
Guidewire type and prior use affects ureteral stent insertion force

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Introduction: To improve the success rate and safety of ureteral stent insertion, we sought to identify the effect of guidewire type and prior use upon the force needed to advance a 6Fr ureteral stent over various guidewires.

Materials and methods: Two-hundred forty stent insertion trials were performed in an ex vivo porcine urinary tract model. Ten trials were randomly performed over 12 new and 12 used guidewires. For each trial, the force required to advance a 6Fr Cook double-pigtail ureteral stent was recorded. Guidewires included the Olympus Glidewire, Cook Fixed Core, and Boston Scientific Amplatz Super Stiff, Sensor, ZIPwire, and Zebra wire.

Results: The mean force needed for stent advancement was the lowest for the new Glidewire (0.18N) and ZIPwire

(0.22N), with no significant difference to each other ($p=0.90$). The following new wires required increasingly higher stent insertion forces compared to the Glidewire, the Zebra (0.60N; $p < 0.01$), Fixed Core (1.25N; $p < 0.01$), Sensor (1.43N; $p < 0.01$), and Amplatz Super Stiff wires (2.03N; $p < 0.01$). There was no statistical difference between new and used Glidewires (0.18N versus 0.29N; $p = 0.14$) and Zebra wires (0.59N versus 0.60N; $p = 0.88$). All other used wires required a significantly greater advancement force than their new counterparts ($p < 0.01$).

Conclusions: For the same stent, the force required for stent advancement varies greatly between guidewire types. In addition, used guidewires typically required more force compared to new guidewires. In long or difficult cases, switching to a new wire may improve the ease of stent placement and reduce potential complications.

Key Words: ureteral catheterization, surgical endoscopy, disposable equipment, ureteral obstruction, stents

Introduction

Ureteral stent insertion is a common endourologic procedure routinely performed in a variety of indications including maintenance of ureteral patency following

complicated ureteroscopic lithotripsy, treatment of ureteral strictures, and treatment of upper tract urothelial tumors.¹⁻³ In the majority of settings, these stents are placed in a monorail fashion over a guidewire. Although there are many guidewires on the market today, the effect of wire type upon the force required for stent placement has not been well-characterized. In addition, there is still no consensus on the best type of guidewire to employ for stent insertion.⁴⁻⁶

It has been established that an ideal wire for stent insertion should be flexible enough to go around an obstruction, while at the same time firm enough

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to allow for advancement of a stent or catheter.⁷ Guidewire tips must also balance being soft enough to prevent tissue damage while remaining stiff enough to bypass any obstruction or narrowing.⁸ If the surgeon chooses a guidewire that is too flexible, issues like kinking, buckling, and even knotting of the wire can occur.⁹ On the other hand, selecting a wire that is too firm increases the risk for ureteral perforation during advancement into the urinary tract.^{10,11}

Previous studies have compared a variety of parameters in new guidewires including tip bending resistance, pull force, and tip puncture ability.⁷ However, there are no previous studies in the literature assessing the durability of guidewires and the effect that prior use of a guidewire has upon the subsequent force required for stent placement. During an endourologic procedure, endoscope passage, laser lithotripsy and other tasks may create alterations in the properties of the guidewire being used resulting in degradation of the wire's stent placement characteristics.^{12,13} The purpose of this study is to identify how guidewire types and their prior use affect the force required for insertion of a 6Fr double pigtail ureteral stent.

Materials and methods

Six different guidewire types were employed for 6Fr double pigtail stent insertion in a benchtop porcine model. Guidewires included the Glidewire (Olympus, Center Valley, PA, USA), Fixed Core guidewire (Cook Medical, Bloomington, IN, USA), Amplatz Super Stiff wire (Boston Scientific, Marlborough, MA, USA), Sensor wire (Boston Scientific), ZIPwire (Boston Scientific), and Zebra wire (Boston Scientific). All guidewires used in the study had a diameter of 0.038". These six wires were chosen as they are the most commonly used at our institution for endourologic procedures.

