fMRI 研究之儀器使用安全 & 相關倫理議題

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Jan 29, 2018 @ NCKU_REC

Outline

1. MRI 介紹
2. MRI 儀器使用安全
   1) To 受試者：fMRI 實驗沒有你想像中那樣可怕！
   2) To 實驗者：如果不小心，後果很嚴重！
   3) fMRI 實驗注意事項
   4) fMRI 緊急狀況應變
   5) MRI 中心（放射師，技術組）對研究者的建議
3. fMRI 相關倫理議題
   1) 研究參與者角度
   2) 研究結果的角度

1. An fMRI video

From http://www.sciencefriday.com/video/05/02/2008/read-my-brain.html

2. MRI 儀器使用安全

1) To 受試者：fMRI 實驗沒有你想像中那樣可怕！
   - Why I say so?
     - A lot of difficulty in recruiting subjects (even in campus, and especially in southern Taiwan)
     - Even students, RAs, and PIs, sometimes resist, too.
   - But..
     - A lot of publications mean a lot of subjects
     - From newborns to 90 yrs olds; from born-blind to vegetative state patients…
     - Magnetism is not X-ray (though always combined in radiology department）
     - Almost all fMRI practitioners are constantly being scanned…

Lists of criteria to exclude subjects…

請回答下列問題.

是否曾接受磁振照影檢查(MRI)？	是 / 否
如果是，在檢查過程中有沒有經歷任何問題？	
是否接受過任何手術？	是 / 否
如果有，請說明。	
是否曾經因金屬物品或外來異物而受傷(例如：砲彈碎片、子彈)？	是 / 否
如果有，該金屬異物是否已經移除？請說明。	

是否曾從事與金屬有關的行業(例如：焊接、刨磨)	是 / 否
如果有，是否都有戴護目鏡？	是 / 否
是否曾被告知有金屬異物進入眼睛，會對你的安全有潛在的威脅？	是 / 否
你是否確定自己沒有處在危險的情況？	是 / 否
是否有"已經懷孕"的可能性	是 / 否
如果有，最近一次生理期(MC)是什麼時候？	/ /
最近是否曾感到頭昏、失去平衡或失去意識？	是 / 否
是否有鼻竇炎或鼻腔的問題？	是 / 否
是否有幽閉空間恐懼症？	是 / 否
是否有任何呼吸問題或行動異常？	是 / 否

請回答身體上或體內是否有任何下列情形.

動脈支架	是 / 否
心率調整器	是 / 否
殖入心內除顫器(ICD)	是 / 否
任何電子植入器	是 / 否
任何核磁性活化的植入器	是 / 否
神經電刺激系統	是 / 否
脊椎神經刺激器	是 / 否
體內電極或電線	是 / 否
骨骼成長或骨融合刺激器	是 / 否
耳蝸、助聽器或其他耳部植入器	是 / 否
胰島素或其它輸液幫浦器	是 / 否
植入式藥物導入幫浦	是 / 否
任何類型的修補手術(義眼、人工陰莖、...等)	是 / 否
心臟瓣膜修補手術	是 / 否
眼瞼手術用線圈	是 / 否
人工義肢	是 / 否
金屬製過濾調節器或金屬線圈	是 / 否
心室或脊椎內引流管	是 / 否
裝置人工血管或導管	是 / 否
放射性植入器	是 / 否

肺動脈導管或熱稀釋導管	是 / 否
使用戒煙、心血管、避孕的藥物貼片(尼古丁、耐絞寧...等)	是 / 否
體內有任何金屬性外物	是 / 否
鋼絲或網狀植入器	是 / 否
體內組織擴張器 (例如, 在胸腔)	
手術用固定器、夾或金屬物	
關節重置術(髖關節、膝蓋等...)	
骨/關節的固定針、螺絲、釘子、線、板...等	
各式子宮、輸卵管避孕器	
矯正器或假牙托	
腹部以上的紋身或持久性的化妝	
身上戴珠寶飾品	
助聽器	
身上有其他植入器(請作說明)	
有色隱形眼鏡	
假髮/植髮	
動脈瘤	是 / 否
癲癇	是 / 否
其他神經疾病或異常(例如：中風、帕金森氏症)	是 / 否
重度與進行性聽力損傷	是 / 否
梅尼爾氏症	是 / 否
聽力損傷/耳鳴	是 / 否

