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Safety Outcomes for Implantable Bone Conduction and Middle Ear Devices: a Systematic Review

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1. Foreword

This paper provides a systematic review of the literature reporting on safety outcomes concerning implantable bone conduction hearing devices (BCHD) and middle ear devices. The document gives a brief overview of the devices currently available, their indications and performance characteristics. The last part summarizes and compares the observed safety outcomes of the devices under review. A concluding paragraph summarizes the main challenges in regards to safety when implanting a hearing device.

2. Introduction

In cases of hearing loss (HL) with a variety of medical conditions of the ear, implantable hearing devices fill a clinical need that often cannot be suitably treated by conventional hearing aids. Due to their invasive nature, however, one of the most obvious concerns with the use of implantable hearing devices is their safety. In this paper, safety outcomes of different commercially available bone conduction and middle ear implants as shown in Table 1 have been systematically reviewed.

INDICATION	CONDUCTIVE AND/OR MIXED HL					CONDUCTIVE, MIXED AND/OR SENSORINEURAL HL					
CATEGORY	Bone Conduction Devices					Middle Ear Implants					
COUPLING	Bone			Skin		Middle Ear					
POWER TRANS-MISSION	Percutaneous		Transcutaneous and **Active**	Transcutaneous and **Passive**		Transcutaneous and **Active**					
						Partially Implantable				Fully Implantable	
MODELS	Baha Connect series	Ponto	BONEBRIDGE	Sophono Alpha	Baha Attract	SOUNDBRIDGE	DACS/ DACI/ CODACS*	MET	Carina	Carina	ESTEEM

Table 1: Overview of the systematically reviewed bone conduction and middle ear devices

*several nomenclatures for the same device, from now on referred to as CODACS, based on Cochlear´s notation

2.1. BONE CONDUCTION DEVICES

- Percutaneous BCHDs: *abutment connection – Cochlear's Baha Connect series, Oticon's Ponto*
  Bone-anchored hearing aids use a surgically implanted fixture to transmit sound by direct conduction through bone to the inner ear, bypassing the external auditory canal and middle ear. A titanium fixture is surgically embedded into the skull with an abutment exposed outside the skin. A sound processor sits on this abutment and transmits sound vibrations to the titanium implant. The implant vibrates the skull and inner ear, which stimulates the nerve fibers of the inner ear, allowing hearing.

- Active transcutaneous BCHDs:
  MED-EL's BONEBRIDGE (BB)
  In active systems, an externally worn audio processor picks up the sound and generates a signal that is transmitted through the intact skin to the implant. The implant accepts the signal and generates vibrational stimulation that is directly applied to the bone ("direct drive bone conduction stimulation").

- Passive transcutaneous BCHDs: *Sophono's Alpha, Cochlear's Baha Attract*
  In passive bone conduction systems the sound processor generates vibrational stimulation that is applied from the outside onto the skin. Skin attenuates sound before it reaches the bone. In contrast to hearing glasses and bone conduction headbands that work according to the same principle, passive transcutaneous bone conduction hearing devices are held in place by an implanted magnet.

2.2 MIDDLE EAR IMPLANTS

- Partially implantable middle ear implants:
  MED-EL's VIBRANT SOUNDBRIDGE (VSB), Cochlear's Direct Acoustic Cochlear Stimulator (CODACS), and Middle Ear Transducer (MET), Soundtec® (withdrawn from the market, represents the precursor of Ototronix's Maxum)
  In partially implantable middle ear implants, an externally worn audio processor picks up the sound and generates a signal that is transmitted through the intact skin to the implant. The implant accepts the signal and generates vibrational stimulation that is applied to a vibratory structure in the middle ear (ossicular chain or round window).

- Fully implantable middle ear implants: *Envoy's Esteem, Cochlear's Carina*
  The Esteem is a totally implanted device based on piezoelectric technology for the microphone fixed on the malleus as well as for the transducer fixed to the stapes. To prevent feedback phenomenon from the device, implantation requires separation of the incus-stapedial joint and resection of a segment of the long process of the incus.The expected battery life of the Esteem is 4.5 years with continuous use (24 hours per day/7 days per week) to 9 years (if only used for 8 hours per day) as stated by the manufacturer - the literature however, reports lower battery life spans *(J. Maurer et al. 2010).* The battery changing is performed as a surgical procedure under local anesthesia.

  The Carina system in its fully implantable mode has the microphone embedded under the skin capturing sounds and sending them to the transducer. The electromagnetic actuator receives the electrical signal, converts it to vibrations and transfers it to the ossicles. This device can be used in a fully implantable mode, however, in more challenging hearing situations an externally worn button processor is required which acts as an external microphone, mainly to address feedback issues and body noises. The implant's battery is charged by a coil placed on the skin over the implant, using a belt or waistband. It may be performed daily during 1 to 1.5 hours and each charge lasts 32 hours. As stated by the manufacturer, the battery lifetime is at least 10 years. On the other hand, *Debeaupte (2015)* reports a battery life span of 16 months, representing a 100% device failure rate in the first generation of the device, after which the entire electronic capsule must be surgically removed for replacement (*M. Debeaupte et al. 2015*).

3. Methods

Cochrane, Pubmed and DIMDI/Embase databases were searched using a comprehensive search strategy (see appendix) to identify articles published between January 1996 (first VIBRANT SOUNDBRIDGE implantation) and January 2017 (DIMDI/Embase search until December 2016). The search was limited to English and German articles. Studies were excluded if less than five participants, or overlapping samples were seen, or if low quality (i.e. not peer-reviewed publications such as proceedings and abstracts) was found. Further relevant articles were identified by searching study bibliographies and relevant Systematic Reviews. A total of 11081 records were identified through the database searches. After removing duplicates, titles and abstracts were screened, unrelated titles were removed, and the full texts of the remaining 811 publications were assessed (see Figure 1 below).

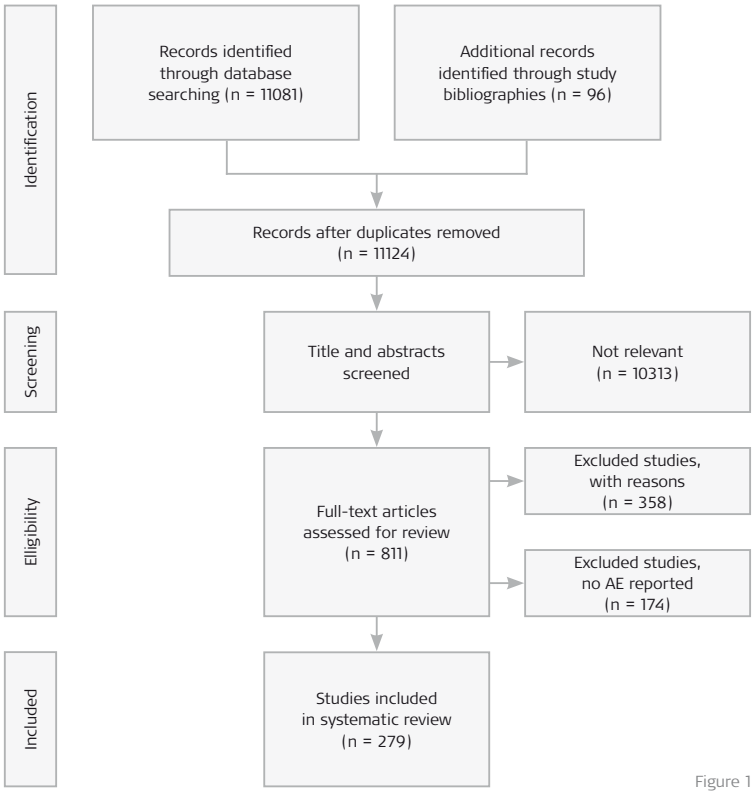
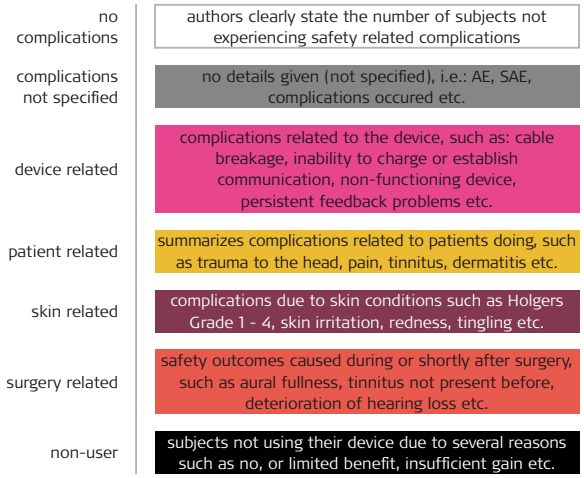


Figure 1

For each device, the number of reported safety outcomes (incidences) was related to the total number of subjects investigated, calculated in percentages and summarized in seven subcategories: *complications not specified, device related, skin related, surgery related, patient related, non-users and no complications*. The subcategory *no complications* represents the group in which it was specifically stated that subjects did not experience any safety related issues (see Figure 2a). In a large part of the population no data regarding complications is available (174 relevant publications not mentioning complications), which could either mean that no complications had been observed, or that they were not reported. Safety outcomes requiring revision surgery (RS) such as implant/device failure, device extrusion, failure to osseointegrate, skin revision surgeries etc. (for details please see table in appendix) are additionally presented in a separate table, aiming to avoid double counting of reported revision surgery as well as pointing out the difference between the so to say minor and major complications. Furthermore, revision surgery is seen as the treatment of a major complication not as a complication itself. The classification into the different subcategories, as shown in Figure 2a and 2b was decided by group discussion. The authors want to emphasize, that some of the incidences may also fit into other categories, such as for example device extrusion, which was grouped into the *device related* category, but may also be assigned to surgery related complications. Outcomes may diverge from original results as incidences

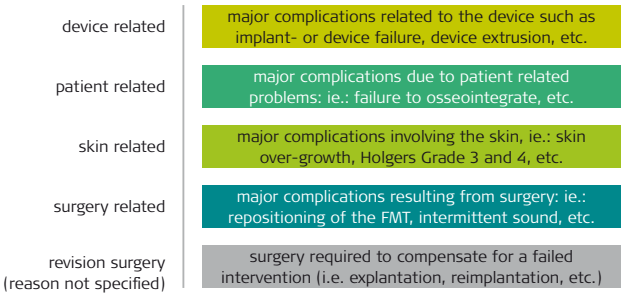
over the full study period (follow up (F/U)) were calculated as percentage of patient numbers. More specifically, safety outcomes are reported as complication rate (in %), to be interpreted as percentage of occurred AEs in a given population. In some cases, the number of incidences may be higher than the number of subjects investigated, thus leading to complication rates above 100%.Major complications requiring revision surgery are presented in tables. The overall complication rate as stated at the end of each device report is calculated by summarizing the total number of incidences - which include major complications - and the number of revision surgeries were the reason is not specified. Please note that sums might slightly deviate due to accumulating round-off errors. The graph below gives an overview and description of the categories in the respective assigned colours as results are presented for each device. For further details please see the Appendix.

