Reference number to be mentioned by correspondence : **B-ENT/03-11124-JANSSENS DE**

B-ENT, 2012, **8**, 000-000

Fixation of cochlear implants: An evidence-based review of literature

S. P. Janssens de Varebeke[1,3], *P. Govaerts*[2,3], *T. Cox*[1], *K. Deben*[1], *K. Ketelslagers*[1] *and B. Waelkens*[1]

[1]Department of ENT Head and Neck Surgery, Jessa Hospital, Campus Virga Jesse, Hasselt, Belgium; [2]The Eargroup, Antwerp – Deurne, Belgium; [3]de "cirkel": Cocheair Implant Reflexie-, Kennis En Leernetwerk, Deurne, Antwerp

Key-words. Cochlear; implant; fixation; migration; device; evidence; based; medicine

Abstract. *Fixation of cochlear implants: An evidence-based review of literature. Hypothesis*: There are numerous cochlear implant fixation techniques to prevent soft tissue complications related to device migration. The literature does not provide sufficient evidence to determine the most suitable fixation method.
Background: Cochlear implants (CI) are becoming a routine treatment for patients with severe to profound deafness. Steadily growing numbers of implant centres and surgeons worldwide are inevitably leading to higher rates of complications, including device migration. It is currently unknown whether this can be prevented by proper implant fixation during surgery. The low prevalence of this complication makes it challenging to interpret publications regarding CI fixation techniques.
Methods: An exhaustive literature review reveals a variety of different fixation techniques. Most authors advocate the creation of a bony well for the CI receiver/stimulator (R/S); however, an increasing number of surgeons no longer secure implants at all. Here we give an overview of all published fixation methods, with special attention to the evidence-based quality and descriptions of the advantages and drawbacks of each.
Conclusions: Literature review reveals an absence of level I evidence-based publications addressing device migration. Existing publications report on too few cases to draw a conclusion on whether surgical fixation prevents implant migration. To have statistical power, studies of alternative or new fixation methods should include high numbers of implantations in each study arm and the studies should be longitudinal and prospective. In default of other evidence, it seems fair to define good practice as the creation of at least a bony well and/or (bony) sutures.

Introduction

Increasing data confirms that cochlear implantation results in significantly improved patient auditory outcomes. This treatment is now considered a valuable treatment option for patients with severe to profound deafness[1,2] and has become a routine procedure, no longer limited to a few implantation centres.[3] To date, the Federal Drug Administration (FDA) reports that more than 188,000 people have been implanted worldwide, illustrating a trend towards multiplication of implantation centres with increasing numbers of performed implantations and additional surgeons gaining experience in cochlear implantation.[4] The surgical technique is well developed and reports claim low complication and failure rates,[5,6] however, additional refinements and developments are needed to further reduce complication rates.

The risks of cochlear implantation include soft tissue complications, e.g. infection of soft tissue, vascular compromise, wound necrosis, and extrusion of the device. Device migration is also associated with soft tissue complications and can lead to reintervention.[5-10]

A huge number of studies have reported different fixation techniques to reduce these risks,[11-34] with each individually reporting outcome figures regarding soft tissue complications and device migrations. However, in an era where implantation centres are proliferating, less experienced surgeons may find themselves confronted with questions like whether and how to fix the implants, highlighting the need for an evidence-based and objective overview of fixation techniques.

The aim of this paper is to present an objective, exhaustive, critical, evidence-based, and practical review of literature, discussing the drawbacks and advantages of all of the different fixation techniques that have been published to date.

Review of literature

The Cochrane Central Register of Controlled Trials, Embase, Medline, and Pubmed databases were searched for publications, from 1980 until 2011, relating to fixation of cochlear implants, soft

tissue complications of cochlear implantation, and device migration, displacement, dislodgement, or slipping. Twenty-seven papers were selected that contained data addressing device migration and/or device fixation methods.[5,9-35] To obtain complete data, we also searched and studied more than thirty additional papers about complications of cochlear implantation and all bibliographies of the above selected papers; of these, seven are included in the references section of this paper for editorial reasons.[1-4,36-38] More than 70 publications were studied in total.

Special attention was focused on the following parameters: date of publication, allocation method, intention-to-treat analysis comparing groups with different fixation methods, number of included implantations, follow-up period, presence of statistical power, specific fixation technique assessed, number and type of complications described, type of incision, and reference to device migration in bibliography. These parameters are further summarized in Table 1. The different fixation methods described for securing cochlear implants are schematized in Table 2. Furthermore, the alleged advantages and drawbacks of all different fixation techniques are summarized in Tables 3 and 4. Concerning complication and device migration rates, Cohen NL, Hoffman RA, and Webb RL are the most cited authors.[5,7-9] Their studies are directly or indirectly referred to in the majority of consecutive publications that discuss the quantification of complications of cochlear implantations, particularly device migration.

