Implantable Medical Devices

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Implantable Devices

In the Hyperbaric Environment

Primary Training Course

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Implantable Devices

In the Hyperbaric Oxygen Environment

Introduction

- Technological advances have allowed the development of a myriad of implantable medical devices in recent years.
  - Micro circuitry
  - Advanced battery technology
  - Biocompatible materials

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Implantable Devices

In the Hyperbaric Oxygen Environment

Introduction

- Newer technologies will continue to enhance the development of implantable medical devices
  - Glass encapsulation
  - Low temperature laser welding
  - Power transfer – mid field technology
  - Internet of Things (IoT)

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Implantable Devices

In the Hyperbaric Oxygen Environment

Introduction

- A number of problems may be associated with the use of Implantable Medical Devices (IMDs) in the setting of hyperbaric oxygen therapy as a result of exposure to increased ambient pressure, oxygen tensions, or both.

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Implantable Devices

In the Hyperbaric Oxygen Environment

Introduction

- Exposure to increased ambient pressure or hyperoxia may result in:
  - Aberrant or inconsistent /unpredictable function
  - Communication / programming disruption
  - Overt device failure
  - Patient / staff safety issues

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Implantable Devices

In the Hyperbaric Oxygen Environment

Outline

- Categorize devices into groups with similar functions, issues, and/or concerns
- Identify potential issues within specific device categories with representative examples provided.
- Discuss potential risk management strategies within the hyperbaric environment.

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Implantable Devices

Active Medical Device (AIMDs)

Definition

- Any medical device that relies on a source of electrical energy or any source of power other than that directly generated by the body or gravity.

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Implantable Devices

Miscellaneous Implantable Devices

Electrical Pulse Generators

- Generally low energy devices
- Self contained
- Highly programmable
- Used for stimulation of various physiological functions
- May have wireless connectivity

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Implantable Devices

Internet of Things (IoT)

Microcomputers

- AIMDs are essentially embedded PCs.
- Consist of both hardware as well as operating system software
- Devices are often interconnected and wirelessly configurable.
- Full radio-frequency based IMDs approved by FDA in 2009

H@cking Implantable Medical Devices. INFOSEC INSTITUTE, April 2014.

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Implantable Devices

Active Medical Devices

Clinical Considerations

- Over 5000 recalls reported to the FDA's Manufacturer and user Facility Device Experience (MAUDE) database (2006-2011).
- Approximately 1.2 million adverse events related to medical devices reported.

Communications of the ACM, October 2013;vol 56:10.

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Implantable Devices

Active Medical Devices

Clinical Considerations

- Nearly one fourth (23%) of the recalls resulted from computer related failures.
- The vast majority (94%) of the events represented a medium to high risk of serious injury or death.

Communications of the ACM, October 2013;vol 56:10.

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Implantable Devices

Internet of Things (IoT)

Clinical Considerations

- Medical hacking is a relatively new topic.
- Most medical devices have little or no intrinsic security.
- Balance must be struck between security and patient safety.

H@cking Implantable Medical Devices. INFOSEC INSTITUTE, April 2014.

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Implantable Devices

Internet of Things (IoT)

Clinical Considerations

- Steel multiplace chambers may function as a Faraday cage.
- May result in loss of wireless communication with device and impact:
  - Command and control
  - "Phone home" capabilities

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Implantable Devices

Implantable Cardiac Pacemakers

Increasing Incidence of Implantation

- More than 200,000 pacemakers are implanted annually in the U.S.
- Atrioventricular block and sinus node disease remain the most common indications for implantation
- Other indications have emerged
  - Neurocardiogenic syncope
  - Cardiac resynchronization therapy

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Implantable Devices

Implantable Cardiac Pacemakers

Technological Advancement

- First patented artificial pacemaker (1932)
- Intracardiac leadless pacemaker (2014)

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Implantable Devices

Implantable Cardiac Pacemakers

Leadless Pacemaker (LP)

- Eliminates vascular injury
- Decreases infection rates
- Decreases radiation exposure
- Preserves vascular access
- Eliminates catheter related failures

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Implantable Devices

Implantable Cardiac Pacemakers

Leadless Pacemaker (LP)

- Decreases risk of pneumothorax
- Extraction and replacement of device facilitated.
- Medtronic Micra® approved for pressures up to 4 ATA.
- St. Jude Nanostim® has not been formally pressure tested.

