Totally Implantable Active Middle Ear Implants

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KEYWORDS

- The Envoy Esteem • The Carina system • Active middle ear implants
- Sensorineural hearing loss • Implantable hearing aid
- Fully implantable hearing device

KEY POINTS

- This article reviews the Esteem and Carina devices, which are active middle ear implants.
- Patients must undergo computed tomography imaging of the temporal bone and comprehensive audiometric testing to determine implant eligibility.
- Patients who cannot tolerate, are unsatisfied, or show no improvement with conventional hearing aids are candidates for the both devices.
- Clinical studies have noted either superior or similar hearing results when compared to conventional hearing aids.

INTRODUCTION

Hearing loss is the most commonly reported sensory deficit.[1] In fact, 1 out of every 5 individuals 12 years of age or older within the United States have a unilateral or bilateral hearing deficit.[2,3] To combat hearing loss, medical devices such as hearing aids are often used to amplify sound, compensating for any deficits along the auditory pathway. In the United States, an estimated 14.2% of individuals with hearing loss

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at or older than 50 years use hearing aids.[4] Hearing aids can bypass conductive middle ear disease through the amplification of sound. In addition, hearing aids can help patients with sensorineural hearing loss (SNHL) by providing amplified sound waves to the remaining hair cells within the inner ear.

Although hearing aids may improve hearing in certain patients, only approximately 30% of patients with hearing loss in the United States use hearing aids.[5] One factor for the lack of hearing aid utilization is device cost. Private and public insurance companies rarely cover hearing aids, leaving the patient to pay at costs often in the thousands of dollars.[6] Furthermore, patients may not use hearing aids due to replacement battery costs, cosmetic appearance of the hearing aid, no perceived need, or increased background noise.[7] In addition to hearing aids, other devices such as cochlear implants are often reserved for patients with severe hearing loss. Thus, although hearing aids are often used for patients with mild to moderate hearing deficiencies and cochlear implants are used for patients with severe to profound hearing deficiencies, fewer options are available for patients with moderate to severe hearing loss. One emerging option is the use of active middle ear implants. The Esteem by Envoy Medical and the Carina system by Cochlear are the only 2 totally implantable active middle ear implants currently available for patients worldwide. Although the Esteem and the Carina system have been previously discussed, recent updates regarding their use remain limited. Therefore, an updated summary of both the Esteem and Carina and their use for the treatment of hearing loss are described.

THE ESTEEM: DEVICE SUMMARY

The Esteem is a nonrechargeable battery-powered implantable hearing device consisting of a sensor, driver, and battery-powered sound processor (**Fig. 1**). The sensor is composed of a piezoelectric transducer, which is attached as a neojoint to the body of the incus. Of note, the Esteem procedure requires partial ossicular chain disruption, which allows for the sensor and driver to be cemented to their correct structures. As sound enters the external auditory canal creating movement of the tympanic membrane, malleus, and incus, the sound energy is transferred to the piezoelectric transducer, which is cemented to the incus body. The sensor transmits this signal to the battery-powered sound processor, which is implanted within the mastoid cavity. The sound processor receives, adjusts, and intensifies sound signals. Thereafter, each sound signal is sent through another piezoelectric transducer known as the "driver," which is cemented to the capitulum of the stapes. This driver translates

Fig. 1. The Envoy device. (*Courtesy of* Envoy Medical Corporation, White Bear Lake, MN; with permission.)

signals from the sound processor into vibrations as it vibrates the stapes against the oval window of the inner ear. Sound vibrations then proceed through the normal cochlear pathway transmitting sound signals to the brain.

THE ESTEEM: PATIENT ELIGIBILITY

Patients with bilateral moderate to severe SNHL who are 18 years of age or older are eligible to be implanted with the Esteem. Eligible patients should have had at least 30 days of experience with customized and properly fitted hearing aids. Patients should have an unaided speech discrimination score of greater than or equal to 40%. Patients additionally must have normal middle ear anatomy, normal eustachian tube function, and normal tympanic membrane function. Patients must have adequate space within the mastoid cavity to fit the Esteem, and thus all eligible patients must undergo a high-resolution computed tomography (CT) scan before the procedure. The cost for the Esteem device and procedure ranges from approximately $30,000 to $45,000. To date, most insurers have not provided reimbursement for the Esteem, and thus each patient must budget accordingly.

