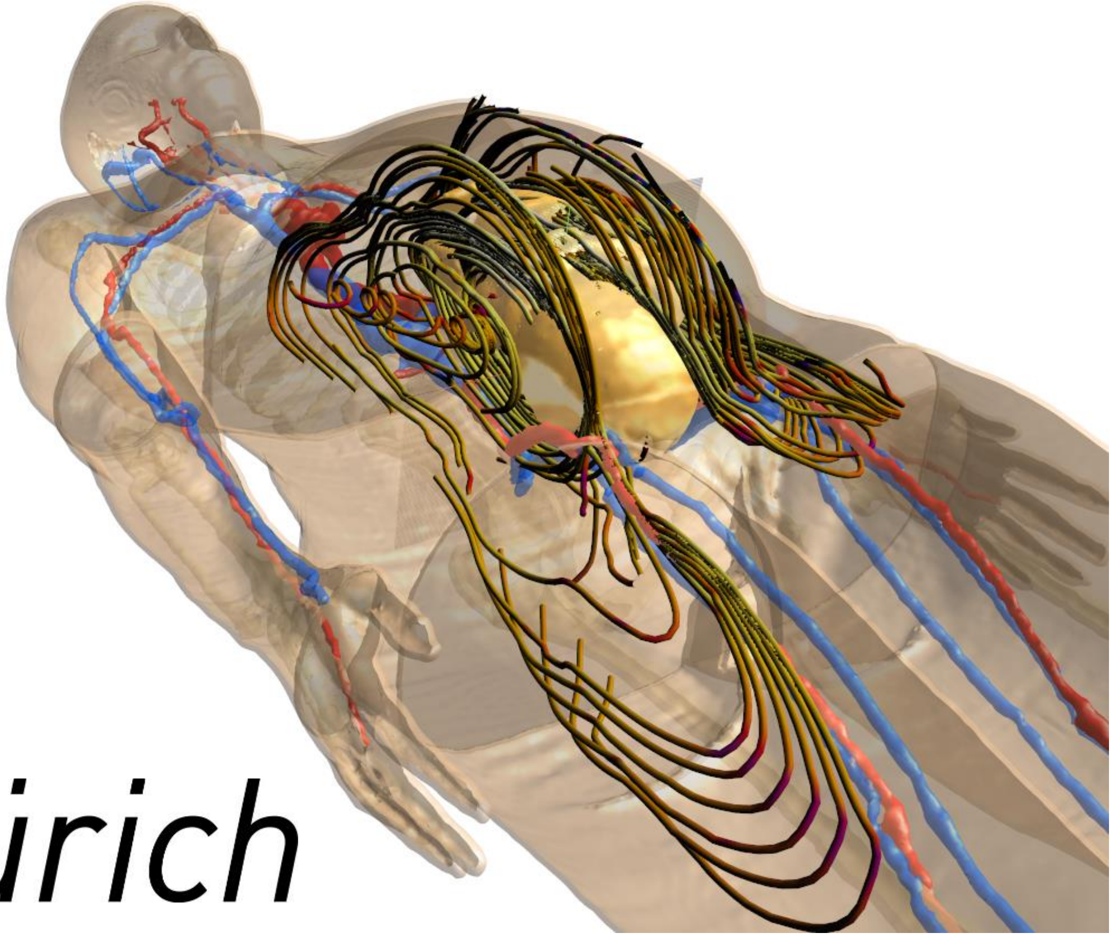
Tissue heating during MR examination as function of RF exposure and local thermoregulation, consequences for the MR safety standard IEC 60601-2-33

Manuel Murbach
Esra Neufeld, Eugenia Cabot, Earl Zastrow,
Juan Córcoles, Wolfgang Kainz, Niels Kuster



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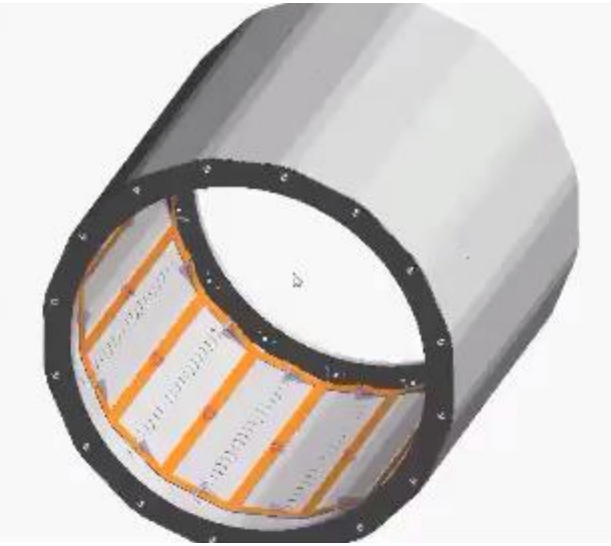
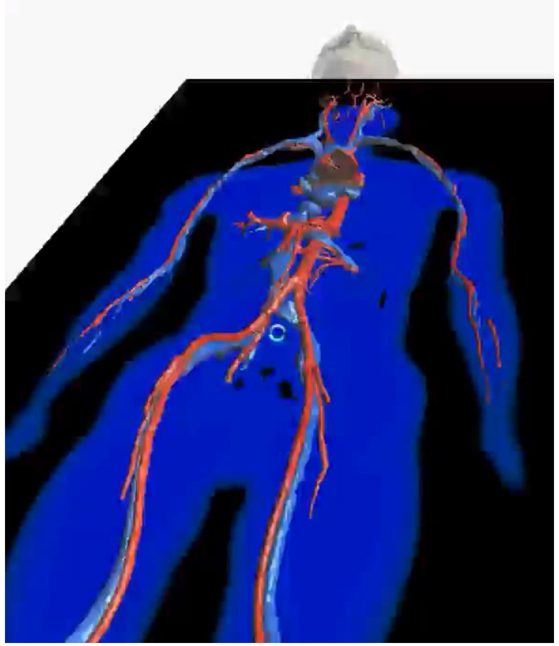
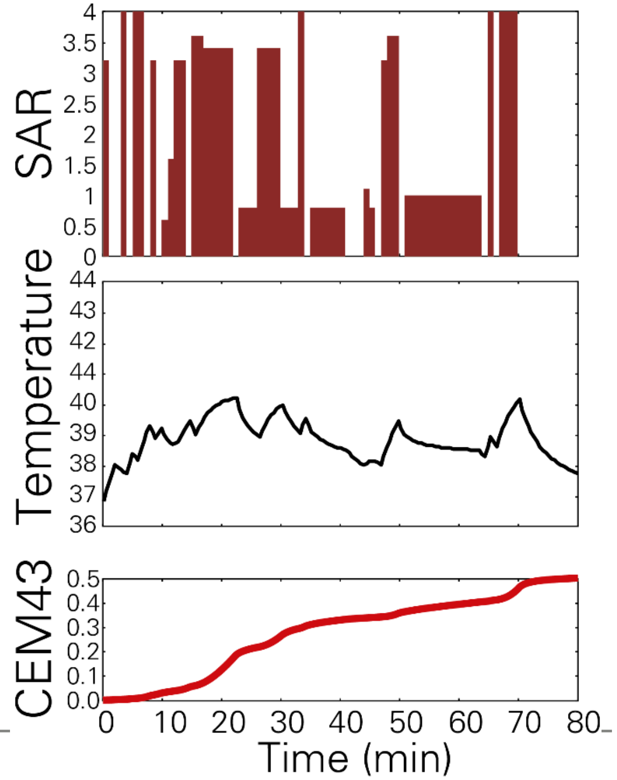
Exposure Chain in MRI

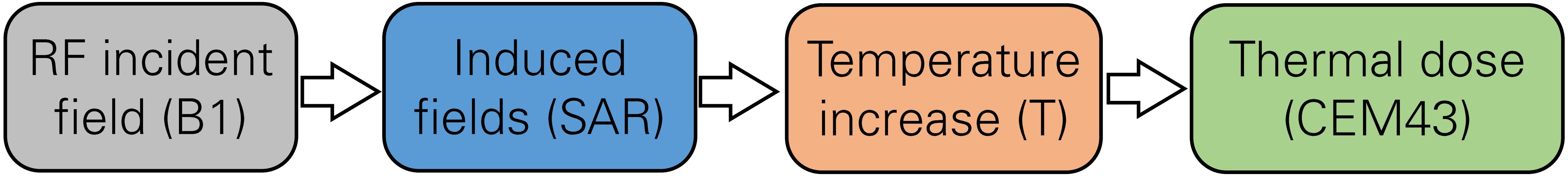
RF incident field (B1) → Induced fields (SAR) → Temperature increase (T) → Thermal dose (CEM43)







Exposure Chain in MRI



B [μT]

whole-body average SAR:
wbSAR [W/kg]

local SAR:
psSAR10g [W/kg]

T [°C]

CEM43 [min]

Exposure Safety Management, IEC 60601-2-33

- about 1 billion scans performed within IEC 60601-2-33 limits
- remarkable history of safe use

