Central Venous Cannulation: Venous Entry Device

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Central Venous Cannulation: Venous Entry Device

- Overview / Background
- Market
- Connector Design and Production
- Handle Design and Production
- Pressure Sensor Design
- Simulator Design
- Validation and Verification
Central Venous Cannulation

• Definition: Insertion of a catheter into a vein leading directly to the heart (Internal jugular most common)

• Purpose:
  • Administer IV fluids when no peripheral veins are accessible
  • Administer drugs that cannot be given peripherally (Vasodilation/constriction drugs)
  • Measurement of central venous pressure
Problems

Steps 1 - 3:

1. Needle inserted into IJ
   - Bulky syringe: physician discomfort, mistakes lead to multiple insertions, lead to infection

2. Tubing connected to check venous entry
   - Blood exposed when removing syringe from needle: infection
   - Significant free space needed to lower and raise tubing
   - Blood exposed during lowering and raising: infection

3. Guide wire inserted into vein through needle
   - Needle short and light, difficult to keep steady while inserting guide wire: complex
Market

By the numbers:

- 5 million CVC procedures per year
- 2,013 incidents of infection every 1,000 patients (year 2000)
- = 10,000 procedures complicated by infection.

- CVC complications costs: $6,000 to $90,000 per patient

- Estimating $10,000 per complication, yearly expenses: $100 million

Vast majority of infections occur during steps 1 – 3...

Solution: Combine these 3 steps!

Device Design

• The design must address the issues which cause complications with the current CVC method

• New design consists of three parts:
  • A three way connector with a one way valve
  • A handle
  • A pressure sensor
Intended Final Device Design

Current device with circuit pressure sensor

Intended device with miniaturized pressure sensor
Three Way Connector

- Provides ports for needle, sensor, and handle
- Handle and needle are in line with each other
- Pressure sensor is perpendicular
- Clear plastic casing for visualizing blood flow
  - Currently SLA
Three Way Connector

- The internal cavity allows blood flow from the vessel
- A duckbill check valve fits into the back port
  - Guide wire can be inserted through valve
Support Handle

• Provides a counter weight to rest on the clinician’s hand
  • Does not require awkward hand positions
  • Allows the clinician more mobility
  • Increased comfort should lead to reduced error in placement
Handle Prototypes

Initial clinician feedback indicated a screw driver-like handle to be held as a pencil would provide comfort and stability.

Clinician feedback: Too fat
Clinician feedback: Too long

Less moment arm, more control

Clinician feedback: Too light
Just right
Device Prototype Production

- Current prototype was fabricated at the Swanson Center by stereo lithography
- Suggested final three-way connector material: polyethylene
  - Cheap
  - Easy to grip firmly with latex gloves
  - Transparent for visualizing blood flow
  - Easily sterilized
- Suggested final support material: rubber coated high density polyethylene
Pressure Sensor

• Key aspect of device design
  • Eliminates syringe
  • Eliminates additional pressure checking step
  • Provides continuous pressure readings to clinician
Pressure Sensor

• Currently the PX05 Pressure Sensor from Omega
  • Tubing from the pressure sensor port allows blood to flow to the sensor
  • Transducer has a voltage output that can be read through LabVIEW
  • LabVIEW converts the voltage to pressure and then provides an output to the display
Pressure Sensor

- Images of the current circuit (bottom) and the LabVIEW readout (right)
Pressure Sensor

Current Pressure Sensor Schematic

Desired Pressure Sensor Display
Pressure Sensor

- Eventually all parts of the pressure sensor circuit can be incorporated on an FPGA chip and fit into the small display case

http://zone.ni.com/devzone/cda/tut/p/id/3357
Proof of Concept of the Pressure Sensor

- Can the pressure sensor distinguish high (~80mmHg) from low (~7mmHg) i.e. above/below 30 mmHg?
- Need to simulate arterial and venous pressures to test this goal
Pressure Generating Apparatus

- To give control over a range of pressures & pulsatility

- Venous pressure:
  - IV bag of known height: to generate pressure following $P = \rho gh$ (estimate!)

- Arterial pressure:
  - 2 IV bags of different heights (same concept)
  - Connect to a solenoid valve to switch between the two and thus create pulsatility

- Verify the pressures/pulsatility from the simulator using a Patient monitor from Dr. Timothy Maul
Pressure Generating Apparatus

IV bags at different heights to create different pressures

Solenoid Valve

Labview Display

“Vein”

“Artery”

Tru-Waves

Pressure Sensor

Spacelabs Patient Monitor
Demonstration Video
Verification of Device

• Goal is for it to correctly distinguish between high and low pressures >90% of the time over a range of pressures
  • Tested both arterial and venous at different heights
  • Compare our LabView display with the patient monitor to verify that the pressures are correct (within 4mmHg)

<table>
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<th>Correct Pressures</th>
<th>Incorrect Pressures</th>
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<th>Incorrect Light</th>
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<tr>
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<td>1</td>
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Results: Correct pressure identification in 21 out of 22 trials (95.5% success rate)
How Does it Compare to the PDS?

- Original goals:
  - Differentiate High/Low pressure
  - Recognize pulsatility
  - Display Waveform
  - LED display
  - Ergonomic handle
  - Cost: no greater than $5 more
  - Fit within 1x1 cm display case
Clinician Evaluation

• Device not ready for med students or large-scale clinical testing…

• Dr. William Mclvor (anesthesiologist extraordinaire) will provide preliminary feedback

• After using the device he will be asked to complete a survey
  • Did he feel comfortable using it?
  • Was it easy to understand?
  • What was the most undesirable aspect?
Division of Labor

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• Evan Hill: Handle and Connector Prototype and Verification
• Jennifer Adams: Pressure Sensor and Verification
• Matt Wolf: Pressure Simulator and Verification
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Questions
Additional Reference

Central Venous Access and Monitoring, Dr Graham Hocking, Frimley Park Hospital, Portsmouth Road, Frimley, Camberley, Surrey, GU16 5UJ