
INTRODUCTION

Umbilical vessel catheterization is performed on newborns to provide arterial and/or venous access through the umbilicus. This access is used for pressure monitoring, blood sampling, and infusion of medications, blood products, nutritional products, and maintenance fluids. The determination of which vessel to catheterize is reflective of the condition of the vessels and the diagnostic needs of the neonate. A clinician may choose to place a catheter in an artery and a vein if both access routes are required.

Recently, Dual-Lumen Umbilical Vessel Catheters (DL UVC) have been introduced which are comprised of two independent lumens within a single UVC. DL UVC’s have been shown to decrease the number of IV punctures, reduce iatrogenic stress due to IV placements, and may not significantly increase mechanical complications when compared to single lumen UVC’s. DL UVC’s perform multiple functions. Ramachandran, et al. reported one lumen of a DL UVC was utilized for CVP monitoring and drug administration while the other lumen was reserved as a closed system for TPN or maintenance fluids. Khilmani, et al. reported that both lumens of a DL UVC were utilized at all times for infusion of medications and fluids. As the use of DL UVC’s becomes more widespread, additional uses for DL UVC’s should be discovered.

Inherent property differences exist between silicone and polyurethane materials. Polyurethane can be a stronger and more durable material than silicone. This allows for thinner catheter walls in polyurethane catheters allowing greater flow, yet strong enough to withstand greater break forces. Polyurethane provides for a firmer catheter which may increase insertion success. Lumen dimensions become critical when utilizing a DL UVC. Care must be taken in design and manufacturing of DL UVC’s to optimize Flow-Rates and Break Strengths.

This study will compare both Flow-Rates and Break Strengths of the Argyle Polyurethane Dual-Lumen UVC vs. a Competitive Silicone Dual-Lumen UVC.

MATERIALS AND METHODS

10 each 3.5 and 5.0Fr. Argyle Polyurethane DL UVC’s and 10 each 3.5 and 5.0Fr. Competitive Silicone DL UVC’s were tested for:

(1) Water Flow-Rate
(2) Catheter Shaft Break Force

1. Water Flow-Rate Test

a. Set-Up

The purpose of this test was to determine the Water Flow-Rate through a horizontal catheter at a constant pressure of 100cm H2O.

The following materials and equipment were utilized for this test: 100cm water column Flow-Rate pressure test fixture (see diagram), Mettler PM 4600 digital scale (grams), source of constant deionized water, hemostat (shut-off mechanism), stopwatch, 500ml beaker, tape, source of compressed air set to 25 psi, male luer-lock tubing adaptor (S & J #A1442) and a thermometer.

b. Procedure:

Turn on deionized water source. Fill holding tank with
deionized water until water flows into drain tube. Place beaker (collection vessel) on scale. Locate scale so top of beaker is below table. Open hemostat and tap line to purge air bubbles.

Connect primary lumen of catheter to water line. Purge air from catheter by running deionized water through for 10 seconds. Fasten catheter to table top, horizontally and straight, with tape. Allow one inch of catheter to lay over edge of table above beaker. Be sure not to tape catheter shaft too tightly as this could restrict water flow through the catheter.

Zero the stopwatch, tare scale, and initiate testing by simultaneously removing hemostat and beginning the stopwatch. Allow deionized water to flow through catheter and into beaker for three minutes, then close hemostat. Flow-Rate is determined by volume/time assuming one cubic centimeter of water = 1 gram. Perform test on primary and secondary lumens of each catheter size (3.5 and 5.0Fr.).

2. Catheter Shaft Break Force Test

a. Set-up

Purpose of this test is to determine tensile strength and percent (%) elongation when catheter shaft breaks.

The following equipment and materials were utilized for the test: Sintech model 1/S tensile testing machine, two manually operated spring-loaded jaws (part #SN5112) for bottom platen and crosshead of tensile testing machine, 6" dividers, and 12" ruler.

b. Procedure

Using a six inch long sample of catheter shaft, make two marks one inch apart, in center of sample. Place catheter in jaws of tensile testing machine.

Start crosshead in motion while holding dividers on two marks. Spread dividers as the two marks spread, until breakage occurs. **If catheter breaks at jaws, data for that sample is disregarded, hence reduction in sample size and mode of failure.**

RESULTS

1. 100cm Water Flow-Rate Test

The Argyle Polyurethane DL UVC (5.0Fr.) primary lumen achieved an average of 17.19cc’s per minute (10 catheters) while the Silicone DL UVC achieved an average of 3.14cc’s per minute (10 catheters).

The Argyle Polyurethane DL UVC (5.0Fr.) secondary lumen achieved an average of 4.51cc’s per minute (10 catheters) while the Silicone DL UVC achieved an average of 3.23cc’s per minute (10 catheters).

A. Argyle Polyurethane DL UVC (5.0Fr.) achieved:

- 447% greater average water flow through primary lumens vs. Silicone DL UVC primary lumen.
- 40% greater average water flow through secondary lumens vs. Silicone DL UVC secondary lumen.

