MDDT SUMMARY OF EVIDENCE AND BASIS OF QUALIFICATION FOR

COMPUTATIONAL TOOL COMPRISING VISIBLE HUMAN PROJECT® BASED ANATOMICAL FEMALE CAD MODEL AND ANSYS HFSS/MECHANICAL® FEM SOFTWARE FOR TEMPERATURE RISE PREDICTION NEAR AN ORTHOPEDIC FEMORAL NAIL IMPLANT DURING A 1.5 T MRI SCAN

BACKGROUND

MDDT NAME: Computational Tool Comprising Visible Human Project® Based Anatomical Female CAD Model and Ansys HFSS/Mechanical® FEM Software for Temperature Rise Prediction near an Orthopedic Femoral Nail Implant during a 1.5 T MRI Scan

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TOOL DESCRIPTION AND PRINCIPLE OF OPERATION

This medical device development tool (MDDT) is categorized as a non-clinical assessment model (NAM). This MDDT is a computational modeling and simulation tool in the form of a complete workbench. It can predict heating of tissues around metallic orthopedic implants when these implants are subjected to radio frequency (RF) electromagnetic fields generated by magnetic resonance imaging (MRI) coils (e.g., when a person undergoes an MRI scan), with the target demographic being the mid-aged and elderly female population primarily affected by osteoporosis and associated bone fractures.

The intent of this NAM is to enable developers of *in vivo* medical devices to assess parameters for MR conditional labeling as well as to calculate a prediction in virtual (simulation) space of the worst-case performance of their designs. The worst-case performance is characterized by the maximum experienced *in vivo* temperature rise in or very close to the device.

This MDDT uses a high resolution anatomical female CAD (computer aided design) model coupled with the proven multiphysics finite element method (FEM) software (Ansys HFSS/Mechanical) to simulate the complete MRI environment. The environment consists of a tuned MRI coil with the given output power, detailed heterogeneous human model within the coil at the given landmark and a properly embedded metallic implant within the anatomical model to compute the extent of heating generated around the implant.

Specifically, this MDDT is the *in silico* analog of an MRI scan for an elderly female subject of 50-70 years old with a higher obesity (BMI or body mass index of 30-36) scanned in a 1.5 T full body circularly polarized cylindrical MRI birdcage coil at 64 MHz. A long femoral nail (a nearly straight long metallic rod) which is subject to most excessive heating during long scan times at 1.5 T was chosen for this MDDT.

CONTEXT OF USE

This MDDT is a non-clinical assessment model used to generate parameters for MR conditional labeling for adults. This MDDT can be used to generate parameters including the RF power deposition, induced temperature rise near passive metallic femoral intramedullary nails and screws (21 CFR 888.3020, product code HSB) as a function of implant geometry, location, material, and multiple scan times and cooling times. It is using the complete *in silico* multiphysics MRI environment and the anatomical human CAD model.

The tool approximates scanning in a 1.5 T magnetic field strength in MRI with Circularly Polarized RF excitation whole-body cylindrical birdcage coil. This tool can augment the widely used ASTM F2182 standard that measures RF implant heating in a homogeneous gel phantom by providing extra safety margins caused by the influence of the realistic heterogeneous human body. It can help to identify the appropriate worst-case implant size, configuration, and orientation as a function of the scan protocol and required scan time/cooling times (the output RF power), including statistical analysis of variations. Summary of input/output tool parameters and variables is given in Table 1.

Table 1. Summary of input and simulated output parameters and variables. The tool outputs B1+, SAR, and temperature at any spatial location within the body, including anywhere near or on the surface of the metallic implant. Additionally, the local temperature is a function of exposure time.

<table>
<tr><th colspan="6">Tool Input Parameters</th></tr>
<tr><th>Target whole body SAR [W/kg]</th><th>Coil Rotation [deg]</th><th>Coil Landmark [mm]</th><th>Implant geometry</th><th>Implant Material</th><th>Total Scan Time [s]</th></tr>
<tr><td>1</td><td>0</td><td>Head</td><td>Radius</td><td>Platinum-Iridium</td><td>600</td></tr>
<tr><td>2</td><td>-90</td><td>Shoulder</td><td>Length</td><td>Titanium</td><td>900</td></tr>
<tr><td>4</td><td>90</td><td>Abdomen</td><td>Bending</td><td>Stainless Steel</td><td>1500</td></tr>
<tr><td>Other</td><td>Other</td><td>Hips</td><td>Location</td><td>Other</td><td>Other</td></tr>
<tr><td colspan="6">Tool Output Variables (anywhere near or directly on the surface of the implant)</td></tr>
<tr><td>B1+ [T]</td><td>Local SAR [W/kg]</td><td>1g Average SAR [W/kg]</td><td colspan="2">Local temperature rise [C] as a function of time and maximum temperature rise</td><td>Stat. significance of variations (p-values of paired t-tests)</td></tr>
</table>

