Bilateral neurostimulation systems used for deep brain stimulation: in vitro study of MRI-related heating at 1.5 T and implications for clinical imaging of the brain

Roongroj Bhidayasiri[a,f,*], Jeff M. Bronstein[a,f], Shantanu Sinha[b], Scott E. Krahl[e],
Sinyeob Ahn[d], Eric J. Behnke[e], Mark S. Cohen[b,c], Robert Frysinger[d], Frank G. Shellock[g]

[a]*Department of Neurology, UCLA Medical Center and Geffen School of Medicine at UCLA, Los Angeles, CA 90095, USA*
[b]*Department of Radiology, UCLA Medical Center and Geffen School of Medicine at UCLA, Los Angeles, CA 90095, USA*
[c]*Department of Psychiatry, UCLA Medical Center and Geffen School of Medicine at UCLA, Los Angeles, CA 90095, USA*
[d]*Department of Biomedical Engineering, UCLA Medical Center and Geffen School of Medicine at UCLA, Los Angeles, CA 90095, USA*
[e]*Division of Neurosurgery, UCLA Medical Center and Geffen School of Medicine at UCLA, Los Angeles, CA 90095, USA*
[f]*Parkinson's Disease Research, Education and Clinical Center (PADRECC) of West Los Angeles Veterans Affairs Medical Center,
University of Souther California, Los Angeles, CA 90073, USA*
[g]*Keck School of Medicine, University of Southern California, Los Angeles, CA 90033, USA*

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Abstract

Deep brain stimulation (DBS) is used increasingly in the field of movement disorders. The implanted electrodes create not only a prior risk to patient safety during MRI, but also a unique opportunity in the collection of functional MRI data conditioned by direct neural stimulation. We evaluated MRI-related heating for bilateral neurostimulation systems used for DBS with an emphasis on assessing clinically relevant imaging parameters. Magnetic resonance imaging was performed using transmit body radiofrequency (RF) coil and receive-only head RF coil at various specific absorption rates (SARs) of RF power. In vitro testing was performed using a gel-filled phantom with temperatures recorded at the electrode tips. Each DBS electrode was positioned with a single extension loop around each pulse generator and a single loop at the "head" end of the phantom. Various pulse sequences were used for MRI including fast spin-echo, echo-planar imaging, magnetization transfer contrast and gradient-echo techniques. The MRI sequences had calculated whole-body averaged SARs and local head SARs ranging from 0.1 to 1.6 W/kg and 0.1 to 3.2 W/kg, respectively. Temperature elevations of less than 1.0°C were found with the fast spin-echo, magnetization transfer contrast, gradient-echo and echo-planar clinical imaging sequences. Using the highest SAR levels, whole-body averaged, 1.6 W/kg, local exposed-body, 3.2 W/kg, and local head, 2.9 W/kg, the temperature increase was 2.1°C. These results showed that temperature elevations associated with clinical sequences were within an acceptable physiologically safe range for the MR conditions used in this evaluation, especially for the use of relatively low SAR levels. Notably, these findings are highly specific to the neurostimulation systems, device positioning technique, MR system and imaging conditions used in this investigation.
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1. Introduction

The use of implantable neurostimulation systems used for deep brain stimulation (DBS) has become increasingly common in the treatment of refractory movement disorders including Parkinson's disease, essential tremor and dystonia [1–3]. Although treatment efficacy has been clearly established, there are potential risks for patients with neurostimulation systems undergoing MRI procedures related to the possibility of excessive MRI-related heating, device movement, dislodging leads and electrodes, induced currents and program interference [1,4–8]. Importantly, recent studies by Rezai et al. [4] and Finelli et al. [5] reported that MRI-related heating of the tips of DBS electrodes can result in substantial increases in temperatures under certain

conditions. Accordingly, this aspect of MRI safety for neurostimulation systems used for DBS is considered to be of the utmost importance.

Magnetic resonance imaging has an increasing role in the evaluation of patients for DBS surgery and particularly in the ongoing management of patients with neurostimulation systems. Furthermore, the implantation of DBS electrodes may be facilitated by using MRI-guided stereotactic localization in order to achieve the most effective location in treating PD [9,10]. Magnetic resonance imaging has also been used in many clinical scenarios, both related and unrelated to the implantation of neurostimulation systems, for example, verification of lead position, assessment of patients with poor surgical outcomes or in the management of unrelated problems in patients with implanted neurostimulators [9,11]. Therefore, to perform MRI procedures without posing a risk to the patient, further studies are clearly needed to determine safety guidelines as well as to expand the current recommendations to include different device configurations and MR system settings.

