The dental management of patients with implantable neurostimulation devices: a suggested protocol

P Clarke[1] and F O'Neill[2]

1. Dental Core Trainee, Restorative Department, 2. Senior Lecturer/Honorary Consultant in Oral Surgery, Oral Surgery Department: Liverpool University Dental Hospital, Liverpool, UK

Abstract

Neuromodulation is a rapidly expanding discipline in medicine due to a variety of applications. This article introduces the concept of neurostimulation, including basic anatomy and clinical background, with discussion of potential interactions with common dental procedures and the implications for the dental team. A protocol for management of these patients is suggested.

Key words: *Dentistry, neurostimulation, electromagnetic interference, dental management*

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Introduction

Neurostimulation is the purposeful stimulation of the nervous system, either peripherally or centrally, in order to beneficially modify a patient's symptoms or function (Arle and Shils, 2011). Stimulation can be achieved non-invasively, for example, using external electrodes as in the already popular Transcutaneous Electrical Nerve Stimulation (TENS) machines or it can be an invasive procedure requiring the implantation of electrodes at the level of the peripheral nerve, ganglion, spinal cord or brain. The use of implantable neurostimulation devices (IND) is a rapidly expanding area of medicine. An increasing number of conditions have been shown to respond to this therapy and this is reflected in market data with average net sales increasing by $149 million in the past 3 years (Boston Scientific, 2011; St. Jude Medical, 2011; Medtronic, 2012; Boston Scientific, 2013; Medtronic, 2013a; St. Jude Medical, 2013). For these reasons the dental practitioner may expect to encounter patients treated with neurostimulation and should be prepared for implications it may have on their dental management.

The aim of this paper is to introduce the reader to the therapeutic modality of neurostimulation and examine its implications in dentistry. Following discussion of pertinent issues surrounding these devices, a protocol for the management of dental patients who have a neurostimulation device implanted is suggested.

Applications of neurostimulators

The first use of an IND was in 1954 for the treatment of chronic pain with deep brain stimulation (DBS) (Levy, 2014). Since then neurostimulation has become a recognised treatment option for the management of: pharmacologically resistant/intractable tremors, dystonias, spasticity, epilepsy, primary headaches/chronic pain and urinary incontinence (Krames *et al.*, 2009). With development, other areas in the central nervous system have been targeted including stimulation of the cerebral cortex, for example, visual cortex implants for restoration of sight and spinal cord stimulation for chronic pain conditions. Peripheral and autonomic nervous system stimulation targets sensory/autonomic ganglia or directly stimulates axonal nerve fibres. Examples of these include auditory cochlear implants which directly stimulate the vestibulocochlear nerve, and stimulation of the peripheral nerve dorsal root ganglion for the treatment of chronic pain.

The uptake of this technology in the National Health Service has been rapid and accordingly the National Institute for Health and Care Excellence (NICE) has released both guidance on interventional procedures and several

technology appraisals (NICE, 2003; NICE, 2006; NICE, 2008; NICE, 2009; NICE, 2011a; NICE, 2011b; NICE, 2012).

In addition to these uses, other applications are being explored including treatment of: personality disorders and depression, stroke rehabilitation, Tourette's syndrome, obsessive-compulsive disorders, Alzheimer's, and hypertension (Krames *et al.*, 2009; International Neuromodulation Society, 2010; Arle and Shils, 2011).

Relevant anatomy and mechanisms of action

Neurostimulation can induce an effect either by the excitation or inhibition of nerve cells or fibres to modify nervous system activity, and by implication produce a response in the patient. Depending on the condition being treated and its proposed pathophysiology, stimulation can be targeted at the level of the central, peripheral or autonomic nervous systems.

Central nervous system stimulation is targeted at deep or superficial structures in the brain, or at various levels of the spinal cord. The brain is a complex organ with many functionally discrete regions as shown in *Figure 1a*. Superficial areas most commonly associated with INDs are the motor and visual cortices. Many targets for Deep Brain Stimulation (DBS) are located within nuclei of the diencephalon, around the thalamus (*Figure 1b*).

Peripheral nervous system stimulation commonly involves cranial nerves such as cochlear implants for hearing loss, and spinal nerves such as the occipital nerve for intractable headaches or dorsal root ganglia for chronic pain.

Tables 1a-c give an overview of more common stimulation sites including examples of autonomic nervous system stimulation. There is debate whether neurostimulation has a local effect (on the specific area targeted) or stimulates complex neuronal pathways involved in modifying the disease process (Arle and Shils, 2011). The likelihood is a combination of both, for example peripheral/spinal nerve stimulation for chronic pain may provide both primary impulse inhibition and secondary segmental blockage (in accordance with the Gate control theory) (Lihua *et al.*, 2013). DBS almost certainly affects multiple systems as can be seen in the delicate balance of its therapeutic window.

