Stiffness Evaluation of Commercially Available Hybrid Guidewires

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Abstract

Objective: To utilize bench testing to conduct a comparative evaluation of shaft stiffness between two commercially available guidewires.

Methods: The 0.035” BARD® SOLO™ PLUS and 0.035” Boston Scientific Sensor™ were evaluated using methods previously published for evaluating urological guidewires. A 15 cm section of each guidewire was compressed a distance of 10 cm using a motorized load cell, and the maximum resulting force was recorded. Five samples of each guidewire were used to obtain 25 measurements of each wire type.

Results: The BARD® SOLO™ PLUS guidewire was found to be significantly stiffer than the 0.035” Boston Scientific Sensor™ guidewire (p<0.001). The 95% confidence interval for the difference between the two wires suggests the BARD® SOLO™ PLUS is 29% to 41% stiffer than the Boston Scientific Sensor™ wire.

Conclusions: The BARD® SOLO™ PLUS was found to be significantly stiffer than the Boston Scientific Sensor™ guidewire. Further studies are warranted to determine whether results obtained in this bench test translate to advantages in a clinical setting.
Introduction and Objective

Guidewires provide a means to gain access and navigate through the upper urinary tract, advance and position various instruments (access sheaths, ureteral catheters, scopes, stents), and may also be used alongside the ureteroscope to allow for stent insertion in the event of ureteral perforation. Although many commercially available guidewires in urology are designed for the same purpose, they may have significantly different properties with regard to tip flexibility, lubricity, and shaft stiffness. Several studies suggest stiffer wires may ease the coaxial passage of catheters, stents, and sheaths, in addition to being less likely to buckle during advancement and manipulation within the urinary tract. In this paper, we utilize bench testing to evaluate shaft stiffness of two commercially available guidewires.

Methods

In this bench test, shaft stiffness is defined as the extent to which 15 cm sections of the guidewire resist deformation in response to an applied force, similar to previously published methods used to characterize guidewire stiffness. The 15 cm section of the guidewire is reduced to a distance of 5 cm (10 cm of compression) at a constant speed (3 in/min) using an automated platform (Instron Model 3365), and the maximum resulting force is measured using a 0-10 lb load cell. The test set-up used is shown below in Figure 1.

A total of five measurements were taken on each guidewire, and five wire samples were used to obtain a total of 25 measurements per wire type. The two commercially available guidewires evaluated include:

1. 0.035” Boston Scientific Sensor™ Dual Flex hybrid guidewire, PN# 670-306
2. 0.035” BARD® SOLO™ PLUS hybrid guidewire, PN# HW35SS

Results

The data collected suggest the 0.035” BARD® SOLO™ PLUS guidewire is significantly stiffer than the 0.035” Boston Scientific Sensor™ guidewire (p<0.0001). The difference in force between the two wires suggests the 0.035” BARD® SOLO™ PLUS is 29% to 41% stiffer than the Boston Scientific Sensor™ wire (p=0.05). A summary of the results is shown in Table 1.

<table>
<thead>
<tr>
<th></th>
<th>0.035” Boston Scientific Sensor™</th>
<th>0.035” BARD® SOLO™ PLUS</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Wires</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Total Measurements (N)</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Average Force (lbs)</td>
<td>0.221 lbs</td>
<td>0.299 lbs</td>
</tr>
<tr>
<td>95% Confidence Interval</td>
<td>0.213 to 0.230 lbs</td>
<td>0.290 to 0.309 lbs</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.0211 lbs</td>
<td>0.0239 lbs</td>
</tr>
</tbody>
</table>

Table 1: Average shaft buckling force and standard deviations from compressing 15 cm sections a distance of 10 cm

Figure 2: Average shaft buckling force measurement for the 0.035” Bard Solo Plus vs. 0.035” Boston Scientific Sensor™

Conclusion

The BARD® SOLO™ PLUS guidewire demonstrated greater stiffness than the Boston Scientific Sensor™ guidewire. Increased stiffness may facilitate easier coaxial passage of catheters, sheaths, and stents, and contribute to a lower likelihood of buckling during advancement when compared to more flexible wires. Results in this preclinical bench top test series warrant future studies to confirm these findings translate to clinical differences.
**Indications for Use:**

The Bard® Solo™ Plus hybrid guidewires are intended for use in facilitating the placement of endourological instruments during diagnostic or interventional procedures. This guidewire is not intended for coronary artery, vascular, or neurological use.

**Warnings:**

- Do not withdraw the guidewire through a metal cannula or needle. Withdrawal through a metal device may result in disposition of these materials in the urinary system and destruction and/or separation of the outer polymer jacket requiring retrieval. Extreme caution should be observed when used with one-wall puncture style needle.

- Use extreme caution when using a laser or electrocautery, making sure to avoid contact with guidewire. Direct contact may cause damage to the wire and/or sever the wire.

- Do not reshape the guidewire in any way. Attempting to reshape the wire may cause damage, resulting in the release of wire fragments to the urinary system.

- When exchanging or withdrawing a catheter over the guidewire, secure and maintain the guidewire in place under fluoroscopy to avoid unexpected guidewire advancement. Otherwise damage to the urinary channel by the wire's tip may occur.

- Manipulate the guidewire slowly and carefully in the urinary system while confirming the behavior and location of the wire's tip under fluoroscopy. Excessive manipulation of the guidewire without fluoroscopic confirmation may result in perforation or trauma of the linings or associated tissues, channels or ducts. If any resistance is felt or if the tip's behavior and/or location seems improper, STOP manipulating the guidewire and/or the catheter and determine the cause by fluoroscopy. Failure to exercise proper caution may result in bending, kinking, separation of the guidewire's tip, damage to the catheter, or damage to the urinary system. If necessary, remove the guidewire and ancillary device or scope as a complete unit to avoid complications.

- Do not attempt to use the guidewire if it has been bent, kinked, or damaged. Use of a damaged wire may result in damage to the linings and associated tissue, channels or ducts or release of wire fragments into the urinary system.

**Adverse Events**

Complications which can result from the use of guidewires in urological applications include:

- Perforation of the urinary tract
- Acute bleeding
- Hemorrhage
- Tissue trauma
- Edema
- Foreign object in body
- Infection
- Hemoglobinuria
- Peritonitis
- Ureter avulsion

**References**


*Preclinical data. Preclinical data may not correlate to outcomes in humans.*