

Feasibility of cerebral magnetic resonance imaging in patients with externalised spinal cord stimulator

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ABSTRACT

Object: Spinal cord stimulation (SCS) is a well-known treatment option for intractable neuropathic pain after spinal surgery, but its pathophysiological mechanisms are poorly stated. The goal of this study is to analyse the feasibility of using brain MRI, functional MRI (fMRI) and Magnetic Resonance Spectroscopy (MRS) as tools to analyse these mechanisms in patients with externalised neurostimulators during trial period.

Methods: The authors conducted an *in vitro* and *in vivo* study analysing safety issues when performing brain MRI, fMRI and MRS investigations in human subjects with externalised SCS. Temperature measurements *in vitro* were performed simulating SCS during MRI sequences using head transmit-receive coils in 1.5 and 3 T MRI systems. 40 Patients with externalised SCS were included in the *in vivo* study. 20 patients underwent brain MRI, fMRI and another 20 patients underwent brain MRI and MRS.

Results: A maximal temperature increase of 0.2 °C was measured and neither electrode displacements nor hardware failures were observed. None of the patients undergoing the MRS sequences at the 1.5 or 3 T MRI scanners described any discomfort or unusual sensations.

Conclusion: We can conclude that brain MRI, fMRI and MRS studies performed in patients with externalised SCS can be safely executed.

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1. Introduction

Implantable systems for spinal cord stimulation (SCS) are increasingly used worldwide for the treatment of intractable pain [1]. This technique applies high-frequency local electrical spinal cord stimulation generated by percutaneously or surgically inserted electrodes connected through subcutaneous extension leads to an implantable pulse generator (IPG)[2]. Although long-term treatment efficacy of SCS has been clinically demonstrated, the exact pathophysiological mechanisms underlying its central action remain unresolved [3–5].

Magnetic resonance imaging (MRI), functional magnetic resonance imaging (fMRI) and magnetic resonance spectroscopy (MRS) of the brain could be used to clarify these mechanisms.

Several safety issues limit the use of MRI in these patients. First, the magnetic field may damage the IPG and/or displace the spinal electrode resulting in diminished treatment efficacy. Second, magnetically induced electrical pulses within the wires may provoke unpleasant and painful stimuli for the patient. The risk is even higher when wire loops are created during implantation of the extensions. Finally, absorption of high energy levels may cause a rapid increase in tissue temperature close to the electrode tip. It is conceivable that, extreme heating might irreversibly damage the spinal cord. For these reasons, manufacturers of IPG's in general discourage MRI use in patients with implanted devices. Only a head MRI, using a radiofrequency (RF) transmit/receive head coil, might be conducted under strict monitoring [6,7].

The use of externalised stimulators with implanted electrodes is a widely employed alternative to evaluate treatment efficacy

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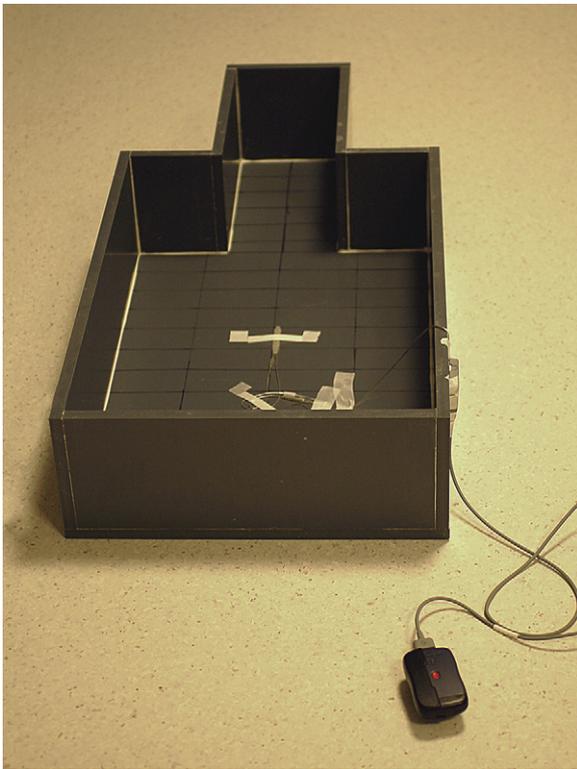


Fig. 1. Global setup: a gel-filled phantom with a spinal cord stimulator-electrode at dorsal vertebral level 6, connected with an external neurostimulator outside the phantom.

during a short trial [8]. Within this time frame the clinician can recognise patients who do not benefit from SCS before definitive implantation.

