Physical Characteristics of Next-Generation Ureteral Access Sheaths: Buckling and Kinking

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OBJECTIVE
To evaluate physical characteristics of next-generation access sheaths that impact clinical failure.

METHODS
Testing of the Cook Flexor (12/14 Fr × 35 cm, Cook), ACMI UroPass (12/14 Fr × 38 cm, ACMI), Bard Aquaguide (11/13 Fr × 35 cm Bard), and Boston Scientific Navigator (11/13 Fr × 36 cm BSCI-11, 13/15 Fr × 36 cm BSCI-13) was performed on a linear motion stage driven by a stepper motor with a resolution of 5 μm per step. Force was measured at a sampling rate of 5 Hz with a Wagner FDIX digital force gauge. Friction force was measured by pulling sheaths at 2.5 mm/s through 2.78 mm (8.3 Fr) holes drilled in 36 mm thick biologic material. Buckling force was measured as the force required to compress a 25-cm length of sheath in a clamp-clamp configuration during a 30 mm move. Kinking was measured as the slope of the force-deflection curve for wall compression over a deflection of 2 mm.

RESULTS
No significant difference was noted in the friction force of the Cook (1.2 N), Bard (1.3 N), BSCI-11 (1.0 N), and BSCI-13 (1.0 N). Buckling force was significantly greater for the Cook (5.1 ± 0.49 N) than the Bard (2.8 ± 0.31 N), BSCI-11 (2.0 ± 0.25 N), ACMI (3.2 ± 0.33 N), and BSCI-13 (2.9 ± 0.31 N). Kinking force was significantly lower with the Bard (9 N/mm) than the Cook (42 N/mm), BSCI-11 (41 N/mm), and BSCI-13 (30 N/mm), and significantly higher with the ACMI (83 N/mm).

CONCLUSIONS
The Cook Flexor sheath is most resistant to buckling forces that would predict failure to advance up the ureter. The Bard Aquaglide is most likely to kink after removal of the inner obturator, whereas the ACMI Uropass is most resistant to kinking.

Ureteral access sheaths have become a useful and widespread tool in flexible ureteroscopy, facilitating the retrograde management of significant intrarenal pathology. Successful placement of an access sheath into the ureter is dependent on the coefficient of friction of the sheath surface and the axial force that results in buckling of the sheath at the ureteral orifice.1 The ability to pass a ureteroscope through the sheath is dependent on the integrity of the wall strength preventing kinking of the sheath from compressive forces.1 We have previously reported the physical properties that impact clinical failure of ureteral access sheaths,1 and herein report the results with the next-generation ureteral access sheaths.

METHODS
Testing of the Cook Flexor (Cook, 12/14 Fr × 35 cm, Spencer, Ind), Gyrus-ACMI UroPass (ACMI, 12/14 Fr × 38 cm, Southborough, Mass), Bard Aquaguide (Bard, 11/13 Fr × 35 cm, Covington, Ga), and Boston Scientific Navigator (BSCI-11, 11/13 Fr × 36 cm, BSCI-13, 13/15 Fr × 36 cm, Natick, Mass) ureteral access sheaths was performed on a linear motion stage driven by a stepper motor with a resolution of 5 μm per step. Force was measured at a sampling rate of 5 Hz with a Wagner FDIX digital force gauge (Wagner Instruments, Greenwich, Ct). Friction force was measured by pulling each sheath at a rate of 2.5 mm/s through a 2.78-mm (8.3 Fr) hole drilled in 36-mm thick biologic material (Oscar Meyer Beef Light bologna 12-oz package, Kraft Foods, Northfield, Ill) (Fig. 1). Buckling force was measured as the force required to compress a 25-cm length of sheath in a clamp-clamp configuration during a 30-mm move (Fig. 2). Kinking was measured as the slope of the force-deflection curve for wall compression over a deflection of 2 mm (Fig. 3). Four new, sterile samples of each device were tested. Statistical comparisons were performed by using Mann-Whitney nonparametric tests. A P value less than 0.05 was considered statistically significant.