In 1988, Cohen *et al.*[7] conducted an extensive survey by sending questionnaires to 115 cochlear implant surgeons throughout the United States; 108 surgeons responded (94%), reporting various complications for a total of 459 cochlear implantations. This set of data did not include any instances of device migration. At that time, large anterior-based C-shaped skinflaps were used and the receiver/stimulator (R/S) was commonly fitted in a carefully drilled bony well and further secured with bony tie-down non-resorbable sutures. This so-called "standard" or "conventional" fixation method is still recommended nowadays by most cochlear implant manufacturers, with the exception of the use of large incisions; the standard incision size has been reduced through the years to lower the risks of skinflap breakdown and wound infections.[10]

In 1991, Webb *et al.*[8] evaluated the complication rates of the Hannover and Melbourne cochlear implantation centres, reporting data on 153 and 100 patients, respectively. Again, not a single case of device migration was reported. The authors were more concerned about devastating outcomes of wound breakdown; they claimed better outcomes with the extended endaural skinflap in comparison to the classical large anterior-based C-shaped and inverted U-shaped skinflaps. Furthermore, they reported that using Dacron as a suture material caused more soft tissue complications (fistulae and necrosis) in the Hannover group, which then switched to using another fixation method – glass ionomer cement. However, the use of cement was quickly abandoned for safety reasons (aluminium encephalopathy and neurotoxicity).[11,12]

In 1993, building on their first survey, Cohen *et al.*[9] further reported complication rates in a total of 2751 implantations. Whereas the total complication rate (12%) was similar to their earlier publication, this paper was the first to report a new and until then unknown complication, namely device migration.

In 1995, a retrospective study of data provided by the Cochlear Corporation was published by Hoffman and Cohen,[5] showing an overall complication rate of 12.2%, with less flap breakdown but more device failure. For a total of 4969 implantations (3064 adults and 1905 children), eight device migrations were registered for the adult group (0.26%) and only one for children (0.05%). This difference was believed to be related to the surgeons' experience, in the sense that implantations in children seemed to be more often performed by more experienced surgeons compared to adult patients.

An elementary step in the standard procedure consists of drilling a bony well and holes for sutures. This step is time consuming. Furthermore, drilling may be awkward in thin cortical bone, as frequently encountered in young children. Drilling may also cause the exposure of large areas of dura, increasing the risk of dural tears, CSF-leaks, and intracranial complications such as cerebral infarction, epi- or subdural hematoma, temporal lobe infarction, lateral sinus thrombose, epidural hematoma, laceration of superficial branch of middle meningeal artery under bony seat, and tentorial herniation.

CI manufacturers address these drawbacks of device fixation by reducing the receiver/stimulators' profile or by modifying its design to provide better attachment

Color print?

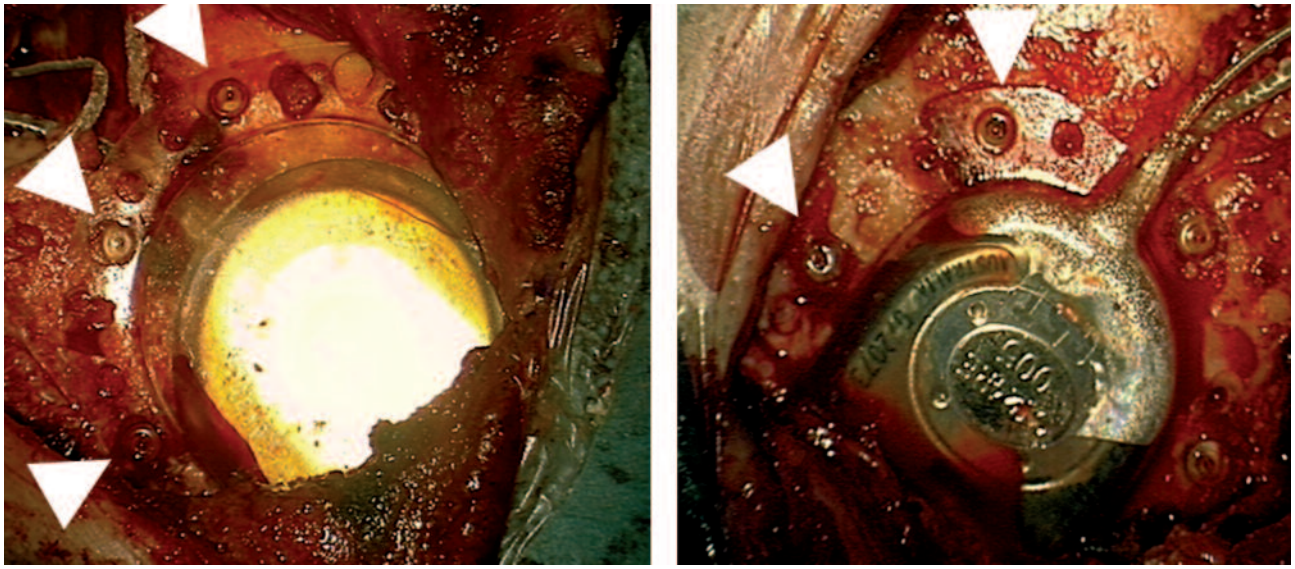

Figure 1
Right: Advanced Bionics HiRes90K cochlear implant fixation with Resorb-X preformed PDLLA mesh. Note the fixation of the mesh with pins (white arrows). Left: Cochlear Nucleus Contour Freedom cochlear implant fixation with Resorb-X preformed mesh. White arrows illustrate pins for fixation.

modalities. Surgeons also try to improve outcomes by modifying their implantation techniques. Some surgeons introduced the use of Gore-Tex or titanium meshes fixed with titanium screws[13] for securing the implants' R/S; they reported 205 successful implantations without migration. The use of polypropylene meshes fixed with titanium screws[14,15] was also proposed, but the authors reported 5 infections out of 285 implantations. In 2007, a novel fixation method was presented, securing implants with resorbable Resorb-X preformed PDLLA (Poly-D and L-Lactic Acid) meshes (KLS Martin) fixed with PDLLA-made resorbable pins (SonicPin Rx). This material was first commercialized for absorbable craniofacial osteosynthesis (Figure 1) (personal communication: Scholtz LU, Meuller J, Brill S, Baier G, Hagen R. Absorbable systems of osteosynthesis: an interesting alternative of cochlear implant fixation. Presented at the EUFOS meeting, Vienna, 2007.). PDLLA material is fully biologically degradable and no foreign body tissue is left after complete resorption of the material. It is believed that, upon resorption of the foreign material, the surrounding scar tissue and natural tissue pressure securely keeps the implant in place. The authors saw no adverse reactions or device migrations during a one-year follow-up. However, it is our experience that this technique does not avoid the need to drill bony wells and holes.