Two recent fMRI studies in a limited number of subjects, demonstrated no major device-linked problems [9,10]. But, no safety studies have been published on the use of MRI in patients with externalised IPC's.

Therefore, we conducted in an *in vitro* and *in vivo* study to investigate the feasibility of cerebral MRI, fMRI and MRS in patients with externalised IPC's.

2. Methods

2.1. *In vitro* phantom study

We created a phantom with shape and dimensions approximating those of an adult human head and torso for the MRI protocol according to the methodology of Rezai et al. and Carmichael et al. [11,12].

2.1.1. The phantom set-up

The phantom was filled with an aqueous gel with similar thermal and electrical properties as human tissue with a total weight of 60 kg. The gel was filled to a depth of 10 cm and composed of a 5.85 g/L polyacrylic acid (Aldrich Chemical) and NaCl 0.9% solution [11,12].

The experiment aimed to mimic the real clinical situation in a patient with an implanted SCS (Fig. 1). The surgical plate electrode (model 39565 Specify565®, Medtronic Inc., Minneapolis, MN) was oriented in caudo-cranial direction and fixed with non-sticky tape in the middle of the gel-filled phantom at dorsal vertebral level 6. This allowed the electrode to move in all directions within a horizontal plane while remaining attached to the bottom. Table 1 summarises the characteristics of the electrode used

Table 1

Characteristics of Medtronic electrode model 3998 Specify® and model 39565 Specify565®.

Characteristics	Model 39565
Shape	Contoured
Conductor resistance	<77 Ω (65 cm)
Length	65 cm
Diameter	1.3 mm
Number of electrodes	16
Electrode shape	Rectangular
Electrode size	1.5 mm × 4.0 mm
Electrode stimulating area	6.0 mm ²
Inline spacing	4.5 mm
Row spacing	1.0 mm
Electrode paddle length	64.2 mm
Electrode paddle width	10 mm
Electrode paddle thickness	2.0 mm
Lead contact length	1.5 mm
Lead contact distance	22.5 mm
Conductor wire	MP35 N
Conductor wire insulation	Fluoropolymer
Electrodes	Platinum-iridium
Electrode paddle	Silicone rubber
Insulation	Polyurethane

in this experiment. Following connection with extensions (temporary extensions model 37081, Medtronic Inc., Minneapolis, MN), an artificial loop was created and fixed with tape at the bottom of the phantom (Fig. 2). *In vivo*, loops are made subcutaneously in order to reduce traction on the electrode by body movements. The extensions were connected to a 153 cm long Snap-Lid (model 35501-31 Snap-Lid cable®, Medtronic Inc., Minneapolis, MN) cable and fixed to the side of the phantom. At the foot of the scanner bed, 150 cm outside the scanner, an external neurostimulator (model 37022 ENS®, Medtronic Inc., Minneapolis, MN) generating programmed pulses and patterns under normal (2 V, 60 Hz and 210 μs) and extremely high settings (10.5 V, 130 Hz and 450 μs) was connected to the snap-lid. Sandbags were put on top of the neurostimulator to avoid attraction of the device to the scanner.

An MRI compatible fibre-optic temperature sensor (FOT-M-SD-C4-F1-M2-R1-ST, FISO technologies, Québec, QC) was placed under the plate electrode in contact with the most cranial contact point since heating is expected to be greatest near the electrode tip where the electrical current flux density is highest [12,13]. A 200 cm long cable connected the temperature sensor to a FTI-10 signal conditioner (FISO technologies, Québec, QC). Interactions between the FTI-10 and the MRI scanner were avoided by placing them as far away as possible from each other. Before the experiment, the temporal resolution of the sensor was found 1.5 s (as well in as outside the MRI scanning room).

2.1.2. Phantom study protocol

Experiments were performed in a 1.5 T (Intera, software level 11, Philips, Best, NL) and in a 3 T (Achieva, software level 2.5, Philips, Best, NL) MRI scanner. In the 1.5 T scanner we used a survey scan, a 3D, an fMRI and a sequence with an as high as possible estimated specific absorption rate (high SAR sequence). All scans were done with the transmit-receive head coil according to current safety guidelines. The fMRI and high SAR measurements were repeated using the body coil to increase the RF power deposit at the electrode site [14]. In the 3 T scanner we performed a survey, a 3D, a GE fMRI, an SE fMRI, an MRS and a high SAR sequence (Table 2). All scans were done with the transmit-receive head coil and no scans were repeated with the body coil.

