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# Neuromodulation Systems in the Setting of Cochlear Implant Treatment Based on Case Reports and Literature Review

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## ABSTRACT

**Objectives:** Cochlear implants are an established and proved method for auditory rehabilitation. In addition, neuromodulation systems for treating severe movement and pain disorders are gaining importance. To date, there is limited information regarding the concurrent use of the various implanted systems and potential electromagnetic interferences.
In this case series, we assess the simultaneous use of cochlear implants and neuromodulation systems such as deep brain stimulation (DBS), occipital nerve stimulation (ONS) and peripheral nerve field stimulation (PNFS) on the basis of three retrospectively investigated case reports from our clinic.

**Materials and Methods:** Case 1 is a patient aged 30 years with preexisting DBS system (Medtronic Activa RC, Medtronic, Dublin, Ireland) for idiopathic dystonia, who underwent cochlear implantation for severe-to-profound hearing loss. Cases 2 and 3 are patients aged 72 and 57 years, respectively, with cochlear implants in whom a neuropathic pain syndrome developed postoperatively. After unsuccessful medical and physiotherapeutic therapy, implantation of an ONS stimulator (Nuvectra-Algovita system, Plano, TX) and a permanent PNFS system with two periauricular electrodes (Boston Scientific WaveWriter R16, Marlborough, MA) was performed.

**Results:** In all three cases, the fitting parameters of the cochlear implant and the postoperative hearing impression were not affected. In the first case, the patient achieved speech understanding of 65% at 65 decibels sound pressure level (dB SPL) in the Freiburg monosyllabic test three months after surgery. In the second and the third case, speech comprehension remained good after ONS and PNFS intervention. DBS stimulation could be continued without complications and the occurrence of neurologic symptoms. Furthermore, a good and long-term reduction in pain intensity was achieved by implanting the ONS stimulator and the PNFS system.

**Conclusion:** This case series shows that the simultaneous use of cochlear implants and other neuromodulation systems seems possible without complications and disruptive interactions.

**Keywords:** Cochlear implant, deep brain stimulation, electromagnetic interferences, occipital nerve stimulation, peripheral nerve field stimulation

## INTRODUCTION

Cochlear implants (CI) are an established and proved method for auditory rehabilitation.[1] According to the World Health Organization, approximately 5% of the global population is affected by hearing loss. Among them, approximately 950,000 individuals have received a CI. In Germany, approximately 60,000 of an estimated 1 million potential candidates for CI have undergone implantation.[1,2] In addition, neuromodulation systems for treating severe movement and pain disorders are gaining importance.[3] Thus, deep brain stimulation (DBS) is a neurosurgical intervention used for conditions such as Parkinson's disease, idiopathic dystonia, and essential

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tremor when medications are no longer effective.[4] Research also is ongoing into treatments for severe psychiatric conditions such as obsessive-compulsive disorder and depression.[5] In addition, the US Food and Drug Administration (FDA) has approved DBS for treating drug-resistant epilepsy to reduce seizure frequency in adults.[6] Occipital nerve stimulation (ONS) and peripheral nerve field stimulation (PNFS) are used in managing neuropathic pain syndromes.[7]

This implies that the indications for the performance of neuromodulation systems have significantly broadened in recent years.[8] Simultaneously, the supply of CIs continues to increase in proportion to the increasing life expectancy.[1] It is expected that a greater number of patients will require treatment with multiple systems in the upcoming years.

To date, there is limited information regarding the concurrent use of the various implanted systems and potential electromagnetic interferences (EMI). Device manuals for neuromodulation systems typically detail possible risks of EMI. In the USA, manufacturers must report these EMI sources to the FDA, whereas adverse events can be reported by healthcare professionals and consumers through the Manufacturer and User Device Facility Experience (MAUDE) data base. Similarly, in Europe, both manufacturers and users are required to report issues, with Germany using the Federal Institute for Drugs and Medical Devices (BfArM) for risk notifications.[9–11]

In literature, only a few cases of patients receiving sequential treatment with a CI and a DBS system have been described.[12–15] Whether the implanted systems with different stimulation strategies interact with each other and operate without complications in all situations remains unclear. At the same time, clinical reports addressing the management of chronic neuropathic pain in patients with CI who have not responded to conservative therapy regimens remain scarce.

