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Over-the-wire deployment techniques of option elite inferior vena cava filter: 3D printing vena cava phantom study

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A R T I C L E I N F O

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A B S T R A C T

Purpose: To compare filter tilt and filter jumping during Option inferior vena cava (IVC) filter deployment with 3 different wires techniques using a 3-dimensional (3D) printing vena cava phantom.
Materials and methods: An IVC 3D printed vena cava phantom was made from a healthy young male's computed tomographic data. Option IVC filters were deployed with 3 different wires: i) original push wire, ii) hydrophilic stiff wire, and iii) bent stiff wire. Right internal jugular and right femoral access were used 5 times with each wire. Filter tilt angle, tilt ratio, jumping, and tip abutment to the IVC wall were analyzed.
Results: The transfemoral approach with original push wire had significantly higher tilt angle than did the transjugular approach (6.1° ± 1.9 vs. 3.5° ± 1.3, $p = 0.04$). Mean tilt ratio was significantly lower with the bent wire with transfemoral access (0.49 ± 0.13 vs. 0.78 ± 0.18 [original push-wire] and 0.67 ± 0.08 [stiff wire], $p = 0.019$). The ratio was lower also with original push wire with transjugular access (0.34 ± 0.19 vs. 0.57 ± 0.11 [stiff wire] and 0.58 ± 0.17 [bent wire], $p = 0.045$). Filter jumping occurred more often with the transjugular approach with original push wire than with stiff or bent-wire delivery. Filter tip abutment to the IVC wall occurred only with the transfemoral approach.
Conclusions: Bent wire with transfemoral access and original push wire with transjugular access had lower filter tilt ratio at Option IVC filter deployment. However, filter jumping was common using the original push wire with transjugular access.

1. Introduction

Venous thromboembolism resulting in pulmonary thromboembolism (PTE) is one of the most significant complications in hospitalized patients, with short- and long-term morbidity and mortality [1–3].

To prevent life threatening complication of PTEs, IVC filter has been used. According to the Society of Interventional Radiology (SIR), IVC filters are typically placed in three clinical scenarios: (i) in patients with VTE and classic indications; (ii) in patients with VTE and extended indications; and (iii) in patients without VTE for primary prophylaxis against PE [4].

As increased in use of IVC filter, complications associated with filter use, such as failure to retrieve the filters when the indication for their use has passed, have also increased [5–7]. The main reasons IVC filter retrieval fails are: (i) the filter hook is embedded in the IVC wall due to filter tilting, and (ii) the filter limbs penetrate adjacent organs. Reducing IVC filter tilting at the time of insertion and prompt retrieval of IVC filter after the risk of venous thromboembolism has ceased are essential for reducing the risk of IVC filter-related complications [8].

Option IVC filter (Argon Medical Devices, Plano, TX, USA) has unique properties with its over-the-wire delivery system for centering the filter. Various wires can be used with the Option IVC filter, such as an original push wire, hydrophilic stiff wire, or bent wire.

The purpose of the current study was to compare filter tilt and filter jumping during deployment of the Option IVC filter using 3 wire techniques in an in vitro experiment with a 3-dimensional (3D) printing

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vena cava phantom.

2. Materials and methods

2.1. Selection of IVC model and segmentation of CT data

We retrospectively selected human CT data to create a 3D printing phantom. The study was approved by our institutional review board, which waived the requirement for informed patient consent. A 23-year-old heathy male's venous phase CT data were selected for segmentation. The CT protocol combined CT pulmonary arteriography and venography of the abdomen and lower extremity. CT angiography was performed with multidetector CT scanners (SOMATOM Force; Siemens Health Care, Forchheim, Germany). CT pulmonary arteriography was performed after intravenous administration of 100 mL Omnipaque 350 (GE Health Care, Seoul, Korea) with an injection rate of 1.5–2 mL/second. After 110 s delay, abdominal and lower extremity venous phase CT images were taken. The IVC course was straight, and the long and short IVC diameter 4 cm below the left renal vein insertion was 26 mm and 17 mm, respectively. Semiautomatic segmentation of venous structures from the internal jugular vein to the common femoral vein was performed with 3D segmentation software (MATERIALISE MIMICS version 13, Leuven Belgium).

