

ORIGINAL RESEARCH

# Excimer Laser Sheath–Assisted Retrieval of “Closed-Cell” Design Inferior Vena Cava Filters

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**BACKGROUND:** Numerous reports have shown that inferior vena cava filters are associated with clinically significant adverse events. Complicating factors, such as caval incorporation, may lead to technical challenges at retrieval. The use of advanced techniques including the laser sheath have increased technical success rates; however, the data are limited on which filter types necessitate and benefit from its use.

**METHODS AND RESULTS:** From October 2011 to September 2019, patients with inferior vena cava filter dwell times >6 months or with prior failed retrievals were considered for laser sheath–assisted retrieval. Standard and nonlaser advanced retrieval techniques were attempted first; if the filter could not be safely or successfully detached from the caval wall using these techniques, the laser sheath was used. Technical success, filter type, necessity for laser sheath application based on “open” versus “closed-cell” filter design, dwell times, and adverse events were evaluated. A total of 441 patients (216 men; mean age, 54 years) were encountered. Mean dwell times for all filters was 56.6 months, 54.4 among closed-cell filters and 58.5 among open-cell filters ( $P=0.63$ ). Technical success of retrieval was 98%, with the laser sheath required in 143 cases (40%). Successful retrieval of closed-cell filters required laser sheath assistance in 60% of cases as compared with 7% of open-cell filters (odds ratio, 20.1;  $P<0.01$ ). In closed-cell inferior vena cava filters, dwell time was significantly associated with need for laser, requiring it in 64% of retrievals with dwell times >6 months ( $P=0.01$ ). One major adverse event occurred among laser sheath retrievals when a patient required a 2-day inpatient admission for a femoral access site hemorrhage.

**CONCLUSIONS:** Closed-cell filters may necessitate the use of the laser sheath for higher rates of successful and safe retrieval.

**Key Words:** excimer laser ■ inferior vena cava filters ■ retrieval ■ vena cava ■ venous thromboembolism

There has been a significant growth in clinical and investigative interest for inferior vena cava filter (IVCF) retrieval. This has been driven by high IVCF implantation rates in the first decade of their availability, followed by numerous reports of device-related adverse events (AEs) associated with retrievable IVCFs.<sup>1–4</sup> AEs include component fracture/embolization with potential for cardiac perforation, arrhythmia, and death; caval wall penetration of components with involvement of the adjacent viscera; and the potential for caval thrombosis, which can result in clinically severe venous stasis syndromes.<sup>4–6</sup> These issues are

further magnified in retrievable IVCFs by historically low retrieval rates, with the majority of devices left in situ beyond their indicated use, thereby exposing patients to greater risk when the potential benefit of mechanical caval prophylaxis from pulmonary embolism has passed.<sup>7</sup> These concerns are mirrored in US Food and Drug Administration’s safety communications, advocating diligent follow-up of patients with retrievable IVCFs, with strong consideration for retrieval once clinically judged to be no longer indicated.<sup>8,9</sup> In contrast, permanent IVCFs have been available for a longer period of time, though overall long-term data are more

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## CLINICAL PERSPECTIVE

### What Is New?

- “Closed-cell” filters may necessitate the use of the laser sheath for higher rates of successful and safe retrieval when compared with “open-cell” filters (odds ratio, 20.1).
- Among closed-cell filters, prolonged dwell times and a prior failed retrieval attempt predicts the need for the laser sheath for successful retrieval.

### What Are the Clinical Implications?

- Patients with in situ closed-cell filters may benefit from laser sheath availability to enable safe and successful retrieval, particularly with prior failed retrieval attempts with prolonged filter dwell times.

## Nonstandard Abbreviations and Acronyms

<b>AE</b>	adverse event
<b>IVC</b>	inferior vena cava
<b>IVCF</b>	inferior vena cava filter
<b>OR</b>	odds ratio

limited. However, there is increasing awareness of AEs associated with permanent devices as well, resulting in a growing experience with endovascular permanent IVCF retrieval when devices are clinically problematic.