The phantom was positioned supine with its head placed in the head coil at the magnet isocentre. All imaging volumes were positioned at the lower part of the head. SAR values were reported as whole body values calculated by the scanner software based

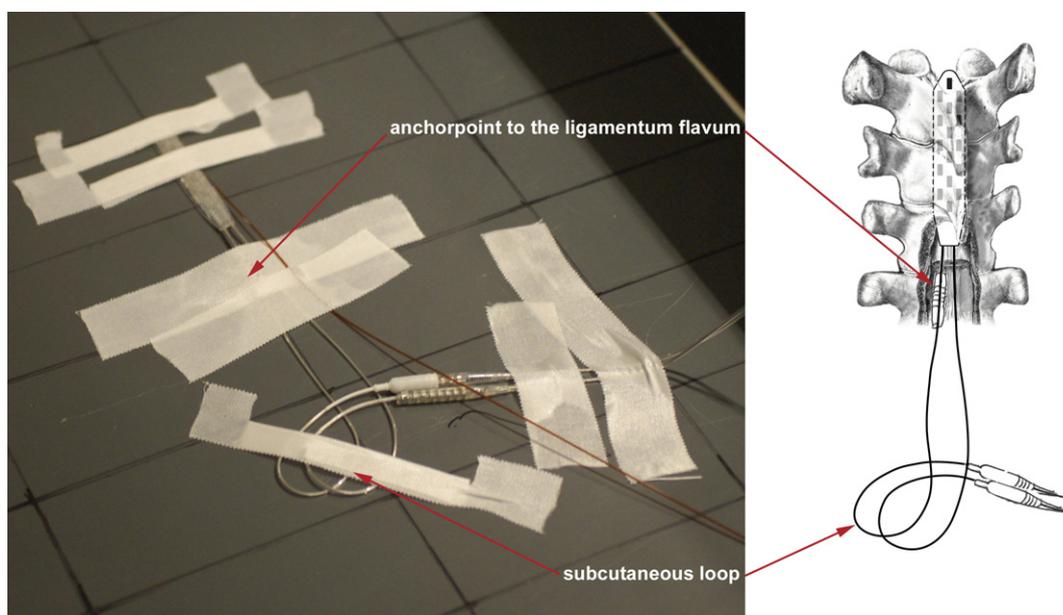


Fig. 2. Experimental setup in correlation with the patient situation: thermometer (copper coloured) in close contact with the electrode.

on the sequence parameters and the entered phantom weight. Due to the positioning of the phantom and imaging volume, the stimulator electrodes received only stray RF and gradient fields as in a real patient situation. Actual SAR values at the stimulator level were unknown but expected to be lower than given SAR values.

We stimulated continuously during the MRI measurements. For the fMRI measurements at 1.5T, we repeated the measurement with a block paradigm of alternating 30 s during blocks with and without stimulation as we planned to do in *in vivo* fMRI measurements. Table 3 gives an overview of the measured sequences and the used stimulation modes.

2.2. *In vivo* clinical study

We enrolled 40 patients with neuropathic back and leg pain after spinal surgery who were eligible for SCS. The study was conducted conform the declarations of Helsinki and approved by the Ethics Committee of the University Hospital of the Vrije Universiteit Brussel. All patients signed an informed consent. A surgical lead connected to an externalised neurostimulator was implanted under epidural anaesthesia covering the lower part of D8 till the upper part of D10. Twenty patients were assigned to the 1.5 T study protocol; subsequently the remaining 20 underwent the 3 T study protocol because of the availability of the 3 T MRI scanner. Stimulation settings were optimised individually in supine position immediately before the start of each MRI.

The study included 3 MRI sessions at the 1.5 T scanner on the same day including a survey and 3D measurement without stimulation and an fMRI with the stimulator switched on and off in 30 s duration blocks. At the 3 T scanner, the study included 3 MRI sessions of a survey and a MRS measurement without stimulation and 3 MRS measurements with continuous stimulation (Fig. 3). Before and after each MRI session, telemetry of the entire neurostimulation system was performed to guarantee the integrity of the stimulation system. This included measurements of estimated battery life and impedance to confirm correct position and function of the lead.

Positioning of the patients was done in accordance to the previous phantom tests (supine position, head first). All MRI measurements were performed with the transmit-receive head coil.

Patients were not sedated but instructed to stay awake and asked to report any unusual sensations at the implantation site.