Rezai et al. [4] and Finelli et al. [5] conducted in vitro MRI-related heating studies using a 1.5-T MR system with bilateral DBS systems positioned in a gel-filled phantom. They reported that temperature increases measured at the electrode tip were dependent on the type of radiofrequency (RF) coil used, the level of RF power and how the electrodes and leads were positioned. Although temperature elevations were found to be clinically insignificant in association with clinical sequences used for brain imaging [5], studies were limited to the use of a transmit–receive RF head coil. Importantly, MRI-related heating associated with the use of a transmit body RF coil and receive-only RF head coil (i.e., the RF coil configuration commonly used by recently installed MR systems) has not been reported for implanted neurostimulation systems used for DBS. Because the use of the body RF coil tends to involve higher levels of RF power and over a larger anatomic region, the risks are likely to be greater for this MRI configuration.

Therefore, the purpose of the present study was to characterize MRI-related heating for bilateral neurostimulation systems used for DBS using a 1.5-T MR system and imaging with a transmit body RF coil and receive-only RF head coil, with an emphasis on assessing clinically relevant imaging parameters. The issue for MRI-related heating relates to the amount of the neurostimulation system that is contained within the transmitting coil (body vs. head).

2. Materials and methods

In vitro testing was performed using a 1.5-T/64-MHz MR system (Sonata MRI, NUMARIS/4 software, Version Syngo MR2002B; Siemens Medical Solutions, Erlangen, Germany) with a transmit body RF coil and receive-only RF head coil. A plastic phantom designed to approximate the size and shape of the human head and torso was filled with a semisolid gel (5.85 g polyacrylic acid and 0.8 NaCl per liter of distilled water) prepared to simulate the electrical conductivity and thermal convection properties of tissue, as previously described by Rezai et al. [4] and Finelli et al. [5]. The dimensions of this phantom were as follows: head portion—width, 16.5 cm; length, 29.2 cm; height, 16.5 cm; torso portion—width, 43.2 cm; length, 61.0 cm; height, 16.5 cm [4,5]. A plastic grid with adjustable plastic posts was placed at the bottom of the phantom to allow consistent positioning and support of the implantable pulse generators (IPGs), extensions and leads of the neurostimulation systems within the phantom.

The neurostimulation system evaluated in this investigation was the Soletra model 7426 IPG, model 7495 quadripolar extensions and model 3389 DBS leads (Medtronic, Minneapolis, MN). Two IPGs and two extension/leads were utilized in this study. The bilateral neurostimulation systems were positioned in the phantom to simulate the clinical use of these devices, as follows [4,5]: IPGs positioned in the subcutaneous pectoral region; subcutaneous extensions along the chest, neck and cranial areas connected to leads; and lead tips positioned to approximate the subthalamic nucleus (STN). The DBS lead is of 40 cm in length. The "excess" lead was looped at the "head" end of the phantom in an axial orientation. The extension length is 51 cm, which typically results in excess wire. The excess length of extension was looped around the perimeter of each IPG. Thus, the positioning configuration for the bilateral neurostimulation systems was the same as that which demonstrated the least amount of MRI-related heating, as reported by Rezai et al. [4] and Finelli et al. [5]. The neurostimulation systems were programmed to the "off" mode (i.e., no stimulation was delivered) and set to 0 V according to the manufacturer's recommendation for patients with this device undergoing an MRI procedure (Medtronic) [12].

Temperature recordings were obtained using an MRI-compatible fluoroptic thermometry system (Model 790; Luxtron, Santa Clara, CA), as previously described [4,13,14]. Fluoroptic thermometry probes were positioned to record representative sites for the neurostimulation systems that would generate the greatest heating during MRI on previous published literatures [4,5,14,15]. Therefore, the thermometry probes were positioned within a 0.1-mm of the center of the distal electrodes of the right and left DBS electrodes (probe 1 and 2, respectively). In addition, a fluoroptic thermometry probe (reference probe) was positioned in a remote position (i.e., approximately 50 cm from the neurostimulation systems) in the gel-filled phantom to record a reference temperature near the edge of the torso portion of the phantom [4,5]. Since this experimental setup lacks blood flow, it represents a "worst case" scenario with regard to MRI-related heating [4,5].

