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The effect of electrical dental equipment on a vagus nerve stimulator's function

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ABSTRACT

Background. Dental patients who have epilepsy with pharmacologically refractory seizures may be treated with an implanted pulse generator that electrically stimulates the left vagus nerve. The pulse generator functions like a cardiac pacemaker. Some electrical dental devices have been shown to cause electromagnetic interference with the function of cardiac pacemakers. The potential effect of similar dental equipment on vagus nerve stimulators is unknown.

Methods. Common electrical dental devices were operated at maximum power settings in close proximity to a representative vagus nerve stimulator. The author assessed any interference of the dental devices with the nerve stimulator function by observing oscilloscope tracings.

Results. Under the conditions of this evaluation, none of the dental devices tested altered the function of the vagus nerve stimulator.

Conclusions. Some commonly used electrical dental devices may be used in close proximity to patients who have implanted vagus nerve stimulators without adverse effects on the nerve stimulator function.

Clinical Implications. Dentists and dental hygienists may encounter patients with implanted vagus nerve stimulators, and they need to be cognizant of developments in the treatment of epilepsy. Under the conditions of this study, use of common dental electrical devices did not alter the function of a vagus nerve stimulator. The findings of this study, however, should not be generalized to all types of electrical dental or medical devices, as a recent report indicates that treatment with diathermy devices is contraindicated for patients with implanted nerve stimulators.

An epileptic seizure is defined as an episode of abnormal and uncontrollable motor, sensory or psychological behavior caused by repetitive, hypersynchronous electrochemical activity that originates in the cerebrum.[1] Epilepsy is a chronic disorder characterized by recurrent seizures in which the seizures themselves become the target for specific therapy.[1] It has been estimated that up to 50 million people worldwide may have epilepsy,[2] including at least 2.3 million people in the United States.[3-5] An estimated 100,000 to 125,000 new cases are diagnosed each year.[6,7] While antiepileptic drugs are the primary means of treating epilepsy,[8] pharmacological therapy alone has had mixed success. Although approximately 500,000 people achieve complete pharmacological control of their seizures,[5] it has been estimated that up to 50 percent of the 2.3 million people in the United States who have epilepsy do not have adequate control of their seizures,[9] and about 25 percent (600,000 people) experience pharmacologically intractable seizures.[3,5,10]

None of the evaluated dental devices produced electrical interference sufficient to alter the proper operation of the pulse generator.

People who have refractory epilepsy represent a major clinical problem, because they have a reduced quality of life. Associated problems include a higher incidence of cognitive and psychiatric impairments, increased injuries and mortality, social stigmatization and isolation.[5,7,11] Neurosurgical techniques involving specific areas of the cerebrum (such as corpus callosotomy, temporal lobectomy, hemispherectomy and focal cortical resection) may provide some reduction in seizure activity; however, these techniques are effective in only a limited number of patients.[7] Moreover, these invasive surgical techniques may be associated with surgical morbidity, which further limits the number of candidates for these invasive neurosurgical techniques.[12]