Visual contact was kept with the patients at all times during the MRI session. In addition, the speaker system inside the MRI allowed direct communication between the patient and a member of the multidisciplinary pain team. Before and after the scans with stimulation the patient was interviewed for any unfamiliar sensations (heating, discharges, paresthesias, burning sensation, etc.) and underwent a thorough physical examination.

After completion of the MRI protocol, telemetry was performed and all system parameters were recorded. Four weeks later, a control visit was scheduled, including telemetry of the whole device.

3. Results

3.1. Phantom measurements

Measured temperatures at both scanners ranged between 22.05 and 23.30 °C. During MRI sequences, temperature fluctuations of less than 0.2 °C were noted. The same variations were also observed outside the MRI scanner and without SCS. Temperature fluctuations between 1.5 and 3 T, body and head coil, high and low SAR measurements, block and continuous stimulation mode and high and normal voltage SCS stimulation measurements were comparable (Table 3).

No electrode displacement or hardware failure was observed during the MRI scanning sessions. Profound device telemetry following MRI sessions showed no alterations in programming settings as compared to the situation before start of MRI.

3.2. Patient measurements

Patients experienced no unusual temperature rise at the implanted electrode or at the extensions site. Changes in stimulation patterns, e.g. increased stimulation intensity during scanning, were not reported. No other unpleasant sensations were felt. Telemetry of the stimulator and impedance measurements after each MRI session did not show any altered setting.

Some problems were experienced while changing the stimulator settings too closely to the scanner bore with an N'vision (Model 8840, Medtronic Inc., Minneapolis, MN), which communicates with

Table 2
Sequences on 1.5 T and 3 T.

	Survey T1 TFE, M2D	3D T1 TFE, 3D	fMRI FFE EPI, MS	High SAR IR TSE, MS		
1.5 T						
EPI factor			63			
TFE factor	42	180		80		
Matrix	256 × 256 × 9	256 × 180 × 80	64 × 63 × 30	336 × 200 × 25		
Voxel size	0.98 mm × 1.05 mm × 10.00 mm	0.94 mm × 1.17 mm × 2.00 mm	3.59 mm × 3.59 mm × 3.00 mm	0.48 mm × 0.48 mm × 3.00 mm		
TR/TE/flip angle			3000 ms/35.0 ms/90°			
TI/TR/TE/flip angle	372.8 ms/15 ms/5.2 ms/20°	1501.7 ms/16 ms/4.6 ms/30°		60 ms/8214 ms/7.0 ms/90°		
NSA	1	1	1	2		
SAR	0.3 W/kg	0.5 W/kg	0.2 W/kg	3.4 W/kg		
Scan time	17.4 s	5 min 6.0 s	7 min 36.0 s	1 min 55.0 s		
Other			SPIR fat suppression 150 dynamics Time resolution = 3 s	SPAIR fat suppression		
	Survey T1 TFE, M2D	3D T1 TFE, 3D	GE fMRI FFE EPI, MS	SE fMRI SE EPI, MS	MRS PRESS, SV	High SAR IR TSE, MS
3 T						
EPI factor			91	95		
TFE factor	64	240				320
Matrix	256 × 128 × 9	240 × 240 × 100	92 × 91 × 26	96 × 95 × 24		400 × 320 × 24
Voxel size	0.98 mm × 1.95 mm × 10.00 mm		2.50 mm × 2.50 mm × 3.00 mm	2.40 mm × 2.40 mm × 4.00 mm	15 mm × 15 mm × 15 mm	0.57 mm × 0.72 mm × 4.00 mm
TR/TE/flip angle			3000 ms/36.0 ms/90°	3000 ms/70.0 ms/90°		
TI/TR/TE/flip angle	800 ms/11 ms/4.6 ms/15°	940 ms/7.6 ms/3.7 ms/8°				50 ms/107,086 ms/10.0 ms/90°
TR/TE					2000 ms/35 ms	
Samples					1024	
NSA	1	1	1	1	96	1
scan time	31.3 s	6 min 22.9 s	7 min 45.0 s	8 min 24.0 s	3 min 48.0 s	1 min 47.1 s
SAR	0.3 W/kg	0.2 W/kg	0.5 W/kg	0.5 W/kg	0.3 W/kg	3.2 W/kg
Other			SPIR fat suppression 150 dynamics time resolution = 3 s	SPIR fat suppression 80 dynamics time resolution = 6.0 s		

EPI, echo planar imaging; TFE, turbo field echo; TR, repetition time; TE, echo time; TI, inversion time; NSA, number of signal averages; SAR, specific absorption rate; M2D, multi 2D; FFE, fast field echo; IR, inversion recovery; TSE, turbo spin echo; MS, multi slice; GE, gradient echo; fMRI, functional magnetic resonance; MRS, magnetic resonance spectroscopy; PRESS, point resolved spectroscopy; SV, single voxel; SPIR, spectral presaturation inversion recovery; SPAIR, spectral selection attenuated inversion recovery.