The tool does provide heating and SAR estimates for RF power deposition in the regions around the femoral nail implant. The tool currently does not provide heating estimates for gradient-coils.

SUMMARY OF EVIDENCE TO SUPPORT QUALIFICATION

A number of modeling and physical processes were tested to validate this MDDT. They include: (i) topological validation of the entire female CAD model (required approximately 4,000 man hours for its construction); (ii) anatomical validation of the constructed human model by anatomical experts; (iii) validation of the human model and FEM software compatibility; (iv) SAR deposition validation in the 1.5 T full-body MRI birdcage coil (accuracy of 10% or better against the experiment); (v) temperature rise validation in a phantom with the actual long femoral nail implant (accuracy of 20% against the experiment) and; (v) temperature rise validation in the detailed human model with the same femoral nail implant located at approximately the same depth (accuracy of 25% or 2.4 °C on average with the standard deviation of or 0.2 °C against the experiments with the phantom).

In the last case, the MDDT testbed predicted a higher temperature rise (by approximately 25% or 2.4 °C higher on average) at the implant tips than the *in vitro* experiments with the simplified gel phantom. An additional validation of the MDDT was therefore made against *in vivo* measurements in living human arm which indicated the temperature deviation of the MDDT from the *in vivo* experiment of only 10%.

Based on these validated processes, we created two working examples to assess parameters for MR conditional labeling. Using these two examples, we compared two commonly used sets of material properties – one from IT'IS Database Switzerland and another from ISO-TS 10974 Tech. Spec. – and no significant differences were observed.

ASSESSMENT OF ADVANTAGES/DISADVANTAGES OF QUALIFICATION

This MDDT addresses the growing number of patient MRI scans and expected prevalence of patients with implanted medical orthopedic devices, specifically mid-aged and elderly women who are most affected by osteoporosis and the associated bone fracture. Newly developed implants, as well as legacy medical implants without MRI safety information, need to be evaluated for safety in the MRI environment.

The widely used ASTM F2182 standard allows measuring RF implant heating in a homogeneous gel phantom. However, the complexity of the human body anatomy, and the heating properties of bone are different from this simplified gel phantom. For safety and completeness, it may be therefore desired to additionally estimate the heating of the same implant in a realistic heterogeneous anatomical human model.

Although this MDDT may help to estimate the induced RF heating of a metallic orthopedic implant in an elderly woman aged 50 to 70 (BMI 30 – 36) at the frequency of 64 MHz (1.5 T MRI scan), the results of the tool would be applicable to MR conditional labeling for all adults. There are no significant differences in femur bone constituents between females and males; The heating properties of bone accounted for in the model are simplified as a simple, homogenous material. The heating properties of the bone may change slightly with age, bone health, or porosity but these differences are menial because the MR induced heating of passive implants is primarily influenced by the local tissue environment around the implant and the BMI of the patient. Higher BMI typically

leads to higher induced electric fields and therefore higher increase in temperature. The local tissue around the implant that experiences the heating is independent of age or sex of the subject. Further, the heating values estimated using this tool that is based on a high BMI woman model provides a conservative estimate that could be used for other subjects of lower BMI, including males. This tool can also help to identify the appropriate worst-case implant size, configuration, orientation, and an allowable scan protocol (coil power) by performing multiple simulations to determine the RF-induced temperature rise as a function of the scan protocol and the required scan time for the purposes of MR conditional labeling.