RESULTS
No significant difference was noted in the friction force of the Cook (1.2 N), Bard (1.3 N), BSCI-11 (1.0 N), and BSCI-13 (1.0 N). The Gyrus-ACMI sheaths were not
available at the time of this testing (Fig. 4). Buckling force was significantly greater for the Cook (5.1 ± 0.49 N, \( P < 0.03 \)) than the Bard (2.8 ± 0.31 N), BSCI-11 (2.0 ± 0.25 N), ACMI (3.2 ± 0.33 N), and BSCI-13 (2.9 ± 0.31 N) (Fig. 5). Kinking force was significantly lower with the Bard (9 N/mm, \( P < 0.002 \)) than the Cook (42 N/mm), BSCI-11 (41 N/mm), and BSCI-13 (30 N/mm), and significantly higher with the ACMI (83 N/mm, \( P < 0.004 \)) (Fig. 6).

**COMMENT**

Technologic innovations may represent technologic advancement; the challenge to the clinician is to objectively assess new technology that is introduced each year and determine their place in the urologic armamentarium. There have been dramatic improvements in ureteral access sheaths technology.

Since its first report in 1974, modifications to the design of ureteral access sheaths have facilitated their acceptance and use in retrograde access to the kidney. Moreover, it has been shown that routine use of a ureteral access sheath for flexible ureteroscopy decreases operative time and costs, facilitates ureteral entry and re-entry, optimizes success with intrarenal ureteroscopic surgery, minimizes pain and morbidity, and maximizes stone-free rates. Thus, given the widespread use of ureteral access sheaths and their increasingly available commercial alternatives, it is relevant to develop studies to elucidate a better understanding of their specific characteristics and clinical impact.

We have previously reported in vitro testing of ureteral access sheaths evaluating physical characteristics that predispose to clinical failure: buckling and kinking. This demonstrated that, at the time, the Cook Flexor sheath was most resistant to buckling and kinking. Validation of this observation was achieved in a subsequent multicenter, randomized, prospective clinical trial. The goal of such studies as this is to establish superiority or equiv-
ence in medical devices before subjecting patients to clinical use.

In this study we used similar in vitro testing on the next-generation ureteral sheaths, and compared the results to the standard set in the initial study; the Cook Flexor. No significant differences among the sheaths were demonstrated in regard to friction force, which is likely caused by the presence of lubricous hydrophilic coating on all of the sheaths.

The Cook Flexor ureteral access sheath required the most force to buckle. This would predict that the Cook Flexor would be least likely to buckle if resistance were encountered while advancing up the ureter. The Gyrus-ACMI UroPass was most resistant to kinking; thus, it is reasonable to infer it has a greater ability to maintain an open lumen in the face of extrinsic compression at the bladder neck, prostate, or site of ureteral narrowing. These significant physical differences should infer clinical superiority over the other sheaths tested.

In our clinical experience, buckling appears to be the more common challenge during placement of the sheath. Well-designed in vitro testing should be the basis for initial evaluations of medical devices before clinical use. If in vitro testing suggests superiority or equivalence, clinical trials should then be conducted. On the basis of this study, it would be reasonable to compare the relative merits of the Cook Flexor sheath with the ACMI UroPass in a randomized clinical trial.

One may question how rigid should a ureteral access sheath be? A sheath should resist buckling up to pressures that an experienced urologist will exert, yet should buckle before a pressure that may result in ureteral perforation is reached. We have previously reported that experienced endourologists use a maximum of 6.6 N of force when placing a ureteral access sheath.\textsuperscript{9} In addition, perforation of a human ureter with a CT-1 needle requires 4.7 N of force; one would anticipate the larger cross-sectional area of a ureteral access sheath would require a substantially larger perforation force.\textsuperscript{10}

**Conclusions**

The Cook Flexor ureteral access sheath is most resistant to buckling forces that would predict failure to advance up the ureter. The Bard Aquaguide is most likely to kink after removal of the inner obturator, whereas the ACMI UroPass is most resistant to kinking.

Demonstrating the physical properties of each commercially available ureteral access sheaths will facilitate refining their qualities for a safer and more efficient procedure.

**References**