Components

The majority of INDs have three components, the electrodes, connecting leads and a pulse generator. Pulse generators are usually powered by a rechargeable battery pack (older versions need replacement), however a few are driven by a remote external power source. Common sites for implantation of the pulse generators include the subclavian region, lower abdomen and upper buttock area (Arle and Shils, 2011) (*Figure 2*). *Figure 3* [Courtesy of Medtronic] depicts examples of a common devices and radiographical appearances.

Implications for patient management in the dental environment

Most patients with implanted neurostimulators can receive routine dentistry in primary care. Clinicians should however be aware of a number of possible complexities and

Figure 1a: Left sagittal view of brain showing functional areas of the cerebral cortex based on original work by Brodmann (Crossman & Neary, 2010). *[adapted from (Crossman & Neary 2010) – copyright Elsevier, reproduced with permission]*

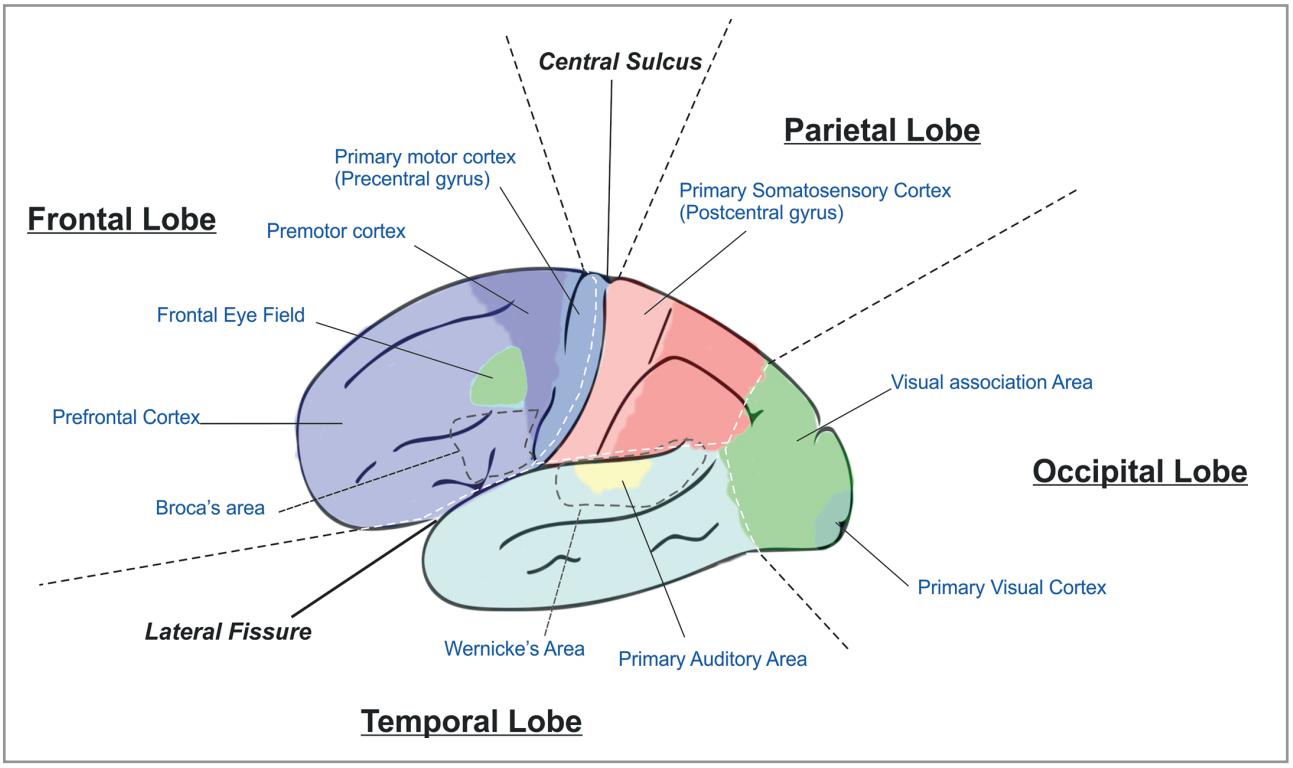
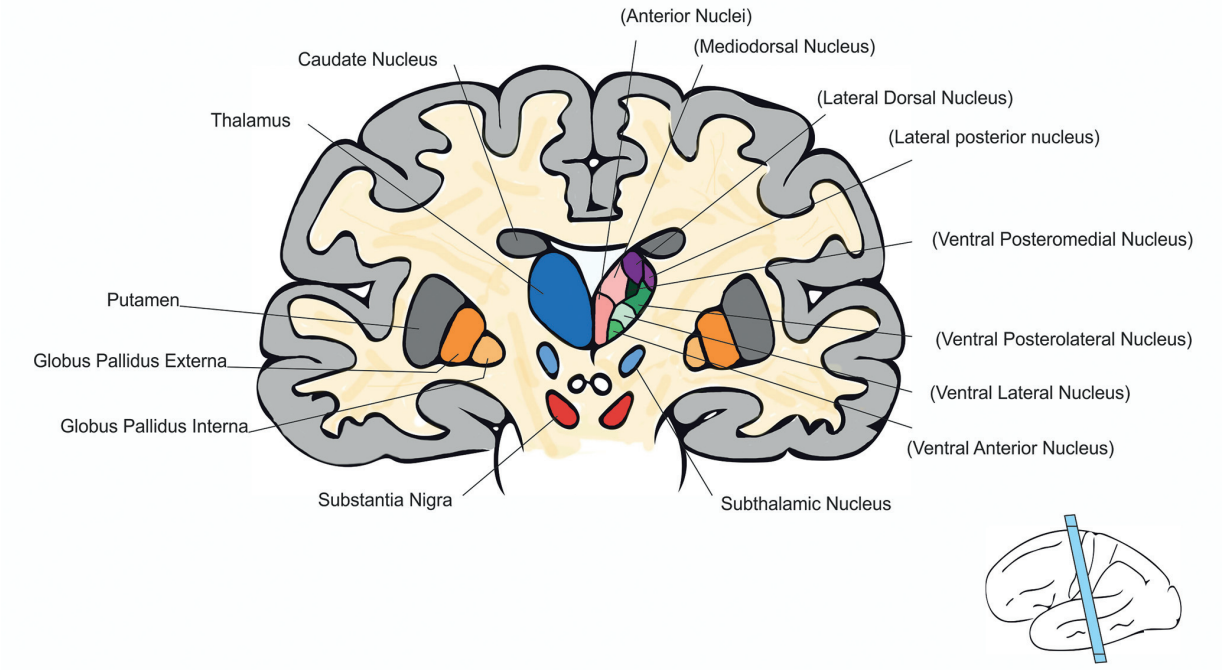