## CASE SERIES

The parallel use of CIs and neuromodulation systems such as DBS, ONS, and PNFS is presented based on three retrospectively investigated case reports from our clinic.

The study was approved by the ethics committee of the Medical Faculty of the Heinrich Heine University Düsseldorf on June 7, 2024 (approval number 2024-2909) and accorded with the Declaration of Helsinki of 1975, as revised in 1983.

### Case 1: Right CI With Bilateral DBS

Material and Methods

A patient aged 30 years with idiopathic dystonia and severe-to-profound hearing loss presented at our clinic for cochlear implantation of the right ear. After the initial manifestation, idiopathic dystonia was treated with botulinum toxin and baclofen over a period of five years. Owing to the absence of symptomatic improvement, a DBS system (Medtronic Activia RC, Medtronic, Dublin, Ireland) with stimulation electrodes in the globus pallidus on both sides was subsequently implanted. The implantable pulse generator (IPG) was positioned subcutaneously on the fascia of the pectoralis major muscle. To date, the patient's movement and coordination disorders have been well-controlled, and a stable therapeutic effect has been observed overall.

Given treatment with conventional hearing aids was no longer sufficient owing to the progression of hearing impairment, cochlear implantation was recommended. For surgical planning, an evaluation of magnetic resonance imaging (MRI) compatibility was conducted preoperatively. The DBS implant was deactivated, and specific manufacturer guidelines for the DBS implant were provided for the examination. With regular anatomy confirmed by imaging, the cochlear implantation (Mi1200, Flex 28, MED-EL, Innsbruck, Austria) of the right ear was successfully performed.

Results

In the first case, the patient was supplied with a CI of the right ear with the DBS system deactivated under operation to prevent potential interferences with the neuromonitoring recordings. Standard intraoperative measurements were conducted to assess CI function, including electrode placement and impedance. Specifically, this implies that stapedius reflexes, auditory nerve response telemetry (ART), and impedance measurements were performed without complications and yielded no abnormal results. In addition, the position of the CI electrodes was verified using intraoperative digital volume tomography (DVT), which is shown in Figure 1. After the procedure, the DBS system was reactivated without any impairment due to the intervention. Notably, there were no adverse effects of the DBS system on CI adjustment. The fitting parameters of the CI remained unaffected during the initial fitting process. All patient-specific settings could be effortlessly adjusted with the DBS system now activated, without encountering any complications. Table 1 lists the various stimulation parameters of the DBS system and the CI of the patient.

Clinically, the patient achieved speech understanding of 65% at 65 decibels sound pressure level (dB SPL) in the Freiburg monosyllabic test three months after surgery. At the same time, DBS stimulation could be continued without complications and the occurrence of neurologic symptoms.

### Case 2: Right CI With Ipsilateral ONS

Material and Methods

A patient aged 72 years was initially successfully treated in our clinic with a CI (Cochlear CI 512 Contour Advance, Cochlear, Sydney, Australia) on the right side owing to severe-to-profound hearing loss. However, shortly after the CI was fitted, pain developed in the distribution area of the patient's occipital nerve in the sense of a causalgia, which progressively worsened over the

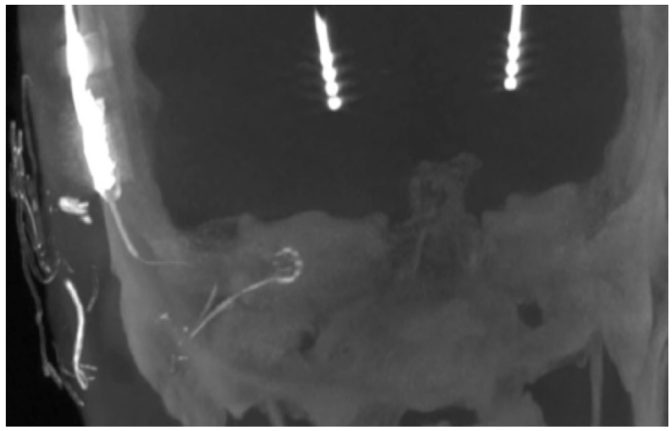

**Figure 1.** Reconstruction of the intraoperative DVT-data set after cochlear implantation. CI unit and electrode, DBS electrodes intracranial (from left to right).




