Implantable Hearing Devices

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Abstract There are many barriers that prevent the use of traditional acoustic amplification including anatomic and medical conditions and patient preference. Implantable hearing devices typically avoid the use of the ear canal and can overcome many of these barriers. Current options include partially and fully implantable devices, devices that make use of bone conduction, devices that directly couple to the ossicular chain, and those that provide more direct cochlear stimulation. This article reviews the major devices that are currently available or in development providing information regarding clinical indications, device components, the general surgical procedure, and typical outcomes. This review should help the clinician understand device options to fit specific patient anatomy and amplification needs.

Keywords Implantable · Hearing device · Bone conduction · Baha · Sophono · Bonebridge · Vibrant Soundbridge · Ponto · Attract · Envoy · Esteem · DACS · CODACS

Introduction

Conventional air conduction hearing aids have been used to treat hearing loss for many years. Perceived cosmetics,

the occlusion effect, sound quality issues, and cost are patient barriers to using conventional hearing aids. In addition, structural anomalies such as atresia and microtia, as well as pathologies causing chronic drainage or otitis externa, can prohibit conventional amplification. Implantable hearing devices have been introduced to increase amplification options for those who have limited success or are unable to wear traditional hearing aids. Implantable devices include bone conduction devices with percutaneous or subcutaneous components and middle ear implants providing auditory stimulation through manipulation of the existing or remnant ossicular chain.

Bone Conduction Implantable Devices

Bone conduction implantable devices are approved for conductive or mixed hearing losses and single-sided deafness in cases where a conventional hearing aid is contraindicated [1]. All current devices are semi-implantable and transmit sound to the cochlea via bone conduction, bypassing the impaired outer or middle ear (Table 1). Traditionally, these systems took advantage of direct osseointegration using a titanium bone fixture and percutaneous abutment connected to an external sound processor [2]. Several methods of transcutaneous transmission with the use of magnetic coupling between the processor and scalp have been more recently introduced (Fig. 1).

Percutaneous Bone-Anchored Hearing Implant

Percutaneous bone conduction systems consist of the osseointegrated titanium implant, percutaneous abutment,

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Table 1 Bone conduction devices

System	Oticon Medical	Cochlear Connect	Cochlear Attract	Sophono	Med El Bonebridge
Type	Percutaneous	Percutaneous	Transcutaneous	Transcutaneous	Transcutaneous
Processor	Ponto Plus	Baha 4 BP110	Baha 4 BP110	Alpha 2	Bonebridge
	Ponto Plus Power	Cordelle II			
CE mark	Yes	Yes	Yes	Yes	Yes
FDA approval	Yes	Yes	Yes	Yes	No
Osseointegrated?	Yes	Yes	Yes	No ^b	No ^b
Bone conduction requirements	0–55 dB PTA ^a	0–65 dB PTA ^a	0–55 dB PTA ^a	0–45 dB PTA	0–45 dB
MRI compatible?	Yes	Yes	Yes to 1.5 Tesla	Yes to 3.0 Tesla	Yes to 1.5 Tesla

^a Processor selection dependent on bone conduction score

^b Fixation screws may osseointegrate

and external speech processor. Currently, both Oticon Medical (Oticon Medical LLC, Somerset, NJ) and Cochlear Ltd. (Cochlear Ltd, Centennial, CO) produce percutaneous bone conduction systems called the Ponto and Baha, respectively. Percutaneous systems rely on osseointegration of the titanium implant with the skull to provide a clear signal to the cochlea.

Clinical Indications

Both the Oticon Medical and Cochlear percutaneous systems are approved for single-sided deafness, conductive hearing loss, and mixed hearing loss in cases where a conventional hearing aid is not appropriate. Air-bone gaps of >30 dB are recommended [3]. The sensorineural component of the mixed hearing loss can be up to 45–65 dB HL, depending on the manufacturer's speech processor. Single-sided deafness applications require a normal contralateral ear bone line with Oticon specifying a hearing level of better than 20 dB HL. Contraindications include thin bone or poor bone quality, conditions that increase the likelihood of skin infections, or the inability to clean and maintain the abutment site [3].