Figure 1b: Coronal section showing nuclei of the diencephalon and basal ganglia.
[adapted from (Crossman & Neary 2010) – copyright Elsevier, reproduced with permission]



interactions with treatment, investigations, and emergency care including:

- Recognition of components and location during examination
- Strong electromagnetic or magnetic fields
- MRI scanning
- Electrocautery
- Defibrillation
- Diathermy
- Ionising radiation
- General anaesthesia
- Electrocardiography (ECG).

Recognition of components and location

Of particular relevance to the dentist is the location of hardware components in the head and neck region and the implications for examination and interpretation of diagnostic tests and treatment. When implanted below the clavicle, the device has a very similar appearance to an implanted pacemaker. Unlike pacemakers, however, the connecting leads can take a long winding course through the head and neck region, depending on the distance from pulse generator to electrode. These can subsequently show as artefacts on some radiographic views. Additionally all of the components are sensitive to induction of current from electromagnetic

Table 1a: Common central nervous targets and suspected mode of action for INDs.

Target	Location	Function	Disorder
Deep Brain: • Globus Pallidus internus • Subthalamic nucleus • Ventral and anterior nuclei of thalamus • Nucleus Accumbens	Usually in the diencephalon	Nuclei of the diencephalon, the thalamus and the limbic system are involved in thinking, movement, pain and emotion. Stimulation of these targets can activate specific neural pathways and modulate neurotransmitter release. Further details on DBS is referenced (Arle and Shils, 2011; Fisher, 2013; Lozano and Hallett, 2013; Munhoz *et al.*, 2014).	Parkinsonian Disease Dystonia Essential Tremors Neuropathic pain Tourette's syndrome Addiction Epilepsy Obsessive-compulsive disorder Anorexia nervosa
Spinal cord	Sacral nerves Area of spinal cord relating to chronic pain.	Targets dorsal pain pathways or cauda aquina fibres in bladder control (Kapural, 2014; Peeters *et al.*, 2014).	Chronic pain Lower urinary tract dysfunction
Primary Visual Cortex (PVC)	Occipital lobe	Direct microstimulation of the PVC can restore partial visual perception. (Fernandesa *et al.*, 2012).	Loss of sight via extraocular components / intracranial pathology

Table 1b: Common peripheral targets and suspected mode of action for INDs.