- **normal** operating mode, **first level controlled** operating mode
- governing limits in temperature (first level: T < 40°C)
- derived limits mainly in wbSAR (first level: wbSAR < 4 W/kg)
- local SAR is NOT limited for body coils
- advanced electrothermal simulation modeling shows:
  - local SAR levels are higher than originally thought
    up to > 80 W/kg psSAR10g possible in first level operating mode
  - local temperature may be higher than envisaged (> 40°C)

MRI as a Very Specific RF Exposure Scenario

- exposure configuration well characterized (frequency, incident field distribution)
- patient with respect to the field well defined (posture & landmark position)
- environment very well defined (temperature, clothing, humidity)
- benefit (excellent)

‣ specific safety concepts possible

Whole-Body vs. Local Heating

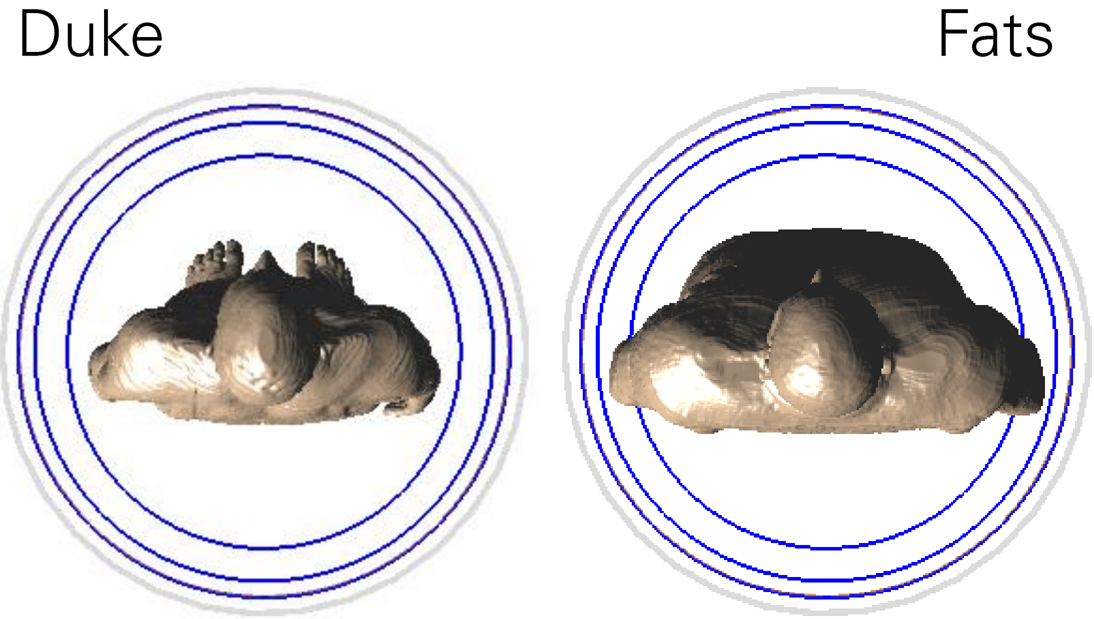
- wbSAR limit is generally providing sufficient protection against **whole-body heating**
  - can be measured reliably via overall dissipated power
  - systemic stress can be assessed, e.g., via subjective well-being of the patient
  - slow changes
- **local heating**, however, may exceed assumed limits
  - cannot be measured directly, simulation models are necessary
  - local temperatures may not be adequately perceived (e.g., limited heat sensation in muscle tissue)
  - multitransmit / pTx makes predictions more complex
  - environment (air temperature, ventilation, sweating) does NOT affect local temperature hotspots inside the body

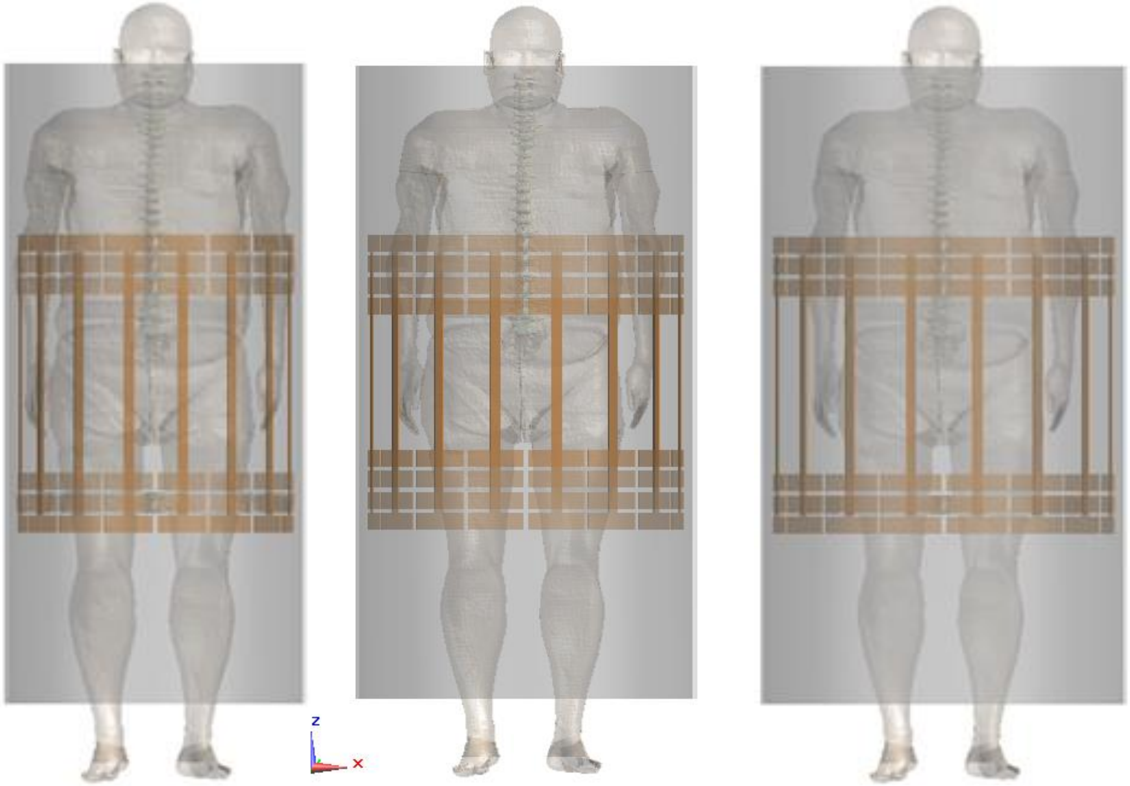
Study Overview

- non-implant RF heating
  - 2011: local SAR enhancements [Murbach et al., 2011]
  - 2011: multitransmit SAR [Neufeld et al., 2011]
  - 2014: correlation with anatomy [Murbach et al., 2014b]
  - 2014: thermal damage evaluations [Murbach et al., 2014a]
  - 2015: CEM43 safety supervision concept [Neufeld, et al, 2015]
  - 2015: RF-Shimming with pregnant women [Murbach 2015, in preparation], [Murbach et al., 2014c]
  - 2015: RF-Shimming with pregnant women [Murbach 2015, in preparation]
  - 2015: pTx for pregnant women [Murbach 2015, in preparation]
- implant RF heating
  - 2009: MRI implant heating [Neufeld et al., 2009]
  - 2011: implant safety [Kyriakou et al., 2011]
  - 2012: RF heating of DBS [Cabot et al., 2012]
  - 2014: validation system of Tier 3 method [Zastrow et al., 2014]
  - 2015: implant RF-heating mitigation [Zastrow 2015, in preparation]
- other
  - JWG: [ISO/TS 10974, 2012]
  - 2013: CEM43 Tissue Damage Thresholds for MR [van Rhoon et al., 2013]

