MRI Induced RF Heating of Transdermal Patches

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Introduction

On March 5, 2009, the FDA issued a Public Health Advisory that warned of the risk of skin burns during MRI scans from transdermal patches with metallic backings. The Advisory identified several transdermal patch products in the U.S. that contain metal components.

It has been proposed that the skin burns are due to heating of the metal component in the patch, which is typically a thin layer of nonferromagnetic vapor coated aluminum in the backing film of the patch. The electromagnetic field used to create the magnetic resonance signal induces an electric current in the conductive metalized layer of the patch. The electric currents may cause ohmic heating enough to damage to the skin beneath the transdermal patch.

The following list of FDA approved transdermal patches contain metalized layers in their backing films:

- Catapres-TTS® (clonidine)
- Synera® (lidocaine / tetracaine)
- Habitrol® (nicotine)
- NicoDerm® CQ® (nicotine)
- Neupro® (rotigotine)
- Transderm Scōp® (scopolamine)
- Androderm® (testosterone)

The FDA Advisory also identified Nicotrol® TD (nicotine), Prostep® (nicotine), SALONPAS® Power Plus (methyl salicylate and menthol), Lidopel® (lidocaine and epinephrine), and an unidentified fentanyl patch in their list of transdermal products containing metalized components. While Nicotrol and Prostep patches do contain metalized components, these products have been discontinued in the U.S. We were unable to confirm the metallic content in SALONPAS Power Plus, Lidopel, and the undisclosed fentanyl patch due to lack of product information or availability.

To date, only anecdotal effects have been reported regarding specific patients experiencing skin burns while wearing metalized transdermal patches during MRI procedures. No skin burns have been reported by patients wearing nonmetalized transdermal patches during MRI procedures. There have been no studies to explore the MRI induced RF heating effect in metalized transdermal patches.

We evaluated the MRI induced RF heating in transdermal patches and component films by using an experimental system which consisted of the magnetic resonance (MR) test system, a phantom gel, temperature sensors, and the test film. We used marketed transdermal patches and commercially available backing films to quantify the temperature increase associated with RF power deposition, and identified factors that influence the degree of temperature increase. These data can be used to understand the MRI safety of transdermal patches.

Experimental Method – MR Test System

The MR test system was a generic 1.5 T (64 MHz) shielded birdcage body coil. A total RF power of 100 W was delivered to the coil to simulate the FDA guideline maximum allowable whole-body-average specific absorption rate (SAR) of 4 W/kg. Time durations and SARs used to produce RF heating were in accordance with the recommendations of ASTM F2182-09 and MR-safety guidelines.

A phantom saline gel was used to simulate the electrical and thermal properties of human tissue at 64 MHz. The gel consisted of 1.32 g/L NaCl (Sigma Aldrich) and 10 g/L polyacrylic acid (Sigma Aldrich) in distilled water. A Lexan container was filled with approximately 25 kg of this tissue-mimicking gelled saline. The container was constructed such that a torso gel phantom could be prepared of dimensions recommended by ASTM F2182-09 to appropriately load the coil and measure heating.

The test films consisted of metalized and nonmetalized backing films (all from 3M Drug Delivery Systems):

- Scotchpak™ 1109 – 1.3 mil tan pigmented PE/metalized PET laminate film
- Scotchpak™ 9723 – 1.7 mil tan pigmented PE/PET laminate film (nonmetalized)
- Scotchpak™ 9735 - 2 mil PE/PET laminate film (nonmetalized)
- CoTran™ 9720 – 3 mil PE film (nonmetalized)
- Scotchpak™ HB-T 19733 - 2 mil EVA/AlOx PET laminate film (nonmetalized)

Commercially available transdermal patches evaluated in this study included Habitrol® (Novartis Consumer Health), NicoDerm® CQ® (GlaxoSmithKline), Catapres-TTS® (Boehringer Ingelheim), and Transderm Scōp® (Novartis Consumer Health). NicoDerm CQ was tested in opaque (metalized) and clear (nonmetalized) versions.

Experimental Method – Procedure

The backing films were evaluated in circular (2.5 and 40 cm^2) and rectangular (40 cm^2) shapes. Two rectangular dimensions were evaluated – short (7.2 cm x 5.6 cm) and long (15.2 cm x 2.6 cm). The transdermal patches were tested in their original converted shapes and sizes. Locations and orientations of the test materials on the phantom gel were chosen according to usage and ASTM F2182-09 recommendations. Each material was placed close to the body coil, since this placement was expected to induce maximum current and maximum heating. Each material was placed horizontally on the gel surface to mimic real-life application.

Temperatures were measured using RF-transparent Fluoroptic® temperature probes (Lumasense Technologies, Luxtron 3000). Temperature probes were taped to each test material to determine maximum heating. Temperature was measured as a function of time at the test material and a reference location on the phantom gel. RF power was deposited for 15 minutes at the measured whole body average SAR of 4 W/kg from the generic body coil.