Safety Outcomes



presented in pie charts
Figure 2a

Major complications requiring surgery



presented in tables
Figure 2b

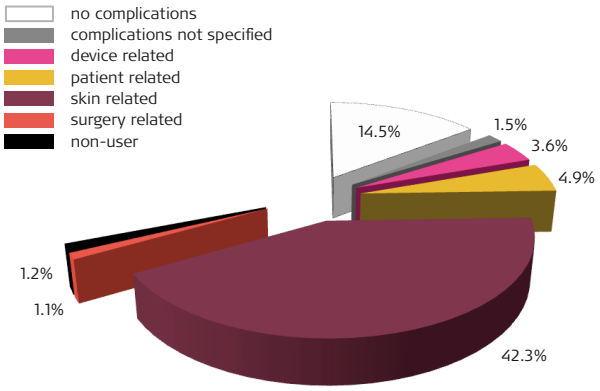
4. Results

A total of 279 studies comprising data from 15054 subjects reported on safety outcomes: The highest number of subjects and studies reporting about complications could be retrieved for the BAHA Connect bone conduction system: 155 studies with a total of 11686 subjects, reflecting the long and intensive use (1st implantation 1977). Oticon Medicals Ponto System was reported in twelve studies in a total of 314 subjects since its first implantation in 2006. In 2011 the first active bone conduction implant, the BONEBRIDGE was implanted and since then fifteen studies assessed safety outcomes in a total of 209 subjects. Since 2011, the transcutaneous bone conduction implant Sophono Alpha has also been available. Seventeen publications evaluating data of 210 subjects reported on safety outcomes for the Sophono Alpha 1 and Alpha 2. Also new on the market, launched in 2014/15 is the Baha Attract system, comprising seven studies with a total of 110 subjects, representing Cochlear's first transcutaneous, passive bone conduction device. Twenty-seven studies covering a total of 841 subjects reported on safety outcomes following SOUNDBRIDGE implantation due to sensorineural hearing loss (SNHL) since 1996. In 2005 the first implantation with the extended indication for mixed or conductive hearing loss (M/CHL) took place, resulting in 55 studies summarizing safety outcome rates in a total of 935 subjects.
Three studies comprising data from 43 subjects reported on complications with the CODACS (direct acoustic cochlear stimulator) by Cochlear, specified device. The same device is also known as the DACI (direct acoustic cochlear implant), and DACS (direct acoustic cochlear stimulator). This manuscript will refer to the device as CODACS, based on *Cochlear's notation.* The safety performance of the MET device was published in four studies, investigating 65 subjects since its first implantation in 2009. The Soundtec device, the precursor model of the Maxum, of which no publications could be retrieved, was first implanted in 2000 and since then investigated in three studies, comprising 173 subjects. The Esteem fully implantable middle ear implant system has been published in six studies, investigating 131 subjects after the first implantations in 2003/04. Seventeen studies evaluating 337 subjects reported on safety outcomes with the Carina since 2006, the second MEI available to date with a fully implantable option.

4.1 Safety outcomes with the Baha Connect series

A total of 155 studies including 11686 subjects were screened for safety outcomes with the percutaneous Baha system. Four publications specifically stated *no complications* in 325 subjects *(D. Gillett et al. 2006, G. Ricci et al. 2010, G. Ricci et al. 2011, J. Ray et al. 2012)*. Together with the reported skin reaction Holgers grade 0, equivalent to normal skin, reported in 1371 subjects (in 21 of the 155 studies), an altogether rate of 14.8% for *no complications* (see graph and tables below and in the appendix) was observed. Most Baha users experienced *skin related* problems: a total of 4944 subjects (42.3%) suffered from problems due to the skin-penetrating coupling of the sound processor. Examining those outcomes in more detail: out of the 4944 above mentioned subjects, 934 experienced major *skin related* problems requiring surgery or more involving treatment and the remaining 4010 reported minor, but reoccurring problems over the whole follow up period of up to 16 years (192 months). *Patient related* issues in terms of trauma to the device or pain occurred in 4.9% of implanted subjects. One-hundred and fourty two *non-users* (1.2%) have been reported in 36 studies.

Baha Connect series – safety outcomes



155 studies - 11686 subjects - 6377 incidents Figure 3

Major complications requiring surgery

device related	2.8
patient related	1.3
skin related	8.0
surgery related	0.2
revision surgery	17.0
Sum of major complications	29.3%

155 studies - 11686 subjects - 3427 major incidents Table 2

Major complications such as insufficient or failed osseointegration, loosening of the implant or skin necrosis which subsequently led to the loss of the implant were reported in several studies and are represented here in Table 2 as major complications requiring surgery. *Device related* issues requiring revision surgery occurred in 2.8% of the treated subjects. *Patient related* major complications resulted in 1.3%, whereas major skin related problems requiring the visit of an operating room/theatre summed up to 8.0%.
Overall, 1985 of the 3427 subjects experiencing major complications underwent explicitly mentioned revision surgery (reimplantation (186 subjects), explantation (47 subjects), revision surgery without further specification (428 subjects), implant- or fixture loss (1270 subjects), abutment/fixture removal (54 subjects). Thus, the frequency of revision surgeries accounts for 17.0% of all subjects implanted with the Baha system (1985/11686).

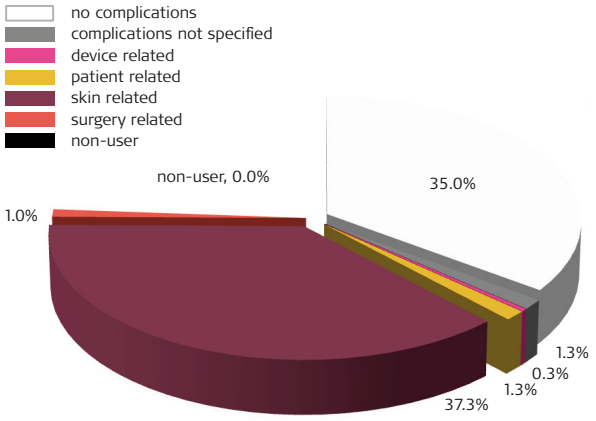
The overall complication rate for major and minor complications together sums up to 71% (7101/11686), which represents more than two thirds of the investigated population.

4.2 Safety outcomes with the Ponto

Complications following Ponto implantation were reported in 12 studies involving 314 subjects reporting 129 incidences related to safety outcomes. Most Ponto users experienced *skin related* problems (37.3%): mainly Holgers Grade 1 (71 subjects) which can be seen as a minor complication, followed by the more severe Holgers Grade 2 (18 subjects) and the even more deteriorating Holgers Grade 3 skin reaction which required revision surgery (10 subjects). 35.0% of the Ponto users reported *no complications* (110 of 314 subjects). *Surgery related* issues were reported in 1.0% of the population followed by *device related* complications resulted in 0.3%, whereas no *non-user* was reported.

NOTE: sums might slightly deviate due to accumulating round-off errors

Ponto – safety outcomes



12 studies - 314 subjects - 129 incidents Figure 4

Major complications requiring surgery

device related	0.3
patient related	0
skin related	4.1
surgery related	0
revision surgery	3.5
Sum of major complications	8.0%

12 studies - 314 subjects - 25 major incidents Table 3

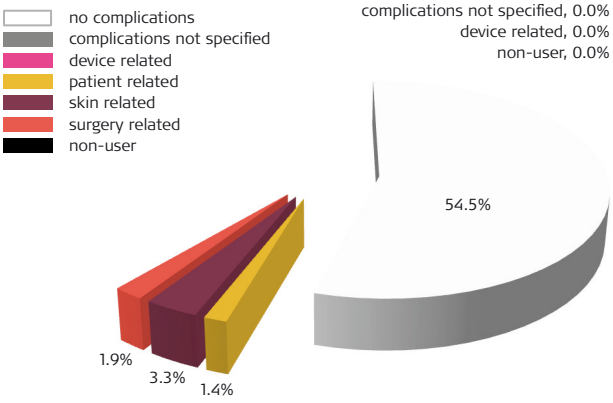
Major complications requiring surgery occurred in 25 of the 314 subjects (8.0%). *Skin related* major complications lead the board with 4.1% followed by the group of revision surgery with 3.5%, which comprises cases of reimplantation, explantation and revision surgery etc. (please see table in appendix for further details).

The overall complication rate for major and minor complications together sums up to 44.6% (140/314), which is almost half of the investigated population.

4.3 Safety outcomes with the BONEBRIDGE (BB)

A total of 15 studies assessing safety outcomes in 209 subjects were identified since the first BB implantation in 2011. Remarkably, the great majority of papers (54.5%) reported that *no complications* over a postoperative course of up to 25 months had been observed. Hence, 92.8% of all subjects implanted with the BONEBRIDGE experienced no safety issues (total of 14 minor events and one revision surgery occurring over a course of 3 to 25.2 months). *Zernotti (2016) and Sprinzl (2013)* reported one single patient each with pain in the early post-operative stage which was relieved with medication *(G. Sprinzl et al. 2013, M. E. Zernotti et al. 2016)*. One subject, reported by *Ihler (2014)* experienced a prolonged wound healing *(F. Ihler et al. 2014). W. D. Baumgartner et al. (2016)* reported a case of itching around the implant. *Sprinzl (2013)* reported one subject with tinnitus which resolved on its own within 1 day after surgery *(G. Sprinzl et al. 2013)*. A second subject experienced headaches and vertigo after being discharged from the hospital, and was treated medically. *Surgery related* complications occurred in 1.9% of the population and includes subjects with limited benefit due to out of criteria implantation (n=2, *D. Riss et al. (2014)). Skin related* issues comprised 3.3%, and were effectively managed with local antibiotics. All *patient related* complications (1.4%) were resolved without surgery within the study period. No *device related* complications occurred after BONEBRIDGE implantation.