This MDDT has demonstrated that it accurately predicts absolute temperature rise for RF-induced heating with acknowledgement of the following limitations:

- The tool is limited to passive, traditional, non-complex femoral IM Nail designs such as cannulated nails and closed-section nails (e.g., either straight or angled or curved intramedullary nails with circular, polygonal, cloverleaf, or star-shaped inner or outer contour of the shaft per ISO 15142). This tool has not been qualified for use on devices with complex geometries, modularity, non-traditional technological characteristics or unique technological characteristics such as united bundle nail or open section design as defined in ISO 15142 or expandable/lengthening nails with internal drive mechanisms.
- This tool is limited to IM nails equal to or less than 320 mm in length. Nail length is limited by the femur length of the female elderly subject used in the MDDT CAD Model.
- The tool is limited for use in adults (22 years of age and older, FDA guidance Premarket Assessment of Pediatric Medical Devices | FDA). The tool has not been qualified for use in adolescence, child or infant populations because of the significant difference in size of the elderly women CAD model compared to these pediatric sub populations. Additionally, these pediatric patients are expected to need smaller diameter components, which may create a worst-case that has not yet been validated.
- Although all separate blocks of the modeling pipeline (human model, coil model, SAR values) were validated separately and in the general case, the end result – temperature distribution along an implant and as a function of time – is limited to one yet most critical implant geometry: a long femoral nail (a nearly straight metal rod) subject to the most excessive heating and possible resonant effects.
- The focus of this MDDT is currently at 1.5 T/64 MHz cylindrical bore MRI systems using circularly polarized RF birdcage full body coils.
- The tool currently does not provide heating estimates for gradient-coils.

ASSESSMENT OF ADVANTAGES OF USING THE MDDT

The main advantage of using this MDDT lies in the possibility to accurately estimate temperature rise near an orthopedic implant in the realistic high-resolution elderly female

human model and thus additionally justify and assess measurements obtained with the ASTM F2182 standard and their safety margins.

While modeling SAR distributions near implants in realistic virtual human models is well understood, accurate modeling and prediction of temperature rise at and near implants in human models is much more difficult. The reason is a necessity to couple an electromagnetic software and a thermal software with a realistic heterogeneous human model including fine implant and tissue details which are best described with the finite element method that is developed for curved and fine geometries.

The present MDDT addresses this knowledge gap by constructing and validating the state-of-the-art multiphysics FEM modeling pipeline. It couples the detailed accurate CAD human model, the Ansys electromagnetic modeling software HFSS including the MRI coil modeling, and the Ansys thermal software, all within one single user-friendly shell – the Ansys Workbench.

The second advantage of using this MDDT is the type of the embedded anatomical female CAD model that is appropriate for middle-aged and elderly female subjects of 50-70 years old with a high obesity. There is no similar anatomical CAD model currently available.

ASSESSMENT OF DISADVANTAGES OF USING THE MDDT. THIS SHOULD TAKE INTO ACCOUNT THE FOLLOWING FACTORS:

As stated previously, the tool's context of use is currently restricted to the long femoral nails and does not include other types of the femoral orthopedic implants. The tool would also be limited to the 1.5 T cylindrical bore MRI system.

PASS/FAIL CRITERIA FOR SUCCESSFUL USE OF THE VHP-FEMALE MDDT WORKFLOW

Based on an analysis of comparisons between experimental data and simulation results included in the Evidence to Support Qualification section, the VHP-Female MDDT workbench will predict correct temperature rises for a long femoral nail implant with ±33% or less uncertainty in the temperature rise prediction. This prediction uncertainty is bounded by common variances in material properties and embedded implant position, variances that govern the successful use of the tool.

CONCLUSIONS

Based on the evidence provided, this non-clinical assessment model MDDT entitled "Computational Tool Comprising Visible Human Project® Based Anatomical Female CAD Model and Ansys HFSS/Mechanical® FEM Software for Temperature Rise Prediction near an Orthopedic Femoral Nail Implant during a 1.5 T MRI Scan" was able to predict, with an uncertainty of 33%, both temperature distribution and its evolution in time along the long femoral nail metal implant caused by RF power deposition from the 1.5 T birdcage MRI full body coil. The tool can also help to identify the appropriate worst-case device and coil size, configuration, and orientation by performing multiple simulations to

determine the RF- induced temperature rise as a function of an MRI scan protocol and required scan times and rest times for the purposes of MR conditional labeling.

All separate blocks of the modeling pipeline – the human model topology and anatomy including co-registration, surgically correct implant embedding, the RF coil model, and the resulting SAR and temperature behavior – have been validated independently and all the validation results have been made available to the user.

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