2.2. 3D printing of vena cava phantom

A vena cava phantom was printed using a 3D printer (ProX950; 3D-SYSTEMS, Rock Hill, SC, USA) according to 3D venous CT data. Rubber-like photopolymers (Tango; Eden Prairie, MN, USA) were used for printing material, which has properties of elongation, flexibility, and tear resistance and is commonly used in a cardiac phantom [9,10]. For limited build-volume of the 3D printer (150 × 55 × 75 mm), 3 parts of the venous phantom were separately printed and attached with glue (Fig. 1).

2.3. Option IVC filter and over-the-wire technique

The Option IVC filter is laser-cut from nickel titanium alloy (Nitinol) tubing, consisting of 6 expandable thermal shape-memory Nitinol with a retention anchor in the caudal portion of each strut and a large hook. A large hook in the apex has a hole in its center. The hole allows the wire to pass through the hook, which helps the IVC filter to be placed in the center of the IVC, which is called an over-the-wire technique [11]. Through this unique hole, various wires can be used to deliver the filter to the target site. In this study, in addition to the original push wire, a hydrophilic stiff guide wire (Terumo Corp, Tokyo, Japan) and bent stiff guide wire (Amplatz Super Stiff, Boston Scientific, Natick, MA, USA) were used to center the filter tip with the over-the-wire technique. The Amplatz Super Stiff wire was bent according to the shape of the inferior vena cava bifurcation (same angle with the inferior vena cava and common iliac vein) (Fig. 2c). When the stiff guide wire and bent stiff wire were used for the over-the-wire technique, a dilator was used as a pusher.

2.4. In vitro experiments

The IVC phantom was fixed in a water tank on the table of an angiographic machine (AlluraXper, Philips Healthcare, Best, The Netherlands). Warm saline was used to keep the temperature at human body temperature, since the Option IVC filter uses a thermal shape memory alloy. IVC filters were inserted through the right femoral and right internal jugular access with 3 kinds of guide wires (Fig. 2).