BONEBRIDGE – safety outcomes



15 studies - 209 subjects - 14 incidents Figure 5

Major complications requiring surgery

device related	0
patient related	0
skin related	0
surgery related	0
revision surgery	1
Sum of major complications	0.5%

15 studies - 209 subjects - 1 major incident Table 4

One explantation occurred in a patient, due to complete lack of benefit as he was implanted outside of the indication criteria for the 2 to 4 kHz range *(D. Riss et al. 2014)*.

The overall complication rate for major and minor complications together sums up to 7.2% (15/209), by far the lowest reported rate for safety outcomes.

NOTE: sums might slightly deviate due to accumulating round-off errors

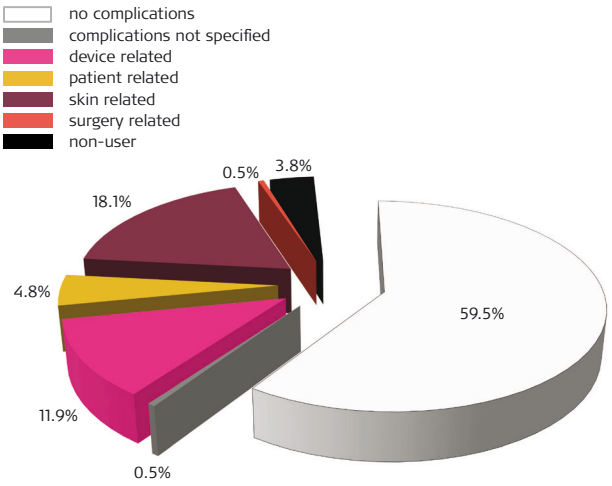
4.4 Safety outcomes with the Sophono

The safety performance of the passive transcutaneous bone conduction system Sophono was collected from 17 studies with 210 subjects, seven of which were conducted in children <18 years *(M.K. Hol et al. 2013, A. Centric et al. 2014, P. Marsella et al. 2014, M.B. O'Niel et al. 2014, F. Denoyelle et al. 2015, H.R. Powell et al. 2015, R.C. Nelissen et al. 2016)*. Out of the 17 publications, 3 authors reported on the Sophono Alpha 2 (17 subjects)*(P. Marsella et al. 2014, H.R. Powell et al. 2015, J.W. Shin et al. 2016)*, the remaining outcomes summarize the Sophono Alpha 1 device.

A total number of 83 complications, comprising 40.6% of all subjects, were reported. In 59.5% of all cases *no complications* were reported. 11.9% of the safety issues were *device related* problems: Twelve subjects displayed erythema of the skin (reddened skin) covering the implant, which was managed by reducing the intensity of the external magnets. *Skin related* problems were determined in 18.1% of all cases implanted with the Sophono (reviewing early generations of Sophono Alpha 1 outcomes, a *skin related* problem rate of 32% was observed). A pressure ulcer was observed in one case. The majority of the subjects complained about pressure discomfort and the device falling off the head, resulting in a *device related* issue rate of 11.9%. One subject experienced several device failures, no details were given *(F. Denoyelle et al. 2015)*.

4.8% of those implanted with the Sophono reported pain and magnet-related problems (*patient related*) from using the device for more than 4 hours a day consecutively, which resulted in reduced use and eight *non-users* (3.8%).

Sophono – safety outcomes



17 studies - 210 subjects - 83 incidents

Figure 6

Major complications requiring surgery

device related	0
patient related	0
skin related	0.5
surgery related	0
revision surgery	1.0
Sum of major complications	1.4%

17 studies - 210 subjects – 3 major incidents

Table 5

Major complications requiring surgery comprise 1.4% of all safety outcomes and are displayed in the table. One explantation, one reimplantation and one skin revision surgery occurred out of 210 subjects, summing up to a major complication rate of 1.4%.

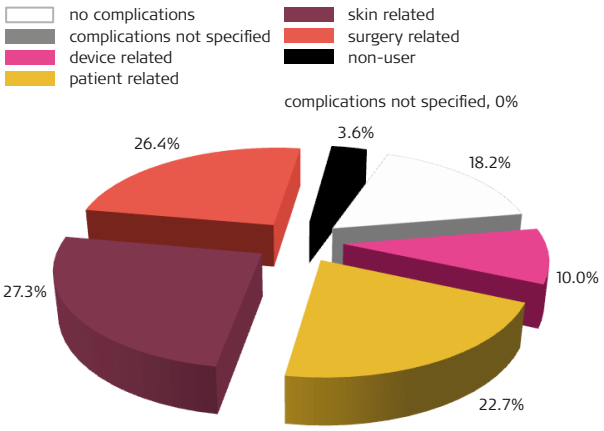
The overall complication rate for major and minor complications together amounts to 40.5% (85/210), comparable to the rate of the percutaneous Ponto device (see Figure 4 and Table 3).

NOTE: sums might slightly deviate due to accumulating round-off errors

4.5 Safety outcomes with the Baha Attract

Seven studies, reported on safety outcomes for a total of 110 subjects. The highest rate of complications (27.3%) was reported for the category of *skin related* problems, such as soft tissue reduction, edema or erythema. *Patient related* problems: mainly pain around the implant side and postoperative pain were reported in 22.7% of the investigated population. *Device related* problems were noted in 10%. 29 incidences of numbness, reduced sensitivity around the implant, or bleeding where recorded, resulting in a *surgery related* complication rate of 26.4%.

Baha Attract – safety outcomes



7 studies - 110 subjects – 99 incidents Figure 7

Major complications requiring surgery

device related	0
patient related	0
skin related	0
surgery related	0
revision surgery	1.8
Sum of major complications	1.8%

7 studies - 110 subjects – 2 major incidents Table 6

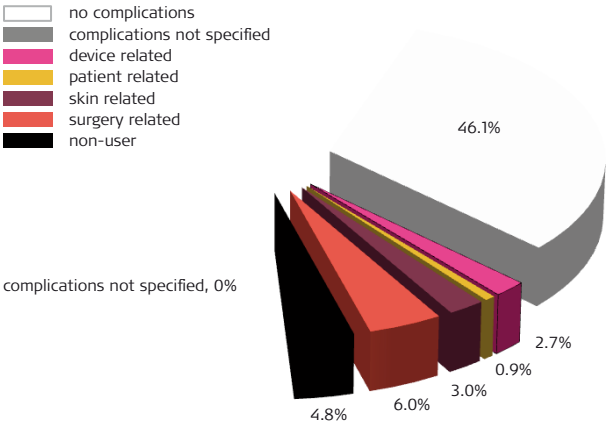
Two major complications (1.8%) were reported in one patient following trauma to the head. The Follow-up period in the studies reviewed was very heterogeneous, ranging from 4 weeks to 24 months. In two studies, the Follow-up time was not even reported.

The overall complication rate for major and minor complications together sums up to 91.8%.

4.6 Safety outcomes with the SOUNDBRIDGE – M/CHL indication

Fifty five studies assessed safety outcomes in a total of 935 subjects after SOUNDBRIDGE implantation due to conductive and mixed hearing loss (M/CHL). *No complications* were reported in 46.1% of the population. *Skin related* problems were reported in 28 subjects (3.0%). In 0.9% of all cases, *patient related* complications occurred. *Surgery related* issues developed in 6.0%, with FMT coupling problems at the round window (RW) being the most frequent ones. Dizziness and vertigo occurred in 5 cases and was resolved over time. 4.8% of *non-users* were reported.

SOUNDBRIDGE M/CHL – safety outcomes



55 studies - 935 subjects - 162 incidents Figure 8

Major complications requiring surgery

device related	1.9
patient related	0.2
skin related	0.4
surgery related	2.4
revision surgery	5.5
Major complications	10.4%

55 studies - 935 subjects - 97 major incidents Table 7

Seven publications indicated device extrusion, displacement or migration, (eleven incidents) device replacement (three incidents and four device failures,) resulting in an overall failure rate of 1.9%. Seven publications specifically mentioned, that no device extrusion, displacement or migration occurred *(L. Bruschini, F. Forli, M. Giannarelli, et al. 2009, V. Colletti et al. 2009, D. Cuda et al. 2009, M. Mandala et al. 2011, M. Barillari et al. 2012, V. Colletti et al. 2012, H. Skarzynski et al. 2014)*. Across all the studies included, 51 revision surgeries were conducted which represents a safety issue incidence rate of 5.5%.

NOTE: sums might slightly deviate due to accumulating round-off errors

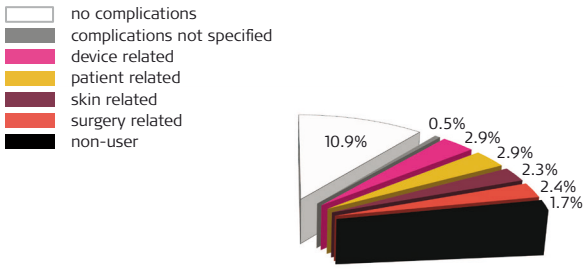
Surgery related complications, such as the need for repositioning of the FMT due to coupling problems onto the RW membrane, was reported in 20 cases, one VSB cable was broken by the otolaryngologist, who attempted to clean the cerumen in the mastoid *(A. Atas et al. 2014)*. Overall, major complications summed up to 10.4%.

The total complication rate including both major and minor complications was 22.9%. This is almost half of what the previously mentioned devices reported, with the exception of the BONEBRIDGE, which displayed the lowest rate (7.4%)(see Figure 5 and Table 4).

4.7 Safety outcomes with the SOUNDBRIDGE – SNHL indication

Safety outcomes following SOUNDBRIDGE implantation due to sensorineural hearing loss (SNHL) were reported in 27 studies evaluating 841 subjects.
Safety issues were observed in 105 cases, which is equivalent to 12.7% of included subjects. In 10.9% *no complications* were reported. The number of studies reporting on *skin related* problems was low with an incidence rate of 2.3%. However, a few superficial skin problems such as superficial wound infections, skin emphysema or mild skin reactions were observed, all resolved with treatment by study end. The *patient related* incidence rate reached 2.9%, with the majority of the population complaining about pain which was resolved immediately or by study end *(B. Fraysse et al. 2001, C. Rameh et al. 2010)*. Four publications reported 14 *non-users* due to insufficient gain or hearing benefit, resulting in 1.7%.

