


ORIGINAL RESEARCH

# Laser-Assisted Removal of Embedded Vena Cava Filters: A First-In-Human Escalation Trial in 500 Patients Refractory to High-Force Retrieval

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**BACKGROUND:** Many patients are subject to potential risks and filter-related morbidity when standard retrieval methods fail. We evaluated the safety and efficacy of the laser sheath technique for removing embedded inferior vena cava filters.

**METHODS AND RESULTS:** Over an 8.5-year period, 500 patients were prospectively enrolled in an institutional review board–approved study. There were 225 men and 275 women (mean age, 49 years; range, 15–90 years). Indications for retrieval included symptomatic acute inferior vena cava thrombosis, chronic inferior vena cava occlusion, and/or pain from filter penetration. Retrieval was also offered to prevent risks from prolonged implantation and potentially to eliminate need for lifelong anticoagulation. After retrieval failed using 3X standard retrieval force (6–7 lb via digital gauge), treatment escalation was attempted using laser sheath powered by 308-nm XeCl excimer laser system (CVX-300; Spectranetics). We hypothesized that the laser-assisted technique would allow retrieval of >95% of embedded filters with <5% risk of major complications and with lower force. Primary outcome was successful retrieval. Primary safety outcome was any major procedure-related complication. Laser-assisted retrieval was successful in 99.4% of cases (497/500) (95% CI, 98.3%–99.9%) and significantly >95% ( $P<0.0001$ ). The mean filter dwell time was 1528 days (range, 37–10 047; >27.5 years), among retrievable-type ( $n=414$ ) and permanent-type ( $n=86$ ) filters. The average force during failed attempts without laser was 6.4 versus 3.6 lb during laser-assisted retrievals ( $P<0.0001$ ). The major complication rate was 2.0% (10/500) (95% CI, 1.0%–3.6%), significantly <5% ( $P<0.0005$ ), 0.6% (3/500) (95% CI, 0%–1.3%) from laser, and all were successfully treated. Successful retrieval allowed cessation of anticoagulation in 98.7% (77/78) (95% CI, 93.1%–100.0%) and alleviated filter-related morbidity in 98.5% (138/140) (95% CI, 96.5%–100.0%).

**CONCLUSIONS:** The excimer laser sheath technique is safe and effective for removing embedded inferior vena cava filters refractory to high-force retrieval. This technique may allow cessation of filter-related anticoagulation and can be used to prevent and alleviate filter-related morbidity.

**REGISTRATION:** URL: <https://www.clinicaltrials.gov>; Unique identifier: NCT01158482.

**Key Words:** endovascular ■ filter retrieval ■ IVC filter ■ laser

Chronic indwelling inferior vena cava (IVC) filters are associated with many potential risks including nonthrombotic injury,<sup>1,2</sup> thrombotic events,<sup>3,4</sup> and the potential need for lifelong anticoagulation.<sup>3,5</sup> The US Food and Drug Administration (FDA) currently

recommends that filters be promptly removed once the risk of acute pulmonary embolism has subsided,<sup>6</sup> but many filters remain chronically implanted and become refractory to standard retrieval methods especially after prolonged implantation. In these patients,

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## CLINICAL PERSPECTIVE

### What Is New?

- This first-in-human study is the largest to date supporting a new indication for endovascular laser use to remove a variety of embedded inferior vena cava filters, including permanent types, regardless of implantation length.
- As the first trial to gather data on objective force measurements during advanced filter retrieval, this study also validates a force-gauge protocol during complex filter removal—demonstrating how routine force gauge use in conjunction with excimer laser technique not only avoids complications associated with excessive force but also allows successful embedded filter removal to be achieved using significantly lower force.
- Although major complications were rare with this technique, tracking these data was important to allow ongoing improvements in anticipation, treatment, and prevention of rare complications related to complex case presentations.

### What Are the Clinical Implications?

- At an experienced center, successful laser-assisted filter retrieval may be achieved (for embedded filters refractory to high-force, standard methods) and used to alleviate filter-related morbidity, to prevent thrombotic and nonthrombotic risks associated with long-term filter implantation and to eliminate the potential need for ongoing/lifelong filter-related anticoagulation.
- This percutaneous technique is minimally invasive and avoids the need for open vascular surgery.