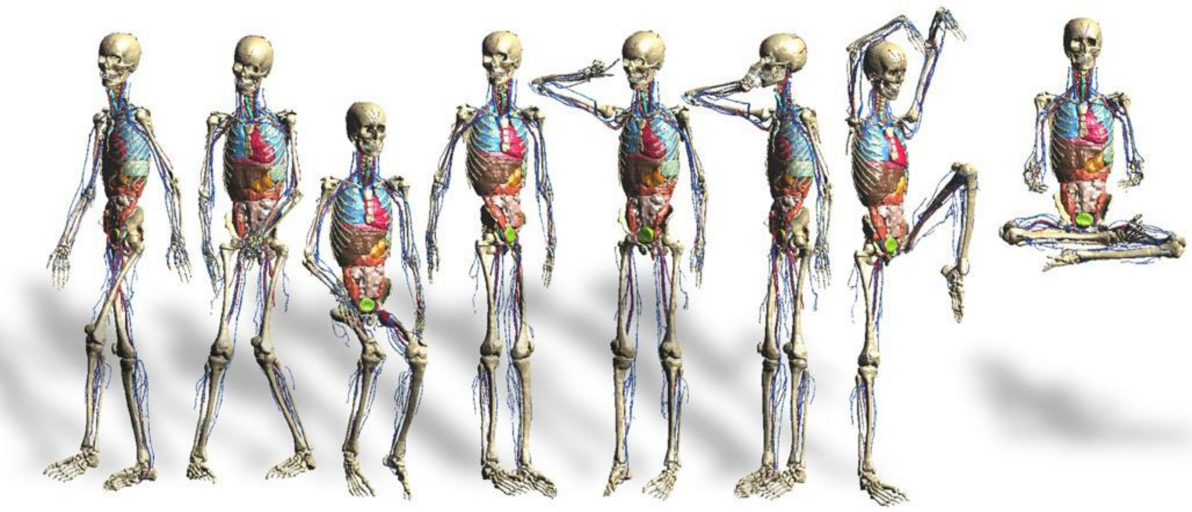
Incident Field

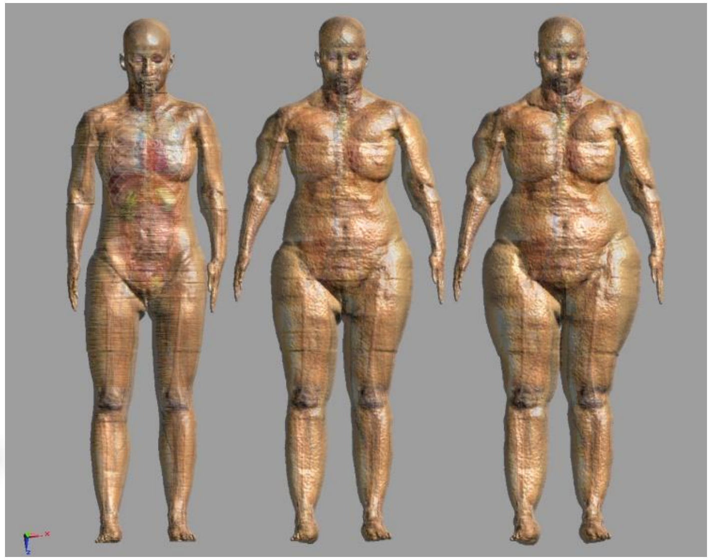
- body coil model ("antenna")
  - excitation scheme (CP, RF shimming)
  - birdcage dimensions:

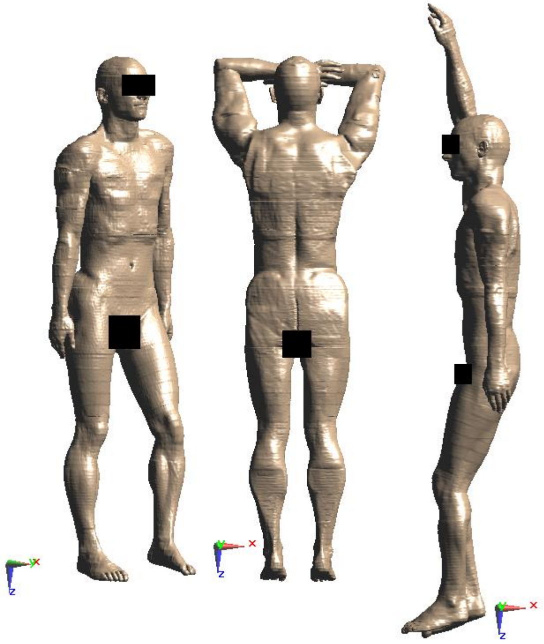




Anatomical Models: Posing / Morphing



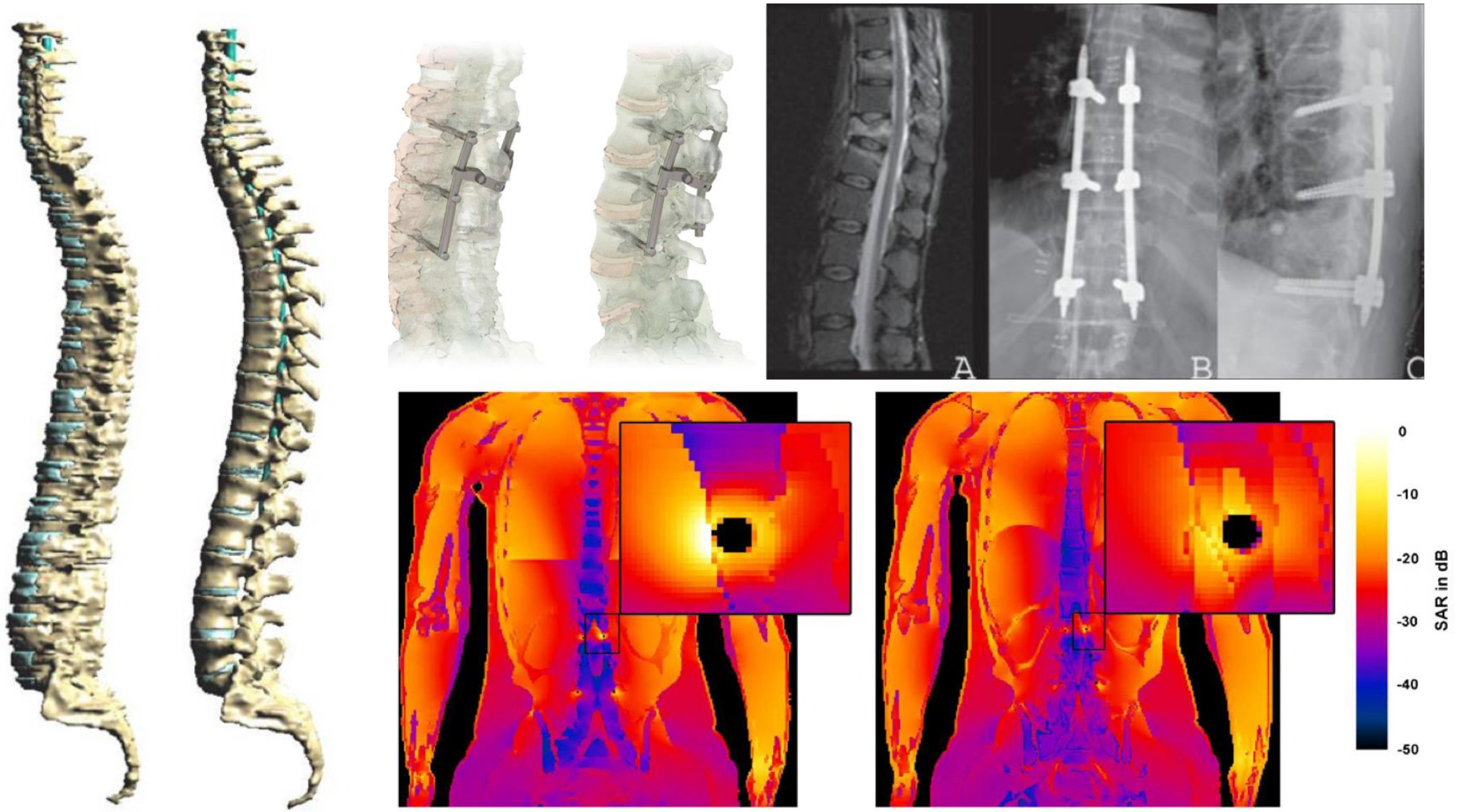




- anatomical human models, e.g., Virtual Population
- posing: volume preserving posture changes
- physics-based morphing to enhance range of coverage

‣ increased population/situation coverage

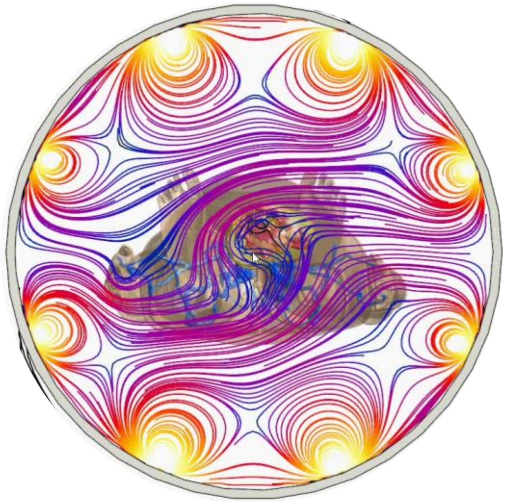
ViP 3.0 - Approaching Clinical Realism



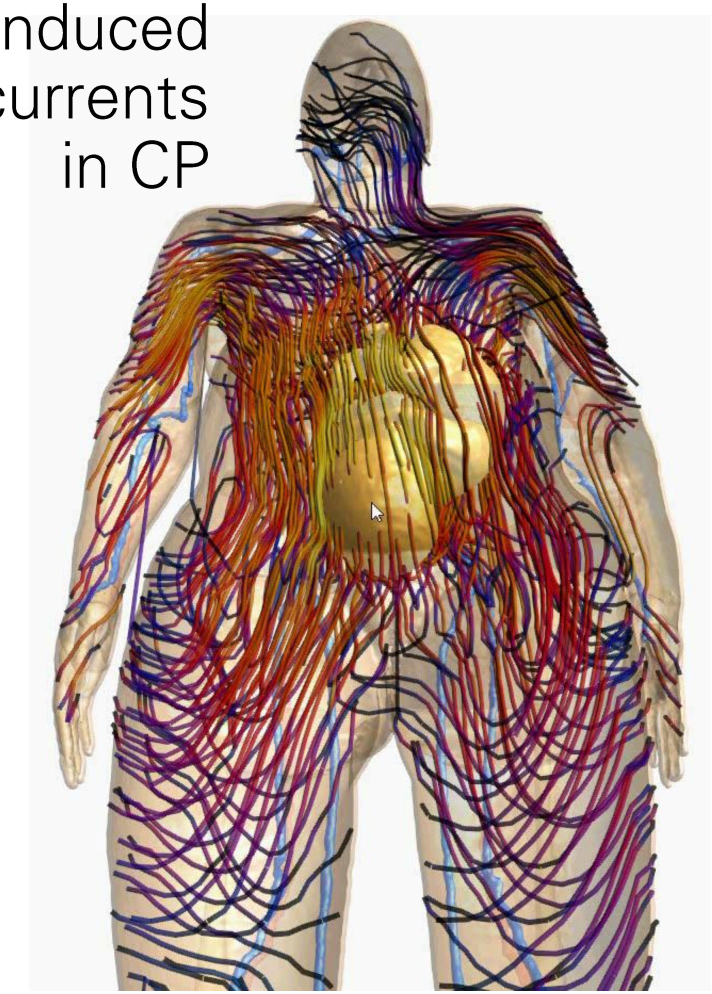
Gosselin et al. (2014). **Development of a new generation of high-resolution anatomical models for medical device evaluation: the Virtual Population 3.0**. Physics in Medicine and Biology, 59: 5287–5303.