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Implantable Devices

Implantable Cardiac Pacemakers

Approach to the Patient

- Observe pressure limits for pacemakers.
- Consult manufacturer for pressure restrictions.
- Turn rate-sensing feature to "Off" if applicable – pressure sensitive.
- Consider the use of continuous ECG monitoring.

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Implantable Devices

Implantable Cardiac Cardioverters - Defibrillators

High Energy Device

- Potential increased risk of fire within the monoplace environment
- Controversies have arisen due to pulse generator / ICD
- Multiple problems have been reported with respect to lead defects.

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Implantable Devices

Implantable Cardiac Cardioverters - Defibrillators

Increasing Incidence of Implantation

- ICD implantation has increased annually some 20 fold over the past 15 years.
- Indicated in patients at risk for life threatening ventricular dysrhythmias
  - Ischemic heart disease
  - Cardiomyopathy

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Implantable Devices

Implantable Cardiac Defibrillators

Electrical Injury

- The American Heart Association nor the International Liaison Committee on Resuscitation offer no formal statement.
- Patient contact during ICD discharge does not pose a safety risk:
  - British Heart Foundation
  - Arrhythmia Alliance
  - UK Joint Royal Colleges Ambulance Liaison Committee
  - European Resuscitation Council
  - Equipment Manufacturers
  - Various Journal Articles

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Implantable Devices

Implantable Cardiac Defibrillators

Electrical Injury

- Diez (2008) – Insulation defects led to multiple arc marks within the ICD pocket and there was a short circuit between denuded leads and the electrically active pulse generator.
- The high current flow generated sufficient heat to damage several circuits of the generator.

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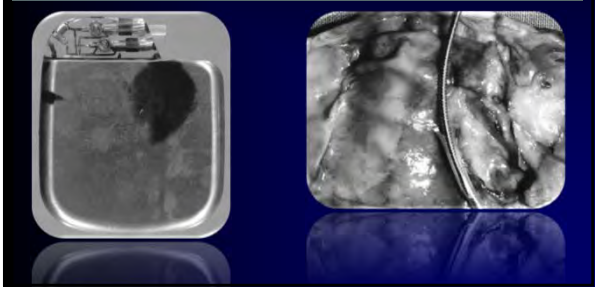
Implantable Devices

Implantable Cardiac Defibrillators

Electrical Injury



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Implantable Devices

Implantable Cardiac Defibrillators

Electrical Potential

- Peters (1998) – "…a considerable potential difference can be detected on the body surface of patients during discharges of transvenous active can ICD systems."

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Implantable Devices

Implantable Cardiac Defibrillators

Electrical Potential

- The maximum device output could be as high as 66.75mA which would yield a theoretical power of 6.07 Watts.
- NFPA 99 (2012) guidelines call for equipment within the hyperbaric environment to produce less than 4 Watts of power – a 150% increase.

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Implantable Devices

Implantable Cardiac Defibrillators

Lead Failures

- Failures most common in pace-sense leads (81%)
- May generate spurious signals leading to multiple inappropriate shocks

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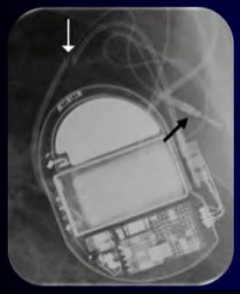
Implantable Devices

Implantable Cardiac Defibrillators

Lead Fracture



- Lead fracture (white arrow)
- Lead disconnection (black arrow)

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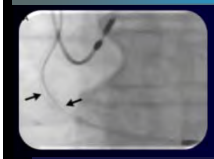
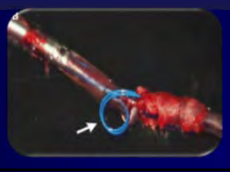
Implantable Devices

Implantable Cardiac Defibrillators

Lead Fracture/Failures



- Lead fractures or failures are relatively common
- Results from excessive torsional forces



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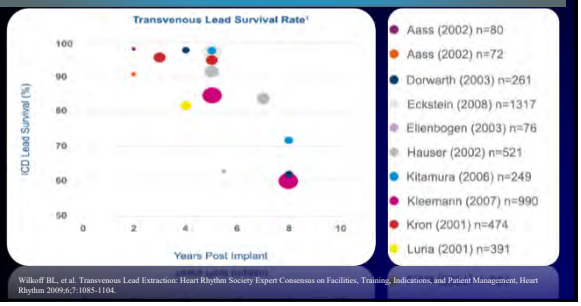
Implantable Devices

Implantable Cardiac Defibrillators

Lead Failures



Wilkoff BL, et al. Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management, Heart Rhythm 2009;6;7:1085-1104.

