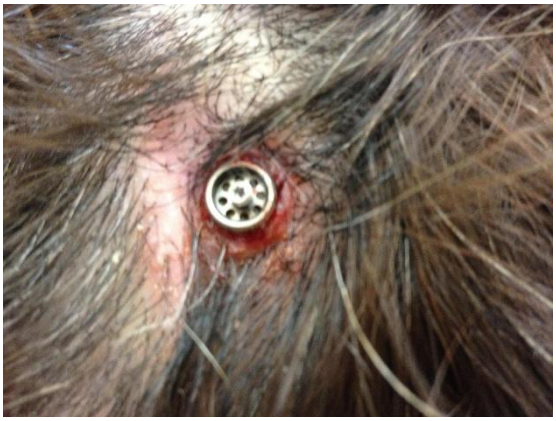

Figure 42: Peri-implant infection

If infection is noted, then more intensive cleaning is necessary and an ointment with antibiotics may be applied.

If a more pronounced tissue reaction is observed, a healing cap can be attached and gauze soaked in a liquid corticosteroid grade III gently wound between the skin and the healing cap. The patient is prescribed the steroid solution and is instructed to keep the gauze wet for 4-5 days until the next clinic visit for wound inspection.

Cauterising agents like silver nitrate can be used for granulation tissue around the abutment. Bacterial samples can be of value to determine whether oral antibiotics are required.

The abutment must be removed only if the infection persists (uncommonly) to get rid of the infection and to allow the skin to heal. The osseointegrated fixture can be used again at a later stage.

Skin pockets

Deep skin pockets are seldom seen with the newer surgical techniques. If they occur, then cleaning is of utmost importance.

Poor osseointegration and fixture loss

This may be due to infection, biological factors, poor bone quality *etc.* and starts early after implantation or later after a first successful osseointegration. Surgical revision placing a new fixture is required once the skin has healed after removal of the old fixture.

Numbness around the abutment

Numbness is a minor issue and is seldom seen with modern techniques and may be confined to only a small area around the abutment. If wide subcutaneous tissue removal is done as with the surgical flap technique, nerves supplying the skin are damaged and permanent numbness in an area of up to 10 cm in diameter may ensue.

Deep pain

Hyperaesthesia sometimes occurs around the abutment. If deeper pain occurs from bone, it may be necessary to drill out the osseointegrated fixture.

Traumatic loss of abutment/fixture

Any direct trauma to the head and the implant area may lead to loss of the implant. The skin heals over the fixture quickly. If only the abutment is lost, a new abutment can be installed under local anaesthesia as an outpatient procedure through a newly punched hole above the remaining fixture. If the entire fixture is lost, then a new surgical procedure must be done in adults. In children the "sleeping fixture" can be used for fixation of a new abutment.

Skin overgrowth *(Figure 43)*

With earlier flap techniques when the skin was extensively thinned and only 5.5 mm abutments were available, skin would at times, even in adults, overgrow the abutment and prevent good connection with the sound processor.

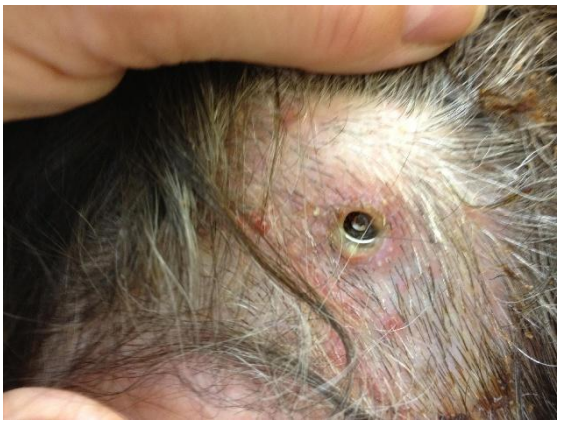

Figure 43: Skin overgrowth over the abutment which makes it impossible to use the processor

In children, new bone formation under the reduced skin was common and caused skin overgrowth. Another surgery was then necessary to thin the skin again and eventually drill some bone away.

Skin overgrowth is less problematic today as skin thinning is not done. With the availability of a range of abutments that allows the physician to unscrew an abutment that is too short and replace it with a longer one, the problem with overgrowth is minor. The exchange to a longer abutment can be done as an outpatient procedure also in children without any local anaesthesia.

New implants on the market

There are several different types of BCDs. They are principally categorised according to whether the skin is intact or not.

In the ***percBCD*** (described in detail above) the skin is penetrated by an abutment attached to an osseointegrated titanium fixture. The sound processor is then pressed onto the abutment.

In ***active transcutaneous BCDs*** the transducer is implanted under intact skin and has direct contact with the skull bone, transmitting sound vibrations to the cochleae. The sound processor is positioned by a low magnetic force onto the skin surface where it converts sound waves to radio signals. Thus, active transcutaneous BCDs do not transmit sound vibrations via the skin and soft tissues, only radio signals.

There are also ***passive transcutaneous BCDs*** where a magnet is implanted under intact skin. The sound processor (the same as used for the percBCD) is then attached to a magnetic plate which is held to the skin surface by magnetic force. Sound vibrations are then transmitted through the skin and soft tissues. The negative features of having the BCD on the skin surface is a loss of high frequency sound transmission, and that the magnet strength towards the skin has to be higher compared to active transcutaneous BCD. With passive transcutaneous BCDs the skin must be inspected, so that the magnetic force does not cause damage.

The last type is the ***conventional BCD***, where the sound processor (the same as used for the percBCD) is placed on the skin surface using a ***soft band or a headband***. As mentioned previously a conventional BCD is mainly used for children before they reach an age suitable for surgery, or as a try-out period for adults to decide whether a BCD is the best option for the patient [15,16,17,18].

The ***new generation of active and passive transcutaneous BCDs will be described in an upcoming new chapter*** for the Open Access Atlas of Otolaryngology, Head & Neck Operative surgery and for the Open Access Guide to Audiology and Hearing Aids for Otolaryngologists.

Instructional video

Linear incision with tissue preservation surgery technique:
https://www.youtube.com/watch?v=7lQsaV6GTA8

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