
*Complication Avoidance and Management*


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University of Toronto · CRANIA · UHN Krembil Brain Institute

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## Conflicts of Interest

- Speaker Fees and/or Ad Board and/or Honoraria and/or support in kind – Abbott, Boston, Medtronic
- Consulting – Aspen, Bluerock, Novonordisk

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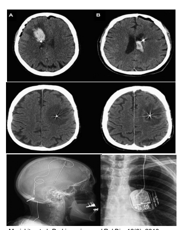
## DBS - Complications

- Hardware Related
- Surgical Complications
  - Intra-operative
  - Post-operative
- Stimulation Related
  - On Target
  - Off Target



Morishita et al. *Parkinsonism and Rel Dis.* 16(3). 2010

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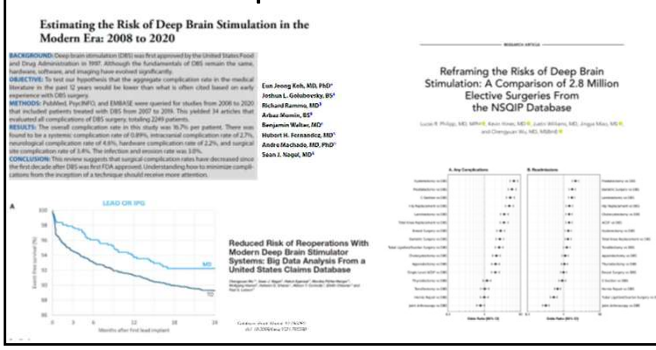
## DBS Complications – Modern Era

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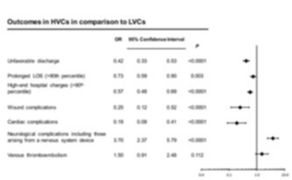
## Multidisciplinary Team for Neurosurgical Interventions

- High volume centers with multi-D teams have:
  - Better outcomes
    - *avoid the "tyranny of partial benefit"*
  - Less treatment failures and reduced short term and long term complications




Predictors of unfavorable outcomes following deep brain stimulation for movement disorders and the effect of hospital case volume on outcomes: an analysis of 33,642 patients across 234 US hospitals using the National (Nationwide) Inpatient Sample from 2002 to 2011

Neurosurg Focus 38 (6):E4, 2015

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The JAMA Network

From: **Management of Referred Deep Brain Stimulation Failures: A Retrospective Analysis From 2 Movement Disorders Centers**

Arch Neurol. 2005;62(8):1250-1255. doi:10.1001/archneur.62.8.noc40425

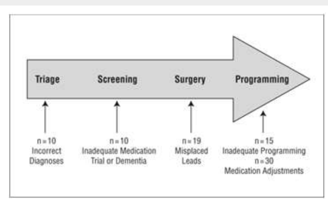


Figure Legend:

Examples of preventable "deep brain stimulation failures" (n = events) in this study. Improvements in triage, screening, operative procedure, and follow-up programming and medication changes may have eliminated the issues identified in the 41 patients in this study.

Date of download: 6/18/2016



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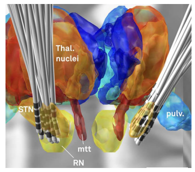
## Successful DBS requires a Multidisciplinary Team

- Patient
- Neurologist
- Neuropsychologist
- Neuropsychiatrist
- Neurophysiologist
- Nursing Team and Allied Health Team (e.g. PT/OT/Speech/Swallow)
- Nutrition
- Anesthesia
- Neurosurgeon

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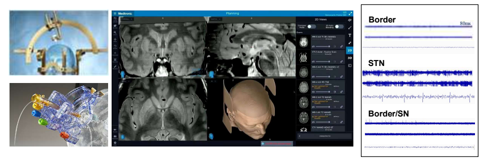
## DBS: THE SURGICAL PROCEDURE




- Local anesthesia +/- sedation vs. GA
- Stereotactic frame vs. "frameless"
- Target planning
- Microelectrode mapping +/- macrostimulation
- DBS electrode insertion
- IPG insertion
- IPG programming and medication adjustments