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Implantable Devices

Implantable Cardiac Defibrillators

Sprint Fidelis® Lead

- ~ 150,000 patients in the US have these leads.
- Pace-sense lead most commonly affected leading to inappropriate shocks.
- In general risk increases over time – 40% after 8 years.

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Implantable Devices

Implantable Cardiac Defibrillators

Lead Fracture/Failures

- Devices should be interrogated prior to treatment
- High lead impedance is indicative of fracture

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Implantable Devices

Implantable Cardiac Defibrillators

Subcutaneous ICD (S-ICD)

- Eliminates vascular injury
- Less potential for infection
- Preserves venous access
- Decreased fluoroscopy time
- Less catheter related issues

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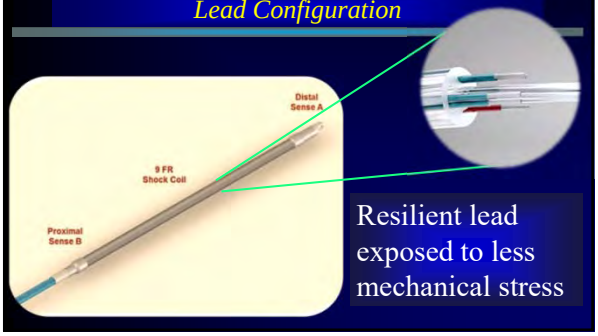
Implantable Devices

Subcutaneous Cardiac Defibrillator

Lead Configuration



Resilient lead exposed to less mechanical stress

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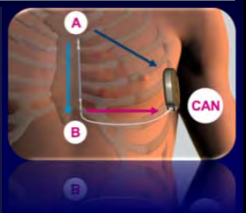
Implantable Devices

Implantable Cardiac Defibrillators

Subcutaneous ICD

- Sensing is primarily from A to B on lead.
- Secondary sensing may occur from lead electrodes and the active can.
- Adaptive shock polarity (lead to can or can to lead)



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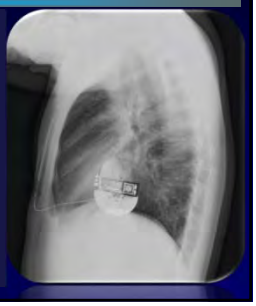
Implantable Devices

Implantable Cardiac Defibrillators

Subcutaneous ICD

- Adaptive shock polarity (lead to can or can to lead)
- Output 80J biphasic – 3 fold greater than TV ICD
- 1 to 5 shocks per series



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Implantable Devices

Implantable Cardiac Defibrillators

Magnet Deactivation

- Deactivation of ICD does not affect pacing function.
- ICD remains deactivated as long as the magnet is in place.
- An audible tone may be heard to signal deactivation – may be continuous.

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Implantable Devices

Implantable Cardiac Defibrillators

Magnet Deactivation Emblem® S-ICD

- Magnet location depends on model
- Magnet should be placed over the device header or lower edge.

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Implantable Devices

Implantable Cardiac Defibrillators

Approach to the Patient

- Observe recommended pressure limits.
- Interrogate the device to assure proper functioning and lead integrity.
- Assure proper patient and chamber grounding where applicable.

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Implantable Devices

Implantable Cardiac Defibrillators

Approach to the Patient

- Consider magnet deactivation for patients with ICDs in the monoplace environment
- Utilize continuous electrocardiographic monitoring.
- Resuscitative equipment should be readily available.

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Implantable Devices

Implantable Pulmonary Artery Pressure Monitor

CardioMEMS®

- First FDA-approved heart failure monitor.
- Measures pulmonary artery pressure.
- Significantly reduces hospital admissions.