請問您對於參與實驗和其安全性是否有任何疑問？

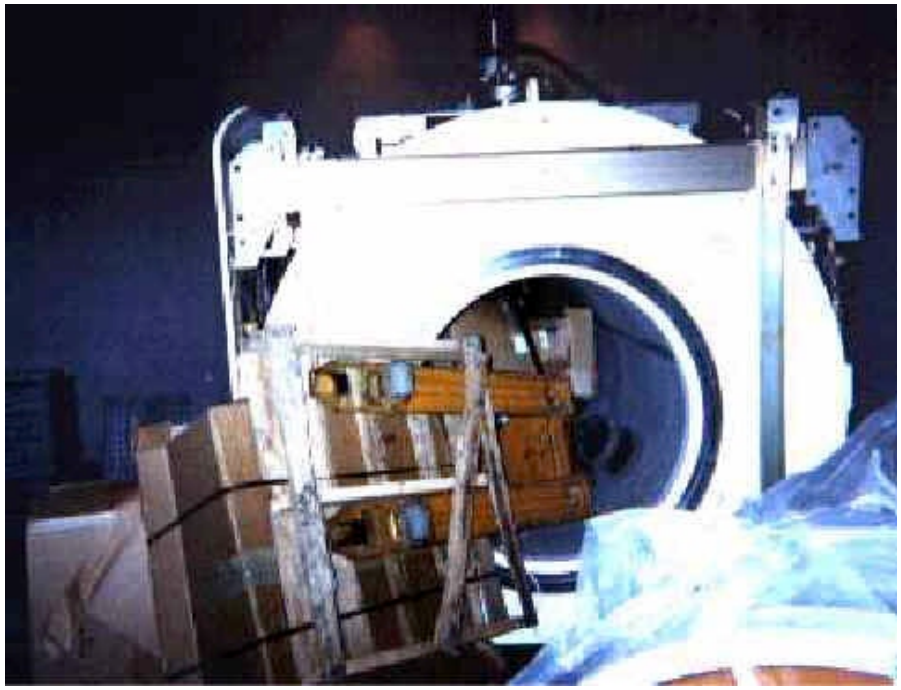
請您務必完成卸妝和脫下身上金屬性物件
(例如，女性胸罩、珠寶、耳環飾品...等)

年長受試參與者的牙套(或金屬填充)，需要PI簽名

2) To 實驗者：如果不小心，後果很嚴重

http://www.fmri4newbies.com/s/Psych9223_F2017_1D_MR-Safety.pptx

Magnet Safety: Big Things



Source: www.howstuffworks.com

Source: http://www.simplyphysics.com/flying_objects.html

"Large ferromagnetic objects that were reported as having been drawn into the MR equipment include a defibrillator, a wheelchair, a respirator, ankle weights, an IV pole, a tool box, sand bags containing metal filings, a vacuum cleaner, and mop buckets."

-Chaljub et al., (2001) *AJR*

Demo


Demonstration of the powerful magnetic field of a clinical 1.5 Tesla MR scanner
Part II - Oxygen bottle
by
G. Starck, B. Vikhoff-Baaz, K. Lagerstrand,
E. Forssell-Aronsson och S. Ekholm
SAHLGRENSKA
UNIVERSITY HOSPITAL
2004

Very Serious Risk

* MDR-175218:
A patient with an implanted cardiac pacemaker died during or shortly after an MR exam. The coroner determined that the death was due to the interruption of the pacemaker by the MR system. (9/18/89)

MDR-349790:
A patient with an implanted intracranial aneurysm clip died as a result of an attempt to scan her. The clip reportedly shifted when exposed to the magnetic field. The staff apparently had obtained information indicating that the material in this clip could be scanned safely. (11/11/92)

MDR-405200:
A pair of scissors was pulled out of a nurses hand as she entered the magnet room. The scissors hit a patient causing a cut on the patient's head. (8/2/93)

