Background

Oclusions in IV Catheters
• Catheter occlusion is defined as a partial or complete obstruction of the PVC, PICC or CVC that prevents the caregivers’ ability to withdraw blood, flush the catheter, administer IV solution, medication, or drugs.1,2
• One of the most common IV complications with PVC, PICC & CVC’s
• ≥ 7 million medical, PVC, and CVC Catheters are placed in the US13
• 90% of patients in the US have a vascular access device placed
• 1 in 3 PVC’s become occluded.14
• 58% of these occlusions are thrombotic (caused by blood reflux)14
• Multiple factors cause blood reflux into catheter15,16,17,18
• Syringe recoil
• Venous pressure movement
• Stressing, coughing, yawning, etc.

One use of improper clamping sequence associated with negative, positive, or neutral displacement connectors.19

Need to assess the performance of various catheters when correct clamping protocol is not followed (in the absence of clamping)

Differences in clamping requirements extremely confusing to users.3,4,5

In a 2011 survey with 554 respondents7
• 134 (24.1%) did not know the type (brand) used with their CVCs
• 132 (23.4%) did not know if their connector was positive, negative or neutral
• 244 (43.2%) did not understand the correct way to flush and clamp a catheter with their needleless connector attached.

Objective and Method

Objective: Determine the quantitative and experimental reflux of negative, positive, neutral and anti-reflux needleless connectors.

Method:
1. Models were fully-dimensioned using SolidWorks® Computer-Aided Design (CAD) software for each needleless connector
2. Theoretical models of reflux upon connection/disconnection were calculated using "worst possible" scenarios with laboratory venous pressure simulator values expected to be lower.
3. The average pressure of the peripheral venous system (17 mmHg or 0.05 inches of water) was maintained during connection/disconnection of the various needleless IV connections.
4. Each barrel/needleless connector was accessed using a standard 20mL, BD syringe luer as the male/luer access device.
5. This data was plotted in order to compare the theoretical vs. experimental (venous pressure simulator) measured reflux with each needleless IV connector.

Theoretical Method

• Theoretical values attained using measurements from SolidWorks models. Change in volume of moving mechanism = maximum possible reflux
• Negative Displacement
  E.K. SmartSite
• Positive Displacement
  E.K. MaxPlus
• Neutral Displacement
  E.K. MicroFlow
• Pressure-Activated Valve
  E.K. Tru-Close

Experimental Method

The (venous pressure simulator) experiment was set up with the following as shown below:

- Standardized height difference between the syringe and water level
- 17 mmHg (0.05 inches of water) mean venous pressure
- Change in elevation of water level observed upon connection and disconnection from luer lock, 3 needleless connector samples of each model tested
- 30 trials for each needleless sample or 30 disconnection and connections per needleless connector.

1. Glass capillary tube
2. Scale
3. 5 mL syringe
4. PVC tubes connectors
5. Needleless IV connector
6. Syringed water

Results

<table>
<thead>
<tr>
<th>Connector Type</th>
<th>Positive Displacement</th>
<th>Neutral Displacement</th>
<th>Negative Displacement</th>
<th>Pressure-Activated Valve</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVC</td>
<td></td>
<td></td>
<td>0.7 μL</td>
<td>0.2 μL</td>
</tr>
<tr>
<td>PICC</td>
<td>1.0 μL</td>
<td></td>
<td>0.8 μL</td>
<td>0.7 μL</td>
</tr>
<tr>
<td>CVC</td>
<td>0.8 μL</td>
<td></td>
<td>0.7 μL</td>
<td>0.2 μL</td>
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</tbody>
</table>
| 3D Auto Computer Aided Design Software Solidworks®

Observations

- The theoretically calculated maximum values for reflux were always within a factor of 5 of the experimentally measured value (in low variance deviation).
- Factors such as manual twisting/squeezing of tubing and syringe during connection & disconnection also contribute to the reflux volume. Due to care taken to minimize these effects our experiments had a high degree of repeatability (low standard deviation).
- Negative Displacement connectors had reflux volumes as high as 123.4 μL.
- Positive Displacement connectors had reflux volumes ranging from 18.2 to 18.8 μL.
- Neutral Displacement connectors had reflux volumes ranging from 10.3 to 5.6 μL.
- Pressure Activated (Anti Reflux) valves had reflux volumes of 2.5 to as low as 0.02 μL.

Conclusions

- Negative/Neutral IV connectors that contained pressure-activated valves provided the best performance in preventing reflux upon connection and disconnection.
- Positive, neutral, and displacement connectors, show no correlation to their specific marketed classification and efficacy in the prevention of fluid reflux.

Ongoing & Future Work

- Compare the abilities of commercially available connectors to prevent reflux if clamping is performed
  - per the recommended protocol.
  - with the “wring” protocol.
- Compare the ability of commercially available connectors to prevent aspiration with repeated use (fatigue analysis).
- Investigate the relationship between volume of reflux and the severity of occlusion (pressure needed to release refluxed material).

References

2) Hinchey, K. “Deep vein thrombosis and the need for safe IV access,” Anesthesiology 1993, 79(6), 1744-1757
6) Hinchey, K. “Deep vein thrombosis and the need for safe IV access,” Anesthesiology 1993, 79(6), 1744-1757

Quantitative Assessment of Catheter Reflux in Commercially Available Needleless Connectors
Garret Hull, and Shramik Sengupta, PhD
Department of Bioengineering University of Missouri Columbia, Missouri 65211

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Theoretical Displacement Maxima (mm$^3$) = $\mu l$

Negative Displacement

[upon unclamped disconnection]

Positive Displacement

[upon unclamped connection]

Neutral Displacement

[upon unclamped disconnection]

Pressure Activated Anti-Reflux

[upon unclamped disconnection]

Theoretical Max.

Experimental

Representation

Results

<table>
<thead>
<tr>
<th>CLAVE®</th>
<th>Clearlink®</th>
<th>Interlink®</th>
<th>Smartsite®</th>
<th>Q-Syte™</th>
<th>MaxPlus®</th>
<th>Ultrasite®</th>
<th>Caresite®</th>
<th>Invision Plus®</th>
<th>Nexus NIS®-6P</th>
<th>Onelink®</th>
<th>Microclave®</th>
<th>Microclave® Clear</th>
<th>Neutron®</th>
<th>Nexus TKO®-S</th>
<th>Nexus TKO®-6P</th>
<th>Nexus TKO®-6PHV</th>
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</thead>
<tbody>
<tr>
<td>9.7 µl</td>
<td>123.3 µl</td>
<td>13.1 µl</td>
<td>50.3 µl</td>
<td>38.4 µl</td>
<td>23.7 µl</td>
<td>38.8 µl</td>
<td>18.2 µl</td>
<td>6.5 µl</td>
<td>3.6 µl</td>
<td>8.5 µl</td>
<td>10.8 µl</td>
<td>10.8 µl</td>
<td>1.5 µl</td>
<td>0.01 µl</td>
<td>0.01 µl</td>
<td>0.01 µl</td>
</tr>
</tbody>
</table>

*registered trademark or ™ Tradenames: Clave®, Microclave®, Neutron® = ICU Medical, Clearlink®, Interlink® and Onelink® = Baxter, Smartsite®, MaxPlus® = Carefusion, Ultrasite®, Caresite® = B. Braun, Q-Syte™ = BD, Kendall®, Invision Plus® = Rymed, Nexus TKO® = Nexus Medical.