There are several contraindications for the implantation of the Esteem. Adult patients with chronic ear diseases such as chronic middle ear infections, cholesteatoma, mastoiditis, recurrent vertigo, Meniere disease, or fluctuating conductive hearing loss are not eligible to be implanted with the Esteem. In addition, patients who have a history of keloid formation; those with chronic wound healing issues; or those with hypersensitivities to silicone rubber, polyurethane, stainless steel, titanium, and/or gold are not recommended for implantation. As general anesthesia is required for this procedure, adequate preoperative overall health to undergo a surgical procedure is required.

THE ESTEEM: PREOPERATIVE ASSESSMENT

Patients who are eligible to be implanted with the Esteem need to be evaluated preoperatively. Surgical clearance from appropriate health care providers must be obtained before surgery. Furthermore, a surgical consent must be provided to each patient, with an adequate discussion of the risks and benefits of the Esteem procedure. Realistic expectations must be considered, and the patient must have an understanding that the Esteem may not lead to expected improvements in hearing function. Memari and colleagues'[8] prospective nonrandomized trial of 10 Esteem-implanted patients described that 2 out the 10 implanted patients did not show any hearing improvements on pure tone audiometry. Patients must be also aware of the adverse events that may happen from implanting the Esteem device. During the surgery, damage to nerves, ossicles, or other surrounding structures may occur. In addition, since the ossicular chain is being disrupted, if the device requires an explantation, a patient may experience possible hearing loss requiring additional surgery. As with any surgical procedure, risks of bleeding, infection, dizziness, vertigo, taste abnormalities, facial paralysis, and tympanic membrane perforation must be discussed with the patient.

Preoperative Computed Tomography Imaging

A preoperative CT scan must be obtained to provide the surgeon with key anatomic information to determine if the implant will fit within the mastoid cavity and provide enough space and proper angles for sensor and driver placement. Anatomic measurements or landmarks including the width of the facial recess area, the distance from the sigmoid sinus to the stapes, the sigmoid sinus anatomic location, and the distance from the tegmen to the superior ear canal need to be assessed. Of note, the distance from the sigmoid sinus to the stapes should exceed 22 mm.[9] The surgeon must

additionally assess the anatomic orientation and landmarks of the temporal and parietal bones to make sure the battery-powered sound processor will fit into the temporal bone cavity.

THE ESTEEM: SURGICAL TECHNIQUE

The patient is placed in the supine, head-turned, position. General anesthesia is induced without paralytics as the facial nerve is monitored during the surgery. The patient's head is supported via a foam head rest with the operative ear facing upwards. A facial nerve monitor is placed and its proper function is verified. A microphone that is to be used during the laser Doppler vibrometry portion of the procedure is inserted into the external ear canal. The surgical field is then prepared and draped.

A postauricular incision is created and anterior and posterior flaps are made over the musculofascial layer. Once the mastoid cortex is exposed, a bony trough is drilled out posterior to the mastoid to recess the battery-powered sound processor. A wide mastoidectomy is performed. A posterior epitympanectomy is then performed exposing the head of the malleus and the incus via a wide facial recess approach (**Fig. 2**). Of note, exposure of the long process of the incus and posterior crus of the stapes must be achieved. The facial recess is then extended leading to the identification of the fibrous annulus. The chorda tympani nerve is often resected because it can impinge on the driver and may cause feedback. The incus and stapes are thereafter assessed for any abnormalities and any adhesions that may need to be removed.[9] The incus and stapes are then assessed for mobility via the use of laser Doppler vibrometry.

Laser Doppler Vibrometry

To assess for adequate ossicular movement of the incus and stapes in response to auditory stimulation, laser Doppler vibrometry is used to determine if the patient's ossicular chain will provide adequate movements to ensure a successful outcome. Before the start of the procedure, a microphone is placed within the ear canal that is used for auditory stimulation in conjunction with laser Doppler vibrometry. Once the mastoid cortex is exposed, auditory stimulation is sent through the ear canal via the microphone at the level of 100 dB across 50 different frequencies. Displacement of the ossicular chain is measured via laser Doppler vibrometry. Laser Doppler vibrometry is noted to be very accurate ($<1 \times 10^{-4}$ μm) and thus is suited to measure microscopic changes in vibratory motion as noted within the ossicular chain.[10] Extreme hypomobility of the incus or stapes is a reason to discontinue the surgery.