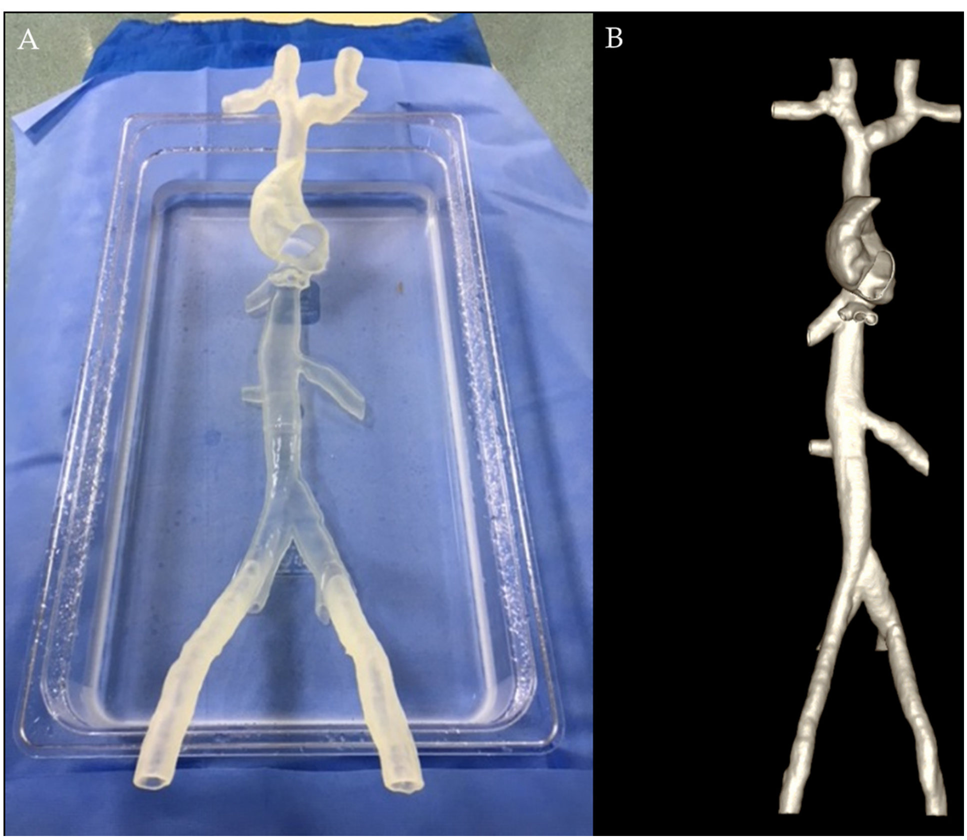

Fig. 1. The vena cava phantom includes anatomy from both internal jugular veins to both femoral veins.
A. 3-dimensional (3D) printed phantom in a saline tank.
B. Volume rendering image of 3D printed phantom.

