

# Third degree skin burns caused by a MRI conditional electrocardiographic monitoring system

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## Abstract

Two unusual cases of third degree skin burns are reported using MRI approved electrocardiographic leads. This is very uncommon as it is most often the electrodes which are the source of heat related issues. Both patients were sedated due to pain related issues of their lower spine. The burns were caused by a combination of using a 3 Tesla MRI scanner and the inability to cry out during scanning. We would like to bring forward a message that even when using MRI conditional equipment, clinical staff must be extremely careful in order to secure safe image acquisition using MRI.

**Keywords:** magnetic resonance imaging; ECG system; skin burns; MRI safety

## Introduction

Magnetic resonance imaging (MRI) is widely used in the clinic due to its excellent soft tissue contrast, which cannot be obtained by any other imaging modality. By default, MRI is safe as it uses non-ionizing radio frequency (RF) electromagnetic waves and magnetic field gradients to generate signals for the imaging process. The continuous development of the MRI technique, which strives towards higher image fidelity at reduced acquisition times, has increased the magnetic field strength, the magnetic field gradients and the amount of RF power that is applied during scanning. Furthermore, as the diversity of MRI examinations has increased, more and more technical gear have been included in the armamentarium of the MRI suite. The combination of the above mentioned parameters have augmented the risk of causing irreversible thermal injuries to patients undergoing an MRI exam. This is especially important when patients have implants or when external devices are in direct contact with the skin. This holds true even in cases in which the devices are compatible in the MRI environments and therefore safe in specified MRI environments. This could be cardiac pacemakers [1], cochlear implants [2], neurostimulators [3], intracranial pressure monitoring devices [4], electrocardiographic (ECG) units and pulse oximetry devices [5].

Of particular interest to this case report is skin burns caused by the ECG monitoring equipment. In general, creation of skin burns is multifactorial and intimately related to temperature and the time it is applied to the area. Temperatures of 47°C may cause third degrees burns after approximately 18 min and after just a few minutes at 51°C [6]. In this context, several cases of ECG electrode

related burns have been reported, while burns caused by the ECG leads are less common. In a review on thermal injuries caused by MRI, Dempsey et al. [7] reported 84 FDA (Food and Drug Administration) cases of electrode related burns while only 1 case was caused by the cables. Both types of burns were primarily caused by cable looping, while large patient size, electrode characteristics and the distance of the cable to the inside surface of the bore wall also influenced on the heating. Only one case report has been found in relation to ECG cabling and in this particular incident, a flame was created at the position of the electrodes [8]. Both types of burns are caused by one of two factors or a combination of both. The first is the 'antenna effect' in which current is induced by the radio frequency (RF) pulses while the second is caused by electromagnetic induction due to the gradient switching [7, 9]. Discriminating between the two may be difficult as the net result is the same, i.e. heating of the ECG system with a concomitant skin burn.

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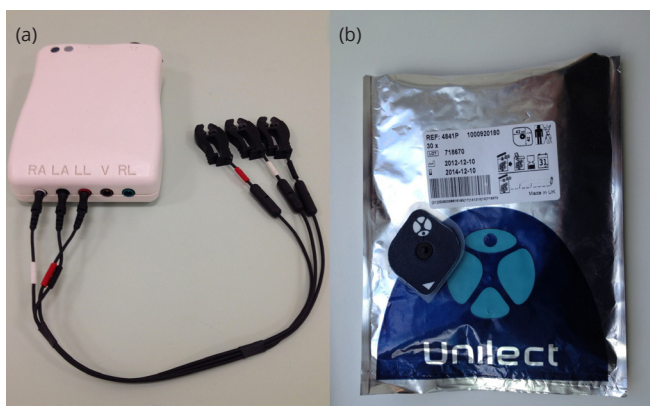
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Regardless of the cause, ECG related skin burns is a rare phenomenon as commodity electrodes and leads exist which can be safely used in conjunction with clinical MRI systems. However, in order for the ECG monitoring system to be MRI conditional, the equipment must meet specific requirements with respect to magnetic field strength, gradient strength and Specific Absorption Rate (SAR) which is related to the wattage deposited in the patient by the RF pulses [5]. Thus, the ECG system must be evaluated with regard to the interaction with the magnet (torque and translational forces), heating caused by gradient related electrical induction, heating caused by the RF system in the conducting material and presence of imaging artifacts during normal operation of the scanner. Also functional and operational evaluations must be carried out to ensure trustworthy measurements. The FDA has issued a comprehensive guide for testing passive medical devices [10, 11].