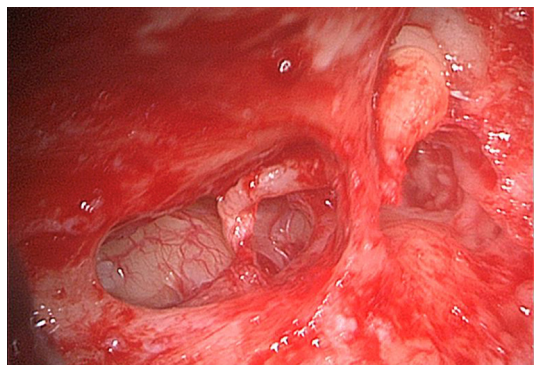

Fig. 2. Middle ear window.

Provided laser Doppler vibrometry demonstrates adequate movement of the incus and stapes, the incudostapedial joint is separated. The long process of the incus is resected using a diode laser (Fig. 3). Moist Gelfoam is recommended during this process to prevent exposure of adjacent structures and provide cooling within the middle ear. Once the distal segment of the long process of the incus is removed, the stapes capitulum and neck of the stapes is freed of mucosa and dried with a laser. Glass ionomeric cement (Envoycem) is then applied to the stapes capitulum and neck. The piezoelectric sensor and driver are brought onto the sterile field. They are attached to a Glasscock stabilizer to facilitate manipulation (Fig. 4). The sensor tip is then inserted into the epitympanum lateral to the incus body, whereas the driver tip is inserted parallel to the stapes crura lateral to the stapes capitulum[9] (Fig. 5). Hydroxyapatite cement (Medcem) is applied around the sensor and driver bodies to fix the transducer bodies to the mastoid. Ionomeric cement is additionally applied to both the sensor and the driver tips. The surgeon must wait for both the hydroxyapatite and ionomeric cements to harden before proceeding (Fig. 6). The mastoid and middle ear are then irrigated with saline and suctioned. Thereafter, the sensor and driver are tested via laser Doppler vibrometry. The sensor and driver are connected to the sound processor, and the system is activated. Laser Doppler vibrometry is then used again to measure the displacement of the incus and stapes with the Esteem system fully activated.[11] If the system is correctly functioning, the device is turned off. The surgical wound is then closed in layers, and appropriate dressings are applied.

THE ESTEEM: SURGICAL AND POSTOPERATIVE COMPLICATIONS

Given the complexity and intricacy of this surgical procedure, several surgical complications may occur. To begin with, when entering the mastoid cavity, damage to surrounding structures such as the tegmen, sigmoid sinus, and facial nerve may occur. Furthermore, before reaching the ossicular chain, damage to the ear canal or tympanic membrane may occur. Given that this procedure involves ossicular chain disruption via a laser, heat injury to surrounding structures such as the tympanic segment of the facial nerve can occur. In addition, because the incus and stapes are being manipulated, injuries such as dislocation or increased mobility to the ossicular chain bones can occur.

When applying the sensor and driver tips to the incus and stapes respectively, any slight malpositioning of these tips may lead to a device malfunction or inadequate

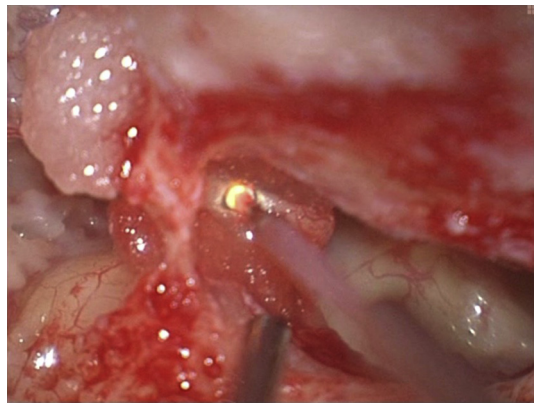

Fig. 3. Resection of the incus with a diode laser.