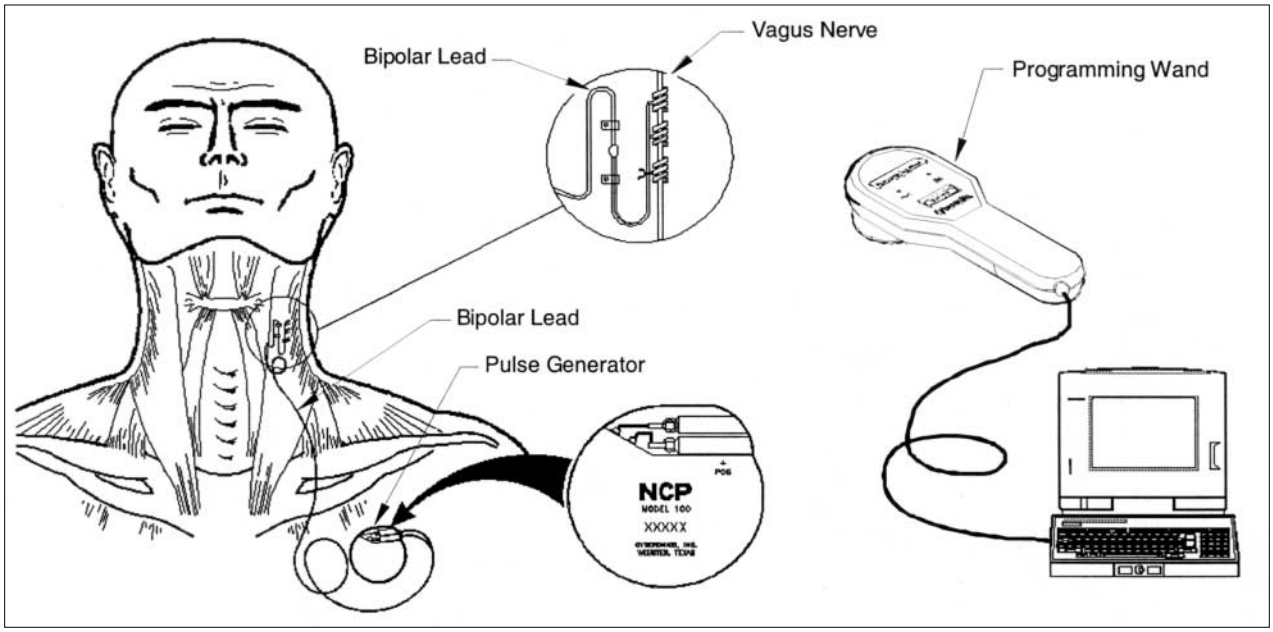

Figure 1. NeuroCybernetic Prosthesis System. Image reproduced with permission of Cyberonics Inc., Houston.

In 1938, Bailey and Bremer[13] first reported that the stimulation of a severed vagus nerve produced a change in cortical electrical activity in the brains of cats. In the early 1950s, Dell and Olsen[14] reported that electrical vagal stimulation evoked potential electrical changes in the thalamus, hypothalamus, cortex, limbic structures, midbrain and cerebellum. The concept of vagal stimulation to control seizures first was proposed by Zabara[15] in 1985 after he found that vagal stimulation produced anticonvulsant effects on experimentally induced seizures in dogs. Shortly thereafter, a company was founded to develop a device similar to a cardiac pacemaker that could stimulate the vagus nerve.[5]

Human use of vagus nerve stimulators began in the late 1980s, and results were reported first in 1990.[16] Based on international and U.S. clinical trials, the U.S. Food and Drug Administration, or FDA, approved vagus nerve stimulation in July 1997 for use as an adjunctive therapy in the treatment of pharmacologically refractory epilepsy.[16-20] Subsequent studies have indicated that vagus nerve stimulation using an implanted pulse generator can safely suppress seizures in humans.[11,17,18,21-26]

The placement of a vagus nerve stimulator is analogous to the placement of a cardiac pacemaker. The electrical pulse generator is implanted surgically in the thoracic wall, and an electrical lead is placed on the left vagus nerve sheath (Figure 1). The NeuroCybernetic Prosthesis, or NCP, System (Cyberonics, Houston) is a device that has been approved by the FDA for controlling refractory seizures. NCP System models 100 and 101 pulse generators (Cyberonics) were approved for adjunctive therapy for reducing the frequency of seizures in adults and in adolescents older than 12 years of age with partial onset seizures who were refractory to antiepileptic medications.

The NCP System includes implantable, multiprogrammable pulse generators that deliver electrical signals to the vagus nerve. The constant current, capacitively coupled, charge-balanced signals are transmitted from the pulse generator to the vagus nerve via the Model 300 NCP Bipolar Lead (Cyberonics). NCP pulse generators are housed in a hermetically sealed titanium case, and feedthrough capacitors are used to filter electromagnetic interference. Cyberonics lists the major components of the NCP pulse generators as a microprocessor, a voltage regulator, a 76.8-kilohertz crystal oscillator, antennas to receive and transmit programming information, and circuitry for control of communication, voltage and impulses.

The NCP pulse generators have a number of programmable settings that allow therapy to be tailored to patients' needs. Telemetry is used to program the pulse generator and provide information concerning the unit's current operating

characteristics via a programming wand that is interfaced with a personal computer. Patients also can alter the pulse generators' functions by using a magnet. Cyberonics offers two magnet styles that patients can use to start the pulse generators' functions when they experience an aura or are beginning to have a seizure. Furthermore, the pulse generator's functions can be stopped temporarily by placing the magnet over the unit.

