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Structural factors influencing the clinical performance of 0.025-inch guidewires for pancreatobiliary endoscopy: An experimental study

Takehiko Koga, Naoaki Tsuchiya, Yusuke Ishida, Takanori Kitaguchi, Keisuke Matsumoto, Makoto Fukuyama, Satoki Kojima, Norihiro Kojima, Fumihito Hirai.

Affiliations below.

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Abstract:
Background and study aims:
To develop a pancreatobiliary endoscopic guidewire with good clinical performance, an understanding of its structure is necessary. This study aimed to investigate the structural factors influencing the clinical performance of pancreatobiliary endoscopic guidewires.
Methods:
Eight types of 0.025-inch guidewires were evaluated. The following structural properties were measured: tip length, tip deflection height, tip weight (TW), ratio of tip core weight to TW, shaft coating type (flat or uneven), outer diameter, and core wire diameter (CWD). Four performance tests were conducted to evaluate shaft stiffness as bending force (BF), shaft lubricity as friction force (FF), torque response as torque response rate (TRR), and seeking ability as total insertion success (TIS) in a technical test using a 3D bile duct model. The correlation coefficients of each variable were analyzed.
Results:
The BF and CWDs were strongly correlated, as well as the FF and CWDs and BF. Among the guidewires with similar CWDs, the guidewires with uneven coating had significantly lower FF than those with flat coating. The TRR was strongly correlated with the CWDs; furthermore, guidewires with lower FF had better TRR. TIS was strongly correlated with the TRR, TWs, and ratio of the tip core weight to TW.
Conclusions:
The CWD affects the shaft stiffness; the CWD and coating type affect shaft lubricity and torque response. Since the TRR and TW are correlated with seeking ability, an appropriate combination of core wire thickness, TW, and coating design is required to develop a guidewire with good seeking ability.

Corresponding Author:
Yusuke Ishida, Fukuoka University Hospital, Department of Gastroenterology and Medicine, Faculty of Medicine, Fukuoka, Japan, y.ishida.cb@adm.fukuoka-u.ac.jp

Affiliations:
Takehiko Koga, Fukuoka University Hospital, Department of Gastroenterology and Medicine, Faculty of Medicine, Fukuoka, Japan
Naoaki Tsuchiya, Fukuoka University Hospital, Department of Gastroenterology and Medicine, Faculty of Medicine, Fukuoka, Japan
Yusuke Ishida, Fukuoka University Hospital, Department of Gastroenterology and Medicine, Faculty of Medicine, Fukuoka, Japan
[...]
Fumihito Hirai, Fukuoka University Hospital, Department of Gastroenterology and Medicine, Faculty of Medicine, Fukuoka, Japan

Introduction

Guidewires are essential to endoscopic retrograde cholangiopancreatography (ERCP) [1, 2]. Conventionally, 0.035-inch guidewires have been used; recently, high-performance 0.025-inch guidewires have been developed and frequently used [3-6]. Additionally, 0.025-inch guidewires have been used for endoscopic ultrasound-guided biliary drainage (EUS-BD) procedures [7, 8]. The 0.025-inch guidewires used for ERCP and EUS-BD are required to have the following clinical performance: good seeking ability, lubricity, flexible tips, and stiff shafts. Several studies have evaluated these performances of specific guidewire products [5, 6, 9-11]. However, these studies have primarily focused on comparisons among guidewire products and lack a structural perspective that could be useful for guidewire development. Furthermore, the structural factors influencing the clinical performance of guidewires have not been investigated. Herein, we analyzed various structural properties of 0.025-inch guidewires prior to experiments to evaluate their clinical performance. This study aimed to investigate the structural factors influencing the clinical performance of guidewires and assist with the future development of better pancreatobiliary endoscopic guidewires.

Methods

Guidewires

During this experimental study, the following eight 0.025-inch, angled-tip guidewires that are commercially available in Japan were evaluated: VisiGlide2 (Olympus Medical Systems, Tokyo, Japan); M-Through (ASAHI INTECC, Seto, Japan); Fielder 25 (ASAHI INTECC); EndoSelector (Boson Scientific, MA, USA); J-WIRE Prologue ST

(J-MIT INC, Kyoto, Japan); RevoWave UltraHard (Piolax Medical Devices, Yokohama, Japan); RevoWave Hard (Piolax Medical Devices); and SeekMaster (Piolax Medical Devices).

Basic construction of the guidewire

The basic construction of the guidewire is illustrated in Figure 1. The basic construction of all guidewires evaluated in this study was identical. The guidewire tip had a black polyurethane coating, and the shaft was coated mainly with polytetrafluoroethylene (PTFE). The core wire was inside the coatings and was gradually tapered toward the tip, and a spiral-coiled spring was wound around the tip of the core wire. Additionally, the core wire material of guidewires investigated in this study was nickel–titanium (Ni-Ti).

Structural measurements

Each structural variable is illustrated in Figure 1.

- **Tip length**

The length of the black polyurethane coating on the guidewire tip was measured.

- **Tip deflection height**

The tip deflection height was measured based on the straight shaft section of the guidewire [11].

- **Tip weight and tip core weight**

The weight of a 50-mm piece cut from the guidewire tip (tip weight) was measured using a micrometer (Sartorius, Tokyo, Japan). Further, the weight of the core wire at the tip (tip core weight) was measured after the removal of the polyurethane coating and spiral-coiled spring of the tip.

- **Ratio of tip core weight to tip weight**

The tip core weight as a percentage of the tip weight was calculated.

- **Shaft coating type**

There are two surface coating methods for guidewire shafts: jacket coating and paint coating. The coating method varied according to the manufacturer. In jacket coating, the core wire is covered with a pre-manufactured polymer jacket, whereas paint coating can either be achieved as dip coating, in which the core wire is dipped into a coating material bath and then dried or cured, or spray coating, in which the core wire is sprayed with the coating material, creating an even layer. In the present study, regardless of the coating method, the surface coating was classified as flat coating (flat and smooth surface treatment) or uneven coating (those with an uneven surface treatment) based on its appearance and texture.