System Components

Both Oticon Medical and Cochlear Ltd. systems consist of a titanium implant, a percutaneous abutment, and an external speech processor. Currently, Oticon Medical offers their OptiFitTM abutments, which come in several different lengths and include an angled abutment for those patients whose external processor touches the scalp causing feedback. Cochlear released their Cochlear Baha DermaLock (BA400) Abutment, which has a hydroxyapatite coating and helps to adhere surrounding tissue to the abutment [4]. The external speech processor is removable,

and the processor chosen is determined, in part, by the amount of sensorineural hearing loss that is present.

Oticon Medical currently offers the Ponto Plus for single-sided deafness, conductive hearing loss, or mixed hearing loss with bone scores up to 45 dB HL. Their Ponto Plus Power is appropriate for bone conduction scores up to 55 dB HL. Both Ponto Plus and Ponto Plus Power processors have a Ponto Streamer accessory, which is worn around the neck and enables the listener to connect to Bluetooth devices such as a cell phone or computer, as well as the television and other devices. Cochlear has three different processors for use with varying sensorineural components. The Baha 4 is compatible with a bone conduction pure tone average of 45 dB HL, the Baha 3 Power (BP110) is for use with scores up to 55 dB HL, and the body-worn Cordelle II can be used for bone scores up to 65 dB HL. The Baha 4 has accessories for use with the processor, which include connection to a cell phone or television, among other devices.

Surgery and Outcomes

The general surgical procedure is similar for both Oticon Medical and Cochlear Ltd. devices. In brief, either a linear or curved incision can be used to expose the pericranium located about 55–60 mm from the external canal at an angle of 45° above horizontal. In thin scalps, using the new DermaLock abutments, some have advocated using a large dermal punch with no incision [5]. In addition, less scalp thinning has been recently recommended, in contrast to the use of a dermatome and complete subcutaneous tissue removal previously advocated [6]. The flange fixture is screwed into the cranium after drilling a 3–4-mm-deep guide hole and using a countersink burr that widens the insertion hole and creates a shallow circumferential lip to seat the fixture flush with the surrounding bone. Care is taken not to over tighten the fixture in the bone to prevent

Fig. 1 Bone conduction devices in which the vibratory component is external to the patient. These include two percutaneous and two transcutaneous systems. Components, configuration, and processors are depicted

stripping and possible extrusion. The abutment is secured to the flange fixture and may come pre-coupled. There have been numerous fixture and abutment revisions in recent years, and it is important the surgeon have the latest surgical manual and instrumentation. For example, the latest Cochlear Ltd. process requires the assembly of a torque wrench from several components to attach and secure the abutment. The skin is then closed around the abutment for a linear incision, or a punch hole is made for the abutment for off-axis incisions. Gauze or Telfa is placed around the abutment and a healing cap attached to the abutment. This holds pressure on the underlying skin to prevent it from over-riding the abutment. We typically change the gauze pressure dressing weekly for 2–3 weeks and wait 8–10 weeks for attachment of the external processor. Cochlear Baha guidelines recommend waiting 3 months for osseointegration before use of the external processor; Oticon provides no specific time period. If no or minimal skin thinning is performed, it is still useful to maintain a pressure dressing for 2–3 weeks to prevent edema leading to skin growing over the abutment.

In children, implantation is typically staged. At the first stage, the flange fixture is placed with an internal cover screw, and the skin is closed for a period of 3–6 months to allow osseointegration. At the second stage, the cover screw is removed and the permanent abutment affixed [3]. Intra-operative fluoroscopy can be useful in locating the internal fixture allowing for a minimal incision at the second stage. If a child has a thin calvarium or has had prior issues with osseointegration, a second fixture (“sleeper”) is implanted during the first stage in the event of a complication with the main implant. Known complications with the percutaneous bone conduction implantable device include skin reactions, infections, skin growth over the abutment, failure to osseointegrate or loss of the implant [7•].

Studies have shown that patients with percutaneous bone conduction implant systems and conductive or mixed hearing loss experience a significant improvement in hearing and speech identification scores, with air-bone gap closure in 80–85 % of patients [8, 9]. Subjectively, patients with a percutaneous system tend to note satisfaction with the device [8, 9]. McNeil and colleagues investigated the subjective outlook of these osseointegrated implants on the recipient’s spouse or partner by having them fill out the Hearing Handicap Inventory for Adults Screening (HHIA-S) questionnaire [10]. The authors found that partners of recipients reported a significant improvement in HHIA-S scores after receiving the device.