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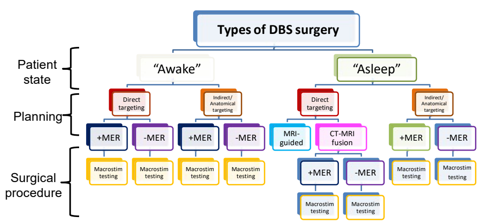


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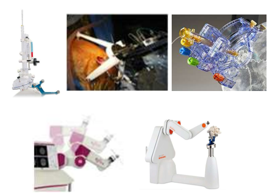
## Electrode Implantation: Frame vs. "Frameless"

*"Frameless" Navigation*

- Planning software for disposable "mini-frame" platforms
  - NexFrame (Medtronic)
  - StarFix (FHC)
  - Clearpoint (MRI Interventions)
- Robotic solutions
  - Rosa
  - Renishaw



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## Frame Placement

- For frame based approach use meticulous placement techniques
- For "frameless" platforms similar considerations apply and include intra-op robotic verification step


**Patient review**
- ☐ Prior shunt
  - ☐ Side of shunt and location of catheter
- ☐ Prior craniotomy
  - ☐ Date of craniotomy
  - ☐ Side of craniotomy (left/right/midline)
  - ☐ Type of craniotomy (frontal/parietal/occipital/pterional)
- ☐ History of local anesthesia experience
  - ☐ Need for more than normal amounts
  - ☐ Medication allergies

**Imaging review**
- ☐ Plain XR
- ☐ CT head/brain
- ☐ MRI head/brain

**Equipment review**
- ☐ IV access
- ☐ Frame components complete
- ☐ Pin and post sets available
- ☐ Topical and local anesthesia available
- ☐ Torque wrenches available

Safaee M, Burke J, Mcdermott M W. (March 25, 2016) Techniques for the Application of Stereotactic Head Frames Based on a 25-Year Experience . Cureus 8(3): e543. DOI 10.7759/cureus.543

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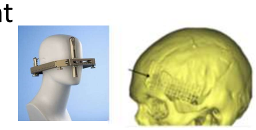
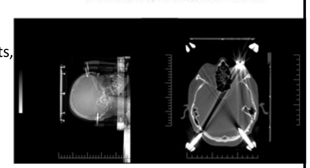
## Frame Placement

- Potential complications:
  - Pin site infection
  - Skull fracture
  - Damage to shunt systems, previous DBS implants, cranioplasty mesh or cranial defects due to previous surgery and/or trauma



Safaee M, Burke J, Mcdermott M W. (March 25, 2016) Techniques for the Application of Stereotactic Head Frames Based on a 25-Year Experience . Cureus 8(3): e543. DOI 10.7759/cureus.543



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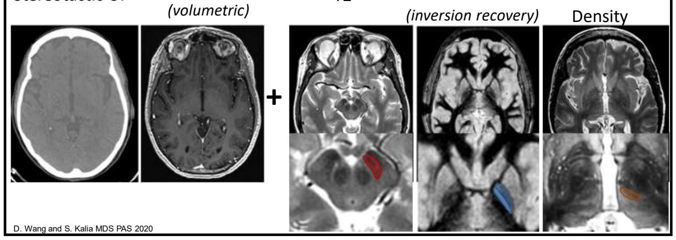
## Images sequences for DBS planning

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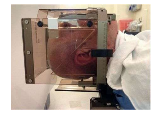
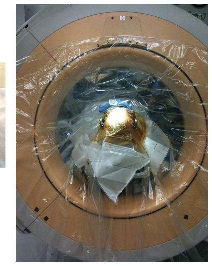
## Stereotactic Frame Scan

- Varies from center to center
- Need to develop a highly accurate imaging protocol with the frame on and a fiducial localizer
  - 1.5T MRI with frame
  - CT with frame
  - Intraop CT with frame





