Measurement Repeatability and Reproducibility in Radiofrequency Implant Heating in Benchtop Exposure Systems

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INTRODUCTION

A standardized test method for RF-related implant heating utilizes direct measurement of RF-induced heating of implant within a phantom [1].

Local SAR (LSAR) can be assessed *in vitro* by direct measure of RF-induced heating of an elongated conductive 10.0 cm long Ti rod within a standardized phantom [1].

Scaling factor, χ, for the rod changes temperature rise, ΔT, to a LSAR value [1] by:

$$LSAR = \frac{\Delta T_{360s}}{\chi}.$$

Testing laboratories operating according to the ISO/IEC 17025 require procedures for calculating/estimating uncertainty of measurements. Participation in inter-laboratory comparisons is required, as is proficiency testing, traceability and understanding variation of measurements.

A need exists to identify contributions of uncertainty components and make reasonable estimations.

The measurement reproducibility reflects experiment errors (e.g. from position of phantom or device), instrument uncertainty (e.g. calibration, coil geometries), and material variations (e.g. electrical conductivity).

Measurement repeatability reflects the variation in test results in test measurement equipment.

PURPOSE

The aim of this study was two fold:

1. To quantify *short-term* (within-a-day) measurements:
   - Repeatability (repeated measurements within a single session)
   - Reproducibility (between different experimenters)
   - Directly from RF-induced heating in a representative orthopedic implant.
2. To quantify *long-term* (day-to-day) measurement:
   - Repeatability (repeated measurements spanning 14 months)
   - Directly from temperature resolved LSAR.

METHODS

Exposure System

All measurements performed on two different transmit-only body RF birdcage Medical Implant Test Systems (MITS) 1.5 and 3.0 [2], corresponding to frequencies of 64 and 128 MHz, respectively.

Figure 1: MITS 1.5/64 MHz (left) and 3.0/128 MHz (right) bench top exposure systems [2].

Table 1: MITS sequence parameters (Software v1.12.10 [2]).

Parameters	MITS 1.5	MITS 3.0
RF on (SAR) [s]:	360	360
RF on (implant heating) [s]:	900	900
Pulse type:	sinc2π	sinc2π
Duty cycle [%]:	40	40
Pulse rep. rate [kHz]:	1.0	1.0
Polarization [°]:	270	90
Frequency [MHz]:	63.33	127.60
Power [dBm]:	59.0	60.2
Whole-body SAR [W/kg]:	2.97 ± 0.04	3.01 ± 0.18
$B_{1,rms}$ [μT]:	4.40	2.86

METHODS

Phantom

An ASTM phantom (42 × 65 × 16.5 cm) was filled with gelled Hydroxyethyl cellulose (HEC) to a height of 9.0 cm [1].

HEC had electrical conductivity of 0.47 S/m ± 10 % and worst case thermal convection properties (i.e. without perfusion) of human tissue. The phantom gel was aligned with the center of the MITS.

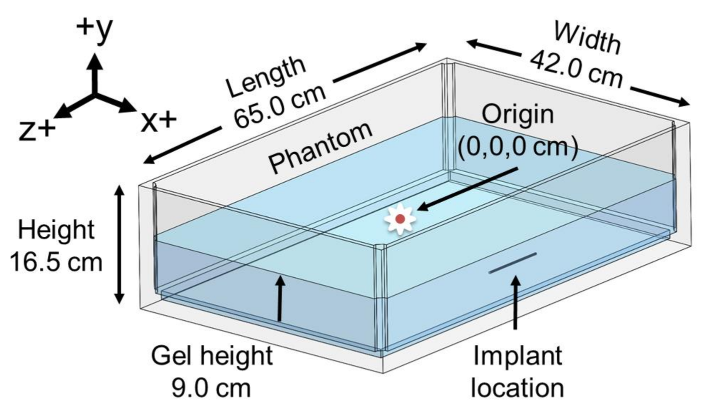

Figure 2: 3-D illustration of phantom container with a reference implant at the implant location for a device test measurement at 128 MHz.

Temperature Monitoring

Omniflex signal conditioner [3] with T1C optical fiber temperature probes [3] was used to monitor temperature.

Normal temperature procedures were followed with acceptable temporal rates [1]. Data collection by a custom built Labview program.

Devices

Within-a-day temperature reproducibility and repeatability using test plate with screws.

Temperature probes placed on ends of plate and tip of screws.

Measurements repeated (3x) within a single session (no change to physical setup). Measurement and setup reproduced (3x) between different experimenters.