Discussion

Both Oticon Medical and Cochlear Ltd percutaneous osseointegrated implant systems continue to be viable options for patients with conductive or mixed hearing loss, or single-sided deafness. Both subjective and audiologic benefits have been proven over the device’s history. The visibility of the abutment and the possibility for skin overgrowth or infection can be barriers to implantation.

Transcutaneous Bone Conduction Hearing Implant

Transcutaneous bone conduction systems are currently available through two manufacturers, Sophono (Sophono, Boulder, CO) and Cochlear Ltd. These systems send the auditory signal by means of bone conduction transmitted through the overlying scalp with no percutaneous abutment. When the external speech processor is not used, there is no visible indication of an implanted device.

Clinical Indications

The current transcutaneous systems are approved in the US for children older than 5 years and adults with conductive hearing loss or mixed hearing loss with bone conduction thresholds no >45 dB HL, and adults with single-sided deafness [2].

System Components

The Sophono system consists of an internal twin magnet fixed to the skull with standard plating screws [1]. The internal magnet holds the external spacer magnet against the scalp. The spacer magnet couples with the speech processor and comes in different strengths depending on the needs of the patient (i.e., scalp thickness). Currently, Sophono offers the Alpha 2 speech processor, a second-generation processor with improvements over the original Alpha 1 device.

The Cochlear Attract system uses the same osseointegrating titanium flange fixture as the percutaneous system. Internally, a magnetic plate is coupled with this fixture and is contained under the skin. An external speech processor (either the Cochlear Baha 4 or Baha 3 Power) is connected to an external spacer magnet that, like the Sophono system, comes in various strengths. This external magnet is lined with a SoftWear Pad, which is a foam pad that helps to spread pressure evenly over the skin and avoid pressure sores. If the patient's hearing decreases in the future, there is an option of removing the internal magnet and changing to the percutaneous abutment.

Surgery and Outcomes

Implantation of the Sophono device can use either a linear or curvilinear incision. It is recommended to use a curvilinear incision for the Cochlear Attract. Thinning of subcutaneous tissue is only recommended if it is thicker than about 6 mm, but some subcutaneous tissue should remain to prevent pain and pressure ulceration. The devices should be placed in a similar location to the percutaneous abutments, and we recommend shifting this slightly more superior to provide for a flatter skull and more overlying tissues. This helps reduce postoperative pain by ensuring the device lies flat.

For the Sophono device, two wells are drilled for the magnets ~2 mm deep and 1 cm in diameter. The device is used as a template for placement, and the wells are aligned vertically. Standard 1.7 mm × 4-mm plating screws are used to secure the magnet in five locations. At least four screws are necessary to ensure stability. Skin is closed in standard fashion, and we allow 6 weeks for reduction of edema before fitting.

For the Cochlear Attract device, a flange fixture is placed as described above in standard manner. A specialized tool is then attached to the flange and rotated

circumferentially to assess clearance from the underlying bone. This ensures the internal magnet will lie flat, preventing a pressure point at one edge. The internal magnet is then attached using the torque wrench. Skin is closed in standard fashion.

When comparing audiologic speech testing outcomes between the Sophono Alpha 1 system and percutaneous systems, results were found to be improved over the unaided condition, but poorer than percutaneous results [2, 11•]. Independent studies are currently not available for the Cochlear Attract because of the novelty of the system.

Discussion

The transcutaneous bone conduction systems provide users a more acceptable cosmetic approach to attending to their hearing loss. These systems also reduce the possibility for skin infections and prevent overgrowth around a percutaneous abutment. However, skin complications have been noted when the patient is using a strength of external magnet that is too high, causing irritation. Studies have shown that current transcutaneous systems do not provide as much gain as their percutaneous counterparts [12••]. As such, our clinic prefers bone conduction thresholds in the normal range when exploring system candidacy for transcutaneous devices.