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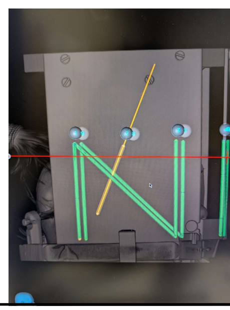
  - 1.5T MRI with frame
  - CT with frame
  - Intraop CT with frame

**need to develop an appropriate and manageable flow for given patients at your institution*

**need to have tight quality control and understand potential inaccuracies that may be unique to your own site*



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## Patient Positioning

- Potential complications:
  - Aspiration
  - Airway issues - *entire team should be familiar with frame removal
  - Compression neuropathies
  - Air embolism
  - Brain Shift


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## Operative Techniques

- Meticulous surgical technique and attention to detail at every step
- Potential intra-operative complications or delayed complications due to poor surgical technique:
  - bleeding
  - seizure
  - lead misplacement
  - acute lead migration
  - Infection
  - hardware damage with insertion or IPG revision

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### Pulsed Radiofrequency Energy Device (PEAK)

1. IPG revisions – due to depletion or other (DBS, SCS, VNS, PNS)
2. Electrode revision or resite surgery requiring preservation of leads

Use of Pulsed Radiofrequency Energy Device (PEAK Plasmablade) in Neuromodulation Implant Revisions

Stereotactic and Functional Neurosurgery

Technical Report

Can Deep Brain Stimulation Withdrawal Syndromes Be Avoided by Removing Infected Implanted Pulse Generator and Cables with Contralateral Replacement in the Same Session?

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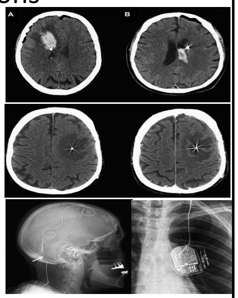
## Surgical Complications

Procedure Related
- Death 0-4.4%
- ICH 0-10%
- Stroke 0-2%
- Infection 0-15%

Hardware Related (overall 8-10%)
- Lead erosion without infection 1%-2.5%
- Lead fracture 0-15%
- Lead migration 0-19%

Stimulation Related
- On target side effects
- Off target side effects – due to mistargeting of lead



Deep Brain Stimulation for Parkinson Disease

An Expert Consensus and Review of Key Issues

Arch Neurol. 2011;68(2):165-171. Published online October 11, 2010. doi:10.1001/archneurol.2010.260

Morishita et al. *Parkinsonism and Rel Dis.* 16(3). 2010

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## Systematic review of bilateral STN DBS for PD: Adverse effects in 737 patients

- Mortality 0.4% (n=3)
- Hemorrhage 2.8% (n=21)
  - Permanent deficit 0.7% (n=5)
  - Asymptomatic or transient deficits 2.1% (n=16)
- Hardware related complications 9.1% (n=67)
  - Lead and IPG problems 5.7% (n=42)
  - Infections of the hardware 3.4% (n=25)
    - Treated only with antibiotics 1.6% (n=12)
    - Required removal of the system 1.8% (n=13)

Hamani et al Neurosurgery 2005

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## Surgical Complications

**Table 1.** Incidence of hardware-related adverse effects revealed as percent of complications per patient

| Authors | Number of patients (leads) | % of infections and/or erosions and infections | % of erosions without a re-ported infection | % of lead fractures | % of leads that migrated or that needed to be repositioned |
|---|---|---|---|---|---|
| Beric et al. [10] | 86 (149) | 1.1 | | | |
| Blomstedt and Hariz [3] | 113 (161) | 3.5 | 0.9 | 6 | 3.5 |
| Constantoyannis et al. [2] | 144 (203) | 7.6 | | 1.4 | 0 |
| Goodman et al. [4] | 100 (191) | 5 | 2 | 1 | 4 |
| Joint et al. [5] | 39 (79) | | 2.5 | 10 | 5 |
| Kondziolka et al. [1] | 66[a] | 10.6 | | 15.2 | 4.5 |
| Lyons et al. [9] | 80 (155) | 8.8 | 1.3 | 2.5 | 18.8 |
| Oh et al. [6] | 79 (124) | 15.2 | 2.5 | 5.1 | 5.1 |
| Temel et al. [7] | 106 (178) | 3.8 | | | |
| Umemura et al. [8] | 109 (179) | 3.7 | 0.9 | | |

[a] This study did not provide the number of leads implanted.