- **Outer diameter**

The guidewires evaluated in this study are sold as having an outer diameter of 0.025 inches (0.635 mm) at the shaft; however, the actual outer diameter varies. Therefore, a digital caliper was used to measure the actual outer diameter of the guidewires.

- **Core wire diameter**

The diameter of the core wire with the surface coating and coil spring removed was measured using a digital caliper, and the core wire diameter at the shaft was obtained. Additionally, the core wire diameter from the tip to 200 mm was measured at 10-mm intervals.

Tip length, tip deflection height, and tip weight were measured based on the hypothesis that they affect seeking ability. Shaft coating type, outer diameter, and core wire diameter were measured based on the hypothesis that they affect shaft stiffness, lubricity, torque response, and seeking ability.

Performance tests

The following experiments were conducted to evaluate clinical performance (Supplementary Table 1).

- **Bending force**

Bending force (BF) was measured to compare the stiffness of the guidewire shafts. The support and pushability during the insertion of devices, such as ERCP catheters or pancreatobiliary stents, into the bile or pancreatic duct depend on the stiffness of the guidewire shafts. Three-point bending tests were performed using a universal testing machine (Strograph; TOYOSEIKI, Tokyo, Japan) to measure shaft stiffness (Figure 2a). The distance between the two points of the fixed guidewire was set to 15 mm. BF was defined as the maximum force measured when the center of the guidewire between the fixed points was pushed vertically with a stick to a depth of 1 mm at a speed of 0.5 mm/sec.

- **Friction force**

Friction force (FF) was measured to compare the lubricity of the guidewire shafts. Lubricity is related to the ease of device exchange and ease of inserting the guidewire into the catheter during ERCP and EUS-BD. An experiment was conducted to verify the lubricity of the guidewire shaft in the catheter (Figure 2b). An ERCP catheter (uneven double-lumen cannula; Piolax Medical Device) was fixed in a semicircle with a radius of 125 mm. The guidewire was then inserted in the 0.025-inch guidewire lumen of the catheter, 400 mm from the tip, and the distal side of the guidewire was fixed to a universal testing machine (Strograph; TOYOSEIKI). FF was defined as the maximum force when the guidewire was pulled 50 mm at a speed of 5 mm/sec.

- **Torque response rate**

Torque response rate (TRR) was measured to compare the torque response of guidewires, which is the circumferential transmission of force from the grip to the tip. Torque response is related to the ease of intended guidewire manipulation during ERCP and EUS-BD. An experiment was conducted to verify the torque response (Figure 2c). An ERCP catheter designed for a 0.025-inch guidewire (MTW Endoskopie, Wesel, Germany) was inserted into a 300×500-mm cylinder by winding it in a one-and-a-half turn. The guidewire was inserted in the catheter so that it protruded 80 mm from the tip. Circumferential rotation was manually applied from the distal side of the guidewire, and the angle of rotation required for the tip to rotate 30° was measured. TRR was defined as the tip movement angle (30°) divided by the rotation angle. The rotation angle was determined by visual measurement. Therefore, it was difficult to measure in 1-degree increments, and measurements were made in 5-degree increments. Three endoscopists evaluated the angle and reached a consensus on the results.

Total insertion success

Total insertion success (TIS) was measured to compare the seeking ability of the guidewires. A 3D-printed silicone bile duct model (BILE360; JMC, Kanagawa, Japan) was used to validate the seeking ability (Figure 2d). An ERCP catheter designed for a 0.025-inch guidewire (MTW Endoskopie) was placed in the common hepatic duct of a water-filled model. The catheter was not operated; the guidewire was manipulated, and the time required to reach the target branch after insertion was measured. Two branches, B3 and B7, were used as the targets because of their complex bends and insertion difficulty. Successful insertion was defined as the insertion of the guidewire into the target branch within 60 seconds. Twenty endoscopists (ERCP experience >500 cases: 5;

500-100 cases: 11; 100-10 cases: 4) participated in the technical test. The number of successful insertions in B3 and B7 were summed to define TIS. A cross-over method was used to set up a different sequence of guidewires to be used by each endoscopist to minimize the influence of the learning curve. Each guidewire was prepared in five products. After each seeking test, the guidewires were inspected for deterioration, and those with bent or peeling coatings were replaced with new ones for the next test. The maximum number of uses for each guidewire was five.

Statistical analysis

The BF, FF, and TRR were measured three times for each guidewire and the average was used as the variable for each; a different guidewire product was used for each of the three measurements. Continuous variables are expressed as means and standard deviations, whereas categorical variables are expressed as proportions. Continuous variables were analyzed using the Student t-test. $p<0.05$ was considered significant. Correlations between the structural variables (tip length, tip deflection height, tip weight, ratio of tip core weight to tip weight, outer diameter, and core wire diameter) and performance variables (BF, FF, TRR, and TIS) were analyzed using simple linear regression and a correlation analysis and expressed as the correlation coefficient (r). A strong positive correlation was considered when $r \geq 0.7$, and a strong negative correlation was considered when $r \leq -0.7$. All statistical analyses were performed using SPSS version 25.0 (SPSS Inc., IBM Corp., Armonk, NY, USA).

Results

Structural measurements

The materials and structural measurements of the guidewires are shown in Table 1. Tip lengths ranged from 50 to 120 mm. Tip deflection heights ranged from 6.0 to 11.5 mm (Figure 3). Tip weights ranged from 41.0 to 94.0 mg. Tip core weights ranged from 6.2 to 16.1% of tip weights. The shaft coating of each guidewire is shown in Figure 4. VisiGlide2, M-Through, J-WIRE Prologue ST, RevoWave UltraHard, and RevoWave Hard have flat coatings. In contrast, the Fielder 25, EndoSelector, and SeekMaster have uneven coatings. RevoWave UltraHard and RevoWave Hard have similar coatings. The outer diameters ranged from 0.57 to 0.61 mm. The core wire diameters of the shaft sections ranged from 0.44 to 0.56 mm. The core wire diameters from the tip to 200 mm are shown in Figure 5. M-Through has an identical core wire diameter with Fielder 25, and RevoWave Hard has an identical core wire diameter with SeekMaster.