## Nonstandard Abbreviations and Acronyms

<b>FDA</b>	Food and Drug Administration
<b>IVC</b>	inferior vena cava

the use of advanced retrieval techniques may be effective, but some centers have reported a risk of major procedure-related complications when these methods appear to involve excessive force.<sup>7–9</sup> Newer retrieval methods such as the laser sheath technique have emerged as previously published,<sup>5</sup> although the use of laser is not yet approved by the FDA for IVC filter removal. We present outcomes from a prospective study on laser-assisted removal of embedded IVC filters using a protocol that avoids excessive force.

## METHODS

The data that support the findings of this study are available from the corresponding author upon reasonable request. Over an 8.5-year period (2010–2018), more than 2500 advanced filter retrievals (defined as any method other than standard snaring and sheathing) were attempted in our center. From this group, 500 consecutive patients undergoing attempted IVC filter retrieval using an endovascular laser-assisted sheath technique, after failure of standard methods and high force, were prospectively enrolled into an institutional review board–approved study (registry-based clinical trial: NCT01158482). All data were captured in a Health Insurance Portability and Accountability Act–compliant electronic database (REDCap).

This study is part of a larger ongoing 4-stage design comparable to a fixed-size design with a sample size of 1000; the multistage design was adopted only for monitoring purposes, not to allow for early stopping. The first stage was performed using 251 patients<sup>10</sup> and the current analysis includes 249 new cases. The 3 primary study end points were defined as follows: successful filter retrieval (complete filter detachment from the caval wall and removal from the body, excluding extravascular filter fragments) versus failure; presence versus absence of major procedure-related complications; and the difference in force applied to a patient's filter both with and without laser assistance during attempted filter removal. Secondary end points were defined as follows: resolution of symptoms in patients with filter-related morbidity, resolution of filter-related anxiety, and further need for filter-related anticoagulation. The primary outcome was successful filter retrieval, and the primary safety outcome was any major procedure-related complication as defined by established guidelines.<sup>11</sup>

Ninety-six percent of patients were referred or self-referred from outside our institution. There were 225 men and 275 women (mean age, 49 years; range, 15–90 years). In all patients, IVC filtration was no longer needed, and the indications for filter removal were classified into 3 categories: (1) symptomatic patients with filter-related morbidity; (2) physically asymptomatic patients with anxiety over the potential risks from an indwelling filter who wished to prevent filter-related complications; and (3) anticoagulated patients among groups 1 and 2, to potentially eliminate the need for ongoing filter-related anticoagulation previously prescribed to mitigate thrombotic risks associated with long-term filter implantation.<sup>3</sup>

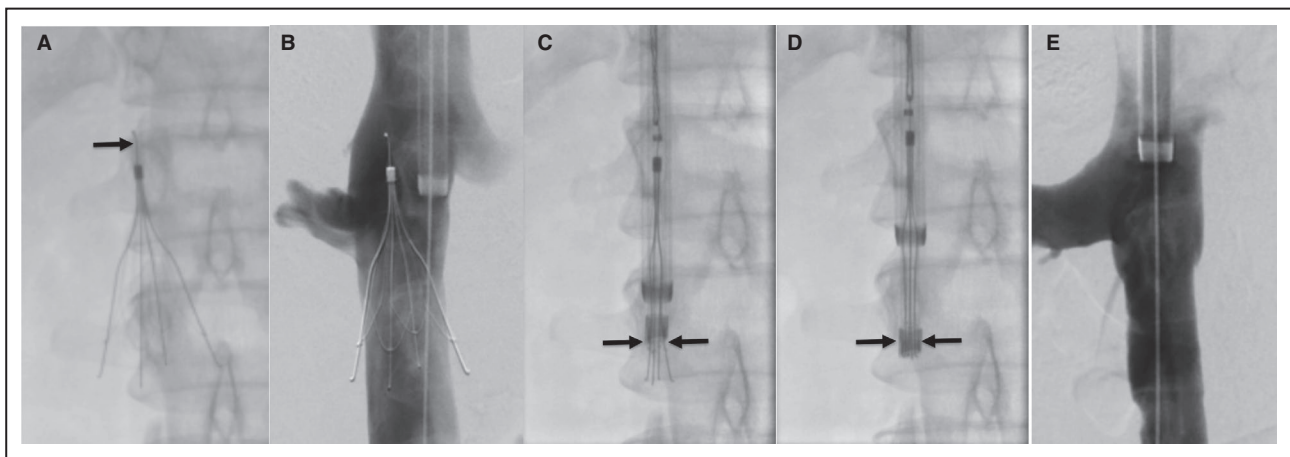
All patients were informed of the potential risks and benefits of advanced laser-assisted retrieval maneuvers versus the risks and benefits of keeping a