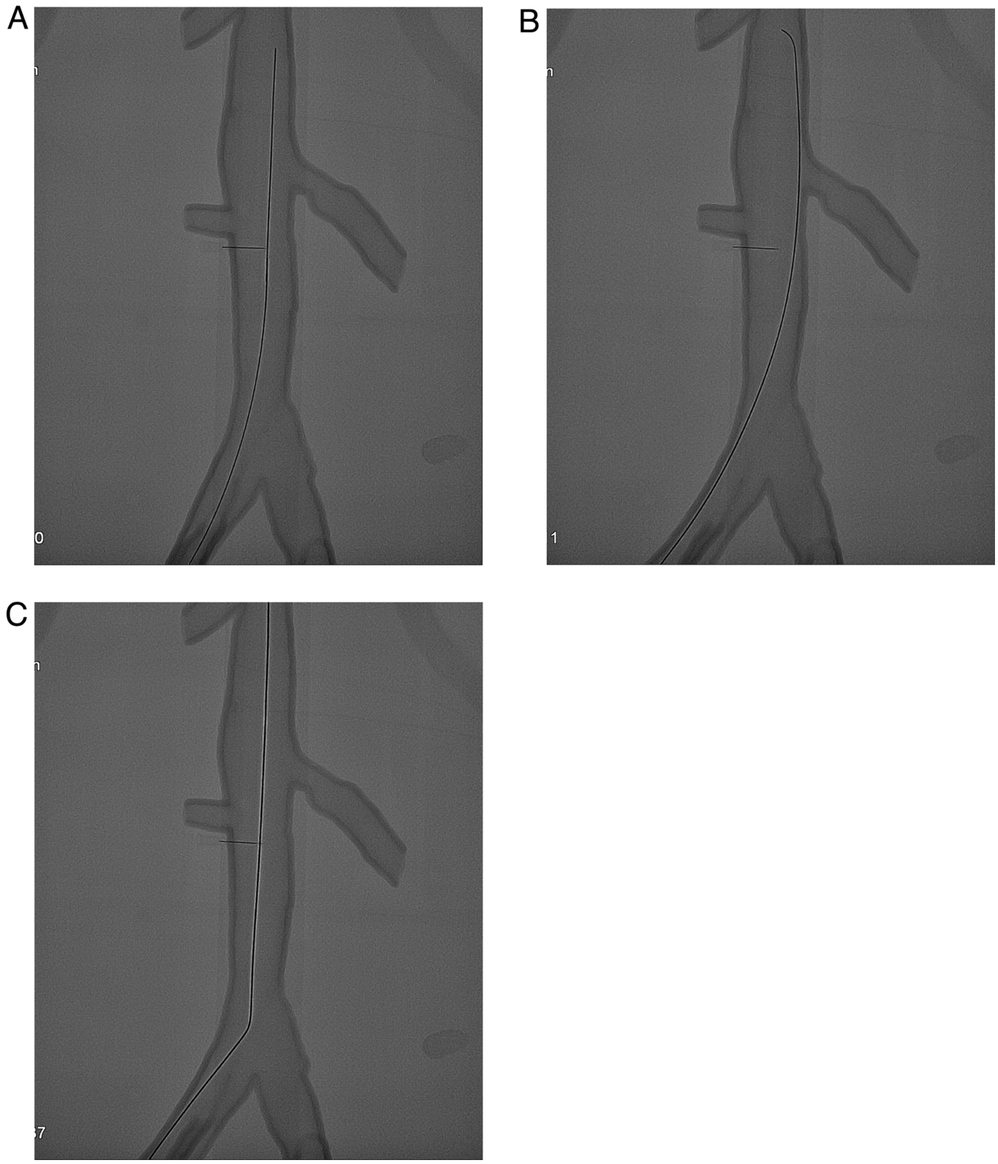

Fig. 2. Images show transfemorally-inserted guidewires.
A. Original push wire.
B. Hydrophilic stiff wire.
C. Bent stiff wire.

Insertion of the filter was performed 5 times, depending on the kind of wire and the venous access. A total of 30 filter insertions was performed. After insertion of the filter, cone beam CT was performed to evaluate filter tilt angle, tilt ratio, filter tip abutment to IVC wall, and vertical jumping at deployment. A 25-gauge needle was placed in the infrarenal IVC to measure vertical jumping. All procedures were performed by an experienced interventional radiologist.

2.5. Data analysis

Filter tilt angle, tilt ratio, filter tip abutment to the IVC wall, and vertical jumping at deployment were measured. Filter tilt angle was defined as angle of the filter's long axis to the long axis of IVC. The tilt ratio was defined as the ratio of the distance between the IVC center and the filter tip to the distance between the IVC center and the IVC wall. Filter tip abutment to the IVC wall was defined as visible abutment of the hook of the IVC filter against the IVC wall. The filter hook was intended to be placed in the lower margin of the right renal vein, which is lower than the left renal vein. Caudal jumping was defined as the distance from the lower margin of the renal vein (needle marker) to the filter hook (Fig. 3).

2.6. Statistical analysis

To compare the filter tilt ratio and vertical jumping for the 3 wires, one-way analysis of variances (ANOVA) was used. The *t*-test was used to compare the difference between venous access sites for each wire. Statistical analyses were performed using MedCalc version 17.5 statistical software (MedCalc SoftwareBVBA, Ostend, Belgium). A p value < 0.05 was considered statistically significant.

3. Results

3.1. Filter tilt angle and tilt ratio

Filter tilt angle and tilt ratio are listed in Table 1. Mean tilt angle of the filter for right femoral access with the original push wire, hydrophilic stiff wire, and bended stiff wire was $6.1 \pm 1.9^\circ$, $4.6 \pm 0.9^\circ$, and