Bonebridge

Clinical Indications

The Bonebridge (MED-EL, Innsbruck, Austria) is a bone conduction device for use with single-sided deafness or conductive or mixed hearing loss with bone conduction thresholds better than or equal to 45 dB [13]. Patients must have appropriate bone thickness and consistency to accommodate the internal device, as determined by a pre-operative CT scan [14•]. Unlike the Cochlear and Oticon Medical devices, the Bonebridge does not require osseointegration [13]. The Bonebridge is MRI compatible up to 1.5 T [13].

System Components

The Bonebridge is a semi-implantable device consisting of both internal and external components which couple similar to current cochlear implants [15]. The external audioprocessor contains the microphones, signal processor, battery, and magnet. The internal device consists of an internal receiver coil, magnet, and Bone Conduction Floating Mass Transducer (BC-FMT). The BC-FMT is fit in a well and secured to the calvarial bone with two titanium screws. The external processor provides the necessary power to the

internal unit as well as the signal transmission transcutaneously. The signal is received by the internal coil and travels to the BC-FMT, which vibrates, transmitting sound to the inner ear via bone conduction.

Surgery and Outcomes

Components for measuring drilling depth and placement for the coil and transducer as well as screws for fixation are included by the manufacturer. The BC-FMT is connected to the internal coil by means of a flexible component that can be bent up to 90° horizontally and 30° vertically depending on optimal placement of the FMT, as determined by the preoperative CT scan [13]. Multiple surgical approaches are considered depending on placement of the device, which is 8.6 mm in depth. This includes within the mastoid or retrosigmoid. Care should be taken not to reach or disturb the dura mater or sigmoid sinuses. Reported adverse events include tinnitus, headache, vertigo, and minor skin infection [14•].

Sprinzel and colleagues activated their patients at 4 weeks after surgery assuming the fixation screws would be secure by that time [14•]. The authors found improved word recognition scores at activation and continued to see improvement up to 3 months after activation. Similarly, Barbara et al. [13] noted an improvement in SRT and word recognition scores compared to the unaided sound field condition. Both studies found no changes in unaided air or bone conduction thresholds postoperatively.

Discussion

The Bonebridge is a novel approach to the traditional bone conduction implantable device, where osseointegration is not necessary and the oscillating portion of the device is internal. This has potential advantages compared to percutaneous devices that require constant care around the abutment site, have the potential for skin issues around the abutment, and in rare situations where the implant fails to osseointegrate.

Middle Ear Implants

Envoy Esteem

Clinical Indications

The Envoy Esteem (Envoy Medical, St. Paul, MN) received FDA approval for use in the US in 2010 for adults ages 18 or over who have a stable bilateral moderate to severe sensorineural hearing loss with unaided word recognition scores of >40 % and a normal tympanic

membrane [16, 17]. Patients must also have enough space for the implanted device and undergo at least a 30-day trial with hearing aids prior to implantation. Co-existing otologic pathologies are a contraindication to the Esteem.

System Components

The Envoy Esteem is a fully implantable device that consists of two piezoelectric bimorph crystals, the sensor and the driver, attached to a processor. The speech processor and non-rechargeable battery are hermetically sealed within titanium casing [18]. The sensor is attached to the incus and acts as the system's microphone, using input from the tympanic membrane [19]. The driver is connected to the stapes. Sound is funneled through the ear canal and vibrates the tympanic membrane, which in turn moves the malleus and incus. The sensor, using the motion of the incus, sends electric impulses to the speech processor, which modifies the signal. The modified signal is sent from the speech processor to the driver, which vibrates the stapes.

Surgery and Outcomes

Surgery has been reported as having a steep learning curve indicated by the time spent in the operating room, with reports ranging from ~4–8 h [16, 18, 19]. Surgery includes a mastoidectomy and epitymanpanectomy to ensure enough room for the device components. The ossicles are disarticulated at the incudostapedial joint, and resection of the long process of the incus is performed with a laser. The transducers are cemented to the appropriate ossicles, and the system is tested intraoperatively using a laser Doppler vibrometer. The device is then turned off until activation.

