

ADVERSE EVENT REPORTING – AN FDA REQUIREMENT

WHAT, WHEN, WHO & HOW

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
77TH ANNUAL MEETING
MARCH 9 - 13, 2010
NEW ORLEANS, LOUISIANA

COMMITTEE ON BIOMEDICAL ENGINEERING

PREPARED BY:

JOHN S. KIRKPATRICK, M.D.

A. SETH GREENWALD, D.PHIL.(OXON)

WILLIAM MIHALKO, M.D., PH.D.

MICHAEL E. BEREND, M.D.

GREGORY A. BROWN, M.D., PH.D.

DENNIS MCGOWAN, M.D.

Most orthopaedic surgeons in the course of their practice will encounter and explant medical devices which have failed. Such failures may simply result from long-term in-vivo device usage, component material breakdown, technique at the time of implantation or patient noncompliance. Changes in the Safe Medical Devices Act of 1990 (SMDA), a Law enacted by the Congress, require that medical device user facilities inclusive of hospitals, ambulatory surgical facilities and nursing homes report such events to the Food and Drug Administration (FDA) and manufacturers. These events are inclusive of device problems which cause or contribute to the death, serious illness or serious injury of a patient. The orthopaedic surgeon is involved in the identification and interpretation of these problems. In June 1993, the FDA introduced MedWatch, a medical products reporting program, to facilitate the reporting of adverse events and product problems that arise from medical device usage.

- ***What is an “adverse event”?***

An event whereby a death or serious injury was, or may have been caused by a medical device. Serious injury can be interpreted to mean requiring medical or surgical management to preclude impairment or damage to the body’s function or structure with removal, observation, medical treatment, or hospitalization.

This includes events resulting from:

- Device malfunction
- Device failure
- Improper / inadequate design
- Manufacturing (problems)
- Labeling (problems)
- Use error

- ***When should an adverse event be reported by an orthopaedic surgeon?***

Adverse events should be reported once the individual patient’s safety is ensured. While hospitals and manufacturers have mandatory reporting, surgeons have no such requirement. Unfortunately, those best able to provide clinical context are removed from the process. Surgeon reporting of any and all device failures and adverse events will bring relevance to the report and improve the safety decisions made by the FDA.

- ***Who should report adverse events?***

Surgeons provide the most relevant and useful information and provide insight into the cause and effect of the event. Perhaps the most important role is to differentiate whether the device failed or the disease process or patient biological issues caused the problem. Surgeons may participate in their facility’s mandatory annual reporting process. Manufacturers are required to file adverse events. Surgeons may also file voluntary reports individually.

- ***How should an adverse event be reported?***

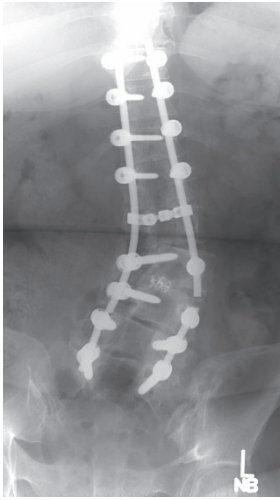
The surgeon can go to <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>. This web page has the instructions and the link to beginning the forms. Part 5 is the most important for surgeons to provide an interpretation of the event. Examples will include answers to Part 5 for the cases in this exhibit.

- ***What about HIPAA?***

The [HIPAA] Privacy Rule permits covered entities to disclose protected health information, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of presenting or controlling disease, injury, or disability. This would include, for example, the reporting of a disease or injury; reporting vital events, such as births or deaths; and conducting health surveillance, investigations, or interventions. A “public health authority” is an agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. Examples of a public health authority include State and local health departments, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, and the Occupational Safety and Health Administration (OSHA).

The following examples illustrate these points.

CASE 1



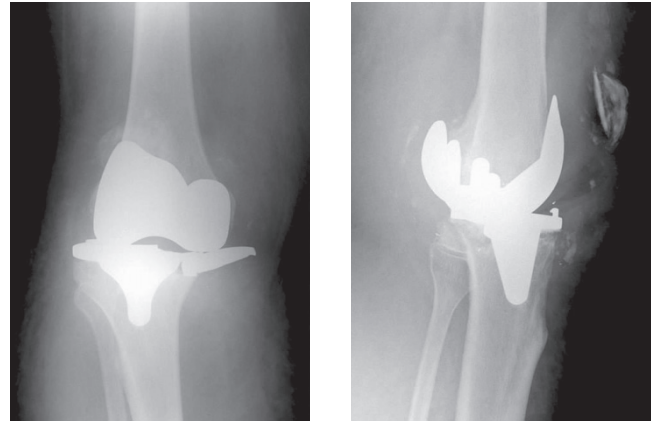
A 50-year-old obese female with multiple sclerosis had multiple failed thoracolumbar spinal fusions for low back pain. One of the fusion attempts had been complicated by a MRSA infection. She developed junctional kyphosis and neurological deficit superior to her construct and had evidence of pseudarthrosis also. She had decompression and re-fusion with replacement of her prior hardware and extension superiorly. Approximately 18 months later she presented with pain and crepitus in her low back and radiographs showed fracture of her rods bilaterally.