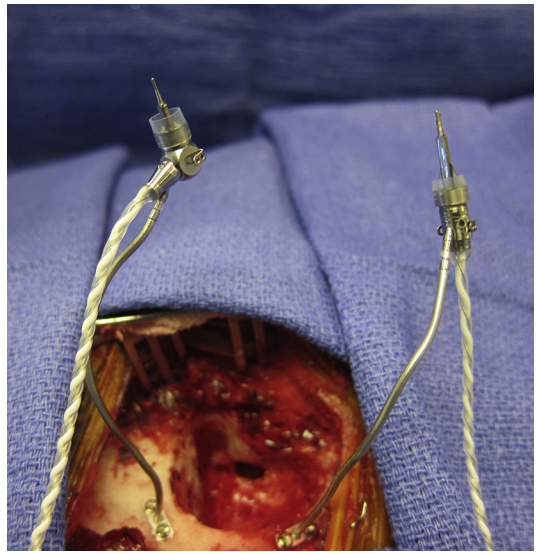

Fig. 4. Attachment of sensor and driver to the stabilizers.

response of the device. Furthermore, although cement is used to anchor these tips to their respective ossicular bones, cement fractures may occur in which additional cement may need to be applied intraoperatively. Postoperatively, if either tip from the sensor or driver becomes loose, the patient may require a revision surgery. Shohet and colleagues'[12] 5-year longitudinal study of Esteem-implanted patients noted a revision rate of 9.8%. Postoperative infections requiring explantation of the device, although possible, are extremely uncommon with rates noted to be 2.0%.[12]

Shohet and colleagues'[13] retrospective case review examined surgical complications, adverse events, and outcomes of 166 patients implanted with the Esteem. Taste disturbance was the most common adverse event occurring in 39.3% of Esteem patients. Three patients experienced a delayed facial paralysis with complete recovery. One patient (0.6%) had a traumatic injury to the facial nerve during the placement of the stabilizer bar due to a slipping of the screwdriver, which directly injured the facial nerve through the mastoidectomy defect. The facial nerve required proximal and distal

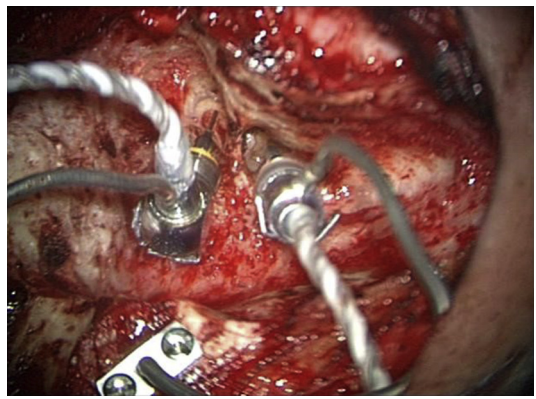

Fig. 5. Sensor and driver placement.

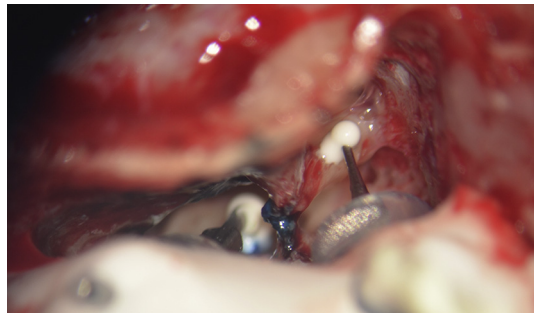

Fig. 6. Sensor and driver bodies fixated in mastoid with hydroxyapatite cement and tips cemented to incus body and stapes capitulum using glass ionomeric cement.

decompression. The patient experienced full facial nerve paralysis postoperatively with eventual recovery at 1 year to House-Brackmann II/VI. In this study, 15.7% of patients underwent revision surgery, with excess feedback occurring in 4.8% of patients, signal intermittency in 2.4% patients, and wound healing issues/excess scar tissue occurring in 4.2% of patients; 1.8% of patients underwent revision surgery after receiving minimal benefit from the device; 4.0% of patients underwent explantation of the device, with 1.8% of patients undergoing explantation for lack of perceived benefit.