**Hardware-Related Complications of Deep Brain Stimulation: A Review of the Published Literature**

Stereotact Funct Neurosurg 2006;84:248–251
DOI: 10.1159/000096499

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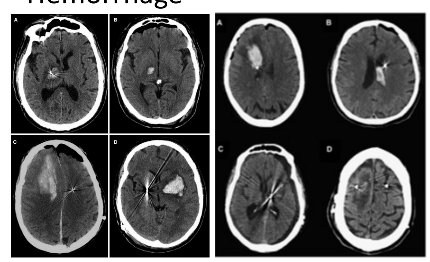
## Hemorrhage

Early identification is critical

Intra-operative management (ABCs)

Post-operative hemorrhage (subacute vs. delayed)



Meet Am Soc Stereotact Funct Neurosurg, New York, N.Y., 2003. Stereotact Funct Neurosurg 2003;80:28–31 (DOI:10.1159/000075156)

Hemorrhagic Complications of Microelectrode-Guided Deep Brain Stimulation

Binder D.K.[a] · Rau G.[b] · Starr P.A.[a,b]

[a]Department of Neurological Surgery, University of California, and [b]Parkinson's Disease Research Education and Clinical Center, SanFranciscoVA Medical Center, San Francisco, Calif., USA

Identification and management of deep brain stimulation intra- and postoperative urgencies and emergencies

Takashi Morishita, Kelly D. Foote, Adam P. Burdick, Yoichi Katayama, Takamitsu Yamamoto, Steven J. Frucht, Michael S. Okun

Parkinsonism and Related Disorders 16 (2010) 153–162

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## Hemorrhage

**Anti-Coagulation and Deep Brain Stimulation: Never the Twain Shall Meet?**

Stereotact Funct Neurosurg 2015;93:373–377
DOI: 10.1159/000441232

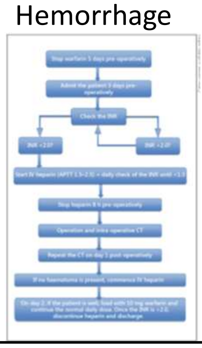


**Fig. 1.** Our peri-operative anti-coagulation flowchart for patients in the high-/moderate-risk group.

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## Hardware Erosion and Infection

**Fig. 2.** Infection in the cranial skin incision. The illustration reveals purulent drain from the cranial incision.

**Fig. 4** This picture was sent by a patient via email showing what he thought was "a staple" remaining in his head. In fact, it was a portion of the exposed lead approaching the connector

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## Hardware Erosion and Infection

-common sites of erosion: burr hole cap, extension wires/connector, edges of IPG

-may be acute or delayed

-can be caused by pressure (thin skin, sleep position, CPAP machine) or by patient picking at incisions

-often needs to be revised, re-sited and/or explanted

**Fig. 4** This picture was sent by a patient via email showing what he thought was "a staple" remaining in his head. In fact, it was a portion of the exposed lead approaching the connector

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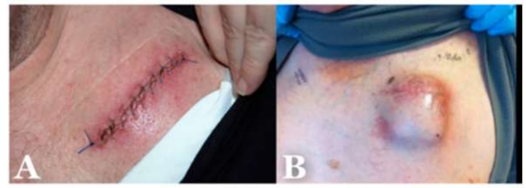
## Hardware Erosion and Infection




Surgical Site Infections after Deep Brain Stimulation Surgery: Frequency, Characteristics and Management in a 10-Year Period