2.1. Protocol

The IPGs, extensions and leads were positioned in the phantom and fixed in place to the positioning posts, as previously described [4,5]. Next, the temperature probes

Table 1
Evaluation of MRI-related heating using a transmit/received body coil for bilateral neurostimulation systems used for DBS

Exp.	Pulse sequence (TE/TR/Avg./matrix/thickness/ETL)	Whole-body averaged SAR (W/kg)	Local SAR (W/kg)		Scan Time (min)	Highest temperature change (°C)	Ref. probe (°C)	$P < .001$
			Head	Exposed body				
1	Axial T1 MPGR 3D (4.4/2050/2/256×256/1/9)	0.1	0.1	0.1	3.10	0.2	0.2	
2	Axial TSE T2 (84/2800/2/256×256/2/9)	0.7	1.2	1.4	2.52	1.0	0.2	*
3	Coronal TSE T2 (84/2800/2/256×256/2/9)	0.7	1.2	1.4	2.50	1.1	0.3	*
4	Coronal TSE T2 (84/2800/2/256×256/2/15)	1.6	2.9	3.2	1.40	2.1	0.1	*

Experimental conditions, time to reach highest temperature and maximal temperature changes.
Note: TE, echo time; TR, repetition time; Avg., averages; ETL, echo train length.
 * Statistically significant, $P < .001$.

were placed in the described above locations and secured in place using 4.0 silk suture. Finally, the phantom was filled with the gel and allowed to equilibrate to the room temperature of the MR environment for approximately 1 h.

Magnetic resonance imaging was performed with the plane of imaging prescribed to pass through the center of the DBS electrodes (i.e., the site known to produce the greatest MRI-related heating [4,5]), using parameters that generated whole-body averaged specific absorption rates (SARs) that ranged from 0.1 to 1.6 W/kg, local head SARs that ranged from 0.1 to 2.9 W/kg, and the local exposed body SARs that ranged from 0.1 to 3.2 W/kg (Table 1). For each experiment, baseline temperatures were recorded for approximately 30 s, and then MRI was conducted for periods ranging from 1 min/40 s to 3 min/10 s (Table 1) with temperatures recorded at 5-s intervals for each experimental condition (see next sections). The time interval selected to study MRI-related heating for the neurostimulation systems was based on the clinical pulse sequence used and pilot studies from our group, and based on findings from Rezai et al. [4] and Finelli et al. [5] insofar as if substantial heating occurs, it will be detected within the first 30 s of MRI.

2.1.1. Magnetic resonance imaging protocols

After three-plane scout images were obtained using parameters a rapid imaging technique of echo time (TE)/ repetition time (TR)/averages/matrix size of 5 ms/20 ms/1 average/128×256 and 10 mm section thickness, a "DBS" protocol was performed, followed by a pulse sequence in which the RF power was increased to relatively high level to create an extreme clinical MRI scenario (see summary in Table 1). The DBS protocol consisted of a three-dimensional axial T1-weighted, multiplanar gradient-echo (MPGR) sequence, followed by an axial and then a coronal plane, T2-weighted, turbo spin echo (TSE). The later two had identical parameters of echo time (TE)/repetition time (TR)/averages/matrix size of 84 ms/2800 ms/2 averages/ 256×256, 2-mm section thickness, contiguous, with an echo train length (ETL) of 9. The above are MR parameters commonly used for brain imaging. The relatively high SAR sequence was similar to the coronal plane TSE except for using approximately five times the band width, ETL of 15, and most importantly, with magne-

tization contrast transfer, fat (chemical) saturation and two side saturation bands switched on (i.e., not a clinical MR pulse sequence).