O'Donoghue *et al.*[16] and others[17] reported absence of device migration in a series of 23 consecutive pediatric cochlear implantations for a median follow-up period of 3.2 years, using a fixation technique which relies on a small incision, the creation of a bony well to lower the R/S' profile, and on natural pericranial pressure of a small subperiosteal pocket that just fits the R/S without the use of any (bony or periosteal) non-resorbable suture/material.

Some authors are not convinced that small incisions, bony wells, and tightly fitted subperiosteal pockets are enough to secure the R/S in all cases.[18,19] For instance, children are particularly exposed to trauma, which could lead to higher risk of device migration. In two series of respectively 100 and 73 consecutive implantations, these authors described a minimal incision technique with the creation of a subperiosteal pocket, to which they added extra fixation of the R/S. In children, this was achieved by creating bony suture holes going through the whole thickness of the skull at the posterior end of the bony well, using special tools in order to protect the dura. In children and adults who presented thicker posterior rims of the bony seat, they used Mitek TACIT QuickAnchor screws (Ethicon Inc) consisting of a self-tapping screw preloaded with two strands of 2.0 Ethibond ligatures. No migrations were reported, but one case of extra-dural hematoma

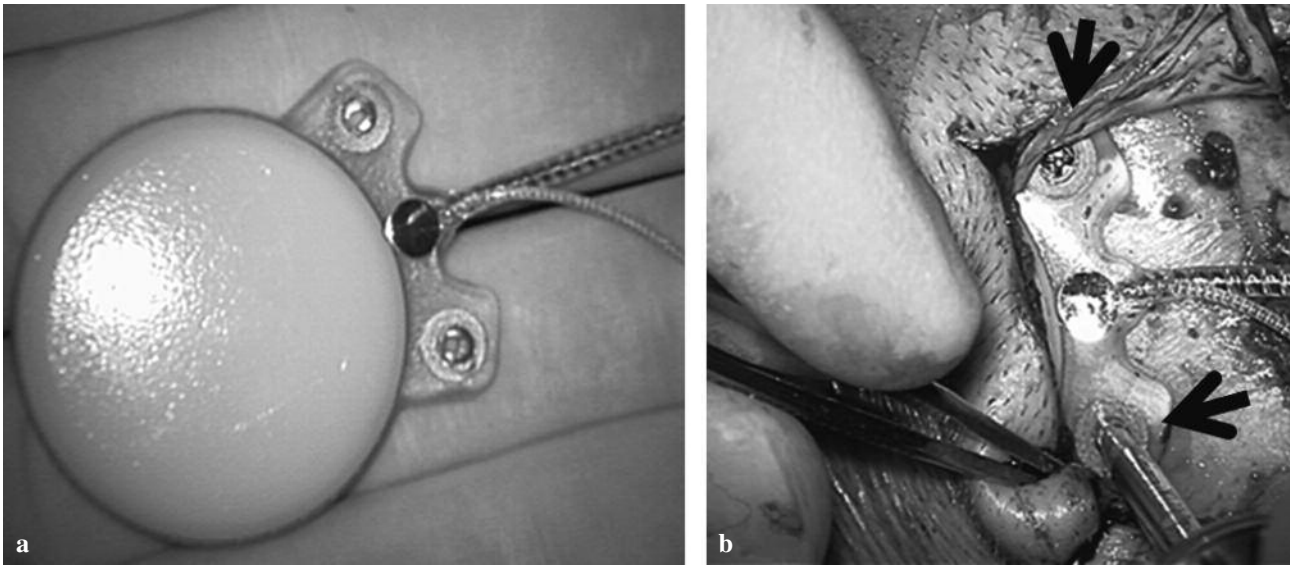

Figure 2
a: Neurelec digisonic SP ceramic silicone-coated implant with two built-in silicone abutments, each with titanium-enforced fixation rings at both sides of the exiting electrode array. b: Neurelec Digisonic SP cochlear implant secured with two self-tapping screws (black arrows).

was observed, attributed to the dural dissection and elevation that were required to manipulate the specific protecting tools.

Other authors are more comfortable with using purpose-built helping gear to gain a better view and to protect surrounding tissues of the subpericranial pocket in case of minimal invasive surgery, using metal bridges[20] or half-cut steel buckets.[21] This also makes it possible to make optional suture holes for ligature.[20] Extra fixation of the implant in a bony seat can also be obtained with the use of self-tapping titanium screws at both sides of the bony well, to which a nylon suture is then tied.[22] However, the placement of screws tends to be difficult when placed more distally in the subperiosteal pocket.