The development of several endovascular techniques, collectively referred to as advanced retrieval techniques, have facilitated the retrieval of IVCF that previously were deemed “irretrievable,” such that most IVCFs can now be removed via an endovascular approach, regardless of dwell time.<sup>10</sup> One common problem encountered with devices with extended implantation times is filter component incorporation, where standard techniques are often insufficient and potentially hazardous while attempting to disengage the IVCF from the caval wall. The use of a 308-nm XeCl excimer laser-sheath (14Fr GlideLight; Philips/Spectranetics, Colorado Springs, CO) has been shown to yield high rates of technical success in retrieval of filters with component incorporation into the caval wall, while significantly reducing the magnitude of required force during filter retrieval.<sup>11,12</sup> However, data are limited on which filters may require the use of the laser sheath for successful retrieval. Filters with “closed-cell” designs, which are devices that include complete circuits of metal or wire that act as potential scaffolds for caval wall incorporation because of greater surface-area

contact with the inferior vena cava (IVC) wall, may benefit from laser sheath–assisted retrieval, with previous studies demonstrating lower retrieval success rates compared with “open-cell” IVCF designs using conventional techniques, as well as increased necessity for advanced techniques for successful retrieval.<sup>13</sup> In comparison, open-cell IVCF designs have relatively limited contact with the caval wall, and may be prone to less component incorporation.<sup>13</sup>

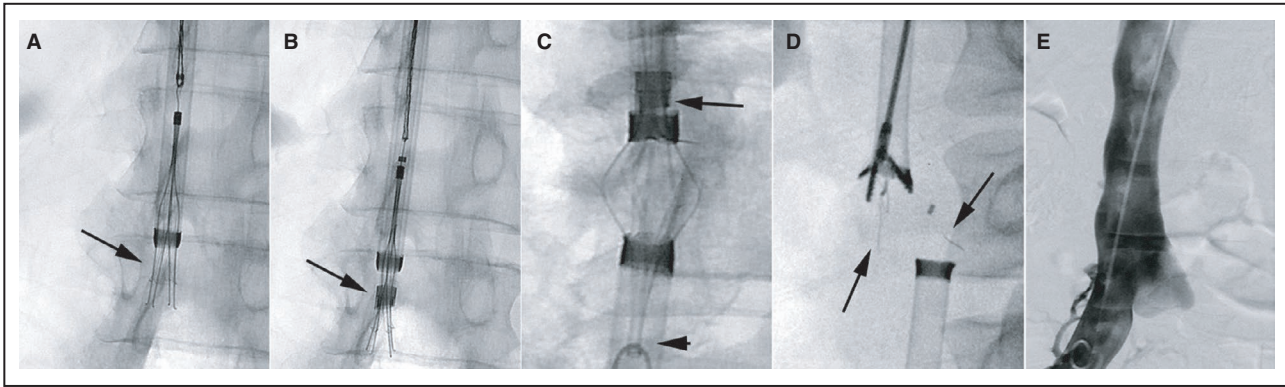
The objective of this study was to analyze which filter designs were more likely to necessitate the laser sheath at retrieval, thereby improving procedural planning, overall retrieval rates, and potentially improving the safety profile of the retrieval procedure.

## METHODS

This study was conducted with local Institutional Review Board approval and written informed consent was obtained from all participants. The authors declare that all supporting data are available within the article. From October 2011 to September 2019, all patients with IVCF implantation times of >6 months<sup>10,14</sup> or those with previously failed retrieval attempts were scheduled for filter retrieval, with the laser sheath immediately available in the procedural suite.