SOUNDBRIDGE SNHL – safety outcomes



27 studies - 841 subjects - 105 incidents Figure 9

Major complications requiring surgery

device related	1.8
patient related	0
skin related	0
surgery related	0.1
revision surgery	6.9
Sum of major complications	8.8%

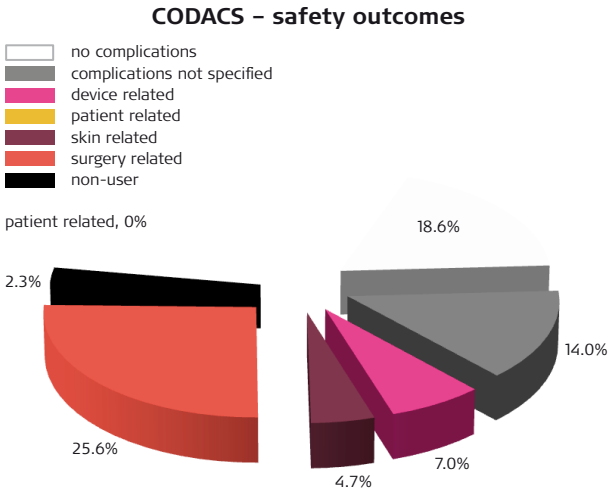
27 studies - 841 subjects - 74 major incidents Table 8

Major complications requiring surgery were reported in 8.8% of the total population. However, as S. *Labassi and M. Beliaeff (2005)* indicated in their retrospective chart-review of 1000 implants, many were device malfunctions and failures of the first generation model of the SOUNDBRIDGE (VORP 501). Very few were observed with the second generation device (VORP 502).The new device generation has proven to be highly reliable, with a 1.8% failure rate (*device related* safety outcomes, please see supplementary table) after implantation due to sensorineural hearing loss. Neither *skin- nor patient related* safety outcomes were reported. 58 revision surgeries (reimplantation, explantation) were performed, requiring a rate of 6.9%. Five of these explantations were performed on patients' request. One *surgery related* incidence occurred, where the VORP was placed upside down and needed to be revised (0.1%).

The overall complication rate for major and minor complications sums up to 19.6% (163/841).

4.8 Safety outcomes with the CODACS

The safety performance of the CODACS system was reported in three studies including 43 subjects. All studies investigated severe to profound mixed hearing loss cases. Out of the 43 investigated subjects, 23 experienced a complication during the follow up period of 3 to 6 months. Most of the complications that occurred were *surgery related* (25.6%) followed by 14% reported complications, with *no specified cause. Device related problems* occurred in 3 cases, resulting in a 7% complications rate. One *non-user* (2.3%) was reported by *T. Lenarz et al. (2014)*. The subject showed profound MHL (and a moderately severe sensorineural component) pre-operatively and exhibited an additional hearing loss on nearly all frequencies after surgery. The subject experienced no WRS improvement and no longer wears the device. *Skin related* complications occurred in 4.7% mainly due to skin irritation in the fold behind the ear. 18.6% reported *no complications* (8/43).



3 studies - 43 subjects - 23 incidents Figure 10

Major complications requiring surgery

device related	0
patient related	0
skin related	2.3
surgery related	7.0
revision surgery	4.7
Sum of major complications	14%

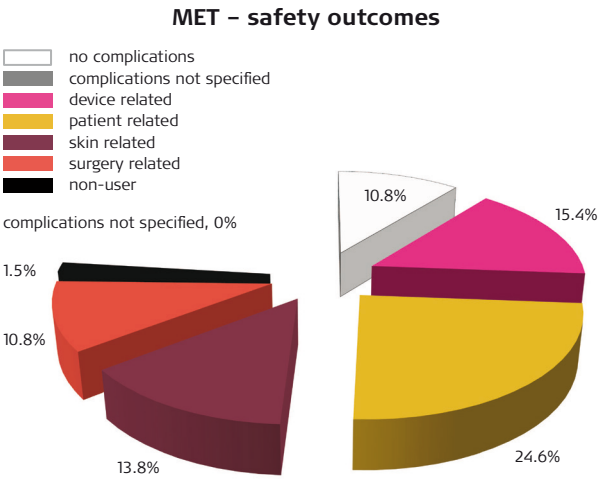
3 studies - 43 subjects - 6 major incidents Table 9

Major complications requiring surgery occured in 6 patients (14%) and can be separated into one *skin related,* (2.3%), 3 *surgery related* problems (7%) and two revision surgeries. *S. Busch et al. (2013)* and *T. Lenarz (2013)* reported each, one revision surgery (4.7%).

The overall complication rate for major and minor complications together sums up to 58.3% (25/43).

4.9 Safety outcomes with the MET

The safety performance of the active transcutaneous and partially implantable middle ear implant system MET was reported in four studies investigating 65 subjects. *Device related* complications such as dysfunction of the transmitter coil occurred in 15.4% of the population. Pain and misplacement of the device, summarized as *patient related* issues were reported with an incidence rate of 24.6%. *Louvrier (2010)* reported one *non-user* who refused explantation (1.5%)*(C. Louvrier et al. 2010). Skin related* reactions occurred in 13.8% incl. wound dehiscence, skin infection and not further specified skin reactions. Seven subjects experienced *surgery related* problems (10.8%). In most instances, these involved dura exposure and dural opening.



4 studies - 65 subjects - 43 incidents Figure 11

Major complications requiring surgery

device related	15.4
patient related	0
skin related	0
surgery related	0
revision surgery	16.9
Sum of major complications	32.3%

4 studies - 65 subjects - 21 major incidents Table 10

Major complications requiring surgery occurred in 21 patients (32.3%), which can be separated into 15.4% *device related* problems and 16.9% revision surgery (reimplantation (6/65) and revision surgery not specified (5/65)). Neither *skin- nor patient related* major complications occurred in the reviewed studies.

The overall complication rate for major and minor complications together sums up to 83.0% (54/65), being one of the highest occurrences rate among the evaluated devices.

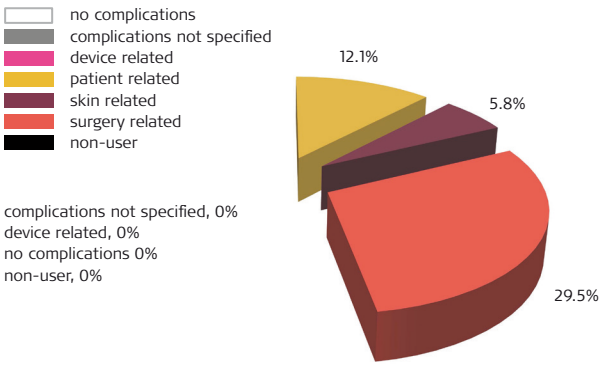
NOTE: sums might slightly deviate due to accumulating round-off errors

4.10 Safety outcomes with the Soundtec

According to the manufacturer, the Maxum is the least invasive of the MEIs but unfortunately no publications with the Maxum could be retrieved and, therefore, safety outcomes of the discontinued forerunner model, the Soundtec, are reported here. The Soundtec, as the precursor model of the Maxum system by Ototronix, differs from the other previously mentioned MEI's in that the sound processor is worn in the external ear canal or behind the ear, as with conventional hearing aids.

Safety outcomes on 173 subjects were described in three studies. Most of the complications that occurred were surgery related (29.5%). These included perception of magnet movement (35/173), haematoma on the tympanic membrane (TM)(5/173), and cases of dizziness or vertigo, residual perforation of the TM and exposed bone, only to mention a few. J.V. *Hough (2002)* reported one patient with a perceivable increase in tinnitus. Magnet instability and noise were the most frequent complaints reported by *Silverstein (2005) (H. Silverstein et al. 2005)*. Pain was reported frequently resulting in a *patient related* complication rate of 12.1%. Neither *non-user* nor *device related* complications were reported.

Soundtec – safety outcomes



3 studies - 173 subjects - 82 incidents

Figure 12

Major complications requiring surgery

device related	0
patient related	0
skin related	0
surgery related	0
revision surgery	0.6
Sum of major complications	0.6%

3 studies - 173 subjects - 1 major incident

Table 11

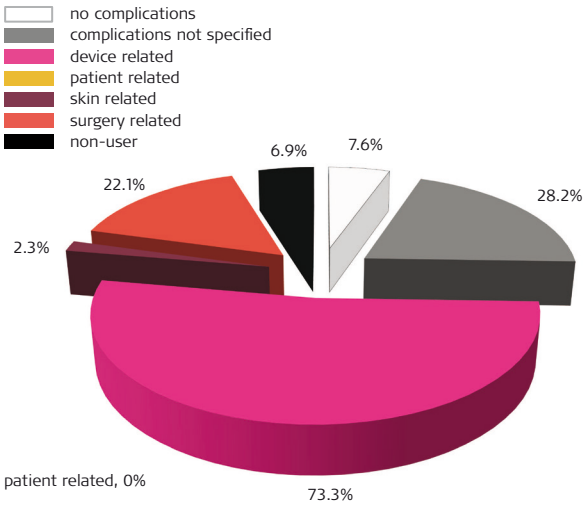
Hough et al. reported two subjects with tympanic membrane perforations: one closed spontaneously, and the other was repaired by myringoplasty, resulting in a revision surgery rate of 0.6%.

The overall complication rate for major and minor complications together sums up to 48.0% (83/173)

4.11 Safety outcomes with the Esteem

The safety performance of the fully implantable Esteem was published in six studies with 131 subjects. The article by Kraus (2011) reported 145 adverse events in 57 subjects *(E.M. Kraus et al. 2011)*.
Device related complications were reported in 73.3% of the investigated populations (96/131), 30% of which were still ongoing twelve months post-operative *(E.M. Kraus et al. 2011)*. Surgery related issues occurred in 22.1% of patients, mainly due to chorda tympani sacrifice (n=8), and/or chorda tympani damage (n=10), and facial nerve damage (n=4). Nine *non-users* were reported resulting in a rate of 6.9% and *no complications* were experienced in 7.6% of the population.
As Esteem implantation induces an additional conductive hearing loss by purposely destroying the ossicular chain, it needs to be mentioned that a significant shift in bone conduction thresholds were observed by *M. Barbara et al. 2014 and E.M. Kraus et al. 2011*.
D.A. Chen et al. 2004 and J.M. Gerard et al. 2012 showed no significant changes of cochlear function by comparing bone conduction threshold before and after implantation of Esteem.
Skin related safety outcomes were reported with an occurrence rate of 2.3%, including one superficial revision surgery 10 months postoperatively due to skin over-growth, reported by *F. Memari et al. 2011*. The number of incidences exceeds the number of the investigated study participants (199/131).