In 2006, the Hannover group presented a prospective analysis of 808 consecutive cases implanted with different kinds of implants, showing excellent outcomes with regard to device migration using a somewhat modified minimal invasive surgical approach, with a 5- to 6-cm curved post-auricular incision line.[23] A subperiosteal pocket was created with a special designed suction hook (modified Langenbeck retractor). Additional R/S fixation was achieved by drilling a bony channel between the bony well and the mastoid cavity, through which the implants' electrode array was pulled before the final placement in the bony well. This technique differs from others previously described because of the absence of any non-resorbable sutures, which are associated with intolerance reactions.[8,23] (personal communication). Loh *et al.*[24] later described a slightly modified version of this bony channel non-sutured technique, in which a channel was drilled between the bony well and the mastoid cavity, creating a cantilever consisting of a deep groove in which the implants' electrode can rest, which is then covered with bone dust after the placement of implant. This technique was found very feasible in 80 adult patients, but it was more problematic in young children.

More minimalistic fixation methods are obtained with periosteal suturing of the musculoperiosteal layer over the implant, as described by Adunka *et al.*[25] in 2007. They reported excellent fixation results in 160 pediatric implantations. However, they felt that a bony well was still necessary.

The so-called "t-pocket" technique of Balkany *et al.*[26] is completely different; it does not require bony wells, thus limiting surgery time and avoiding potential intracranial and dural complications. In this technique, a subpericranial t-pocket is created between the two condensation lines of the pericranium, superiorly at the temporoparietal suture and more inferiorly at the lamboid suture. Fixation of the cochlear implant relies solely on native subpericranial tension, which is possible due to the reduced thick-

Table 1

Overview of publications, with regard to fixation techniques and their outcome

Publication (in order of citation in main text)	**N**	**Fixation method and incision**	**T**	**Migration of R/S**	**EBM level**	**G**
Hoffman *et al*.[5]	4969	– Classical – Incision not specified	?	adult:8 children: 1	2b	B
Cohen *et al*.[7]	459	– Classical (bony well, bony sutures) – Extended anterior C-skin flap incision	?	–	2b	B
Webb *et al*.[8]	253	– Classical (N = 108), glass ionomer cement (N = 145) – Inverted U-shaped skinflap and extended endaural incision	?	–	4	C
Cohen *et al*.[9]	2751	– Classical – C-shaped incision	?	+	2b	B
Djalilian *et al*.[13]	180*	– Bony well; titanium mesh (N = 170), Gore-Tex patch (N = 10) – Hockey-stick incision	?	–	4	D
Davis *et al*.[14]	285*	– Bony well, polypropylene mesh, and titanium screws – Incision type not specified	16	–	4	C
Alexander *et al.*[15]	320	– Bony well; bony sutures (N = 182), propylene mesh and screws (N = 98), periosteal sutures (N = 40) – Minimal access	26	–	4	D
O'Donoghue *et al.*[16]	23	– Bony well, small subperiosteal pocket – Small 3– to 4-cm postauricular incision	18	–	4	C
Anagiatos *et al*.[17]	145	– Bony well, L-shaped muscle flap, periosteal sutures – Minimal access	84	–	2b	C
Campisi *et al.*[18]	73	– Bony well, Mitek QuickAnchor – Minimal incision	?	–	4	D
James *et al*.[19]	100	– Bony well, bony holes for sutures, small subperiosteal pocket – Small 3– to 4-cm postauricular incision	?	–	4	C
Jiang *et al*.[20]	49*	– Bony well, bony sutures – Minimal incision	1-16	–	4	D
Cuda[21]	30*	– Bony well, sutures (N = 14), no sutures, periosteal (N = 16) – Small incision 4 cm posterior to template	?	–	2b	C
Lee *et al.*[22]	45*	– Bony well, titanium screws with nylon sutures – Incision type not specified	1-20	–	4	D
Mack *et al*.[23]	808*	– Bony well, bony channel – Minimal incision 5-6 cm curved	1-84	–	2b	B
Loh *et al*.[24]	87*	– Bony well, bony groove and bone dust – Small incision 5 cm	?	–	4	D
Adunka *et al.*[25]	160*	– Bony well, periosteal sutures – Small incision 4 cm	?	–	4	D
Balkany *et al.*[26]	171*	– T-pocket subpericranial, periosteal suture – Small incision	16.4	–	2b	C
Guldiken *et al*.[27]	148	– Standard (N = 83), subperiosteal pocket (N = 65) – Minimal access	26.8	–	4	C
Stratigouleas *et al.*[28]	176	– Subperiosteal pocket – Minimal incision	6	3	4	C
Molony *et al.*[30]	285	– Bony well; bony sutures (N = 221), periosteal sutures (N = 63) – Small incision, except first 15 cases	6-84	–	4	C
Davids *et al.*[31]	462	– Bony well, tie down bony sutures – Small incision	36	–	2b	C
Eskander *et al*.[32]	971 to 738 children	– Bony well, bony sutures – Incision type not specified	20	–	2b	B
Guevara *et al.*[33]	156	– Subperiosteal pocket, titanium screws in tailfins – Minimal incision	35	1	2b	C

N: number of implantations (*: it is unknown whether the number refers to implantations or patients); T: follow-up time in months (?: the figure is unavailable); EBM level: level of evidence-based medicine according to the Oxford Centre of EBM, http://www.essentialevidenceplus.com/product/ebm_loe.cfm?show=oxford (38); G: grade of recommendation.