## Procedure Details

Procedures were performed under intravenous moderate sedation, monitored anesthesia care, or general anesthesia; the choice of anesthetic was based on patient factors/comorbidities. If patients were on anticoagulation, it was not held periprocedurally. All venous access was obtained under ultrasound guidance. Filter retrieval was performed via internal jugular access, except for retrieval of OptEase and TrapEase (Cordis Endovascular, Santa Clara, CA), which required either common femoral access or dual femoral and jugular access. Filter retrieval was first attempted using standard customary traction-countertraction techniques, including snare; if this was unsuccessful, nonlaser advanced retrieval techniques such as the loop wire and endobronchial forceps (Lymol Medical, Woburn, MA) were used, as described in previously published literature.<sup>15,16</sup> Once the filter apex was captured, attempts were made to collapse the entirety of the device within the sheath. If this was not possible because of significant resistance secondary to strut incorporation (Figure 1A), the excimer laser sheath was employed for assisted retrieval. The laser sheath was inserted over the filter capture device (snare or looped wire) and advanced to the point of maximal resistance, where filter components were densely adhered to the caval wall (Figure 1B). The laser was then activated to perform tissue ablation, releasing



**Figure 1. Laser sheath–assisted retrieval of inferior vena cava filters.**

**A**, Retrieval is attempted with conventional traction-countertraction techniques. The filter is unable to be explanted because of firmly embedded filter struts in the caval wall (arrow). **B**, The laser sheath is advanced to the point of maximal resistance (arrow), and ablation is performed. **C**, Access from above and below is obtained to allow for laser sheath ablation (arrow) at both areas of cava incorporation of the TrapEase filter. A loop-wire technique is used at the caudal end (black arrowhead). **D**, Fractured filter components (arrows) are retrieved using endobronchial forceps. **E**, Completion fluoroscopy is performed to assess for complications including thrombosis, extravasation, and fractured filter components.

the incorporated components from the cava. Once the adherent struts were released, the filter was removed via the primary access sheath. In retrievals requiring dual groin and jugular access, the laser was sequentially used from each access to release the embedded components (Figure 1C). After filter retrieval, fluoroscopy and cavography were performed to evaluate for complications including thrombosis, perforation, or fractured/remaining filter components (Figure 1D and 1E).

### Data Abstraction

Data abstraction for procedural technical success, filter type, categorization of open versus closed cell design, laser use, filter dwell times, fluoroscopy time, and adverse events was performed. Technical success was defined as complete extraction of the indwelling IVCF from the IVC, including any intravascular fractured fragments. If fractured fragments were present, multioblique inferior vena cavography was performed to assess whether these fragments were intraluminal and therefore potentially accessible from an endovascular approach. Adverse events were defined according to the Society of Interventional Radiology guidelines.<sup>17</sup>

### Statistical Analysis

Necessity of the laser sheath for successful IVCF explanation, technical success, occurrence of an adverse event, filter type, dwell times >6 months, and previous failed retrieval were reported as categorical variables and presented as frequencies (percentages). Dwell time, radiation dose, and fluoroscopy times were reported as continuous variables and presented as means with SE. To assess for differences in

dwell time, radiation dose, and fluoroscopy times between laser sheath–assisted and unassisted cases, an independent samples t test was performed. Independent sample t tests were also used to identify any differences in dwell times between patients with open- and closed-cell filters. Simple linear regression models were used to assess the continuous association between dwell times with the necessity of laser use, and additional subgroup analysis was performed by stratifying open- and closed-cell filters. Regression model diagnostics were performed to evaluate for linearity, independence, and normality. Simple logistic regression was used to assess associations between the outcome of laser necessity with filter types (including closed- versus open-cell designs), dwell times >6 months, previous failed retrievals, technical success, and AEs. Linear regressions were expressed as dependent-variable coefficients with 95% CIs. Logistic regressions were expressed as odds ratios (ORs) with 95% CIs. Significance was assumed at  $P < 0.05$  with a 2-sided tail. Analyses were performed using STATA/SE (version 14.2; StataCorp, College Station, TX).