Esteem – safety outcomes



6 studies - 131 subjects - 174 incidents Figure 13

Major complications requiring surgery	
device related	0
patient related	0
skin related	0.8
surgery related	0
revision surgery	19.1
Sum of major complications	19.8%

6 studies - 131 subjects - 26 major incidents Table 12

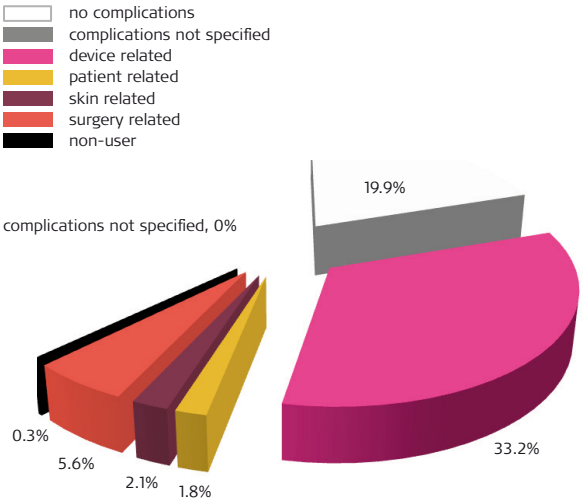
Major complications requiring surgery were reported in 19.8% of the population. Revision surgery was performed explicitly in 25 subjects resulting in a 19.1% revision surgery rate. *J. Maurer et al. 2010* reported several complications requiring revision surgery due to battery problems: one patient was explanted after 31 months of successful usage requiring processor replacement due to battery life depletion. Afterwards he refused to get a new implant fearing further battery changes. One patient who continuously used the device on a 24-hour basis required a battery change after 28 months. Two more patients had battery changes after 37 and 39 months. The remaining patients use their Esteem between 3 and 40 months *(J. Maurer et al. 2010)*. One already mentioned *skin related* complication occurred, requiring revision surgery (0.8%). Neither patient- nor surgery related major issues were reported, which would cause the necessity of a revision surgery.

The overall complication rate for major and minor complications together sums up to 151.9% (more incidences than patients investigated 199/131).

4.12 Safety outcomes with the Carina

Complications following Carina implantation were reported in 17 studies evaluating 337 subjects. The majority of complications were *device related* with 33.2%. Out of 112 incidences for *device related* issues, 15 reported on device extrusion, displacement or migration; eleven cable breakages and/or problems with charging the battery were found. The rate for *surgery related* issues was calculated with 5.6%, mainly due to aural fullness, lightheadedness, dizziness and vertigo, insufficient loading of transducer onto ossicular chain and increased conductive hearing loss. Four publications, on the other hand, showed no complication up to 12-month follow-up with the Carina *(R. Siegert et al. 2007, P.P. Lefebvre et al. 2009, N. Verhaert et al. 2011, R. Siegert et al. 2014)*. *No complications* were reported in 19.9% of the study participants. *Skin related* problems occurred seven times (wound dehiscence and infection), resulting in an incidence rate of 2.1%.

Carina – safety outcomes



17 studies - 337 subjects - 145 incidents Figure 14

Major complications requiring surgery	
device related	26.4
patient related	0
skin related	0
surgery related	0.9
revision surgery	22.8
Sum of major complications	50.7%

17 studies - 337 subjects - 171 major incidents Table 13

Major complications requiring surgery occurred in 50.7% (171/337). This can be subdivided into 26.4% *device related*, 22.8% revision surgery (inkl. reimplantation and

NOTE: sums might slightly deviate due to accumulating round-off errors

explantation in 77 cases) and 0.9% *surgery related* complications. *Bruschini (2010)* reported a case of a patient who had the microphone implanted in the tip of the mastoid and complained of too much feedback noise, especially when turning the head *(L. Bruschini et al. 2010)*. It was necessary to reposition the implant. *K. Uhler et al. (2016)* reported at the 1-year conclusion of the trial, 10 of the 50 subjects had been explanted. Overall the US phase IIB trial experienced a 17% (equivalent to 9 subjects) transducer failure rate at 1 year.

The overall complication rate for major and minor complications together sums up to 65.8% (222/337).

5. Summary

The following Figures summarize the safety outcomes for the different devices.
While Figure 15 displays the sum of complications, Figure 16 shows major complications that require surgery. Table 14 displays the subcategories of complications including revision surgery and the resulting overall complication rate for each device reviewed.

Summary of complications

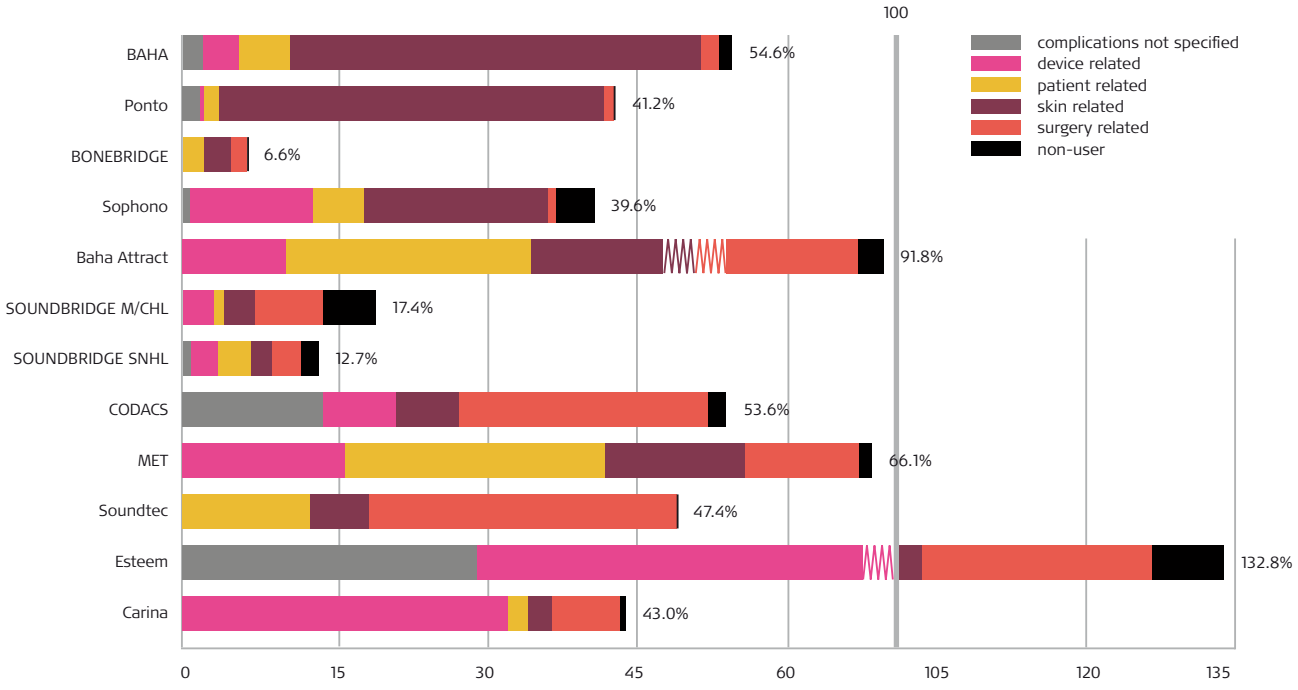


Figure 15

NOTE: sums might slightly deviate due to accumulating round-off errors

Summary of major complications requiring surgery

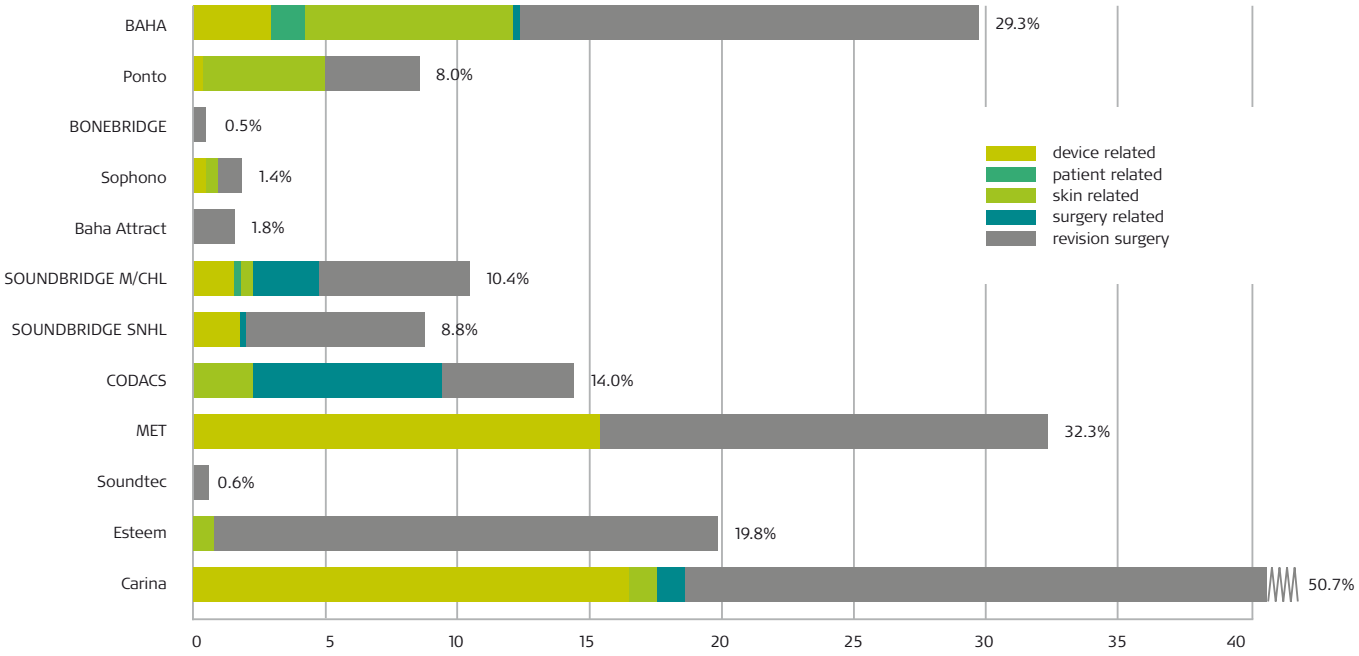


Figure 16

List of complications in percent (%)

	compli-cations not specified	device related	patient related	skin related	surgery related	non-user	revision surgery	OVERALL COMPLICATION RATE
BAHA	1.5	3.6	4.9	42.3	1.1	1.2	17.0	71.6
Ponto	1.3	0.3	1.3	37.3	1.0	0.0	3.5	44.6
BB	0	0	1.4	3.3	1.9	0.0	0.5	7.2
Sophono	0.5	11.9	4.8	18.1	0.5	3.8	1.0	40.5
Baha Attract	0	10.0	22.7	27.3	26.4	3.6	1.8	91.8
VSB M/CHL	0	2.7	0.9	3.0	6.0	4.8	5.5	22.9
VSB SNHL	0.5	2.9	2.9	2.3	2.4	1.7	6.9	19.6
CODACS	14.0	7.0	0	4.7	25.6	2.3	4.7	58.3
MET	0	15.4	24.6	13.8	10.8	1.5	16.9	83.0
Soundtec	0	0	12.1	5.8	29.5	0	0.6	48.0
Esteem	28.2	73.3	0	2.3	22.1	6.9	19.1	151.9
Carina	0	33.2	1.8	2.1	5.6	0.3	22.8	65.8