Adverse events and adverse device effects noted in patients implanted with the Envoy Esteem ranged from mild to serious and included wound infections, delayed-onset facial paresis or numbness, delayed fibrosis that impeded device function, taste disturbance, tinnitus, vertigo, and headache [16, 18]. Reports on audibility with the Esteem indicate improvement in air conduction thresholds over both preoperative unaided and aided (with a conventional hearing aid) scores, although not always a statistically significant difference [17, 18].

Discussion

Literature regarding the Envoy Esteem has been limited and includes small sample sizes and restricted follow-up durations. Patients should appreciate the ease of use, full-time wearability, and invisible equipment. Unlike surgical procedures of other implantable hearing systems, the removal of the long process of the incus during Esteem

implantation creates additional hearing loss and could limit options should the patient decide not to use the Esteem in the future. Surgical changing of the battery is also a factor to consider as exposure to noisy environments and use of high gain can significantly shorten the expected battery life. Battery life expectancy is reported by the company at 4.5–9 years with reports in the literature of several patients with battery changes between 28 and 39 months [20].

Otologics MET and Carina

Clinical Indications

The Middle Ear Transducer (MET) (Otologics, Boulder, CO) is a semi-implantable hearing device that has been used in adults with moderate to severe sensorineural hearing loss [21]. Otologics later updated the MET to a fully implanted hearing device named Carina for use in adults with moderate to severe sensorineural hearing loss, which later received a CE Mark in Europe for use in conductive and mixed hearing losses [22, 23]. Because of the flexibility of the internal components, Carina candidacy can encompass patients that have certain middle-ear anomalies, which would have excluded them from the Envoy Esteem implantable hearing aid [22].

System Components

The Otologics MET is comprised of both internal and external components. External components consist of a Button Audio Processor that houses the signal-processing system, microphone, battery, and transmitter coil [24]. Internal components include the electronics capsule and mechanical transducer [25]. The lead of the MET could be disconnected from other internal components to allow conversion to the fully implanted device without disturbing transducer placement, once such a device was made available. The Button Audio Processor processes and transmits the signal to the internal capsule transcutaneously by means of FM transmission [24, 25].

The fully implantable Otologics Carina includes an internal magnet, battery, signal processor, receiver coil, and connector all housed in an electronics capsule, as well as a microphone and the transducer system [23, 26]. There are multiple transducer types with the selection of a transducer type dependent on where the transducer is to be placed, determined by the patient's middle ear anatomy [26, 27]. The receiver coil allows for transcutaneous programming of the device and recharging of the battery. To charge the battery, a special external charger is placed over the implant site for ~1–1.5 h. A remote control is also available to adjust volume and power off and on the device.

Surgery and Outcomes

Microphone and transducer positioning are very important during surgical placement of the Otologics Carina device. The microphone placement can be in the temporalis region, the retroauricular region, or on the mastoid tip, avoiding areas that are prone to tissue thickness changes and contraction effects of the temporalis and sternocleidomastoid muscles [26, 27]. Just as there are many available transducer tips, there are also many configurations for transducer placement. Reports of transducer placement have included mounting directly onto the incus, into a hole drilled into the body of the incus, at other ossicular sites including the footplate of the stapes, and at the round window membrane [21, 23, 26–28]. Efficient coupling is important at the transducer site to prevent unnecessary battery drain, achieve appropriate gain, and avoid additional hearing loss [27, 28]. Adverse events and adverse device effects reported throughout the literature include partial or total device or microphone extrusion, a fullness or pressure sensation, conductive hearing loss, lightheadedness, tinnitus, middle ear effusion, feedback, device failure, and extended length of time for the battery to recharge [26–28].

Improvement in hearing and speech perception when compared to preoperative hearing testing has been noted on multiple occasions, although thresholds below 30 dB HL were not regularly observed [21, 23, 26]. Subjective benefit using the APHAB questionnaire indicated that patients prefer the Carina over traditional amplification or their preoperative unaided condition, but there was also an increase in aversiveness to sound with the Carina [23, 26].

Discussion

The fully implantable Otologics Carina introduces options for patients with abnormal middle ear anatomy due to the variety of available transducer tips. However, the Carina is not MRI compatible, and surgery is needed to change the battery. Literature is limited, and additional studies comparing outcomes and long-term effects of the Carina and MET are warranted. In June 2013, Otologics was purchased by Cochlear Ltd., which plans to incorporate the technology into acoustical implant development (Cochlear Annual Report, 2013).

