Implantable Medical Devices

D. Lindsie Cone, MD, UHM, FUHM

Implantable Devices

In the Hyperbaric Environment

Primary Training Course

1

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

2

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)

3

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.

4

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

5

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.

6

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.

7

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

8

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.

9

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.

10

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.

11

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.

12

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

13

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

14

Implantable Devices

Implantable Cardiac Pacemakers

Technological Advancement

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

15

Implantable Devices

Implantable Cardiac Pacemakers

Leadless Pacemaker (LP)

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

16

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.

17

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.

18

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.

19

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

20

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

21

Implantable Devices

Implantable Cardiac Defibrillators

Electrical Injury

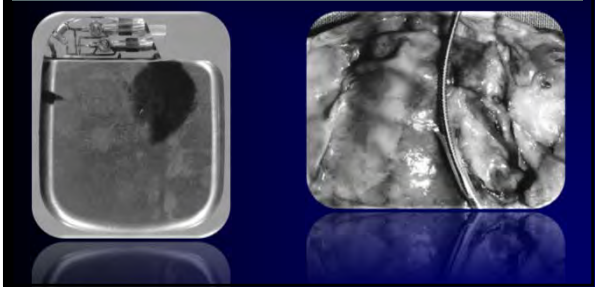
- Diez (2008) – Insulation defects led to multiple arc marks within the ICD pocket and there was a short circuit between denuded leads and the electrically active pulse generator.
- The high current flow generated sufficient heat to damage several circuits of the generator.

22

Implantable Devices

Implantable Cardiac Defibrillators

Electrical Injury



23

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."

24

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.

25

Implantable Devices

Implantable Cardiac Defibrillators

Lead Failures

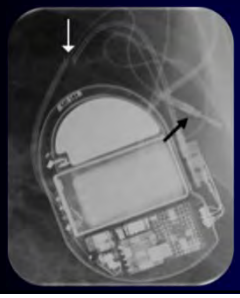
- Failures most common in pace-sense leads (81%)
- May generate spurious signals leading to multiple inappropriate shocks

26

Implantable Devices

Implantable Cardiac Defibrillators

Lead Fracture



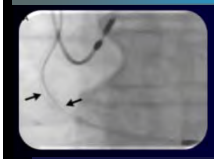
- Lead fracture (white arrow)
- Lead disconnection (black arrow)

27

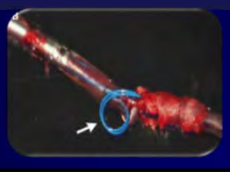
Implantable Devices

Implantable Cardiac Defibrillators

Lead Fracture/Failures



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

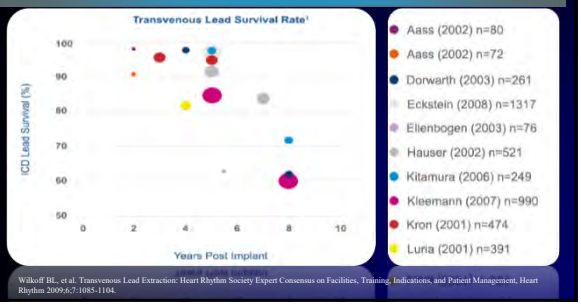


28

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.

29

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.

30

Implantable Devices

Implantable Cardiac Defibrillators

Lead Fracture/Failures

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

31

Implantable Devices

Implantable Cardiac Defibrillators

Subcutaneous ICD (S-ICD)

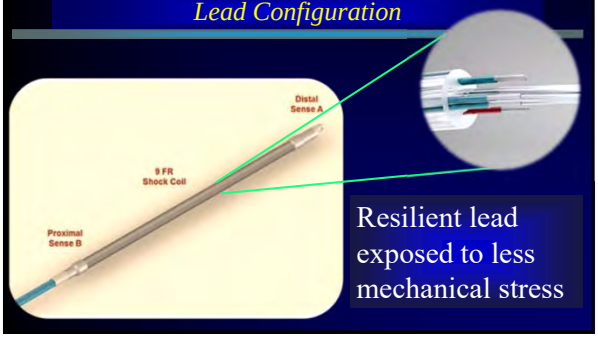
- Eliminates vascular injury
- Less potential for infection
- Preserves venous access
- Decreased fluoroscopy time
- Less catheter related issues

