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**Thermal Injury in Human Subjects
Due to 94-GHz Radio Frequency
Radiation Exposures**

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14. ABSTRACT The objective of this study is to compare the exposure data for millimeter wave (MMW) radiation induced thermal injury in humans at 4 W/cm ² and 6 W/cm ² to those previously obtained involving dose-response exposure data in experimental porcine models. Where possible, this study aims to extrapolate the probable for eliciting a human skin thermal response to MMW exposures by comparing data gathered and within the porcine exposure database. Due to the inherent difficulties in acquiring human subjects and exposing them to up to potential damaging levels of MMWs, the conclusions presented will be based upon the results of a small study sample (N=6). Therefore, these results serve as an initial guide to the acceptable human exposure safety margins for the employment of MMW devices, but should not be considered or received as written as a definitive study.					
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TABLE OF CONTENTS

1.0	INTRODUCTION	1
2.0	METHODS AND PROCEDURES.....	2
2.1	Human Use Protocol	2
2.2	MMW Exposure Methodology	2
2.3	Pathology.....	4
2.4	Analysis of Images	5
2.5	Characterizing the Spot	5
3.0	RESULTS AND DISCUSSION	5
3.1	Histopathology	5
3.2	Comparison of Exposures	6
	REFERENCES	8

LIST OF FIGURES

Figure 1. Beam pattern of RF source. 2

Figure 2. Orientation of experimental setup. 3

Figure 3. Thermal response of pig and human skin. 7

LIST OF TABLES

Table 1. Temperature rises and pathology scores of each exposure. 4

LIST OF ACRONYMS

711 HPW/RHDR	Air Force Research Laboratory, 711th Human Performance Wing, Human Effectiveness Directorate, Bioeffects Division, Radio Frequency Bioeffects Branch
711 HPW/RHDV	Air Force Research Laboratory, 711th Human Performance Wing, Human Effectiveness Directorate, Bioeffects Division, Veterinary Sciences Branch
ADS	Active Denial System
CLT	Carbon loaded Teflon®
IR	Infrared
MMW	Millimeter Waves
RFR	Radio Frequency Radiation
USAF	United States Air Force

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Funding for this effort was provided by the Joint Non-Lethal Weapons Directorate.

EXECUTIVE SUMMARY

The objective of this study was to compare the exposure data for millimeter wave (MMW) radiation induced thermal injury in humans at 4 W/cm² and 6 W/cm² to previously obtained dose-response exposure data in a porcine model. The comparison allows one to extrapolate the probable human skin thermal response to MMW exposures from the porcine database.

Due to the limits on recruiting human subjects and exposing them to damaging levels of MMWs, the conclusions presented will be based upon the assumption that the skin properties in the small sample human population surveyed in this experiment (N=6) are indicative of the human population as a whole. Therefore, these results can be considered an initial guide to the acceptable safety margins for the human exposure to MMW devices, but are not presented as a definitive study.

1.0 INTRODUCTION

The United States Air Force (USAF) currently operates many radio frequency radiation (RFR) emitters. The recent developments of hardware systems capable of generating millimeter waves (MMWs) and the increased use of MMW energy for both military and civilian purposes has spawned significant interest in the possible bioeffects and health hazards of exposures to these waves. This experiment is designed to assess if previous studies of MMW skin damage in pigs (Parker et al., 2015b) is indicative of similar thermal thresholds in humans. This knowledge is essential to ascertain safe exposure limits for USAF personnel and to assess the potential for injury after accidental exposure. Additionally, the Air Force Research Laboratory, 711th Human Performance Wing, Human Effectiveness Directorate, Bioeffects Division, Radio Frequency Bioeffects Branch (711 HPW/RHDR) is utilizing MMW technology to develop a non-lethal Active Denial System (ADS) that has completed an Advanced Concept Technology Demonstration. ADS exploits the natural aversion response produced by skin heating, eliciting a repel reaction in the target consisting of the desired behavioral response of escape/retreat from the energy source. Possible missions suitable for ADS deployment include force protection, crowd dispersal, and hostage rescue. With this interest in MMW technology, it is incumbent upon the Air Force to investigate and clarify potential adverse bioeffects of this technology. Determining an effective dose that limits burn risk is therefore of paramount concern. Results from this study will help to anchor safety and risk of significant injury requirements for that system. Specifically, this experiment seeks to determine if the dose-response relationship for Yucatan minipigs to 94-GHz RFR as reported in Parker et al. (2015b) is useful for computing safe thresholds in the human population.