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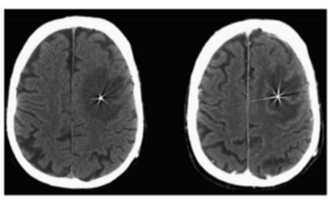
## Hardware Erosion and Infection



T. Morishita et al. / Parkinsonism and Related Disorders 16 (2010) 153–162


Surgical Site Infections after Deep Brain Stimulation Surgery: Frequency, Characteristics and Management in a 10-Year Period

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## Hardware Erosion and Infection

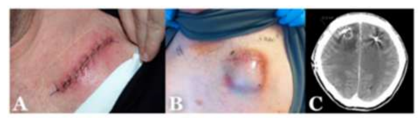


**Figure 1. Examples on the different types of infection.** A) Superficial incisional SSI. B) Deep incisional SSI. C) Organ/space SSI. (SSI = surgical site infection).
doi:10.1371/journal.pone.0105288.g001

-may be acute or delayed (approximate 10 year risk is 5-10%)

-risk factors largely from case series that vary from study to study and include:
age, DM, smoking, immunosuppression, length of procedure, etc

Surgical Site Infections after Deep Brain Stimulation Surgery: Frequency, Characteristics and Management in a 10-Year Period

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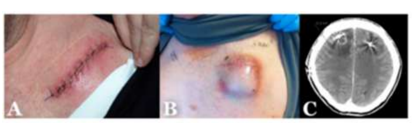
## Hardware Erosion and Infection

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doi:10.1371/journal.pone.0105288.g001

-superficial incisional infection may be managed with antibiotic trial

-deeper incisional space infections may be managed with partial removal plus antibiotic trial

-intracranial infection usually warrants removal of hardware

Surgical Site Infections after Deep Brain Stimulation Surgery: Frequency, Characteristics and Management in a 10-Year Period

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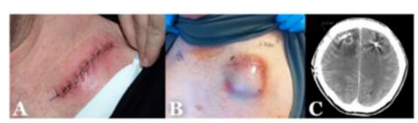
## Hardware Erosion and Infection

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doi:10.1371/journal.pone.0105288.g001

-most common species in case series reviews
S. aureus, coagulase-negative staph (S. epidermis and S. capitis)
P. acnes

-C-Reactive Protein (CRP) is not commonly elevated - likely not useful to rule out indolent infection

-lifelong suppressive therapy can be considered

Surgical Site Infections after Deep Brain Stimulation Surgery: Frequency, Characteristics and Management in a 10-Year Period

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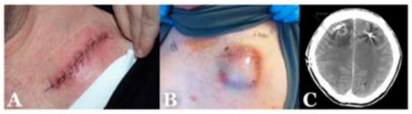
## Hardware Erosion and Infection

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doi:10.1371/journal.pone.0105288.g001

*-case by case team based consideration with ID consultation and close follow-up*
*i) trial of antibiotic only (short course vs. long course vs. suppressive therapy)*
*ii) partial removal plus trial of antibiotic*
*iii) definitive explantation plus antibiotic*

*-antibiotic selection, and duration vary widely center to center*

*-antibiotic therapy alone has approximately 50% success rate*

**Surgical Site Infections after Deep Brain Stimulation Surgery: Frequency, Characteristics and Management in a 10-Year Period**

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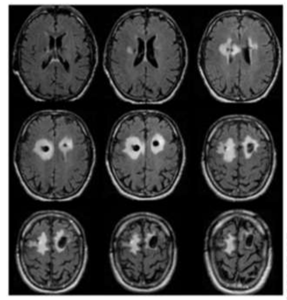
## Edema and fluid collections



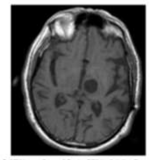


Fig. 2 MRI image of a cyst following DBS implantation. Four months postoperatively, MRI T1 axial image depicted a cyst when patient developed new-onset paresthesias and weakness. Removal of the DBS system led to immediate improvement in the patient's symptoms and long-term resolution of the cyst

**Unusual complications of deep brain stimulation**

Figure 2 Axial fluid-attenuation inversion recovery (FLAIR) imaging 9 months postsurgery, showing bilateral oedema around the deep brain stimulation leads with large non-enhancing cystic cavities extending from the subcortical region to the deep white matter near the lateral ventricles.

