Effects of Hyperbaric Exposure on the Integrity of the Internal Components of Commercially Available Cochlear Implant Systems

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Hypothesis: This study investigated whether pressure changes common to scuba diving and to hyperbaric oxygen therapy would not cause crush damage or leakage from critical seals in commercially available cochlear implants.
Background: The implanted packages of cochlear implants are susceptible to electrical failure caused by leakage from critical seals and to crush injury when exposed to changing barometric pressures encountered in recreational diving and in hyperbaric oxygen therapy.
Methods: Six Clarion 1.2, eight MED-EL Combi-40+, six Nucleus CI22M, and six Nucleus CI24M cochlear implants underwent three exposures at 165 feet of seawater (FSW) (6 ata abs), 99 FSW (4 ata abs), and 60 FSW (2.8 ata abs), simulating rates in accordance with U.S. Navy dive tables for nondecompression dives. Dives to 45 FSW (2.4 ata abs) simulated wound therapy. Before each dive began, after each dive, and after completion of the dive protocol, each device underwent telem-etry and electrical integrity checks. All implants were returned to their respective factories for final electrical and quality control testing.
Results: All 26 devices completed the dive protocol. One Nucleus CI24M implant had a fault recorded at electrode lead 18 on predive and final product testing, which was absent during interval dive measurements. All 26 devices passed final electrical and quality control testing. In addition, the six Clarion units passed repeat helium leak testing.
Conclusion: The implanted components of the Clarion 1.2, MED-EL Combi-40+, and Nucleus CI22M and CI24M were safely subjected to repeated pressure changes up to 6 atm abs, equivalent to 165 feet of seawater, without electrical failure from leakage at critical seals or crush damage. **Key Words:** Hyperbaric—Cochlear implants—S.C.U.B.A.—Leak testing—Internal components.
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The benefits of cochlear implant (CI) use have been well documented, with evidence continuing to mount that implantation at an earlier age increases performance in regard to speech development (1,2). Each CI manufacturer lists activities and procedures to be avoided by device users. For example, before exposure to ionizing radiation, diathermy, electroconvulsive therapy, or magnetic resonance imaging, recipients are requested to consult the particular CI company to acquire specific instructions to ensure patient safety, to avoid device malfunction, and to maintain the manufacturer's warranty. As more people of all ages receive CIs, therapeutic hyperbaric oxygen therapy (HBO$_2$) and recreational ex-

posures—conditions that potentially could challenge the integrity of the device—will become more common. As far as we are aware, there are currently no reports in the literature that systematically evaluate the effects of hyperbaric pressure on the implanted components of commercially available CI systems.

This study was limited to examining hydrostatic effects on the implanted CI components because external hardware is removed during water immersion. Barometric pressure is 760 mm Hg (14.7 psi) at sea level and is given the reference of 1 atmosphere absolute (atm abs). Pressure increases linearly with increase in underwater depth. Each additional 33 feet of seawater adds 1 atm abs. Of the roughly 350 hyperbaric chambers available in the United States, approximately 100 are capable of pressurizing patients to 6 ata abs. The Professional Association of Diving Instructors estimates that there are 3 million active recreational divers in the United States, who average 17 dives per year each. Approximately 1,000

divers will be treated for decompression illness. Although most recreational dives do not exceed 150 feet of seawater (FSW), an increasing subpopulation of technical divers is extending the range to more than 200 FSW. Commercial and military diving systems are capable of extreme pressures of more than 1,000 FSW (3).

Commercially available CI receiver/stimulators (R/S) have housings made of either medical-grade ceramics or titanium that are hermetically sealed to prevent device failure from exposure of internal components to the corrosive effects of body fluids. This study evaluates the stability of the R/S housing and hermetic seals of the Clarion 1.2 (Advanced Bionics Corp., Sylmar, CA, U.S.A.), MED-EL Combi-40+ (MED-EL Corp., Innsbruck, Austria), and Nucleus-22 and Nucleus-24 (Cochlear Corp., Lane Cove, NSW, Australia) implant systems to barometric exposures common to recreational diving and HBO_2.