Table 2
Different fixation techniques described in literature

Fixation method
1. Classical (extended incision, bony well, bony non-resorbable sutures)[5,7-10]
2. Subperiosteal pocket with small incision, bony well[16,17]
3. Conventional incision, bony well, titanium screws, nylon sutures[22]
4. Conventional incision with Gore-Tex and titanium meshes, titanium screws, PDLLA meshes and pins[13-14]
5. Subperiosteal pocket, small incision, bony well, metal bridge/bucket as helping gear, bony sutures[20-21]
6. Subperiosteal pocket, small incision bony well, full-thickness cortical holes or Mitek QuickAnchor ligatures[18-19]
7. Small curved 5- to 6-cm incision, bony well, bony channel or cantilever (groove and bone dust)[24]
8. Small incision, bony well, periosteal sutures[25]
9. Small incision, t-pocket, periosteal sutures[26-27]
10. Digisonic SP (Neurelec): tailfins titanium screws[33]
11. Concerto Pin System (Med-El): pin at bottom of R/S[34]

ness of many implant devices, particularly the Nucleus CI512. After a preliminary study on 48 cadaveric specimens, the authors retrospectively reviewed 227 charts, comparing a group of 171 subjects implanted using the t-pocket technique with another group of 56 patients who underwent a "standard" technique (drilling bony wells and sutures if necessary). The authors observed "no differences"; however, it should be noted that the study arms were relatively small and that device migration occurred in neither group. Another possible bias may arise from the fact that, during surgery, the surgeons switched from the novel to the standard technique if the pocket was felt to be inappropriate, that is, if the silicone dummy popped out of the pocket in response to pressure at the posterior edge of the R/S. The authors do not advise using this technique for revision surgery. Another comparative chart review was recently conducted with similar conclusions.[27]

Stratigouleas *et al.*[28] had previously described a similar subpericranial technique without any fixation in 2006; they reported three cases of device migration out of 176 implantations. Furthermore, a recent study conducted on 83 devices in 51 children indicates that the retentive capacity of the subpericranial pocket may be less predictable and insufficient to resist device migration without additional fixation.[29]

A retrospective study comparing the bony well technique plus bony tie-down sutures (221 cases) with a bony well technique and periosteal sutures (63 cases) did not show any difference in complication rates between both groups.[30] Again, not a single device migration was observed in the two study groups.

Despite all considerations, many surgeons still consider device fixation to be a principle of good practice, which is especially important in pediatric patients because of their thinner soft tissues and higher exposure to trauma compared to adults.[31] Yoshikawa *et al.*[6] conducted a questionnaire-based anonymous survey; out of 106 surgeons, 62 responded (58.8%). The majority of the respondents preferred to drill a well for the R/S, both for adult (83.3%) and pediatric patients (78.6%). Less uniformity was found in answers regarding additional techniques used; conventional bony anchored suturing was used by 56.1% for adults and 50% for children. In children, fascial and periosteal sutures were used equally often. Some respondents would never secure the internal receiver in adults (17.5%) or in children (17.9%).

Over time, cochlear implant manufacturers have redesigned their implants and reshaped the implants' R/S. All manufacturers (Advanced Bionics, Cochlear, Med-El, Neurelec) have reduced the thickness of the internal device. The Digisonic SP device (Neurelec, France) features two anteriorly positioned silicone tailfins (fixation rings) enabling quick securing with self-tapping titanium screws (Figures 2a,b). The first generation of these tailfins were not reinforced by titanium rings, which eventually gave rise to a few cases of device migration due to perforation of the tailfin by too tightly fixed titanium screws.[33] With the new generation of titanium-reinforced tailfins, no device migrations have been reported to date.[33] This type of implant per-

Table 3

Overview of advantages and disadvantages of the two main cochlear implant approaches

		Advantages	Disadvantages
Standard fixation technique	– somewhat larger incisions (6 cm)* – bony well – bony sutures (non-resorbable) – elevation larger flap	– better direct view – lower profile of device – easy to perform drill work – better control in case of bleeding, etc. – additional fixation – more permanent fixation – better fixation in case of seroma, hematoma, and infection	– longer surgical time – longer healing time – more hair shaving – somewhat higher risk of wound infections – exposure of dura – risk of intracranial complications – risk of dural complications – irritation from/intolerance to suture material
Minimal invasive method**	– subperiosteal pocket – very small incisions (3-4 cm)	– less risk of infection* – less wound breakdown* – less hair shaving – shorter surgery time – shorter healing time – shorter hospital stay – earlier activation of device – no additional foreign bodies	– narrow exposure of tissues – unsuitable for revision – difficult drill work and suture placement – troublesome in case of complications – troublesome for bulky devices – learning curve

*: Smaller incisions can also be considered in the standard fixation technique and the risks of wound infection, flap breakdown, and extrusion of cochlear implant are not restricted to the standard technique alone.
**: When minimal invasive technique is used together with the creation of bony wells, as shown in Table 2, the risks related to this surgical time should be considered.

mits rapid implantation without the need to drill bony wells or any other bony fixation. The newest Concerto devices of Med-EL are the smallest and flattest titanium-cased devices and are alos available in the Concerto Pin version, which features two fixation pins at the anterior half of the bottom of the R/S to facilitate attachment of the implant to the skull. A dummy guides the surgeon to drill the holes at positions exactly matching the implant's Pin System.[34] It is our experience that the bony seat has to be flattened in such a way that not a single irregularity or bulge might intervene in the fixation of the implant; a perfect fit is absolutely essential for the attachment, otherwise the implant could lose its fixation. The manufacturer, however, still advocates the need for additional bony tie-down sutures and, to our experience, the surgery time is not dramatically shorter. Furthermore, there is still some drilling needed for fixation.