Intact porcine kidneys, ureters, and bladders were harvested and used to create the urinary tract model. Once assembled, saline was continuously infused at a rate of 1 cc/min into the right kidney using a pediatric 10Fr. Foley catheter to simulate urine production, Figure 1a. Guidewires were inserted in a randomized fashion into the ipsilateral kidney, and subsequently a stent was inserted over each wire. For each trial, a new, soft 6Fr Cook double-pigtail multi-length ureteral stent (Cook Medical, Bloomington, IN, USA) was placed over the guidewire. New stents were used in trials of both new and used guidewires.

Six types of guidewires were included in our study and we tested 2 new and 2 used of each type (total 24 guidewires). Each wire was tested 10 times resulting in 240 total stent placements. The used guidewires

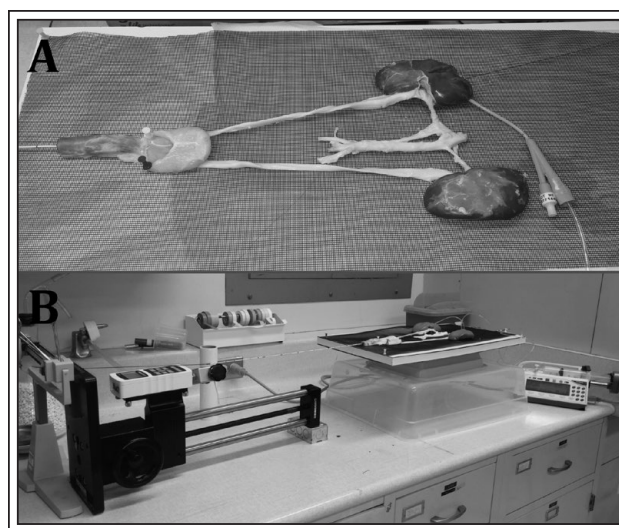


Figure 1. (A) Experimental setup of porcine model. (B) Mark-10 force gauge and wire.

were collected by an attending endourologist after use in actual clinical ureteroscopy cases. A Series 5 Mark-10 digital force gauge (Mark-10 Corporation, Copiague, NY, USA) was attached to the stent to accurately measure the force (reported in Newtons, N) needed for advancement through the urinary tract during each trial, Figure 1b.^{14,15} To standardize the rate of insertion, each stent was advanced at a rate of 0.508 cm per second, which equates to 2 rotations per second with the force gauge apparatus.

The primary outcome of the study was to measure the average force required for stent insertion. Continuous variables were analyzed using Analysis of Variance (ANOVA) for 6 groups and further post-hoc pair-wise comparisons were performed using Tukey's B with an alpha level of 0.05.

A secondary outcome of the study was to examine the new and used guidewires using scanning electron microscopy to determine structural factors that could mechanistically account for differing stent insertion forces. Following completion of trials, new and used guidewires of each type were imaged using a VEGA LSH scanning electron microscope (Tescan USA, Warrendale, PA) at an accelerating voltage of 10.0 kV and magnification range of 117–215 ×. Guidewire preparation involved upright affixing onto aluminum Pin Stub Mounts with PELCO Tabs Carbon Conductive Tabs (Ted Pella, Inc., Redding, CA, USA) and plating with a Cressington 108 Auto Sputter Coater (Cressington Scientific Instruments Ltd., Watford, United Kingdom) using gold–palladium. Resulting images were then compared for structural differences.