32

Implantable Devices

Subcutaneous Cardiac Defibrillator

Lead Configuration



Resilient lead exposed to less mechanical stress

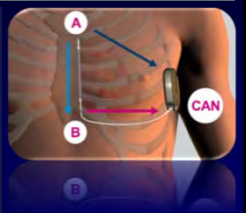
33

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)



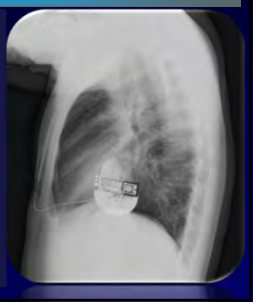
34

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

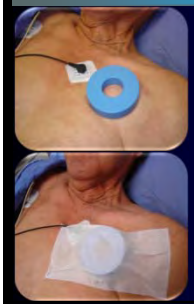


35

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.

36

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.

37

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.

38

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.

39

Implantable Devices

Implantable Pulmonary Artery Pressure Monitor

CardioMEMS®

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

40

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.

41

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

42

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

43

Implantable Devices

Biosensors

Continuous Glucose Monitors

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

44

Implantable Devices

Continuous Glucose Monitors

Glucose Oxidase

- Glucose oxidase

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

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

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

45

Implantable Devices

Continuous Glucose Monitors

Glucose Dehydrogenase

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

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

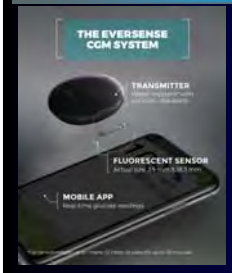
$$\text{NADH} \longrightarrow \text{NAD}^{+} + \text{H}^{+} + 2\text{e}^{-}$$

46

Implantable Devices

Biosensors

Eversense® Glucose Monitors



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

47

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

48

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)

49

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."

50

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

51

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

52

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.*

53

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.*

54

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.*

55

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.*

56

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.*

57

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.*

58

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

59

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.

60

Implantable Devices

Air/Gas-filled Devices

Mechanical Considerations

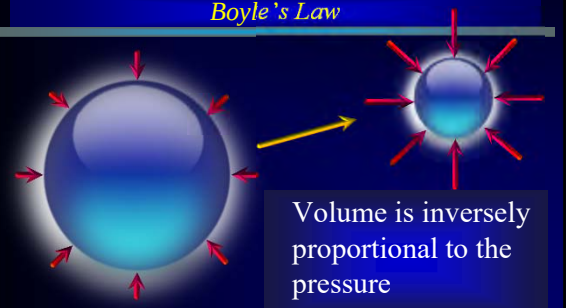
- Gas–filled devices will typically obey Boyle's Law.
- Volume changes of the device may lead to untoward patient consequences.
- Device failure may occur if structural design is inadequate.

61

Implantable Devices

Gas-filled Devices

Boyle's Law



Volume is inversely proportional to the pressure

62

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

63

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

64

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."

65

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

66

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.

67

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

68

Implantable Devices

Fluid-filled Devices

Mechanical Considerations

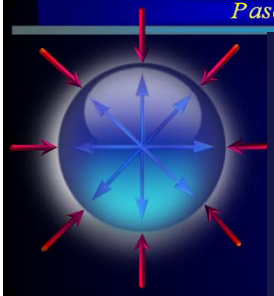
- Fluid–filled devices will typically obey Pascal's Law
- Device volume will not change with increases in ambient pressure
- Transmural wall stress is not expected to change with constant radius of curvature.

69

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.

70

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

71

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.

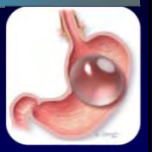
72

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.



73

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

74

Implantable Devices

Devices with an Internal Void or Reservoir

Electronic and Mechanical Considerations

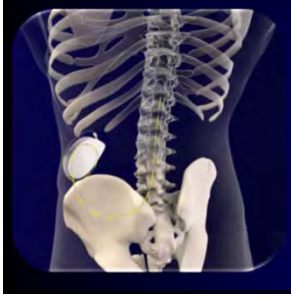
- Electronic components may have similar problems as other active implantable devices.
- A void within the device may lead to mechanical stresses leading to deformation or failure.