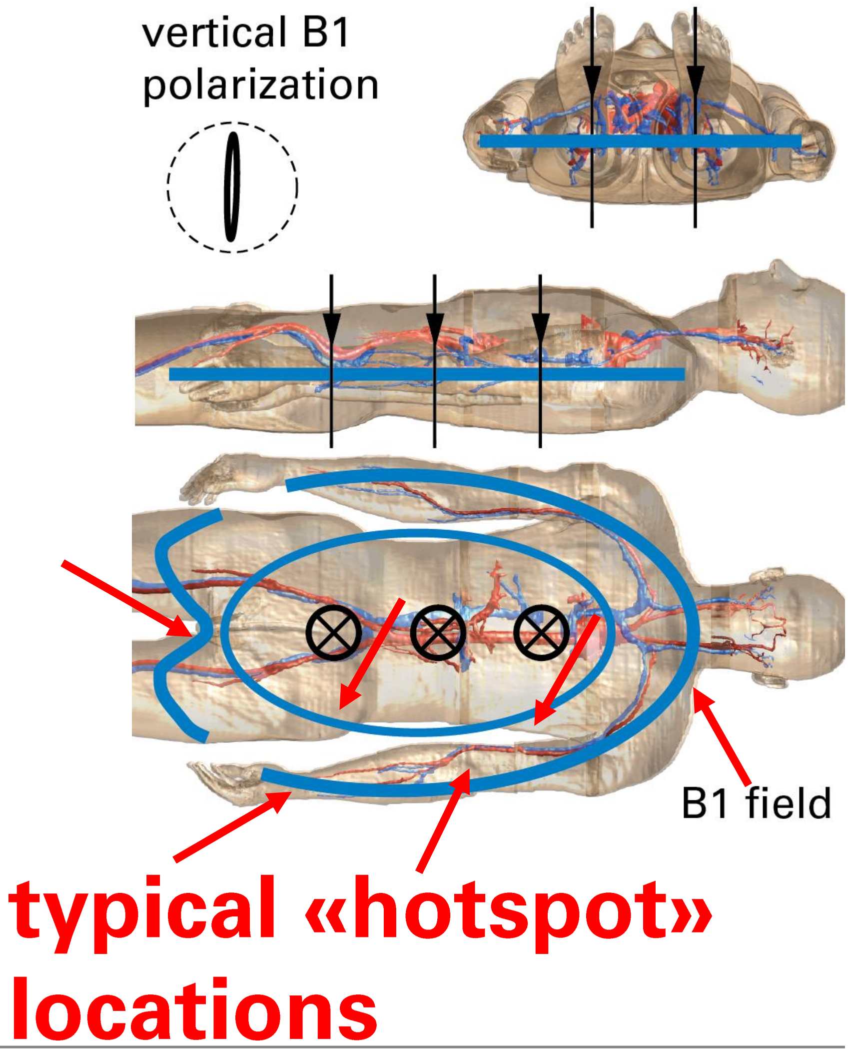
Exposure Pathway through Induced Eddy Currents

B1-Field in CP



induced eddy-currents in CP

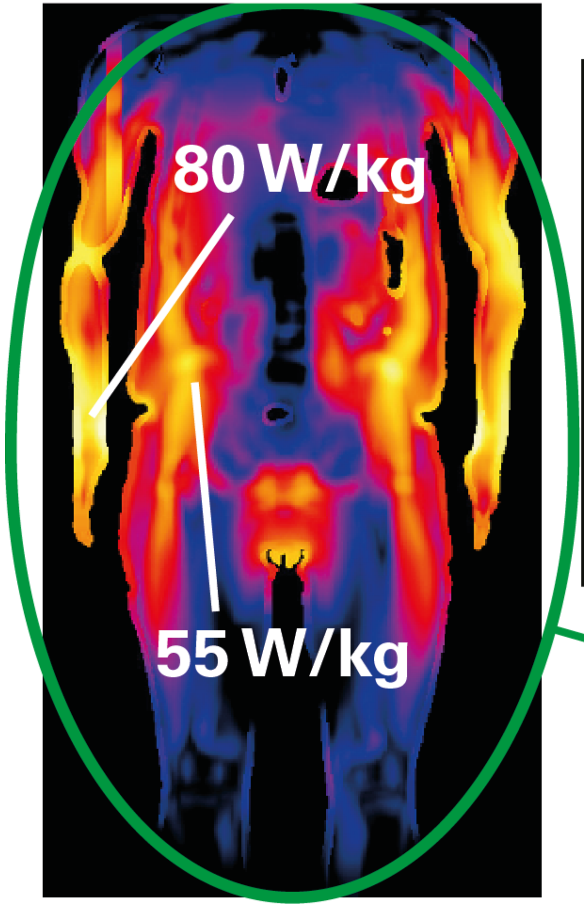




Example High-SAR Scan Scenario

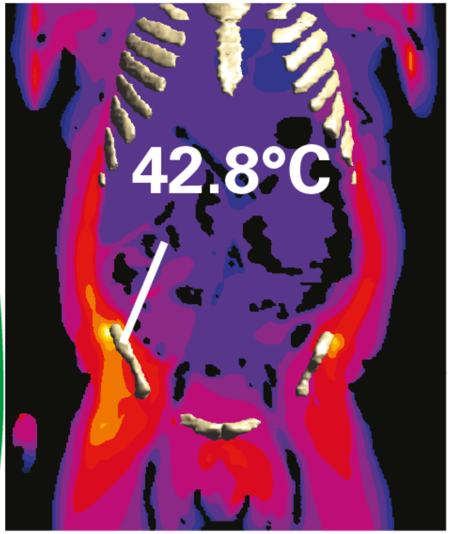
- Fats (obese model)
- pelvis imaging position
- 1.5T CP
- maximum allowance (wbSAR = 4 W/kg)

psSAR10g (W/kg)

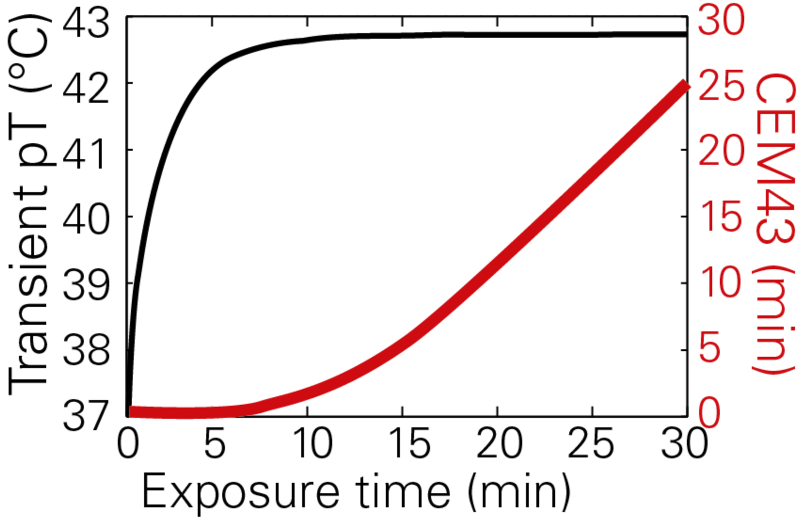


wbSAR = 4 W/kg

Temperature (°C)