Performance tests

The BF, FF, and TRR measurements are presented in Table 2 and Figure 6. The BFs ranged from 1.25 to 3.39 N. Guidewires with core wire diameters ≥0.5 mm had significantly higher BF than those with core wire diameters <0.5 mm ($p<0.001$).
The FFs ranged from 0.049 to 0.100 N. Of the guidewires with a core wire diameter ≥0.5 mm, the guidewires with uneven coating exhibited a significantly lower FF compared to those with flat coating ($p=0.048$). Similarly, of the guidewires with a core wire diameter <0.5 mm, the guidewires with uneven coating showed a significantly lower FF than those with flat coating ($p<0.001$). The TRR ranged from 7.0 to 22.0%. In a comparison between guidewires of the same core wire diameters, the guidewires with uneven coating (Fielder 25 and SeekMaster) had higher TRR than those with flat

coating (M-Through and RevoWave Hard). The results of the seeking ability tests using the 3D-printed bile duct model are presented in Table 3. The TIS rates were highest for Fielder 25 (38/40; 90%), VisiGlide2 (34/40; 85%), and J-WIRE Prologue ST (34/40; 85%).

Correlation between structure and performance

The correlation matrix for each variable is shown in Figure 7. The BF and core wire diameters were strongly positively correlated (r=0.983). The FF was strongly positively correlated with the core wire diameter (r=0.788) and BF (r=0.757). Moreover, the TRR was strongly positively correlated with the core wire diameter (r=0.711). The TIS rate was strongly positively correlated with the tip weight (r=0.785) and TRR (r=0.772), and was strongly negatively correlated with the ratio of tip core weight to tip weight (r=-0.772).

Discussion

This experimental study of 0.025-inch pancreatobiliary guidewires demonstrated that structural factors of core wire diameter, coating type, tip weight, and the ratio of tip core weight to tip weight affect clinical performance of shaft stiffness, shaft lubricity, torque response, and seeking ability.

Previous reports on pancreatobiliary guidewires can be divided into two broad categories: clinical and experimental. Several clinical studies have compared 0.025-inch and 0.035-inch guidewires, as well as angled and straight tips [12-19]. In selective bile duct cannulation, it has been reported that angled-tip guidewires were superior to straight-tip guidewires, and 0.025-inch guidewires were equal to or superior to 0.035-inch guidewires. Based on these studies, currently, the 0.025-inch, angled-tip guidewires are commonly used for ERCP and EUS-BD procedures. Additionally, there are various competing products of 0.025-inch guidewire in the market. However, the detailed differences between them have not been disclosed. Therefore, the guidewire selection by endoscopists or their assistants often depends on personal preferences, experiences, perceptions, and marketing. That is, the guidewire selection has not been based on objective indicators. In contrast, experimental studies may be helpful for objective assessment of the clinical performance of guidewires. Recently, five studies involving experiments to evaluate guidewire performance have been reported [5, 6, 9-11]. In these studies, several guidewire products were examined and compared regarding clinical performance, including stiffness, lubricity, seeking ability, and ease of loop shaping. However, the findings were based on specific guidewire products and lacked versatility. To overcome this problem, the structural properties underlying the clinical performance of the guidewire should be clarified.

In the present study, eight types of 0.025-inch guidewires were evaluated. All guidewires were manufactured using Ni-Ti core wires with a PTFE coating on the shaft. The standard deviations of the BF, FF, and TRR measurements were 0–0.042 N, 0–0.01 N, and 0.05–0.9% respectively, showing minimal statistical dispersion. No correlation was found between the outer diameter and BF. In contrast, the core wire diameter was strongly positively correlated with the BF. These results indicate that the shaft stiffness is affected by the core wire diameter, regardless of the surface coating thickness. That is, to increase the shaft stiffness of a guidewire comprising the same material and specifications, it is beneficial to use a thicker core wire and thinner surface coating to fit within the standard outer diameter.

The FF was strongly positively correlated with the core wire diameter and BF. This may have occurred because the frictional resistance between the catheter lumen and surface of the guidewire shaft increased in a curved catheter when the core diameter was thick and the BF was high. Concisely, there is a trade-off between shaft lubricity and core thickness. However, in a comparison among guidewires with similar core wire diameters, the guidewires with uneven coating resulted in significantly lower FF than those with flat coating. It was considered that the uneven coating reduced the contact area of the guidewire surface inside the catheter, thus contributing to improved shaft lubricity.

The TRR was strongly positively correlated with the core wire diameter. It was assumed that this occurred because thicker core diameters have higher torsional stiffness and better torque response from the grip to the tip. In a comparison among guidewires with identical core wires, the guidewires with uneven coating had better TRR than those with flat coating. Although no correlation was found between the FF and TRR, for the same core wire, the uneven guidewire with a lower FF is considered to have better TRR than the flat guidewire with a higher FF. When considering the torque response of guidewires, a balance between the core wire diameter and FF may be essential.

During a seeking ability test involving 20 endoscopists, Fielder 25, VisiGlide2, and J-WIRE Prologue ST had high TIS rates. Kobayashi *et al*. have conducted a technical test involving two endoscopists to verify the seeking ability of seven guidewires using a bile duct model [11]. Although the methods and the bile duct model used were different from our test, the results of the good seeking ability of Fielder 25 and VisiGlide2 were consistent. Furthermore, they noted that the tip deflection height and length of the hydrophilic coating were related to the seeking ability. In contrast, in the present study, the TRR was strongly positively correlated with the TIS. Furthermore, the tip weight and the ratio of the tip core weight to the tip weight affected TIS. The guidewires with high TIS had a tip core weight of 6–7%, whereas those with low TIS had a tip core weight of 15–16%. The weights of the components at the tip other than the core wire (i.e., the weight of the tip coating and spiral-coiled spring) may contribute to tip flexibility and suppression of whip motion of the guidewire. Further investigation is required to validate this hypothesis.