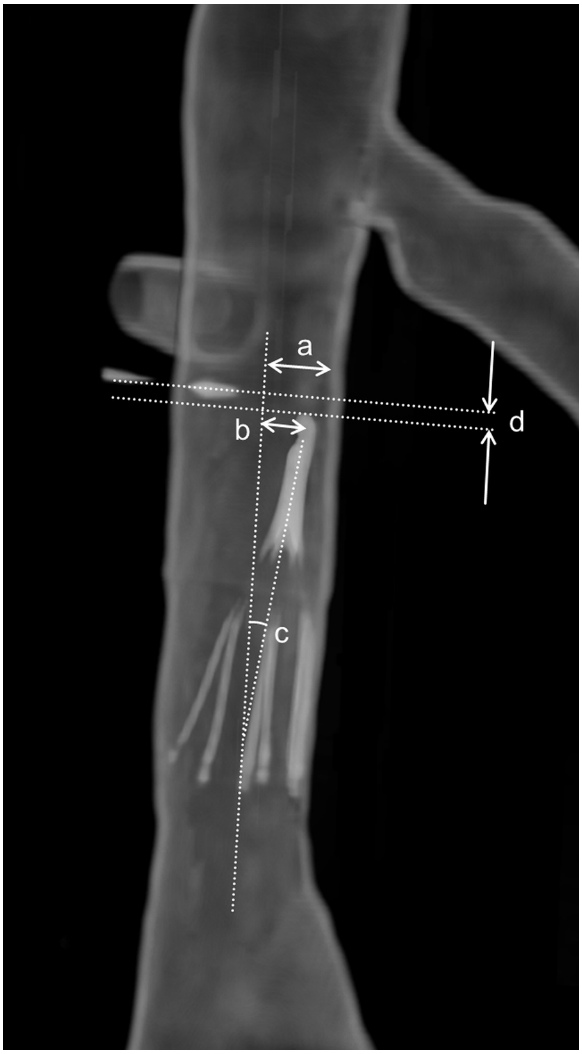

Fig. 3. Three-dimensionally reconstructed cone beam CT image of vena cava phantom and deployed Option inferior vena cava filter. a: distance from IVC wall to IVC center, b: distance from filter tip to IVC center, c: filter tilt angle, d:caudal migration at deployment. Filter tilt ratio:a/b.

4.8 ± 1.5°, respectively, and for right internal jugular access was 3.5 ± 1.3°, 5.4 ± 1.6° and 5.1 ± 1.1°, respectively. There was no statistical difference in tilt angle between wire techniques. Mean tilt angle with the original push wire was significantly higher via transfemoral access than with transjugular access ($p = 0.04$), but there was no statistically significant difference between the access sites with hydrophilic stiff wire and bent stiff wire techniques.

Mean tilt ratio was significantly lower with the bent wire technique via transfemoral access (bent wire: 0.49 ± 0.13, vs normal and hydrophilic stiff wire: 0.78 ± 0.18 and 0.67 ± 0.08, respectively, $p = 0.019$). However, for transjugular access, original push wire delivery had a significantly lower tilt ratio than did stiff or bent stiff wires (original wire: 0.34 ± 0.17, vs hydrophilic stiff and bent stiff wire: 0.57 ± 0.11 and 0.58 ± 0.17, respectively, $p = 0.045$). There was a significantly lower mean tilt ratio via transjugular access with the original push wire ($p = 0.0046$). However, there was no statistical difference between the hydrophilic stiff and bent stiff wire with venous access.

Table 2
Caudal filter jumping with 3 over-the-wire techniques for transfemoral and transjugular approach.

Approach	Original push wire	Stiff wire	Bent wire	*P*-value[a]
Transfemoral (mm ± SD)	1.7 ± 1.1	2 ± 1.9	1.8 ± 0.8	0.948
Transjugular (mm ± SD)	10.1 ± 3.0	2.4 ± 0.9	1.0 ± 1.0	< 0.001
P-value[b]	0.0003	0.6372	0.1832	

SD-standard deviation.
[a] One-way analysis of variances (ANOVA).
[b] *t*-test.

3.2. Vertical filter jumping

Vertical filter jumping values are listed in Table 2. Mean vertical jumping of the filter for right femoral access with the original wire, hydrophilic stiff wire, and bent wire was 1.7 ± 1.1 mm, 2.0 ± 1.9 mm, and 3.7 ± 4.6 mm, respectively. For right internal jugular access, the values were 10.1 ± 3.0 mm, 2.4 ± 0.9 mm, and 1.0 ± 1.0 mm, respectively. Interestingly, transjugular access with the original push wire technique had more caudal jumping than via transfemoral access ($p = 0.0003$).

3.3. Filter tip abutment to IVC wall

An example of filter abutment to the IVC wall is illustrated in Fig. 4. Abutment was present only with transfemoral access and the original wire (2/5; 40%) and hydrophilic stiff wire (1/5; 20%), whereas there was no filter tip abutment via transjugular access with any wire techniques (Table 3).

Table 1
Tilt angle and tilt ratio with 3 over-the-wire techniques for transfemoral and transjugular approach.