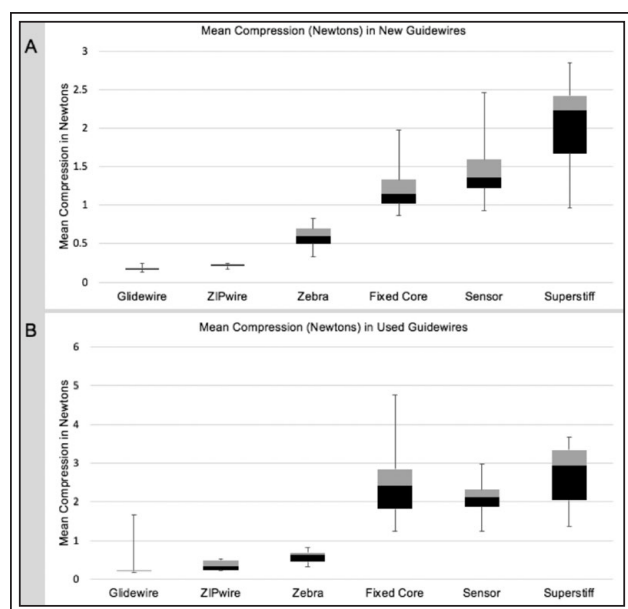


Figure 2. (A) New and (B) used insertion forces.

Results

The insertion forces required for double-pigtail stent placement over each type of new wire are demonstrated in Figure 2a. Of the 6 new wires tested, the Glidewire had the lowest mean insertion force (0.18 N) and required significantly less force for stent insertion than the Zebra (0.60 N; $p < 0.01$), Fixed Core (1.25 N; $p < 0.01$), Sensor (1.43 N; $p < 0.01$), and Super-Stiff wires (2.03 N; $p < 0.01$), Table 1. The ZIPwire

also required significantly lower insertion force than the Zebra, Fixed Core, Sensor, and Super Stiff wires ($p < 0.01$ for all). There was no significant difference between the new Glidewire and ZIPwire (0.18 versus 0.22 N; $p = .90$).

Although the Zebra wire required significantly more force to advance a stent than the Glidewire or the ZIPwire, it required significantly less force than the Fixed Core, Sensor, and Super Stiff wires ($p < 0.01$ for all). Fixed Core and Sensor guidewires showed no significant difference from each other (1.25 N versus 1.43 N; $p = 0.47$). The Amplatz Super Stiff required significantly more force for stent insertion than every other wire tested ($p < 0.01$ for all).

The forces required to advance a stent over each type of previously used guidewire are shown in Figure 2b. The used Glidewire required the lowest mean force for stent placement (0.29 N), followed by the used ZIPwire (0.36 N), Zebra (0.59 N), Sensor (2.09 N), Fixed Core (2.40 N), and Super Stiff wires (2.68 N). The used Glidewire, ZIPwire, and Zebra wires were not significantly different from each other ($p > 0.05$), Table 2. However, these three wires required significantly less insertion force than the used Sensor, Fixed Core, and Super Stiff wires ($p < 0.01$ for all). The used Fixed Core wire did not differ significantly from the used Sensor and the used Super Stiff wires ($p = 0.42$ and 0.52 respectively). The used Sensor required significantly less insertion force than the used Super Stiff wire ($p < 0.01$).

Compared to new wires of the same type, the used Glidewires (0.18 versus 0.29 N; $p = 0.15$) and Zebra

TABLE 1. Comparison of new guidewires forces

New guidewire insertion force comparison					
	Glidewire	ZIPwire	Zebra	Fixed Core	Sensor
ZIPwire	0.5800				
	$p = 0.90$				
Zebra	6.1084	5.5284			
	$p < 0.01^*$	$p < 0.01^*$			
Fixed Core	15.3677	14.7877	9.2593		
	$p < 0.01^*$	$p < 0.01^*$	$p < 0.01^*$		
Sensor	17.9099	17.3299	11.8015	2.5422	
	$p < 0.01^*$	$p < 0.01^*$	$p < 0.01^*$	$p = 0.47$	
Super Stiff	26.5462	25.9662	20.4378	11.1785	8.6363
	$p < 0.01^*$	$p < 0.01^*$	$p < 0.01^*$	$p < 0.01^*$	$p < 0.01^*$