NCP pulse generators have integrated electromagnetic interference filters that are designed to limit the effect of unintentional electromagnetic fields on their operation. The patient's manual states that properly operating microwave ovens and routine diagnostic radiography are not expected to affect the performance of the NCP Pulse Generator.[27] The manufacturer, however, warns that certain electrical or electromechanical devices that may have a strong or pulsing magnetic field (for example, strong magnets, hair clippers, vibrators, loudspeakers) can cause accidental activation of the pulse generator. Cyberonics recommends that these devices be kept at least 6 inches away from the pulse generator.

Some electrical devices routinely used in the delivery of dental care, such as ultrasonic scalers, electrosurgical units and ultrasonic bath cleaners, can generate electromagnetic fields that have been shown to interfere with cardiac pacemaker activity.[28-32] Although the original design for a vagal stimulation device was based on a cardiac pacemaker,[5] the effect of electrical dental devices on the performance of pulse generators has not been reported in the literature. I conducted this study to investigate any potential interaction of commonly used electrical dental devices on the function of the NCP Pulse Generator.

METHODS AND MATERIALS

I connected the bipolar lead of the NCP Pulse Generator Model 101 in series with a 4,700-ohm resistor (per the manufacturer's testing recommendation) to the input leads of an oscilloscope (Model 54645A, Hewlett-Packard, Palo Alto, Calif.). I then programmed an NCP System Model 101 Pulse Generator using an NCP Model 201 VNS Therapy Programming Wand (Cyberonics) to the parameter settings listed in the table. I chose a 0.50-milliampere output current with a 500-microsecond pulse width because I could view it easily in series on the oscilloscope in the U.S. Air Force Dental Investigation Service's dental equipment testing laboratory.

I tested each dental device listed in the box three times by activating and operating it at its maximum power level while I placed it directly against the outer surface of the NCP Pulse Generator in active mode. I noted any deviation in the pulse generator's baseline current output and frequency. If a deviation occurred, I assumed the device had the potential to interfere with the pulse generator's proper operation.

To determine if the dental device generated a magnetic field sufficient to cause the pulse generator to begin operating inadvertently, I operated the dental devices in a similar manner with the pulse generator in a nonactive mode. If I observed the initiation of the pulse generator's electrical function, I stopped it and repeated this

TABLE

PULSE GENERATOR PARAMETER SETTINGS.

PARAMETER	SETTING
Output Current	0.50 milliamperes
Signal Frequency	30 hertz
Pulse Width	500 microseconds
Signal On Time	60 seconds
Signal Off Time	35.0 minutes
Magnet Current	0.25 mA
Magnet On Time	60 seconds
Magnet Pulse Width	500 µs seconds

BOX

ELECTRICAL DENTAL DEVICES TESTED.

- Cavitron SPS Ultrasonic Scaler (Dentsply Professional Division, York, Pa.)
- Cascade delivery unit with Model 6330 light (A-dec, Newberg, Ore.)
- Automix amalgamator (Kerr Dentistry, Orange, Calif.)
- Analytic pulp tester (Sybron Dental Specialties Inc., Orange, Calif.)
- Optilux 501 High Output Curing Light (Kerr Dentistry)
- Versalux LED Light Curing Unit (Centrix Inc., Maple Valley, Wash.)
- Ellman Surgitron electrosurgical unit (Ellman International Inc., Hewlett, N.Y.)

