MRI Safety – 7 T and Beyond

Andrew J Fagan Ph.D.
Professor of Medical Physics
Department of Radiology
Mayo Clinic,
Rochester MN

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Overview

1. Ultra High Field MRI – current state-of-play
2. Safety concerns relating to B_0 and Gradients
3. Safety concerns relating to RF @ ≥ 300 MHz
4. Scanning of implanted medical devices
5. Ensuring Safety - logistics & practicalities

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1. Ultra High Field MRI – current state-of-play

- Early UHF systems
  - 8 T installed in 1998 (Ohio State university)
  - 7 T installed ~ 2000 (CMRR, Univ. Minnesota)
- Current install base (UHF human scanners currently at field):
  - ~ 75 x 7 T (approx. 20-30% performing some degree of clinical scanning)
  - ~ 5 x 9.4 T
  - 10.5 T (Uni. Minnesota)
- Roadmap for UHF MRI scanners:
  - FDA 2003 [1] - MRI up to 8 T constitutes a non-significant risk for adults, children and infants > 1 month
  - ICNIRP 2009 [2] - no serious health effects from exposure to static magnetic fields up to 8 T
  - IEC 2015 [3] (60601-2-33) - increased the first-level controlled operating mode for the static magnetic field to 8 T

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1. Ultra High Field MRI – current state-of-play

- 7 T Regulatory status
  - Clinical diagnostic scanning - Siemens Magnetom Terra
  - CE Labelling - Aug 23, 2017
  - FDA 510(k) clearance - Oct 12, 2017
  - Head & knee imaging
  - For patients ≥ 30 kg

Courtesy: Siemens Medical Systems

7T Terra, Mayo Clinic, Rochester MN

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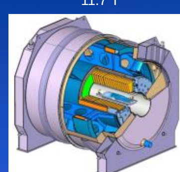
1. Ultra High Field MRI – current state-of-play

- > 8 T – U.S. FDA Investigational Device Exemption (IDE) required
  → granted already for 9.4 and 10.5 T systems

10.5 T

https://research.umn.edu/inquiry/post/u-scientists-scan-worlds-first-105-tesla-human-mri-image

11.7 T



http://www.makery.info/en/2017/07/11/un-irm-geant-pour-explorer-la-face-cachee-du-cerveau/

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2. Safety concerns relating to B_0 and Gradients

- Forces (translational, torque) on objects

material / force	paramagnetic and unsaturated ferromagnetic	saturated ferromagnetic
translational	$F_{trans} \propto B_0 \lvert\nabla B_0\rvert$	$F_{trans} \propto B_S \lvert\nabla B_0\rvert$
torque	$F_{torque} \propto B_0$	F_{torque} insensitive to B_0

B_S – saturation flux densities (typically < ~ 2.5 T)

- Torque
  - complex function of magnetic properties, geometry, mass distribution, B_0
  - inversely proportional to length – hence, most concern for short, elongated objects

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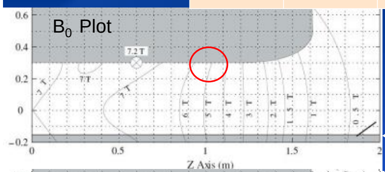
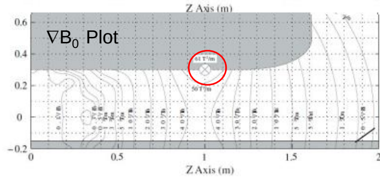
2. B_0 & Gradients

	max $\|\nabla B_0\|$	max B_0	max $B_0 \|\nabla B_0\|$
Shielded 7 T	12.2	7.2	87.8
3 T [4]	19	3.7	62.9
1.5 T [4]	17	2.4	45.6

[4] Woods et al, J Testing Eval, ASTM International, 2019



patient table



Shielded 7 T magnet

patient table

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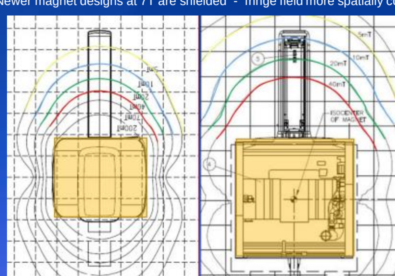
2. B_0 & Gradients

- Many UHF scanner magnets are unshielded
  - → potentially lower spatial gradients
  - → but extended fringe field
- Newer magnet designs at 7T are shielded - fringe field more spatially contained



3 T 7 T

Implications for scanner siting, magnetic field shielding, safety protocols, etc.

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2. B_0 & Gradients

Bioeffects - exposure to static B_0 and movement through spatial gradients

- Differentiate between long-term and transitory effects
- Potential long-term effects - DNA damage [5]
  - inconsistent / conflicting data in literature
  - Potential source (if even present) not clear
    - RF quantum energy at 7T is 10,000 times smaller than Boltzmann thermal energy
    - ? Disruption of DNA repair mechanisms due to low-frequency EM fields in MRI?
  - Long history of safe use of MRI (including ~ 55,000 scans at 7 T)
  - Likely to be significantly smaller than for ionizing radiation (2017 ICNIRP statement [6])

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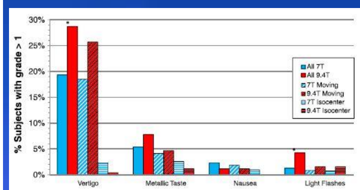
2. B_0 & Gradients

Potential Transitory effects - all exacerbated at UHF

- dizziness, nystagmus, vertigo, feeling of 'moving on a curve'
  - Can result in nausea in extreme cases
  - Lorentz force on charged ionic fluid flow in inner ear
- magnetophosphenes
- metallic taste



Actively-shielded 7T [16]

- dizziness 84% (n=130)
- moving on curve 70% (n=108)
- headache 52% (n=81)
- Metallic taste 43% (n=81)
- Nausea 51% (n=66)

[7] Rauschenberg et al 2014

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2. B_0 & Gradients

Potential Transitory effects - all exacerbated at UHF

- Cognitive effects [8,9]
  - conflicting data in literature
  - possible that any effect present may be due to disturbance of the vestibular system [10,11]
- ECG waveform distortion
  - magnetohydynamic effect, significantly elevated T-wave
  - issue for cardiac gating
- Physiological effects [12,13], e.g. heart rate, blood pressure
  - Modelling of magnetohydynamic equations suggest < 0.2% change in blood pressure in human vasculature at 10 T [14]
  - No effects in animal models measured up to 10.5 T [15]
- Most studies report subjects willing to undergo further UHF scan (> 90% [16])
- May be more relevant for occupational exposure of staff
  - e.g. workers performing maintenance or cleaning in the bore
  - advice to avoid activities such as driving immediately afterwards….

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2. B_0 & Gradients

- 10.5 T (CMRR, Uni Minnesota)
  - To determine effects of 10.5T exposure on human volunteers with respect to physiologic parameters, the vestibular system and cognition
  - Some very minor effects reported to date [17]
    - O_2 saturation, nystagmus, blood pressure, cognitive executive functioning
    - biological significance under investigation
  - Most pronounced effect compared to lower fields - Increases in metallic taste in mouth

- Dental amalgam 2018 study
  - reported increase of mercury from ex vivo samples after 7T scanning [18]
  - Several methodological issues unclear
  - Reproduction of experiment required

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2. B_0 & Gradients

Switching gradient fields

- Similar amplitudes and slew rates to 3T scanners
  - 80 mT/m
  - 200 T/m/s
  - No increase in risk of cardiac ventricular fibrillation
  - Recent study reported higher incidence of PNS on one actively-shielded 7T scanner
    - 67% of subjects reported PNS (n = 103) [16]
    - corroboration required on other scanner designs, image scan protocols, etc.
- Acoustic noise
  - Not appreciably higher at 7T than 3T scanners
  - Head coil is narrower – fitting headphones is an issue

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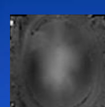
3. Safety concerns relating to RF @ ≥ 300 MHz

- Higher RF frequency → increased power absorption in tissue
- RF wavelength is short relative to body dimensions
  - e.g. at 7T for ^{1}H, 300 MHz, λ fat is 40 cm, liquids 10 cm
  - Result
    - RF interference effects, highly dependent on Tx coil configuration, tissue composition, etc.
    - RF Tx field is very inhomogeneous – birdcage designs obsolete for anything larger than head
- Regional peaks in local SAR may occur
- No longer operating in the quasi-static electromagnetic regime
  - 1.5T, 3T - magnetostatic approximation is useful (Biot-Savart law etc)
  - > 3T - electromagnetic regime, full set of Maxwell's equations need to be solved
  - RF simulations are essential for SAR prediction & RF coil design

$$\lambda = \frac{c_0}{f_0\sqrt{\mu_r \varepsilon_r}}$$



B_1 map @ 7T

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3. RF @ ≥ 300 MHz

- Quasi-static estimates predict SAR will increase with B_0^2
  → electromagnetic regime – not expected to follow this exact trend
- Regulatory limits are nonetheless the same (IEC 2015)
- However, the lack of 'volume' RF coils at UHF means we must consider Local SAR for safety assessments and RF monitoring

	Operating mode		
	Normal	1st Level Controlled	2nd Level controlled
Global SAR [W/kg]			
Whole body	2	4	> 4
Partial body	2-10	4-10	> 4-10
Head	3.2	3.2	> 3.2
Local SAR [W/kg]			
Trunk	10	20	> 20
Limbs	20	40	> 40

averaged over 6 minutes

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Local SAR [W/kg]			
Trunk	**10**	**20**	**> 20**
Limbs	**20**	**40**	**> 40**

averaged over 6 minutes

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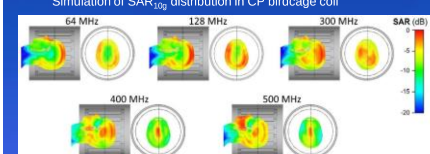
3. RF @ ≥ 300 MHz

- Global SAR – can be determined directly from absorbed power in the exposed body region
  - measurement of the [forward – backward] RF power into the Tx coil
- Local SAR - more difficult to assess and monitor
  - requires SAR simulations which solve full Maxwell equations in realistic anthropomorphic virtual human models

Simulation of SAR_{10g} distribution in CP birdcage coil



SAR_{10g} distribution, normalized to individual max

[20] Felder, et al Neurolm, 2017

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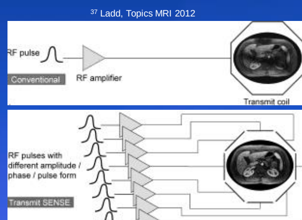
3. RF @ ≥ 300 MHz

- Parallel Tx coils becoming ubiquitous at UHF
  - Useful for B_1^+ homogeneity and RF power reduction
  - Independently vary phase and amplitude of waveforms applied to each Tx channel
  - Results in very complex local SAR patterns
    - → potential for SAR hotspots, which furthermore can vary during application of the RF pulse

[37] Ladd, Topics MRI 2012



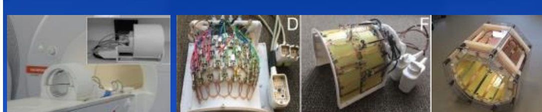
- SAR_{10g}
  - can be scaled to any B_1 shim using Q-matrices formulism and compressed 'Virtual Observation Points' for quick estimation of SAR_{10g}
  - validation required

4. Scanning of implanted medical devices

- Current lack of widespread experience with scanning metallic implants at UHF
  - Many research sites exclude everything
- Decision to scan
  - Information from manufacturers
  - Data in scientific literature
  - prior experience
  - risk-benefit analysis
- Very few devices certified 7T MR Conditional by OEMs
  - www.glaukos.com
  - www.gracemedical.com
  - www.kurzmed.com
    - } small (< 10 mm) middle ear implants
  - www.novatech.fr } tracheal support implant – 35 mm
- Low numbers of UHF scanners
  - low incentive for OEMs to certify devices
  - no integrated RF Tx body coil – makes standardization difficult

4. Implant scanning

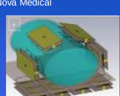
- Several studies in literature - safety testing of devices
  - Limitations - results only applicable to the specific experimental set-up
    - RF coils used – different design concepts with different RF distributions
    - RF Tx method



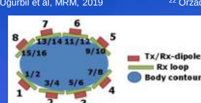
1 Tx BC / 32 Rx
Nova Medical

16 Tx / 64 Rx
[21] Ugurbil et al, MRM, 2019

8 Tx meander
[22] Orzada et al, ISMRM, 2009



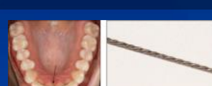
8 Tx meander / 32 Rx loop
[23] Rietsch et al, MedPhys 2018

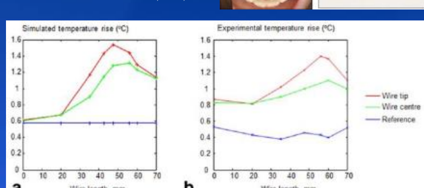


8 Tx fract dipole / 16 Rx loop
[24] Steensma et al, MAGMA 2018

4. Implant scanning

[25] Wezel et al, MRM, 2014

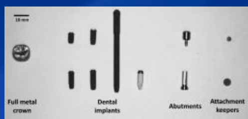




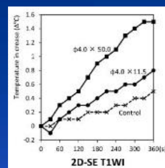
Max heating occurred for wires of 47 mm in length (~ ⅓ - ½ of λ)

→ max 1.5°C rise at 5 x global SAR limit , i.e. at 5 x [3.2 W/kg]

4. Implant scanning



- Implants 7 to 13 mm long - < 0.8 °C
- Implants 50 mm long - 1.5 °C



[26] Oriso et al, MRMSci 2016

[27] Nourredine et al 2015

- retainers, braces, bridges, crowns and pivot teeth (n = 93)
    - small relative to the RF wavelength
- Essen group – reported (Mar 2019)
    - 105 retainers
    - 76 bridges, crowns
    - 86 other dental implants

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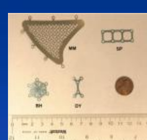
4. Implant scanning

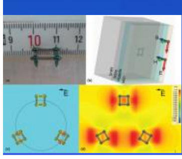
Cranial Fixation Devices

- [27] Sammet et al MRI 2013
- Max temperature increase < 1 °C



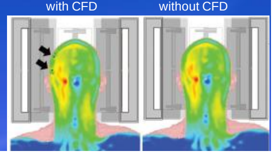
[27] Kraff et al, MedPhys 2013

- Position of max SAR_{1g} did not change



SAR_{10g}
red = 0.49 W/kg
yellow ~ 0.37 W/kg

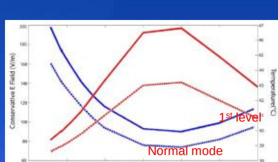
with CFD   without CFD



4. Implant scanning

Aneurysm clips

- [30] Noureddine et al 2018 MRM



- Clips < 18.8 mm can be scanned with no limitations
- Longer clips may require reduced SAR sequences

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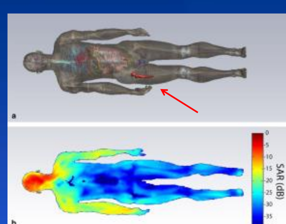
4. Implant scanning

- Orthopedic devices [27, 31, 32]
  - Screws, nails, rods, plates, knee and hip prostheses
- Stents [27, 31, 33, 34]
- Inter-uterine devices [27]

4. Implant scanning

Implants <u>within</u> versus <u>outside</u> the Tx coil

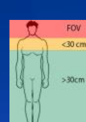
- Simulation of subject with hip implant
- Custom head coil
- SAR levels at implant
  - < 100 times lower than in head
- Caveat
  - travelling wave phenomena at UHF (e.g. > ~ 300 MHz)

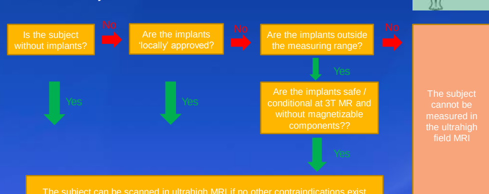


[27] Noureddine et al, MAGMA, 2015

4. Implant scanning

- German Ultrahigh Field Imaging (GUFI) network
  - published recommendations for potential inclusion of people with certain passive implants [34]
  - a potentially 'safe' distance of > 30 cm from the RF Tx coil is used in some centers
  - case-by-case decision





4. Implant scanning

Future directions

- Limit on some measure of thermal dose → likelihood of tissue damage
- Pre-calculated temperature VOPs
  - Additional parameters increases the complexity of thermal simulations
    - e.g. thermal tissue properties (conductivity, specific heat), metabolism, blood perfusion, heat transfer coefficient at body surface
  - Better thermoregulation / blood perfusion models required
  - Verification of numerical results difficult
    - insensitivity of current MR Thermometry techniques
    - thermo-regulation - differences *in vivo* versus simulation
- Many studies focus on RF heating only
  - Further studies required to assess other safety aspects
  - Useful e.g. when considering implants outside the RF Tx field

4. Implant scanning

In Practice

- Many small objects can be scanned routinely
  - Dental implants < 30 mm
    - consider lower SAR protocols for longer objects (for brain imaging)
  - Orthopedic implants located far from Tx field
    - If ferrous-free
    - Hip/knee replacements
    - Screws, rods, spinal fusion plates
  - Cranial fixation plates
    - < 30 mm long
    - > 40 mm separation
- Other objects considered on case-by-case basis
  - Stents, clips, IUDs, objects within/close to Tx field

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5. Ensuring Safety - logistics & practicalities

- UHF Safety Committee
  - Develop / review policies & procedures to adhere to local regulation and best practice
  - Perform risk-benefit analyses as required
- Significant pre-screening of patients required
  - to identify patients/subjects suitable for 7T imaging
    - certain indications only
    - patients > 30 kg - due to lack of suitable anatomical models for small children
  - to assess any implants and weed-out contraindicated devices
    - implant model number, location in body, proximity to other devices or thermosensitive tissue, date of implantation
    - consider taking planar X-rays if no prior imaging is available
    - MR Conditionality at 3T
    - prior study at 7T

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5. Logistics & Practicalities

- Technologist training
  - Core group of "7T MR Technologists" who operate the scanner
  - Many items scanned without a second thought at 3T may be contraindicated at UHF
  - Patient / Subject handling
    - use of dielectric pads
    - post-scan dizziness
  - RF coil handling - positioning important
  - Input accurate patient height & weight
  - Fever / thermoregulatory compromise
  - Magnet room environmental conditions (temperature, humidity)
  - SAR limitations & scan parameter changes

Dielectric pad placement in 7T knee coil

- Radiologist training
  - different image contrast
  - some new / altered image artifacts

Summary

- UHF MRI
  - significant step-change in MR technology
  - already in clinical arena (at 7 T)
- Higher B_0
  - increased forces on para- and ferro-magnetic objects
  - potential for increased long-term & transient physiological effects
- RF – higher f_0 and shorter λ
  - potential for SAR hotspots
  - shorter resonant lengths near metallic implants
- Rapidly evolving field
  - new RF coil design concepts, Tx modes
- Further research
  - implant safety studies – simulations, with physical phantom verification
- ISMRM Working Group
  - White Paper – "7T MRI Safety"
  - due Q4 2019

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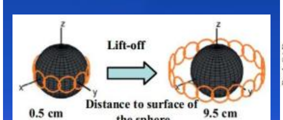
Thank you!

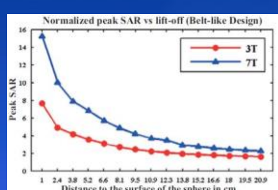
Fagan.Andrew@mayo.edu

ADDITIONAL SLIDES

3. RF @ ≥ 300 MHz

- Lack of 'body' RF coils at UHF
- Local Tx coils
  - produce strong E fields close to the coil conductors
  - can lead to very high local power absorption even though global SAR remains small

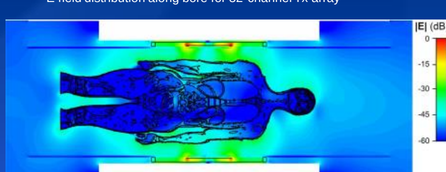




[19] Deniz et al MRM 2016

3. RF @ ≥ 300 MHz

E field distribution along bore for 32-channel Tx array



[38] Orzada et al, Proc ISMRM, 2016

Wave propagation effects at UHF
- Wavelength small relative to bore
  → bore acts as a waveguide for the RF
- Consider wider boundary conditions for simulations

4. Implant scanning

Implants within the RF Tx field

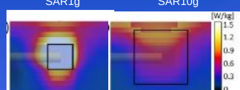
- WB-averaged SAR underestimates risk
  - SAR_{10g} preferred method of predicting temperature increase near metallic implant
  - Supervised on UHF scanners
- However, doubt over whether 10g (or even 1g) of tissue gives sufficient spatial resolution to detect hot-spots near implants
  - particularly when object has narrow geometrical feature

3T simulation

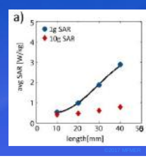
SAR_{10g} exceeded 50 W/kg, despite SAR_{wb} < 2 W/kg

[36] Powell et al, 2012, MRM

SAR1g SAR10g



[37] Winter et al, 2015, MRM



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