Target	Location	Function	Disorder
Retinal implants	Retina	Replicates retinal function, capturing light and stimulating retinal ganglionic cells (Fernandesa *et al.*, 2012).	Intraocular loss of sight where optic nerve remains intact
Trigeminal nerve (TNS)	All branches of the trigeminal nerve	Targets sensory fibres of the trigeminal nerve but these fibres also innervate the solitary tract (see vagus nerve) (Fanselow, 2012).	Trigeminal Pain Epilepsy Intractable headaches Depression
Occipital Nerve (ONS)	Occiput emerging from between the 1st/2nd cervical vertebrae	Thought to modulate central nociceptive processing in brainstem as fibres converge on spinal trigeminal complex (Lambru and Matharu, 2014)	Intractable headaches
Vestibulocochlear nerve	Inner ear	Implant substitutes sensory hair cells in the cochlear, with electrodes directly stimulating the cochlear nerve (Vincenti *et al.*, 2014).	Sensorineural hearing loss
Dorsal Root Ganglion (DRG)	Dorsal root ganglion of spinal cord	Stimulation of sensory nerve cell bodies in DRG causes pain attenuating parathesia. (Van Buyten *et al.*, 2014).	Chronic pain

Table 1c: Autonomic Nervous System Targets used in Neurostimulation.

Target	Location	Function	Disorder
Vagus Nerve (VNS)	Carotid sheath, deep neck structure (CNS)	Thought to act through changes in noradrenaline release via solitary tract neurons or elevation of gamma-aminobutyric acid levels (Fanselow, 2012)	Epilepsy Depression *Alzheimer's*
Sphenopalatine ganglion (SPGS)	Pterygopalatine fossa	Inhibition of parasympathetic activation of the trigeminal autonomic reflex (Schoenen *et al.*, 2013).	Cluster headaches

interference and trailing leads from dental equipment may unwittingly come into close proximity with IND components. Therefore, a thorough history of component location should be taken from the patient as well as being observant of any visible surgical scars. Relevant further details will be discussed below regarding component location and specific treatment therapies.

Indirect energy application

Electromagnetic interference

High frequency electrical equipment or strong magnetic fields can cause electromagnetic interference (EMI) within the circuitry of implantable devices (Dyrda and Khairy, 2008). These sporadic currents within the circuitry can cause momentary or sustained disruption of equipment and/or programming. Depending on device functionality this can have disastrous effects, for example, unsupported bradycardia after disruption of cardiac pacemaker rhythm. Newer devices have some safety features to protect against EMI including: non-magnetic and shielding metallic casing, filters, interference rejection circuits, bipolar sensing and lead energy dispersal systems (Dyrda and Khairy, 2008; Medtronic, 2014a) but it is impossible to tell whether a device has these features without detailed information of manufacturer, model number and serial codes which often even the patient does not have.

Within dentistry the most recognised source of EMI is from ultrasonic scalers. There is conflicting evidence regarding interactions between ultrasonic scalers and pacemakers (Miller *et al.*, 1998; Patel *et al.*, 2005; Brand *et al.*, 2007; Roedig *et al.*, 2010; Maiorana *et al.*, 2013) which is

Figure 2: Common sites for location of pulse generators/battery packs.

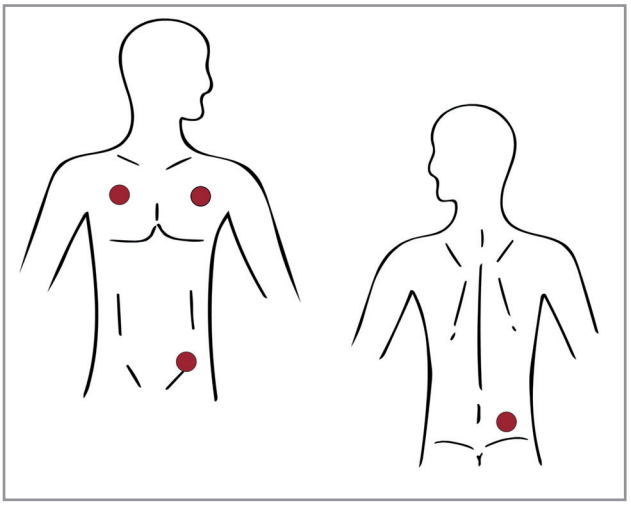


Figure 3: Examples of Neurostimulation devices *[images courtesy of Medtronic – reproduced with permission]* and their radiographical appearance *[image courtesy of Dr Ian Bickle and Dr Frank Gaillard et al., Radiopaedia.org – reproduced with permission.]*

reflected by the Board of Trustees of the American Academy of Periodontology rescinding their position paper on ultrasonic scalers in 2007 which recommended avoiding the use of ultrasonic scalers in cardiac pacemaker patients (American Academy of Periodontology, 2007). Given their similarity in construction to INDs this information is relevant.