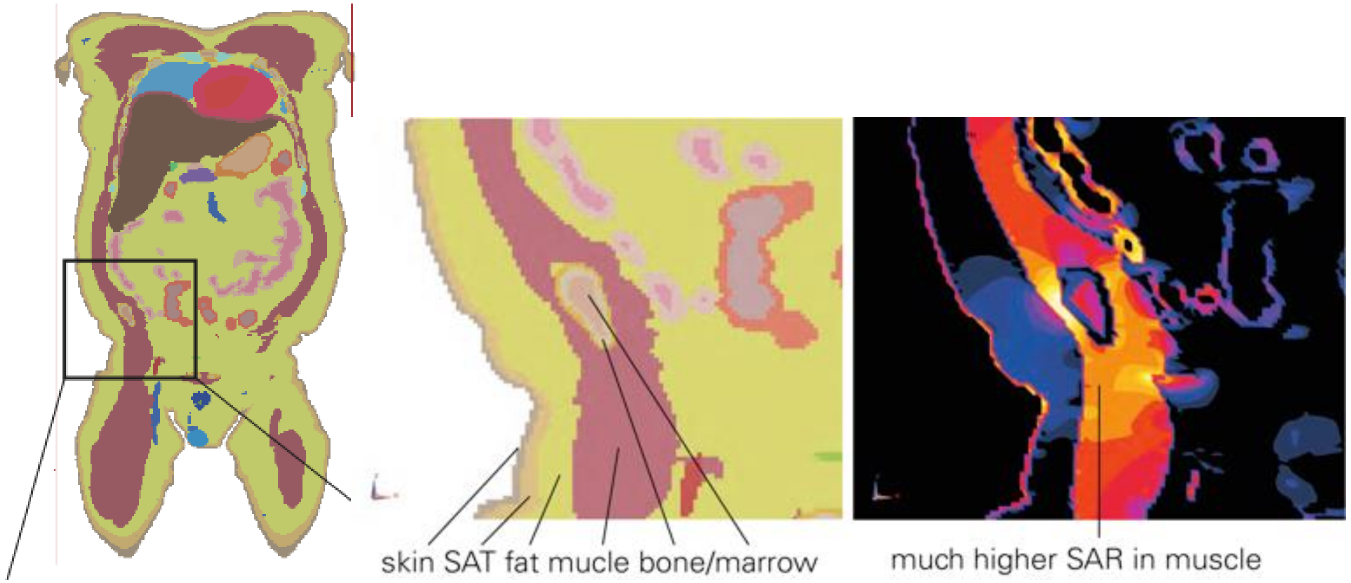


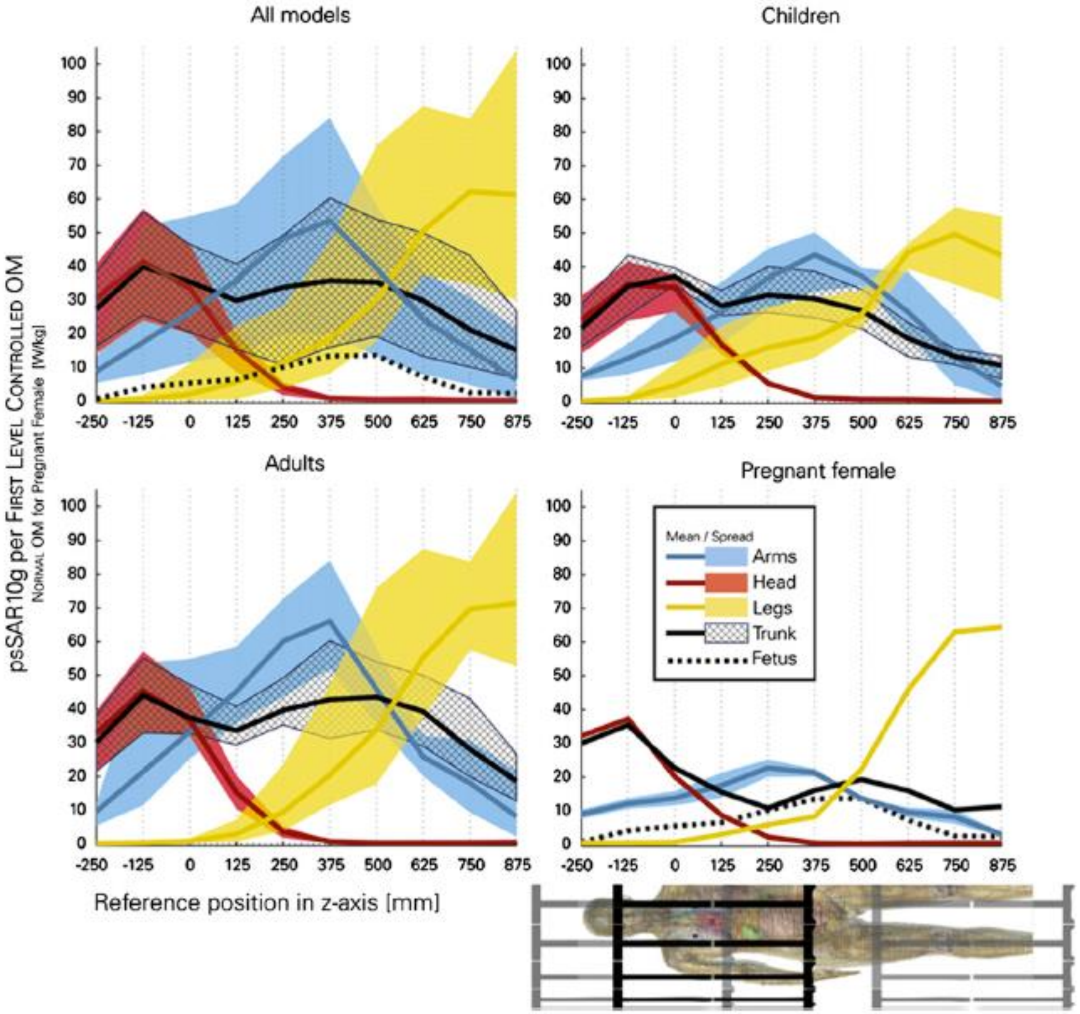
Temperature & CEM43



2011: Local SAR Enhancements (1.5T)

- local SAR (psSAR10g) can reach > 80 W/kg (in First Level OM)





Murbach, M., Cabot, E., Neufeld, E., Gosselin, M.-C., Christ, A., & Kuster, N. (2011). **Local SAR enhancements in anatomically correct children and adult models as a function of position within 1.5 T MR body coil.** Progress in Biophysics and Molecular Biology, 107(3), 428–433.

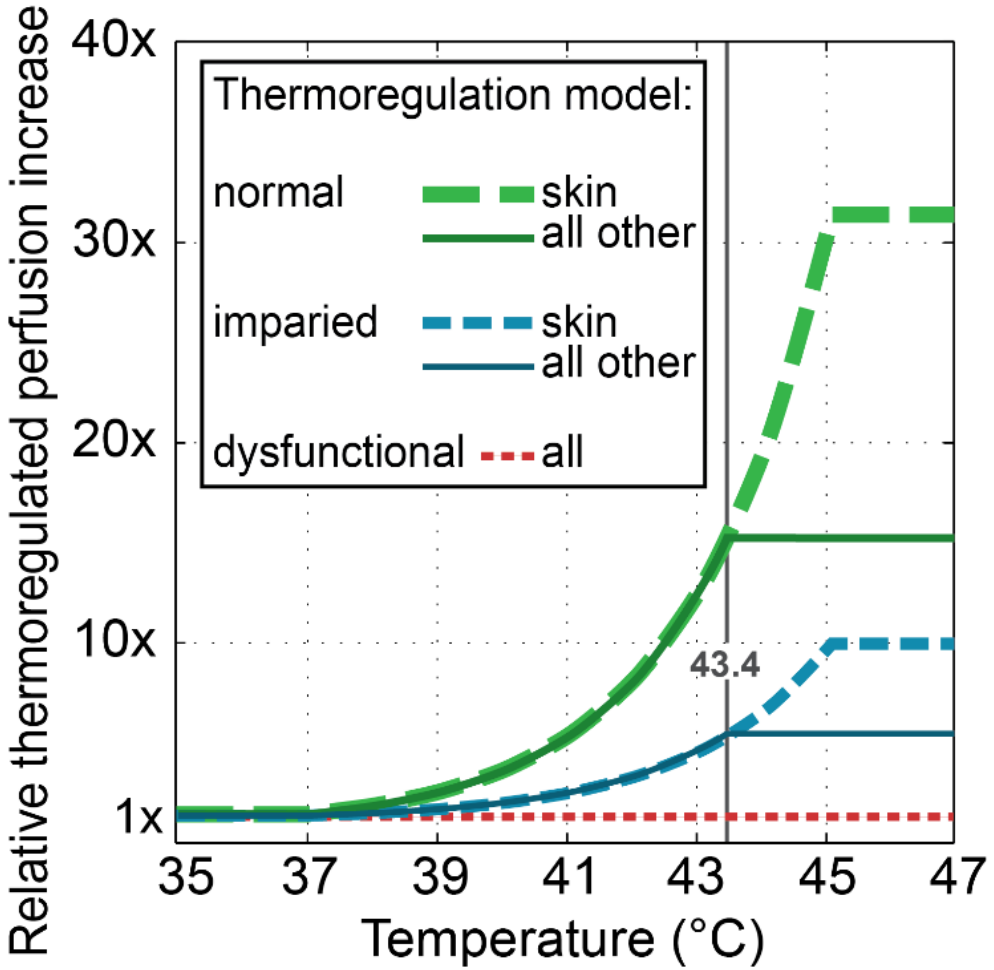
Local Thermoregulation Model

- local thermoregulation is the most important parameter for local temperature increases [Laakso & Hirata 2011] for MR exposures (> 20 W/kg)
- thermally induced blood-flow increase of factor > 10
- the ability to up-regulate the local blood-flow has often been underestimated

