Tip Safety Evaluation of Commercially Available Hybrid Guidewires

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Abstract

Objective: To utilize bench testing to isolate the physical properties and characteristics of guidewires tips for two commercially available wires.

Methods: The 0.035" Bard® Solo™ Plus and 0.035" Boston Scientific Sensor™ were evaluated using methods previously published for evaluating urological guidewires. For tip flexibility measurements, the guidewire is secured 5 cm from the tip, which is placed in a 0.5 cm deep hole (0.04 mm diameter) drilled into a block to prevent the tip of the wire from slipping against the solid surface. A motorized force gauge (Instron C-P6419/C-40594, 0-10lbs range load cell) is used to close the 5 cm distance to 2 cm at a constant speed, while the force is continuously measured. Perforation force measurements are obtained by securing each guidewire to the same motorized digital force as above, which is inserted through a 10 cm portion of a 10/12Fr ureteral access to stabilize the wire and prevent bending. The tip of the sheath is placed flush to an aluminum foil layer (0.016 mm thick) which is secured between two metal washers, and the guidewire is advanced at a constant speed until perforation occurs. Five samples of each guidewire were used to obtain 25 measurements of each wire type for both tip bending and perforation evaluations.

Results: No significant difference in tip perforation measurements was found between the Bard® Solo™ Plus guidewire and the Boston Scientific Sensor™ wire (p=0.10), while an average difference of 0.0006 lbs was observed for tip flexibility measurements between the two wire types.

Conclusions: The Bard® Solo™ Plus guidewire and the Boston Scientific Sensor™ demonstrate a similar extent of tip safety in an in vitro setting. Due to the lack of standards related to guidewires, it remains difficult to correlate the magnitude of the forces found in this study to clinically relevant forces. Future clinical studies are warranted for determining impact within a clinical setting.
Introduction and Objective

Guidewires are considered the urologists’ lifeline. During ureteroscopy, the ability to reliably gain access and successfully navigate through the upper urinary tract is essential for a favorable outcome. Although overall complication rates are relatively low during ureterscopy, ureteral perforation is the most common intraoperative complication reported. Appropriate guidewire choice is important to help maximize procedural efficiency as well as reducing risks associated with specific clinical tasks, such as bypassing tight ureteral strictures and impacted stones. Despite guidewires being available in a wide range of physical properties, a flexible and lubricious tip is designed to be desirable for almost all clinical situations to help optimize safety and help reduce the risk of accidental puncture during advancement. In this paper, we utilize bench testing to isolate the physical properties and characteristics of guidewire tips for two commercially available guidewires.

Methods

Flexibility

In the first part of this testing, tip flexibility is defined as the extent to which the distal 5 cm tip section of the guidewire resists deformation in response to an applied force. Methods used to determine tip flexibility reflect those of three previously published bench studies evaluating urological guidewires. Such methods attempt to simulate the clinical situation in which a guidewire encounters a point of resistance, such as a stricture or impacted stone, measuring the force at the tip as a result of guidewire advancement.

The guidewire is secured 5 cm from the tip, which is placed in a 0.5 cm deep hole drilled into a block to prevent the tip of the wire from slipping against the solid surface. A motorized force gauge (Instron C-P6419/C-40594, 0-10lbs range load cell) is used to close the 5 cm distance to 2 cm at a constant speed, while the force is continuously measured. Figure 1 provides an example of the set-up used to evaluate tip flexibility. The maximum force measured during the tip compression process is used to calculate the average force for each type of wire, with higher force values positively correlating to stiffer guidewire tips.

Perforation

The second part of this study evaluated the risk of perforation using a similar aluminum foil model described in three previous publications comparing urological guidewires. Methods used for this evaluation attempt to simulate a worst case clinical scenario, similar to when the body of the guidewire is isolated as it may be when passing through a tight lumen, scope, or sheath, and the wire is advanced with only the tip protruding out of the lumen directly toward tissue.

To simulate this scenario, the guidewire is secured to a motorized digital force gauge (Instron C-P6419/C-40594, 0-10lbs range load cell), which is inserted through a 10 cm portion of a 10/12Fr ureteral access to stabilize the wire and prevent bending. The tip of the sheath is placed flush to an aluminum foil layer (0.016 mm thick) which is secured between two metal washers, and the guidewire is advanced at a constant speed until perforation occurs. The maximum force measured is used for determining average perforation force for each type of wire, with higher force values being suggestive of a lower likelihood to perforate.

Materials

The two commercially available guidewires evaluated for both flexibility and perforation evaluations include:

1. 0.035” Boston Scientific Sensor™ Dual Flex hybrid guidewire, PN# 670-308
2. 0.035” BARD® SOLO™ Plus hybrid guidewire, PN# HW355S

For each type of evaluation, a total of five repetitions were conducted on five wires samples, for a total of 25 measurements per wire type for each test.
Results

Figure 3: Average calculated tip bending force and standard deviation for the 0.035" Bard® Solo™ Plus and the 0.035" Boston Scientific Sensor™ wire (p=0.044). N=25 measurements for each type of wire.

Figure 4: Average calculated perforation force and standard deviation for the 0.035" Bard® Solo™ Plus and the 0.035" Boston Scientific Sensor™ wire (p=0.10). N=25 measurements for each type of wire.

Table 1: Summary of average and standard deviation values for tip perforation and tip bending evaluations

<table>
<thead>
<tr>
<th>Guidewire Type</th>
<th>Tip Bending (lbs)</th>
<th>Tip Perforation (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Solo™ Plus</td>
<td>Sensor™</td>
</tr>
<tr>
<td>Average</td>
<td>0.0146</td>
<td>0.014</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.000985</td>
<td>0.000833</td>
</tr>
<tr>
<td>T-Test (p-value)</td>
<td>0.044</td>
<td>0.10</td>
</tr>
</tbody>
</table>

Discussion

In this study, we present findings from comparative evaluations of two commercially available hybrid guidewires. Tip bending results suggest the tip flexibility between the Bard® Solo™ Plus guidewire and the Sensor™ differ by an average of 0.0006 lbs of force (p=0.044). In vitro studies indicate the force required to puncture a human ureter with a guidewire requires approximately 0.79 lbs of force, which suggests the minimal difference in tip flexibility values between the two wires is unlikely to have an impact on perforation risk.

Values obtained from perforation testing indicate there is no statistical difference between the Bard® Solo™ Plus and Boston Scientific Sensor™ when comparing perforation force (p=0.10).

Conclusion

The Bard® Solo™ Plus guidewire and the Boston Scientific Sensor™ demonstrate a similar extent of tip flexibility in an in vitro setting. Due to the lack of standards related to guidewires, it remains difficult to correlate the magnitude of the forces found in this study to clinically relevant forces. Future clinical studies are warranted for determining impact within a clinical setting.

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


Note: Pre-clinical testing may not correlate to outcomes in humans.

Please consult product inserts and labels for any indications, contraindications, hazards, warnings, cautions and directions for use.