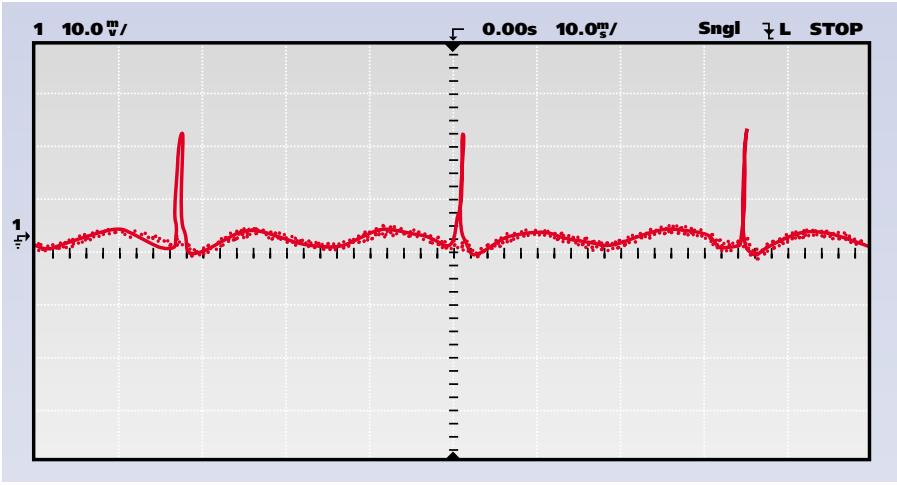

Figure 2. NeuroCybernetic Prosthesis System (Cyberonics Inc., Houston) pulse generator baseline oscilloscope signal.

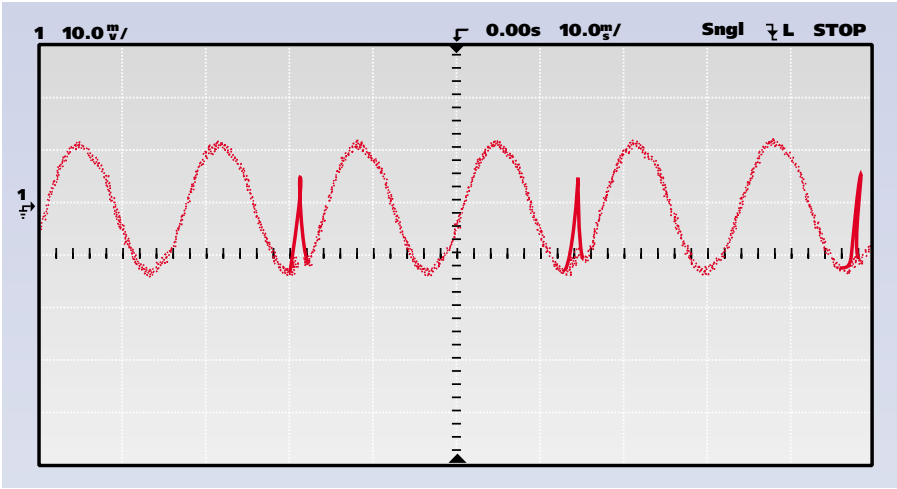

Figure 3. NeuroCybernetic Prosthesis System (Cyberonics Inc., Houston) pulse generator signal with active visible light-curing unit.

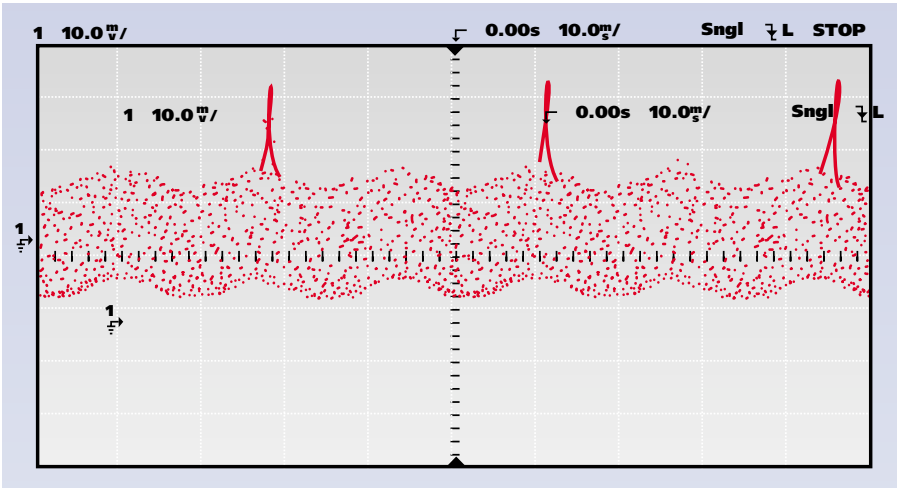

Figure 4. NeuroCybernetic Prosthesis System (Cyberonics Inc., Houston) pulse generator signal with active magnetorestrictive ultrasonic scaling unit.

procedure at a further distance from the pulse generator until no pulse generator initiation was noted. At that point, I recorded its distance from the pulse generator.