Local Thermoregulation Models

- we suggest the following definitions
  - normal thermoregulation:
    factor 32 (skin) and 16 (other) increase
  - impaired thermoregulation:
    70% reduction in perfusion change

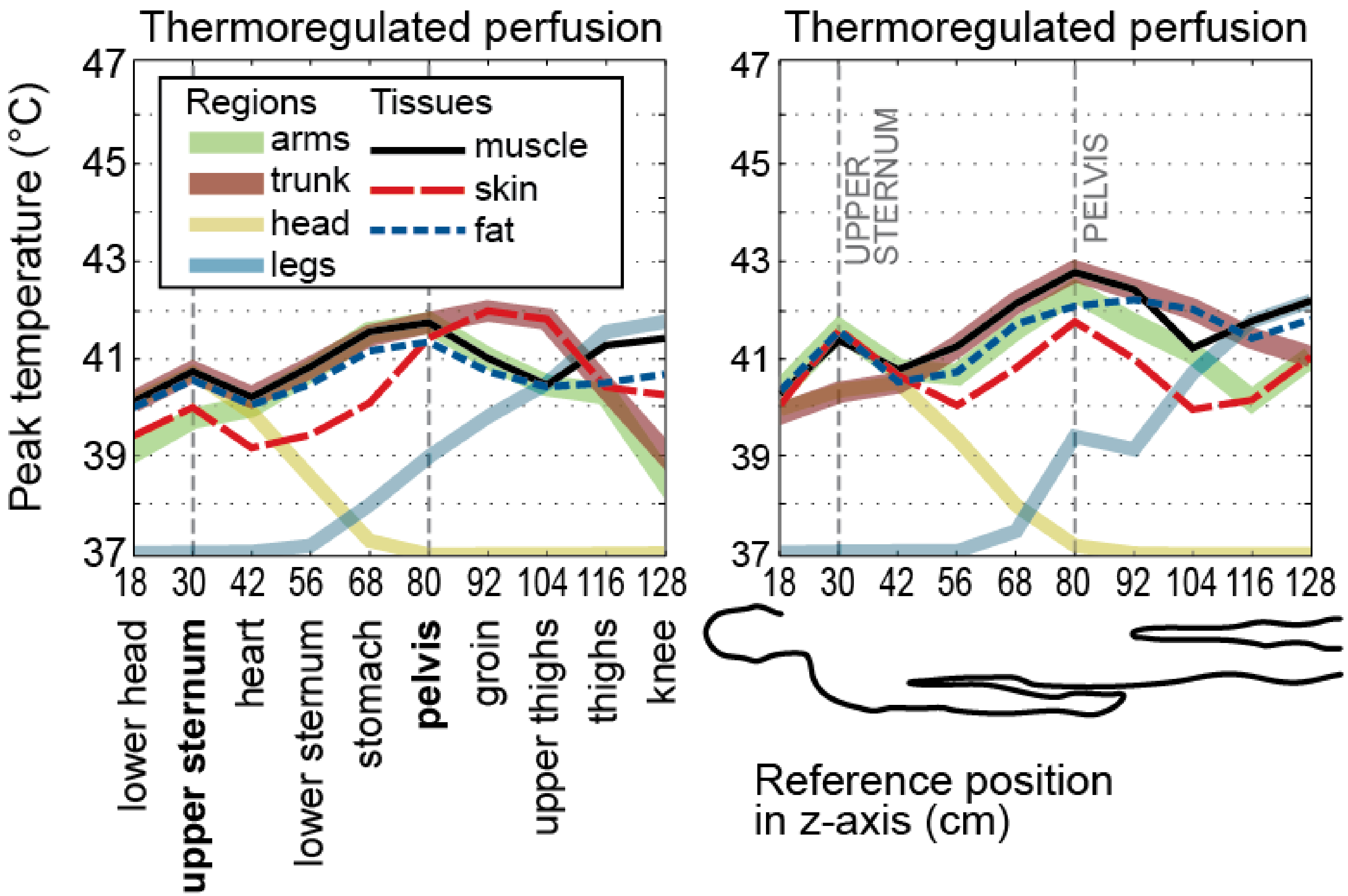
  – impaired thermoregulation for conservative estimations
  – thermal hyperaemia is impaired in:
    diabetes, age, smokers, renal failure, cardiovascular disease. (range: 21% - 61%)



Local Temperature Evaluations (1.5T)

Duke

Fats



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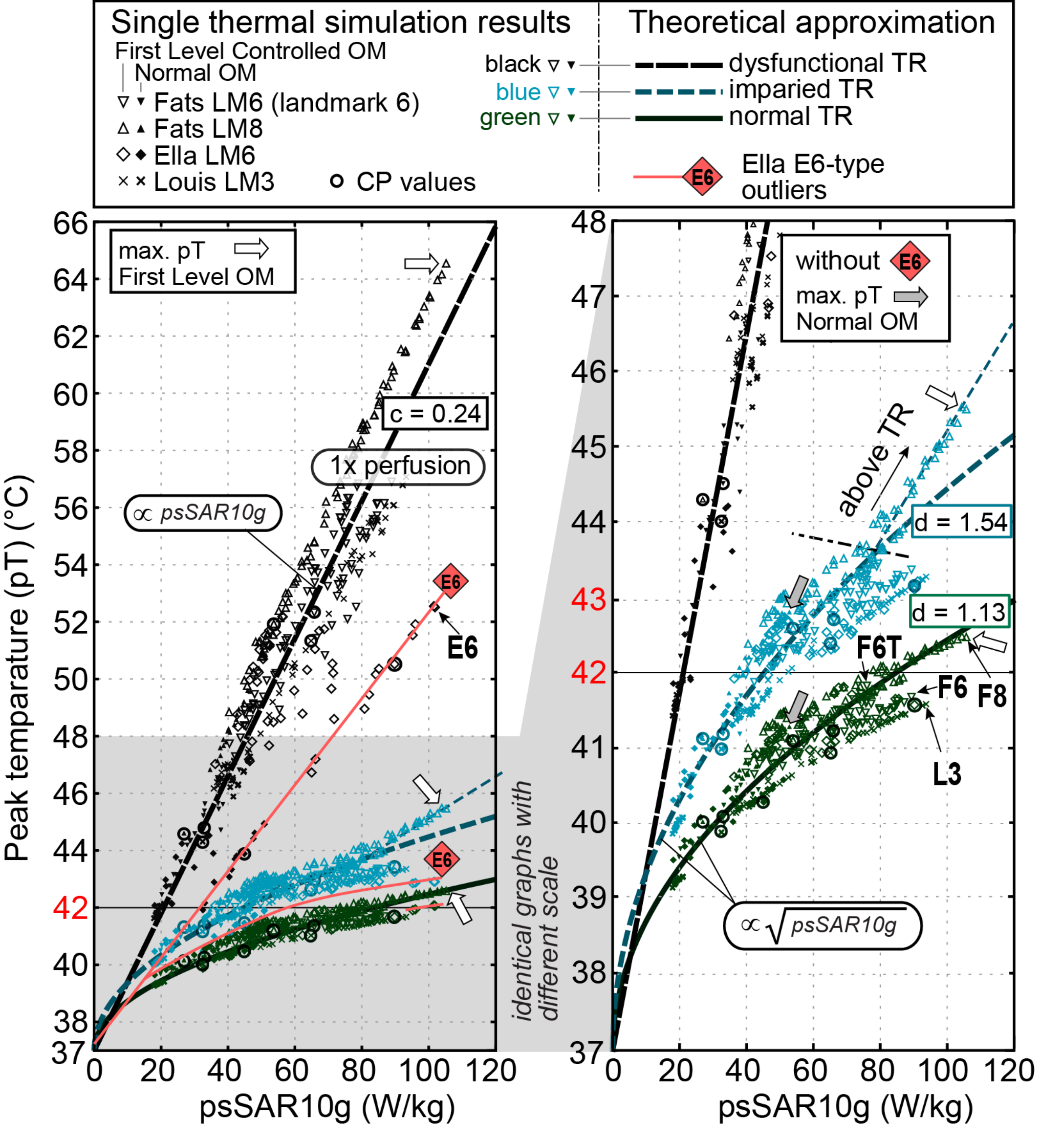
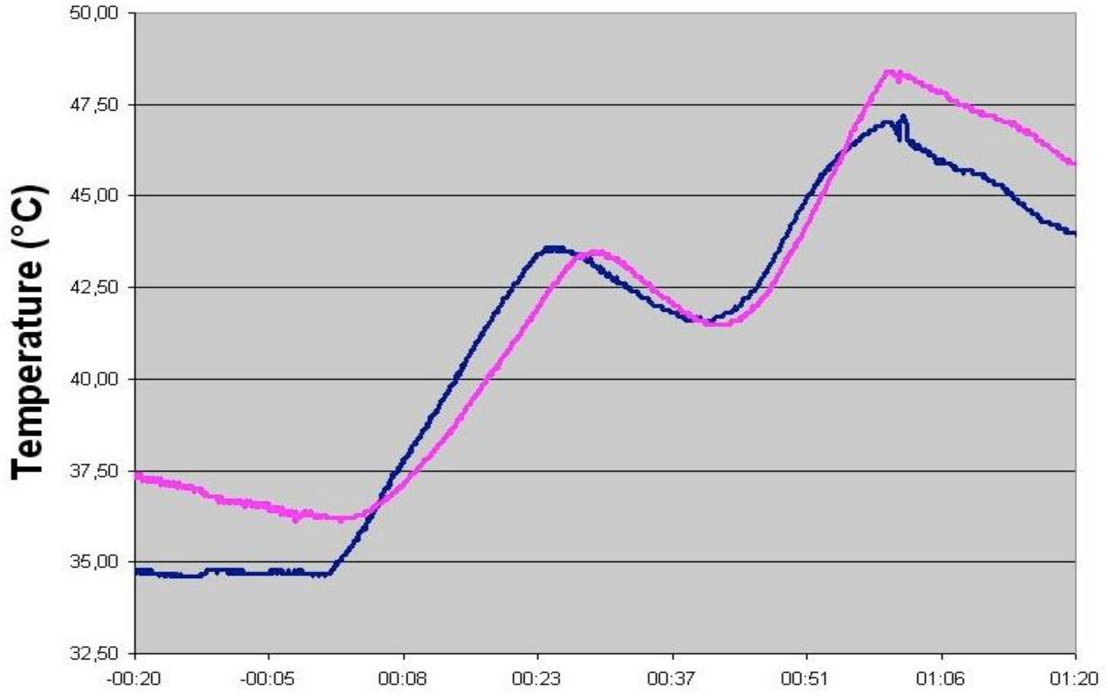
Local Temperature (3T)