The strength of the present study is that it measured the differences in the structural properties between guidewires and analyzed them in relation to clinical performance. Because the results of the present study were based on a structural perspective, they may provide pancreatobiliary endoscopists the knowledge necessary to select a guidewire and may be useful in the development of future guidewires. To the best of our knowledge, this is the first study to clarify the relationship between the structural properties and clinical performance of pancreatobiliary guidewires. However, this study had three limitations. First, the environment of this study differed from *in vivo* conditions. The lubricity of the guidewire could be altered by contact with bile or contrast media, and experiments could not be performed under these conditions. Second, the seeking ability test was a subjective measurement and may not yield the same results if the participating endoscopists change. Third, only guidewires that were commercially available in Japan were validated. However, this study revealed a correlation between structural properties and clinical performance. Therefore, the results of this study are considered universal and can be applied to guidewires that have not yet been validated.

In conclusion, regarding the guidewire structure, the core wire diameter affects the shaft stiffness, and both the core wire diameter and coating type affect the shaft lubricity and torque response. Furthermore, the torque response, tip weight, and tip core weight affect the seeking ability. To develop a guidewire with good seeking ability, it is critical to strike a structural balance between appropriate core wire thickness, tip weight, and coating design.

Author contributions: Takehiko Koga conducted the structural measurements, mechanical property tests, and wrote the paper; Yusuke Ishida, Naoaki Tsuchiya, Takanori Kitaguchi, Keisuke Matsumoto, Makoto Fukuyama, Satoki Kojima, Norihiro Kojima, and Fumihito Hirai made important revisions; Yusuke Ishida supervised the preparation of the manuscript and approved the final manuscript.

Conflicts of interest: The authors declare no conflicts of interest.

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Figure legends

Figure 1. Basic construction of the guidewire and structural variables

The guidewire tip has a polyurethane coating, and the shaft is coated mainly with polytetrafluoroethylene. The core wire is inside the coatings. It is gradually tapered toward the tip, and a spiral-coiled spring is wound around the tip of the core wire.

Tip length, tip deflection height, tip weight, tip core weight, outer diameter, and core wire diameter are measured.

Figure 2. Performance tests

(a) The three-point bending test using the universal testing machine. The shaft stiffness (bending force) of the guidewire is measured.

(b) Measurement of shaft lubricity of guidewire in the catheter using the universal testing machine. The maximum friction force is measured as the guidewire is pulled inside the catheter.

(c) The torque response of the guidewire is measured. Rotation is applied from the distal side of the guidewire in the circumferential direction, and the angle of rotation required to rotate the tip 30° is measured.

(d) The 3D-printed silicone bile duct model. Twenty endoscopists participated in the seeking test to determine the insertion success of each guidewire. The target branches are B3 and B7.

Figure 3. The tip deflection heights of the guidewires

The tip deflection height is measured based on the straight shaft section of the guidewire.

(a) VisiGlide2; (b) M-Through; (c) Fielder 25; (d) EndoSelector; (e) J-WIRE Prologue

ST; (f) RevoWave UltraHard; (g) RevoWave Hard; (h) SeekMaster.

Figure 4. **Shaft coating of the guidewires**

(a, b, e, f, g) Flat coatings, (c, d, h) Uneven coatings.

(a) VisiGlide2; (b) M-Through; (c) Fielder 25; (d) EndoSelector; (e) J-WIRE Prologue ST; (f) RevoWave UltraHard; (g) RevoWave Hard; (h) SeekMaster.

Figure 5. The core wire diameter from the tip to 200 mm

M-Through has an identical core wire diameter with Fielder 25. RevoWave Hard has an identical core wire diameter with SeekMaster.

Figure 6. Performance test results

Guidewires with core wire diameters ≥0.5 mm have significantly higher bending force than those with core wire diameters <0.5 mm (*p*<0.001). Of the guidewires with a core wire diameter ≥0.5 mm, the uneven guidewires exhibited a significantly lower friction force compared to the flat guidewires (*p*=0.048). Of the guidewires with a core wire diameter <0.5 mm, the uneven guidewires showed a significantly lower friction force than the flat guidewires (*p*<0.001). In a comparison between guidewires of the same core wire diameters, the uneven guidewires (c and h) had higher torque response rate than the flat guidewires (b and g).

Figure 7. Correlation matrix between structural and performance variables

The numbers in the matrix indicate the correlation coefficients (r) between each variable.

The following pairs show strong positive correlations (r≥0.7): bending force and core wire diameter (r=0.983); friction force and core wire diameter (r=0.788); friction force and bending force (r=0.757); torque response rate and core wire diameter (r=0.711); total insertion success and tip weight (r=0.785); and total insertion success and torque response rate (r=0.772). The total insertion success and ratio of tip core weight to tip weight show a strong negative correlation (r=-0.772).

Table 1. Materials and structural measurements of 0.025-inch guidewires

Guidewires	Core material	Tip coiled spring	Tip coating material	Shaft coating material	Tip length (mm)	Tip deflection height (mm)	Tip weight (core/ total) (mg)	Ratio of tip core weight to tip weight (%)	Shaft coating type	Outer diameter (mm)	Core wire diameter (mm)
VisiGlide2	Ni-Ti	Yes	Hydrophilic polyurethane	PTFE	75	8.5	5.8/ 94.0	6.2	Paint/ Flat	0.60	0.56
M-Through	Ni-Ti	Yes	Hydrophilic polyurethane	PTFE	70	8.0	5.8/ 77.9	7.4	Paint/ Flat	0.59	0.55
Fielder 25	Ni-Ti	Yes	Hydrophilic polyurethane	PTFE PFA	71	9.5	5.8/ 78.6	7.4	Paint/ Uneven	0.61	0.55
EndoSelector	Ni-Ti	Yes	Hydrophilic polyurethane	PTFE FP*	65	7.0	6.7/ 58.6	11.4	Jacket/ Uneven	0.58	0.53
J-WIRE Prologue ST	Ni-Ti	Yes	Hydrophilic polyurethane	PTFE	120	8.0	5.2/ 77.1	6.7	Jacket/ Flat	0.61	0.48
RevoWave UltraHard	Ni-Ti	Yes	Hydrophilic polyurethane	PTFE Silicone	50	6.0	7.1/ 44.1	16.1	Jacket/ Flat	0.61	0.48
RevoWave Hard	Ni-Ti	Yes	Hydrophilic polyurethane	PTFE Silicone	50	8.5	6.3/ 41.0	15.3	Jacket/ Flat	0.57	0.44
SeekMaster	Ni-Ti	Yes	Hydrophilic polyurethane	PTFE Silicone	50	11.5	7.8/ 69.0	11.3	Jacket/ Uneven	0.59	0.44

Ni-Ti: Nickel-titanium, PTFE: polytetrafluoroethylene, PFA: Perfluoroalkoxy alkanes, FP: fluoropolymer

*The type of fluoropolymer is not disclosed.