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**Table 1.** Overview of the Stimulation Parameters of the DBS System and the CI of the Patient.

| | | | | |
|---|---|---|---|---|
| DBS (Medtronic Activia RC): | | | | |
| GPi left 1 | 4.1V | 210 μs | 125 Hz | Therapeutic impedance 1008 Ω |
| GPi left 2 | 0.9V | 210 μs | 125 Hz | Therapeutic impedance 1597 Ω |
| GPi right 1 | 1.6V | 120 μs | 125 Hz | Therapeutic impedance 1215 Ω |
| GPi right 2 | 0.9V | 120 μs | 125 Hz | Therapeutic impedance 1100 Ω |
| CI MED-EL (Mi1200, flex 28): | | | | |
| Biphasic | 2.08 μs | Logarithmic | 100–8500 Hz | |

GPi, internal segment of the globus pallidus.

upcoming months and did not respond to physiotherapy and medical treatment. Owing to the patient's multiple allergies to local anesthetics, local infiltration anesthesia could not be applied successfully. MRI diagnostics were limited on this side. The magnet was not removed because, in our opinion, there were no clinically serious suspicions that would justify this intervention. Computed tomography (CT) findings showed neither signs of alteration in the bone around the implant nor any other findings that could have explained the pain syndrome. After extensive consultation with the patient, we decided to have an ONS stimulator implanted by our neurosurgery colleagues eight months later. The patient was surgically treated with a Nuvectra-Algovita system (Nuvectra, Plano, TX). Two stimulation electrodes were placed subcutaneously toward the right mastoid and one electrode toward the first cervical segment. The IPG also was placed in a subcutaneous pocket in the pectoral region.

Results

In the second case, implanting the ONS stimulator also was complication free despite the presence of the preexisting CI. The postoperative follow-up was unremarkable, and no new deficits occurred. With physiotherapeutic support and adequate pain management, the patient was able to be mobilized without any problems. Four weeks postoperatively, the ONS system was activated. In comparison with the intraoperative assessment, no differences were observed in the impedance levels and ART measurements despite the ONS stimulator being activated.

### Case 3: Bilateral CI With Ipsilateral PNFS

Material and Methods

In a patient aged 57 years bilaterally supplied with CIs (Cochlear CI 612 Contour Advance) owing to profound hearing loss on both sides, severe retroauricular pain in the area of the left CI developed four weeks postoperatively, in the sense of a neuropathic pain syndrome. On this side, there is a history of multiple surgical interventions on the tympanic membrane and mastoid cavity. In summary, the patient was unable to wear a hearing aid on the left side owing to recurrent ear canal infections caused by occlusion of the ear canal with ear molds and to the predisposition to diabetes mellitus. However, with progressive hearing loss, the existing BAHA attract system (Cochlear, Sydney, Australia) on the left side no longer provided sufficient benefit. Therefore, the implantation of a CI was the only option to rehabilitate hearing in the left ear. In addition, the patient had already benefited greatly from the CI on the right side. Owing to chronic otitis media with persistent tympanic membrane perforation and multiple tympanoplasties, a subtotal petrosectomy with obliteration of the middle ear was performed in preparation for the CI. The neuropathic pain syndrome was therefore attributed to postoperative scar tissue resulting from multiple surgeries around the left ear. Despite medical and physiotherapeutic treatments, the patient continued to experience intense pain in the area of the CI implantation. Systemic pain medication could not be sustained at a high enough dose to effectively alleviate the pain in this relatively small area. However, local infiltration anesthesia provided reliable short-term relief. The positive response to the infiltrations suggested a favorable outcome with PNFS. After outpatient PNFS testing, a permanent PNFS system with two periauricular electrodes (Boston Scientific WaveWriter R16, Marlborough, MA) was implanted by our neurosurgery colleagues 33 months later. The system applies PNFS to the terminal branches of the greater and lesser occipital nerves in addition to the greater auricular nerve. As in the first two cases, the IPG was implanted pectorally.