## RESULTS

A total of 441 patients were encountered in this prospective cohort study; 216 (49%) were men (mean age, 54; range, 16–89 years), and 225 (51%) were women (mean age, 52; range, 20–89 years). One-hundred forty-eight patients presented for possible laser sheath–assisted filter retrieval because of a previous failed attempt at retrieval, 375 patients presented for a first attempt retrieval with an implantation time of >6 months, and 82 of these patients had

a combined dwell time of >6 months and a failed prior retrieval attempt. Mean dwell times for all filters was 56.6 months (SE, 4.2 months); 54.4 months among closed-cell filters and 58.5 months among open-cell filters ( $P=0.63$ ; Table 1). Six closed-cell filter types were encountered, including the Gunther Tulip (Cook, Inc, Bloomington, IN), Option and Option Elite (Argon Medical Devices, Inc, Plano, TX), OptEase and TrapEase, and Simon Nitinol (Bard Peripheral Vascular, Tempe, AZ). Open-cell filters encountered were Celect and Celect Platinum (Cook, Inc); ALN (ALN International, Ghisonaccia, France); G2, G2X, Eclipse, Denali, Recovery, and Meridian (Bard Peripheral Vascular, Tempe AZ); and Greenfield (Medi-Tech/Boston Scientific; Natick, MA) (Table 2, Figure 2).

Overall technical success rate was 98% (434/441) with the laser sheath required in 143 cases (40%). Among 298 cases where the laser was not employed, standard retrieval alone was successful in 119 cases. In 123 cases, endovascular forceps were sufficient for successful retrieval; and in 56 cases, the loop-snare technique was sufficient for successful retrieval.<sup>15,18,19</sup>

Technical success in laser sheath-assisted cases was 96% (134/143). A total of 3 (0.6%) major adverse

**Table 1. Cohort and Procedure Summary**

Total number of patients	441
Closed-cell IVCFs	210
Open-cell IVCFs	231
Age, y	
Mean	54
Range	16–89
Sex, n (%)	
Male	216 (49%)
Female	225 (51%)
Inclusion criteria	
Dwell time >6 mo	375
Previous failed retrieval	148
Dwell time >6 mo and previous failed retrieval	82
Dwell time, mo	
All IVCFs	56.6
Closed-cell IVCFs	54.4
Open-cell IVCFs	58.5
Fluoroscopy time, min	
Mean	16.7
Standard error	1.0
Radiation dose, mGy	
Mean	880
Standard error	73.5
Technical success, n (%)	434/441 (98%)
Laser sheath assistance, n (%)	143/441 (40%)

IVCFs indicates inferior vena cava filters; and mGy, milligray.

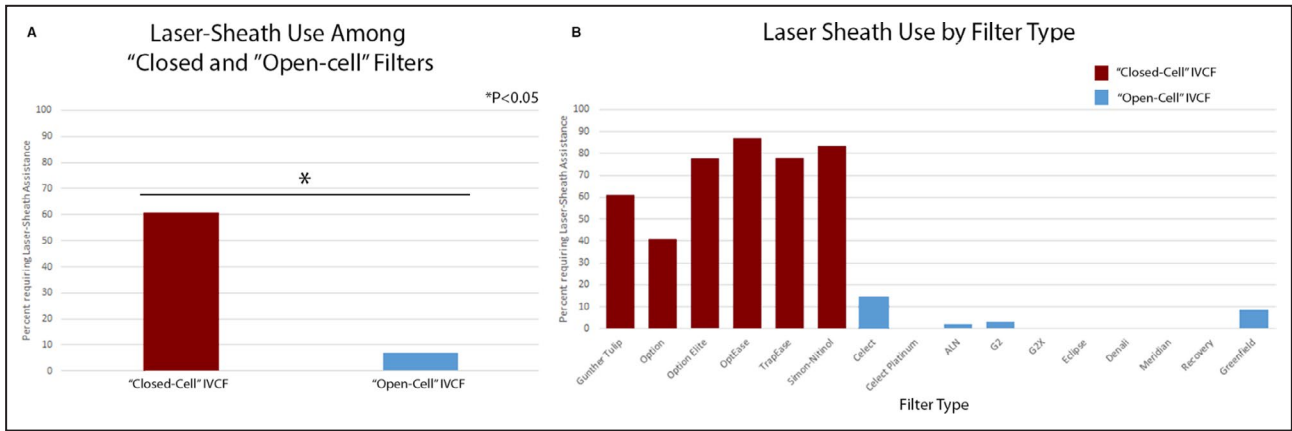
**Table 2. Laser-Assisted Retrieval Rates of Closed-Cell and Open-Cell Filters**