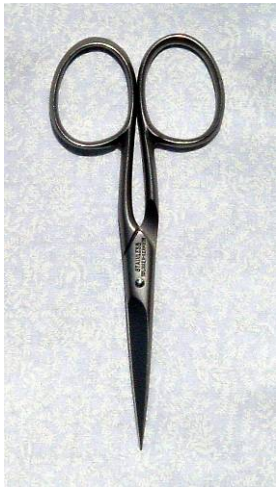
MDR-591457:
A child received a burn to the right hand from an ECG cable while the patient was anesthetized. A skin graft was required to treat the affected area. (1/26/95)

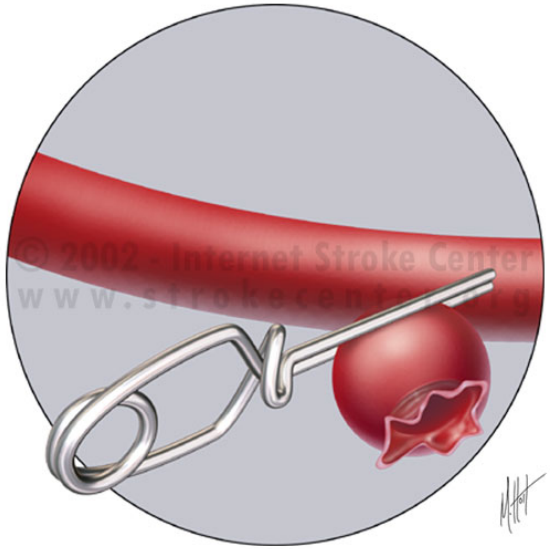
MDR-100222:
Dislodgement of an iron filing in a patient's eye during MR imaging resulted in vision loss in that eye. (1/8/85)

MDR-391667:
A patient received small blistered burns to the left thumb and left thigh. Reportedly, the operator input an inaccurate patient weight resulting in an incorrect SAR value. (2/10/93)

Source: http://www.fmrib.ox.ac.uk/%7Epeterj/safety_docs/fda_primer.html

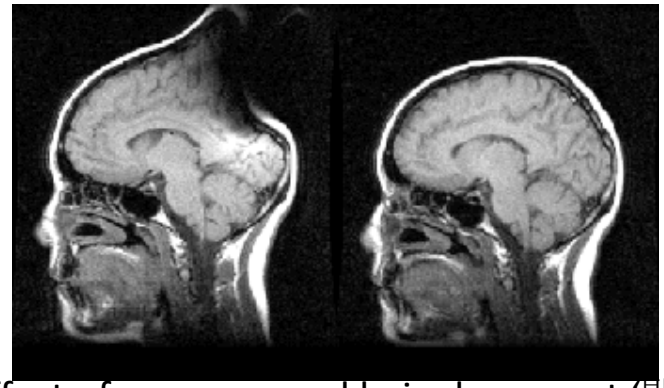
Magnet Safety: Little Things





Aneurysm clips can be pulled off vessels, leading to death

Flying things can kill people.
Even in less severe incidents, they can fly into the magnet and damage it or require an expensive shutdown.



Effect of a unremoved hair clamp, not '開頂'