Results

Similarly, in the third case, there were no interactions with the CI after the PNFS implantation, and the postoperative course was without complication. The radiologic examination confirmed the proper placement of the electrodes. Tables 2 and 3 show the various stimulation parameters of the ONS and PNFS system and the CIs of the patients, respectively.

Clinically, speech comprehension remained good, and the subjective hearing impression was unchanged after the ONS and PNFS interventions, as exemplified in Figure 2. The initial setting of the PNFS system caused a good and long-term reduction in pain intensity on the visual analog scale from 8 of 10 to 4 of 10 with a positive stimulation effect.

## DISCUSSION

There are only limited data of patients with both a CI and another neuromodulation system. To date, these reports have primarily focused on simultaneous treatment with a CI and a DBS system. Clinicians must be aware of the risk of EMI.[11] Medtronic notes potential interactions between DBS systems and devices such as cardiac pacemakers, defibrillators, and CIs.[16] To prevent direct EMI between these different devices, manufacturers have implemented distance recommendations. For instance, a separation of ≥15 cm (6 inches) is advised between a CI and a pacemaker.[17] However, there are currently no well-established distance guidelines concerning CIs and other neuromodulation systems, including DBS. Despite distance restrictions, all devices must be in proper working condition and used as intended.[16,17]

Various cases are described in which complications occurred when the DBS system was exposed to high-energy electromagnetic fields.[18,19] Although these risks exist, our case report of a patient with a preexisting DBS system who underwent cochlear implantation indicates that the simultaneous use of both systems is feasible and safe and seems possible without complications and disruptive interactions. This aligns with prior findings of several reports highlighting successful implantations of both implanted




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**Table 2.** Overview of the Stimulation Parameters of the ONS System and the CI of the Patient.

| | | |
|---|---|---|
| ONS (Nuvectra Algovita): | | |
| Frequency 50 Hz | Pulse width 360 μs | Max 1.35 mA |
| CI Cochlear (CI 512 Contour Advance): | | |
| Biphasic | ACE | Per channel 900 Hz |

ACE, advanced combination encoder.

systems. De Los Reyes et al documented a case in which a patient with a preexisting CI underwent DBS implantation. The authors observed no significant EMI and noted improved clinical outcomes.[12] Moreover, Buell et al showed that in their patients, there were no adverse effects indicating EMI between the CI and DBS electrodes.[13] Eddelman et al documented a case of a patient with concurrent DBS and CI implantation, highlighting the importance of individualized surgical planning to avoid complications.[14] This also is illustrated by the working group led by Bolier et al who presented a surgical technique and workflow for DBS surgery in patients with preexisting CIs. The authors emphasize the safety and feasibility of these procedures when appropriate precautions are taken.[15] Furthermore, our case report indicates that both systems can operate simultaneously within their specifications, despite differing stimulation strategies, without mutual interferences. Generally, the risk of interferences is minimized when both systems are set to bipolar configurations.[11] This accords with other reports, eg, on the simultaneous use of DBS systems and pacemakers. The lack of interferences is due to the small electrical field used for stimulation and the compact size of the sensing circuit.[20]

In this context, MRI compatibility also is becoming increasingly significant during surgical planning. Strong magnetic fields can interfere with the various implanted systems. Adhering to MRI guidelines is crucial when performing an MRI examination after the implantation of a CI or DBS system. Currently available DBS systems are MRI conditional.[11,13,15] In our case report, cochlear implantation was conducted with a preexisting DBS implant. The DBS system could be temporarily deactivated for surgical planning.