Table 2. Results of performance tests

Guidewires	Bending force, Newton (SD)		Friction force, Newton (SD)		Torque response rate, % (SD)	
VisiGlide2	3.39	(0.014)	0.100	(0)	16.4	(0.5)
M-Through	3.25	(0.007)	0.087	(0.003)	12.7	(0.6)
Fielder 25	3.14	(0.007)	0.055	(0.009)	22.0	(0.9)
EndoSelector	3.31	(0.042)	0.060	(0.01)	14.1	(0.4)
J-WIRE Prologue ST	1.89	(0)	0.051	(0.001)	10.1	(0.2)
RevoWave UltraHard	1.92	(0)	0.051	(0.001)	7.1	(0.05)
RevoWave Hard	1.25	(0)	0.049	(0)	7.0	(0.1)
SeekMaster	1.29	(0.007)	0.038	(0.003)	12.7	(0.3)

SD: standard deviation

Table 3. Results of seeking ability test using 3D-printed bile duct model

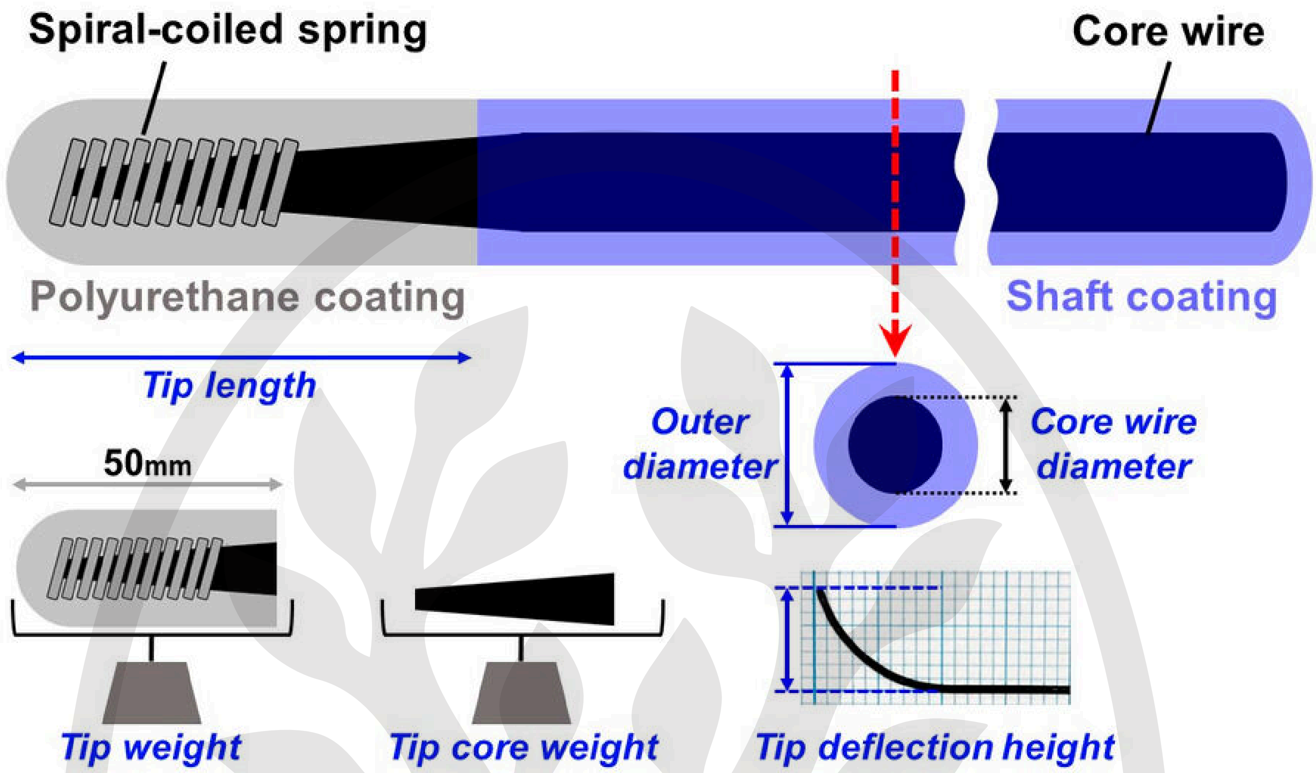
Guidewires	Insertion success n (%)			Insertion time* sec (SD)	
	Total (B3 and B7)	B3	B7	B3	B7
VisiGlide2	34 (85)	20 (100)	14 (70)	12.4 (9.7)	36 (17.7)
M-Through	25 (62.5)	11 (55)	14 (70)	23.1 (15.4)	27 (15.2)
Fielder 25	38 (90)	20 (100)	18 (90)	7.7 (5.1)	25 (15.9)
EndoSelector	31 (77.5)	18 (90)	13 (65)	16.3 (13.9)	25 (11.3)
J-WIRE Prologue ST	34 (85)	17 (85)	17 (85)	15.4 (11.5)	18.4 (13.7)
RevoWave Ultra-hard	22 (55)	14 (70)	8 (40)	27.1 (14.6)	38.0 (13.3)
RevoWave Hard	18 (45)	10 (50)	8 (40)	44.8 (9.3)	31.0 (15.6)
SeekMaster	32 (80)	16 (80)	16 (80)	19.8 (10.6)	12.0 (6.7)