MATERIALS AND METHODS

Hyperbaric exposures were delivered in an air-pressurized, multiplace chamber. A multiplace chamber allows for multiple patients to be pressurized simultaneously in an upright or supine position and is generally capable of 6 atm abs or more. Each implant package arrived from its respective factory having passed helium leak testing according to Military Specification Standard 882.10.14 for microcircuits (usually a value less than 0.99×10^{-9} cc/atm/s) and electrical testing consistent with a device prepared for human implantation. All Clarion, MED-EL, and Nucleus CI22M devices passed production testing. The Nucleus CI24M implants had one or more electrode shorts or open faults identified in production testing, which were verified with telemetry immediately before dive testing to establish baseline measurements. Telemetry was completed on each device before hyperbaric exposure. The implant packages were completely submerged in a fixed volume of normal saline within a clear plastic container ($1.0 \times 0.5 \times 0.1$ m) positioned adjacent to a well-lighted Plexiglas chamber port for gross observation. Applied rates of descent and ascent represented likely exposure scenarios to pressures up to the standard of practice for HBO_2. For example, an 82.5 foot per minute (FPM) descent to 165 FSW simulated the most extreme standard of care for hyperbaric treatment of a diving-related arterial gas embolism (4). Descents at 30 FPM to 99 and 60 FSW simulate recreational scuba diving, and descents at 10 FPM to 45 FSW simulate HBO_2 treatment of wound healing. Ascents from 60, 90, and 165 FSW simulate conservative rates in accordance with U.S. Navy dive tables for nondecompression dives. The 5 FPM ascent from 45 FSW is typical after HBO_2 therapy to enhance wound healing. Table 1 summarizes the dive protocol.

Six Clarion 1.2 ICS devices without electrodes, from the implant production facility in Sylmar, California, were used. Before the current protocol, these devices were assessed in a 10-cycle dive protocol (4 ata abs) for separate purposes. Four of the devices completed the additional dives in the current protocol. In addition to full production testing at the manufacturing facility, each device was tested on site with the Portable Clarion ICS Tester (PCIT-MMT6202; Advanced Bionics Corp., Sylmar, CA, U.S.A.), a hand-held diagnostic tool, which allows for induction of lock status or system error conditions (errors in reading certain on-board voltages). Functional headpieces (Model AB5031), connected to a 42-in cable (Model AB5403R; Advanced Bionics Corp.), were sealed in a plastic bag for telemetry testing with precautions against electrostatic discharge, including wrist strap and an antistatic mat at the test station. Each device was tested to the limits of the link range obtained during manufacturing after each cycle with a 2- to 10-mm space-testing jig. As an additional measurement to evaluate for loss of function in the R/S with pressure cycling, the presence of a back-telemetry signal (peak frequency, 10.7 mHz nominal) was measured with a radiofrequency spectrum analyzer (Hameg 3003; HAMEG Instruments, Frankfurt, Germany). All six devices were returned to the factory in Sylmar, CA, U.S.A., for fine leak testing, system link, and evaluation of electrical output.

Six Nucleus complete CI22M and six Nucleus CI24M units arrived from the implant production facility in Sydney, Australia. A prototype Crystal integrity test system (serial no. 001; Cochlear Corp., Lane Cove, Australia) was used for testing between dives and at the conclusion of chamber testing. The appropriate transmitter coil was plugged into the transmitter lead and placed under the plastic dish beneath the receiver coil of the device being tested. Testing consisted of using the Crystal integrity test system to stimulate every electrode of the device (scanning from electrodes 1 to 22) in several different stimulation modes. For the CI22M devices, the voltages induced in the saline were recorded through electrodes placed in the saline bath. Common ground and bipolar +1 stimulation modes were used. For the CI24M devices, a similar procedure was followed using monopolar 1 and monopolar 2 stimulation modes (to ensure that the two extracochlear electrodes were fully tested). In addition, electrode voltage measurements were made during the testing using back-telemetry to further confirm the functionality of the device R/S and electrode arrays. All 12 implants were then returned to the Cochlear production facility in Sydney, Australia, for final electrical testing. Because these 12 implants were complete internal systems with final Silastic coating, helium leak testing could not be reliably done; any hermetic leaks would have been detected as faults in electrical testing.

Eight MED-EL Combi-40+ units arrived from the production facility in Innsbruck, Austria. The diagnostic interface box (DIB) was used to obtain telemetry readings of each device before and immediately after removal from the packaging.