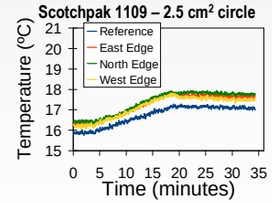
Results and Discussion

Results in the table below show the maximum temperature increase (dTmax) beneath each film and patch associated with RF power deposition from the MR test system. dTmax is the difference between the maximum temperature (after 15 minutes of RF power deposition) and the initial temperature when RF power deposition started. The dTmax for the gel reference location is also provided in parentheses.

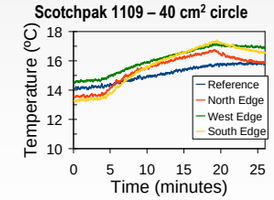
Backing Film	Metalized	Configuration Tested	dTmax (ºC)
Scotchpak 1109	Yes	2.5 cm^2 circle	1.6 (1.5)
		40 cm^2 circle	4.1 (1.5)
		40 cm^2 short rectangle	4.0 (0.8)
		40 cm^2 long rectangle	10.5 (1.7)
Scotchpak 9723	No	40 cm^2 circle	1.5 (1.3)
		40 cm^2 long rectangle	1.5 (0.8)
Scotchpak 9735	No	40 cm^2 long rectangle	1.5 (1.0)
CoTran 9720	No	40 cm^2 long rectangle	2.0 (1.4)
Scotchpak HB-T 19733	No	40 cm^2 long rectangle	1.3 (0.9)

Transdermal Patch	Metalized	Configuration Tested	dTmax (ºC)
Catapres TTS	Yes	3.5 cm^2 square (0.1 mg)	1.6 (1.5)
		10.5 cm^2 square (0.3 mg)	1.7 (1.3)
Habitrol	Yes	10 cm^2 circle (7 mg)	2.0 (1.2)
		30 cm^2 circle (21 mg)	2.7 (1.3)
Nicoderm CQ (Opaque)	Yes	22 cm^2 rectangle (21 mg)	2.3 (1.1)
Nicoderm CQ (Clear)	No	22 cm^2 rectangle (21 mg)	1.9 (1.1)
Transderm Scōp	Yes	2.5 cm^2 circle (1.5 mg)	1.8 (1.0)

Scotchpak 1109 – 2.5 cm^2 circle



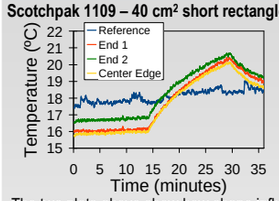
Scotchpak 1109 – 40 cm^2 circle



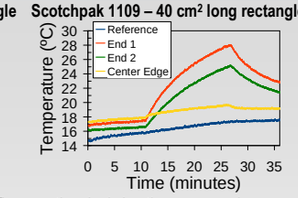
The plots above show results from two different configurations for circular Scotchpak 1109 films. For each, the temperature rises coincided with the start of RF power deposition. The discontinuation of RF power deposition coincided with constant or decrease in temperature. The temperature rise for the small film was equivalent to that for the gel reference location. Here, the effect can be attributed solely to heating of the gel. Similar temperature profiles were observed with the nonmetallic films. The large film showed significantly more heating. Here, the effect can be attributed to ohmic heating of the film.

Results and Discussion, continued

Scotchpak 1109 – 40 cm^2 short rectangle

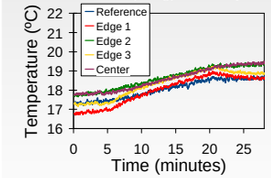


Scotchpak 1109 – 40 cm^2 long rectangle

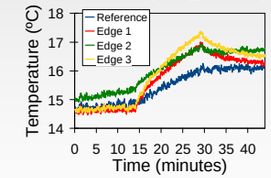


The two plots above show how shape influences the ohmic heating response in rectangular Scotchpak 1109 films. The short rectangular film (nearly square) heated equivalently at all edges. The long rectangular film heated significantly more at its two ends compared to its center, which showed heating no different than the gel reference.

Habitrol – 10 cm^2 (7 mg) circular patch



Habitrol – 30 cm^2 (21 mg) circular patch



Significant ohmic heating was observed only for 2 of 6 patches. For these two patches, 30 cm^2 Habitrol and 22 cm^2 Nicoderm CQ, the temperature rises were 1ºC more than the temperature rises in the respective gel reference locations. Two representative plots are shown above. For the 10 cm^2 Habitrol patch, the temperature rises at the patch edges were slightly greater than the reference. The temperature rise in the center of the patch was equivalent to that of the reference, which again suggests that location influences the degree of ohmic heating. For the 30 cm^2 Habitrol patch, the temperature increased significantly more at each edge location compared to the 10 cm^2 Habitrol patch.

Conclusion

MRI induced ohmic heating occurred only in metalized backing films. The heating was attributed solely to the metalized layer in the films. In addition, the results show that the degree of ohmic heating was a function of the size and shape of the film and location on the film. The greatest heating occurred at the edge of 40 cm^2 films, particularly at the edge of large, rectangular films.

For transdermal patches, ohmic heating was negligible for patches less than 10 cm^2 in size. Significant ohmic heating occurred only in the 30 cm^2 Habitrol patch and the 22 cm^2 Nicoderm CQ patch.