75

Implantable Devices

Medication Delivery Systems

Implantable Pumps



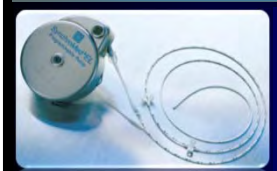
- Intrathecal pumps
  - Anti-spasmodic drugs
  - Opioid analgesics
  - Alpha adrenergic agents
- Intra-arterial pumps
  - Chemotherapeutic drugs for primary liver cancer
  - Colon cancer with liver metastases.

76

Implantable Devices

Medication Delivery Systems

Intrathecal Pumps



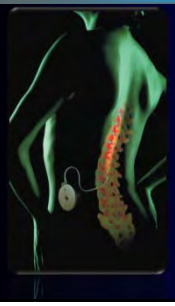
- Battery-powered pump
- Refillable drug reservoir
- Programmable logic for sophisticated dosing regimens

77

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.

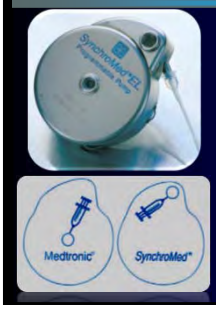
SYNCHROMED® and ISOMED® Implantable infusion systems Information for Prescribers

78

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

79

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

80

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

81

Implantable Devices

Ventriculo-Peritoneal Shunt

Hyperbaric Therapy

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

82

Implantable Devices

Programmable Ventriculo-Peritoneal Shunt

Hyperbaric Therapy

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

83

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.

84

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.

85

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.

86

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.

87

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.

88

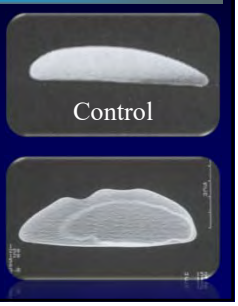
Implantable Devices

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.

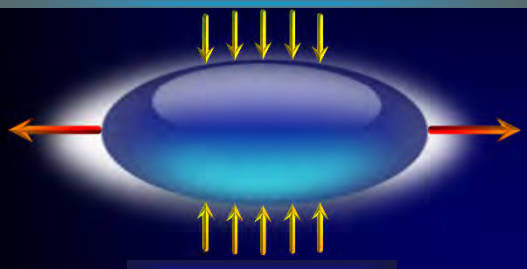


89

Implantable Devices

Fluid-filled Devices

Unequal Application of Pressure



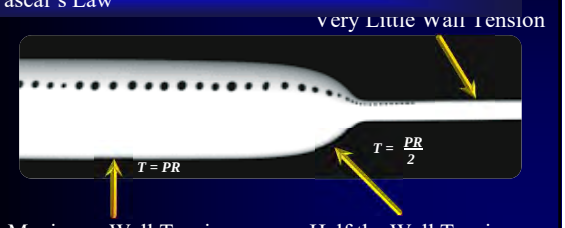
90

Implantable Devices

Fluid-filled Devices

Laplace's Law

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

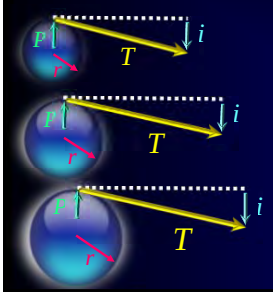


91

Implantable Devices

Fluid-filled Devices

Wall Tension and Radius



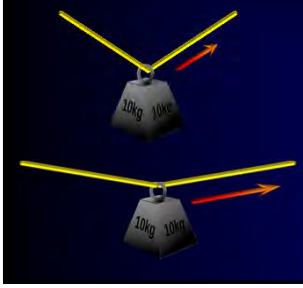
- For any given internal pressure (*P*), the inward component of the wall tension (*i*) must be equal at equilibrium.
- Wall tension (*T*) increases with increasing radius (*r*)

92

Implantable Devices

Fluid-filled Devices

Suspended Mass Analogy



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

93

Implantable Devices

Fluid-filled Devices

Unequal Application of Pressure

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

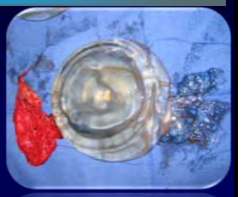
94

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.

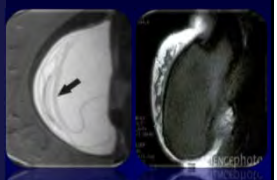
95

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.

96

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.

97

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.

98

Implantable Devices

Breast Implants

Patient Considerations continued

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

99

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.

100

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.

101

Implantable Devices

…Questions?

Thank You

102