Deep brain stimulation complicated by bilateral large cystic cavitation around the leads in a patient with Parkinson's disease

Jonathan Jagid,[1] Karthik Madhavan,[1] Neel Desai,[1] Amade Bregy,[2] Mehul Desai,[2] Amanda Ruiz,[2] Robert Quencer,[2] Howard J Landy[2]

Jagid J, et al. BMJ Case Rep 2015. doi:10.1136/bcr-2015-211470

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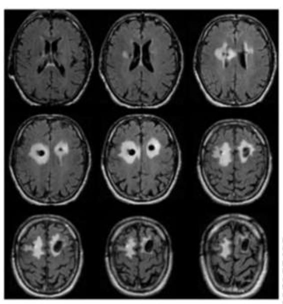
## Edema and fluid collections



**DIFFERENTIAL DIAGNOSIS**
- Microhaemorrhage
- Allergic reaction or hypersensitivity
- Infection
- Venous infarct
- Luxury perfusion from breakdown of the blood–brain barrier
- Microparticulate contamination
- Cerebrospinal fluid migration along the length of the electrode

Figure 2 Axial fluid-attenuation inversion recovery (FLAIR) imaging 9 months postsurgery, showing bilateral oedema around the deep brain stimulation leads with large non-enhancing cystic cavities extending from the subcortical region to the deep white matter near the lateral ventricles.

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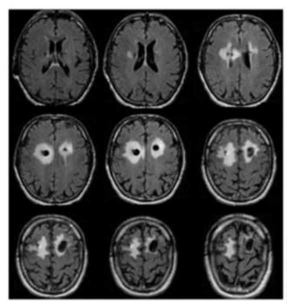

-exuberant edema +/- collections can also occur around electrodes

-may be asymptomatic or significantly symptomatic

-clinical and radiographic correlation needed to be comfortable that the process is unlikely infectious

-hypersensitivity and allergy workup is a consideration

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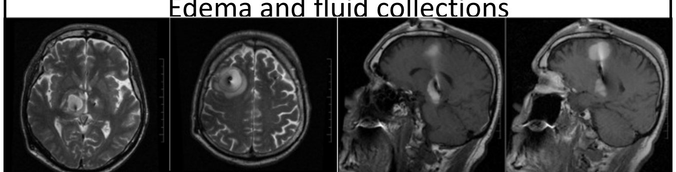
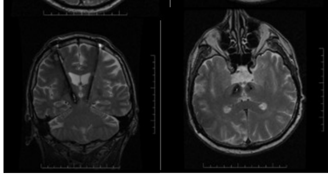
## Edema and fluid collections





-can consider trial of steroids if edema or collection is symptomatic

-requires close radiological and clinical follow-up

-DBS electrodes may still need to be explanted if progressive deficit or does not resolve

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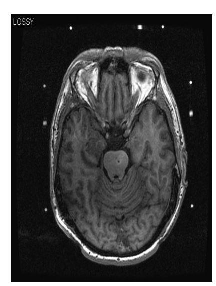
## Mistarget or Migration

-may be acute or delayed

-presents as inability to adequately program therapy or loss of ability to do so

-change in off-target side effects or loss of efficacy

-can be diagnosed on routine imaging (CT and/or MRI)

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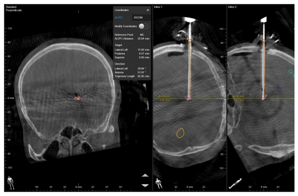
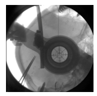
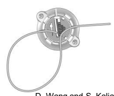
## Lead Placement Verification: Imaging

- Final Lead localization
  - Fluoroscopy
  - Intraoperative CT
  - Intraoperative MRI
- Lead is secured at the burr hole according to manufacturer instructions
- ***TIP***
- Use fluoroscopy during anchoring process to ensure no lead pull-out