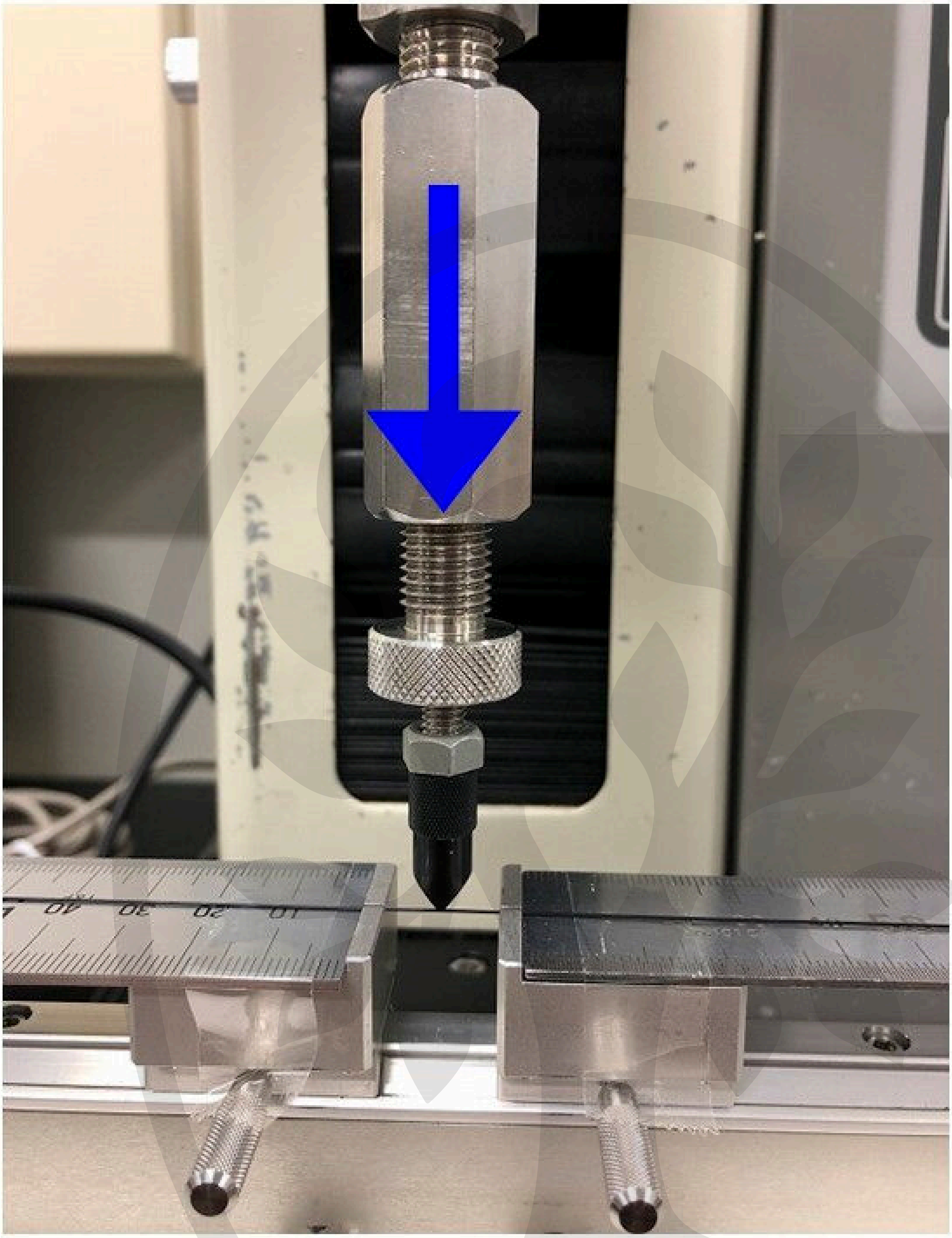
SD: standard deviation * the mean insertion time for a successful insertion.

Supplementary Table 1. Explanation of experimental measurements

Bending force (BF)	Bending force was measured to compare the stiffness of the guidewire shafts. Stiff related to the ease of device insertion during ERCP and EUS-BD.
Friction force (FF)	Friction force was measured to compare the lubricity of the guidewire shafts. Lubri related to the ease of device exchange and ease of inserting the guidewire into the catheter during ERCP and EUS-BD.
Torque response rate (TRR)	Torque response rate was measured to compare the torque response of guidewires, which is the circumferential transmission of force from the grip to the tip. Torque response is related to the ease of intended guidewire manipulation during ERCP and EUS-BD.