2.2. Data analysis

The temperature recordings obtained from the three fluoroptic thermometry probes were collected digitally and analyzed in Excel (Microsoft, Seattle, WA). The temperature changes were calculated by subtracting the baseline temperature (average for 10 measurements) before the beginning of each protocol ("ON" MRI) from the highest temperature change recorded during the experiment. Plots of temperature versus time during MRI with the clinical imaging sequences were also constructed. A *t* test was used to determine the statistical significance of any observed temperature changes, comparing the baseline temperature to the highest temperature measured. The relationship between the whole-body averaged and local exposed-body SARs and the mean temperature elevation measured for the highest temperature was analyzed using linear regression.

3. Results

Table 1 summarizes the results of this investigation. For the use of the transmit body RF coil and receive-only RF
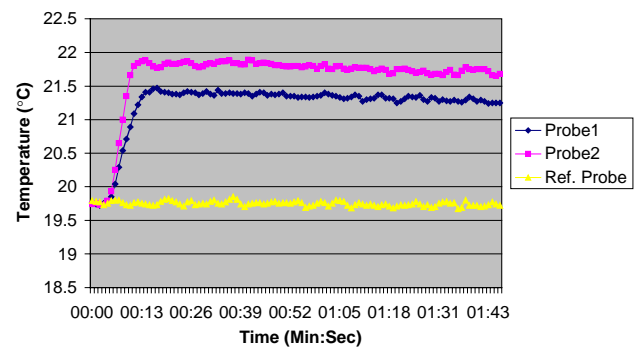

Fig. 1. Plot of the relationship between temperatures recorded on probe 1 (tip of electrode, right), 2 (tip of electrode, left) and 3, reference probe and duration of scan for experiment 4. Note that the temperature increased to the highest level, +2.1°C, within the first 14 s of MRI.

head coil, the highest temperatures recorded at the distal electrodes in these experiments ranged from 19.7 to 21.8°C. The highest temperature changes recorded at the distal electrodes ranged from +0.2 to +2.1°C. The highest temperature change measured by the reference probes ranged from +0.1 to +0.3°C.

In general, the temperatures increased to the highest levels within the first 14 s of MRI and tended to plateau afterward without further temperature increase throughout the approximately 3-min duration of imaging. Experiment 4 showed the largest temperature change (+2.1°C) involving the use of whole-body averaged SAR of 1.6 W/kg, local head SAR of 2.9 W/kg and local exposed body SAR of 3.2 W/kg (Fig. 1). The lowest temperature change, +0.2°C, occurred during experiment 1 (whole-body averaged, local head and exposed body SARs of 0.1 W/kg).

4. Discussion

Deep brain stimulation of the globus pallidus interna and STN has grown increasingly common in recent years, in part due to advances in knowledge concerning the subcortical pathophysiology of Parkinson's disease [16]. In consideration of the efficacy of using neurostimulation systems for DBS in ameliorating the cardinal motor symptoms of PD, it is likely that the number of patients receiving these devices will continue to increase [17]. Therefore, it will become more common for radiologists to receive requests for MR procedures in patients with neurostimulation systems, raising concerns about the safety for these patients. Although MRI has been commonly used for verification of the placement of implanted electrodes not only at our center but also elsewhere [9], there are possible dangers of performing MRI in patients with neurostimulation systems based on the presence of static, gradient and RF fields [18].

The static magnetic field can potentially exert torque and translational attractive forces on ferromagnetic objects, resulting in displacements. Pulsed RF fields induce currents in electrical conductors that can result in an induced voltage and excessive heating across the body tissue resistance [19,20]. For electrodes, heating will be greatest where the electrical current flux density is highest, which is near the electrode tips [4,5]. In addition, the rapidly changing magnetic field gradients can induce currents in the electrodes that may result in stimulation of neurons and fibers; these currents will be larger when circulating through the low resistance path offered by the electrode wires [21–23]. However, it is well known that gradient fields do not contribute to heating of implanted objects [13–15].

Finally, exposure to the electromagnetic fields used for MRI can potentially result in malfunction of, or damage to, the implanted pulse generators of neurostimulation systems [5,13,15,18,24].

Recognizing that excessive MRI-related heating is a primary concern for patients with neurostimulation systems used for DBS [4,5,18], this study was designed to expand the current safety information that would permit patients with these implants to safely undergoing MRI procedures of the brain using the currently used RF coil configuration: transmit RF body coil and receive-only head RF coil. This is important because previous in vitro studies of MRI-related heating for neurostimulation systems were limited to the use of a transmit/receive body RF coil or a transmit/receive RF head coil [4,5,20]. To our knowledge, there are currently no published data to characterize MRI-related heating for performing MRI of the brain in patients with neurostimulation systems using a transmit body RF coil and a receive-only RF head coil.