Table 14

NOTE: sums might slightly deviate due to accumulating round-off errors

6. Discussion

The present review collects and summarizes number and type of safety outcomes published on implantable hearing devices which aim to correct hearing loss together with malformations, and/ or other medical conditions of the ear. The body of evidence on safety outcomes identified in this review reflects the current state of peer reviewed publications and is therefore limited regarding the quality, the number of reports and studies as well as the reporting integrity and completeness itself. For example, no data regarding safety outcomes is available for a large part of the reported populations, which could be interpreted as either no complications had been observed or haven't been completely reported. Another aspect that needs to be taken into consideration is that the reported safety data from a literature review over a longer time period may not always reflect the design status of the newest models of each of the devices.

The investigated devices proved to be safe and effective in means of hearing rehabilitation. Surgical complication rates are device specific, and postoperative problems are minimal. The most outstanding complication is connected to skin related conditions in the percutaneous group (both in the Baha Connect series and Ponto, with 42.3%, 37.3%), and in the transcutaneously implanted cohort (the Sophono, with 18.1%)(see Figures 3, 4 and 6). This is particularly surprising with the Sophono being a transcutaneous implant, aiming to avoid soft tissue related complications. Especially for the Alpha 1 generation in several publications, *skin related* complication rates (inflammation, infection, redness, skin revision surgery, edema or erythema etc.) comparable to the Baha percutaneous systems are given *(M.B. O'Niel et al. 2014 (10/10), P. Marsella et al. 2014 (2/6), F. Denoyelle et al. 2015 (5/15), F. Denoyelle et al. 2013 (2/6))* (see Figure 6 and Table 5). The MET, together with the BAHA Attract system showed the highest occurrence of *patient related* problems, such as pain etc. (24.6% and 22.7% respectively). The highest incidence rate for *device related* complications occurred in the ESTEEM, Carina and the MET systems (73.2%, 33.2% and 15.4% respectively). 29.5% and 26.4% *surgery related* complication rates were reported for the Soundtec and BAHA Attract systems.

The lowest percentage of overall safety outcomes by far, was seen in active transcutaneous bone conduction hearing devices, the BONEBRIDGE, with 7.2%, which includes one revision surgery (0.5%). Skin related complications do not seem to be an issue with this type of hearing implant system. Furthermore special emphasis needs to be drawn on the high rate of no complications (54.5%) in the BB outcomes as specifically stated for the reported implanted population (see Figure 5 and Table 4).
With regard to partially implantable active middle ear implants (as reported on the SOUNDBRIDGE, see Figure 8 and 9), it is worthwhile to mention that complication rates are not only dependent on the specific device but also on the indication and underlying pathology, and therefore type of Vibroplasty. Complication rates are higher in conductive and mixed hearing loss cases (see Figure 8) that often comprise preoperated ears and malformations than in sensorineural hearing loss cases (see Figure 9) which imply complete and healthy anatomical structures in the ear. Emphasis needs to be drawn on the, besides the BONEBRIDGE, lowest rates of overall complications for the SOUNDBRIDGE: 22.9% and 19.6% for M/CHL and SNHL indication respectively (sum of safety outcomes rate of 17.4% + 5.5 revision surgery and 12.7% + 6.9%, revision surgery, respectively)(see Table 14). For the CODACS and MET devices, as well as the Soundtec device, which is no longer commercially available, only few publications reporting on safety outcomes are available. The indications for fully implantable middle ear implants like the Carina and Esteem are not only applied for SNHL. Some authors had shown outcomes using these devices for subjects with atresia, external ear and ossicular chain defects, therefore applying the devices beyond approved indications to conductive and mixed hearing losses *(R. Siegert et al. 2014).* No changes in bone conduction thresholds before and after implantation were observed in most of the studies for the Carina. As Esteem implantation induces an additional conductive hearing loss due to the disruption of the ossicular chain, several studies showed an increased conductive threshold *(E.M. Kraus et al. 2011, M. Barbara et al. 2014).* This requires special attention as in middle ear devices such as the VIBRANT SOUNDBRIDGE an increase in conductive threshold after surgery is reported as a safety outcome, whereas in the population receiving an Esteem device, this is part of the surgical procedure, making it difficult to accurately compare the devices.
The main complications with Esteem implantation were related to the device (73.3%) and the surgical procedure (22.1%)(see Figure 13 and Table 12). It should be kept in mind that with this device, the need for explantation will demand reconstruction of the ossicular chain. Otherwise, the hearing threshold will increase due to the overlapping of conductive hearing loss on a preexisting SNHL.
For Carina devices, additionally to events related to surgical procedure, many studies reported on device malfunction or failure with a need for revision surgery or explantations ((22.8%) see Figure 14 and Table 13).

7. Conclusion

In conducting a systematic review of the literature regarding safety outcomes of implantable bone conduction and middle ear devices, we identified 279 studies including 15054 subjects treated for all kinds of hearing loss indications. The data presented here shows that there is a broad range of hearing implants suitable for all kind of indications, etiologies and anatomical conditions, which have proved themselves as safe and effective.

Comparing the systematically obtained results which were grouped into categories of safety outcomes one can conclude, that subjects implanted with the BONEBRIDGE experience the least number of complications with 6.6% and major complications requiring surgery occurred in 0.5% resulting in an overall complication rate of 7.2%. These pleasing results are followed by the VIBRANT SOUNDBRIDGE. Emphasis needs to be drawn on differences in safety outcomes dependent on the underlying pathology and therefore type of Vibroplasty. The rates of safety outcomes are higher with 17.4% in the mixed and conductive hearing loss cases, which often comprise preoperated ears and malformations, compared to sensorineural cases with 12.7%. When taking the revision surgery rate into account an overall complication rate of 22.9% (M/CHL) and 19.6% (SNHL) respectively can be noted. The other investigated bone conduction devices showed overall complication rates from 40.5% (Sophono) up to 91.8% in the BAHA Attract.

Especially major *skin related* problems requiring revision surgery account for a great amount in the Baha Connect series and in the Ponto device (8% and 4.1%, respectively.

The rates of safety outcomes for the investigated middle ear implants such as the MET, Carina and Esteem ranged from 43.0% to 132.8%. With the Esteem experiencing more safety related issues than subjects investigated (132.8%). Some of those devices exceeded the 30% rate for major complications requiring surgery. It should be kept in mind that the need for explantation of the Esteem will demand reconstruction of the ossicular chain. Otherwise, the hearing threshold will increase due to the overlapping of conductive hearing loss on a preexisting SNHL. The overall complication rate for the Carina and Esteem devices, taking the revision surgery into account ranged between 65.8% up to 151.9%.

Assuming similar beneficial audiological outcomes/ benefits of the here presented devices within their specific indication ranges, the pros and cons regarding surgery, long-term safety and quality of life of the patient need to be taken into account when deciding on a device. Careful selection of patients is required by the implantation team to confirm suitability for a device and for the surgery, before the patient himself makes the decision for the device of choice.

8. Literature

Baha Connect series

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PONTO

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BONEBRIDGE

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9. ACRONYMS

AC	Air conduction
ADE	Adverse device events
AE	Adverse events
BAHA	Bone anchored hearing aid/device
Baha	Cochlear specific series (Baha Attract etc.)
BB	BONEBRIDGE
BC	Bone conduction
BCD	Bone conduction device
BCHD	Bone conduction hearing device
BCI	Bone conduction implant
CSF	Cerebrospinal fluid
dB	Decibels
dB HL	Decibels hearing level
diff.	Different
CO	Chronic otitis
COE	Chronic otitis externa
DACI	Direct acoustic cochlear implant
CODACS	Cochlear's direct acoustic cochlear stimulator
COM	Chronic otitis media
compl. ns	Complications not specified
DAC	Direct acoustic cochlear implant
DACS	Direct acoustic cochlear stimulator
FDA	Food and drug administration
FMT	Floating mass transducer
HL	Hearing loss
kHz	Kilohertz
M/CHL	Mixed and conductive hearing loss
ME	Middle ear
MEI	Middle ear implant
MET	Middle ear transducer
mo	Months
no.	Number of
no compl.	No complications
ns	Not stated
OE	Otitis externa
OW	Oval window
PTA	Pure tone average
RS	Revision surgery
RW	Round window
SD	Standard deviation
SE	Standard error
SNHL	Sensorineural hearing loss
SSD	Single sided deafness
TM	Tympanic membrane
VORP	Vibrating ossicular prosthesis
VSB	VIBRANT SOUNDBRIDGE
wks	Weeks
yrs	Years

10. APPENDIX

Databases search: Pubmed, DIMDI/EMBASE, COCHRANE
Search terms

SOUNDBRIDGE **OR** Floating mass transducer **OR** FMT **OR** Middle ear implant **OR** MEI **OR** Vibroplasty **OR** middle ear surgery **OR** implantable hearing aid **OR** Carina **OR** Direct acoustic cochlear implant **OR** DACI **OR** Direct acoustic cochlear stimulator **OR** DACS **OR** Direct acoustic cochlear implant actuator **OR** CODACS **OR** Middle ear transducer **OR** Envoy **OR** MAXUM **OR** ear reconstruction surgery **OR** Soundtec **OR** bone conduction implant **OR** bone conduction hearing implant **OR** bone conduction device **OR** bone conduction hearing device **OR** bone conduction hearing aid **OR** BCHI **OR** BCI **OR** bone anchored hearing implant **OR** bone anchored hearing device **OR** bone anchored hearing aid **OR** Baha **OR** Ponto **OR** BONEBRIDGE **OR** Sophono **OR** safety# **OR** adverse event# **OR** complications# **OR** revision#
AND hearing loss
NOT Systematic Review **NOT** case report **NOT** cochlear implant*