She requested removal of her hardware and attempted fusion of her persistent pseudarthrosis. Was this a failure of the hardware? Technically yes, but this must be qualified by the failure of the patient's biology to heal her fusion while the hardware was in place.

MEDWATCH PART 5

"Patient had fusion with posterior fixation for failed prior fusion with a MRSA infection. The rods were noted to be broken and the patient had pain and crepitus from the broken rods rubbing together. Patient had removal and re-fusion of the non-union 18 months following implantation. In light of the patient's clinical setting this was interpreted as a failure of the patient's biology, not a failure of the device."

CASE 2



This patient had a sudden onset of pain and difficulty ambulating 21 months after bilateral primary total knee arthroplasty surgery. He had no signs of infection and only had difficulty with his right knee. Radiographs revealed a catastrophic fatigue failure of the modular tibial baseplate and possible failure of the polyethylene insert as well. It is difficult to tell if excessive polyethylene wear or fatigue of the metal baseplate were the initial events in the implant failure. The patient underwent revision total knee surgery where failure of both the baseplate and polyethylene inserts were confirmed.

MEDWATCH PART 5

"Patient had catastrophic failure of the tibial base plate and polyethylene insert at less than two years after implantation. Unfortunately, pre-failure radiographs were not available. The potential contributing factors for this failure mechanism include: varus component positioning, excessive patient weight (BMI>40), and possible soft tissue imbalance adding stress to the medial aspect of the implant. There may also have been inadequate fixation of the medial aspect of the baseplate. While these factors may have contributed to the failure mechanism, the failure at such a short time period after implantation must also be a result of material or design failure as well."

CASE 3

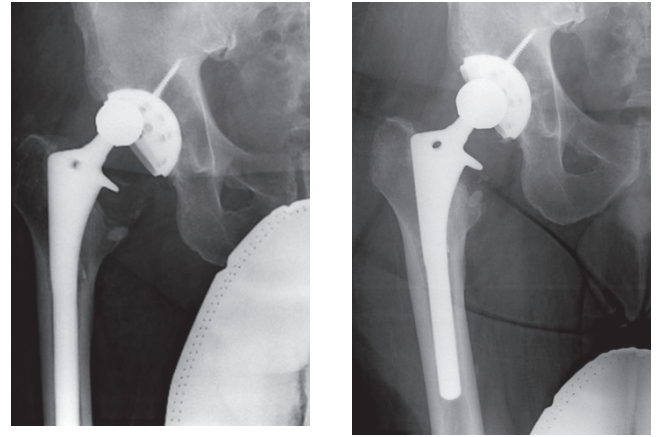


A 68-year-old white female s/p placement of a Dorsal Column Stimulating generator in left buttock for intractable bilateral neuropathic leg pain refractory to all other treatments. The wound initially healed without complication--never any suggestion of an unstable or infected wound. After the wound was healed, the patient was taught the procedure for recharging the system. The patient was very satisfied with the system and had good control of the bilateral neuropathic leg pain. The patient continued to do well until approximately five months s/p system placement when she developed pain about the generator site when recharging. She went to the emergency room and was found to have a burn over the generator. The pocket was aspirated and no evidence for a deep infection. She was covered with antibiotics and the burn was followed. The burn broke down, the generator was exposed as shown in the picture, and required removal of the system. The wound closed with dressing changes. Risk factors included a history of alcoholism and poor nutrition.

MEDWATCH PART 5

"Patient with implantable stimulator with chronic wound, healed initially without incident. No other risk factors or evidence for infection, cultures with cutaneous organisms. Material of connector at wound was different than the rest of the device. It is unclear whether wound breakdown was from the primary infection, a reaction to the material, or the placement of the device in a relatively prominent area near the iliac crest."

CASE 4

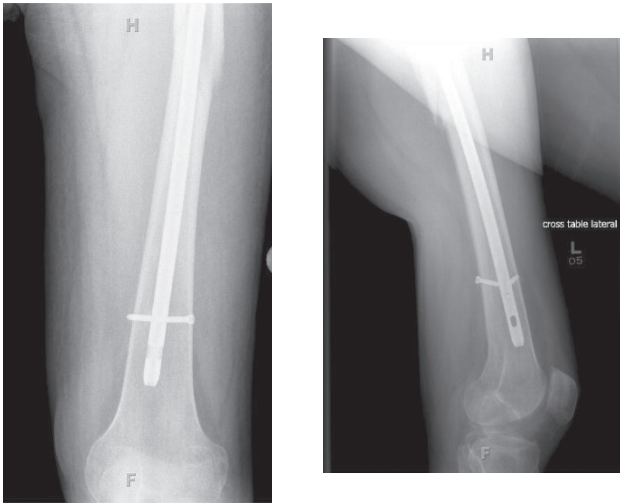


This patient had sudden onset pain and difficulty ambulating 15 years after a right primary total hip arthroplasty procedure. He reported no symptoms prior to the event where he described getting out of bed and feeling a "pop" and having difficulty bearing weight with a grinding sensation. A radiograph 6 months earlier confirmed some asymmetric wear but the new radiograph showed dissociation of the polyethylene liner from the metallic shell. Breakage of the locking mechanism was also evident. The patient underwent a revision with cementation of a new liner into the well fixed shell where confirmation of failure of the locking mechanism was determined. The liner had some asymmetric wear but was not catastrophic.