Ultrasonic scalers are based on magnetostrictive or piezoelectric principles. In the former electromagnetic energy is converted into mechanical energy, a property of ferromagnetic materials, producing vibrations and heat. In the piezoelectric principle, deformation of crystals occurs when a current is applied resulting in mechanical oscillation (Maiorana *et al.*, 2013). The majority of studies have looked at the effect of dental equipment on pacemakers *in vitro*. Two of these studies reported interference with pacemaker function where components were within 23.0 - 37.5 cm of the device; both of these used magnetostrictive type scalers (Miller *et al.*, 1998; Roedig *et al.*, 2010). In comparison one, *in vitro* study with a piezoelectric scaler demonstrated no interaction (Brand *et al.*, 2007) and two *in vivo* studies found no significant interaction with implanted pacemakers, when investigating both piezoelectric and magnetostrictive type scalers (Patel *et al.*, 2005; Maiorana *et al.*, 2013). Furthermore their results also suggest interactions occur with the analysis equipment rather than the pacemaker itself (Patel *et al.*, 2005).

Modern pacemakers and INDs have shielding components, therefore when examining the available evidence it is also important to account for the age of the patient's device. Most manufacturers consider ultrasonic scalers safe to use with their pacemakers (St Jude Medical, 2009; Medtronic, 2014b); however, this may be an area that warrants further investigation as anecdotal experience of a pacemaker rhythm being reset inadvertently has been experienced by one of the authors. Only one study has been published testing IND interference against dental equipment and no significant interaction was demonstrated; although only one type of IDN was tested (Roberts, 2002).

Additionally, there is a theoretical possibility of current being induced in connection leads if an electromagnetic field is close by. Therefore, care should be taken to avoid unnecessarily draping ultrasonic scaler cables across the path of superficially implanted connection leads.

Although definitive evidential agreement is not present, a recently published review of the available literature on the interactions of ultrasonic scalers with pacemakers concluded that it is the dentist's responsibility to act in the patient's best interest, but that there was no compelling evidence to avoid the use of ultrasonic scalers in modern pacemakers (George *et al.*, 2014). Moreover it may be detrimental to successful management of periodontal disease if not used, and all types of ultrasonic scalers should be used if appropriate (George *et al.*, 2014). As most IDNs are similar to implantable cardiac rhythm devices and shielded from EMI, it is reasonable to assume that ultrasonic scalers are safe to use in these patients, however in view of the lack of published consensus the manufacturer's instructions should be consulted prior to their use.

Magnetic Resonance Imaging

Magnetic Resonance Imaging (MRI) is an important diagnostic tool, especially for examination of neoplastic tumours, soft tissue swellings or TMJ pathology, and its use in patients with INDs has been problematic. Concerns over tissue damage from component heating, damage to circuitry or inappropriate stimulation from radiofrequency pulses and physical displacement of the device in magnetic fields led to this imaging modality being contraindicated (Medtronic, 2010). As mentioned previously, some manufacturers have tried to address these issues with the development of MRI compatible components, for example, Medtronic SureScan® (Minneapolis, Minnesota) designed for their spinal cord stimulators. However, these systems have only been cleared for use in 1.5 Tesla MRI scanners so far and are yet to be validated directly for DBS stimulators and head and neck imaging. Further discussion and guidance of safe scanning of patients with these MRI compatible components can be found elsewhere (Krames *et al.*, 2009; Venkatraghavan *et al.*, 2009; Medtronic, 2010); Arle and Shils 2011; Zrinzo *et al.*, 2011).

Direct application of energy

Diathermy

Electrosurgery (or surgical diathermy) involves the use of electrical current to either cauterise or cut tissue and is most commonly used to control haemostasis. Two forms exist; monopolar and bipolar.

Monopolar diathermy units transmit a current from an active electrode to a dispersive electrode adhered to the patient; effectively using the patient to complete the circuit. The path of electrical transfer is not predictable and follows the path of least resistance, often resulting in a significant portion of the patient transmitting the charge (Bashetty *et al.*, 2009). Monopolar units should not be used in patients with IDNs as they risk significant damage to components.

Bipolar diathermy units send current between two electrode tips in a handpiece, allowing greater control and localised application of the current (Bashetty *et al.*, 2009). The greatest risk associated with bipolar diathermy is if the diathermy tips

are applied across neurostimulator connection leads. This could transmit the full diathermy current along the length of the connecting leads resulting in burning and destruction of tissue at the target site of the neurostimulator electrode. Bipolar diathermy may be used with caution provided location of device components is known and avoided.

