

# MRI Induced RF Heating of Transdermal Patches

R. Gordon<sup>1</sup>, R. Visaria<sup>2</sup>, D. Shrivastava<sup>3</sup>, and J. Thomas Vaughan<sup>3</sup>

<sup>1</sup>3M Drug Delivery Systems, St. Paul, MN, 55144, USA

<sup>2</sup>MR Safe Devices LLC, Burnsville, MN, 55306, USA

<sup>3</sup>Center for Magnetic Resonance Research, University of Minnesota, Minneapolis, MN, 55455, USA  
[rgordon@mmm.com](mailto:rgordon@mmm.com)

## ABSTRACT SUMMARY

Magnetic Resonance Imaging (MRI) induced radiofrequency (RF) heating of transdermal patches and individual component films was measured. The results showed that ohmic heating occurred beneath patches and individual films that contain metalized layers when exposed to RF power. Moreover, the extent of the temperature increase was influenced by the size and shape of the film. Films free of metalized components did not demonstrate ohmic heating when subjected to RF power.

## INTRODUCTION

Patients undergoing MRI procedures are advised to remove any transdermal patches they are wearing that contain metalized components<sup>1</sup>. Because the metalized component is usually a thin layer of nonferromagnetic vapor coated aluminum in the backing film of the patch, the safety risk is not due to concern that the patch will be ripped off the patients skin by the strong magnetic field. Rather, failure to remove the metalized transdermal patch may result in skin burns<sup>2</sup>.

The skin burns are due to heating of the metal component in the patch. It has been proposed that the electromagnetic field used to create the magnetic resonance signal induces an electric current in the conductive metalized layer of the patch<sup>3</sup>. The electric currents may cause ohmic heating enough to damage to the skin beneath the transdermal patch.

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 heating effect in metalized transdermal patches. We used marketed transdermal patches and commercially available backing films to quantify the temperature increase associated with this event, and identified factors that influence the degree of temperature increase. These data can be used to understand the MRI safety of transdermal patches.

## EXPERIMENTAL METHODS

The experimental system consisted of the magnetic resonance (MR) test system, phantom gel, temperature sensors, and the test film. The MR test system consisted of a generic 1.5 T (64 MHz) shielded birdcage body coil. To produce heating near the test film, a continuous wave (CW) signal was generated using a signal generator (Hewlett Packard Model 83620B-H80), and was

amplified with a power amplifier (Communication Power Corp.). 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. The power delivered to the coil was measured continuously using a power meter (Gigatronics Model 8652A). RF heating produced due to a given frequency of CW RF power has been shown to be equivalent to the worst case RF heating produced with the same frequency pulsed power of an MRI scan of the same average SAR<sup>4</sup>. RF power was deposited for 15 minutes at the measured whole body average SAR of 4 W/kg from the generic body coil. 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 formulation was used to simulate the electrical and thermal properties of human tissue at 64 MHz. The formulation consisted of gelled saline made by mixing 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 phantom was covered with a plastic sheet when not in use to minimize evaporation and contamination.

Temperatures were measured using RF-transparent Fluoroptic<sup>®</sup> temperature probes (Lumasense Technologies, Luxtron 3000). The Fluoroptic<sup>®</sup> probes have a standard deviation of less than 0.2°C and are regularly used to determine RF heating in MRI applications. Three temperature probes were taped to the test film to determine maximum heating. Temperature was measured as a function of time at the test film and a reference location on the phantom gel. Temperatures were recorded every 2 seconds for at least 2 minutes before the RF-power was delivered to determine baseline temperatures, for 15 minutes during the RF-power deposition to determine heating, and for approximately 10 minutes after the RF-power deposition was stopped.

The individual films tested in this study were Scotchpak<sup>™</sup> 1109, Scotchpak<sup>™</sup> 9723, Scotchpak<sup>™</sup> 9735, and Scotchpak<sup>™</sup> HB-T 19733 (all from 3M Drug Delivery Systems). Each film, except for 19733, is a backing film used in commercialized transdermal patches. Scotchpak 1109 is a 1.3 mil metalized backing film that consists of three layers: polyester, vapor coated aluminum, and tan pigmented polyethylene. Scotchpak 9723 is a 1.7 mil nonmetalized backing film of tan

pigmented polyethylene layer laminated to polyester. Scotchpak 9735 is a 2 mil translucent, nonmetalized backing film of polyethylene laminated to polyester. The materials used in Scotchpak 9723 and 9735 are the same as those used in Scotchpak 1109. Scotchpak HB-T 19733 is a 2 mil translucent nonmetalized high-barrier backing film that consists of three layers: ethylene vinyl acetate copolymer, polyester, and aluminum oxide high barrier coating.

Two commercially available transdermal patches were tested in this study: Habitrol<sup>®</sup> and Transderm Scop<sup>®</sup> (both from Novartis). Habitrol, a circular nicotine replacement patch, was tested at two strengths (patch size), 21 mg (30 cm<sup>2</sup>) and 7 mg (10 cm<sup>2</sup>). Transderm Scop<sup>®</sup> (Novartis) is a 2.5 cm<sup>2</sup> circular patch that delivers scopolamine. Both patches use tan, metalized backing films. The 21 mg Habitrol patch was reported to cause skin burns if worn during MRI procedures<sup>3,4</sup>.

