Beyond Tip Stiffness

Flexural Rigidity Distributions of Guidewires and Specialty Devices

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BACKGROUND AND OBJECTIVE

There is a paucity of data describing the mechanical properties of current guidewires, microcatheters and specialty devices beyond *"tip load"* measurements that only characterize the terminal 10 mm [1, 2]. It is hypothesized that clinical performance of crossing devices, including steerability, penetration and deliverability, may depend on mechanical properties, design and construction over a much greater length than the distal tip. Moreover, the development of new devices might benefit from nuanced comparison to existing benchmarks.

A study was initiated by SoundBite to measure and compare the local flexural rigidity (i.e. EI, the product of the local elastic modulus E and section moment of inertia I) of various devices. It is believed that such information will help interventionists and the industry to better select and design the next generation of percutaneous transluminal angioplasty (PTA) devices.

METHOD

A circular beam (rod, wire or tube) subjected to a three-points bend test, as shown on figure 1, behaves as described by equation 1, where F is the applied force, w_0 is the downward displacement of the circular beam at the force application point, l is the distance between the two base supports, E is the Young's modulus and I is the second moment of inertia [3]. In the special case where the circular beam is a rod or a wire, the second moment of inertia I can be expressed by equation 2, where r is the radius.

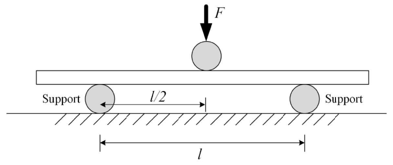

Figure 1: Three-point bend test

$$F = \frac{48 w_0 EI}{l^3} \tag{1}$$

$$I = \frac{\pi r^4}{2} \tag{2}$$

Equation 1 provides insight about the flexural rigidity of a circular beam and can be used to evaluate its flexibility profile. This is accomplished by repeating the same experiment at different points along the length. To facilitate the analysis and comparison of the flexural rigidity profile between devices, it is more appropriate to plot the resulting EI values along the device's length. By doing so, devices of different configurations (for example, guidewire versus catheter) could be compared on the same chart.

Looking at equations 1 and 2, the force to displacement ratio is proportional to the fourth power of the radius. Therefore, a slight change in diameter greatly affects the flexural rigidity value. Also, a circular beam having a smaller radius will allow larger flexural displacement for the same applied force. These information are particularly important to know when selecting a device for its support ability, trackability, kink resistance and tip load. Interestingly, a similar relationship exists between the applied torque, the resulting twist angle and the fourth power of the radius.

The local flexural rigidity distributions of various guidewires, catheters, microcatheters, balloons and specialty devices were measured over their distal 0-500 mm by performing sequential three-point bend tests at 10 mm increments. The local EI value was extracted using common slender beam formulas from the known applied load and deflection defined at equation 1. A motorized test stand model ESM303 and a M5-2 digital force gage (2 lbf) from Mark-10 (Copiague, United States) were used. The pusher and the two supports used were cylindrical metallic rods with a diameter of 3.2 mm. A fix displacement of 1.5 mm was used with a distance of 20 mm between the two supports. The downward speed rate of the pusher was fixed at 10 mm/min. Each measurement point was repeated five (5) times and the average was computed. New, packaged, but expired devices were used for this test without any pre-conditioning.

RESULTS

Flexural rigidity distributions were obtained for various popular commercial guidewires, catheters, and other specialty devices. Results are presented in figures 2 to 6 for devices with coronary an peripheral indication. The flexural rigidity of the novel Active Wire 14 and 18 from SoundBite Medical (Montreal, Canada), were found to be comparable to guidewires with devices of similar intended use.

CONCLUSION

Flexural rigidity distributions of various devices have been measured and compared over extended lengths. This method may better quantify mechanical attributes that determine clinical performance. This method also has the advantage to compare multiple devices over a standardized value. Angioplasty devices have different geometries, designs and mechanical properties in order to achieve different tasks. Knowledge of these are capital for interventionists when selecting a device.