Table 3
Temperature measurements.

Scanner	Coil	Sequence	Stimulation mode	ΔT_{\max}	
1.5T	Head	No measurement	No stimulation	0.1	
		Survey	No stimulation	0.1	
		3D	No stimulation	0.1	
		fMRI	No stimulation	0.05	
	Body	High SAR	Continuous	0.1	
			Block	0.1	
			No stimulation	0.1	
			Continuous	0.1	
		Survey	No stimulation	0.1	
			fMRI	No stimulation	0.05
			Continuous	0.05	
			Block	0.1	
High SAR	No stimulation	0.05			
	Continuous	0.1			
	3 Tesla	Head	No measurement	No stimulation	0.1
			Survey	No stimulation	0.05
3D			No stimulation	0.1	
GE fMRI			Continuous	0.05	
SE fMRI			Continuous	0.2	
MRS			Continuous	0.2	
High SAR	Continuous	0.1			

No stimulation (the stimulator is attached, but does not stimulate); continuous (the stimulator stimulates continuously); block (stimulation: 30 s on, 30 s off).

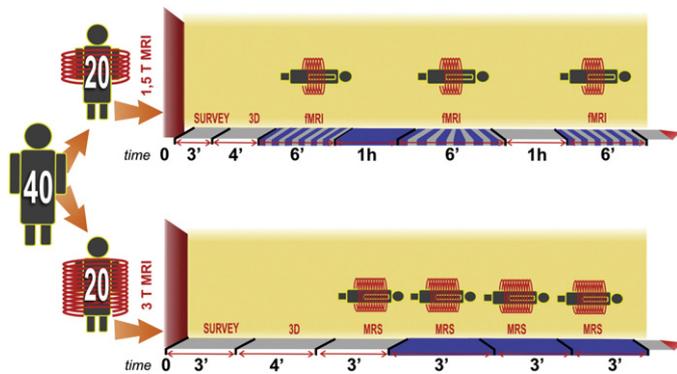


Fig. 3. Study protocol at 1.5 T and 3 T: blue: stimulation, grey: without stimulation.

the stimulator using magnetic induction. The latter was overruled by the magnetic field inside the scanner room. The problem was solved by using MyStim (Model 37743, Medtronic Inc., Minneapolis, MN) inside the scanner bore to activate the stimulator after setting the patients' parameters outside the scanning room by the N'vison.

Attraction of the neurostimulator towards the magnet when the patient was inside the scanner was avoided by putting a sandbag on top of it.

At the 4 weeks follow up visit, full telemetry of the device revealed no changes as compared to baseline.

4. Discussion

Similar to implantable cardiac devices, deep brain stimulators and spinal fusion stimulators, spinal cord stimulators may cause problems regarding patient safety and MRI use [12,14–27]. MRI guidelines were developed to reduce the risk of patients with implantable devices when undergoing MRI scans. These guidelines recommend physicians not to perform MRI in patients carrying not fully implanted systems who undergo trial neurostimulation [6,14]. Nevertheless, a small number of patients underwent investigation of cerebral activity during trial periods of neurostimulation

without reporting abnormalities or unfamiliar sensations during MRI measurements [9,10].

The present study investigated the safety of implantable surgical electrodes during trial periods of spinal cord stimulation *in vitro* as well as *in vivo*.

Heating of the electrode will be greatest at the level of highest electrical current flux density, which is near the tip. Excessive heating at this level might destroy neural tissue and provoke irreversible spinal cord damage [28].

Reversible thermal lesions occur when local temperature increases into a 42–44 °C range (a 5–7 °C elevation above normal body temperature of 37 °C). Thermal lesions become irreversible when local temperature exceeds 45 °C (>8 °C temperature rise above normal body temperature) [29]. Therefore, transient temperature elevations ≤ 2 °C in association with the use of the relatively high level of RF energy is unlikely to cause significant adverse thermogenic effects.

After achieving thermal equilibrium between temperature sensor and surroundings, we investigated local heating around the electrodes during different MRI sequences, with different stimulation modes and at the 1.5 and 3 T scanners.