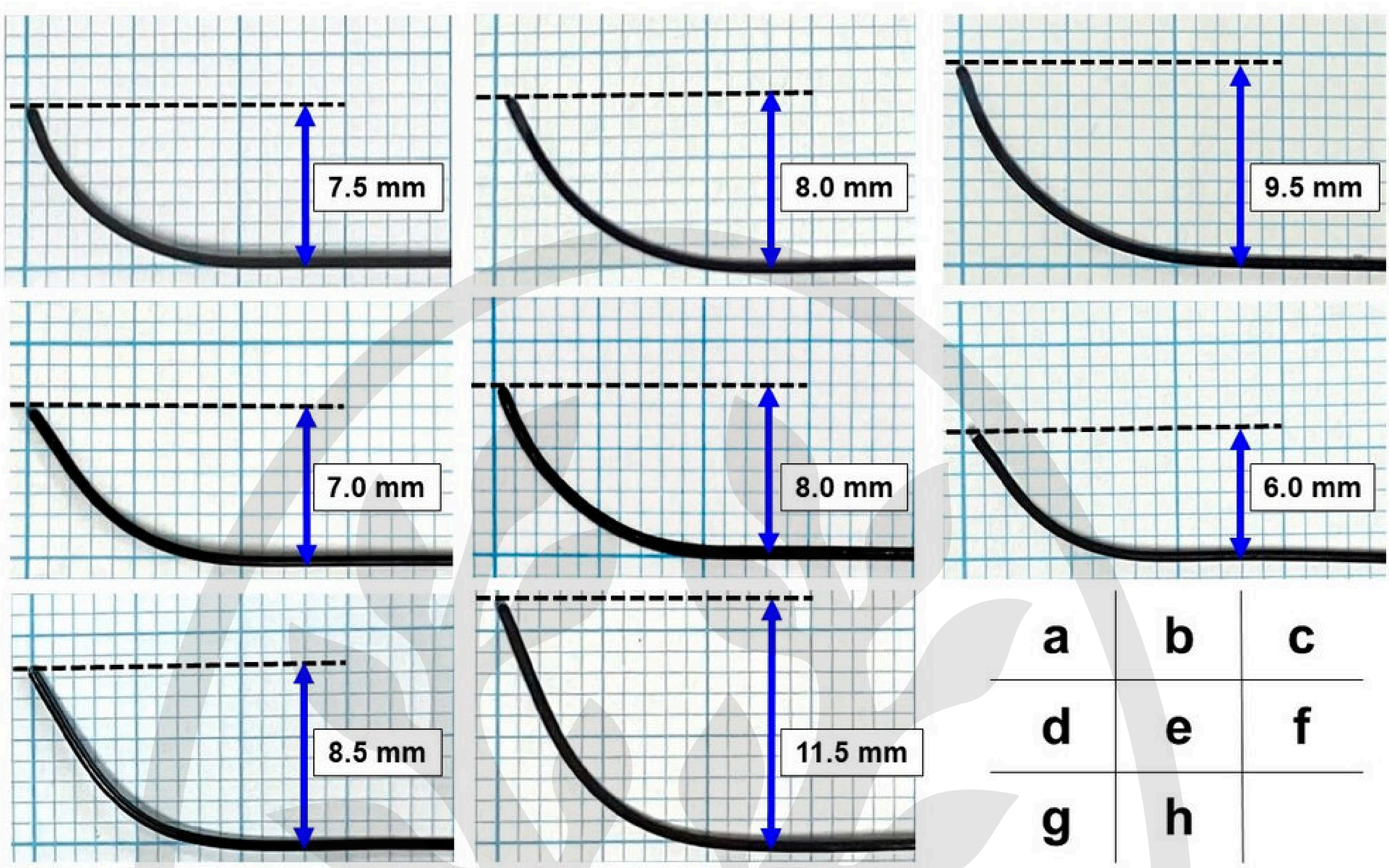
ERCP: endoscopic retrograde cholangiopancreatography, EUS-BD: endoscopic ultrasound-guided biliary drainage

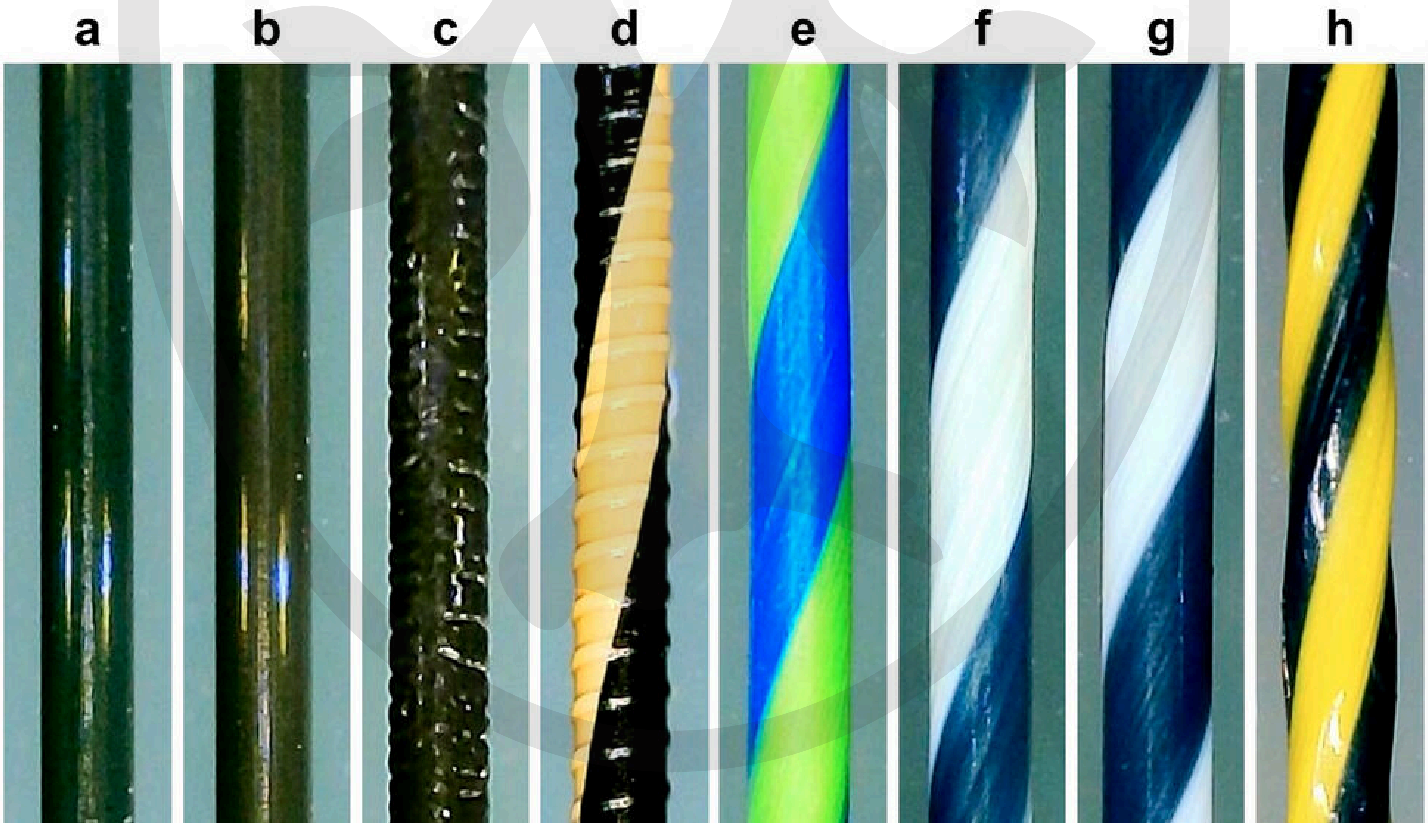

Spiral-coiled spring
Core wire
Polyurethane coating
Shaft coating
Tip length
Outer diameter
Core wire diameter
50mm
Tip weight
Tip core weight
Tip deflection height