Magnetic artifacts from CIs can complicate subsequent DBS procedures, potentially requiring pre-CI MRI images or CT angiography for accurate DBS planning. In some cases, temporary removal of the CI magnet might be necessary, although this can be performed under local anesthesia with short operation times.[13,15] The MRI compatibility and approval of CIs have thus become crucial quality markers for modern auditory implants. Increasingly, CIs are being approved for MRI scans, with the latest models featuring self-aligning magnets that counteract displacement in a 3-Tesla magnetic field.[21,22] To enhance image quality and reduce artifacts without CI magnet removal, Nospes et al recommend using high-resolution fast imaging employing steady-state acquisition (FIESTA) or constructive interference in steady state (CISS) sequences, avoiding fat-saturation algorithms, and imaging in multiple planes.[22] Furthermore, studies by Carlson et al and Crane et al show adequate visualization of the ipsilateral cerebellopontine angle and internal auditory canal in 94% and 95% of 1.5-Tesla MRI brain scans, respectively.[23,24] Similar results have been reported by Walton et al.[25]

**Table 3.** Overview of the Stimulation Parameters of the PNFS System and the CI of the Patient.

| | | |
|---|---|---|
| PNFS (Boston WaveWriter R16): | | |
| Ear anterior: | Rate 50 Hz | Pulse width 90 μs |
| Ear posterior: | Rate 40 Hz | Pulse width 150 μs |
| CI Cochlear (CI 612 Contour Advance): | | |
| Biphasic | ACE | Per channel 900 Hz |

ACE, advanced combination encoder.

In summary, it can be concluded that all these cases underscore the feasibility of combining CI and DBS systems with careful surgical planning and interprofessional collaboration, indicating the potential for positive outcomes in complex situations.

Simultaneously, there remains a shortage of clinical reports on treating chronic neuropathic pain in patients with CI who are unresponsive to conventional treatments such as medical and physiotherapeutic therapy. Sethi et al describe that some patients experience pain after cochlear implantation without any signs of infection, inflammation, or hearing loss. This pain may be linked to CI soft failure, a condition suspected when device malfunction cannot be proved and only confirmed by improvement after reimplantation. The conditions of these patients are challenging to diagnose and manage, given their pain often begins weeks to months after surgery without a clear cause. Treatment is uncertain owing to unclear pathology and limited evidence. On the basis of a literature review, the authors included four patients experiencing delayed pain around the CI site without an identifiable cause. Pain management was successful with medical therapies in 41% of cases and local treatments in 63%. Surgical interventions (explantation, magnet replacement, tympanic neurectomy) resolved pain in 100% of cases.[26] Similar results are shown in a study by Celerier et al. In that study, the authors review long-term pain after cochlear implantation in 20 of 1448 patients with normal device function and no history of trauma, infection, magnet displacement, or device failure. The study describes only medical or surgical treatments, leading to reimplantation in 12 cases, with pain often causing the patients to become nonusers.[27] However, no treatment option has been described so far that effectively reduces pain without surgical intervention once conservative treatment methods have been exhausted. Specifically, the literature does not contain any case studies in patients who have received treatment with another neuromodulation system such as an ONS or PNFS system in addition to a CI. In our case series, we were able to show that after strict indication and exhaustion of all conservative therapy options, the concurrent use of CIs and neuromodulatory ONS or PNFS systems seems possible without complications and disruptive interactions. This approach can be a safe and promising therapeutic alternative for managing neuropathic pain. An initially suspected interference from varying stimulation frequencies and pulse durations was not clinically observed in the patients. Bipolar stimulation also was used in these cases, which likely contributed to minimizing the risk of possible interference.[11,20]

Consistent with other studies in which CI functionality remains unchanged with no alteration in hearing function after DBS surgery,[14] our case series also showed that hearing perception was unaffected in all three cases. The first patient showed significantly improved speech comprehension just three months after CI implantation. Moreover, speech comprehension remained good, and the subjective hearing impression was unchanged in the second and the third case after ONS and PNFS interventions.




