MRI Conditionality in Patients with Spinal Cord Stimulation Devices

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**Background**

Spinal cord stimulation (SCS) devices are surgically implanted tools against difficult-to-treat pain states such as failed back surgery syndrome, complex regional pain syndrome, and other types of chronic pain [1]. Until very recently, SCS device manufacturers recommended abstaining from magnetic resonance imaging (MRI) in patients with implanted SCS devices, in order to avoid patient hazards or device malfunctioning [2].

MRI is considered the gold standard for extensive clinical evaluation and diagnosis of numerous disorders of the central nervous system, musculoskeletal system and cardiovascular system [3]. Thus, being unable to safely undergo MRI clinically disadvantages implanted device patients such as those who undergo SCS. In the past, SCS devices have frequently been explanted when clinical care necessitates an MRI [1]. Explantation is a significant event that requires a surgical procedure and, thus, imposes tremendous physical and economic burdens on patients.

The growing number of patients undergoing implantation of SCS devices made the need for MRI conditional systems more apparent [1]. Multiple studies have demon-
Stratified that under specific conditions, MRI can be safe with SCS devices [4, 5]. Concerns regarding the impact of MRI on patient safety will continue to grow as more patients opt to undergo surgical treatment for alleviation of their chronic pain [6]. Nearly 28,000 SCS surgeries are performed annually worldwide, contributing to a rapidly increasing patient population with implanted SCS devices [7]. It has been shown that an estimated 82–84% of SCS patients are expected to require at least 1 MRI within 5 years after implantation [8]. Though this issue has been hotly debated, the reality is that physicians caring for patients order MRIs as their definitive examination, and it remains difficult and time-consuming to convince patients that they do not need these diagnostic tests, even when the indications are ‘soft’.

In light of the changing device capabilities, this article provides a general reference that can be useful for implanting and treating physicians of the specifications of SCS devices.

<table>
<thead>
<tr>
<th>Leads</th>
<th>Systems (IPG)</th>
<th>Scan permitted</th>
<th>Restrictions/programming</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic SCS&lt;sup&gt;1&lt;/sup&gt;</td>
<td>SureScan Models</td>
<td>Full-body 1.5-tesla closed, horizontal bore</td>
<td>30 min active scan time; no extensions; only Injex anchors 97791, 97792; stimulation on MRI mode SAR &lt;2.0 W/kg for whole body and &lt;3.2 W/kg for head</td>
<td>Specific MRI settings</td>
</tr>
<tr>
<td>Perc.: 1 × 8 Vectris SureScan</td>
<td>Restore, Prime, Synergy, Versitrel, Itrel4 Models starting with 377 or 74</td>
<td>Head-only 1.5-tesla closed, horizontal bore</td>
<td>Must have all components out of head coil; stimulation off SAR &lt;3.2 W/kg</td>
<td>Titan 3550-39 /Injex 97791, 97792 anchors and extensions 37081, 82, 83 can be used provided they are not located by the calvarium; no active scan time restrictions; specific MRI settings</td>
</tr>
<tr>
<td>Paddle: specify SCS Standalone SureScan</td>
<td>SureScan Models</td>
<td>Full-body 1.5-tesla closed, horizontal bore</td>
<td>30 min active scan time; patient should not exceed 30 min of active scan time within a 90-min period; stimulation on normal mode SAR &lt;2.0 W/kg for whole body and &lt;3.2 W/kg for head</td>
<td>Specific MRI settings; within a 90-min window, there should be a total of 60 min of nonscan time</td>
</tr>
<tr>
<td>St. Jude SCS&lt;sup&gt;2&lt;/sup&gt;</td>
<td>3771 Protégé</td>
<td>Head/extremity-only 1.5-tesla closed, horizontal bore</td>
<td>30 min active scan time; LE approved except hip; UE approved only for wrist; perc. lead tip must be between T7 and T12 vertebrae; maximum of 2 perc. leads can be implanted; must have all components out of head coil; no extensions; stimulation off</td>
<td>Must be positioned supine with arms at side; all lead anchors/port plug 1111 are MR compatible; specific MRI settings</td>
</tr>
<tr>
<td>Perc.: 3186 Octrode</td>
<td>Senza NIPG1000 or NIPG1500</td>
<td>Head/knee/wrist-only 1.5/3-tesla closed, horizontal bore</td>
<td>15 min active scan time; must have all components out of head coil; stimulation off</td>
<td>LEAD2008-xxB (extension), ACCK5xxx (lead anchor) and ACCK7000 (IPG port plug) MR compatible; specific MRI settings</td>
</tr>
<tr>
<td>Paddle: 3228 Penta Lamitrode</td>
<td>Precision spectra model</td>
<td>Head-only 1.5-tesla closed, horizontal bore</td>
<td>Transmit and receive lead coil only, stimulation off, wait 6 weeks before MRI, lead must be below T5 level</td>
<td>Clik anchor and Med A adaptor are MRI compatible US-SAR &lt;3.2 W/kg EU-SAR &lt;1.5 W/kg No abandoned leads, and they must be connected to the IPG</td>
</tr>
</tbody>
</table>