permanent filter and provided consent. Patients with permanent filters were also informed that their filter types were not designed, FDA-approved, or originally intended for removal. Before retrieval, acute lower extremity deep venous thrombosis was excluded and acute caval thrombus was removed with thrombolysis as previously described.<sup>5</sup>

Procedures were performed using moderate sedation or general anesthesia per earlier criteria.<sup>5</sup> All patients received intraprocedural therapeutic anticoagulation before the procedure to minimize thrombotic risk per prior protocol<sup>5</sup> and this was reversed if major hemorrhage developed. If filter penetration into adjacent bowel was identified on preprocedure imaging, prophylactic intravenous antibiotics were administered and patients were observed overnight to exclude sepsis before discharge.

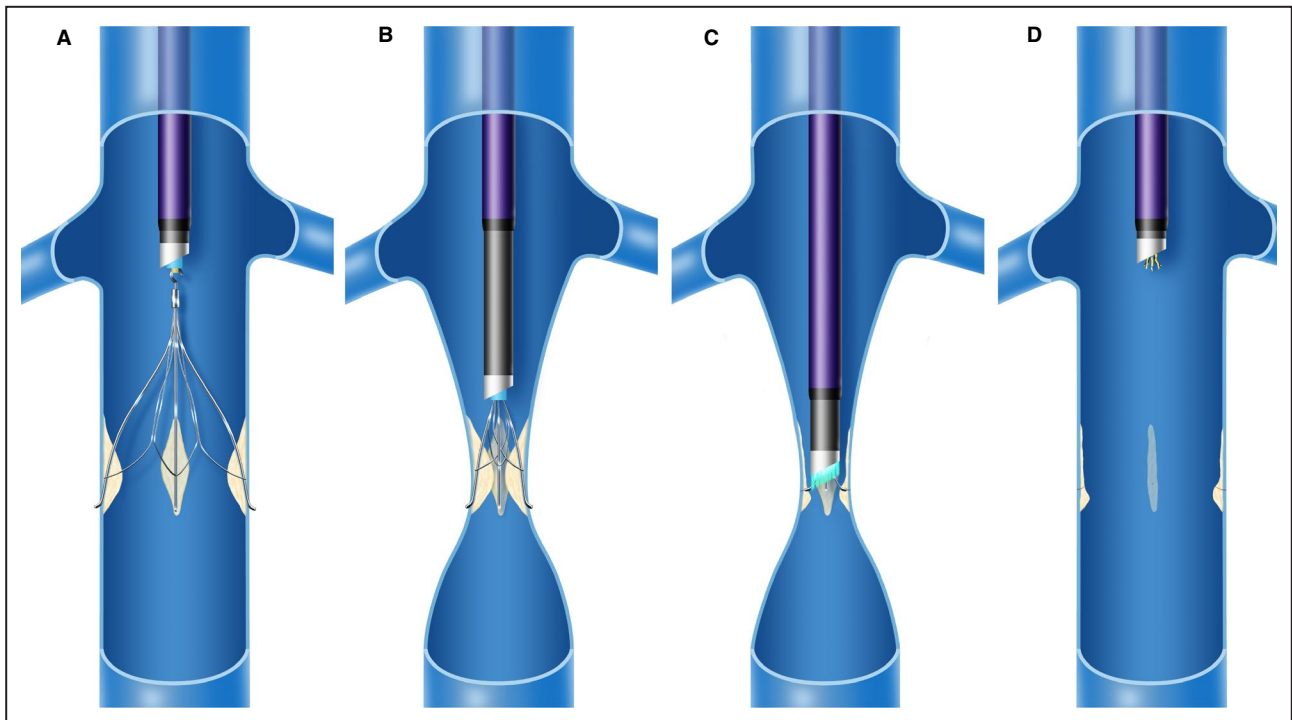
After capturing the filter hook or apex (using forceps and/or wire loop methods if needed), an embedded filter was identified if any portion of the filter could not be sheathed using high force. After the first 15 patients, a digital force meter (McMaster-Carr) was introduced to measure forces in all subsequent cases. Based on preliminary data<sup>5</sup> and the known standard retrieval force of 2 lb,<sup>12</sup> failure of standard retrieval using high force was defined as an inability to sheath the filter despite applying at least 6 lb of tension (3 times the standard force). The force gauge was also used to