*indicates a significant difference between wires

TABLE 2. Comparison of used guidewires forces

Used guidewire insertion force comparison					
	Glidewire	ZIPwire	Zebra	Fixed Core	Sensor
ZIPwire	0.6628 p = 0.90				
Zebra	2.6600 p = 0.42	1.9971 p = 0.69			
Fixed Core	18.2068 p < 0.01*	17.5439 p < 0.01*	15.5468 p < 0.01*		
Sensor	15.5511 p < 0.01*	14.8882 p < 0.01*	12.8911 p < 0.01*	2.6557 p = 0.42	
Super Stiff	20.6257 p < 0.01*	19.9629 p < 0.01*	17.9657 p < 0.01*	2.4190 p = 0.52	5.0747 p < 0.01*

*indicates a significant difference between wires

wires (0.60 versus 0.59 N; $p = 0.87$) did not require significantly greater insertion force. However, there was a significant difference in insertion forces between new and used ZIPwire (0.22 versus 0.36 N; $p < 0.01$), Fixed Core (1.25 versus 2.40 N; $p < 0.01$), Sensor (1.43 versus 2.09 N; $p < 0.01$), and Super Stiff wires (2.03 versus 2.68 N; $p < 0.01$), Figure 3.

One new and one used wire of each type was visualized under scanning electron microscopy, Figure 4. The hydrophilic coating of the new Glidewire, Zebra and ZIPwire is visibly smoother than the coiled surface of the Fixed Core, Sensor and Super Stiff wires. This may explain the differences in the mean stent insertion forces of these new wires, Table 3. The Teflon coating of the used Fixed Core, Sensor and Super Stiff wires appears to have been damaged during use with resultant flaking of the Teflon coating, which may explain the

increased insertion forces for used versions of these wires. The surfaces of the used Zebra and ZIPwires show obvious cracks and dents, however the used Glidewire demonstrated no obvious structural changes.

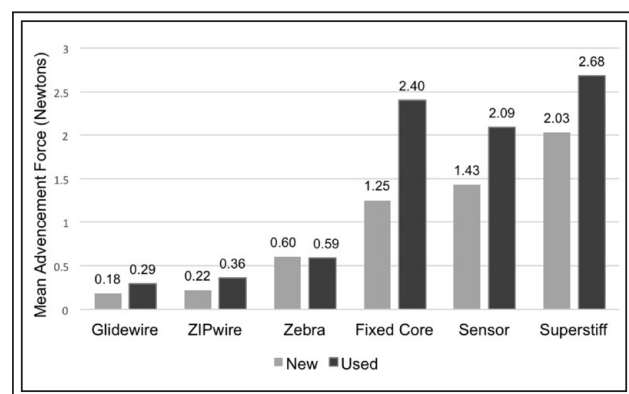


Figure 3. Mean stent advancement forces.

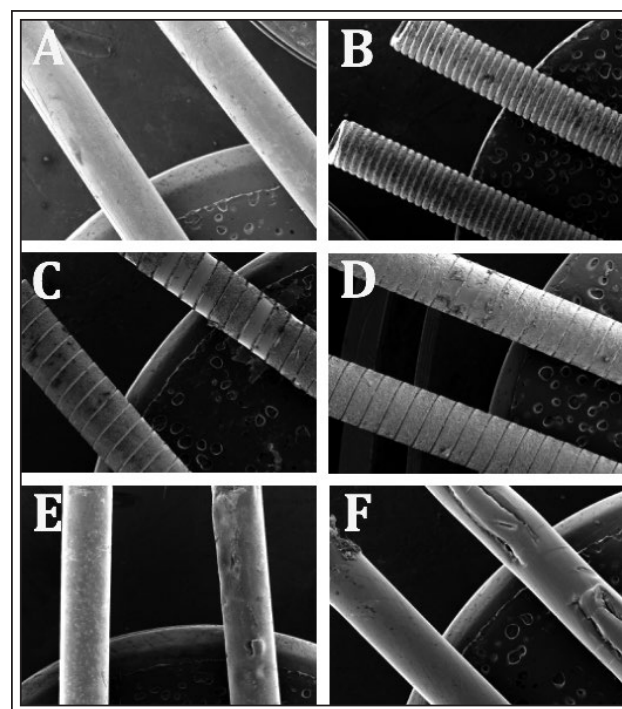


Figure 4. New (left) and used (right) guidewires visualized under scanning electron microscopy. (A) Glidewire (B) Fixed Core (C) Super Stiff (D) Sensor (E) Zipwire (F) Zebra.