In this manuscript two unusual cases of skin burns are reported which were caused by MRI conditional ECG leads during scanning.

### Materials and methods

The applied MRI scanner was a Siemens Skyra 3.0 Tesla (Software release VD11, Siemens Healthcare AG, Erlangen, Germany) using the standard Siemens 32 channel spine receive coil. The patients entered the scanner in the supine position with their heads first. In order to safely monitor the health of the patients during the scan, a Medrad® Veris MR Monitor with a concomitant three lead ECG system (Bayer HealthCare AG, Leverkusen, Germany) was used in conjunction with MRI conditional electrodes (Unilect™ 4841P ECG electrodes, Unomedical Ltd., Stonehouse, Great Britain). An image of the ECG box and electrodes can be seen in Figure 1.



**Figure 1** (a) Three lead electrocardiogram module box which is connected to a Medrad® Veris MR Monitor (Bayer HealthCare AG, Leverkusen, Germany). The leads are connected to the ECG box and the box is connected to the main monitoring unit using an optical cable; (b) The MRI conditional electrodes (Unilect™ 4841P ECG electrodes, Unomedical Ltd., Stonehouse, Great Britain).

The electrodes are labeled MR conditional by the manufacturer for magnetic field strengths up to 3.0 Tesla if the SAR is kept below 2 Watts/kg. The electrode manual states that this relates to a temperature increase of 2.3°C during 15 min a continuous scanning in a non-clinical test assessed by calorimetry. The ECG monitoring system is

also labeled MR conditional up to fields strengths of 3.0 Tesla. With respect to the ECG signal, no skin preparation or conditioning were used before placing the electrodes in a standard 3-lead setup. The first electrode was placed 2-3 cm to the left of the middle position of the sternum, the second was placed approximately 3 cm below the xiphoid process and the third was placed 6-8 cm to the left of the xiphoid process at the same level as the second electrode. The ECG leads were braided to reduce electrical induction and no distance separated the cables from the patients skin. The leads went to the ECG box placed on the belly of the patients.

The MRI sequences used were a combination of T1-weighted and T2-weighted Turbo Spin Echo sequences (echo train lengths of 2-27, scan time of each sequence = 152-235 seconds), flip angles 135-160°, repetition times (TR) = 560-5423 ms. Due to the composition of the sequences, it was necessary to enter 'First-level' mode in some cases causing the limit of 2 Watts/kg to be exceeded (SAR<sub>n</sub> = 2,23-2,72 Watt/kg) during periods of scanning (minutes:seconds; 1:32-3:55).

### Ethical approval

For this type of study formal consent is not required. However, the two incidences were reported to the Danish Patient Safety Database.

### Informed consent

Informed consent to publish was obtained from all individual participants included in the study.