THE ESTEEM: POSTOPERATIVE FOLLOW-UP

This procedure is usually performed on an outpatient basis. Patients are typically given a dose of preoperative antibiotics and another dose before discharge. They are seen 1 to 2 weeks postoperatively to check the incision site for any signs of infection, dehiscence, or hematoma. A serosanguinous effusion may occur within the middle ear that should resolve in 4 to 8 weeks. Once signs of effusion are absent, the device may be activated (usually 8 weeks postoperatively) at the first postoperative audiology appointment. Patients are then seen periodically in an effort to achieve maximal gain. Audiologists and technicians can additionally adjust the device if issues within the system arise.

THE ESTEEM: POST-IMPLANT CONTRAINDICATIONS

Previously, it was recommended that patients who were implanted with the Esteem should avoid receiving any magnetic resonance imaging (MRI). However, the Esteem device recently received conditional approval for the use of MRI. Providers should monitor for updates from the Food and Drug Administration (FDA) regarding future recommendations for the use of MRI in patients implanted with the Esteem. Furthermore, if an implanted patient undergoes any additional operations near the surgical site, the use of monopolar electrocautery should be avoided; however, if the patient is having surgery in the chest cavity or below and the ground is placed on the thigh, monopolar cautery theoretically should be safe, although bipolar cautery could be considered more prudent. Patients should notify their surgeon of the Esteem implant before undergoing any other procedures.

THE ESTEEM: BATTERY LIFE OF THE SOUND PROCESSOR

The Esteem system is powered by a nonrechargeable lithium battery. The expected battery life of the Esteem device may range from 4.5 years to 9 years depending on

the frequency of use.[14] Of note, Shohet and colleagues'[12] 5-year longitudinal study of Esteem patients noted an average battery life of 4.9 years. Thus, the patient must understand that once the battery is depleted, another procedure is required to insert a new battery into the system. This battery replacement can be done under local or general anesthesia.[15] Furthermore, patients must be aware of the potential risk of a device malfunction of the battery requiring a replacement earlier than the expected battery life range.

THE ESTEEM: PROGRESSION OF HEARING LOSS

Patients may experience progression of their hearing loss leading to reduced effectiveness of the Esteem device. Otolaryngologists are discouraged from off-label implantation of the Esteem for patients with severe to profound SNHL because no perceived benefit may be noted by the patient. Patients with bilateral severe to profound SNHL should instead be considered candidates for cochlear implantation.[16] If patients who are implanted with an Esteem continue to progress with their hearing loss and are classified as severe to profound, the Esteem device may no longer be satisfactory and could be removed and replaced with a cochlear implant if they meet FDA criteria.

THE ESTEEM: CLINICAL RESULTS

In the earliest efficacy study with the original Esteem implant, Chen and colleagues[17] in 2004 implanted 7 patients, with 5 patients having a working system at the 2-month activation period. At 4 months postactivation, the functional gain of those implanted with the Esteem was 20 dB as compared with 17 dB with hearing aids. Slight improvements in speech reception thresholds (SRT) for patients implanted with the Esteem were noted as compared with each patient's best-fit hearing aid. Regarding word recognition scores (WRSs) at 50 dB, an improvement of 17% was noted after the implantation of the Esteem as compared with hearing aid conditions. Of the 7 implanted patients, 3 patients noted benefits at device activation, and 4 patients did not experience any benefit, with 3 undergoing revision surgeries in which 2 were successful.

Barbara and colleagues[18] in 2008 implanted 6 patients, with 3 patients having the device activated. The average surgical time for the procedure was 5 hours and 45 minutes (range: 3 hours and 50 minutes to 8 hours and 10 minutes). The mean (250–4000 Hz) actual hearing gains compared with the preoperative thresholds were 26 dB, 9 dB, and 11 dB.