#DIMDI/EMBASE only, as PubMed only searches abstracts, not full text
*finding all terms that begin with 'cochlear implant'

Study population details

Device	No. studies	Indication / Aetiology	Age range	No. of males	No. of females	F/U	Total n
Percutaneous Bone Conduction Devices							
Baha Connect series	157 studies	Mixed- and conductive HL, SSD: COM, atresia, microtia, otosclerosis, stenosis, OM, OE, diff. Syndromes, Menieres disease, osteogenesis imperfecta, otorrhoeha, vestibular schwannoma, diff. types carcinoma, viral infection, meningioma, mumps, idiopathic sudden HL	1 - 94 yrs	3493	3974	0 - 192 mo	11686
Ponto	12 studies	Mixed and conductive HL, SSD: congenital atresia	17 - 81 yrs	159	209	0 - 62 mo	314
Transcutaneous and Active Bone Conduction Device							
BONEBRIDGE	15 studies	Mixed- and conductive HL, SSD: atresia, CO, radical mastoid, labyrinthitis	6 - 80 yrs	60	68	3 - 22 mo	209
Transcutaneous and Passive Bone Conduction Devices							
Sophono	17 studies	Mixed- and conductive HL, SSD: atresia, COM, diff. syndromes, mumps, ototoxicity, vestibular schwanoma, otosclerosis, cholesteatoma, congenital ossicular chain anomaly	3.8 - 71 yrs	47	50	4 - 43.2 mo	210
Baha Attract	7 studies	Mixed- and conductive HL, SSD: COM, atresia, microtia, neurofibromatosis, stenosis	2-72 yrs	34	45	4 wks - 24 mo	110
Partially Implantable Middle Ear Implants							
SOUNDBRIDGE M/CHL	55 studies	Mixed and conductive HL: congenital microtia, atresia, COM, COE, dermatitis, cholesteatoma, diff. syndromes, radical cavities, canal stenosis, otosclerosis, aplasia, hemifacial microsomia	0.2 - 84 yrs	339	336	2 - 64 mo	935
SOUNDBRIDGE SNHL	27 studies	Sensorineural HL: OE, COE, malformations	18 - 84 yrs	283	280	1 - 180 mo	841
CODACS	3 studies	Mixed HL: Otosclerosis, previous failed stapes surgery	47 - 79 yrs	14	29	3 - 6 mo	43
MET	4 studies	Sensorineural HL	18 - 88 yrs	22	23	1 - 153 mo	65
Soundtec	3 studies	Sensorineural HL	40 - 86 yrs	106	63	1 - 13 mo	173
Fully Implantable Middle Ear Implants							
Esteem	6 studies	Sensorineural HL: ototoxicity, antibiotics, hereditary	17 - 88 yrs	69	39	10 - 40 mo	131
Carina	17 studies	Sensorineural-, mixed- and conductive HL: atresia, COM, otosclerosis,	13 - 86 yrs	123	78	2 - 28 mo	337
						TOTAL POPULATION	15054

Summary of complications:

Safety outcomes

Description / more details			Percutaneous BCDs				Active transcutaneous BCHDs		Passive transcutaneous BCHDs				Active partially Implantable MEIs										Fully Implantable MEIs			
			BAHA Connect		Ponto		BONEBRIDGE		Sophono		Baha Attract		SOUNDBRIDGE M/CHL		SOUNDBRIDGE SNHL		CODACS		MET		Soundtec		Esteem		Carina	
			no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents	
no compl.		Holgers grade 0 (normal skin)	1371		96																					
		no. of Patients without AE (not specified)	325	14.5	14	35.0	114	54.5	125	59.5	20	18.2	431	46.1	92	10.9	8	18.6	7	10.8		0	10	7.6	67	19.9
compl. not specified		complications	177	1.5	4	1.3		0	1	0.5		0		0	4	0.5	6	14.0		0		0	37	28.2		0
device related	RS	abutment change	41														3									
		adverse device events (ADE)																					96			
		adverse events of the implant																							4	
		AP magnet too strong											2													
	RS	BAHA replacement	1																							
	RS	cable breakage or problems with the battery																							11	
	RS	device extrusion / displacement / migration	58		1								11		15										15	
		device falling off the head							5		5															
		device repair	20																							
	RS	device replacement											3													
	RS	dysfunction of the transmitter coil																	10							
		external device repair	47																							
		feedback problems																							8	
		hair friction perceived by implanted mic		3.6		0.3		0		11.9		10.0		2.7		2.9		7.0		15.4		0		73.3	2	33.2
	RS	implant/device/fixture failure	230						2				4		8										50	
		inability to charge or establish communication																							2	
		increased charging times beyond 1.5 hours																							7	
		insufficient gain													1											
	RS	mic repositioning due to feedback problems																							4	
		no Sound from the device (RS considered but not performed)											1													
		non-functioning device											2													
		problems with magnet: difficulties finding correct balance to prevent slippage (too weak) or skin irritation (too strong)									6															
		persistent feedback problems	2																							
		pressure discomfort							18				2													
		processor repair	16																							

		Description / more details	Percutaneous BCDs				Active transcutaneous BCHDs		Passive transcutaneous BCHDs			Active partially Implantable MEIs								Fully Implantable MEIs			
			BAHA Connect		Ponto		BONEBRIDGE		Sophono		Baha Attract	SOUNDBRIDGE M/CHL		SOUNDBRIDGE SNHL		CODACS		MET		Soundtec		Esteem		Carina	
			no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents	no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents	
patient related (1)		abnormal ear sensation		4.9		1.3		1.4		4.8	22.7		0.9		2.9		0		24.6	1	12.1		0		1.8
		abutment loss	28																					
	RS	bony overgrowth	19																					
		cardiovascular disorder																		1				
		chronic ME aeration problems												1										
		chronic pain	4																					
		chronic/persistent pain	17																					
		dermatitis	3																					
		dizziness not device related										1												
		ear disorder																		1				
		ear edema																		1				
		ear infections/otorrhea	102																					
		ear pain							5											14				
	RS	extrusion of the implant due to trauma	3																					
	RS	failure to osseointegrate	127																					
		fever but no sign of infection			1																			
		fixture and/or Abutment removed or lost	25																					
		headaches					1		1			1												
	RS	implant removal requested by the patient	2																					
		insufficient gain due to patient-related factors												2										
		loose implant/abutment	143																					
		loss or displacement of the device																6						
		magnet 2 falling off and magnet 3 uncomfortable							1															
		middle ear effusion																					3	
		mild pain	8				1				15													
		moderate pain	1																					
		Neuralgia	7																					
		otitis externa																		1				
		occasional discomfort at implant side without skin irritation										1												
		occasional unpleasant interferences										1												

		Description / more details	Percutaneous BCDs				Active transcutaneous BCHDs		Passive transcutaneous BCHDs				Active partially Implantable MEIs										Fully Implantable MEIs			
			BAHA Connect		Ponto		BONEBRIDGE		Sophono		Baha Attract		SOUNDBRIDGE M/CHL		SOUNDBRIDGE SNHL		CODACS		MET		Soundtec		Esteem		Carina	
			no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents	
patient related (2)		otitis media		4.9		1.3		1.4		4.8		22.7		0.9		2.9		0		24.6	1	12.1		0		1.8
		pain and delayed healing after microtia repair											1													
		pain at implant side									8				3											
		pain due to ossification																	1							
		pain ns	15		3				3		2				13				9						1	
		progression of hearing loss (not device related)													2											
		recurrent cavity infection											1													
		recurrent infection	4																							
		recurrent vestibular schwanoma	1																							
		sensorineural impairment without any apparent cause											1													
		spontaneous fixture/device loss	4																							
		Tinnitus					1								3						1				2	
		transducer displacement after MRI											1													
		trauma	50																							
		trauma to the implant	7																							
skin related (1)		abscess at the abutment		42.3	1	37.3		3.3		18.1		27.3		3.0		2.3		4.7		13.8		5.8		2.3		2.1
		adjacent tissue transfer	11																							
		adverse skin reaction (soft tissue problem requiring repeated visits to clinic for wound care and therapy)	104																							
		cellulitis	27																							
		chronic infection	7																							
		combination of granulation and skin overgrowth	8																							
		fluctuating tissue edema																					1			
		free skingraft											1													
		granulation	65																							
		haematoma subcutaneous	8																							
		hair overgrowth	2																							
		healing difficulties	1																							
		hematoma	1		1				2		2		1								9					
		Holgers grade 1 (slight redness or crust formation)	1613		71						2															

		Description / more details	Percutaneous BCDs				Active transcutaneous BCHDs		Passive transcutaneous BCHDs				Active partially Implantable MEIs								Fully Implantable MEIs			
			BAHA Connect		Ponto		BONEBRIDGE		Sophono		Baha Attract		SOUNDBRIDGE M/CHL		SOUNDBRIDGE SNHL		CODACS		MET		Soundtec		Esteem		Carina	
			no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents	
skin related (2)		Holgers grade 2 (infection or skin overgrowth)	1213		18																			
	RS	Holgers grade 3 (infection or skin overgrowth which needs surgical revision)	325		10																			
	RS	Holgers grade 4 (extrusion of the implant because of infection)	103																					
		hypertrophic scarring at skin-graft site	1																					
		impaired wound healing													2									
		implant site soft tissue reactions	4																					
		incomplete healing of the graft	42																					
		Infection	179		1		1						4		1								3	
		inflammation	23						2															
		inflammation around the external baseplate							4															
		inflammation under magnet							1															
		itching around the AP					1																	
		keloid formation			2																			
		ischemia of the reconstructed earlobe					1																	
		keloid scar	2																					
		local abscess							1															
	RS	major soft tissue related complications	12	42.3		37.3		3.3		18.1		27.3		3.0		2.3		4.7		13.8		5.8		2.3		2.1
		mild erythema during immediate healing period	10		5																			
		neuroma at abutment site	2																					
	RS	new abutment fixture due to soft tissue hypertrophy and/or overgrowth	15																					
		new baseplate							1															
	RS	partial skin graft failure	3																					
		persistent itch around the abutment			1																			
		poor healing with exposure of the implants and surrounding skull	3																					
		post-operative seroma											1											
		pressure necrosis							2				1											
		pressure sore							1															
		pressure ulcers							1												1			
		prolonged wound healing with superficial revision					1																	
		seroma	1				2				1				1									
	RS	skin complications MAJOR	31														1							
		skin complications MINOR	147														1							
		skin crust							1															