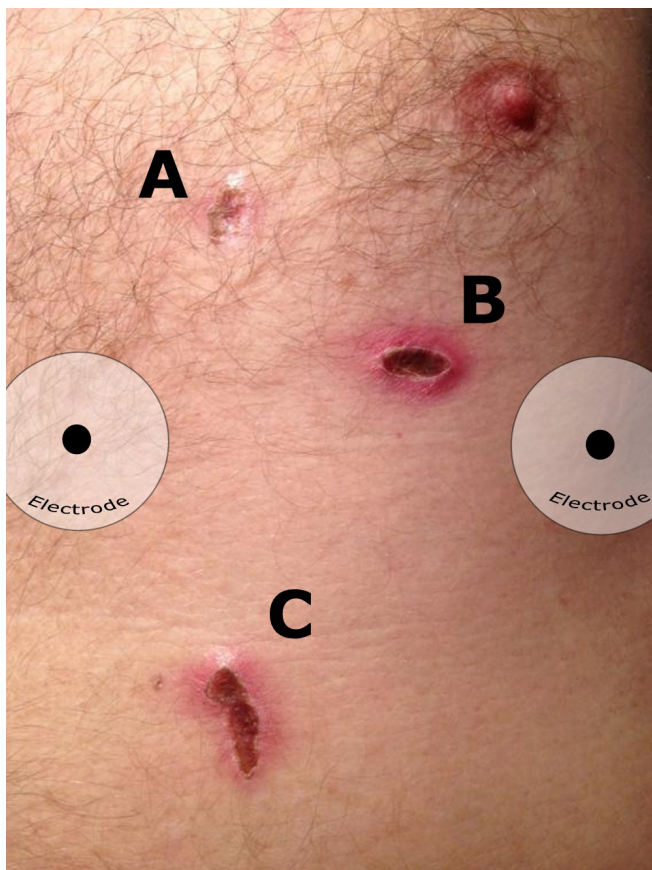
### Results and discussion

Two patients were referred to an MRI of their lumbar spines. Due to pain related issues, both patients were sedated (not anesthetized) prior to entering the MRI scanner for imaging. As the patients were unconscious during scanning, they could not cry out when the leads started to heat up. Unfortunately, there was a delay in communication between the referring department and the Radiology Department and the second patient was therefore scanned (and injured) before we received information of the first incident.

### Case 1

The first case was a 74-years-old male (body weight 90 kg). The patient was referred to an MRI due to postoperative complications related to his lumbar spine. Figure 2 shows three elongated burn lesions caused by heating one week after the MRI. The wounds are covered with crusts and surrounded by reddened, inflamed skin and are therefore no longer in the acute phase. This is consistent with the time of injury one week prior to the image recording. The wounds are oriented in a zig zag pattern between the electrodes (as indicated by the graphical overlay), which indicates trauma caused by the ECG leads instead of the ECG electrodes. The skin of the patient was not particularly sweaty and two of the three burn wounds were placed on areas without much body hair.

After detection of the burns, the patient was treated by removing crust of necrotic tissue. The wounds were



**Figure 2** Case 1: Image of skin burns caused by ECG leads. Placement of the electrodes is indicated by the graphical overlay. The image is dated one week after the MRI scan and demonstrates three elongated burn lesions caused by heating (A, B & C). The lesions are covered with crusts and surrounded by reddened, inflamed skin and are therefore no longer in the acute phase which is consistent with the time of injury. The wounds are oriented in a zig zag pattern between the electrodes, which indicates trauma caused by the ECG leads instead of the ECG electrodes.

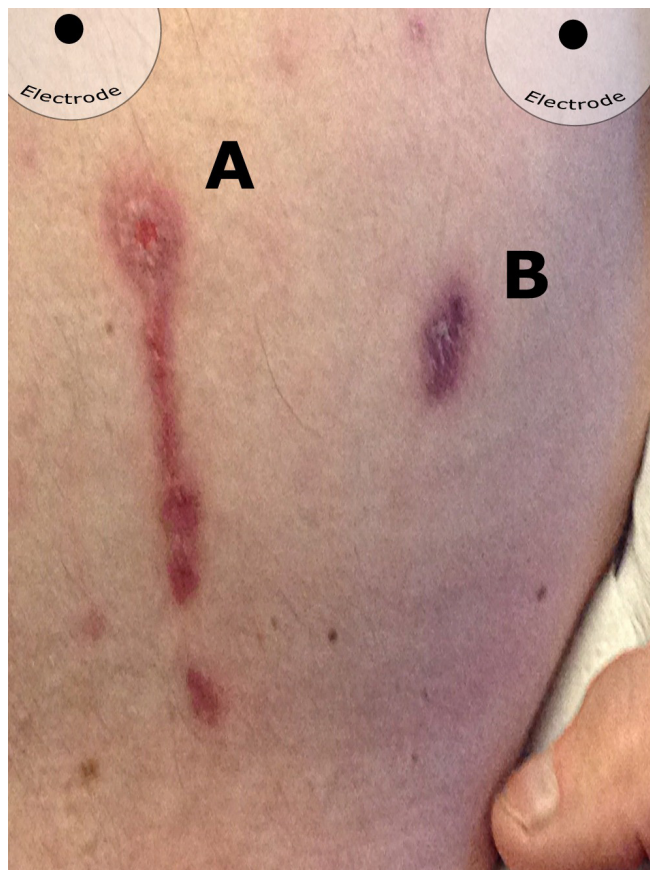
sedated locally with EMLA® (AstraZeneca, active drugs are lidocain and prilocain) before cutting the necrotic tissue with a scalpel. Hereafter the wounds were treated by Aquagel Ag Hydrofiber® and a foam bandage.