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Implantable Devices

Implantable Pulmonary Artery Pressure Monitor

CardioMEMS®

- Encrypted wireless transmission of data through internet connection
- Wireless, battery-free device
- Approved for pressures up to 2 ATA without alteration in calibration.

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Implantable Devices

Implantable Cardiac Monitor

Reveal LINQ™

- Smallest implantable monitor
- Functional life of 3 years
- Wireless transmission of rhythm
- Approved for up to 4 ATA

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Implantable Devices

Biosensors

Continuous Glucose Monitors

- Billion-dollar industry
- Multiple devices approved
- Accuracy and compatibility within the hyperbaric hyperoxic environment
- Safety considerations
- Closed loop systems available

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Implantable Devices

Biosensors

Continuous Glucose Monitors

- Electro-chemical assays
  - Glucose oxidase
  - Glucose dehydrogenase
- Photometric
  - Fluorescence

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Implantable Devices

Continuous Glucose Monitors

Glucose Oxidase

- Glucose oxidase

$$\text{Glucose} + \text{GOx} - \text{FAD}^{+} \longrightarrow \text{Glucolactone} + \text{GOx} - \text{FADH}_2$$

$$\text{GOx} - \text{FADH}_2 + \text{O}_2 \longrightarrow \text{GOx} - \text{FAD} + \text{H}_2\text{O}_2$$

$$\text{H}_2\text{O}_2 \longrightarrow 2\text{H}^{+} + \text{O}_2 + 2\text{e}^{-}$$

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Implantable Devices

Continuous Glucose Monitors

Glucose Dehydrogenase

- Glucose Dehydrogenase
  - GDH-pyrroquinolinequinone (PDQ)
  - GDH-nicotinamide-adenine dinucleotide (NAD)

$$\text{Glucose} + \text{NAD}^{+} \longrightarrow \text{Gluconolactone} + \text{NADH}$$

$$\text{NADH} \longrightarrow \text{NAD}^{+} + \text{H}^{+} + 2\text{e}^{-}$$

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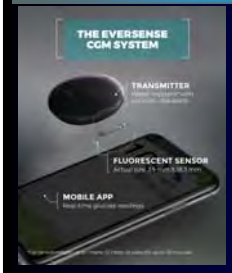
Implantable Devices

Biosensors

Eversense® Glucose Monitors



- First FDA approved subcutaneous CGM
- Detachable transmitter
- Compatible with smart devices

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Implantable Devices

Biosensors

Eversense Glucose Monitors - Sensor

- Sensor contains no battery
- Powered wirelessly from transmitter
- Photometric (fluorescence) analysis
- Utilizes near-field (NFC) communication
- Sensor implanted every 90 days

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Implantable Devices

Biosensors

Eversense Glucose Monitors - Transmitter

- Transmitter utilizes a silicone adhesive
- Removal of transmitter doesn't affect the sensor
- Rechargeable battery last 36 hours/charge
- IP67 water resistant (1 meter for up to 30 minutes)

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Implantable Devices

Biosensors

Eversense Glucose Monitors

- "We do not have a controlled test for performance characterization either in the hyperbaric chamber or after exposure to hyperbaric chamber.
- Based on the characteristics of the sensor, at present, there is no known mechanism to cause damage to the sensor such as to result in a safety concern.
- We do not have test data, which characterizes the performance after the hyperbaric chamber treatment. Any drop in performance can however be monitored with a fingerstick calibration over a few days after the hyperbaric treatment."

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Implantable Devices

Biosensors

Eversense Glucose Monitors - Summary

- Sensor not pressure tested by the manufacturer
- Implanted sensor is probably OK for pressure exposure.
- Accuracy under hyperbaric conditions not tested
- Transmitter must be removed
- Accuracy should be assessed by fingerstick blood sugars

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Implantable Devices

Biosensors

Dexcom® G6 Glucose Monitor

- Comprised of sensor, transmitter, and receiver
- Transmitter contains a 3V, 130 mAh (0.39 W) lithium manganese dioxide battery
- Circuit boards are fully encapsulated in epoxy
- Autoclaved at 90 psi at 40°C for up to 72 hours

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Implantable Devices

Biosensors

Dexcom® G6 Glucose Monitor

- Utilizes glucose oxidase reaction
- Hermetically sealed in epoxy
- Exposed electrical contacts
- Bluetooth communications

Bliss C, et al. UHM 2020, Vol. 47 No. 1 – *Continuous glucose monitoring during HBO2 therapy.*

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Implantable Devices

Biosensors

Dexcom® G6 Glucose Monitor - Testing

- Multiplace chamber
- $FiO_2 \leq 23.5\%$
- Six transmitters attached to EGVGs
- Underwent 11 serial two-hour pressurizations to 2.4 ATA.