TABLE 1. *Dive protocol[a]*

Equivalent depth (in FSW)	Descent rate (feet/min)	Time at depth (in min)	Ascent rate (feet/min)	Total dive time (in min)	No. of dive repetitions per device
165 (6 atm abs)	82.5	30	20	39	3
99 (4 atm abs)	30	30	20	38	3
60 (2.8 atm abs)	30	30	20	35	3
45 (2.4 atm abs)	10	30	5	43	3

[a] FSW, feet seawater; atm abs, atmospheres absolute.

Each impedance measurement required approximately 3 seconds. Values were displayed in kilohms for each electrode lead on individual arrays. The DIB can indicate poor conductivity at the site of electrode contacts. Impedances reading as HI signify that the channel is not in contact with fluid or tissue or is malfunctioning. If an electrode fails an initial integrity check, or if weak coupling between the implant package and the DIB occurs, impedance readings are blank on the DIB screen. Successful communication between the DIB and the CI is indicated by an "OK" in the indicator field. Implant package integrity is also displayed. During testing, voltages are measured on each of the 12 electrodes on the array. A voltage table is created that enables identification of short circuits between channels. A normal indicator in each of these screens implicitly confirms correct functioning of critical implant electronics.

Telemetry was recorded from each MED-EL device after each dive by taking the implant packaging out of the saline solution while keeping the electrodes in the bath. The DIB coil was placed over the R/S using a sterile gauze pad between the coil and the implant to ensure optimum link. Impedances consistent for the respective electrodes were then recorded in each instance. The telemetry unit was checked with a C40+ detector box in advance of every series. The devices were then returned to the factory in Innsbruck, Austria, for final electrical testing. As with the Nucleus implants, the MED-EL devices were tested as complete units with electrodes intact; leaks would have manifested as faults on integrity checks, telemetry, and final electrical testing.

RESULTS

All 26 implant packages completed testing without visible damage in the hyperbaric chamber. There were no interruptions in testing, and the conditions were as close to identical as possible for each device. The protocol was designed to simulate the pressures and rates of change expected in normal recreational diving and routine as well as extreme HBO_2 conditions.

Before the first dive cycle and for each subsequent cycle, each Clarion device yielded a PCIT reading of Test OK. All CIs achieved link with the PCIT unit at a spacer distance of 11 mm. No drift was noted in the BTEL signal, which might have produced a loss of link or even link itself, given enough change from the nominally tuned frequency of 10.7 mHz. No significant difference was observed in electrical testing before and after diving. Helium leak rate testing revealed no significant change in any device (Table 2).

Because the Nucleus CI22M implants do not have

back telemetry and the Nucleus CI24M do, the criteria used to describe the nature of the faults reported from Crystal scan plots were reported slightly differently for the two Nucleus device types. For CI22M devices, electrodes with pulse amplitude heights that were judged to be significantly different in amplitude or phase compared with the general trend of amplitudes in the plots were reported as electrode faults. For CI24M devices, if the reported impedance from the telemetry test was up to 20 $k\Omega$, the electrode was open; if the reported impedance was less than 700 Ω, the electrode was a short. All other impedances were designated none.

The six Nucleus CI22M implants had no open or short electrodes in testing done before the first dive, between each of the three dives at each depth, or after completion of the protocol. Production electrical testing was normal on return to the Cochlear factory. Five of the six CI24M devices had faults detected before dive testing that remained consistent throughout the experiments. In CI24M device with serial number CI63322, the fault in electrode 18 was not evident before testing, during intracycle testing, or at the conclusion of testing at our facility. An open circuit on electrode 18 was evident on production testing. The remaining five implants completed production testing and quality control evaluation without changing fault status after return to the Australian facility. Table 3 outlines the faults in each CI24M system.

In all eight MED-EL Combi-40+ implants, the telemetry read HI with the R/S in the packaging. No faults were detected once the electrodes were placed in the saline bath before the first dive, between dives, or at the conclusion of dive testing. DIB and CI coupling was OK, and each implant maintained normal integrity checks between dives. Final factory electrical and quality control testing revealed no faults after completion of the dive testing and transport to Austria.