In the present investigation, experiment 4 (Table 1, Fig. 1) showed the largest temperature elevation (+2.1°C) involving the use of the relatively high level of RF energy (whole-body averaged SAR of 1.6 W/kg, local head SAR of 2.9 W/kg and local exposed body SAR of 3.2 W/kg). Other experiments showed that the temperature elevations ranged from +0.2 and +1.1°C, with rapid temperature increases within the first 14 s. Notably, these temperature changes were associated with the use of MR parameters that would commonly be used for clinical imaging of the brain.

Previous studies of RF and other thermal ablation techniques have shown that reversible thermal lesions occur when the local temperature is elevated to 42 to 44°C range (a 5 to 7°C elevation over the normal body temperature of 37°C), and that irreversible thermal lesions can occur when the local temperature exceeds 45°C (>8°C rise in temperature over normal body temperature) [25–27]. Therefore, transient temperature elevation of 2°C or less in association with the use of the relatively high level of RF energy is unlikely to cause significant adverse thermogenic-related effects.

Finelli et al. [5] reported that MRI-related heating for clinical pulse sequences including fast spin-echo, gradient-echo and echo-planar imaging sequences using a transmit/receive RF head coil was correlated linearly with local SAR values for single and multislice fast spin-echo images, and that sequences performed at local SARs below 2.4 W/kg (whole-body averaged SAR of 0.09 W/kg) should be safe from a standpoint of MRI-related heating. Our findings were essentially consistent with those of Finelli et al. [5]. With the use of the transmit RF body coil and receive-only head coil in this study, the highest temperature changes ranged from +0.1 to +2.1°C. The highest temperature change of +2.1°C was recorded with a whole-body averaged SAR of 1.6 W/kg, local head SAR of 2.9 W/kg and local exposed body SAR of 3.2 W/kg (extreme-case scenario). By interpolation, the SAR values at which 1°C temperature increase at the electrode tips are approximately 1.3 W/kg local, and the local SAR at which a 2°C temperature increase at the electrode tips would be approximately 2.9 W/kg local.

The background temperature increase (i.e., the reference probe temperature measurement) was <0.3°C for all measurements, even at high SAR values. In addition, the temperature increase was within the first 14 s after the

onset of MRI and tended to plateau afterward, without further temperature increases throughout the duration of the scan. Importantly, none of these clinical imaging sequences were associated with DBS electrode temperature elevations greater than 1.1°C. The temperature elevations observed with a three-dimensional axial plane, T1 MPGR sequence, axial and a coronal plane, TSE T2 imaging sequences, were within 1°C of that predicted by the regression analysis above. Therefore, this in vitro model indicates that all of the DBS imaging sequences performed with these specific parameters and SAR levels are associated with relatively minor MRI-related heating.

We performed these imaging sequences using a transmit body RF coil and receive-only head coil (local SARs ranging from 0.1 to 3.2 W/kg) with temperature elevations of less than 2°C, except when using a relatively high level of RF energy, further confirming that it is possible to safely obtain stereotactic three-dimensional, gradient-echo images and coronal or axial plane, T2-weighted turbo spin-echo images in patients with bilateral neurostimulators with this coil configuration.

Based on the findings from this study as well as previous published reports, MRI-related heating may not present a major safety concern in patients with bilateral neurostimulation systems who undergo MRI as long as guidelines are carefully followed with regard to positioning, programming of the devices and parameters used for MR imaging [4,5,20]. While previous published experiments were conducted using other RF coil configurations, our study has expanded the safety results to include a transmit body RF coil and a receive-only head RF coil using common clinical pulse sequences. Even though our results confirm minor temperature elevations with different clinical sequences, our study has not addressed other MR safety concerns, for example, magnetic field interactions, induced voltages and programming changes, indicating the need for further investigations of these potential MR safety issues.