Filter Design	Number of Filters	Retrievals Requiring Laser Sheath Assistance, n (%)	P Value/OR (95% CI)
Closed-cell IVCFs	210	127 (60.5)	<0.01/ 20.1 (11.5–36.7)
Gunther Tulip	110	67 (60.9)	
Option	32	13 (40.6)	
Option Elite	9	7 (77.8)	
OptEase	38	33 (86.8)	
TrapEase	9	7 (77.8)	
Simon-Nitinol	6	5 (83.3)	
Open-cell IVCFs	231	16 (7.0)	
Celect	83	12 (14.5)	
Celect Platinum	4	0 (0.0)	
ALN	43	1 (1.9)	
G2	30	1 (3.3)	
G2X	1	0 (0.0)	
Eclipse	10	0 (0.0)	
Denali	20	0 (0.0)	
Meridian	3	0 (0.0)	
Recovery	8	0 (0.0)	
Greenfield	23	2 (8.7)	

IVCFs indicates inferior vena cava filters; and OR, odds ratio.

events were encountered per previously published Society of Interventional Radiology clinical practice reporting guidelines, one of which occurred in a case in which the laser sheath was used.<sup>17</sup> There was no statistical difference in rate of AEs between laser sheath-assisted and unassisted cases ( $P=0.24$ ). The 2 major adverse events among nonlaser retrievals were embolization of a previously fractured IVCF strut to the right ventricle requiring surgical intervention for removal and an IVC injury that required stent placement without further clinical sequelae. The single adverse event in the laser-assisted cohort was a patient who required a 2-day inpatient hospital stay following the procedure because of bleeding at the common femoral access site, which resolved without further intervention.

Retrieval of closed-cell filters required laser-sheath assistance in 127 of 210 (60.5%) of cases for successful retrieval as compared with open-cell filters requiring the laser sheath in 16 of 231 (7.0%) (OR, 20.1; 95% CI, 11.5–36.7;  $P<0.01$ ) (Table 2). The OptEase design required the laser sheath in 33 of 38 cases (87%), which was the highest rate of laser sheath assistance of all filters encountered (OR, 4.2; 95% CI, 1.5–11.7;  $P<0.01$ ). Among open-cell filters, the Celect filter required the laser sheath for retrieval most often (12/83 cases [15%]; OR, 9.09; CI, 1.12–71.4;  $P=0.04$ ).



**Figure 2. Necessity of laser sheath for successful retrieval of closed vs open-cell IVCF.** **A**, Laser sheath necessity for successful retrieval in closed-cell and open-cell filters. \*Denotes  $P < 0.05$ . **B**, Laser sheath necessity by filter types encountered in this study. IVCF indicates inferior vena cava filters.

Dwell time as a continuous variable was not predictive for laser sheath assistance during retrieval for open-cell IVCF patients ( $P = 0.86$ ). In closed-cell IVCF retrievals, dwell time was significantly associated with need for the laser sheath, with a 0.2% increase in laser sheath use per month of implantation time ( $\beta = 0.002$ ; 95% CI, 0.001–0.004;  $P = 0.01$ ). Closed-cell designs with dwell times  $> 6$  months required the laser in 111 of 174 (64%) retrievals (Table 3).