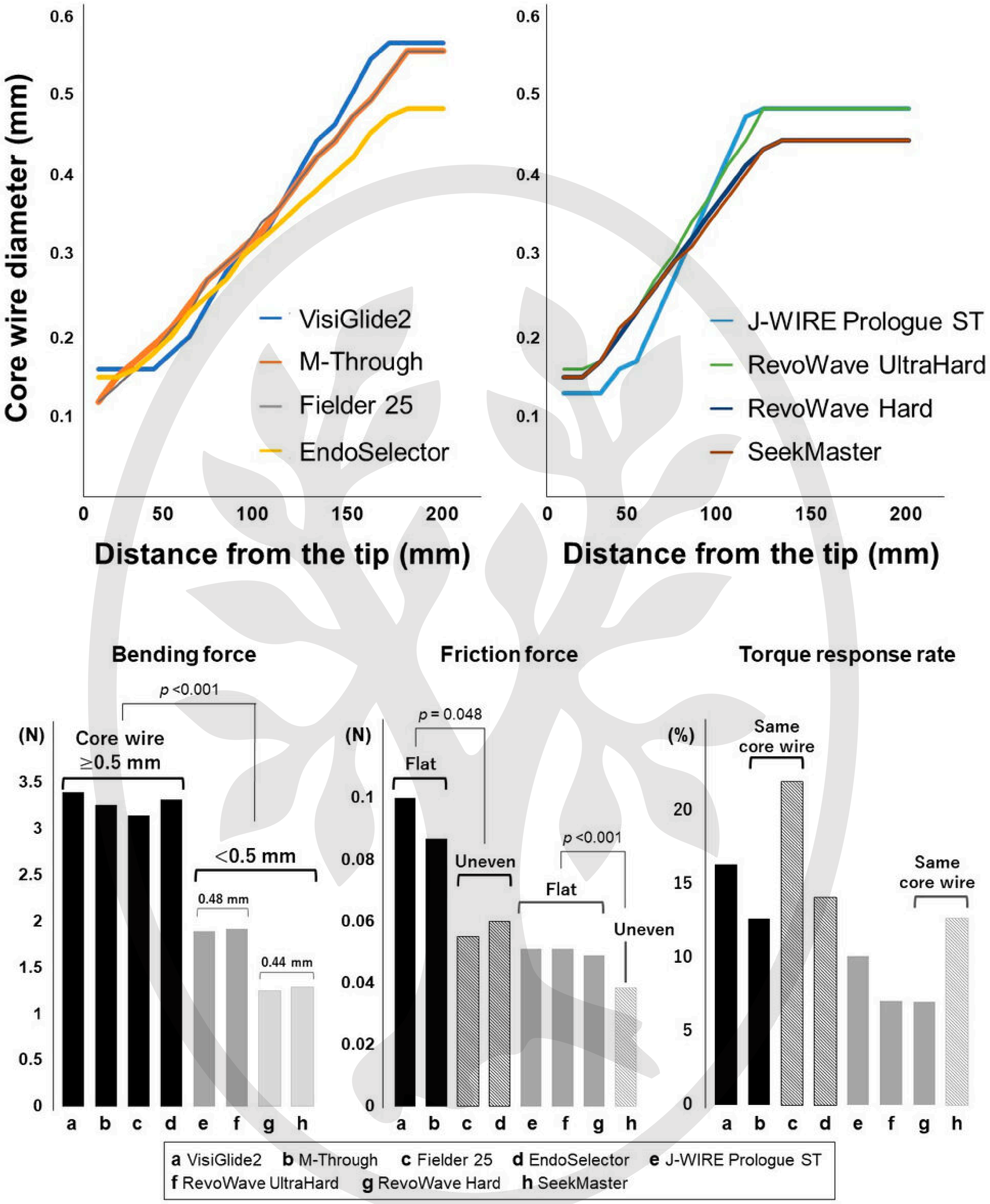



50N
ZERO
UP


B7
B3
B3
B7


7.5 mm
8.0 mm
9.5 mm
7.0 mm
8.0 mm
6.0 mm
8.5 mm
11.5 mm
a
b
c
d
e
f
g
h


a
b
c
d
e
f
g
h


Core wire diameter (mm)
0.6
0.5
0.4
0.3
0.2
0.1
0
50
100
150
200
Distance from the tip (mm)
VisiGlide2
M-Through
Fielder 25
EndoSelector
J-WIRE Prologue ST
RevoWave UltraHard
RevoWave Hard
SeekMaster
Bending force
Friction force
Torque response rate
(N)
(%)
p <0.001
Core wire
≥0.5 mm
<0.5 mm
0.48 mm
0.44 mm
p = 0.048
Flat
Uneven
Flat
p <0.001
Uneven
Same
core wire
Same
core wire
3.5
3
2.5
2
1.5
1
0.5
0
0.1
0.08
0.06
0.04
0.02
0
20
15
10
5
0
a b c d e f g h
a VisiGlide2 b M-Through c Fielder 25 d EndoSelector e J-WIRE Prologue ST
f RevoWave UltraHard g RevoWave Hard h SeekMaster

		Structural variables						Performance variables			
		Tip length	Tip deflection height	Tip weight	Ratio of tip core weight to tip weight	Outer diameter	Core wire diameter	Bending force	Friction force	Torque response rate	Total insertion success
Performance variables	Bending force	0.203	-0.352	0.585	-0.604	0.177	**0.983**				
	Friction force	0.174	-0.382	0.618	-0.562	0.047	**0.788**	**0.757**			
	Torque response rate	0.146	0.326	0.698	-0.680	0.298	**0.711**	0.687	0.325		
	Total insertion success	0.541	0.327	**0.785**	**-0.772**	0.506	0.452	0.437	0.108	**0.772**	