avoid overexertion or excess force during procedures (<8–9 lb along cylindrical filters, <6–7 lb for conical devices) based on prior experience,<sup>5,11</sup> where device deformity, retrieval apparatus breakage, and/or vessel injury was observed when exceeding these thresholds. Specifically, the yield strength (upper limit of force without permanent deformation) for a Günther-Tulip filter hook was identified to be 6 to 7 lb. After confirming that the filter was refractory to high-force retrieval attempts, treatment escalation was initiated by placing a laser sheath (Spectranetics) connected to a 308-nm XeCl excimer laser generator (CVX-300, Spectranetics), to attempt fibrotic tissue ablation as previously described.<sup>5</sup> During the procedure, lower tension was applied while advancing the laser sheath through scar tissue around the filter (Figures 1 and 2). After the first 100 patients, if chronic thrombotic occlusion was identified within filter components preventing sheath advancement, debulking and/or softening the chronic thrombus was attempted using a TurboElite catheter (Spectranetics) and/or high-pressure balloon angioplasty before the retrieval attempt. However, after subsequent analysis of these cases,<sup>10</sup> calcified thrombus within cylindrical filter components was identified as a predictor of procedure failure, and subsequent prolonged attempts at debulking the thrombus and attempting filter retrieval were deferred in favor of stenting through the filter.



**Figure 1.** A 48-year-old woman underwent prophylactic placement of an inferior vena cava (IVC) filter 9 years prior at an outside hospital after sustaining polytrauma and multiple long bone fractures.

The patient recovered from her injuries and underwent attempted filter removal at her local hospital  $\approx$ 1 year later, but this was unsuccessful. Several years later, during a routine evaluation by her primary physician, her indwelling filter was rediscovered. Her local physician recommended reevaluation for potential filter removal to avoid risks associated with long-term implantation, and she was referred to our center to undergo advanced filter retrieval. **A**, Spot fluoroscopic image shows a Günther-Tulip IVC filter. The filter hook is deformed and straightened (arrow) from prior manipulation indicating that high force (>6–7 lb) was previously applied to the filter (exceeding the metallic yield strength) during the failed retrieval attempt. **B**, Initial IVC venogram shows a patent vein with evidence of filter leg penetration. **C**, Fluoroscopic images demonstrate attempted capture of the Günther-Tulip IVC filter using a standard snare and sheathing method, but the distal filter legs cannot be sheathed despite confirming 6 lb of tension applied along the attachment sites (arrows). **D**, After laser activation and ablation through the adherent scar tissue, the filter is completely captured within the laser sheath (arrows) using only 3 lb of tension. **E**, Post-retrieval venogram shows expected postprocedure vasospasm, but there is no acute injury and no extravasation.