**Case 2**

The second case was a 59-years-old male (body weight 100 kg). He was MRI scanned due to a suspected lumbar prolapse. Figure 3 demonstrates two elongated burn lesions caused by heating during healing. The image is dated two weeks after the MRI scan which is consistent with the time of injury. The wounds are oriented in between the electrodes (as indicated by the graphical overlay) and indicates trauma caused by the ECG leads. The skin of the patient was not sweaty and the two acquired burns were placed on areas without any body hair. Even though the patient suffered from 3rd degree burns, no medical or surgical intervention was performed.

*General comments*

After the observation of the skin burns, Bayer HealthCare AG, Denmark (BHCD) and the Danish ECG electrode distributor, Ambu® were contacted. BHCD had a radiology service engineer perform a system service check and found the unit to be operating to specification. There was no evidence of product malfunction. The electrodes were also



**Figure 3** Case 2: Image of skin burns caused by ECG leads. Placement of the electrodes is indicated by the graphical overlay. The image is dated two weeks after the MRI scan and demonstrates two elongated burn lesions caused by heating (A & B) during healing which is consistent with the time of injury. The wounds are oriented in between the electrodes, which indicate trauma caused by the ECG leads instead of the ECG electrodes.

inspected and found to be in working condition (tears and electrode gel). Bayer Quality Assurance Product Analysis reviewed the complaint record and pointed towards four observations of use error: no skin preparation gel was used on the patients, applications of non-recommended electrodes, placement of the ECG module within the imaging plane and missing insulation of the ECG leads from the patient's skin. In this context, the applied electrodes are MRI conditional up to 3T and have been used for several years at 1.5T and at 3T at our institution. As no wounds were seen under the electrodes, we do not believe that the thermal injuries were caused by the electrodes or by absence of electrode gel. Furthermore, BHCD recommends to physically position the ECG module (white box on Figure 1) out of the imaging plane as neglecting this may contribute to heating of the leads and electrodes due to the 'antenna effect' (4;12). As the module was in fact placed within the imaging plane, this may in theory have lead to the incidents.

The Applied Turbo Spin Echo [13] imaging sequence utilizes many RF pulses in rapid order which may have raised the RF deposition for short periods of time as indicated by the SAR values stated above. In this relation, SAR limits are calculated as the average over 6 min and the operator must accept that the following imaging sequence will be raised above the 2 Watts/kg standard level. This is also known as first-level scanning. As the extension of the burns converge

with the location of the leads, we therefore assume that the burns were caused by the direct skin contact with the leads and a marginal crossing of the assigned compatibility specifications of the leads. Furthermore, if the leads had been supported by a foam spacer or similar to avoid direct skin contact, the heating of the lead may not have caused the injuries. In this context, the placement of the ECG leads, with no distance separating the cables from the patient's skin have been the standard practice on our Siemens Avanto 1.5 Tesla MRI system for several years. No incidents have occurred using that practice. As we only have access to one MRI conditional ECG monitoring system (and one type of electrodes), the personnel is very familiar with the system. However, in rare cases we allow level 1 imaging on the 1.5T system for the patient group reported in this case report without experiencing any problems. Thus, the monitoring system was well known, thoroughly tested at 1.5T (including the leads and electrodes) and marked as MRI conditional. Moving the examination of the patients to 3T, using the same practice as on the 1.5T may have been the catalyst of the thermal injuries.

#### *Guidelines and recommendations*

MRI scanning of sedated patients calls for special attention from healthcare professionals as the patients cannot cry out in the event of extreme heating which may lead to skin burns. Using MRI conditional ECG equipment may still cause patient skin burns if precautions are not taken. The guidelines below should minimize the risk of ECG monitoring related skin burns in the future: (a) always use an ECG monitoring system which is MRI conditional, (b) ensure that the applied ECG electrodes are approved for the type of MRI system being used, (c) ensure that a gap is established between the ECG leads and the patient's skin (using a cloth or a foam spacer), (d) avoid any looping of the wires to avoid induction of electrical current and (e) be very cautious when accepting first-level scanning even when MRI conditional ECG equipment is being used.

#### **Conclusion**

Using MRI conditional ECG equipment should be handled close to specifications and all precautions should be taken. Deviations, like exceeding SAR limits with even minimal values should be avoided as this may lead to heating of not only the electrodes, but also the leads as described in this case report. Healthcare professionals must exercise appropriate care in order to secure safe monitoring of patients during MRI examinations. Standard procedures cannot always be directly transferred from 1.5 Tesla to 3.0 Tesla MRI systems as the thermal and electrical behavior of devices may differ as shown in this case report.

#### **Conflicts of Interest**

The authors declare that they have no conflicts of interest.

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