TABLE 3. Coating properties of tested guidewires

Guidewire coating and insertion forces			
Guidewire name	Coating type	Insertion force (over a new wire)	Notes
Glidewire	Hydrophilic	0.18N	
ZIPwire	Hydrophilic	0.22N	
Zebra	Hydrophilic and PTFE	0.60N	Distal 60 cm coated with hydrophilic coating
Fixed Core	PTFE	1.25N	
Sensor	Hydrophilic and PTFE	1.43N	Distal 5 cm coated with hydrophilic coating
Super Stiff	PTFE	2.03N	

Interestingly, the used and new Zebra wires performed similarly despite obvious damage to the used wire.

Discussion

Guidewires are not all equal in stiffness, malleability, and lubricity.^{7,11,16,17} Subsequently it stands to reason that certain wires may allow placement of a double pigtail stent more easily than other wires. A better understanding of stent advancement forces could improve patient safety and procedure success. Pedro et al reported that the average force to perforate a human ureter with the back end of a 0.035 inch Boston Scientific Super Stiff guidewire was 0.79 ± 0.25 pound-mass (lb(m)).¹⁸ Assuming gravity as the acceleration this equates to an average force of 3.51 N. Our experiment generated forces in excess of this value during some individual trials, although our highest mean force was 2.68 N (also with the Boston Scientific Super Stiff wire). Although these values may seem too close for comfort, the forces reported by Pedro et al were measured using a guidewire advancing perpendicularly into the ureter wall while our forces were acquired while advancing a stent over a wire, parallel to the ureter's ...direction.¹⁸

In clinical practice we frequently experienced cases where proper stent placement was crucial. We originally thought that the stiffest wires would provide the most control and support of the stent and allow for easier stent placement. However, situations arose where we could not get the stent to track over the stiff guidewire or the stent would accordion up and get stuck on the guidewire. Later attempts to remove the guidewire from the stent had even resulted in the guidewire uncoiling or fragmenting. This would occur in cases where precise stent placement was most crucial

to prevent significant morbidity and complications to the patient. This was the impetus for this study.^{10,19,20}

Understanding the differences between the guidewires on the market can be difficult as they vary greatly in shaft materials and surface coatings. Matters are further complicated by a lack of precise and standardized terminology.²¹ For example, Harrison et al noted that two guidewires from different companies labeled as "extra stiff" had a 5-fold difference in the calculated stiffness or "flexural modulus" of their wires.²¹ This lack of uniformity in the nomenclature used by various manufacturers, makes estimating the performance of each guidewire a difficult task.

The Glidewire has achieved a significant amount of attention in recent studies. Clayman et al tested 9 guidewires and found that the Glidewire generated the least friction when advancing a 5Fr catheter through a gel cylinder ureter model.⁷ Patriciu et al also showed that the Glidewire outperformed most standard alternatives in its ability to advance a 6Fr catheter in a silicone tubing ureter model.²² Our study was novel in its use of an intact porcine urinary system to more accurately model the angles and urothelium present in a genitourinary system and by our inclusion of the ZIPwire. Our study also evaluates the insertion of a larger double-pigtail stent which may be more difficult to place compared to the 5Fr straight ureteric catheter studied previously. Similar to the above studies, we found that the Glidewire required the least amount of force to facilitate stent advancement. Additional studies have also reported that the Glidewire has both the safest tip in regards to piercing force as well as the best lubrication for guiding the stent into place.^{7,16,17} The Glidewire has also been shown to have the best "shape memory" as it is able to maintain its structure despite any significant forces applied.²³ Shah et al

reported that physicians felt more comfortable using the Glidewire than other hydrophilic wires due to its lubrication and tip shape retention.²⁴

These findings can also be explained by the fact that the Glidewire, when examined under scanning electron microscopy, showed no structural damage or superficial abrasions after use. As demonstrated in Figure 4, other wires had varying degrees of damage ranging from flaking Teflon coatings to jagged nicks and irregularities. These changes in coating are likely correlated with the higher insertion force required to advance stents over the used guidewires. Used Super Stiff, and Fixed Core wires required a high mean advancement force, these findings may suggest that it would be preferable not to use them repetitively during the same intervention. For example, if stent placement was crucial in the setting of an injured ureter, switching to a new wire before stent insertion may be advisable.