Filter tilt angle				
Approach	Original push wire	Stiff wire	Bent wire	*P*-value[a]
Transfemoral (° ± SD)	6.1° ± 1.9	4.6° ± 0.9	4.8° ± 1.5	0.287
Transjugular (° ± SD)	3.5° ± 1.3	5.4° ± 1.6	5.1° ± 1.1	0.097
P-value[b]	0.0404	0.3569	0.681	
Filter tilt ratio				
Approach	Original push wire	Stiff wire	Bent wire	*P*-value[a]
Transfemoral (Mean ± SD)	0.78 ± 0.18	0.67 ± 0.08	0.49 ± 0.13	0.019
Transjugular (Mean ± SD)	0.34 ± 0.19	0.57 ± 0.11	0.58 ± 0.17	0.045
P-value[b]	0.0046	0.1328	0.3405	

SD-standard deviation.
[a] One-way analysis of variances (ANOVA).
[b] *t*-test.

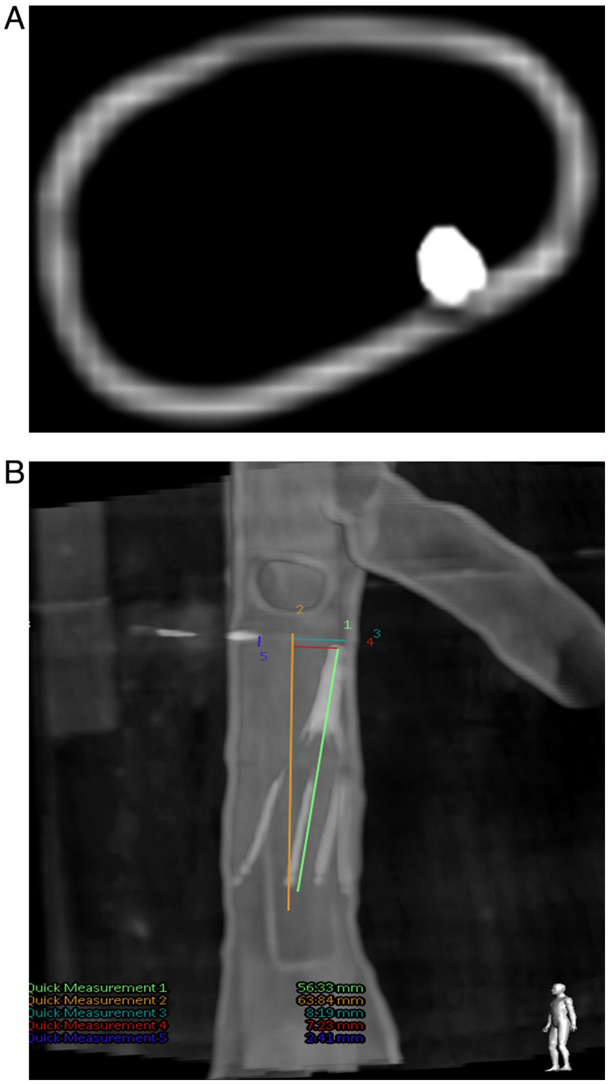

Fig. 4. Abutment of filter tip to the IVC wall. A. Axial image of cone beam CT. B. Reconstructed image.

4. Discussion

This study assessed filter tilt and vertical jumping of the Option IVC filter with 3 different over-the-wire techniques using a 3D printing vena cava phantom. For transfemoral access, the bent stiff-wire technique had less tilt ratio than the other wires techniques. For transjugular access, the original push wire had less tilt ratio than other wires. Filter tip abutment to the IVC wall occurred only with transfemoral access. Filter jumping during deployment was most common with the transjugular-accessed original wire technique.

The degree of IVC filter tilt is known to be correlated with the difficulty of its subsequent retrieval [12]. In recent studies, a tilt angle of 15 degrees was the most commonly cited standard [13]. However, this degree of filter tilt does not always mean an IVC filter is abutting the IVC wall or embedding itself into the IVC wall, because there are other contributing factors, such as the diameter of the IVC, the presence of external compressing structures, or severe angulation of the IVC itself [14–16].