RESULTS

None of the dental devices I tested caused the unit to malfunction, regardless of its power level or distance from the pulse generator. Furthermore, no devices generated a magnetic field sufficient to cause activation or deactivation of the pulse generator.

Figure 2 displays the baseline oscilloscope signal for the NCP Pulse Generator operating under the parameters used in this evaluation. I used programmed settings that allowed the best signal to be captured by the available oscilloscope. As the various dental devices were operated, I often observed electrical interference noise in the signal baseline, but elimination of the noise revealed that neither the frequency nor signal output of the pulse generator had been altered.

Figure 3 and Figure 4 show the results of activating and using a visible light-curing unit (Optilux 501 High Output Curing Light, Kerr Dentistry, Orange, Calif.) and a magnetorestrictive ultrasonic scaler, respectively, that were in direct contact with the pulse generator. The electrical baseline noise produced by the electrical circuitry of the dental equipment being evaluated was evident. Although the ultrasonic scaler generated a thick baseline electrical noise level, measurement of the pulse generator's current signals showed no change in output or frequency. Furthermore, the magnetic field generated by the ultrasonic scaler did not initiate magnet activation of the pulse generator.

When I used the electrosurgical unit in tissue-cutting (for example, filtered current) mode, baseline electrical noise level was minimal. When I changed to a tissue-cutting and coagulation (for example, rectified current) mode, I observed some increase in the baseline noise level. When I tested the pulse generator against both of these settings, I observed no change in the pulse generator's current output or frequency (Figure 5 and Figure 6). When I tested the electrosurgical unit in a strict coagulation mode (for example, partially rectified current), the oscilloscope tracing showed both an elevated and rhythmical spiking of electrical noise caused by the partially rectified current (Figure 7). Measurement of the pulse generator current signals contained within this noise pattern, however, revealed no change in current output or frequency. As with the ultrasonic scaler I tested in this evaluation, the electrosurgical unit did not generate a sufficient magnetic field to activate or deactivate the pulse generator, regardless of its functional mode or power setting.

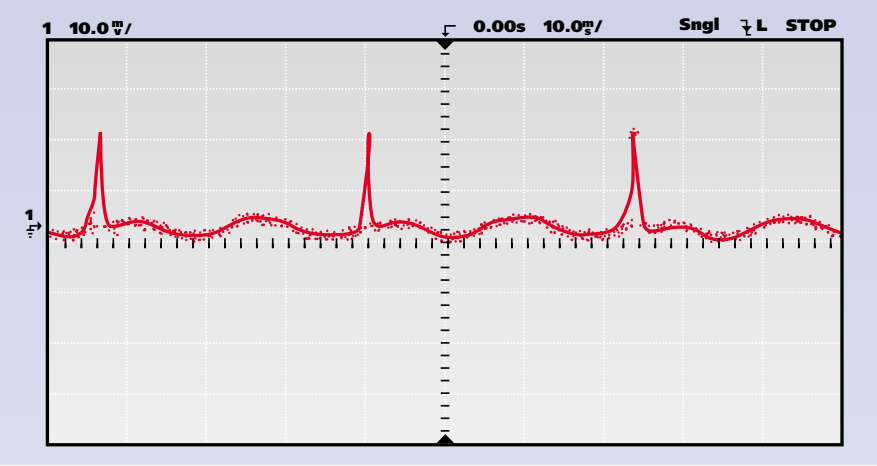

Figure 5. NeuroCybernetic Prosthesis System (Cyberonics Inc., Houston) pulse generator signal with active electrosurgical unit in cutting mode (that is, filtered current).