Bliss C, et al. UHM 2020, Vol. 47 No. 1 – *Continuous glucose monitoring during HBO2 therapy.*

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Implantable Devices

Biosensors

Dexcom® G6 Glucose Monitor - Testing

- Simulated glucose values were recorded during hyperbaric exposures.
- EGVGs were set to report values within:
  - a hypoglycemic range (<70 mg/dL)
  - a euglycemic range (80-140 mg/dL)
  - a hyperglycemic range (>180 mg/dL)

Bliss C, et al. UHM 2020, Vol. 47 No. 1 – *Continuous glucose monitoring during HBO2 therapy.*

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Implantable Devices

Biosensors

Dexcom® G6 Glucose Monitor - Testing

- Receivers (smartphone) were kept outside the chamber.
- Receivers were tested at distance of ~ 20 ft.

Bliss C, et al. UHM 2020, Vol. 47 No. 1 – *Continuous glucose monitoring during HBO2 therapy.*

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Implantable Devices

Biosensors

Dexcom® G6 Glucose Monitor - Results

- No issues with Bluetooth connectivity to receiver through the chamber hull or port windows.
- Recorded glucose values remained unchanged for the series of 11 two hour exposures.
- Post HBO evaluation with no noted device issues

Bliss C, et al. UHM 2020, Vol. 47 No. 1 – *Continuous glucose monitoring during HBO2 therapy.*

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Implantable Devices

Biosensors

Dexcom® G6 Glucose Monitor - Results

- "The CGM transmitter meets section 14.2.9.3.17.5 of the 2018 NFPA 99 requirements for battery-operated devices allowed for use in a hyperbaric environment."
- "This analysis revealed no significant safety concerns with subjecting Dexcom G6 CGM transmitters to hyperbaric environments."

Bliss C, et al. UHM 2020, Vol. 47 No. 1 – *Continuous glucose monitoring during HBO2 therapy.*

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Implantable Devices

Biosensors

Dexcom® G6 Glucose Monitor - Closed Loop System

- Insulin pumps are not approved for hyperbaric hyperoxic exposure
- Insulin dosing changes have been demonstrated with insulin pumps with changes of 0.3 ATA

Bertuzzi F, et al. Unintended insulin pump delivery in hyperbaric conditions. *Diabetes Technology & Therapeutics*, Vol 19, No. 4, 2017

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Implantable Devices

Non-electrical Devices

Mechanical Considerations

- Non-electrically powered devices subjected to mechanical forces leading to stress/strain.
- Loss of function, decreased longevity, or overt structural failure may result.

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Implantable Devices

Air/Gas-filled Devices

Mechanical Considerations

- Gas–filled devices will typically obey Boyle's Law.
- Volume changes of the device may lead to untoward patient consequences.
- Device failure may occur if structural design is inadequate.

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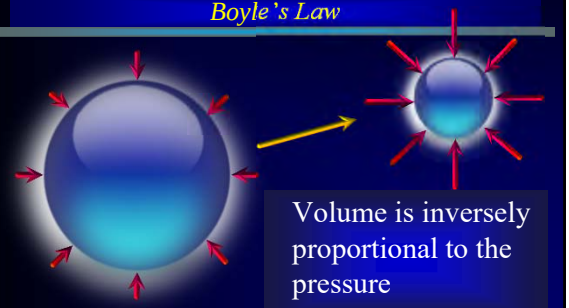
Implantable Devices

Gas-filled Devices

Boyle's Law



Volume is inversely proportional to the pressure

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Implantable Devices

Gas-filled Weight Loss Devices

Obalon Gastric Balloons

- Swallowable by patient
- Up to 3 balloons are inflated by a thin micro catheter
- Filled with a proprietary patented blend of gases – Nitrogen-sulfur hexafluoride

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Implantable Devices

… Gas-filled Devices

HBO and Exotic Gas Blends

- Will result in loss of volume and possible collapse under pressure – Boyle's Law.
- Migration of the balloons distally in the GI tract
- Possible intestinal obstruction or perforation of a hollow viscus upon decompression

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Implantable Devices

Gas-filled Weight Loss Devices

Obalon®

- "Do not place balloons if the patient expects to permanently reside at an elevation > 4000ft or < 2500ft from balloon placement elevation."
- "Patients should not undertake scuba diving or travel in unpressurized airplane cabin."