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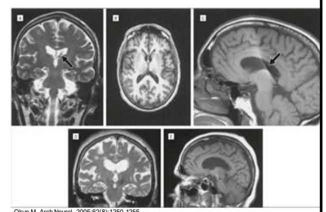
## Mistarget or Migration

Mistarget/Misplaced leads – 2%

-depending on extent of deviation can consider programming for benefit first

-if no benefit or significant off target side effects the mistargeted leads should be revised

-usually due to deviation secondary to operative technique or due to brain shift which should be minimized during surgery



Okun M. Arch Neurol. 2005;62(8):1250-1255. doi:10.1001/archneur.62.8.noc40425

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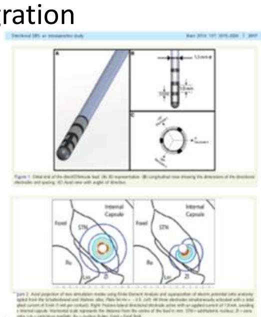
## Mistarget or Migration

Mistarget/Misplaced leads – 2%

-directional stimulation may allow for optimal programming despite suboptimal lead placement

*Directionality is not an insurance policy or alternative to ideal contact position

Options to optimize – MER, awake testing, imaging (fluroscopy or CT lead placement confirmation or image assisted lead placement by MR guidance).



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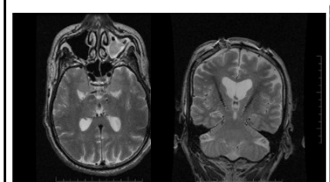
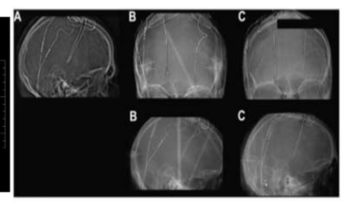
## Mistarget or Migration





Migration of leads – 5%

Acute - usually at time of tunnelling

Chronic - variety of causes including trauma, scar tissue tethering, brain atrophy and ventriculomegaly

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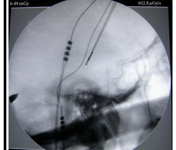
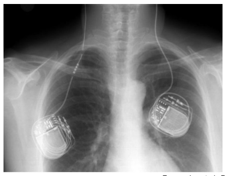
## Hardware Problems – leads and connectors

May present in a variety of ways

- -loss of stimulation benefit (may be sudden or slow)
- -intermittent or unpredictable clinical benefit
- -intermittent on or off target side effects (e.g. flashing lights, double vision, paresthesia, contractions)
- -rapid IPG depletion
- -patient may report "shock" like sensation at IPG or connectors





Fernandez et al. *Parkinson's Disease*. Volume 2010. Garg et al. *Parkinson's Disease*. Volume 201

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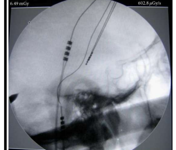
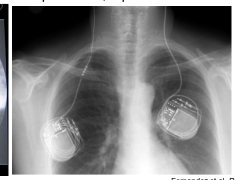
## Hardware Problems – leads and connectors

Can be difficult to diagnose the root cause

- -imaging: static or dynamic
  - X-Ray may reveal break or disconnection
- -diagnostic testing of IPG (impedance testing)
  - open circuit: high impedances
  - short circuit: lower impedances, rapid drain of IPG





Fernandez et al. *Parkinson's Disease*. Volume 2010. Garg et al. *Parkinson's Disease*. Volume 201

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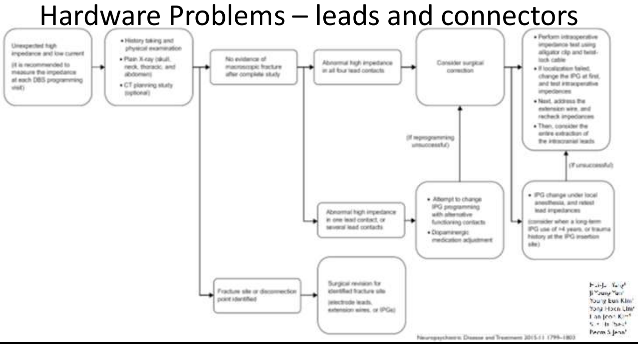
## Hardware Problems – leads and connectors