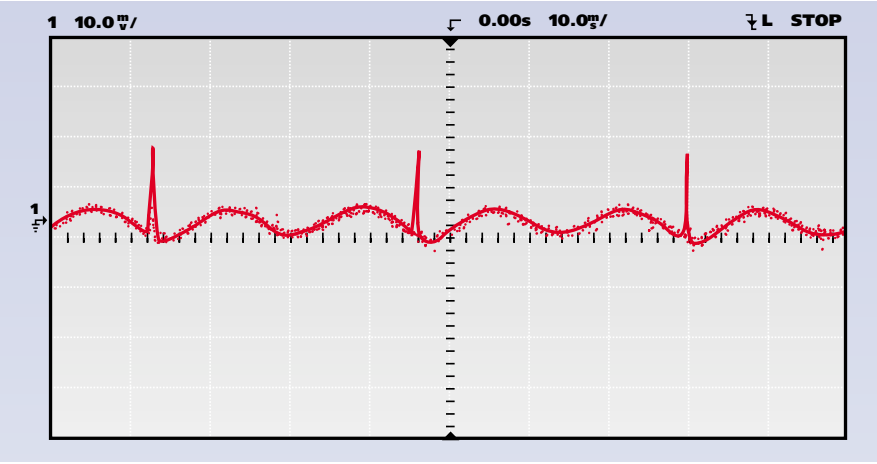

Figure 6. NeuroCybernetic Prosthesis System (Cyberonics Inc., Houston) pulse generator signal with active electrosurgical unit in tissue cutting and coagulation mode (that is, rectified current).

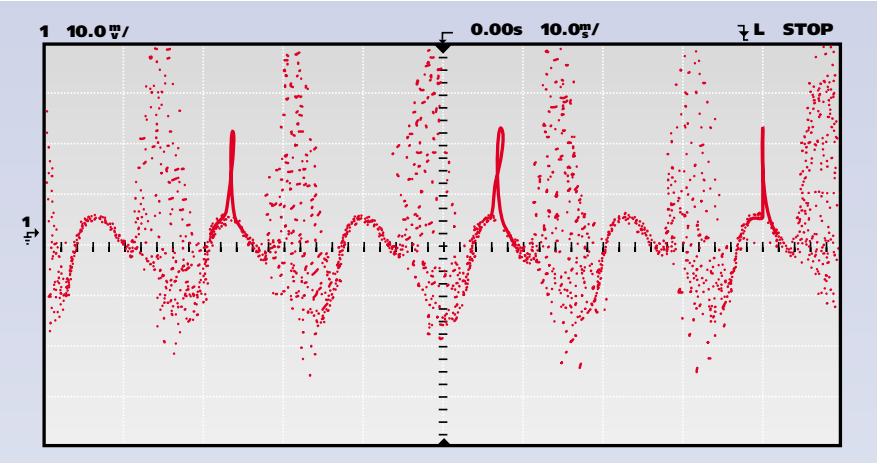

Figure 7. NeuroCybernetic Prosthesis System (Cyberonics Inc., Houston) pulse generator signal with active electrosurgical unit in coagulation mode (that is, partially rectified current).

DISCUSSION

Despite medical and surgical advances, being able to control epileptic seizures predictably using medication remains a major clinical problem that may affect more than 300,000 people in the United States.[11] As I discussed previously, an implantable device has been approved by the FDA to augment therapy for refractory epilepsy.[11] Since 1997, the NCP System has been used as an acceptable treatment for intractable partial-onset seizure disorders.[33] Although it initially was approved for patients older than 12 years of age, vagus nerve stimulation also has been reported to be safe and effective for some pediatric patients.[25,34-36] More

than 15,000 NCP systems have been placed, with about 5,000 being placed annually (written communication, Brent Tarver, Cyberonics Inc., January 2002).

Before widespread placement of vagus nerve stimulators, it was assumed that patients with poor seizure control would receive most of their dental care in a hospital setting. However, since patients with implanted pulse generators may have better control of their seizures, nonhospital-based dentists and dental hygienists may be treating more of them than in the past. Furthermore, vagus nerve stimulation is being evaluated as an adjunctive therapy modality for treatment-resistant psychological depression[37-39]; FDA approval is expected in the near future. Accordingly, outpatient dental facilities may more frequently encounter patients with implanted pulse generators seeking routine care. It is critical, therefore, that dental health care providers know whether common dental equipment affects the proper operation of pulse generators.

Since patients with implanted pulse generators may have better control of their seizures, nonhospital-based dentists and dental hygienists may be treating more of them than in the past.