**Figure 2.** Illustration of laser-assisted filter retrieval.

**A**, A chronically embedded inferior vena cava (IVC) filter is shown with fibrotic tissue along the endoluminal contact points. Distal leg penetration is also present. The filter is confirmed to be embedded after standard sheathing methods and high force (up to 6–7 lb) fail to remove the filter. **B** and **C**, The laser-tipped sheath is advanced over the filter until reaching the point of resistance. While activating the excimer laser to ablate through the fibrotic tissue, only one half (3–3.5 lb) of the prior high-force tension is needed to capture the filter legs. At a 308-nm wavelength, the excimer laser ablates 50 to 100  $\mu\text{m}$  from the laser tip sheath. Since the energy is emitted parallel to the vessel walls, the risk of significant vessel injury is minimized. Once the adherent tissue is ablated, the distal filter legs including the penetrating components can now be retracted safely into the vessel lumen and captured within the laser sheath. **D**, Using a lower amount of force, the chronically embedded filter is now completely and safely detached from the IVC without vessel wall injury.

After analyzing outcomes from the initial 251 cases as previously published,<sup>10</sup> noting a case of right renal infarction related to removal of a penetrating filter apex that had impaled through the posterior caval wall and into the proximal renal artery, we began to routinely catheterize the right renal artery with placement of a guidewire in parallel if filter penetration near this artery was identified or suspected on preprocedure cross-sectional imaging. Oftentimes, the wire was observed to lift the renal artery superiorly and away from the filter apex aiding in protection. In these cases, concomitant wire localization along with intermittent renal angiography, injecting 5-cc aliquots of contrast by hand through a 6F renal double curve sheath (Terumo) at the renal ostium, at  $\approx$ 1- to 2-minute intervals was performed during filter retrieval. If any renal artery injury was identified or exposed during filter removal, the artery was immediately repaired with endovascular stent graft placement.

Concomitant with addressing the filter, venous revascularization was also performed as previously described<sup>10</sup> in patients with symptomatic venous occlusion. If debulking of chronic calcified clot was

not possible through cylindrical filter components to permit filter removal, then stenting through the filter was performed to restore IVC patency. Treatment of major caval injury was achieved with percutaneous stent graft placement as described earlier.<sup>10</sup> Routine clinical follow-up was performed to evaluate for postprocedure complications and improvement in filter-related morbidity, and the presence of filter-related anxiety was assessed in preprocedure and postprocedure clinic assessments. Among patients on prior filter-related anticoagulation, an attempt was made to discontinue the anticoagulation within 2 to 3 months post-retrieval.

Our hypothesis for the first end point, success, was that the proportion of successful cases would be  $>95\%$ ; this was tested with a 1-sided binomial test. Our hypothesis for the second end point, major complications, was that the proportion of major complications would be  $<5\%$ ; this was also tested with a 1-sided binomial test. Our hypothesis for the third end point, applied force, was that applied force during laser-assisted removal attempts would be less than in nonlaser-assisted removal attempts for the same filter;

this was tested with a 1-sided paired *t* test. To calculate interim analysis criteria, the Wang-Tsiatis method (RDocumentation) with a parameter value of 0.25 was used, as a way to balance the tradeoffs of the common Pocock and O'Brian-Fleming methods. Using Bonferroni correction to adjust for 3 end points, the nominal threshold *P* value for the tests at each of the 4 stages was 0.0007, 0.0035, 0.0075, and 0.0118, respectively. Thus, a significance level of 0.0035 was used for this interim analysis. Reported 95% CIs are approximate, and all statistical analyses were performed using Stata Release 16.1 (StataCorp LLC).

## RESULTS

Among 3 categories of retrieval indications, the number of patients was as follows (Table 1): (1) 140 physically symptomatic patients (28%, 140/500) with filter-related morbidity, (2) 360 physically asymptomatic patients with filter-related anxiety (72%, 360/500), and (3) 78 patients (16%, 78/500) receiving filter-related anticoagulation among groups 1 and 2 with no underlying thrombophilia. Laser-assisted retrieval was successful in 99.4% (497/500) (95% CI, 98.3–99.9%) and this was significantly higher than 95% ( $P < 0.0001$ ). The mean filter dwell time was 1528 days (4.2 years; range, 37 to 10 047 days [ $>27.5$  years]). The median dwell time was 569 days (interquartile range, 260–2348 days). The