Kraus and colleagues' prospective nonrandomized multiinstitutional phase II trial from 2008 to 2009 led to the implantation of 57 patients. Regarding SRTs, improvements compared with each patient's best-fit aid conditions were noted with the activation of the Esteem (mean best-fit aid speech threshold: 41.2 dB, 12-month post-Esteem implant: 29.4 dB [$P \leq .001$]). In addition, improvements in WRSs at 50 dB were noted at 12 months postoperatively (mean best-fit aid score preimplant: 46.3%, mean 12-month post-Esteem: 68.9%). Finally, pure tone averages for post-Esteem–implanted patients improved by 27 dB (± 1, 95% CI: 25–30). Of the 57 implanted patients, 6 patients were noted to have severe adverse events. Of these 6 patients, 3 revisions were completed due to fibrosis, which limited transducer functioning; 2 patients developed postoperative wound infections, which led to an explantation in one patient; and 1 patient noted delayed facial paralysis with a full functional surgical recovery.[19]

Memari and colleagues'[8] prospective nonrandomized trial led to the implantations of 10 patients with an Esteem from 2007 to 2009. The surgical time for the first 2 cases

was roughly 7 hours each, whereas each of the last 2 cases took roughly 4 hours. Hearing gains were noted to be similar to conventional hearing aids (10–22 dB), although 2 out of 10 implanted patients did not show any improvements in hearing gain on pure tone audiometry; overall, patients in this study noted subjective improvements in hearing quality. Of the 10 patients, one patient experienced facial weakness without any hearing improvements and thus was explanted. Another patient underwent successful revision surgery due to excessive postoperative middle ear bone growth.

Barbara and colleagues'[20] study published in 2011 described 21 implanted patients, with 3 having mild hearing loss, 9 having moderate hearing loss (MHL), and 9 having severe hearing loss (SHL). Postoperative air conduction thresholds improved from 70 dB (preoperatively) to 48 dB for the total cohort, from 64 dB (preoperatively) to 42 dB for the MHL cohort, and from 82 dB (preoperatively) to 58 dB for the SHL cohort. The mean speech reception score at threshold levels of 60 dB (MHL) and 75 dB (SHL) increased from 42% to 79% of intelligibility for the MHL group and from 30% to 72% for the SHL group.

Gerard and colleagues'[21] study published in 2012 described 13 Esteem-implanted patients from 2008 to 2010. Postoperatively, the mean pure-tone average gain was 25 $\pm$ 11 dB. The mean word recognition score at 50 dB was 64 $\pm$ 33%. Using the abbreviated profile of hearing aid benefit questionnaire, 84% of patients noted device satisfaction compared with their previously used conventional hearing aids. Five minor complications occurred, including 1 temporary facial nerve palsy, 1 secondary hearing loss, and 3 revision surgeries due to poor device function. Two patients suffered major complications requiring explantations, with both being postoperative wound infections.

Monini and colleagues'[22] retrospective study published in 2013 evaluated 15 patients who were implanted with an Esteem device. The patients were divided into 2 groups: moderate to severe SNHL (group A) and severe-to-profound SNHL (group B). Both groups were assessed without the use of any hearing aid, with the use of a conventional hearing aid, and with the Esteem implant. Significant improvements in SRTs and WRS were noted when assessing unaided values as compared with Esteem values. However, when comparing the Esteem values against conventional hearing aid values, no statistically significant differences in SRTs or WRS were noted. Esteem patients in this study noted dissatisfaction with conventional hearing aids due to several factors, including aesthetic appearance, ear canal infections, inability to wear the hearing aid at night, and interference with leisure or sporting activities. These quality of life measures were noted by patients as reasons to be implanted with the Esteem. Thus, Monini and colleagues' study noted that for patients who are dissatisfied with conventional hearing aids, the Esteem implant can offer similar improvements in hearing, with additional improvements in quality of life measures and patient compliance.

Shohet and colleagues'[12] publication enrolled 51 patients who were previously involved in their 2008 to 2009 phase II trial in a longitudinal study evaluating hearing outcomes at the 5-year mark. Forty-nine out of the 51 enrolled patients had follow-up data at the 5-year endpoint. Compared with baseline-aided conditions, SRTs improved at every annual follow-up for patients implanted with the Esteem. WRS at 50 dB were improved in 49% of patients and similarly in 41% of patients at the 5-year follow-up. WRS improved by 17% at the 5-year follow-up. Finally, the average battery life was 4.9 years. Of note, 5.8% of patients required explantation (1 being due to poor performance).