Severe filter tilt or filter tip abutment to the IVC wall may result in filter-tip epithelialization or penetration into the IVC wall. These events can increase the risk of filter retrieval and may require advanced retrieval techniques, such as endobronchial forceps- or laser-assisted retrieval of the embedded filter tip [17–20], which impose increased radiation exposure to the patient and the operator and add medical cost [15,16].

Filter tilt angle has been used as a surrogate for degree of filter tilt [21,22]. However, because of the ovoid or crescent shape of the IVC on axial imaging, the degree of filter tilt angle on imaging may be inaccurate. Tilt ratio is the relationship between the filter tip and the adjacent IVC wall, and it is not affected by the shape of the IVC and the orientation of the filter tilt. In this study, for transfemoral access, the bent wire technique had a lower filter tilt ratio than did the original push or hydrophilic stiff wire techniques. The angle between the IVC and the iliac vein affects filter tilting at deployment [23–25]. The bent-wire technique reduces the angle and allows the filter tip to be positioned in the center of the IVC lumen, as illustrated in Fig. 2. In contrast, the original wire and the hydrophilic stiff wire are limited when centering the filter tip because of the angle of the IVC and iliac vein. For transjugular access, the original push wire had a lower tilt ratio than did the hydrophilic stiff wire or bent wire techniques. Usually, the superior vena cava (SVC) and the IVC have a straight course, and the original push-wire technique alone can place the filter tip in the center of the IVC. However, in this study, the bent-wire technique had the highest filter tilt ratio via transjugular access. It is possible that, in the straight course of the SVC and IVC, filter tilting is facilitated by an artificial wire angle. However, if the SVC or IVC is angulated, the bent-wire technique may be advantageous by reducing the tilt ratio.

Although the original push-wire technique with transjugular access reduced the tip ratio, filter jumping occurred with use of that wire. This problem occurs when the filter is deployed in a small-caliber delivery sheath (6 F) of the Option IVC filter, which seems to occur when the resistance of the wire and the filter hook is low. Filter jumping was least with the bent wire because it is coated with polytetrafluoroethylene (PTFE), which increases the resistance compared with that of the original push wire. Therefore, attention should be paid to filter jumping when the original-wire technique is used.

The 3D printing phantom can better reflect human anatomy than can animal experiments or a cylinder-shaped pipe phantom [25,26]. Using patients' CT data, a phantom that is like the human body can be produced. With 3D printing, material with tension and elasticity like those of human blood vessels may be developed. Thus, 3D printing technology may produce models that will make it possible to pre-test clinical applications. In addition to simulating anatomical structures, models of the human body's hemodynamic status may be produced, using a flow-generating pump system [27,28], which could facilitate experiments with intravascular devices. Although 3D printing technology has been used in research on congenital heart disease (9, 10) and vascular flow [27], we know of no report of its use in the

Table 3
Filter tip abutment with 3 over-the-wire techniques for transfemoral and transjugular approach.

Approach	Original push wire	Stiff wire	Bent wire	*P*-value[a]
Transfemoral (abutment/total)	2/5	1/5	0/5	0.335
Transjugular (abutment/total)	0/5	0/5	0/5	NA
P-value[a]	0.444	1	NA	

NA-not available.
[a] Fisher's exact test.

deployment of IVC filters.

We acknowledge that our study has limitations. 1) Since the study was conducted in vitro, we could not test for adverse events that might occur with in vivo placement of IVC filters, such as progressive filter tilt with prolonged indwelling time of filters, IVC perforation, or filter-induced thrombosis. 2) The in vitro filter-placement environment was not the same as that of filter placement in the human body because IVC phantoms are made of artificial material, and they have no blood flow. 3) Filter insertion was performed only by an experienced interventionalist.

In conclusion, in experiments using a 3D printing vena cava phantom, the bent stiff-wire technique with transfemoral access and the original push-wire technique with transjugular access had a low filter tilt ratio in the deployment of the Option IVC filter. However, attention should be paid to filter jumping when using the original push-wire with transjugular access.

Transparency document

The Transparency document associated with this article can be found in the online version.

Declaration of Competing Interest

None.

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