**Table 1. Symptomatic Filter-Related Complications**

Complication	No.
Pain caused by retroperitoneal filter penetration including concomitant radiographic findings:	81*
Small bowel penetration (n=21) (1 with GIB)	
Pancreas penetration (n=3)	
Liver penetration (n=1)	
Psoas muscle penetration (n=6)	
Vertebral body penetration (n=10)	
Aortic penetration (n=8)	
Filter fracture and central embolization (n=4)	
Retained wire fragment in the right ventricle and pulmonary artery from prior failed retrieval (n=1)	
Possible nickel hypersensitivity (n=1)	
Chronic IVC thrombosis including:	44
One associated caval rupture from venous hypertension*	
Recurrent acute IVC thrombosis including:	15
Concomitant acute pulmonary embolism (n=2)	
Concomitant underlying chronic IVC stenosis (n=10)	
Total	140

GIB indicates gastrointestinal bleeding; and IVC, inferior vena cava.

\*Post-retrieval pain was alleviated in all patients except 2.

\*The patient required emergency open surgery at an outside hospital. Laser-assisted retrieval and revascularization were subsequently successful without complication.

filter types and implantation lengths are summarized in Table 2. Successful filter retrieval alleviated filter-related morbidity in 98.5% of cases (138/140; 95% CI, 96.5%–100.0%) and allowed cessation of anticoagulation in 98.7% of cases (77/78; 95% CI, 93.1%–100.0%).

Among 485 cases with digital force assessments, all filters failed high-force retrieval attempts, with an average of 6.5 lb (range, 6.0–9.0 lb); and the average force applied during laser-assisted retrievals was significantly lower at 3.6 lb (range, 3.0–8.5 lb) ( $P < 0.0001$ ). The median prelaser force was 6 lb (interquartile range, 6–7 lb) and the median force during laser was 3.1 lb (interquartile range, 3–4 lb). Three cases failed retrieval because of bulky calcified thrombus (refractory to thrombectomy) within cylindrical-shaped filter components (2 Optease, 1 Trapease), creating a volume that was too large to be captured within the bore of the existing laser sheath apparatus.

The major complication rate was 2.0% (10/500) (95% CI, 1.0%–3.6%), significantly less than the 5% threshold ( $P < 0.0005$ ), and all complications were successfully treated with either medical management and/or percutaneous endovascular therapy without the need for open surgery. The rate of iatrogenic

**Table 2. Summary of Filter Types and Implantation Lengths**

Total	Filter Type	Mean Dwell Time in d [Range] (Maximum d=xy)
202	Günther-Tulip (Cook)	651 [62–5876] (5876 d=16.1 y)
40	Option (Rex Medical)	367 [92–1680] (1680 d=4.6 y)
35	Celect (Cook)	636 [37–2363] (2363 d=6.5 y)
7	Celect Platinum (Cook)	652 [225–1201] (1201 d=3.3 y)
12	Denali (Bard)	162 [39–263] (263 d=0.7 y)
5	G2 Meridian (Bard)	1325 [428–2020] (438 d=1.2 y)
65	Optease (Cordis)	532 [71–3616]* (3616 d=9.9 y)
29	Trapease† (Cordis)	2150 [105–4340]‡ (4340 d=11.9 y)
25	Titanium Greenfield† (Boston Scientific)	4552 [873–10 047] (10 047 d=27.5 y)
24	12F Stainless Steel Greenfield† (Boston Scientific)	3234 [70–6288] (6288 d=17.2 y)
8	Simon-Nitinol† (Bard)	2566 [531–3829] (3829 d=10.5 y)

\*Two retrieval failures at 188 and 3011 days were each associated with chronic caval thrombus.

†Permanent-type inferior vena cava filter.