Discussion

This review of the literature available on CI-fixation reveals a number of publications on this subject with a huge variation in techniques (summarized in Tables 1 and 2). The majority of these fixation techniques are derived from two basic approaches. On one hand there is the "standard" or conventional fixation method that necessitates the drilling of a bony well and bony suture holes. The other approach includes "minimal invasive" techniques that involve creating a tight sub-periosteal pocket in which the R/S is fitted, which is occasionally supported by periosteal sutures. With the latter technique, R/S fixation mostly relies on the natural retention capacity of the periosteal tissues. The advantages and disadvantages of both methods are summarized in Table 3. Additional fixation can be utilized with both standard and minimal invasive techniques, including meshes, screws, sutures, Pins, ligatures, etc. As shown in Table 4, some implant devices are especially designed with incorporated permanent fixation systems, such as the titanium reinforced silicone tailfins of Digisonic SP devices and the Concerto Pin System of Med-El. In theory this would provide more security when compared to the T-pocket technique alone. Obviously, the quickest technique would be the minimal invasive technique without bony well.

There is currently no resource available for cochlear implant surgeons to readily obtain a clear overview of these different fixation techniques. This is why we have composed this comprehensive evaluation of these papers using evidence-based criteria.

The problem with publications comparing the use of different fixation techniques to prevent device migration is that, to date, the exact prevalence of this complication remains unknown. The FDA's MAUDE online database, an

Table 4
Advantages and disadvantages of additional cochlear implant fixation techniques

Additional fixation	Advantages	Disadvantages
Bony groove/channel	inexpensive covers electrode array and root adds further fixation of device easy to perform	learning curve time consuming problematic in thin cortical bone could damage electrode array risk of dural and intracranial complications could be more problematic in narrow pockets
Gore-Tex, Titanium meshes	no drillwork needed permanent fixation fast technique easy to perform	adds another foreign body in wound enhanced profile with titanium meshes extra costs risk of dural and intracranial complications
Titanium screws + sutures	fast technique resorbable mesh	intolerance to non-resorbable sutures bony well needed bony well needed
PDLLA-meshes + SonicPin Rx	adds firm temporary fixation	holes for pins have to be predrilled adds another foreign body in wound very expensive time consuming risk of intracranial/dural complications
Mitek QuickAnchor screws + ligature	easy to perform adds fixation excellent in narrow spaces easy to perform	extra costs posterior rim of bony well must be thick tailfin must be reinforced
Digisonic SP device + tailfins (Neurelec, France)	adds permanent fixation no magnet migration tailfin is part of device fast surgery	large footprint ceramic casing, higher profile if bony well chosen, quite a lot of drillwork needed, more risks adds another foreign body in wound
Concerto Pin System (Med-El, Austria)	pins attached at bottom of device adds permanent fixation	cortical bone must be flattened perfectly lack of long term study results

online listing of cochlear implant complications, does not provide figures on the prevalence of device migration.[35] The only useful data are those reported by Cohen, Hoffman, and colleagues (n = 4696),[5] who found device migration rates of 0.2% for adult patients and 0.05% for pediatric implant recipients. This indicated low prevalence of device migration should be kept in mind as new techniques are being developed to attempt to reduce this specific complication. Any comparative study should be designed such that the rare event of a migrating device would at least occur once or several times in the control arm. If we consider a 0.2% probability of migration occurring, only sample sizes of an absolute minimum of 2000 (per study arm) have a reasonable chance of offering sufficient statistical power to demonstrate a difference between 0.2% and 0% complication rates. In such a study, the control arm should demonstrate device migration in 6 or more cases out of 2000 (probability ~ 11% by binomial calculation) compared to nil cases in the study arm (Chi-square with Yates correction <0.05). Alternatively, if a novel technique would have a higher risk for device migration, this would only become significant if 500 cases were included in each study arm, with the control arm showing the complication in 1 case and the study arm in 8 or more cases. Comparisons of alternative surgical techniques in smaller sample sizes are very unlikely to meet evidence-based level I criteria, even if all other conditions were met, like in prospective ramdomized, blinded trials.

Table 1 summarizes evaluations of a series of publications reporting on different fixation methods with respect to the criteria of the Oxford Centre of Evidence Based Medicine (EBM).[36] The statistical quality of all papers evaluated does not reach any higher than EBM level 2b, with recommendation grade B. This is due to numerous shortcomings in the study design of the majority of the publications, small sample sizes, and unequal distribution of subjects in different study arms. Many of the selected papers provide such sparse information on study set-up

and data collection that they can only be defined as "chart reviews" and "reports" instead of real trials or cohort studies. Only 2 out of the 24 publications in Table 1 were clearly prospective.[21,23] All other studies either were retrospective chart reviews or lacked sufficiently clear details of study design to be categorized as prospective. In addition, only one study included a large study population (808 implantations).[23] But even these numbers are too low, and furthermore, the study was not randomized and was not really comparing different fixation techniques. Only Cuda[22], Balkany *et al*.,[26] Molony *et al*.,[30] and Güldiken *et al*.[29] conducted comparative studies, but all fail to meet at least 2 other criteria to qualify as level I evidence, with each study suffering from some combination of too low sample sizes,[21,26,27,30] the lack of some form of randomized allocation,[21,26,27,30] retrospective comparative chart reviews,[26,27,30] unequal distribution of sample sizes in each studied branch,[26,30] and/or too many cases lost to follow-up or excluded due to incomplete data.[26,27]

Some of the selected papers address important matters regarding amelioration of fixation methods and contribute to developing more efficient implant fixation protocols. Nevertheless, when it comes to prove a new fixation method is safe, reliable, and therefore better than standard technique, than the quality of the study has also to be taken into consideration. To date, none of the publications on the risk of device migration that compare alternative fixation techniques to standard techniques qualify as A Grade, level 1b of evidence.