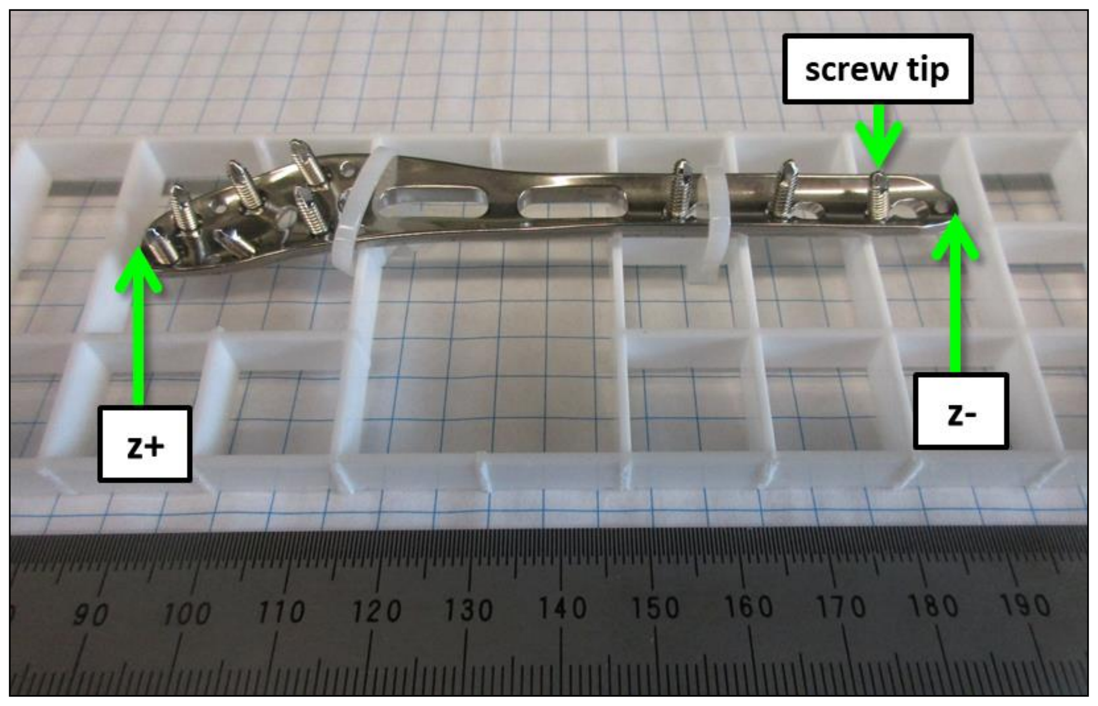

Figure 3: Stainless steel (grade 316L) distal fibula test plate with screws for testing at 128 MHz.

Day-to-day reproducibility using 10.0 cm long 1/8-inch diameter Grade 5 Ti with 1.0 mm diameter holes. Temperature sensors [3] were placed in the holes to monitor temperature.

Implant Positioning

Data taken at points submerged in gel, parallel to long-sided wall at different spatial increments (1-2 cm) centered on the typical implant testing location (33 mm from x-axis, 52 mm from phantom floor).

Analysis

Day-to-day: Measured temperature change was converted to LSAR by scalar factors of 1.30 and 1.45 ºC/W/kg for 64 and 128 MHz, respectively [1].

Within-a-day: Variation quantified from corresponding standard deviation (SD) of the mean temperature change.

RESULTS

Within-a-day Repeatability

Data is collected multiple times with the same setup.

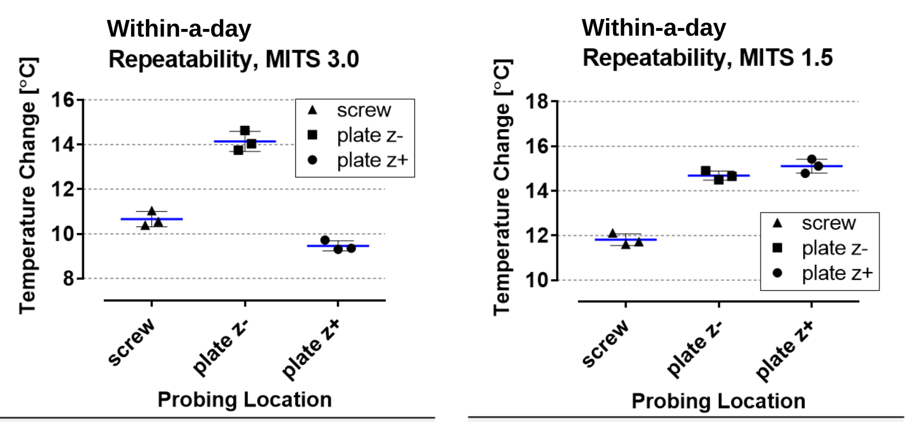

Figure 4: Scatter plot with mean and standard deviation (top) and corresponding summary tables (bottom)