Patients presenting with a previous failed retrieval attempt required the laser 2.6 times more than first retrieval attempts (OR, 2.6; 95% CI, 1.7–3.9;  $P < 0.01$ ). Among the 148 patients presenting after a failed retrieval, success was achieved in 142 cases (96%) and the laser was employed in a total of 69 (47%) cases (Table 4). Eighty-five patients with closed-cell and 63 patients with open-cell filter designs presented for a second attempt retrieval with 59 (69%) and 10 (16%) cases respectively requiring the laser. The average

IVCF implantation time in laser sheath–assisted cases was 57.6 months as compared with 56 months in cases that did not require a laser sheath ( $P = 0.95$ ). There was a statistically significant difference between fluoroscopy times (23.3 minutes and 12.5 minutes;  $P < 0.01$ ), radiation doses (1239 mGy and 649 mGy;  $P < 0.01$ ) and technical success rates (96% versus 99%;  $P < 0.01$ ) between laser-assisted and unassisted cases, respectively.

## DISCUSSION

In this study of 441 patients, we demonstrate that filters with closed-cell designs require the laser sheath for successful retrieval  $\approx 20$  times more than their open-cell counterparts when the filter has been in place for  $> 6$  months or has previously failed retrieval. Further, dwell times of closed-cell filters are directly correlated with an increasing need for laser sheath assistance. Prior failed retrieval was found to more than double the need for laser sheath assistance across the whole cohort, primarily in patients with closed-cell IVCF in situ.

**Table 3. Association Between Filter Dwell Time and Necessity of Laser Sheath Assistance**

	Increase in Laser-Sheath Assistance Per 1 mo of Increased Dwell Time, %	P Value
Total		
Closed-cell IVCFs	0.2	$< 0.01$
Open-cell IVCFs	0.00	0.5
Retrievals requiring laser sheath assistance		
Closed-cell IVCFs	127/210 (61)	
Dwell times $> 6$ mo	111/174 (64)	
Dwell times $< 6$ mo	16/36 (44)	
Open-cell IVCF	16/231 (7)	
Dwell times $> 6$ mo	12/201 (6)	
Dwell times $< 6$ mo	4/30 (13)	

IVCFs indicates inferior vena cava filters.

**Table 4. Technical Details of Laser-Assisted vs Unassisted Cases**

	Laser-Assisted Cases	Cases Without Laser	P Value
Total	143	298	
Previous failed retrieval	69	79	$< 0.01$ ; OR, 2.6
Fluoroscopy time (mean, min)	23.3	12.5	$< 0.01$
Radiation dose, mGy	1239	649	$< 0.01$
Technical success, n (%)	136/143 (95)	297/298 (99)	$< 0.01$
Dwell times (mean, mo)	57.6	56	0.95

mGy indicates milligray; and OR, odds ratio.

These findings may help guide management of filter retrieval as well as consideration of filter type at the time of placement.

Advance knowledge of variables that predict the need for laser is important for procedural planning. The laser-sheath requires a procedural suite equipped with the appropriate infrastructure to support the laser generator, and therefore may not be readily available for all retrieval cases. Identification of factors that predict necessity of the laser sheath for successful retrieval may improve patient outcomes by aiding procedural planning, thereby avoiding multiple retrieval attempts, associated healthcare costs, and potential AEs and improve overall successful retrieval rates.