Having said this, dental electrosurgery units have not been shown to interfere with the function of INDs (Roberts, 2002) or implantable cardiac rhythm devices (Patel *et al.*, 2005; Brand *et al.*, 2007). The authors, however, would err on the side of caution and bipolar is strongly preferred over monopolar systems, at lower voltage modes if possible. Following manufacturers' advice is again recommended.

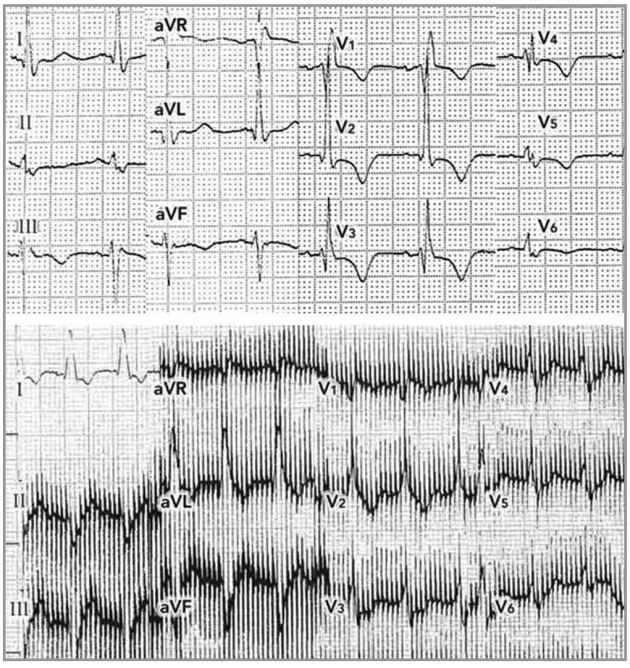
Defibrillation

Other equipment capable of delivering direct current to patients are cardiac defibrillators. Defibrillation intentionally produces a high energy depolarising current to heart muscle to disrupt dysrhythmia. Damage may result if neurostimulator (and similarly pacemaker) device components are situated in the path of current flow between defibrillator pads. Manufacturers, the Resuscitation Council (UK) and the Medicines and Healthcare Products Regulatory Agency (MHRA) have made suggestions on how to limit device damage if defibrillation is required (detailed below) (Resuscitation Council, 2011; Medtronic, 2013b; MHRA, 2013), however defibrillation and any necessary measures to restore life take precedence in this eventuality.

Diagnostic and therapeutic ultrasound

Ultrasound is used both diagnostically and therapeutically. Within Dentistry, diagnostic ultrasound is most commonly used for salivary gland imaging and occasionally soft tissue swellings. Therapeutic ultrasound is rarely used but it is sometimes conducted in the treatment of myofascial pain and temporomandibular disorders. Serious damage to INDs or surrounding soft tissue can be caused by direct dissipation of sound wave energy on device components (Nutt *et al.*, 2001; Roark *et al.*, 2008). It is therefore recommended that neither diagnostic nor therapeutic ultrasound be used within six inches of any device components (Medtronic, 2013b).

Figure 4: Example of ECG tracing whilst neurostimulation device is inactive (top) and active (below). *[Copyright 2004 The Medical Journal of Australia – reproduced with permission. (Bonvini and Camezind, 2004)].*



Ionising radiation

It is postulated that significant doses of ionisation radiation to device components may result in movement of freed electrons and random build-up of positive charge; this may cause leakage of current within device circuitry (Dyrda and Khairy, 2008). The result of radiotherapy on implanted electrical devices is unpredictable and can still be problematic even if the components are located outside the primary beam due to scatter. In this instance, the device should be deactivated during treatment and examined by a specialist following completion of radiation therapy (Hurkmans *et al.*, 2005). If device components are within the proposed field of radiotherapy then removal of the device components prior to treatment may be recommended. All issues regarding radiotherapy should be discussed within a multidisciplinary and specialist treatment centre context prior to treatment.