MITS 3.0:

	screw	plate z-	plate z+
Mean [°C]	10.66	14.14	9.46
SD [°C]	0.34	0.45	0.22
Pct. Error [%]	3.18	3.18	2.36
Std Err. of Mean [°C]	0.20	0.26	0.13

MITS 1.5:

	screw	plate z-	plate z+
Mean [°C]	11.81	14.68	15.11
SD [°C]	0.26	0.21	0.32
Pct. Error [%]	2.22	1.41	2.09
Std Err. of Mean [°C]	0.15	0.12	0.18

Within-a-day Reproducibility

Experiment is setup from the beginning by a different operator.

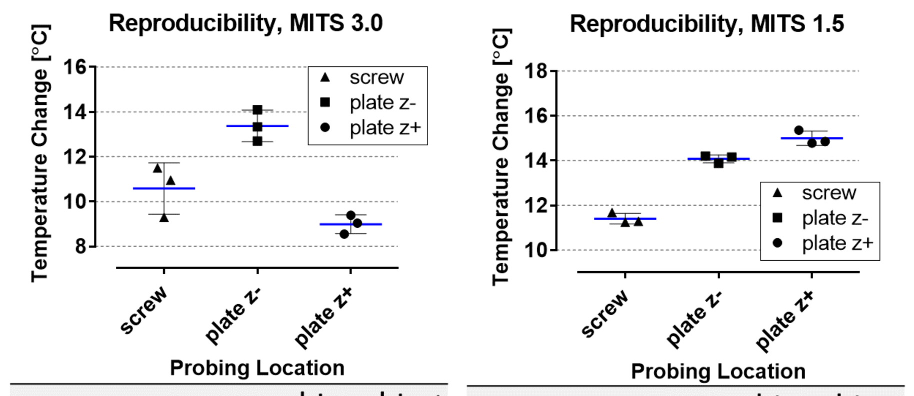

Figure 5: Scatter plot with mean and standard deviation (top) and corresponding summary tables (bottom)

MITS 3.0:

	screw	plate z-	plate z+
Mean [°C]	10.58	13.38	8.99
SD [°C]	1.14	0.70	0.42
Pct. Error [%]	10.82	5.24	4.69
Std Err. of Mean [°C]	0.66	0.40	0.24

MITS 1.5:

	screw	plate z-	plate z+
Mean [°C]	11.41	14.08	15.00
SD [°C]	0.24	0.18	0.32
Pct. Error [%]	2.08	1.28	2.11
Std Err. of Mean [°C]	0.14	0.10	0.18

MITS	Δy [cm]	n	Local SAR [W/kg]	SD [W/kg]	Percent Error [%]	95% Confidence Interval
1.5	0.7	32	7.61	0.20	2.62	7.54 - 7.68
1.5	1.7	37	8.38	0.28	3.36	8.37 - 8.55
3.0	0.7	25	10.22	0.45	4.39	10.04 - 10.39
3.0	1.7	8	13.36	0.50	3.71	13.02 - 13.71

Table 2: Long-term day-to-day (span of 14 months and 6 different HEC batches) measurement repeatability of resolved LSAR in vitro from RF-field induced heating of an ASTM 10.0 cm long Ti rod.

DISCUSSION AND CONCLUSION

Within-a-day repeatability Highest variation was 3.18 % (128 MHz) and 2.22 % (64 MHz).

Within-a-day reproducibility Highest variation was 10.82 % (128 MHz) and 2.08 % (64 MHz).

Greatest variation of 10.82 % (128 MHz) possibly by:

1. Stronger/sharper variations at 128 MHz are known.
2. Could be due to probe placement error.

More work needs to be done with greater number of tests and operators. Future work will involve optimizing experimental techniques to reduce error. In particular, greater effort in positioning and handling of equipment, devices and probes.

This study presents quantitative determination of RF-induced implant measurement repeatability and reproducibility values corresponding to test cases involving conductive medical implants in an RF benchtop exposure system.

ACKNOWLEDGEMENTS

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REFERENCES

[1] ASTM International F2182-11a. [2] (ZMT, Zurich, Switzerland). [3] (Neoptix, Québec, Canada).