- data from 3T 2-port shimming
- 4 worst-case scenarios with Fats, Ella, and Louis, considering various RF shimming excitations
- good correlation with theoretical approximations published in [Neufeld 2015]

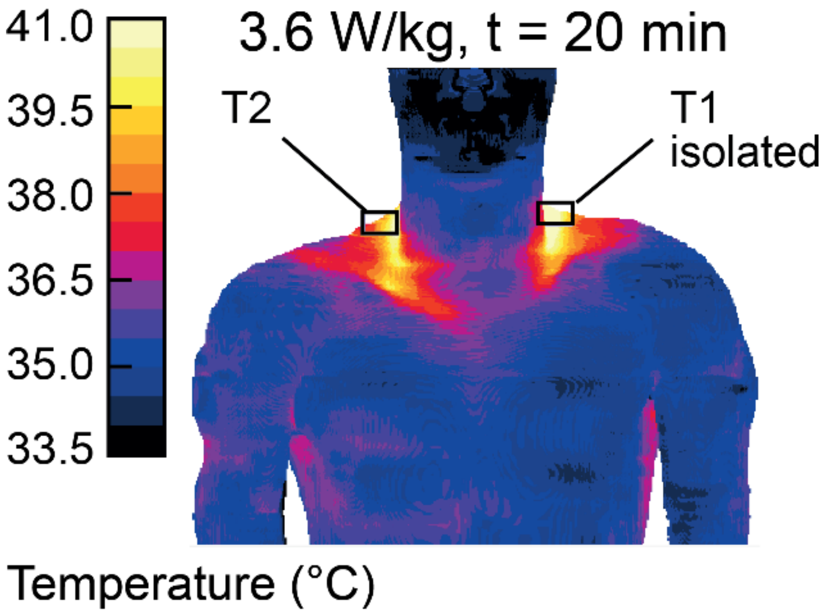


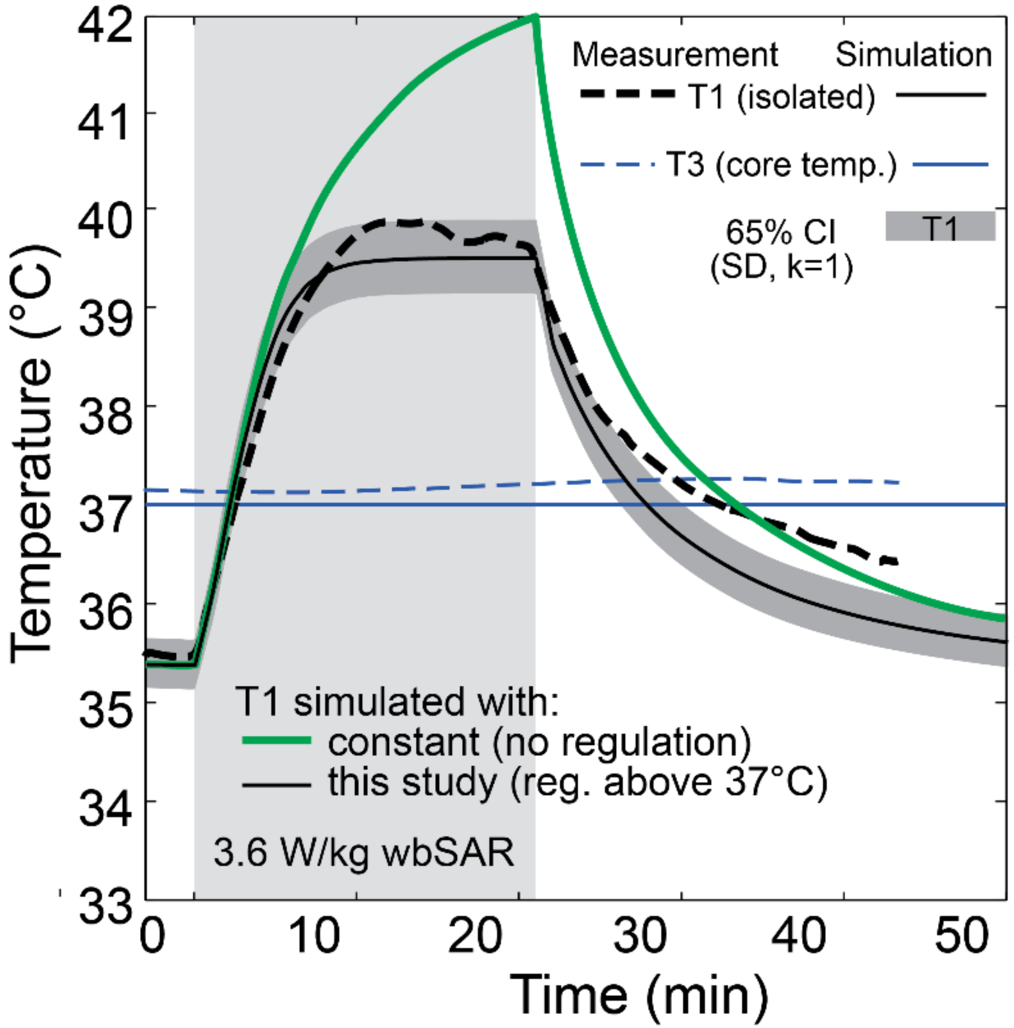
Reality Check: In Vivo (swine)

- data from MRI+ partners Charité/Siemens
  - Evaluation of #24, wbSAR=4 W/kg, t_expo=60 min
    - NOTE: this exposure level is allowed for human exposure



Local Temperature Validation in Human





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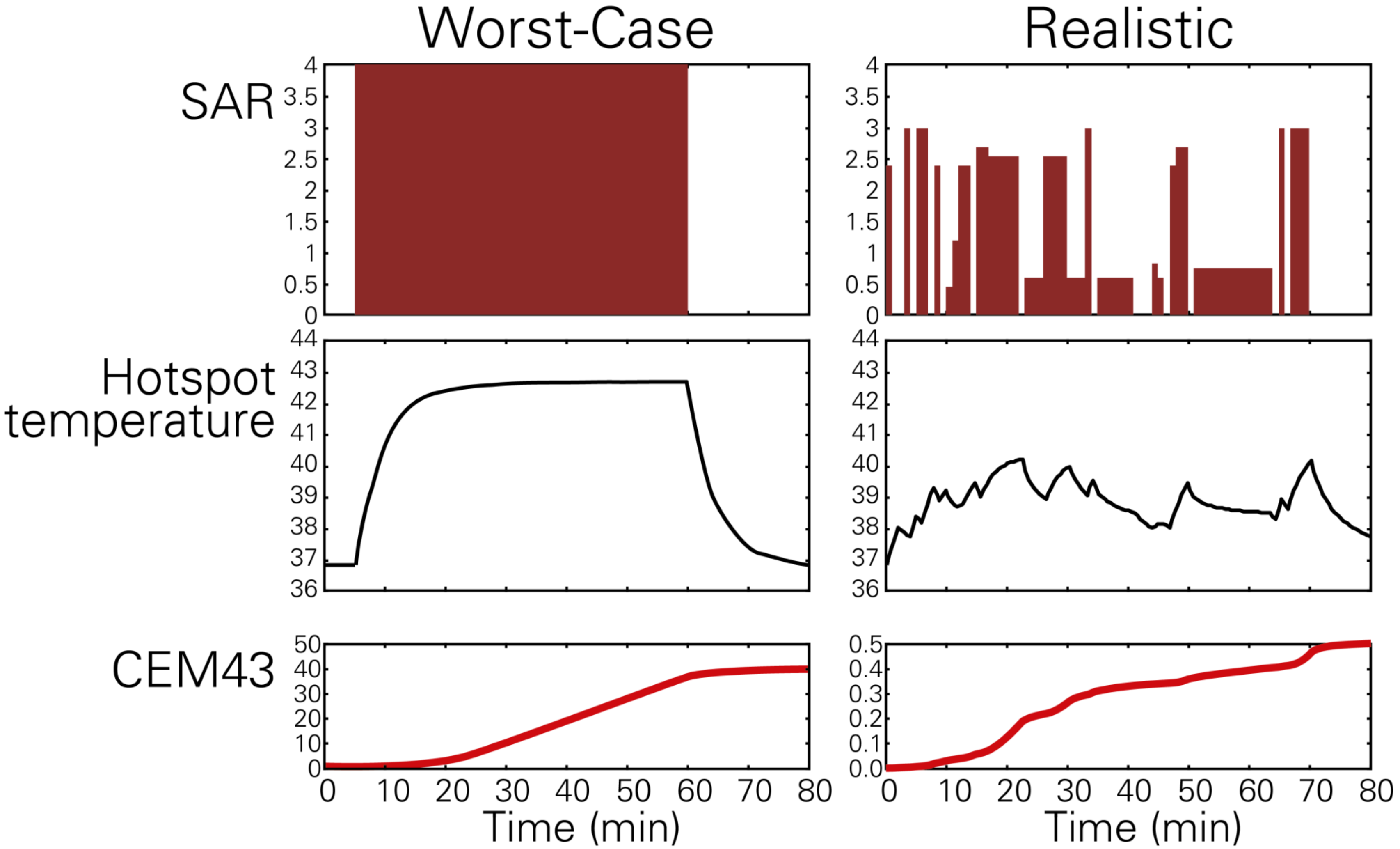
Thermal Dose Accumulation