DISCUSSION

HBO_2 treatment of the 13 conditions approved by the Undersea and Hyperbaric Medical Society (5), including diving injuries, is well accepted (Table 4). HBO_2 therapy is defined as a regimen whereby a patient breathes 100% oxygen while in a chamber controlled at a pressure >1 atm abs. Although treatment protocols vary according to the pathologic condition, the majority of treatments are administered between 2 and 3 atm abs. Nemiroff and Rybak (6) summarized applications for HBO_2 common to conditions of the head and neck. Interestingly, Schweitzer and Burtka (7) reported a case using HBO_2 as an adjunct to vascularized local flap rotation in a patient with scalp flap necrosis after CI. The Nucleus device was functioning normally 18 months after HBO_2 therapy. Zenner (8) suggested that the internal components of any middle ear implantable system designed to treat sensorineural hearing loss should be able to dive to a depth of 2 or 3 meters to avoid damage to the device with routine swimming.

A growing body of literature concerning the medical

TABLE 2. *Clarion helium leak rate[a]*

Device serial no.	Helium leak rate (cc/atm/s)	
	Pretest	Post test
71060	0.05×10^{-9}	0.35×10^{-9}
71061	0.50×10^{-9}	0.10×10^{-9}
71062	0.40×10^{-9}	0.20×10^{-9}
71063	0.05×10^{-9}	0.20×10^{-9}
70164	0.45×10^{-9}	0.15×10^{-9}
71065	0.25×10^{-9}	0.20×10^{-9}

[a] atm, atmosphere.

TABLE 3. *CI24M Electrical testing results*

Device serial no.	Faults in production electrical testing before dives	Faults immediately before dives	Faults after 45-ft dives	Faults after 60-ft dives	Faults after 99-ft dives	Faults after 65-ft dives	Faults in production electrical testing after protocol completion
CI60806	22 open	22 open	22 open	22 open	22 open	22 open	22 open
CI63322	18 open	None	None	None	None	None	18 open
CI61914	15 open	15 open	15 open	15 open	15 open	15 open	15 open
CI60886	3,4 short	3,4 short	3,4 short	3,4 short	3,4 short	3,4 short	3,4 short
CI63092	5, 10, 14 open	5, 10, 14 open	5, 10, 14 open	5, 10, 14 open	5, 10, 14 open	5, 10, 14 open	5, 10, 14 open
CI63083	8 open	8 open	8 open	8 open	8 open	8 open	8 open

consequences of diving-related pathologic changes describes the causes of most injuries in terms of the behavior of gases under conditions of changing pressure. Tissue injury resulting from gas-filled body compartments failing to equalize internal pressure in response to external pressure fluctuations is termed barotrauma. Although the risk of decompression sickness can be minimized by strict adherence to prescribed rates of descent/ascent and to times allowed at specific depths, symptoms are possible after almost any dive because of other risk factors.

The three commercially available implant systems consist of a subcutaneous R/S, an electrode array fed into the cochlea, and external antenna and speech processor. This study concerned only the effects of pressure changes on the internal device, because external components would most likely be removed in water. It is feasible, however, that a patient with a CI would desire to use the device if undergoing HBO_2. Testing of the external components may be useful in a future protocol. The Clarion 1.2 implant packages used in these experiments are an alumina composite with a mean static crush strength of 120 pounds, typical for Clarion implants fabricated after January 1, 1997. Since the introduction of this case in 1997, an alumina-zirconia composite with a crush strength of 400 pounds is now used. The crush strength figure can be expressed as follows: static measurement in pounds/circular area of 0.322 in^2. The MED-EL Combi-40+ device is also made of an alumina ceramic composite (resistant to a crush force between opposing flat surfaces of 1,000 N). The Nucleus implants achieve a hermetic seal by use of a welded titanium case with ceramic feed-through. The feed-through consists of a small piece of ceramic fired with platinum pins running between both faces of the ceramic, which is then braised to the titanium case to produce the hermetic seal. Changing pressure and the effects of pressure cycling common to sport diving and HBO_2 challenge the integrity of the hermetic seals on CI devices.

The testing protocol was designed to examine only the effects of hydrostatic pressure per se on the cochlear implant housings. The R/S of commercially manufactured CI undergo routine factory testing using a vise to roughly 500 pounds of pressure (1,550 psi). The hyperbaric chamber allowed for uniform transmission of pressure, from all directions, up to 165 FSW (88 psi, or 13,000 foot-pounds). Implanted devices exposed to increased ambient pressure are subject to additional stresses imposed by the increased partial pressure of dissolved gasses. Dissolved gases will migrate into the R/S through any faults in the implant housing. Decompression would generate an outward force to distort or break the housing, producing a fault on electrical testing. Our testing protocol did not attempt to reproduce increases in partial pressure of nitrogen with increased ambient pressure. Simulating the exponential uptake of nitrogen would have required complex paradigms that were not relevant to these experiments.