Radiography

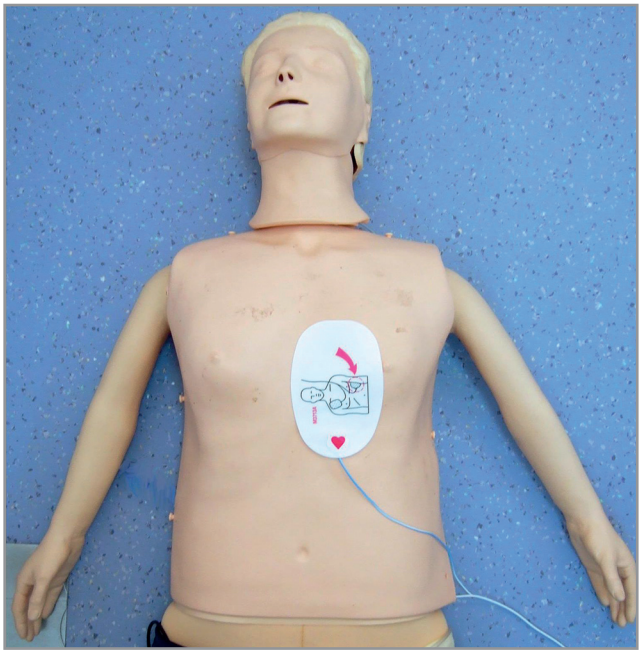
Momentary discomfort has been reported during the use of diagnostic computed tomography (CT). This is most likely to be due to diffuse electromagnetic fields generated by electronic components of CT equipment rather than the direct effects of ionising radiation. Manufacturer's advice is that INDs are compatible with CT scanning but that consideration should be given to deactivation prior to CT scanning (Medtronic, 2013b). To date, there have been no reports in the literature of safety issues with cone beam computed tomography.

Radiation from the taking of plain film radiographs is insufficient to cause significant damage to device components. However, components may produce artefacts or ghost images on a number of dental and maxillofacial views as a result of hardware positioning. Therefore, if possible images should be chosen that will not require the IND hardware to be between the x-ray tube and the desired target.

General anaesthesia

The main issue with INDs under general anaesthesia is the production of artefact on electrocardiograph (ECG) recording, preventing effective cardiac monitoring. *Figure 4* shows the appearance of an ECG tracing with a DBS turned on (Bonvini and Camezind, 2004)). It is therefore preferable to deactivate the device for the period of anaesthesia. Whether this is done before or after induction of anaesthesia depends on what condition the device is treating. If the IND was implanted to reduce tremors or treat any other

Figure 5a: Alternative defibrillation electrode positioning: anteroposterior position – anterior pad over left precordium and the posterior pad behind the heart just inferior to the left scapula.



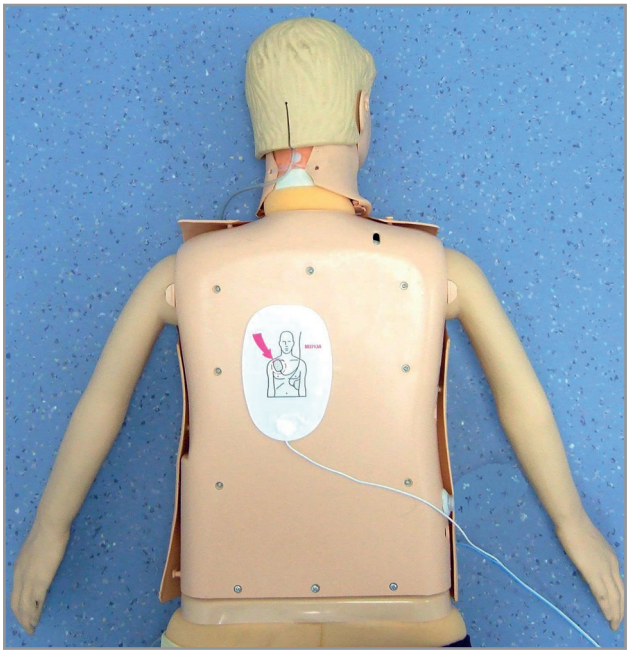
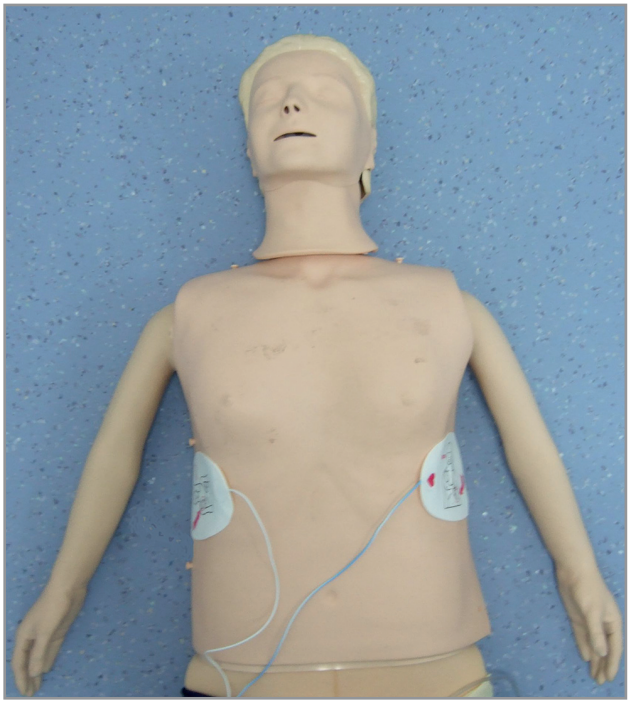


Figure 5b: Bilateral chest position – left pad in standard apical position in the left mid-axillary line and right pad mirrors this in right mid-axillary line.



movement disorder then deactivation before induction, and therefore return of tremor, could make the successful anaesthetic induction impossible.