Each of the different fixation techniques elaborated in Tables 2, 3, and 4 has its own particular advantages and drawbacks. A surgeon who feels familiar and comfortable with one particular technique, can always decide during surgery to proceed with a different one if deemed necessary. From an evidence-based point of view, the existing publications do not provide enough evidence to justify a conclusion that any of the alternative fixation techniques is better, equal, or worse in preventing device migration compared to the standard technique. Therefore, we cautiously conclude that some kind of permanent fixation should be advocated in cochlear implant surgery and that the standard technique should be considered good clinical practice until proof of the contrary is provided. With an increasing number of cochlear implant wearers becoming exposed, electively or accidently, to higher magnetic forces, such as MRI, demagnetisation of the internal magnet is a concern and not fixating the device's R/S poses an additional risk, which may become even higher in future,. This is another argument in favour of adequate and durable implant fixation, even if the magnet itself is rarely secured by these techniques and still can migrate during MRI examination.[37] To prevent this kind of migration, one should strictly follow the guidelines endorsed by the implant manufacturers.

Conclusions

With regard to device migration after cochlear implantation, this literature review reveals that, to date, no level I trials are available comparing the standard technique with an alternative one. To have adequate statistical power, such trials should incorporate sufficiently high numbers of implantations in each study arm. We conclude that fixation of cochlear implants, even if not widely accepted as extremely important, should always be attempted. In the absence of other evidence, the standard technique of drilling a bony well with bony sutures seems to remain the standard of good clinical practice.

Acknowledgements

The authors wish to thank Kristin Daemers, Geert De Ceulaer, Karolien Weekers, Katrien Van Eynde, Sien De Niel, and Carina de Beukelaer from The Eargroup, Deurne Antwerp, for their help and support in the field with our patients.

References

1. Beadle EA, McKinley DJ, Nikolopoulos TP, Brough J, O'Donoghue GM, Archbold SM. Long-term functional outcomes and academic-occupational status in implanted children after 10 to 14 years of cochlear implant use. *Otol Neurotol.* 2005,26(6):1152-1160.
2. Deggouj N, Gersdorff M, Garin P, Castelein S, Gérard JM. Today's indication for cochlear implantation. *B-ENT*. 2007;3(1):9-14.
3. Vlastarakos PV, Candiloros D, Papacharalampous G, Tavoulari E, Kampessis G, Mochloulis G, Nikolopoulos TP. Diagnostic challanges and safety considerations in cochlear implantation under the age of 12 months. *Int J Pediatr Otorhinolaryngol*. 2010;74(2):127-132.
4. NIH Publication No 09-4798 Available at: www.nidcd.nih.gov/health/hearing/coch.asp, **www.fda.gov/MedicalDevices/Prosthetics/cochlearImplants/default.ht**. Accessed August 20, 2009.
5. Hoffman RA, Cohen NL. Complications of cochlear implant surgery. *Ann Otol Rhinol Laryngol Suppl.* 1995;166:420-422.