The force needed to advance the stent over a new ZIPwire (0.22 N) was relatively low compared to every alternative aside from the Glidewire. The used ZIPwire only required 0.36 N of force to advance a stent through the urinary tract. This was the second-best performance out of all the used wires tested, surpassed only by the used Glidewire (0.29 N). Ohki et al also reported that the ZIPwire had the best torque and maneuverability compared to two other guidewires including the Glidewire.²³

Another interesting finding of this study was that the Zebra wire had the least change in the force needed to advance the stent between the new (0.60N) and used wires (0.59N). New and used Glidewires also showed no statistical difference to each other (0.22N vs 0.29N). In contrast to the Zebra wire, the Fixed Core wire reported the highest change in advancement force after prior usage, where the force needed almost doubled between new and used guidewires (1.25N to 2.40N).

There are some limitations of our study. The intact porcine urinary tract may not completely replicate the human urinary tract. Although Ohki et al and Patriciu et al simulated the urinary tract with plastic or silicone tubing, we chose the porcine tissue model to provide a more accurate representation of the elasticity and tension guidewires encounter in patients.^{22,23,25-28} Conducting the study in human volunteers was not feasible due to the number of trials needed and challenges measuring insertion forces in live patients.²⁹ Wolf et al compared the urinary tract microanatomy of multiple animals to human microanatomy and the pig was found to have the closest approximation of epithelial polarization, muscle fiber orientation and linear cross-sectional thickness to human tissue.^{26,27} We

therefore elected to use a porcine model to achieve the most realistic simulation possible while still allowing us to control all aspects of the study. Our saline irrigating solution did not have the same pH and composition as urine, but this likely constituted a very minute change in the lubricity of the stents used and perhaps resulted in a negligible change in the mean force for stent insertion.

Another potential source of error comes from the employment of used guidewires, which were subjected to the wear and tear of actual ureteroscopy before being used in our study. We decided to employ guidewires used in actual cases to most accurately represent the trauma occurring to wires during clinical cases. However, it is possible that some of the differences in guidewire performance could arise from variations in the surgical procedures. However, wires were only obtained after uncomplicated ureteroscopy cases. We attempted to minimize this confounder by obtaining 2 wires of each tested type from cases performed by a single attending endourologist. In addition, we measured 10 trials for each used guidewire (for a total of 20 trials per guidewire type) to characterize the force required for stent advancement. After use, the wires degrade as demonstrated on the scanning electron microscopy, and it becomes more difficult to insert stents over them. While the scanning electron microscopy is a useful tool to detect surface changes on wires, the pictures we obtained are only small representative sections of the entire length of each wire. This limits our ability to quantify the extent of the damage to used wires. For example, the imaged section of the used Zebra wire looks very different from the new wire, but the performance of the wires was not significantly different.

Conclusions

Guidewires vary greatly in the force required to advance stents over them. Furthermore, use of wires may create surface changes that would increase the difficulty of stent placement. The Glidewire required the lowest insertion force and showed great potential for reusability, possibly due to its resilient hydrophilic coating. In contrast, employing a used Fixed Core, Super Stiff, or Sensor wire may result in additional force placed on the urinary tract as their coatings can be less durable. In these cases, surgeons may benefit by switching to a new wire prior to stent placement. Knowledge of the forces required for stent insertion will allow urologists to make informed decisions when choosing wires to improve the ease and safety of stent placement.

Disclosures

D. Duane Baldwin certifies that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (e.g., employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: speaker for Cook, consultant for Olympus, board member for DARRT Medical, and board member for StepLite.

The remaining authors have nothing to disclose. □

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