Certain dental equipment has been shown to cause cardiac pacemakers to malfunction.[28-32] I undertook this evaluation to determine if some of the more commonly used electrical dental devices could affect the function of the NCP Pulse Generator similarly. I conducted the evaluation based on a protocol like that used by Miller and colleagues[28] for evaluating the effect of dental devices on cardiac pacemakers. Results indicated that none of the dental devices used during the evaluation caused alterations in the electrical current output or frequency of a programmed NCP Pulse Generator. Also, none of these devices generated a sufficient magnetic field to inadvertently activate or deactivate the pulse generator.

DENTAL MANAGEMENT CONSIDERATIONS

The proper management of the care of dental patients with epilepsy has been well-discussed by Little and colleagues.[40] General considerations include obtaining proper medical consultation, identifying and eliminating (if possible) known seizure-triggering stimuli, and properly managing the care of a patient during a seizure. It also is important to be knowledgeable about medication side effects and potential drug interactions. These considerations remain important even for patients who also are being treated with the NCP System, as they cannot be considered to be "cured" or free of seizures. As with dental patients who have cardiac pacemakers, patients with implanted pulse generators should not require antibiotic prophylaxis for bacteremia-producing dental procedures.

Although the conditions of this study did not identify any electrical interference that caused alteration of the vagus nerve stimulator's function, these findings cannot be generalized to all types of electrical dental devices. In the event that an electrical dental device were to alter the pulse generator's function, most patients should be able to identify alterations in vagus nerve stimulator function and alert their dentists, as tingling sensations and momentary hoarseness commonly are felt by patients.[27] In most cases, the NCP System will return to the programmed treatment schedule once the electromagnetic interference has ceased.[27]

Nutt and colleagues[41] recently reported a case in which severe brain damage resulted from the interaction of a diathermy unit (for example, shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy) and an implanted pulse generator. In this report, a patient had received an implanted pulse generator (Itrel Model 7424, Medtronic, Minneapolis) with electrodes (Model 3387, Medtronic) implanted into the subthalamic nucleus region of the brain as adjunct treatment for advanced Parkinson's disease. Nineteen months after the pulse generator was placed, the patient received diathermy treatment using a Magnatherm unit (International Medical Electronics, Kansas City, Mo.) one day after all of his maxillary teeth were extracted. The diathermy treatment was prescribed to facilitate postsurgical healing. At the end of the treatment, the patient could not be aroused and required hospital admission. Neurological evaluation revealed extensive tissue damage in the areas of the brain associated with the implanted electrodes; the diathermy unit had induced a radio frequency that produced heating of the pulse generator's electrodes.[41] Although not commonly used in dentistry, diathermy is used by a variety of health care professionals to admin-

ister a radio frequency current to effect heating within tissues to relieve musculoskeletal or orthopedic pain, reduce postsurgical swelling and pain, and promote wound healing. Due to Nutt and colleagues' report,[41] Cyberonics has issued a safety alert warning that patients with implanted pulse generators should not receive any diathermy treatment, regardless of location of the planned diathermy treatment. Use of diathermy devices can cause heating of any element of the NCP System that may result in permanent damage to nerve or vascular tissue.[42] Given this warning, the use of diathermy treatment on a patient with any type of pulse generator should be contraindicated.

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CONCLUSION

I evaluated commonly used electrical dental devices in close proximity to the Cyberonics NCP Pulse Generator. Under the conditions of this study, none of the dental devices produced electrical interference sufficient to alter the proper operation of the pulse generator. Furthermore, none of the devices generated a magnetic field of a magnitude sufficient to affect the pulse generator's normal function.

Although it can be generalized that the tested dental devices are safe for use with patients with implanted pulse generators, it is important to note the dental equipment's effects may vary according to the specific brand of dental device. Therefore, dental professionals need to be cognizant of potential electrical interference that could exist between other dental devices that generate magnetic fields and the NCP Pulse Generator.

Although patients with implanted pulse generators should not require antibiotic prophylaxis before the dental procedures, management of the care of these patients should be consistent with that of other patients with seizure disorders. Lastly, a recent report indicates that the use of diathermy is contraindicated in any patient with an implanted nerve stimulator. ■

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The opinions expressed in this article represent those of the author only and do not constitute the official opinion of the U.S. Air Force, the U.S. Department of Defense, or the U.S. Government.

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