100cm WATER FLOW-RATE COMPARISON

<table>
<thead>
<tr>
<th>Lumen Type</th>
<th>Flow Rate (cc/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argyle Polyurethane</td>
<td>17.19</td>
</tr>
<tr>
<td>Competitive Silicone</td>
<td>3.14</td>
</tr>
</tbody>
</table>

On average, 447% more water flowed through the 5.0Fr. Argyle Polyurethane catheter primary lumen than through the 5.0Fr. Silicone catheter primary lumen.

(17.19-3.14)/3.14*100=447.5%

100cm WATER FLOW-RATE COMPARISON

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<td>4.51</td>
</tr>
<tr>
<td>Competitive Silicone</td>
<td>3.23</td>
</tr>
</tbody>
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On average, 40% more water flowed through the 5.0Fr. Argyle Polyurethane catheter secondary lumen than through the 5.0Fr. Silicone catheter secondary lumen.

(4.51-3.23)/3.23*100=39.6%
The Argyle Polyurethane DL UVC (3.5Fr.) primary lumen achieved an average of 4.37cc's per minute (10 catheters) while the Silicone DL UVC (3.5Fr.) primary lumen achieved an average of 2.39cc's per minute (10 catheters).

The Argyle Polyurethane DL UVC (3.5Fr.) secondary lumen achieved an average of .57cc's per minute (10 catheters) while the Silicone DL UVC (3.5Fr.) secondary lumen achieved an average of .35cc's per minute (10 catheters).

B. Argyle Polyurethane DL UVC (3.5Fr.) achieved:
- 83% greater average water flow through primary lumen vs. Silicone DL UVC primary lumen.
- 63% greater average water flow through secondary lumen vs. Silicone DL UVC secondary lumen.

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2. Catheter Shaft Break Force Test

The Argyle Polyurethane DL UVC (5.0Fr.) withstands an average pull force of 12.1 pounds while the Silicone DL UVC (5.0Fr.) withstands an average pull force of 3.6 pounds.

A. Argyle Polyurethane DL UVC (5.0Fr.) achieved:
- 236% greater pull force vs. Silicone DL UVC (5.0Fr.)

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CATHETER SHAFT BREAK FORCE COMPARISON

5.0Fr. (n=9)

![Graph showing pull force comparison between Argyle Polyurethane and Competitive Silicone catheters.](image)

On average, the 5.0Fr. Argyle Polyurethane catheter withstands a 236% greater pull force than the 5.0Fr. Silicone catheter.

\[ \frac{(12.1-3.6)}{3.6*100} = 236.1\% \]

The Argyle Polyurethane DL UVC (3.5Fr.) withstands an average pull force of 6.1 pounds while the Silicone DL UVC (3.5Fr.) withstands an average pull force of 2.5 pounds.

B. Argyle Polyurethane DL UVC (3.5Fr.) achieved:
- 144% greater pull force vs. Silicone DL UVC (3.5Fr.)

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CATHETER SHAFT BREAK FORCE COMPARISON

3.5Fr. (n=9)

![Graph showing pull force comparison between Argyle Polyurethane and Competitive Silicone catheters.](image)

On average, the 3.5Fr. Argyle Polyurethane catheter withstands a 144% higher average pull force than the 3.5Fr. Silicone catheter.

\[ \frac{(6.1-2.5)}{2.5*100} = 144\% \]
DISCUSSION
Flow-Rate through each lumen of a DL UVC is an essential performance criteria for proper function of the catheter. A greater Flow-Rate offers the clinician the means to infuse and aspirate rapidly as well as decrease the risk of lumen clotting. With the addition of a second lumen in a UVC, individual lumen cross-sectional area is decreased to make the necessary room for two lumens.

The Argyle Polyurethane DL UVC shows superior Flow-Rates vs. a Competitive Silicone DL UVC. Superior Flow-Rates exhibited by the Argyle Polyurethane DL UVC may lead to a reduction of mechanical complications as the higher flowing lumens are less likely to clot off. Medications and fluids may be infused faster with the Argyle Polyurethane DL UVC to optimize clinical intervention. Maintenance of the lines by the nursing staff may be reduced when utilizing the Argyle Polyurethane DL UVC as a result of lumens clotting less frequently.

Catheter strength is also a critical issue. A strong catheter material is required to insure strength during insertion, infusion, aspiration, and manipulation. The Argyle Polyurethane DL UVC, as tested, was superior to the Silicone DL UVC in catheter break strength. Breakage during UVC use can lead to serious complications such as blood loss, air emboli, sepsis, and early catheter removal or replacement. The Argyle Polyurethane DL UVC increased catheter break strength will assure a well functioning catheter during the entire catheter life.

Increased break strength provides a firmer catheter to increase the insertion success rate of the catheter. The benefits of a higher insertion success rate are many, including the reduced need for additional vascular access as well the savings of clinician time required for insertion.

CONCLUSION
The Argyle Polyurethane DL UVC offers improved Flow-Rates and increased break strength resulting from a firmer material which may improve the insertion success rate of the catheter.

* Tests were performed at Sherwood Medical Research and Development Facility, St. Louis, Mo.