Shohet and colleagues'[13] retrospective case review in 2018 examined 166 patients with SNHL who were implanted with the Esteem from 2004 to 2015. Both the Esteem

device and baseline hearing aids provided improvements in gain compared with the unaided. At both 1500 and 2000 Hz, the amount of gain was significantly greater for Esteem patients as compared with baseline-aided patients, $P<.001$. Compared with baseline-aided conditions, SRTs were significantly improved for patients implanted with the Esteem (29.9 dB vs 38.5 dB, $P<.001$). WRS at 50 dB was significantly superior in Esteem patients as compared with baseline-aided patients (65.6% vs 45.5%, $P<.001$).

THE CARINA SYSTEM: DEVICE SUMMARY

Originally developed by the Otologics company and later purchased by Cochlear Corporation, the Carina system is a fully implantable hearing prosthetic device for patients with moderate to severe SNHL or those with mixed hearing loss. The Carina system may also be used in patients with ossicular chain defects in which ossiculoplasty is not indicated or unsuccessful.[14] The Carina system consists of a microphone, rechargeable battery, magnet, sound processor, actuator, and transducer (**Fig. 7**). The transducer may be placed on the body of the incus, the stapes, the oval window, or the round window through the use of modified extensions.[23] The Carina system also includes an external charger, which charges the device through magnetic contact, as well as a remote control, which allows the user to adjust the volume and power of the device.[23] The Carina system is currently not available within the United States; however, it is available in Europe, the Middle East, and Africa.

THE CARINA SYSTEM: DEVICE OUTCOMES AND COMPLICATIONS

Compared with unaided patients, patients with the Carina system have been noted to experience a mean functional gain of 24 dB,[23] 26.4 dB,[24] or 29 dB.[25] In addition, WRS were significantly improved for Carina patients as compared with their unaided condition.[25] Compared with conventional hearing aids, no significant differences in increased functional gain or WRS were observed for patients with the Carina system implant according to Kam and colleagues.[26] However, increased perceived benefit

Fig. 7. The Carina system. (*Courtesy of* Cochlear Limited, © 2018. The Cochlear Carina System is not approved by the FDA for use in the United States. Cochlear and Carina are either trademarks or registered trademarks of Cochlear Limited, Sydney, Australia.)

was noted for patients implanted with the Carina system as compared with those with conventional hearing aids in Kam and colleagues' study, likely due to the "cosmetically appealing" design of the device.[26] Furthermore, Lefebvre and colleagues[27] described threshold levels for frequencies greater than 3 Hz were similar for Carina-implanted patients as compared with those with conventional hearing aids. Bruschini and colleagues[23] noted patients implanted with the Carina system expressed satisfaction with the device due to its cosmetic appealing design and ability to perform daily activities with less hindrance. Complications have been previously noted for patients implanted with the Carina system device. In 2008, Jenkins and colleagues' study of 20 patients identified ear fullness, middle ear effusion, vertigo, tinnitus, and conductive hearing loss as possible complications of the Carina system implant. In addition, Martin and colleagues'[25] study of 11 patients had 2 patients who experienced postoperative infections.

THE ESTEEM AND THE CARINA SYSTEM: SUMMARY

The Esteem is a battery-powered device designed for patients with bilateral moderate to severe SNHL who have an unaided speech discrimination score of greater than or equal to 40%. Patients who cannot tolerate, are unsatisfied, or show no improvement with conventional hearing aids are ideal candidates for the Esteem device. Furthermore, patients must undergo CT imaging of the temporal bone to identify candidates who will have a successful implantation for the Esteem. Because of the complexity of this procedure, the operation may take several hours. However, postoperative hospital stay is usually not required. Clinical studies have noted either superior or similar hearing results as compared with conventional hearing aids. Of the studies that noted similar results in comparison to conventional hearing aids, patients subjectively reported improvements in hearing as well as noted improvements in their quality of life. Although more expensive than conventional aids, the Esteem offers patients with bilateral moderate to severe SNHL another opportunity to experience improvements in hearing and lifestyle. The Carina system is a battery-powered device designed for patients with moderate to severe sensorineural hearing loss or those with mixed hearing loss. Furthermore, the Carina system offers patients the ability to charge their device externally as well as control the device via an external remote. The Esteem is currently available in the United States, whereas the Carina system is currently available only in Europe, the Middle East, and Africa.

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