<sup>1</sup> Perc. = Percutaneous; IPG = internal pulse generator; SAR = specific absorption rate; LE = lower extremity; UE = upper extremity. Activa Models have received European Union (EU) approval for conditional full-body MRI; not currently full-body MRI compatible in the USA. 1 Approved for use in the USA and EU. 2 Approved only for the USA. 3 Approved in the USA, EU and Australia. 4 Approved in the USA and EU. All other models are not MRI compatible.

Table 1. MRI conditionality of SCS devices

MRI Conditionality

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services as well as a summary of the literature on its safety to date. By providing insight regarding the type of MRI appropriate for various systems, we aim to improve safety for patients with SCS devices who are undergoing MRI.

Methods

We first performed a literature search of ‘SCS and MRI’ in PubMed in English from 1992 to 2015 and located 4 articles which discuss the clinical experience with imaging in SCS. We then reviewed the available literature on SCS devices to create a comprehensive table, which specifies the devices with MRI conditionality and their restrictions of the available SCS devices. Since SCS MRI conditionality was approved in the USA just over the last 3 years, there is a limited published experience in this arena. Our article discusses 3 cases where we performed lumbar MRI with the MRI conditional devices.

Results

The MRI condition specifications for SCS devices in the USA and European Union are shown in table 1. In table 2, we describe the clinical experience of MRI with SCS. There are 4 reports in the literature – 3 performed with non-MRI conditional devices with varying experiences seemingly dependent on whether there was an internal pulse generator or not and what the specific absorption rate was [9]. The latter is a dosimetric variable that represents the amount of radiofrequency power absorbed per unit of mass that is generally used to characterize the thermogenic properties of an electromagnetic field [10]. It is expressed in weight per kilogram. A letter to the editor is the only report of MRI with an MRI conditional SCS lead in place [2, 11, 12]. In our time of implanting MRI conditional leads, we have attempted to order 3 MRIs. The first patient unfortunately had a question of infection at the lead site; as

Table 2. Published clinical experience with MRI conditional and MRI nonconditional devices