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Implantable Devices

Gas-filled Devices

Capsule Endoscopy

- Self-contained device first approved in the US in 2001.
- Contains a camera, LED light source, battery, RF transmitter, and antenna

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Implantable Devices

Gas-filled Devices

Capsule Endoscopy

- PillCam acceptable pressure operating range: 10.2 - 15.4 psia (0.69 – 1.05 ATA)
- Other device likely to have similar pressure constraints.

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Implantable Devices

Capsule Endoscopy

Approach to the Patient

- Non-emergent HBO should be held until device passes.
- ASGE guidelines:
  - If not passed > 2 weeks, device should be endoscopically or surgically removed

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Implantable Devices

Fluid-filled Devices

Mechanical Considerations

- Fluid–filled devices will typically obey Pascal's Law
- Device volume will not change with increases in ambient pressure
- Transmural wall stress is not expected to change with constant radius of curvature.

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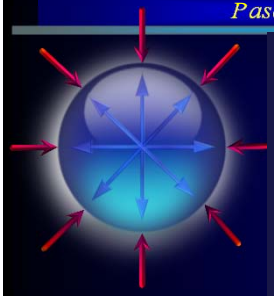
Implantable Devices

Fluid-filled Devices

Pascal's Law



"pressure exerted anywhere in a confined incompressible fluid is transmitted equally in all directions throughout the fluid such that the pressure ratio (initial difference) remains the same."

Bloomfield, Louis (2006). *How Things Work: The Physics of Everyday Life (Third Edition)*. John Wiley & Sons. pp. 153.

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Implantable Devices

Fluid-filled Devices

Pascal's Law

- Trieste filled with gasoline for buoyancy
- Fluid-filled to prevent implosion
- Withstood ~1086 ATA at ~ 36,000 fsw

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Implantable Devices

Fluid-filled Devices

Fluid-filled Reservoir

- Transmural pressure ($P_{inside} - P_{outside}$) unchanged with changes in ambient pressure according to Pascal's Principle.
- Volume changes and mechanical stress on the device are not expected.

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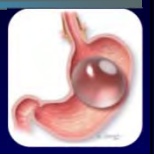
Implantable Devices

Fluid-filled Weight Loss Devices

Orbera® and Penile Implants

- Devices inflated with sterile water to occupy space within the stomach.
- Non-compressible medium removes risk of volume changes.
- Transmural pressures are not expected to change.



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Implantable Devices

Penile Implants

Fluid-filled Reservoir

- Penile system with fluid-filled reservoir in the pelvis and scrotal pump.
- No effect secondary to ambient pressure

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Implantable Devices

Devices with an Internal Void or Reservoir

Electronic and Mechanical Considerations

- Electronic components may have similar problems as other active implantable devices.
- A void within the device may lead to mechanical stresses leading to deformation or failure.

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Implantable Devices

Medication Delivery Systems

Implantable Pumps

- Intrathecal pumps
  - Anti-spasmodic drugs
  - Opioid analgesics
  - Alpha adrenergic agents
- Intra-arterial pumps
  - Chemotherapeutic drugs for primary liver cancer
  - Colon cancer with liver metastases.

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Implantable Devices

Medication Delivery Systems

Intrathecal Pumps

- Battery-powered pump
- Refillable drug reservoir
- Programmable logic for sophisticated dosing regimens

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Implantable Devices

Medication Delivery Systems

Hyperbaric Therapy

- Pressures greater than 2.0 ATA could result in pump damage.
- Reservoir should be filled to capacity prior to exposure to hyperbaric conditions.