6. Yoshikawa N, Hirsch B, Telischi FF. Cochlear implant fixation and dura exposure. *Otol Neurotol.* 2010;31(8): 1-4.
7. Cohen NL, Hoffman RA, Stroschein M. Medical or surgical complications related to the Nucleus multichannel cochlear implant. *Ann Otol Rhinol Laryngol Suppl.* 1988;135:8-13.
8. Webb RL, Lehnhardt E, Clark GM, Laszig R, Pyman BC, Franz BK. Surgical complications with the cochlear multiple-channel intracochlear implant: experience at Hannover and Melbourne. *Ann Otol Rhinol Laryngol*. 1991; 100(2):131-136.
9. Cohen NL, Hoffman RA. Surgical complications of multichannel cochlear implants in North America. *Adv. Otorhinolaryngol.* 1993;48:70-74.
10. Ray J, Gibson W, Sanli H. Surgical complications of 844 consecutive cochlear implantations and observations on large versus small incisions. *Cochlear Implant Int.* 2004;5(3):87-95.
11. Kempf HG, Issing PR, Lenarz T. Ionomer cement in cochlear implant surgery – applications and long-term outcome [in German]. *Laryngorhino-otologie*. 1996;75(7):388-391.
12. Reusche E, Pilz P, Oberascher G, Lindner B, Egensperger R, Gloeckner K, Trinka E, Iglseder B. Subacute fatal aluminium encephalopathy after reconstructive otoneurosurgery: a case report. *Hum Pathol*. 2001;32(10): 1136-1140.
13. Djalilian HR, King T, Faust RA, Smith S, Levine SC. Securing cochlear implants to the skull: two alternative methods. *Ear Nose Throat J*. 2001;80(3):171-173.
14. Davis BM, Labadie RF, McMenomey SO, Haynes DS.Cochlear implant fixation using polypropylene mesh and titanium screws. *Laryngoscope*. 2004; 114(12):2116-2118.
15. Alexander NS, Caron E, Woolley AL. Fixation methods in pediatric cochlear implants: Retrospective review of an evolution of 3 techniques. *Otolaryngol Head Neck Surg*. 2011;144(3):427-430.
16. O'Donoghue GM, Nikolopoulos TP. Minimal access surgery for pediatric cochlear implantation. *Otol Neurotol*. 2002;23(6):891-894.
17. Anayiotos A, Gekeler J, Luers JC, Lang-Roth R, Beutner D. Is the suture fixation of cochlear implants in pediatric patients really necessary? *Int J Ped Otorhinolaryngol.* 2011;75(Suppl 1):24.
18. Campisi P, Hayward L, Papsin B. Mitek QuickAnchor fixation of cochlear implants using a minimal access technique. *Int J Pediatr otorhinolaryngol*. 2005;69(12):1655-1658.
19. James AL, Papsin BC. Device fixation and small incision access for pediatric cochlear implants. *Int J Pediatr Otorhinolaryngol*. 2004;68(8):1017-1022.
20. Jiang D, Bibas A, O'Connor AF. Minimally invasive approach and fixation of cochlear and middle ear implants. *Clin Otolaryngol Allied Sci*. 2004;29(6):618-620.
21. Cuda D. Cochlear implantation with Pulsar Med El: a novel small incision technique. *Acta Otorhinolaryngol Ital*. 2009;29(2):76-78.
22. Lee DJ, Driver M. Cochlear implant fixation using titanium screws. *Laryngoscope*. 2005;155(5):910-911.
23. Mack KF, Heermann R, Issing PR, Lenarz T, Schwab B. Four years' experience with the minimally invasive surgical approach in cochlear implant surgery. *Minim Invasive Ther Allied Technol.* 2006;15(3):187-192.
24. Loh C, Jiang D, Dezso A, Fitzgerald O'Connor A. Non-sutured fixation of cochlear implants using a minimally-invasive approach. *Clin Otolaryngol.* 2008;33(3):259-261.
25. Adunka OF, Buchman CA. Cochlear implant fixation in children using periosteal sutures. *Otol Neurotol.* 2007;28(6):768-770.
26. Balkany TJ, Whitley M, Shapira Y, Angeli SI, Brown K, Eter E, Van De Water T, Telischi FF, Eshraghi AA, Treaba C. The temporalis pocket technique for cochlear implantation: an anatomic and clinical study. *Otol Neurotol*. 2009;30(7):903-907.
27. Güldiken Y, Orhan KS, Yigit O, Basaran B, Polat B, Günes S, Acioglu E, Deger K. Subperiosteal temporal pocket versus standard technique in cochlear implantation: a comparative clinical study. *Otol Neurotol*. 2011; 32(6):987-991.
28. Stratigouleas ED, Perry BP, King SM, Syms CA 3rd. Complication rate of minimally invasive cochlear implantation. *Otolaryngol Head Neck Surg*. 2006;135(3):383-386.
29. Hubbard BJ, Wong DD, Cushing SL, Gordon KA, Papsin BC. Characterization of retentive capacity of the subpericranial pocket in children. *Int J Ped Otorhinolaryngol*. 2011;75(Suppl 1):25.
30. Molony TB, Giles JE, Thompson TL, Motamedi KK. Device fixation in cochlear implantation: is bone anchoring necessary? *Laryngoscope*. 2010;120(9):1837-1839.
31. Davids T, Ramsden JD, Gordon KA, James AL, Papsin BC. Soft tissue complications after small incision pediatric cochlear implantation. *Laryngoscope*. 2009;119(5):980-983.
32. Eskander A, Gordon KA, Papaioannou V, Cushing SL, James AL, Papsin BC..Pediatric cochlear implant failures may be reduced by suture fixation of device. *Int J Ped Otolaryngol*. 2011;75(Suppl 1):25.
33. Guevara N, Bébéar JP, Sterkers O, Meller R, Magnan J, Mosnier I, Amstutz I, Lerosey Y, Triglia JM, Roman S, Gahide I. Multicenter evaluation of the Digisonic® SP cochlear implant fixation system with titanium screws. *Int J Ped Otorhinolaryngol*. 2011;75 (Suppl 1):92.
34. Sprinzl GM, Wolf-Magele A, Schnabl J, Anwar E, Riechelmann H. Minimal invasive cochlear implantation with the Concerto Pin in children and adults – First surgical experiences. *Int J Ped Otorhinolaryngol*. 2011;75 (Suppl 1):16.
35. Battmer RD, Linz B, Lenarz T. A review of device failure in more than 23 years of clinical experience of a cochlear implant program with more than 3,400 implantees. *Otol Neurotol*. 2009;30(4):455-463.
36. Philips M. Oxford centre for evidence based medicine. Available at: http://www.essentialevidenceplus.com/product/ebm_loe.cfm?show=oxford. Accessed December 15, 2011.
37. Stokroos RJ, van Dijk P. Migration of cochlear implant magnets after head trauma in an adult and a child. *Ear Nose Throat J*. 2007;86(10):612-613.

Sebastien P. Janssens de Varebeke, M.D.
Jessa Hospital, Campus Virga Jesse
Department of ENT Head and Neck Surgery
Stadsomvaart 11
B-3500 Hasselt, Belgium
Tel.: ++32 11 309081
Fax: ++32 11 247669
E-mail: drsjanssens@gmail.com