MEDWATCH PART 5

"Patient had a successful total hip arthroplasty for many years. For this amount of time wear of polyethylene was noted due to the eccentric position of the femoral head in the acetabular shell. On retrieval both wear of the polyethylene and failure of the locking mechanism were noted. Since the implant had been in place for 15 years, some wear was expected and this was not out of the ordinary for the time period. The failure of the locking mechanism was the problem that led to the need for revision surgery."

CASE 5

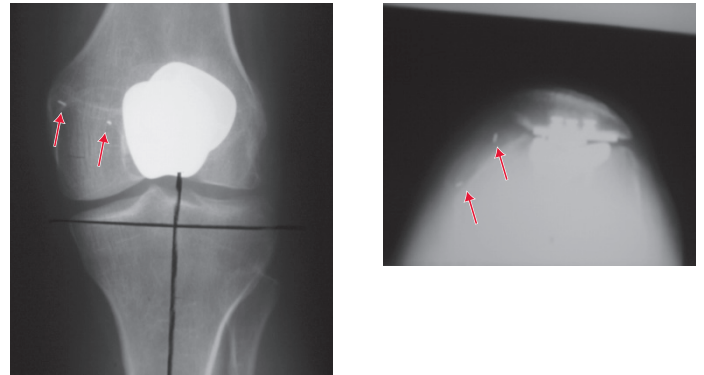


A 71-year-old male presented with acute onset of left hip/thigh pain after a fall. Initial radiographs demonstrated a reverse oblique/spiral intertrochanteric/subtrochanteric unstable proximal femur fracture. The patient was treated with a long intramedullary hip screw with a single static distal interlocking screw. The implant is marketed for immediate post-operative weight bearing. Immediate post-operative radiographs demonstrated adequate fracture reduction and alignment. The patient's weight bearing status was weight bearing as tolerated immediately after surgery to allow the earliest possible mobilization and ambulation. The patient was discharged from the hospital to a transitional care unit for rehabilitation. Radiographs at the two week post-operative time period demonstrated no change in the intramedullary fixation. Radiographs at the eight week post-operative time period demonstrated breakage of the distal interlocking screw. Physical examination and radiographs demonstrated minimal shortening of the limb, but 15-20 degrees of increased external rotation compared to the contralateral extremity.

MEDWATCH PART 5

"Patient was treated for an unstable subtrochanteric femur fracture with a long intramedullary hip screw and single static distal interlocking screw. The patient was weight bearing as tolerated in the immediate post-operative period. The distal interlocking screw was noted to be broken at 8 weeks post-op. The "dynamization" may have helped fracture healing, but allowed a 15-20 degree external rotation femoral malunion."

CASE 6



A 43-year-old female s/p patellofemoral arthroplasty with pain, mechanical symptoms, and patellar instability. The mobile bearing patellar component was noted to be dislocated medially as seen on the A/P and sunrise radiographs with the two metallic markers in the polyethylene displaced into the medial gutter. This was treated with revision to a non-modular fixed bearing cemented total knee arthroplasty with standard CR components.

MEDWATCH PART 5

"Patient with patellofemoral arthroplasty with mobile polyethylene patellar component. Polyethylene displaced from component with no trauma. Appears to be a failure of intended component interactions and motion limits."

MEDWATCH

For VOLUNTARY reporting of
adverse events, product problems and
product use errors

Page ____ of ____

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY	
Triage unit sequence #	

A. PATIENT INFORMATION

1. Patient Identifier In confidence	2. Age at Time of Event, or Date of Birth:	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight _____ lb or _____ kg
--	---	--	--------------------------------------

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. Adverse Event Product Problem (e.g., defects/malfunctions)
 Product Use Error Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event
(Check all that apply)

Death: _____ (mm/dd/yyyy) Disability or Permanent Damage
 Life-threatening Congenital Anomaly/Birth Defect
 Hospitalization - initial or prolonged Other Serious (Important Medical Events)
 Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)

5. Describe Event, Problem or Product Use Error

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

Yes No Returned to Manufacturer on: _____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 _____
#2 _____

2. Dose or Amount	Frequency	Route
#1 _____	_____	_____
#2 _____	_____	_____

3. Dates of Use (If unknown, give duration) from/to (or best estimate)

#1 _____
#2 _____

4. Diagnosis or Reason for Use (Indication)

#1 _____
#2 _____

5. Event Abated After Use Stopped or Dose Reduced?

#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply

6. Lot # 7. Expiration Date

#1 _____ #1 _____
#2 _____ #2 _____

8. Event Reappeared After Reintroduction?

#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other: _____
Catalog #	Expiration Date (mm/dd/yyyy)	
Serial #	Other #	

6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
 Yes No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address

Phone # E-mail

2. Health Professional? 3. Occupation 4. Also Reported to:

Yes No Manufacturer
 User Facility
 Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:

PLEASE TYPE OR USE BLACK INK