NCKU MRI Safety Zone Ⅰ

1F 大門

Safety Zone Ⅱ

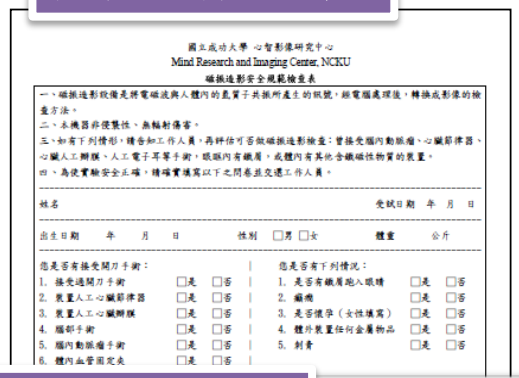
Safety Zone Ⅱ

- 研究小間:聽取實驗說明、填寫實驗同意書
- 更衣室
- 填寫磁振造影安全檢查表

研究小間

更衣室

安全檢查表


國立成功大學 心智影像研究中心
Mind Research and Imaging Center, NCKU
磁振造影安全規範檢查表

一、磁振造影設備是將電磁波與人體內的氫質子共振所產生的訊號，經電腦處理後，轉換成影像的檢查方法。
二、本機器非侵襲性、無輻射傷害。
三、如有下列情形，請告知工作人員，再評估可否做磁振造影檢查：曾接受腦內動脈瘤、心臟節律器、心臟人工瓣膜、人工電子耳等手術，眼眼內有鐵屑，或體內有其他含鐵磁性物質的裝置。
四、為使實驗安全正確，請確實填寫以下之問卷並交還工作人員。

姓名　　受試日期　年　月　日

出生日期　年　月　日　　性別　□男 □女　　體重　　公斤

您是否有接受開刀手術：			您是否有下列情況：		
1. 接受過開刀手術	□是	□否	1. 是否有鐵屑跑入眼睛	□是	□否
2. 裝置人工心臟節律器	□是	□否	2. 癲癇	□是	□否
3. 裝置人工心臟瓣膜	□是	□否	3. 是否懷孕（女性填寫）	□是	□否
4. 腦部手術	□是	□否	4. 體外裝置任何金屬物品	□是	□否
5. 腦內動脈瘤手術	□是	□否	5. 刺青	□是	□否
6. 體內血管固定夾	□是	□否			

金屬手持探測器

Safety Zone Ⅲ

Console Table

Safety Zone Ⅳ

金屬探測門

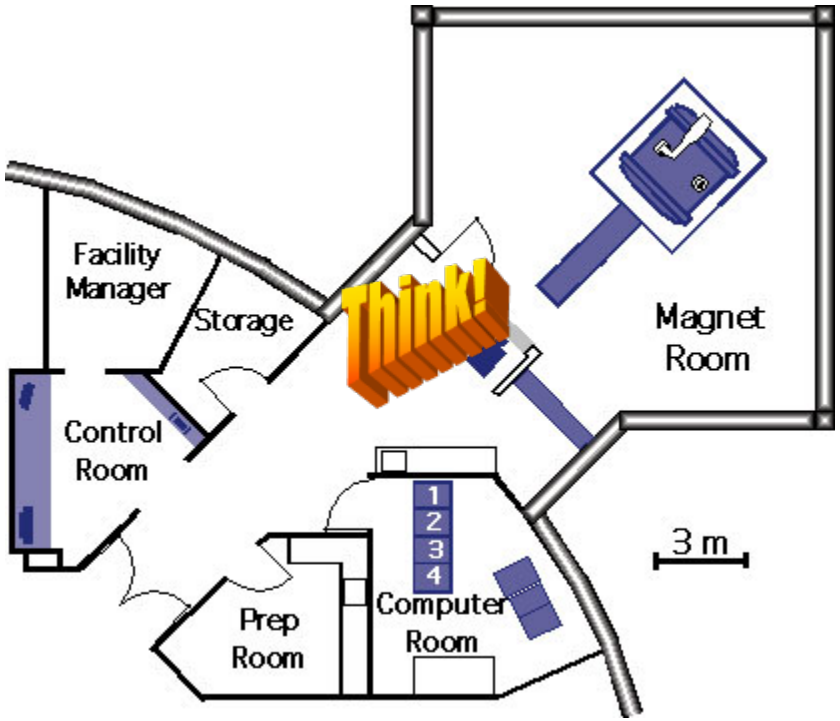
“GO”！

顯示金屬位置

ENTER

Magnet Safety

1. Principal Investigators should be sure all lab members are aware of hazards.
2. Make sure that anyone who is about to enter the magnet room has been filled out consent and screening forms (subjects, lab members, visitors).
3. Remove all metal, coins, credit cards etc. as soon as you enter the magnet area.
4. Think! Train yourself to mini-screen yourself <u>every</u> time you approach the magnet room.
5. Do not enter the magnet room with any tools (e.g., scissors). Use only magnet-friendly tools in the toolbox in the magnet room.



Do the "Metal Macarena!"