Vibrant SoundBridge (VSB)

Clinical Indications

The Vibrant Soundbridge (MED-EL, Innsbruck, Austria) is a semi-implantable hearing system that received FDA approval for use in the US in 2000 [29]. The device is approved for adults with moderate to severe sensorineural hearing loss who cannot benefit from a conventional

hearing aid [29–32]. Audiometric candidacy criteria include bone conduction thresholds up to 65 dB HL at 500 Hz and 85 dB HL at 6,000 Hz [29]. Uses for both children and mixed hearing loss have also been investigated [29, 30, 33]. Like the Otologics MET and Carina, flexibility of the internal component placement has the potential to make this device appropriate for patients with a wide range of middle ear anomalies.

System Components

The Vibrant Soundbridge (VSB) consists of an external audio processor and an internal Vibrating Ossicular Prosthesis (VORP) [32, 34]. The audio processor contains a microphone, speech-processing capabilities, transmitting coil, magnet, and battery [29, 35]. The internal VORP is comprised of a receiver module, magnet, conductor link, and floating mass transducer (FMT). Magnetic force between the audio processor and internal device keeps the external unit in place. Speech is processed in the audio processor, which transmits the signal transcutaneously to the internal receiver unit. The signal then travels to the electromagnetic FMT where vibrational energy is realized and either the ossicular chain or inner ear is stimulated directly, depending on FMT placement.

Surgery and Outcomes

Traditional placement of the FMT for patients with sensorineural hearing loss is to clip the device to the long process of the incus. There are concerns regarding possible necrosis of the ossicle using a clip; however, significant widespread cases of necrosis were not identified in a literature search [30, 32]. Investigations of alternative coupling sites in the middle ear have been explored to address instances where conductive or mixed hearing loss is present because of ossicular structural abnormalities. FMT placement sites include placement at the stapes head, crura, mobile footplate, or oval window and can be used in conjunction with a PORP, TORP, or other coupler [29, 31, 36•].

In cases where the stapes footplate is not mobile or not intact, the FMT can be coupled to the round window [37–39]. Placement of the FMT at the round window has been shown to be a safe and effective method for overcoming conductive or mixed hearing loss [36•, 37]. This unique placement can provide amplification in cases where ossicles or a tympanic membrane are not present such as in canal wall down cavities. Potential complications for all approaches include FMT displacement, additional hearing loss, dizziness, device failure, facial nerve paralysis, postoperative wound-healing issues, and gustatory disorders, although some studies fail to report any complications [29, 31, 33, 36•, 37, 40].

Few or no changes in unaided air conduction thresholds or bone conduction thresholds have been reported postoperatively [30, 31, 33, 36•, 37]. Improvement in hearing thresholds and word recognition scores were noted when comparing use of the VSB over an unaided condition. Boheim and colleagues reported that long-term postoperative audiologic results using the VSB were stable at an average of 40 months when compared to postoperative scores at 3 months [36•]. Performance with the VSB has shown comparable hearing benefit to use with conventional hearing aids [41••].

Discussion

As with all implantable hearing devices, the risk of surgery must be weighed with expected benefit. This is particularly true when outcomes do not show any statistical performance benefit over conventional amplification. Use of MRI is currently contraindicated with the VSB. Although the FDA has approved this device for use in the US, insurance coverage continues to be a barrier to treatment. The VSB has shown utility for patients with all types of hearing loss and, unlike the Envoy Esteem, can be used when the ossicular chain is not intact.

Direct Acoustic Cochlear Stimulator Partial Implant (DACS)/Codacs

Clinical Indications

The DACS (Phonak Acoustic Implants SA, Switzerland) is a partially implantable hearing device for moderate to severe mixed hearing loss [42, 43]. Both Phonak Acoustic Implants SA and Cochlear originally collaborated on the development of the system [44]. The DACS (a.k.a. DACS-PI) was primarily investigated for use with advanced otosclerosis using the idea of applying a power-driven stapes piston to stimulate the cochlea directly rather than performing a traditional stapedectomy and then utilizing a conventional hearing aid to overcome any remaining conductive or sensorineural hearing loss [42, 43, 45]. Recommended audiometric criteria for bone conduction thresholds are between 40 and 80 dB [44]. The Codacs (Cochlear Ltd., Sydney, Australia) is a modified version of the DACS [46•].