The field penetration depth of 94-GHz RFR has been calculated to be approximately 0.3 mm, implying that most of the MMW energy absorbed in animals will occur in the cutaneous region (Erwin & Hurt, 1981; Gandhi & Riazzi, 1986). Because MMW absorption occurs in the skin, the potential for thermal damage induced by inadvertent exposure is of considerable interest. Current publications addressing MMW absorption leverage classic literature defining thresholds for burn injury produced by application of hot objects to the skin (Moritz & Henriques, 1947). In this paper, Moritz and Henriques (1947) determined the temperature-duration relationship necessary to produce varying levels of thermal injury in both porcine and human skin. For example, it was found that a “first-degree reaction” (i.e., hyperemia without epidermal loss) could be accomplished by application of fluids at 45 °C for 2 hr, 48 °C for 15 min, and 53 °C for 30 s. Furthermore, production of “second- and third-degree reactions” (i.e., complete epidermal necrosis) requires application of fluids at 48 °C for 18 min, 51 °C for 4 min, and 60 °C for 5 s. Two studies have been conducted by 711 HPW/RHDR to examine thermal damage from MMW exposure. The previous work produced curves describing probability thresholds for various levels of MMW-induced thermal injury in the rat (partial-thickness, full-thickness) (Miller et al., 2003) and pig (superficial, partial-thickness) (Parker et al., 2015b) as functions of exposure times at fixed power densities and mean skin temperatures. This study uses a subset of those exposure parameters to determine the accuracy of extrapolations from the porcine data to humans.

2.0 METHODS AND PROCEDURES

2.1 Human Use Protocol

Six adult volunteer subjects were recruited from among military personnel, Department of Defense civilians, and government contractor personnel. Volunteers of either gender were at least 18 years old. The study was completed in four months.

2.2 MMW Exposure Methodology

Variable duration, essentially continuous wave, 94-GHz electromagnetic fields are generated by a MMW source and transmitted through a waveguide terminated by a horn into an enclosed Eccosorb RF-absorbing anechoic chamber. Two exposure conditions were chosen for this study: 4 W/cm² for 3 s and 6 W/cm² for 3 s. The RF radiation emitted by the horn is approximately radially symmetric and exhibits a typical beam shape, with the first null manifesting approximately 10 degrees off the beam axis as shown in Figure 1. The RF beam's main lobe was directed onto a dielectric lens and reflected off a plane mirror in order to focus the beam into a 3 cm diameter region (about the size of a US quarter), providing the MMW energy for human subject exposures (Figure 2).

Figure 1. Beam pattern of RF source.

Figure 2. Orientation of experimental setup.

After application of anesthetics, the upper buttock/lower back of each subject was exposed to MMW energy and subsequently biopsied 2 days after the exposure. Before the exposure, the area around the exposure site was anesthetized by subcutaneous injection of less than 5 cc of 1% lidocaine without epinephrine, to avoid the vasoconstrictive effects in the sample pathology that potentially occur with lidocaine/epinephrine anesthetic mixtures. Only the anesthetized area was exposed to the MMW beam. Post exposure, a protective dry dressing was applied to minimize irritation by clothing. Two days post exposure, each subject, accompanied by a medical observer, went to the Wilford Hall Medical Center Dermatology Clinic. There, the clinic doctors injected the site with 1% lidocaine and then performed a 4 mm diameter, single center, punch biopsy. The biopsy site was closed with 1-2 non-absorbable, 4-0 prolene or nylon sutures. The medical observer collected the specimens and transported them to Air Force Research Laboratory, 711th Human Performance Wing, Human Effectiveness Directorate, Veterinary Sciences Branch (711 HPW/RHDV) for histopathologic processing and analysis.

For each exposure, a FLIR ThermoCAM® S60 infrared (IR) camera was triggered 0.5 s prior to the exposure, in order to capture the heating response of the skin at a video rate of 30

frames per second. After the duration of the RF exposure was complete, the camera continued to capture images for the next 3-66 s. The camera was placed 1 m away from the target site, aligned with the axis of the MMW beam, and directed towards the subject (Figure 2). Exact camera positioning has negligible effect upon the average temperatures calculated.

Consistency of RF power output was maintained by calibration measurements performed prior to each subject's exposure using a 15 x 15 cm sheet of 15% carbon loaded Teflon® (CLT). The heating characteristics of CLT when irradiated by 94-GHz MMWs have been documented (Parker et al., 2015a), permitting power density estimates of the RF field from measurements of the temperature rise versus time in the illuminated CLT. The exposure condition (the transmitter power density and duration settings) for each subject is listed in Table 1.

Table 1. Temperature rises and pathology scores of each exposure.