3) fMRI實驗注意事項

- Before the scan
  - Pre-test (could book mock scanner room for compatibility test of equipments: response box, computer program, trigger receiving, synchronization, etc)
  - Prepare a backup laptop (been checked for compatibility)
  - Fill in 儀器申請書 & 設備需求單 (parameter consultation)
  - Prepare a log-book for each RA/student

儀器申請書 & 設備需求單 範例

心智影像研究中心 2013.04 第十五次中心會議修訂
心智影像研究中心 2013.07 第十八次中心會議修訂
心智影像研究中心 2014.05 第二十六次中心會議修訂

成功大學心智影像研究中心「心智科學腦研究推動網」儀器使用申請書

申請單位		計畫主持人		
計畫名稱				
執行期間		聯絡人及連絡方式	姓名：	
受試者族群/來源			電話(分機)： 手機： 電子信箱	
經費來源(機關)	□國科會(計畫編號：_____) □政府機關補助：_(機關名稱)_____ □其他：_____			
參與人員	編號	姓名	工作性質	單位職稱
	1		□計畫主持人 □協同/共同主持人 □其他：_____	單位：_____ 系所：_____ □教授 □副教授 □助理教授 □博士後研究員 □博 □碩 □大專生 □專案工作人員 □其他：_____
	2		□計畫主持人 □協同/共同主持人 □其他：_____	單位：_____ 系所：_____ □教授 □副教授 □助理教授 □博士後研究員 □博 □碩 □大專生 □專案工作人員 □其他：_____
	3		□計畫主持人 □協同/共同主持人 □其他：_____	單位：_____ 系所：_____ □教授 □副教授 □助理教授 □博士後研究員 □博 □碩 □大專生 □專案工作人員 □其他：_____
	(以上若欄位不足請自行增加)			
填寫人(簽名或核章)		主持人(簽名或核章)		

敬請備妥以下表件與附件資料(*為必備)，並經計畫主持人核章後，與本申請書一併送至心智影像研究中心辦公室。

□設備需求單*

□經費來源證明*(例：計畫核定清單)

□IRB/REC 相關文件*(通過證明、受試者同意書)

□MRI 安全講習認證*(**限本中心核發之認證**)

□CITI 認證

□其他有利審核資料：_____

心智科學腦研究推動網　心智影像研究中心設備需求單

申請人簽名	龔俊嘉	主持人簽名	

註 1：若需變更使用配備，請直接將更新後之版本交由中心操作員。

註 2：加 * 號者為預設推薦選項。

請勾選實驗所需的配備：

1. fMRI 刺激設計實驗用電腦系統

備註 1：刺激控制程式由研究者自行撰寫，本中心負責協助中心電腦設備架設。

備註 2：本中心另製作中心電腦與相關儀器地的使用操作，

☐ 本中心之 Windows 桌上型電腦(Windows 7)

使用軟體：

□ E-Prime 2.0	□ DMDX	□ Presentation 16.3
□ MATLAB	□ 其他：	

■ 本中心之

MAC 桌上型電腦(OS X Mavericks)

使用軟體：

■ MATLAB	□ 其他：	

☐ 自備筆電

2. MRI 系統

心智科學腦研究推動網　心智影像研究中心 2014.05 修訂

MRI 掃描參數設定

■ 使用中心預設之參數　□ 使用自行設定之參數　□ 需 MRI 掃描參數諮詢

附註：
(1) 使用中心預設參數，請填寫下列一、二、四-1、四-2、四-11 項。
(2) 使用自行設定之參數，請填寫下列一~四項。
(3) 若需 MRI 掃描參數諮詢，請於通過申請審核後，將諮詢服務申請單，送至本中心。

一、 Protocol Name: NCKU_Kunglab_Greeble (ex:NCKU_ShawLab)

二、 Sequence Management:

Example	
1. 3 Plane Loc (00:17)(min:sec) 2. Asset Calibration (00:06) 3. structural image , Name：T1 (03:38) 4. EPI image, Name：resting1 (05:30) 5. EPI image , Name：cyber_run1 (05:30) 6. EPI image , Name：cyber_run2 (05:30) 7. EPI image , Name：resting2 (05:30) Total scan time = 26:01	1. 3 Plane Loc (00:17)(min:sec) 2. Asset Calibration (00:06) 3. structural image , Name：T1 (03:38) 4. EPI image, Name：Greeble_loc1 (05:30) 5. EPI image, Name：Greeble_loc2 (05:30) 6. EPI image, Name：Greeble_NIV1 (05:30) 7. EPI image, Name：Greeble_NIV2 (05:30) 8. EPI image, Name：Face_NIV1 (05:30) 9. EPI image, Name：Face_NIV2 (05:30) 10. EPI image, Name：Greeble_veri1 (05:30) 11. EPI image, Name：Greeble_veri2 (05:30) 12. EPI image, Name：Greeble_veri3 (05:30) Total scan time ≒ 60min 30s

三、 Structural Sequence (FSPGR/T1-weighted) Parameters：

參數項目	中心預設參數值	自行設定參數值
1. FOV (Freq：cm / Phase：倍數)	22.4 / 1 *(註):Phase 方向 FOV 為 Freq 方向 FOV 的 1 倍*	
2. Matrix size (Freq / Phase)	224 /224	
3. Flip angle (°)	12	
4. Slice thickness (mm)	1	
5. Bandwidth	31.25	
6. Locs per slab	170	

Scan time = 03:38(min:sec)

心智科學腦研究推動網　心智影像研究中心 2014.05 修訂

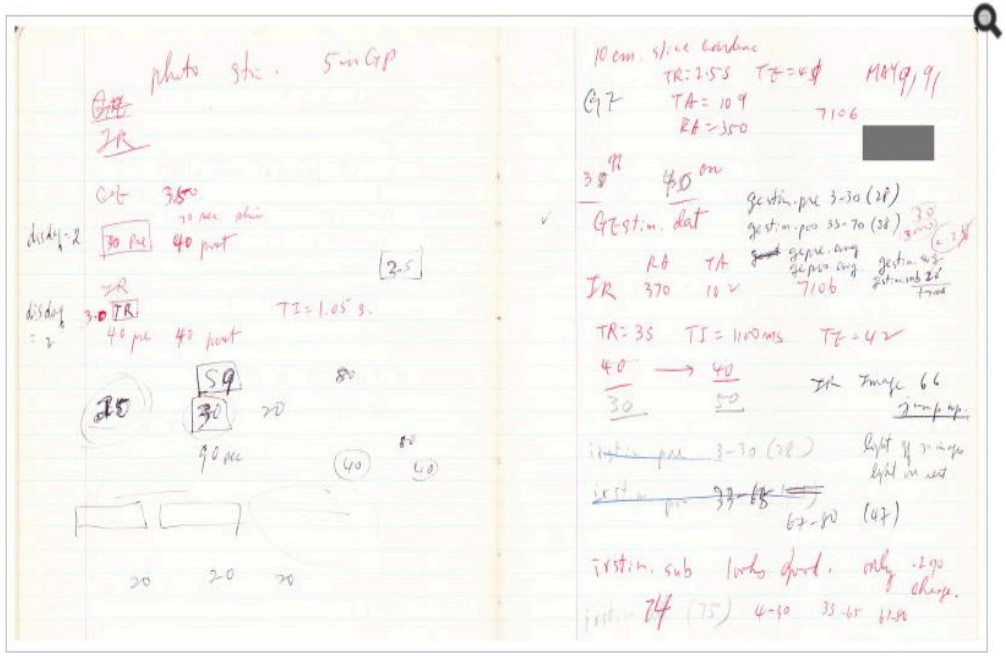
During the scan

- Have at least a lab partner (sometimes two) to help!
- Mentally rehearse the procedure (because it is a highly pressing environment)
- Have someone experienced to accompany (especially at the beginning)—always helpful if “onsite debugging” happens…
- Write down anomalous points (subject motion/complaints, program glitches, screen blackouts, etc)

From: Neuroimage. Author manuscript; available in PMC Aug 15, 2013.
Published in final edited form as:
Neuroimage. Aug 15, 2012; 62(2): 610–612.
Published online Aug 3, 2011. doi: 10.1016/j.neuroimage.2011.07.089