Air bubbles on the electrode surface, generated with depressurization, heavily influence the values of impedances because air partially blocks the contact area between the electrode and the saline solution. Elevated impedances caused by air bubbles or by movement of the electrode leads within the saline bath could cause statistically significant differences between predive and post dive impedance measurements without determining the status of the electrical implant, only determining how many air bubbles are on the electrodes. Monitoring of impedances was used to indicate whether a device was functioning correctly (could boot up, receive electrical signals, send back a signal by telemetry, and generate electrical pulses). Impedance levels also indicated whether any shorts or open circuits existed on individual electrodes.

Only one implant showed results that differed between production testing and dive testing in this study. Nucleus

TABLE 4. *Approved conditions for treatment with hyperbaric oxygen therapy[a]*

Air or gas embolism
Carbon monoxide poisoning
Clostridial myositis and myonecrosis (gas gangrene)
Crush injury, compartment syndrome, and other acute traumatic ischemias
Decompression sickness
Enhancement of healing in selected problem wounds
Exceptional blood loss (anemia)
Intracranial abscess
Necrotizing soft tissue infections
Osteomyelitis (refractory)
Delayed radiation injury (soft tissue and bony necrosis)
Skin grafts and flaps (compromised)
Thermal burns

[a]From Hampson NB, ed. *Hyperbaric Oxygen Therapy, 1999 Committee Report.* Kensington, MD: Undersea and Hyperbaric Medical Society, 1999 (5).

CI24M No. 63322 had an open circuit fault on electrode 18 in production electrical testing before shipment to our center for dive testing. It showed no faults throughout the protocol but had the same open circuit fault when subjected to final production testing at the factory in Sydney, Australia. Because this fault was present both before and after dive testing, it most likely represented an intermittent open circuit fault, possibly affected by international shipping or handling. Because the other 11 Nucleus devices had testing results that were consistent in the factory and at the test site, irregularities in on-site methodology or test equipment evaluation were unlikely.

If it is assumed that the open circuit fault in CI24M-63322 represents an intermittent electrode unrelated to dive testing, the internal R/S packages from the three available C1 systems maintained electrical integrity with repetitive pressure exposures up to 165 FSW (6 atm abs). No visible or cosmetic flaws were found in the ceramic (Clarion and MED-EL) or in the titanium (Nucleus) casings. Helium leak testing did not change after exposures in the Clarion 1.2 casings. The MED-EL and Nucleus implants were tested with electrodes and final silicone coating in place, so leak testing could not be completed reliably after their return to the factory.

CONCLUSIONS

This series of experiments supports the safety of device integrity for patients who dive recreationally or receive standard HBO_2 therapy. The conclusions of this study do not necessarily apply to technical, military, and commercial diving, where submersions exceed the 165 FSW (6 ata abs) testing limits of our protocol. The study was not designed to evaluate any of the other normal effects of scuba diving, such as the effect of increased partial pressure of nitrogen with increased ambient pressure. These conclusions may not hold for the R/S and electrodes under development with new product designs.

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INVITED COMMENT

One question I have heard from cochlear implant (CI) patients and candidates as well as from referring physicians is whether concern about three issues is pertinent to CI patients. The first concern has been whether the internal components of the CI can withstand the barometric pressure changes associated with diving. This article clearly shows a lack of any electrical problems or leaks at critical seals and provides important information for scuba divers and hyperbaric oxygen patients alike. The second concern is that all divers are subject to the risks of inner ear decompression sickness as well as inner ear barotrauma, the latter of which may involve perilymphatic fistula (1001).

Whether CI patients are at greater risk for inner ear decompression sickness or inner ear barotrauma because of their resulting round window tissue seal or changes in inner ear fluid dynamics remains to be investigated. The third concern, most pertinent in discussions regarding patients with hearing loss syndromes that predispose to perilymph fistula (Mondini malformations) or labyrinthine pressure abnormalities (enlarged vestibular aqueduct, patent enlarged internal auditory canal) is whether such abnormalities put patients at increased risk for catastrophic underwater inner ear complications such as inner ear barotrauma whether or not they have a CI in the affected ear. This article answers one important issue concerning hyperbaric exposure of a CI and will likely spur further work that sheds light on the latter issues addressed above.

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