<table>
<thead>
<tr>
<th>First author [Ref.], year</th>
<th>Device</th>
<th>Study</th>
<th>MRI</th>
<th>Patients</th>
<th>AEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>De Andres [9], 2014</td>
<td>2 MRI conditional Vectris Surescan leads in thoracic region with Restore sensor IPG (Medtronic); IPG location not specified</td>
<td>Case study</td>
<td>1.5-tesla MRI thoracic and lumbar spine Sagittal T1, T2, stir and axial T1</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Mutter [2], 2013</td>
<td>Medtronic SCS leads in thoracic region (not MRI conditional but leads otherwise not specified) with IPG (Prime Advances, Itrel 3, Restore Ultra, Synergy) in buttoks (IPG deactivated prior to MRI and checked after MRI)</td>
<td>Prospective</td>
<td>1.5-tesla MRI spine; SAR restricted to &lt;0.74 W/kg T2 axial, coronal and sagittal; T1 sagittal</td>
<td>13 with 16 MRIs</td>
<td>3 patients with warmth at electrodes and 1 with intermittent LE tingling</td>
</tr>
<tr>
<td>Moens [12], 2012</td>
<td>Medtronic 565 in thoracic region externalized (no IPG)</td>
<td>Prospective</td>
<td>1.5-tesla brain MRI (T1 TFE M2D, T1 TFE 3D, FFE EPI, MS, IR TSE MS, fMRI), and 3-tesla brain MRI (T1 TFE 3D, FFE EPI, MS, SE EPI, MS, PRESS, SV, IR TSE MS, MRS, fMRI)</td>
<td>40 patients</td>
<td>None</td>
</tr>
<tr>
<td>De Andres [11], 2007</td>
<td>1 or 2 four-electrode leads in cervical or lumbar region and an Itrel III® or Synergy® (Medtronic Inc., Minneapolis, Minn., USA) IPG (location not specified); IPG turned off at 0 V prior to MRI and checked following MRI</td>
<td>Prospective</td>
<td>1.5-tesla MRI, cervical, thoracic, lumbar, brain receiver coils for spine scans and head transmit coil for brain scans; SAR &lt;0.9 W/kg</td>
<td>31 patients</td>
<td>2 IPG malfunctions necessitating surgical revision; 5 patients felt stimulation; 2 patients felt IPG warmth; 4 patients had programming change; 1 patient had increased impedances; 1 patient required decreased amplitude after</td>
</tr>
</tbody>
</table>

AEs = Adverse events; SAR = specific absorption rate; LE = left extremity; IPG = internal pulse generator; TFE = turbo field echo; M2D = multi-2-dimensional; fMRI = functional magnetic resonance imaging; FFE = fast field echo; EPI = echo planar imaging; MS = multislice; SE = spin echo; IR = inversion recovery; TSE = turbo spin echo; GE = gradient echo; MRS = magnetic resonance spectroscopy; PRESS = point resolved spectroscopy; SV = single voxel.
this is a contraindication to lumbar imaging, we were unable to obtain this imaging. The second patient was a 71-year-old male with failed back surgery syndrome. After a successful SCS trial, he was implanted with the percutaneous MRI conditional SCS. One year postoperatively, he had an acute exacerbation of chronic lower back pain with radicular complaints. He failed conservative therapy and ultimately underwent lumbar MRI, which showed a disk herniation causing foraminal stenosis at the level above his fusion (fig. 1). The third and final patient had new onset radicular symptoms 3 months following thoracic SCS. Despite vigorous education on initiating conservative therapy, this patient remained adamant regarding an MRI after 2 weeks of medical management and physical therapy. In light of the fact that epidural steroid injections were our next recommendation, we obtained the MRI.

There are 3 principal magnetic fields in MRI that may interact with surgically implanted systems: the static field, the radiofrequency field, and the pulsed gradient field [13]. The static magnetic field induces mechanical force and torque on ferromagnetic objects, such as those contained within SCS systems [13]. Pulsed gradient magnetic fields can induce voltages and currents on leads. Surgically implanted devices can concentrate these induced currents, which could result in electrical interference or even nerve stimulation. The radiofrequency magnetic field can also induce current into the body – this in turn can lead to dangerous heating of surrounding tissues (e.g. leads) [4, 13].

Innovations in SCS technology are aimed at resolving the two most common issues causing MRI incompatibility: (1) patient discomfort due to movement or heating of the device [5] and (2) image artifacts produced due to the implanted device [14]. Heating of the lead in SCS devices can be controlled by the modification of several factors, including impedance of the wire, diameter of the lead, and properties of surrounding insulation material [15]. Lead movement is less likely to occur if the patient is positioned such that the imaging coil is located distant to the implanted SCS device. Additionally, the establishment of a thermal dose limit is an integral step in the development and configuration of neuromodulation systems that are conditionally safe during MRI procedures [5].

Conclusion

In this study, we provide a user-friendly comprehensive table of specific compatibility of SCS devices in the USA and European Union. We also examine the existing literature on the clinical experience with MRI and SCS and provide data into our early experience with full body MRI conditionality. We hope for this investigation to serve as a general guide to MRI compatibility with SCS devices and a review of clinical experience including ours with SCS systems.

Disclosure Statement

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References


