Medical Device Failure Analysis

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What is a medical device?

- Any appliance used in the performance of direct patient care that does not achieve its primary intended purposes by chemical action (i.e. not a drug)
- Medical devices also include diagnostic aids such as reagents & test kits for in vitro diagnosis.
What Constitutes Failure?

• When the device does not adequately perform its intended function

• Causes can include electrical, mechanical, thermal, software, materials problems
Why is Failure Analysis Important?

• Rigorous analysis allows us to determine the true cause of a failure, not just guess
• Once we know the root cause, we can then modify design (if necessary) to preclude additional failures
• Failure analysis is an integral part of product design and refinement
The Good News/Bad News

• The Good News
  – Problems with drugs much larger than with problems with devices (235,000 reports annually for adverse drug events)

• Bad News
  – 80,000 to 85,000 reports on device problems annually
What are Typical Issues Involved in Medical Device Failures?

Almost all can be classified into 2 general (or 3 specific) categories:

1. **Product Defects**
   - Design defect
   - Manufacturing defect

2. **Misuse/abuse**
   - Greater loads than expected, finite shelf life, poor healing, maintenance, adherence to instructions for use (IFU) – hospital, surgeon, technician
Examples of Historic Medical Device Failures

From 1959 to 1969 medical devices caused 10,000 injuries and 750 deaths (Geddes)

- Pacemakers
- IUDS
- Bjork-Shiley heart valves
Pacemakers

• Significant defects in pacemakers resulted in 89 deaths and 186 injuries prior to 1970 (FDA)

• Contributed to 1976 Medical Device Amendments to the “FDA and Cosmetic Act”
IUDs

• Prior to 1970, IUD devices were linked to 10 deaths and 8,000 injuries (FDA-1997)

• Contributed to 1976 Medical Device Amendments to the “FDA and Cosmetic Act”
Bjork-Shiley Heart Valves

- Certain heart valves manufactured by Shiley, Inc., turned out to have increased fracture rates.
- Changed the way FDA expects manufacturers to communicate significant risks of medical devices.
Bjork-Shiley

- 86,000 valves were implanted worldwide until recall in 1986
- 1,450 valve outlet-strut fractures, leading to approximately 1,000 deaths
- FDA became very sensitive about the concept “Earn while you learn”
- Contributed to enactment of the 1990 Safe Medical Devices Act
1990: Safe Medical Devices Act (SMDA)

- Act placed greater emphasis on postmarket surveillance
- Hospitals and other institutional users required to report to the FDA product defects (including those that cause injuries or death)
- Provides for rapid suspensions of device approval, recalls of defective products and civil penalties for violators
- Device user facilities must report device-related problems to the FDA and the manufacturer, if known (MDR)
Medical Device Reporting Regulation (MDR)

- Mechanism for FDA to receive adverse reports from manufacturers, importers, and user facilities
- Domestic distributors do not have to file MDRs, but must maintain a complaint file
- Importers must file MDRs
- User facilities must file an annual report to summarize their adverse events
- User facilities (e.g., hospitals, nursing homes) are required to report suspected medical device related deaths to both the FDA & manufacturers.
- User facilities report medical device related serious injuries only to the manufacturer.
Failure Analysis Investigation

1. Analysis of a specific unit
2. Analysis of a product line (recall)

**Questions to Answer:**
- Failure mode?
- Manufacturing defect?
- Design defect?
- Unanticipated loading/usage?
- Misuse?
- How do we correct the problem?
- Did changes work?
Failure Analysis Process: Specific Unit (Materials Specific)

- **Nondestructive:**
  - Collect all data (lot number, drawings, calculations, changes, exemplars, x-rays, manufacturing records)
  - Visual, low magnification examination
  - Documentation, photo and stereoscope
  - Scanning electron microscopy
  - Calculations/analysis

- **Destructive**
  - Cleaning
  - Scanning electron microscopy
  - Metallography
  - Mechanical property testing (tensile, hardness, fracture toughness)
  - Destructive testing of exemplars for comparison or to reproduce failure
  - Chemical analysis