Introduction and Objective

Balloon dilation catheters are used in both ureteroscopic and percutaneous applications to aid in difficult calculus extraction.\(^1\)\(^,\)\(^2\) In either case there is the opportunity for the balloon to come into contact with sharp calculi, possibly compromising the integrity of the balloon material and causing a puncture.

During ureteroscopy, stones often become lodged in a narrowed portion of the ureter, at which point a balloon dilation catheter would be utilized to widen the narrowed portion.\(^1\) It is at this point that an unseen stone fragment may become lodged between the wall of the ureter and the wall of the balloon causing a puncture. Additionally, during a percutaneous nephrolithotomy procedure, a balloon dilation catheter is introduced into the renal pelvis to create a working tract.\(^2\) This introduction may bring the balloon into contact with sharp calculi that could disrupt the balloon material.

Given this possibility of puncture by calculi, it is important that balloons are designed to withstand forces that could cause disruption. The objective of the following testing is to compare the puncture resistance of the X-Force™ Balloon Dilation Catheter to other commercially available balloon dilation catheters.

Methodology

In order to test the force required to puncture a balloon, an Instron® Universal Materials Testing Machine fitted with a puncture test probe was utilized. The Instron machine was set up with a 20lb load cell, set for a compression rate of 10in/min. The puncture test probe was then mounted in the upper jaws of the Instron machine. The balloons were then mounted to a sled fixture in the lower jaws of the Instron machine and secured at both ends. All balloons were inflated to 20 ATM using deionized water, ensuring that no air bubbles were present. Once all components were in place, the Instron machine was activated and the peak force required to puncture the balloon was recorded.

The balloons used in this test were:
15 x Bard® X-Force™ U30 Balloon Dilation Catheter - 5mm x 4cm
10 x Bard® X-Force™ N30 Nephrostomy Balloon Dilation Catheter - 10mm x 15cm
15 x Boston Scientific® UroMax Ultra™ Ureteral Balloon Dilation Catheter - 5mm x 4cm
10 x Boston Scientific® NephroMax™ Nephrostomy Balloon Dilation Catheter - 10mm x 12cm
10 x Cook® Ultraxx™ Nephrostomy Balloon Dilation Catheter - 10mm x 15cm

Results

<table>
<thead>
<tr>
<th>Balloon Type</th>
<th>Average</th>
<th>Standard Deviation</th>
<th>Median</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-Force™ U30 Balloon</td>
<td>8.6</td>
<td>1.7</td>
<td>8.9</td>
<td>5.5</td>
<td>11.7</td>
</tr>
<tr>
<td>X-Force™ N30 Balloon</td>
<td>8.5</td>
<td>1.7</td>
<td>7.5</td>
<td>7.0</td>
<td>11.7</td>
</tr>
<tr>
<td>UroMax Ultra™ Balloon</td>
<td>3.4</td>
<td>0.2</td>
<td>3.3</td>
<td>3.2</td>
<td>4.0</td>
</tr>
<tr>
<td>NephroMax™ Balloon</td>
<td>3.3</td>
<td>0.5</td>
<td>3.2</td>
<td>2.7</td>
<td>4.2</td>
</tr>
<tr>
<td>Ultraxx™ Balloon</td>
<td>3.9</td>
<td>0.4</td>
<td>3.8</td>
<td>3.5</td>
<td>4.7</td>
</tr>
</tbody>
</table>

*Statistical analysis was performed using Mann-Whitney tests to compare the median puncture force of the X-Force™ U30 balloon to the UroMax Ultra™ balloon (p-value: 2.22E-12), Mann-Whitney analysis was also used to compare the median puncture force of the X-Force™ N30 balloon to the NephroMax™ balloon (p-value: 0.0001) and to the Ultraxx™ balloon (p-value: 0.0001).
Conclusion
As measured by this testing, the Bard® X-Force™ U30 and N30 Balloon Dilation Catheters have an average puncture resistance as measured by this testing, that is higher than the leading urological balloon dilation catheters. The X-Force™ U30 balloon was found to have a puncture resistance average that is 152% higher than the UroMax Ultra™ balloon. The X-Force™ N30 balloon was found to have a puncture resistance average that is 116% and 154% higher than the Ultraxx™ balloon and the NephroMax™ balloon respectively.

References


*Study performed by C.R. Bard, Inc., Data on File.
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