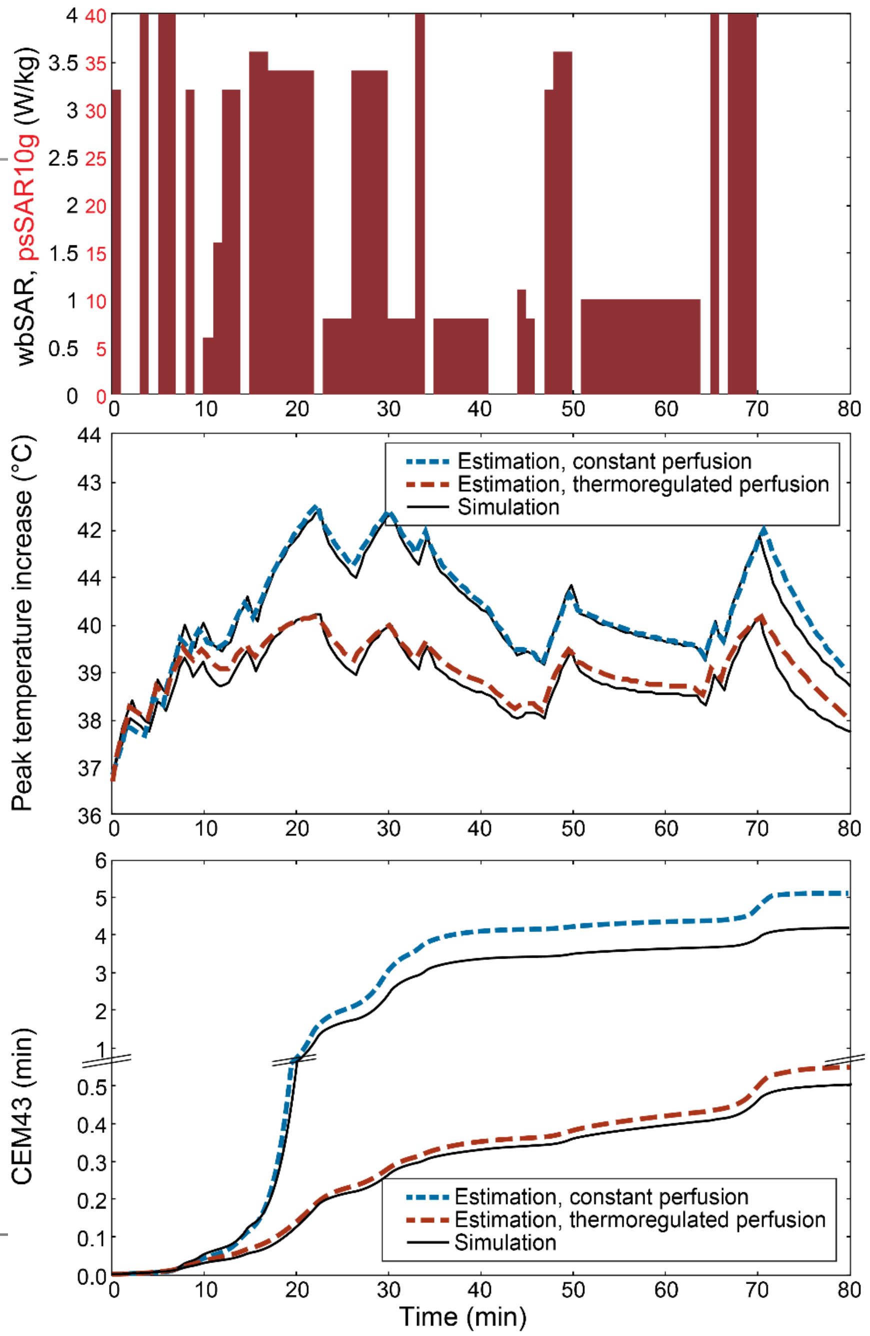


$$\mathrm{CEM43} = \int_{0}^{t_{duration}} R^{T(t)-43}\,dt$$

Rapid Method for Dose Estimation

- Neufeld E, Fuetterer M, Murbach M, Kuster N. Rapid method for thermal dose-based safety supervision during MR scans. Bioelectromagnetics 2015 10.1002/bem.21919 (early view)

- exponential approximations of temperature, based on SAR
- peak temperature and time constant derived from simulations
- model can include local thermoregulation
- good agreement between model prediction and full simulation results



Conclusions

- enforcement of ICNIRP localized SAR limits would be too conservative
- strict enforcement of the current temperature limits (39°/40°) may be very restrictive and overly conservative regarding the history of safe use
- risk-benefit analysis and the well controlled environment (exposure/environment) justify a more progressive safety concept
- governing limitations should be based on thermal dose (CEM43) rather than temperature or local SAR

Consequences for MR Safety Standard IEC 60601-2-33

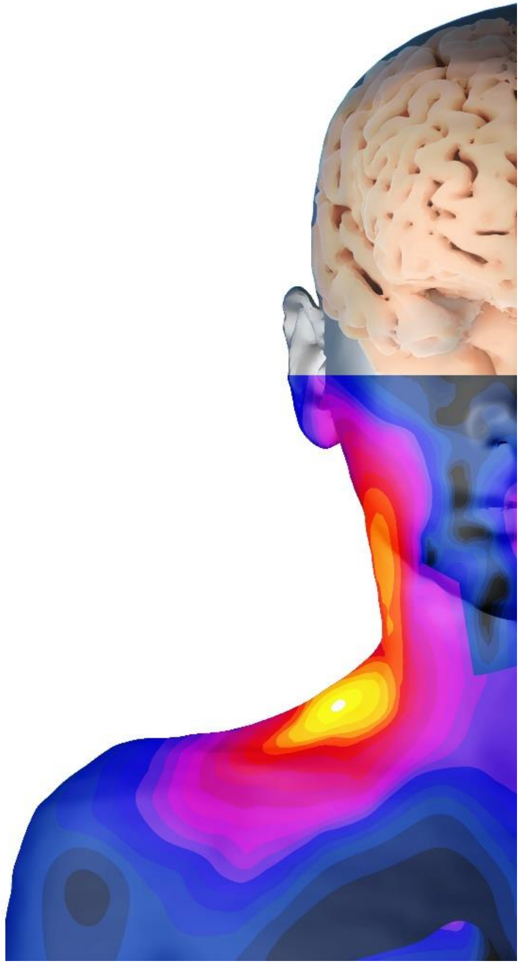
- thermal dose considerations are more appropriate than current limits
- thermal dose considerations may provide improved rationales for current/future exposure safety management
- proposed multi-tier approach:
  - **TIER1: Conservative SAR considerations**
  - **TIER2: SAR-based conservative thermal dose (CEM43) estimation**
  - **TIER3: Modeling of the thermal response of the patient**
    considerable progress in recent years. However, workflow for patient-specific estimates is not yet ready
- find agreement on safe thermal dose limits (e.g. CEM43 = 2min)

Open Questions

- reset time of CEM43
  - when can we start again with CEM43=0, after X hours?
    - 3 hours [Yarmolenko], safety margin?
- large low- or non-perfused regions (pathological, temporary constrictions)
- highly localized hotspots, e.g. RF loops
- conservativeness, how and where apply appropriate safety margins
- patients in anesthesia (no patient feedback)
- medication potentially compromising thermoregulation
- thermal hysteresis, thermal memories, resilience

Thank You

Manuel Murbach



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