		Description / more details	Percutaneous BCDs				Active transcutaneous BCHDs		Passive transcutaneous BCHDs				Active partially Implantable MEIs										Fully Implantable MEIs			
			BAHA Connect		Ponto		BONEBRIDGE		Sophono		Baha Attract		SOUNDBRIDGE M/CHL		SOUNDBRIDGE SNHL		CODACS		MET		Soundtec		Esteem		Carina	
			no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents	
skin related (3)		skin edema or erythema	6	42.0		37.3		3.3	11	18.1	6	27.3		3.0		2.3		4.7		13.8		5.8		2.3		2.1
		skin emphysema													2											
	RS	skin flap failure requiring revision procedures	4																							
	RS	skin flaps required	8																							
	RS	skin graft resuture	1																							
		skin grafts required	14																							
		skin hypertrophy	34																							
		skin infection	115				1		1		3				2				3							
		skin irritation due to magnet							6																	
	RS	skin necrosis	10																							
	RS	skin overgrowth	92																							
		skin reaction (not further specified)	167												10				5							
		skin redness							1																	
	RS	skin RS (skin overgrowth/cellulitis)	260		3				1				3										1			
		skinflap healing difficulties	14										4										1			
	RS	skinflap necrosis	35										1													
		slightly hyperdense tissue											10													
		small skin lesion	1																							
		soft tissue / skin overgrowth	65		1																					
		soft tissue problems	27																							
	RS	soft tissue reduction	8								16															
	RS	soft tissue revision	24																							
		superficial wound infection													1											
		swelling	8						1																	
		tearing of flap due to tenting by healing screw	1																							
		tingling of the skin							1																	
		treatment of abscess	6																							
		wound debridements	32																							
		wound dehiscence	18		3								2												2	
	RS	wound repair	3																							
	RS	wound dehiscence major																							2	

Description / more details			Percutaneous BCDs				Active transcutaneous BCHDs		Passive transcutaneous BCHDs				Active partially Implantable MEIs										Fully Implantable MEIs			
			BAHA Connect		Ponto		BONEBRIDGE		Sophono		Baha Attract		SOUNDBRIDGE M/CHL		SOUNDBRIDGE SNHL		CODACS		MET		Soundtec		Esteem		Carina	
			no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents	
surgery related (1)		abdominal hematoma		1.1		1.1		1.9		0.5		26.4	1	6.0		2.4		25.6		10.8		29.5		22.1		5.6
		aural fullnes													2										4	
		bleeding			1						1															
		bleeding from dural vessel					1																			
		cable break											1													
		cable exposure											1													
		cerebrospinal fluid (CSF) leak	1																							
		chorda tympany sacrificed													2								8			
		complications during surgery																	3							
		conductive hearing loss																							4	
		conductor wire extrusion											4													
		copious venous bleeding during countersinking	1																							
		CSF rhinorrhea	4																							
		CSF fistula	1																							
		delayed incisional CSF leak	1																							
		deterioration in hearing sensitivity after surgery													1											
		deterioration in sensorineural HL	1																							
		development of SNHL	2																							
		displayed facial weakness (HB4 and HB5)																					3			
		dizziness/vertigo	3				1						5								2				1	
		drop of inner ear function											1													
		dura exposure																	2							
		surgery related AE															8									
		RS															3									

		Description / more details	Percutaneous BCDs				Active transcutaneous BCHDs		Passive transcutaneous BCHDs				Active partially Implantable MEIs										Fully Implantable MEIs			
			BAHA Connect		Ponto		BONEBRIDGE		Sophono		Baha Attract		SOUNDBRIDGE M/CHL		SOUNDBRIDGE SNHL		CODACS		MET		Soundtec		Esteem		Carina	
			no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents	
surgery related (2)		dura opening		1.1		1.0		1.9		0.5		26.4		6.0		2.4		25.6	1	10.8		29.5		22.1		5.6
		elevated thresholds																							1	
		exposed bone at abutment site	5																							
		external auditory canal fistula											1													
		external auditory collapse													1											
		facial nerve damage/facial palsy											1		1								7			
		facial numbness																					1			
		failure with deep and sudden worsening of the hearing threshold											1													
		fasciculation near the zygomatic branch											1													
		greenish discharge due to surgery							1																	
		hearing loss																							3	
		hematoma on the TM																			5					
		high frequency HL in implanted ear													1											
		incus erosion													4											
		insufficient contact to incus																	1							
		insufficient coupling FMT (minor AE)													1											
		insufficient loading of transducer onto ossicular chain																							2	
	RS	intermittent sound after Revision surgery											1													
		intraoperative complications	48																							
		laceration of skin in external ear canal											5													
		laceration of the chorda tympany													4											
		lack of hearing benefit at frequencies between 2 and 8 kHz											1													
		Laryngospasm post-op requiring tracheostomy	1																							
		lightheadedness																							2	
		limited benefit due to out of criteria implantation					2																			
		multiple drilling sites necessary	1																							
		nausea																			1					
		paresthesia / abnormal sensation of the ear																			1					
		periabutment paraesthesia	3																							
		persistent bleeding	2																							
		percepting magnet movement																			35					
		pulmonary embolism											1													
		reduced skin sensitivity/numbness	9		2						2															

		Description / more details	Percutaneous BCDs				Active transcutaneous BCHDs		Passive transcutaneous BCHDs				Active partially Implantable MEIs										Fully Implantable MEIs			
			BAHA Connect		Ponto		BONEBRIDGE		Sophono		Baha Attract		SOUNDBRIDGE M/CHL		SOUNDBRIDGE SNHL		CODACS		MET		Soundtec		Esteem		Carina	
			no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents	
surgery related (3)	RS	repositioning to improve the coupling of FMT and RW membrane		1.1		1.0		1.9		0.5		26.4	20	6.0		2.4		25.6		10.8		29.5		22.1	1	5.6
		residual hearing affected											2													
		residual TM perforation																			2					
		severe deterioration of hearing	2																							
		sigmoid sinus injury during operation	1																							
	RS	skin graft failure (surgery related)	27																							
		skin numbness									26															
		skull paraesthesia	5																							
		surgical complications (not specified)																			1					
		taste disturbances / chorda tympani damage											3		1						2		10			
		temporary facial nerve paresis											2													
		temporary torn tympanic membrane																			1					
		tinnitus (not present before)											3		1										1	
		vomitting																			1					
	RS	VORP placed upside down													1											
	RS	VSB cable broken due to otolaryngologist who attemptd to clean the cerumen in the mastoid cavity											1													
non-user		NO BENEFIT / limited benefit / non-user	142	1.2		0		0	8	3.8	4	3.6	45	4.8	14	1.7	1	2.3	1	1.5		0	9	6.9	1	0.3

Summary of complications:

Major complications requiring surgery

Description / more details		Percutaneous BCDs				Active transcutaneous BCHDs		Passive transcutaneous BCHDs				Active partially Implantable MEIs										Fully Implantable MEIs			
		BAHA Connect		Ponto		BONEBRIDGE		Sophono		Baha Attract		SOUNDBRIDGE M/CHL		SOUNDBRIDGE SNHL		CODACS		MET		Soundtec		Esteem		Carina	
		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents	
device related	abutment change	41	2.8		0.3		0		0.5		0		1.9		1.8		0		15.4		0		0		26.4
	BAHA replacement	1																							
	cable breakage or problems with the battery																							11	
	device extrusion / displacement / migration	58		1								11		15										15	
	device replacement											3													
	dysfunction of the transmitter coil																	10							
	implant/device/fixture failure	230						1				4												50	
	transducer failure																							9	
	mic repositioning due to feedback problems																							4	
patient related	bony overgrowth	19	1.3		0		0		0		0		0.2		0		0		0		0		0		0
	extrusion of the implant due to trauma	3																							
	failure to osseointegrate	127																							
	implant removal requested by the patient	2																							
	severe candida infection with TORP extrusion. VSB function preserved											1													
	transducer displacement after MRT											1													
skin related	Holgers grade 3 (infection or skin overgrowth which needs surgical revision)	325	8.0	10	4.1		0		0.5		0		0.4		2.3		2.3		0		0		0.8		0.6
	Holgers grade 4 (extrusion of the implant because of infection)	103																							
	major soft tissue related complications	12																							
	new abutment fixture due to soft tissue hypertrophy and/or overgrowth	15																							
	partial skin graft failure	3																							
	skin complications MAJOR	31												1		1									
	skin flap failure requiring revision procedures	4																							
	skin flaps required	8																							
	skin graft resuture	1																							
	skin necrosis	10																							
	skin overgrowth	92																							
	skin revision surgery (skin overgrowth. cellulitis)	260		3				1				3										1			
	skinflap necrosis	35										1													
	soft tissue reduction	8																							
	soft tissue revision	24																							
	wound repair	3																							
	wound dehiscence major																							2	

Description / more details		Percutaneous BCDs				Active transcutaneous BCHDs		Passive transcutaneous BCHDs				Active partially Implantable MEIs										Fully Implantable MEIs			
		BAHA Connect		Ponto		BONEBRIDGE		Sophono		Baha Attract		SOUNDBRIDGE M/CHL		SOUNDBRIDGE SNHL		CODACS		MET		Soundtec		Esteem		Carina	
		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents		no. and % incidents	
surgery related	insufficient loading of transducer onto ossicular chain		0.2		0		0		0		0		2.4		0.1		7.0		0		0		0	2	0.9
	intermittend sound after Revision surgery											1													
	repositioning to improve the coupling of FMT and RW membrane											20												1	
	skin graft failure (surgery related)	27																							
	surgery related SAE															31									
	VORP placed upside down													1											
	VSB cable broken due to otolaryngologist who attemptd to clean the cerumen in the mastoid cavity											1													
revision surgery (RS)	abutment removal	30	17.0	7	3.5		0.5		1.0		1.8		5.5		6.9		4.7		16.9		0.6		19.1		22.8
	abutment replacement																								
	device loss											3													
	explantation	47				1		1				16		17								7		33	
	explantation at patients request													5											
	explantation due to misdiagnosed severe HL											1													
	implant loss	1144		1						1															
	loss of the fixture	126																							
	reimplantation	186		2				1				12		10				6				4		40	
	resiting of fixture	24																							
	revision surgery	427		1						1		19		26		2		5		1		14		4	
	revision surgery coupling to sleeper implant	1																							

Notes:

Notes: