Human Subjects in fMRI Research
Outline

- **fMRI Risks to Human Subjects**
  - Static B0 fields
  - RF B1 fields - tissue heating
  - Switched gradient fields - peripheral nerve stimulation
  - Acoustic Noise

- **Practicing Safe Imaging - minimize risks**

- **Minimizing Distress in the MR Environment**

- **Ethical Conduct of fMRI Research involving Human Subjects**
Static $B_0$ Fields

- No established adverse health effects
- Projectile accidents
- Metallic object screening
- Magnetohydrodynamic effects
Static $B_0$ fields- Projectile Accidents

Photo removed for copyright reasons.
Wheeled cart pulled into MRI machine.
45 y.o. male 2+ years s/p altercation

Courtesy of Alma Gregory Sorensen. Used with permission.
Ohmic heating of patient tissue is due to resistive losses from induced electric fields

Greatest effect at periphery or surface

Described in terms of Specific Absorption Rate (SAR)

Scanner determinants: RF frequency, type of RF pulse, TR and type of RF coil

Body determinants: thermoregulatory function

Electrical Burns
Switched Gradient Fields

- Peripheral Nerve Stimulation
- Metallic Taste
- Magnetophosphenes
- Skeletal Muscle Contractions

- By Faraday’s Law of Induction exposure of conductive tissue to time-varying magnetic fields will induce an electric field.
Peripheral Nerve Stimulation

B

$B_{\text{max}}$

B

Z

$z_0$

$F_{\text{OV}}_s$

$F_{\text{OV}}_l$

Z - gradient

9 / Gradient-tutorial.ppt
F. Schmitt, MGH
Stimulation Aspects(I)

- Stimulation thresholds vary
  - linearly with rise time
  - ramp shape
  - fct (#pulses)
**Faster & Stronger Gradients**

- “shorten” the gradient coil typically results in:
  - higher stimulation thresholds, when expressed in mT/m
  - lower inductance, i.e., higher SR, $G_{\text{max}}$
  - but more geometric image distortions

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Courtesy of Franz Schmidt. Used with permission.
Why does EPI make so MUCH noise?

Strong, Static Magnetic Field

Current pulse to create gradient fields

Together, these produce mechanical forces on the coils that create the gradient fields; so the coils move.

The result is acoustic noise.
Acoustic Noise .. and how to avoid?

- **passive damping**
  - acoustic insulation
  - more mass & stiffer
  - ~ 10 - 15 dB

- **encapsulation & vacuum**
  - cooling
  - MRI system becomes longer
  - ~ 20 - 30 dB

- **“active” damping**
  - avoid mechanical / acoustical resonance
  - ~ 20 dB

- do not allow that sequence peak coincides with acoustic modes
- change TR, echo spacing, ...
Current FDA Criteria for Non-significant Risk

- Field strength < 4T
- SAR < 3 W/kg averaged over 10 minutes in head
- SAR < 8 W/Kg in any 1 cc of tissue in head averaged over 5 minutes
- Acoustic Noise <140 dB peak and 99 dB average with ear protection
- No painful or severe peripheral nerve stimulation
Subjective Distress in the MRI Environment

- Incidence of distress among clinical MRI is high
- Distress can be caused by many factors including: confined space, noise, restriction of movement
- Distress can range from mild anxiety to full blown panic attack
- Distress can result in subject motion and disrupt image quality
Minimizing Subjective Distress

- Careful screening
- Complete explanations
- Make them comfortable in the scanner
- Maintain verbal contact
- Give them the panic button
Safety is Your Responsibility

- Become familiar with the material posted on your institution’s Human Subjects web site

- Read
  - Belmont Report
  - Title 45 Code of Federal Regulations Part 46 Protection of Human Subject

- Review NIH presentation from the Office of Human Research Protection
Human Subject Considerations

- Informed Consent
- Risk/Benefit Considerations