<< Prev

Fig. 1



20130423_PapaBuy_LYY Open with Microsoft Word

2013.04.18 fMRI實驗紀錄

Subject: [redacted] (LYY) 2歲男

Round	實驗內容	紀錄
1	SPGR	200 s
2	Resting State	TR 2s, 310 s, slice 40, Flip angle 76,
3	Father Shopping_1	Dummy 10s + 320 s, 第一trial受試者hold住按鍵,直接跳至第二trial
4	Father Shopping_2	10s + 320 s
5	Father Shopping_3	10s + 320 s Subject pressed warning ball
6	Father Shopping_4	10s + 320 s, 某一trial, fixation時出現黑屏
7	Father Shopping_5	10s + 320 s, 某一trial, fixation時出現黑屏
8	Father Shopping_6	10s + 320 s
9	Father Shopping_7	10s + 320 s Subject 不舒服，下床活動
10	Father Shopping_8	10s + 320 s, 某一trial, fixation時出現黑屏
11	Father Shopping_9	10s + 320 s
12	Father Shopping_10	10s + 320 s, 某一trial, fixation時出現黑屏
14	Resting State	310s

Reproduction of Kwong's log book pages recording the fMRI experiment on May 9, 1991. In this particular reproduction, the name of the imaging volunteer had been crossed out for privacy protection.

After the scan

- Prepare a USB-3 or thunderbolt (more expansive) portable HDD for faster data transfer

(<5 min)

(<20 min)

- Copy behavioral data files (or put in Dropbox/ GoogleDrive)
- Incidental findings have to be carefully handled (refer to PI for better informing)

Some concluding points for PIs…

- Never take it too lightly.
  - NCKU MRI center requires all practitioners (including PIs) do safety exams EVERY YEAR!
- PI is recommended to be your own first subject.
  - Only after scanned, you know what it is like being a participant
  - Also easier to debug the program, how to better relaxed, and when to rest
- “Unconditional” monetary rewards are encouraged
  - When subjects quit, still give them money (and ***no discounts please!***) and thank them

4) 緊急應變處理

- Fire safety
  - always give subjects a panic button
  - make sure that subject can be evacuated quickly if needed
  - have an MR-compatible fire extinguisher available
  - operator must know safety protocols (**stop firefighters from entering the MR!**)
- Quenching
  - rapid decrease in magnetic field strength
  - helium boils off and can fill room (displacing oxygen)
  - can occur spontaneously
  - only voluntarily initiated in extreme situations
- Burns
  - do not loop any wires or cables
  - do not place electrodes on subjects' skin
- Flooding/earthquakes/power-outs/etc
  - stop the experiment, exit the subject
  - power down the system (if possible), call for help
  - get upstairs and get help

Other safety issues

- Claustrophobia
  - subject screening
  - could be tested in mock scanner
- Peripheral nerve stimulation
  - rapid switching of gradients can lead to generation of currents in the body that stimulate the nerves (e.g., twitching)
  - manufacturers limit rate of gradient switching to avoid problems
- Acoustic noise
  - without ear protection, could cause hearing loss
  - soundproofing
  - earplugs
  - headphones

Improving quality: An analysis of MRI safety incident reports (2015)

- A total of 1,290 MRI-related incidents were reported for the 362,090 MRI exams performed at MGH between April 2006 and September 2012. This represents a rate of 0.35%, or one incident report for every 281 MRI exams performed.
- The most common reason for a MRI-related incident report was related to diagnostic test orders. These 406 reports represented almost one-third of the total. Examples included exams not planned at the correct time, failure to order contrast, ordering an exam for the wrong side of the body, or failing to screen a patient in advance about the presence of a metallic foreign body.

http://appliedradiology.com/articles/improving-quality-an-analysis-of-mri-safety-incident-reports