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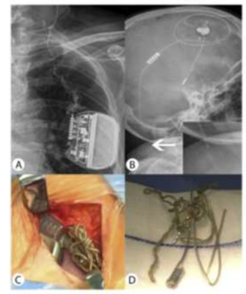
## Hardware Problems – Twiddler Syndrome




Twiddler syndrome in a patient with tremor dominant Parkinson's disease. A case report and literature review

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## Scarring, Tethering and "Bowstringing"

- "I feel that the cables along my neck are pulling" or "the cables along my neck feel too short"
- Not an infrequent complaint

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## Scarring, Tethering and "Bowstringing"

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- Not an infrequent complaint

Fig. 1. Patient 1, who underwent bilateral DBS for dystonia with dual left-sided extension wires, presented with wire tethering. a Prior to the first revision surgery the prominence ('bowstringing') and tightness of the dual extension wires is evident. b Postoperatively releasing the wires from the IPG site was ineffective in relieving the tethering. c After re-positioning of the dual extension wires to the contralateral side and, in addition, transecting the scar in 4 places along the longitudinal cord, the tethering was completely relieved.

Wire Tethering or 'Bowstringing' as a Long-Term Hardware-Related Complication of Deep Brain Stimulation

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## Scarring, Tethering and "Bowstringing"

- Rarely is the pulling related to the cables – these are long and redundant
- Scarring builds up along the tract, which can cause discomfort and "Bowstringing"
- Revision is possible, but does not always help

Table 2. Incidence of wire tethering after DBS surgery by type of surgery and diagnosis

| Diagnosis | Dual-unilateral extension wires | | Bilateral extension wires | | Unilateral extension wires | |
|---|---|---|---|---|---|---|
| | # tethered/total patients | % | # tethered/total patients | % | # tethered/total patients | % |
| PD | 1/34 | 2.9 | 0/62 | 0 | 1/67 | 1.5 |
| Dystonia | 2/18 | 11.1 | 0/6 | 0 | 0/7 | 0 |
| Tremor | 0/19 | 0 | 0/11 | 0 | 0/26 | 0 |
| Epilepsy | 1/13 | 7.7 | 0 | 0 | 0 | 0 |
| Other[a] | 0/15[b] | 0 | 0 | 0 | 0 | 0 |
| Total | 4/99 patients<br>4/100 sides[b] | 4.0 | 0/79 patients<br>0/158 sides | 0 | 1/100 patients<br>1/100 sides | 1.0 |

[a] Includes patients with monopolar depressive disorder or Tourette syndrome.
[b] One patient had 4 DBS leads attached to 2 sets of dual extension wires and 2 dual-channel IPGs, which is reflected in the figure for the total number of sides.

Wire Tethering or 'Bowstringing' as a Long-Term Hardware-Related Complication of Deep Brain Stimulation

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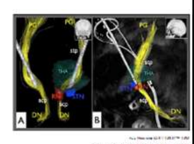
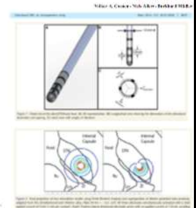
## Current and Future Developments that may mitigate complications

- Novel imaging techniques (DTI)
- More efficient work flows that decreases electrode placement time
- Low profile devices
- Antibiotic cages
- Directional electrodes
- Closed loop stimulation paradigms



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## Conclusions

- Meticulous planning and operative technique mitigate perioperative and late complications
- Diagnosis and management of surgical complications should be efficient, team based and definitive
- DBS teams should continuously review local processes to improve efficiency and accuracy of their DBS team – an active not a reactive process

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