Previous studies have shown that closed-cell IVCF designs can present significant challenges at retrieval and have overall low retrieval success rates at prolonged implantation times.<sup>20–22</sup> The design of these filters act as effective scaffolds for neointimal hyperplasia and fibrosis and they can become densely adhered and embedded into the caval wall.<sup>12,23</sup> Previous literature has shown that the probability of successful retrieval of these filters using standard retrieval techniques falls precipitously with dwell time and that technical success can fall as low as 37% after 12 months of implantation time.<sup>24</sup>

With the use of the excimer laser sheath, filters were retrieved with high rates of technical success despite a very long mean implantation (56.6 months). Dwell times did not predict need for laser-sheath assistance across all filters in this cohort, which may in part be attributed to the inclusion criteria skewing toward extended dwell times beyond 6 months, previously shown to be associated with a need for advanced techniques.<sup>14</sup> However, exclusive to closed-cell designs, dwell time was significantly associated with the need for laser-assisted filter retrieval; this finding supports the hypothesis that their unique design may be more prone to becoming embedded with increasing implantation times, relative to their open-cell counterparts. Together, these data suggest that filter type, specifically closed-cell filter designs, are most predictive of the need for laser sheath-assisted retrieval to achieve high rates of technical success, especially in cases of prolonged dwell time.

In a 5-year study of 251 consecutive patients with IVCFs with a mean dwell of time of 31 months undergoing laser-assisted filter retrieval, technical success was achieved in 99.2% of patients with a major complication orate of 1.6%.<sup>12</sup> This study employed a force-gauge during retrieval and demonstrated that use of the laser-sheath significantly decreased the force required compared with traction-countertraction techniques, hypothetically decreasing the

risk of possible AEs such as IVC injury. However, no studies have identified or validated extraction force thresholds that place patients at higher risk of adverse events. Here, we report comparable rates of AEs without the use of a force gauge, primarily using the laser sheath when standard and nonlaser advanced techniques fail to disengage the IVCF from the caval wall because of component incorporation. Our findings suggest that filter design is an important determinant in the possible necessity for laser sheath assistance, and further supports the safety of the laser technique at centers with experience in advanced filter retrieval. Given these results, earlier consideration of laser sheath use may be cost effective in cases where control of the filter apex is obtained, but detachment of the filter from the IVC wall is not possible or safe with standard or nonlaser advanced techniques; if employed earlier, it could reduce the need for multiple retrieval attempts. Further research aimed specifically at cost-benefit analysis of the laser sheath may be helpful in understanding its role earlier in the retrieval algorithm.

Previous advanced techniques that have been described include using endobronchial forceps with 12 Fr, 14 Fr, and 16 Fr combinations or a modified loop-snare technique with a 16-Fr sheath.<sup>15,25</sup> Prior studies assessing major AEs of advanced retrieval techniques have reported rates as high as 5.3%, which is markedly higher than the rate of 0.6% reported herein.<sup>26</sup> The lower AE rate in the present study may suggest that laser sheath assistance can improve the safety of advanced retrieval by mitigating the amount of required force for filter extraction.

This study has some limitations. All cases reported in this study were performed by technically experienced interventionalists at a single center specializing in advanced filter retrieval. Previous studies have noted increased AE rates early in their experience with the device and that there is a substantial learning curve to advanced filter retrieval.<sup>12</sup> Therefore, similar rates of technical success and occurrence of AEs may not be reproduced in centers early in their experience employing the laser sheath. Further, sample sizes remain limited for certain filter types. This limits filter-specific analysis of variables such as dwell time, complication rates, and need for laser sheath assistance.

The excimer laser sheath is an important tool in retrieval of embedded inferior vena cava filters; in particular, it appears that closed-cell filter designs frequently require application of the laser sheath for successful retrieval, particularly at extended dwell times. Procedural planning for these filter designs, ensuring availability of the laser sheath with appropriate procedural expertise, may avoid the necessity for multiple

attempts and unnecessary healthcare costs while also increasing rates of retrieval success.

## ARTICLE INFORMATION

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Dr Desai is consultant and on the speaker's bureau for Cook Medical, Boston Scientific, Philips/Spectranetics, W.L. Gore, Becton Dickinson/Bard, and Walk Vascular. Dr Ryu is a consultant and on the speaker's bureau for Argon Medical, Philips, and B Braun Medical Inc. The remaining authors have no disclosures to report.

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