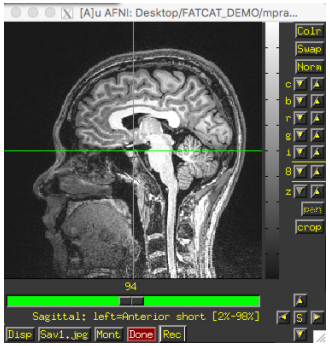
5) 放射師＆技術組對研究者的建議

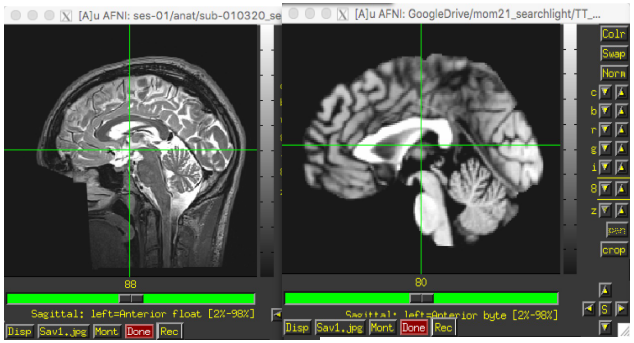
- Decide fMRI parameters beforehand.
- Prepare for everything
- Relaxed
- Hope for the best, but prepare for the worst (make sure no one gets hurt!)

3. fMRI 研究相關倫理議題

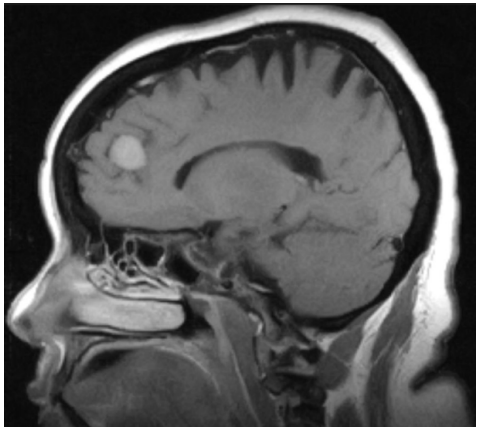
1) 研究參與者的角度

- Anonymity: de-facing or head-stripping





- How to inform those people with ‘incidental finds’?
  - PI: calm, friendly, and care (if possible)
  - Recommend further exam (and electronic pictures ok if needed)



2) fMRI 研究的其他倫理議題

Table 1. Qualitative description of the major potential ethical concerns identified in the articles retrieved. fMRI: functional magnetic resonance imaging.

Concerns	Number of articles[a]
Recruitment of vulnerable groups	5
Informed consent	4
Incidental findings	11
Limitations of the technique, interpretation and validity of results	9
Risks and safety	4
Confidentiality and privacy	8
fMRI applications outside the laboratory	
• Presurgical planning	4
• Diagnostic and predictive potential	5
• Forensic, security and military use	9
• Commercial use	6
Public communication of research results	9

[a]The sum of the number of articles is superior to the total number retrieved (n = 42) because the majority of articles found (64%) focused on multiple ethical issues

Source: Seixas et al. (2008). Ethics in fMRI studies. Clinical Neuroradiology.

Pre-surginal planning and psychiatric treatment/intervention examination

- "It is in psychiatric disease, however, that fMRI has its greatest use", Rosen says. ""MGH researchers are using the tools of functional imaging to understand the abnormalities and why the brain isn't functioning properly for people who have post-traumatic stress disorder, obsessive-compulsive disorder and schizophrenia, among others. fMRI allows us to study the brain while it's working to understand how different treatments allow function to return, preserve or enhance function."

Source http://fMRI25.org

Nature. 2008 Jun 12;453(7197):869-78. doi: 10.1038/nature06976.

What we can do and what we cannot do with fMRI.

Logothetis NK[1].

Author information

Abstract

Functional magnetic resonance imaging (fMRI) is currently the mainstay of neuroimaging in cognitive neuroscience. Advances in scanner technology, image acquisition protocols, experimental design, and analysis methods promise to push forward fMRI from mere cartography to the true study of brain organization. However, fundamental questions concerning the interpretation of fMRI data abound, as the conclusions drawn often ignore the actual limitations of the methodology. Here I give an overview of the current state of fMRI, and draw on neuroimaging and physiological data to present the current understanding of the haemodynamic signals and the constraints they impose on neuroimaging data interpretation.

Thank you!

And Qs?