Scotchpak 1109 was tested at 2.5 and 40 cm<sup>2</sup> areas, and in circular and rectangular configurations. The other nonmetalized patches were only tested at their potential worst-case configuration of 40 cm<sup>2</sup> rectangles. Locations and orientations of the test films and patches on the phantom were chosen according to usage and ASTM F2182-09 recommendations. Each test film was placed close to the body coil, since this placement was expected to induce maximum current and maximum heating. Each test film was placed horizontally on the phantom gel surface to mimic real-life application. Temperature was also measured of the phantom gel at a reference location.

## RESULTS AND DISCUSSION

For Scotchpak 1109 film, the greatest ohmic heating of 10.5°C was observed at the end edge as a 40 cm<sup>2</sup> long rectangle (width of 15.2 cm). The center edge of the film displayed slight ohmic heating (Figure 1). As a 40 cm<sup>2</sup> short rectangle (width of 7.2 cm) and a 40 cm<sup>2</sup> circle (7.1 cm diameter), Scotchpak 1109 had similar ohmic heating of 4.2°C and 4.1°C, with heating independent of the probe location. As a 2.5 cm<sup>2</sup> circle, Scotchpak 1109 did not demonstrate ohmic heating greater than the reference location on the phantom, 1.6°C and 1.5°C, respectively.

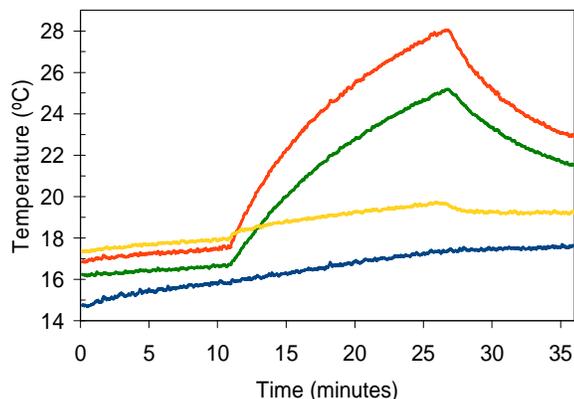


Figure 1. MRI induced ohmic heating in Scotchpak 1109 film, 40 cm<sup>2</sup> long rectangle, at end 1 (red), end 2 (green), and center edge (yellow), relative to the reference (blue).

Each nonmetalized film (Scotchpak 9723, Scotchpak 9735, and Scotchpak HB-T 19733) was tested as 40 cm<sup>2</sup> long rectangles (width of 15.2 cm). None demonstrated ohmic heating greater than the phantom reference. These results suggest that the ohmic heating in Scotchpak 1109 is solely due to the electric currents induced in the aluminum layer. The other materials, polyester and tan pigmented polyethylene, do not contribute to ohmic heating since these same layers are present in Scotchpak 9723 and 9735. For Scotchpak HB-T 19733, substituting aluminum oxide for aluminum as the high barrier coating eliminates the risk of inducing ohmic heating in this film.

For the transdermal patches, only the 30 cm<sup>2</sup> circular Habitrol transdermal patch exhibited significant ohmic heating (Figure 2), with a maximum temperature change of 2.7°C, compared to the phantom gel reference temperature change of 1.3°C. The maximum temperature changes for the 10 cm<sup>2</sup> Habitrol patch and Transderm Scop patch were 2.0°C and 1.8°C, respectively, compared to 1.2°C and 1.0°C for their respective references.

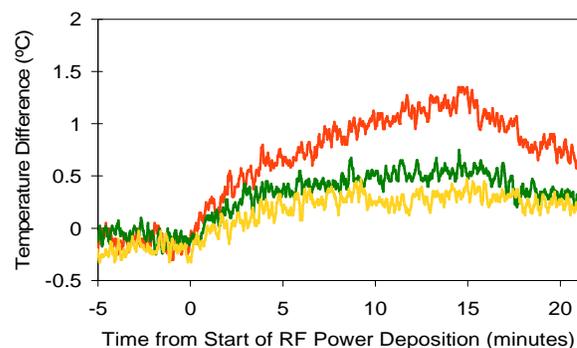


Figure 2. MRI induced ohmic heating of Habitrol 30 cm<sup>2</sup> (red), Habitrol 10 cm<sup>2</sup> (green), and Transderm Scop (brown). Data are plotted as the temperature difference between the patch and the gel reference temperature.

## CONCLUSION

MRI induced ohmic heating occurred only in metalized 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 or patch, with the greatest heating occurring at the end of large, rectangular films.

## REFERENCES

1. [www.fda.gov/drugs/drugsafety/publichealthadvisories/ucm111313.htm](http://www.fda.gov/drugs/drugsafety/publichealthadvisories/ucm111313.htm). **2009**
2. Hong, I.; Gabay, M.; Ladolce, A. *Hosp. Pharm.* **2010**, 45, (10), 771-778.
3. [www.ismp.org/Newsletters/acutecare/articles/20040408.asp](http://www.ismp.org/Newsletters/acutecare/articles/20040408.asp).
4. Shrivastava, D.; Hanson, T.; Kulesa, J.; Tian, J.; Gregor, A.; Vaughan, J. T. *Magn. Reson. Med.*, **2011**, (in press).

## ACKNOWLEDGMENTS

Financial support by 3M Drug Delivery Systems. MR testing by MR Safe Devices, LLC, Burnsville, MN.