The principal mechanism for heat dissipation in the phantom gel is thermal conduction and convection within the gel itself mimicking heating of neural tissue under the electrode.

In this study, the maximum ΔT (temperature difference between maximal temperature and temperature before specific MR sequence) at the tip of electrode was 0.2 °C. This could be explained by the fact that the brain but not the spinal cord was the targeted imaging area. Our findings suggest that, MRI induced heating is not a major concern in patients with trial period SCS who undergo brain MRI.

Little attention has been given to monitoring magnetic field interactions on the epidural electrode. Such interactions are proportional to field strength and spatial gradient of the MR systems and to mass, shape and magnetic susceptibility of the electrode.

Baker et al. tested displacement forces and magnetically induced torque at 1.5 and 3 T MR scanners for several neurostimulation devices or IPGs. They found that, depending on the system, patient discomfort and/or movement of the implanted IPG device represents a real problem [30].

We used an external IPG during the trial period that was attracted towards the scanner. However, this effect was easily

countered by putting sand bags on top of the neurostimulator and thus did not affect the comfort of the patient.

Epidurally implanted electrodes for SCS are at risk for displacement particularly during the first weeks after implantation. Even minor displacements may result in decreased pain relief.

Electrode displacements during the MRI session were not observed *in vitro*. Patients also did not feel a change of stimulation pattern, indicating that the electrode did not migrate.

The present study provides new information related to magnetic field interactions for a currently used plate electrode exposed to 1.5- and 3 T MR systems during trial periods. MRI scans of the brain do not influence the position of the dorsally placed electrode, even when the electrode is implanted within 10 days.

Accidental electrical pulses in the implanted wires and electrodes can be provoked by low-frequency pulsed magnetic gradients. These pulses depend on the magnitude of the magnetic gradient change, but are insignificant under normal orientations of the neurostimulator in the magnet [11,15].

Due to pulsed RF fields, radiofrequency currents can be induced in coils of wires near the RF source by the “antenna effect”. Besides these currents, RF fields can provoke heating due to absorption of RF energy.

The connection between the electrode and the extensions is usually implanted in subcutaneous or subfascial tissue. A number of loops are made to reduce tension on the electrode and to anchor the connection. RF gradients may influence these loops by inducing accidental radiofrequency currents due to the Faraday Effect.

Several authors have considered these RF pulses as insignificant [11].

None of the patients in the present study experienced any changes in stimulation during MRI sessions.

Hardware failure due to MRI influences on the SCS devices (IPG, extensions and electrode) was not noticed *in vitro* and *in vivo*.

The IPG did not indicate any software malfunctions and worked perfectly. The IPG was only slightly attracted towards the scanner.

The MyStim programmer used to adjust and manage stimulation inside the scanning room functioned without restriction or failures. This allowed synchronizing of stimulation sequences with scanning sequences.

For both 1.5 and 3 T scanners we added a sequence with a SAR around 3.2 W/kg whole body during the phantom measurements. The maximum SAR allowed by ICNIRP [31] and FDA regulations is 4 W/kg whole body and 3 W/kg head only. Most MRI sequences have a SAR of ~0.5 W/kg total body. By using a transmit/receive head coil, the actual SAR at the level of the electrodes is even less. Our results show no temperature increase at the level of the electrodes while performing MRI head examinations on a 1.5 T and 3 T system with the transmit/receive head coil even during high SAR sequences. These results expressed as $\Delta T/SAR$ are specific to our MRI scanners and cannot be generalised across all MR-systems [32].

The results in this observational study are obtained using 2 MRI systems with sequences as indicated in Table 3. Other MRI systems and MR sequences have not been tested. The *in vitro* protocol registered only temperature changes and no torque alterations nor stimulator output. The *in vitro* tests were only performed in a 2D setup.

5. Conclusion

We investigated *in vitro* and *in vivo* crucial safety issues when using brain MRI, fMRI and MRS during trial periods of SCS.

The *in vitro* study revealed no temperature change at the tip of the electrode or hardware failure of the neurostimulator in 1.5 T and 3 T MRI scanners.

In vivo use of an externalised neurostimulator caused no subjectively experienced effect of accidental electrical pulses, no alterations of stimulation pattern nor any hardware failure. Our findings underscore the feasibility to perform MRI, fMRI and MRS of the brain, investigating pathophysiological circuits of the brain during SCS, even during trial periods with an external neurostimulator.

Disclosure

The authors declare that they have no competing interests.

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