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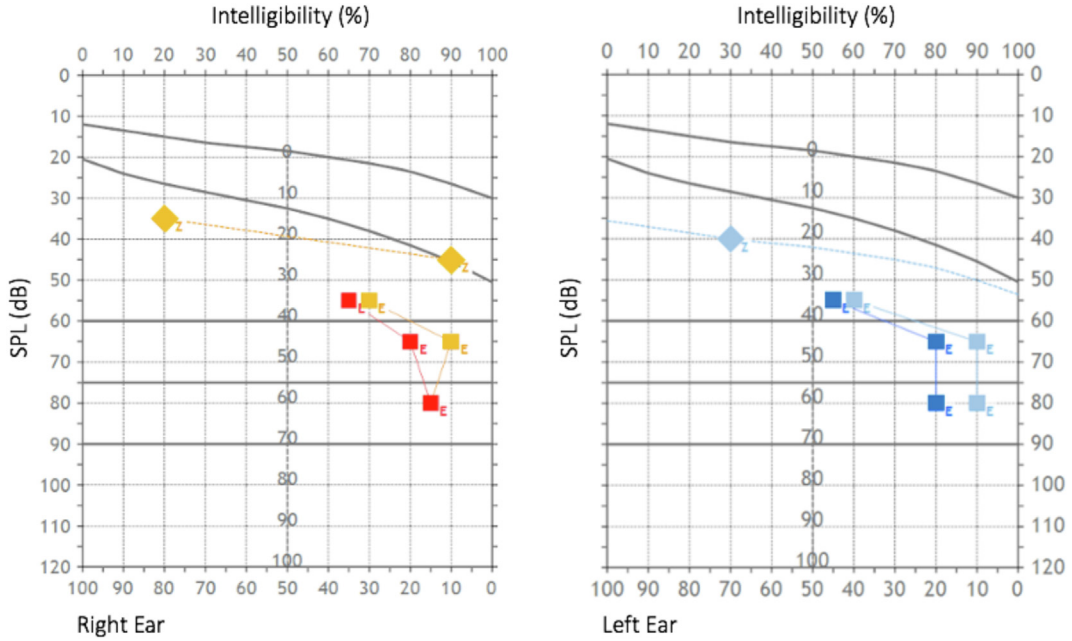


**Figure 2.** Freiburg monosyllabic test with CIs before and after PNFS intervention. Right Ear: before PNFS intervention (red), after PNFS intervention (yellow). Left Ear: before PNFS intervention (dark blue), after PNFS intervention (light blue). [Color figure can be viewed at www.neuromodulationjournal.org]

At the time of publication, the patients had been followed up for 96 months in the first case, 80 months in the second case, and 12 months in the third case. This suggests that midterm clinical improvements can be achieved in hearing rehabilitation and in neurosurgical treatment.

## CONCLUSIONS

This case series indicates that the simultaneous use of CIs and neuromodulation systems such as DBS, ONS, and PNFS seems possible without complications and disruptive interactions. In the future, there could be significant advantages for a substantial group of patients who have an indication for both systems. Moreover, this method may be considered as an option for managing chronic neuropathic pain.

### Authorship Statements

Friederike Weise and Thomas Klenzner contributed significantly to the conception of the work and to the interpretation and analysis of data for the work. Friederike Weise, Thomas Klenzner, Katharina Schaumann, Simone Volpert, Philipp J. Slotty, and Jan Vesper made substantial contributions to the acquisition of data for the work and revising it critically for important intellectual content. All authors approved the final version to be published. All authors agree to be responsible for all aspects of the work to ensure that issues relating to the accuracy or integrity of any part of the work are adequately investigated and resolved.

### Conflict of Interest

Thomas Klenzner has received travel grants from MED-EL GmbH, Cochlear GmbH, and Advanced Bionics and research grants from MED-EL GmbH and Advanced Bionics. The remaining authors reported no conflict of interest.


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