SYNCHROMED® and ISOMED® Implantable infusion systems Information for Prescribers

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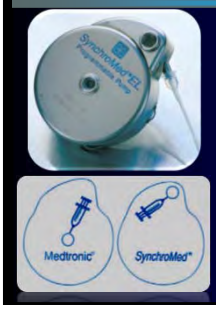
Implantable Devices

Medication Delivery Systems

Refilling Errors



- Utilize the appropriate template for accessing the *reservoir refill port* vs. the *catheter access port*.
- Strictly adhere to manufacturer's refilling procedures

Medication Safety Alert © 2005 Institute for Safe Medication Practice

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Implantable Devices

Medication Pumps

Approach to the Patient

- Before exposure to hyperbaric pressures, patients should discuss the effects of high pressure with their physician – *informed consent*.
- As pressure increases, pump flow decreases.

SYNCHROMED® and ISOMED® Implantable infusion systems Information for Prescribers

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Implantable Devices

Medication Pumps

Approach to the Patient

- Continued pressure increases will eventually result in a loss of or change in therapy.
- May lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug *underdose*.

SYNCHROMED® and ISOMED® Implantable infusion systems Information for Prescribers

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Implantable Devices

Ventriculo-Peritoneal Shunt

Hyperbaric Therapy

- Programmable VP Shunt
- Pressure settings from 30 to 200mmH_2O.
- Obviates the need for operative shunt revision.

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Implantable Devices

Programmable Ventriculo-Peritoneal Shunt

Hyperbaric Therapy

- Multiple configurations available.
- No intrinsic power supply
- Fluid-filled catheter and reservoir.

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Implantable Devices

Programmable Ventriculo-Peritoneal Shunt

Hyperbaric Therapy

- Programming via external controller.
- Not formally pressure tested.
- Manufacturer reports no malfunctions in known exposures to HBO.

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Implantable Devices

Fluid-filled Device

Breast Implants

- Breast implants with fluid-filled reservoir (saline or silicone) respond according to Pascal's Principle.
- Transmural pressure ($P_{inside} - P_{outside}$) unchanged with changes in ambient pressure.

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Implantable Devices

…breast implants

Exposure to Pressure

- Grippaudo (2002) – subjected breast implants to 40 simulated recreational dives.
- Goal was to determine if implants exposed to elevated pressure results in structural or conformational changes.

Grippaudo FR. Mammary implants: laboratory simulation of recreational diving conditions. *British J. Plastic Surgery*. 2002;55:120-123.

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Implantable Devices

…breast implants

Exposure to Pressure

- Dive profiles were to 39m twice daily with an 8 hour surface interval between dives for a total of 20 days.
- Staged decompression was carried out in accordance with US Navy tables.
- Implants were inspected for integrity and CT scans were performed after all dive were completed.

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Implantable Devices

…breast implants

Exposure to Pressure

- No shell ruptures were noted.
- No changes in volume were noted.
- Conformational changes were noted in the cohesive gel implants.

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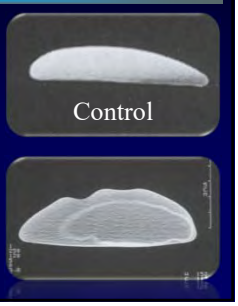
Implantable Devices

Breast Implants

Changes with Pressure

Distortion of cohesive implants remained after 12 months.

Repetitive stress leading to distortion may decrease the lifespan of the implants.



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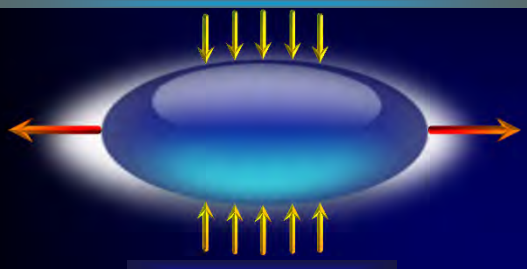
Implantable Devices

Fluid-filled Devices

Unequal Application of Pressure



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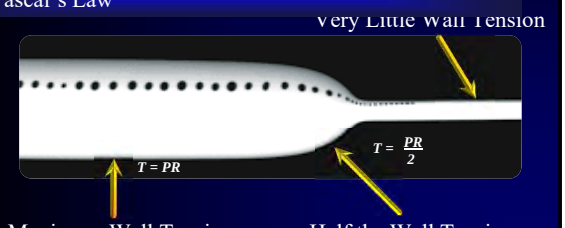
Implantable Devices