Subject ID	Date of Exposure	Exposure Condition	Mean Difference (° C)	Peak Difference (° C)	Highest Mean Temperature (° C)	Highest Peak Temperature (° C)	Pathology
N05-151	28 Feb 05	4 W/cm ² -3s	16.6	19.9	46.8	50.9	1
N05-411	26 Apr 05	4 W/cm ² -3s	13.6	19.9	44.6	51.7	0
N05-412	26 Apr 05	4 W/cm ² -3s	15.5	22	45.7	52.6	0
N05-413	27 Apr 05	4 W/cm ² -3s	17.3	23.6	49.1	56.3	0
S05-423	23 May 05	6 W/cm ² -3s	15.6	25	49.1	59.3	1
S05-426	01 Jun 05	6 W/cm ² -3s	N/A	N/A	N/A	N/A	0

2.3 Pathology

The skin biopsies from the exposure site, submitted to 711 HPW/RHDV for histopathology, were paraffin processed, sectioned, and stained with hematoxylin and eosin. Representative sections of the submitted biopsy specimen were evaluated by a board-certified veterinary pathologist, in consultation with a board certified physician dermatopathologist and an anatomic pathologist physician with extensive experience evaluating thermal injury in tissues. Sections were scored based on the overall severity of the lesion observed. Since it was not possible to histologically evaluate every area of the exposed skin, some areas affected by the irradiation may not have been represented in the examined biopsy section. Based on the findings, the specimens were grouped into two categories. These categories are identical to corresponding categories of the pathology severity scale used in a previous study (Parker et al., 2015b).

0. Essentially normal tissue
1. Equivalent to first-degree burn - Necrosis and/or degeneration of cells in the epidermis. If necrosis is present, it does not extend through the full thickness of the epidermis.

2.4 Analysis of Images

For the sequence of IR images of the skin collected during each exposure, two frames are selected to characterize the response of the skin to the RF heating. The first frame selected corresponds to the image of the target at the instant prior to the RF source irradiation, indicating the initial conditions present at the skin's surface and designated by the frame immediately before the frame exhibiting the initial temperature rise above the baseline temperature. The second frame is chosen at the moment the subject's skin attains the highest temperature during the entire exposure. This frame should correspond to the instant the RF source stops transmitting MMWs, as no other significant heat sources are present in the room.

2.5 Characterizing the Spot

The area of each subject's skin that exhibited increased surface temperatures as a result of the RF exposures was approximately 3 cm in diameter, as measured by the IR camera. The beam intensity profile over the surface of the skin is approximately Gaussian. Thus, to measure the reaction of the skin to the RF heating, the peak temperature was extracted from the recorded IR imagery during the exposure and the average temperature for a circular region 21 pixels in diameter (corresponding to the 3 cm diameter exposure area) centered on the hottest spot was determined. The pre-exposure skin temperatures were also extracted from the IR imagery using the frame prior to the beginning of the RF exposure. Peak temperature and average temperature of the 21-pixel diameter circle located at the same position relative to the hot spot in subsequent exposure frames were recorded. Ambient temperature (21 °C) and relative humidity (50%) were stabilized and maintained in the chamber throughout each subject's exposure. The IR optics were stored in the chamber prior to the experiment for a sufficient period to achieve thermal equilibrium with the ambient temperature. The emissivity of human skin (0.98) was used for temperature computations in the thermal images. ThermaCAM® Researcher 2002 was used to transform the FLIR camera IR spectral measurements of each pixel to temperature values and correct these displayed temperature values for emissivity and background thermal effects.

3.0 RESULTS AND DISCUSSION

The initial hypothesis for these experiments is that the injury thresholds to RF exposures in humans should be comparable to injury thresholds in Yucatan minipigs due to similar skin structure (Eggleston et al., 2000). At 94 GHz, the RF field is reduced to 37% of the incident surface field at a skin depth of approximately 0.3 mm, and at that superficial level, pig skin and human skin are similar. Because this study only conducted a few exposures on humans, one cannot make a definitive statement; however, the experiment provides some similarity between humans and the porcine data, as described subsequently.

3.1 Histopathology

Specimens scored as normal (0) had no lesions that could definitively be attributed to the experimental exposure. As specimens were evaluated for microscopic changes only at one timepoint, it is possible that some exposure sites may have experienced minor damage which resolved and appeared essentially normal two days post-exposure. Specimens with a score of one represent lesions with mild injury to the epidermis which appears to be healing normally. Mild lymphocytic inflammation in the superficial dermis, both perivascular and along the

dermal-epidermal junction (interface dermatitis) was seen in a few specimens. It could not be determined if this inflammation was preexistent or secondary to the experimental exposure.

3.2 Comparison of Exposures

Table 1 lists the relationship between the rise in temperature and the thermal injury observed in the skin. Out of the six exposures, two (33%) exhibited superficial first-degree burns. The average temperature of the human exposure conditions is plotted in Figure 3, against the sensitivity of pig skin to RF exposures derived from the previous work (Parker et al., 2015b) for comparison. The agreement between the pig data and human data suggests that the pig's skin thermal response would be a good surrogate for the human condition as expected from previous laser studies (Eggleston et al., 2000). No temperature data is available for subject S05-426 because the computer image files were corrupted due to a hardware malfunction.

Uncertainty in the location of the single human data point is difficult to quantify with a small sample (N=6). The standard deviation of the exposures is plotted in Figure 3.

Figure 3. Thermal response of pig and human skin.

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