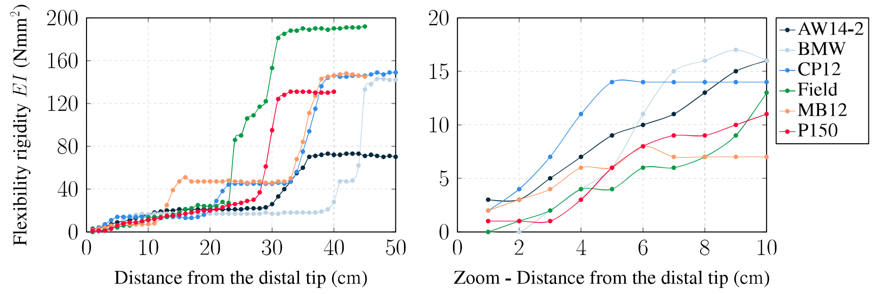

Figure 2: 0.014" guidewires

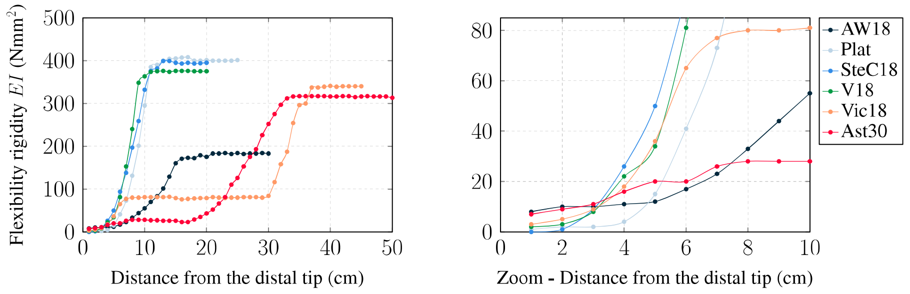

Figure 4: 0.018" guidewires

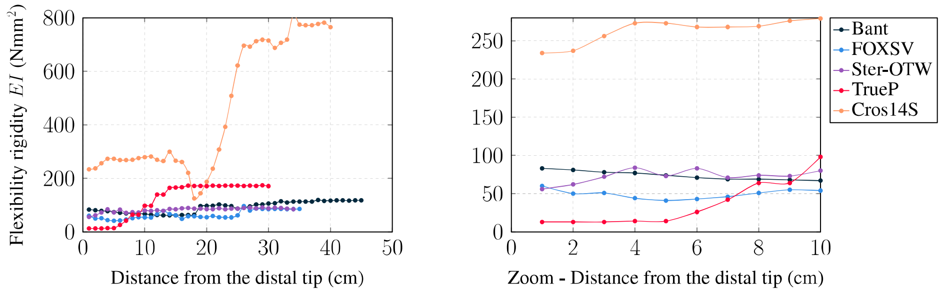

Figure 6: 0.018" compatible balloon and specialty devices

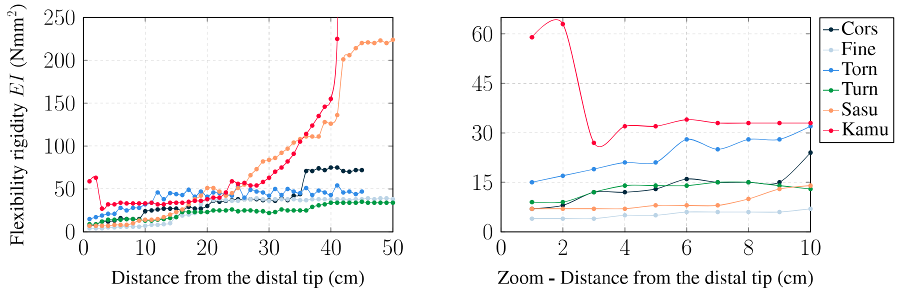

Figure 3: 0.014" compatible support and balloon devices

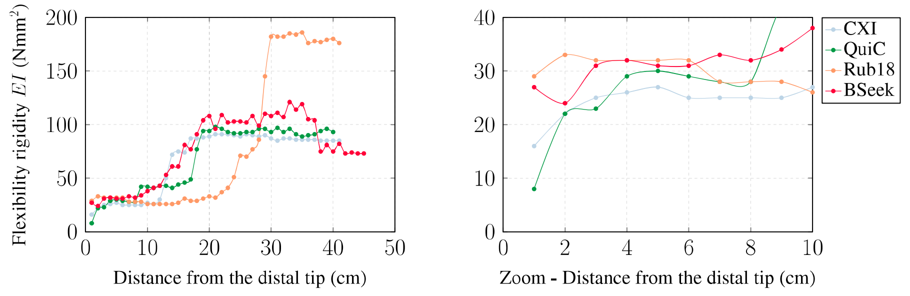

Figure 5: 0.018" compatible support devices

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