Fluid-filled Devices

Laplace's Law

Pressure is equal throughout the balloon according to Pascal's Law



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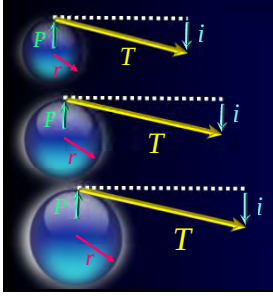
Implantable Devices

Fluid-filled Devices

Wall Tension and Radius



- For any given internal pressure (*P*), the inward component of the wall tension (*i*) must be equal at equilibrium.
- Wall tension (*T*) increases with increasing radius (*r*)

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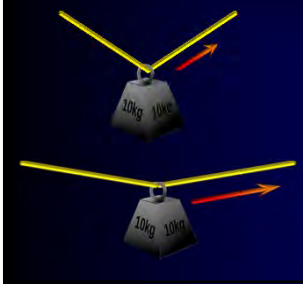
Implantable Devices

Fluid-filled Devices

Suspended Mass Analogy



Less sag in the suspending cable requires greater tension to be applied.

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Implantable Devices

Fluid-filled Devices

Unequal Application of Pressure

- Shape deformation
- Increased areas of wall stress
- Increased structural strain

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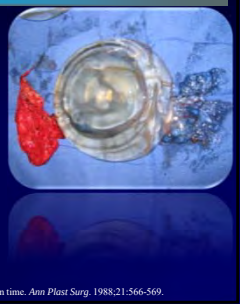
Implantable Devices

Breast Implants

Implant Rupture

- Van Rappard (1988) tested the breaking strength of silicone gel implants.
- Negative correlation between pressure resistance and the duration of implantation.



Van Rappard JHA. Pressure resistance of breast implants as a function of implantation time. *Ann Plast Surg*. 1988;21:566-569.

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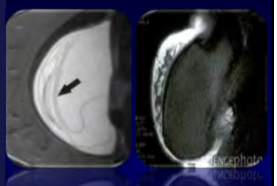
Implantable Devices

Breast Implants

Implant Rupture

- Peters (1981) tested the breaking strength of silicone gel implants.
- Compression breaking strength varied from 0.62 – 10.8 psi.



Peters WJ. The mechanical properties of breast prostheses. *Ann Plast Surg*. 1981;6:179-181.

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Implantable Devices

Silicone Devices

Gas Permeability Across a Silicone Membrane

Gas	Permeability x 10^9 $cm^3 \cdot cm/(sec \cdot cm^2 \cdot cmHg)$	Diffusivity x 10^6 cm^2/sec	Solubility $cm^3(STP)/cm^3 \cdot atm$
H_2	65	43	0.12
He	35	60	0.045
CO_2	323	11	2.2
N_2	28	15	0.15
O_2	62	16	0.31
CH_4	95	13	0.57

Zhang, H. "Global Advances in Materials and Process Engineering", proceedings, Coatings and Sealants Section, November 6-9, 2006, Dallas, TX.

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Implantable Devices

Breast Implants

Patient Considerations

- Capsular contractures may convey an asymmetric pressure on implants.
- Reconstruction patients are at higher risk for rupture.
- Older implants may have already ruptured.
- Silicone's high oxygen permeability may have some chemical influence on the implant integrity.

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Implantable Devices

Breast Implants

Patient Considerations continued

- Ruptured detection is difficult by physical exam.
- Consider pretreatment MRI.
- Obtain an adequate informed consent

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Implantable Devices

…In Summary

- A growing number of sophisticated IMDs are becoming available.
- Functional changes related to hyperbaric pressures and/or oxygen should be understood.
- Wireless communication with devices must be considered.
- Device pressure limits should be observed.

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Implantable Devices

…In Summary

- Proper filling of implantable pumps prior to exposure to pressure.
- Consider deactivation of ICDs in the monoplace setting.
- Proper monitoring should be instituted to determine a device malfunction where feasible.
- Appropriate use of HBO requires a clinical determination of the risk of treatment vs. the benefit.

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Implantable Devices

…Questions?

Thank You

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