It is important that prior to treatment as much information is gathered about the device as possible including, manufacturer, model, location and severity of the patient's condition with the stimulator turned off. Following treatment, the device needs to be reactivated and checked that it is functioning correctly. Sometimes these stages can be completed by a carer or family member who is used to regularly checking the device, although liaison with the patient's neuromodulation support team is advisable.

A clinical point specific to vagal nerve stimulators relates to its sensory and motor effects on innervation of the larynx and diaphragm. Long term vagal nerve stimulation can produce respiratory side effects such as altered breathing patterns, decreased airflow and heightened respiratory effort during sleep. In combination with residual anaesthetic effects this poses an increased risk of respiratory compromise during recovery (Venkatraghavan *et al.*, 2009). One interesting case has already documented partial airway obstruction when using a laryngeal mask airway as a result of this dysfunction during general anaesthesia (Bernards, 2004); alternative intubation methods may therefore be required for patients with vagal nerve stimulators undergoing GA.

Although no formal guidelines on management of these patients exist, some guidance notices are present in the literature (Association of periOperative Registered Nurses, 2005; Venkatraghavan*et al.*, 2009).

Summary

This article is an introduction to the subject of implantable neurostimulation devices for the dental practitioner. It briefly summarises indications for this emerging treatment modality and highlights important considerations for the management of patients with INDs who require dental treatment.

The neural-bioengineering interface is an exciting and rapidly expanding area of medical therapy. Already this has extended to the trialling of brain controlled robotic artificial limbs for rehabilitation of amputees responding to activity recorded from electrode arrays implanted directly in the patient's cerebral motor cortex (Velliste *et al.*, 2008). These techniques truly herald the bionic age of medicine and practitioners of all disciplines can expect to encounter such devices in the future. As such we must become familiar with the technology and understand potential implications on

dental practice. A protocol for the management of such implications is proposed (*Table 2*), however the available evidence specific to IDNs is limited and further research in this area is required.

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Address for correspondence:

Francis O'Neill
Liverpool Dental Hospital, Pembroke Place
Liverpool L3 5PS, UK
Email: foneill@liv.ac.uk

Table 2: Suggested Protocol for management of patients with INDs.

In patients with implantable neurostimulation devices requiring dental treatment, record the following information: • Reason for implantation and severity of condition with implant turned off • Responsible clinician and neuromodulation support team • Make and model and of location implanted device/components	
Ultrasonic Scalers	Both magnetostrictive and piezoelectric ultrasonic scalers should be suitable to use with these devices but until definitive guidance is produced consult manufacturers' instructions.
Therapeutic & diagnostic ultrasound	Both diagnostic and therapeutic ultrasound can be used as long as any implanted device is at least six inches outside the field of interest.
MRI	MRI is contraindicated in patients with implanted neurostimulation devices. Even if make and model is proven MRI compatible these have not yet been approved for head and neck scanning. Alternative imaging modalities such as Computed Tomography should be employed. In extremis and if components are proven MRI compatible then seek specialist advice and follow manufacturer specific instructions. Limit to 1.5 Tesla MRI scanner.
Diathermy	**Do not** use monopolar diathermy. Use bipolar diathermy with caution, and keep away from site of connector leads and pulse generator.
Defibrillation Devices	Do not delay cardiac defibrillation; this takes priority over concerns of damage to implanted devices. Follow the 'IPOT' steps (MHRA, 2013): Identify – the presence of an IND *(a record may be present in the patient's notes, or the device outline visible on examination)* Position – pads at least 10-15cm away from components Orientate – pads perpendicular to IDN (e.g. antero-posteriorly or bilateral chest – bilateral chest will reduce the interruption to chest compressions) (see *Figure 5*). Testing – of the device after successful medical management should be conducted by a specialist to check for damage.
General Anaesthetic	When general anaesthesia is required: • Liaise with anaesthetic team well in advance and inform of device presence and location (may require radiographs to locate) • Liaise with the neuromodulation support team to discuss deactivation/reactivation of the device. • Deactivate device during the anaesthetic to eliminate ECG monitoring artefact. • Ensure device functioning appropriately on reactivation. • Avoid Laryngeal mask airway in long standing VNS patients.

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