System Components

The DACS system consists of both an external audio processor and internal components [45]. The original DACS audio processor included two microphones, a battery, and a sound processor [47]. The audio processor would connect to the internal system by means of an

Fig. 2 Currently available implantable devices in which sound stimulation is generated within the patient. The Bonebridge uses bone conduction and can overcome modest sensorineural losses in addition to conductive losses. Vibrant Soundbridge and Envoy Esteem provide direct stimulation of the ossicular chain and in the case of the former can provide direct cochlear stimulation with the round window configuration (top middle picture)

implanted percutaneous plug. The external processor was later modified to include a magnet and RF coil to allow for transcutaneous signal delivery to the internal device, negating the need for the percutaneous plug. The internal system consisted of a percutaneous plug that was later replaced by an RF link, a fixation system, a transducer with an artificial incus, and a piston prosthesis.

The Codacs device includes a modified Cochlear Nucleus Freedom sound processor (Cochlear Ltd., Sydney, Australia) and RF coil as its external components. Internally, the device consists of a receiver coil, transducer, electronics, and fixation system.

Surgery and Outcomes

Limited reports on the DACS make comprehensive surgical information difficult to report. Hausler and colleagues reported surgical times ranging from 5 to 2.5 h, with time reduction as surgical experience was gained [45]. The DACS transducer is surgically placed behind the ear and the actuator is placed near the incus. The footplate of the stapes is removed, and a conventional prosthetic stapes is crimped onto the actuator. In order to have the patient achieve improved hearing even with the DACS system turned off, the surgeon has the option to include a second prostheses attached to the patient's incus parallel to the first prosthetic [45]. Postoperative complications reported in the literature range from no complications to infections around the percutaneous plug in the older device, pain, dizziness, and need for ear canal reconstruction [43–45].

No significant changes in bone conduction thresholds were reported postoperatively, and thresholds remained stable for up to 2 years after surgery [44, 45]. Busch et al.

[44] compared postoperative hearing between the activated DACS system and a conventional hearing aid and found improved APHAB scores with the DACS over the hearing aid as well as improved speech scores and soundfield thresholds, although results were not always statistically significant.

Lenarz et al. [46•] indicate that, while the actuator of the Codacs is the same as the DACS device, the fixation system has been modified to include a ball joint, which is intended to improve device placement options. Adverse events that occurred in the investigational device studies included strange sound sensations, inferior sound quality with the device compared to a hearing aid, nausea, tinnitus, sensation at receiver site, deterioration of bone conduction thresholds, facial palsy, and feedback from the device. Audiometric results showed improvement in word recognition abilities and the ability to amplify high frequencies compared to both the unaided condition and a conventional hearing aid. APHAB scores improved in all subscales except Averseness to Sound (AV) subscale, which showed no changes.

Discussion

The DACS-PI showed promising results comparing subjects using the DACS system and a conventional hearing aid on the same ear postoperatively with a sample size of nine patients [44]. Lack of larger sample sizes and long-term follow-up, inconsistent testing methods, and limited published literature prevent further evaluation of both the DACS system and Codacs and can invite bias when compiling results. To the authors' knowledge, Phonak Acoustic Implants is no longer producing the DACS. Codacs has recently received the CE Mark for use in Europe, and only one study could be found regarding the device.

Conclusions

Numerous implantable devices are options for hearing rehabilitation in patients unable or unamenable to proceeding with traditional acoustic amplification. Bone conduction devices involve low risk and generally simple surgeries and are excellent options for patients with normal to near normal bone thresholds. Those with mixed or sensorineural losses may be amenable to middle ear implants with options that take advantage of a normal ossicular chain and those capable of bypassing ossicular abnormalities (Fig. 2). Insurance authorization remains a potential barrier to using many of these devices, and continued reports and demonstration of efficacy are important to changing current policy.

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Compliance with Ethics Guidelines

Conflict of interest John Smith, Paula Taylor, and Mike Schultz declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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- Of major importance

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