The MRI-related heating for electronically activated devices is rather complicated in that many different factors may impact the heating profile for a given device [5,13–15, 18,20]. These include, but are not limited to, the electrical characteristics of the particular neurostimulation system; the field strength of the MR system; the orientation of the IPG, extension (the extension is the cable that connects the IPG to the implanted lead) and lead relative to the source of RF energy; the type of RF coil used (e.g., transmit/receive body coil, transmit body coil with receive-only head coil, transmit/receive head coil); the anatomy imaged (e.g., the landmark position, or the anatomic site undergoing MRI, that is associated with heating depends on the geometry of the RF coil and the amount of the DBS lead contained within this coil); the amount of RF energy delivered (i.e., the SAR); and how the SAR is calculated by a given MR system.

Importantly, different MR system manufacturers calculate SARs using different methods and may even use different calculations in older compared to newer MR

system models, or particular software releases (F.G. Shellock, unpublished observations, 2003). As such, MR safety criteria defined using a particular MR system configuration may not be readily applied to another. This issue warrants further research.

The above concern is underscored by a serious injury that occurred recently. Spiegel et al. [28] reported that a 73-year-old patient with bilateral implanted DBS electrodes for Parkinson's disease exhibited dystonic and partially ballistic movements of the left leg immediately after undergoing an MRI procedure of the head using a transmit/receive head RF coil on a 1.0-T MR system (Expert; Siemens). The investigators suggested that this incident was due to induced current in the implanted leads that caused heating and consecutive thermal tissue damage [28].

In another case, a patient with one IPG implanted in the abdomen and the other subclavicularly, underwent MRI of the spine at 1.0 T using a transmit/receive body coil [29]. (Rezai et al. [4] and Finelli et al. [5] studied MRI-related heating for neurostimulators in association with IPGs positioned in the more commonly used subclavicular implant site.) Although the entire details for this case are currently unavailable, the patient developed a neurological deficit in association with the MR procedure (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=474005) [29]. Importantly, according to the report made to the Food and Drug Administration, the manufacturer instructed the "healthcare professional" that full-body coil MRI is not to used on patients with this implant due to heating and electrical conduction during MRI [29].

These serious incidents emphasize the fact that while MR examinations may be performed in patients with DBS devices under specific, well-controlled conditions, the generalization of these conditions to other neurostimulation system positioning schemes, other MR systems and imaging scenarios, is potentially dangerous [29].

Regarding the use of MRI in patients with the neurostimulation system used in this study, the Physician and Hospital Staff Manual [12] currently states:

– Use only a transmit and receive type RF coil to minimize the exposure of the lead/neurostimulation system to the MRI RF fields. Do not use a whole-body RF coil.
– Select imaging parameters to perform MRI at a SAR that does not exceed 0.4 W/kg in the head.
– Carefully weigh the decision to perform MRI scans on patients who require the neurostimulator to control tremor. Image quality during MRI scans can be reduced, because the tremor may return when the brain stimulator is turned off.

Given the results of the present study, we believe that the recommendations for using MRI in patients with this neurostimulation system may be modified in consideration of the fact that most modern-day MR systems operate with a

transmit body RF coil and a receive-only head RF coil. Based on the MRI-related heating information obtained in this study and in consideration of the threshold temperatures known to produce reversible (i.e., range, 42°–44°C) and irreversible (i.e., >45°C) thermal lesions [27], a temperature change of 2.1°C is considered to be safe from a thermophysiologic consideration.

5. Conclusion

Magnetic resonance imaging-related heating was assessed for bilateral neurostimulation systems used for DBS to assess a relatively high level of RF exposure and clinically relevant imaging scenarios. The findings indicated that temperature elevations associated with MRI procedures performed using clinical relevant pulse sequences were within a physiologically acceptable range, especially if the level of RF power deposition is restricted during the MRI procedure.

Notably, the findings presented herein are specific to the neurostimulation system, positioning scheme used for the neurostimulation system, the MR system (i.e., in consideration of the specific static magnetic field strength) and the MRI conditions used for this evaluation. The exact safety criteria for the particular neurostimulation system with regard to the pulse generator, leads, electrodes, operational conditions for the device, the positioning of these components and the MR system conditions must be carefully followed for MRI [4,5]. Failure to do so may result in serious, temporary or permanent injury to the patient including the possibility of transient dystonia, paralysis, coma or even death.

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