‡One retrieval failure at 1124 days was associated with chronic caval thrombus.

filter fracture was 0% (0/500) (95% CI, 0.0%–0.74%). Among the 485 cases using a digital meter to avoid excessive force, the rate of procedure-related device deformity and/or retrieval apparatus breakage was 0% (0/485) (95% CI, 0.0%–0.76%). Among patients with no physical filter-related morbidity, none developed any major procedure-related complications, and all reported relief of filter-related anxiety and achieved cessation of filter-related anticoagulation (if previously prescribed) following filter removal. There were 10 different combinations of major complications and their causes encountered over the first 7 years (Table 3), and there were no major complications observed over the final 1.5 years of the study. Three complications (0.6%) (3/500) (95% CI, 0%–1.3%) were directly attributed to laser activation causing IVC hemorrhage. These complications were caused by conditions that prevented the laser sheath from remaining safely centered within the IVC lumen. One resulted from asymmetric pulling of the laser sheath tip against focal IVC wall caused by lasing along a severely tilted and embedded filter apex. Two resulted from asymmetric advancement of the laser sheath tip against focal IVC wall caused by lasing along 1 fractured cylindrical type and 1 fractured conical type filter. Among the first 15 patients enrolled, 2 complications occurred from excess force applied during retrieval, before routine force gauge assessments. One patient developed sepsis after removal of a penetrating filter component from the small bowel; this patient required 1 week of hospitalization while receiving intravenous antibiotic therapy before hospital discharge on an outpatient antibiotic regimen, and the patient eventually recovered without need for further intervention. Two patients had existing filter penetration into adjacent arterial branches. One of these resulted from prior low filter deployment into the iliac vein confluence resulting in filter leg penetration and erosion into an adjacent median sacral artery; the arterial hemorrhage was subsequently identified and treated with endovascular occlusion. One patient had suspected hemorrhage from filter leg penetration into a branch of the gastroduodenal artery and this was treated with embolization. Two patients had existing injuries from filter component penetration into the right renal artery. In the first case, filter apex penetration through the posterior caval wall and into the right renal artery was not obvious on preprocedure computed tomography, and removal of the penetrating filter component resulted in arterial thrombosis with subsequent renal infarction; the patient was managed medically with close nephrology follow-up and avoidance of nephrotoxic agents, and preservation of overall renal function was achieved via the contralateral kidney. In the second case, filter apex penetration through the

IVC wall and into the adjacent right renal artery was identified on preprocedure computed tomography. This allowed planning for simultaneous renal arterial catheterization during filter removal. On removal of the penetrating filter apex, an arteriovenous fistula was identified and the arterial defect was immediately repaired with stent graft placement to preserve renal artery perfusion. A summary with classification of all major complications is provided in Table 3.

## DISCUSSION

Despite unclear clinical benefit,<sup>13</sup> the use of IVC filters in the United States has been relatively high and up to 25 times more than an equivalent population in Northern Europe.<sup>14</sup> A recent analysis of the US National Inpatient Sample revealed that >1.1 million devices were implanted over a 10-year period,<sup>15</sup> and this high implantation rate combined with historically low retrieval rates and limited clinical follow-up<sup>16–18</sup> has resulted in the current rise in filter-related complications.<sup>6,19</sup> For instance, serious nonthrombotic risks including pain and organ injury from penetration, filter fracture with risk of cardiopulmonary embolization, and death from cardiac injury have been reported.<sup>2,5,20</sup> The placement of IVC filters without prompt retrieval has also been associated with major thrombotic complications including filter-related acute venous thromboembolism, chronic caval occlusion, chronic deep venous thrombosis, and post-thrombotic syndrome—a chronic debilitating condition with no cure.<sup>3,4,17</sup> Consequently, many patients with indwelling filters refractory to removal are routinely managed with ongoing anticoagulation solely in an attempt to reduce thrombotic risks associated with chronic filter implantation, and these patients are subjected to the additional cost, inconvenience, and bleeding risks associated with lifelong anticoagulation. Finally, awareness of all of these risks can result in filter-related anxiety, and many patients will experience ongoing anxiety if the filter cannot be removed.<sup>10</sup> Because of rising filter-related complications over the past decade, the US Food and Drug Administration has issued 2 safety communications,<sup>6,19</sup> alerting all physicians who care for patients with IVC filters to consider removing the filter as soon as protection from pulmonary embolism is no longer needed, and preferably within 1 to 2 months after implantation.<sup>6</sup> However, prior studies have shown that the majority of retrievable filters are never removed,<sup>16–18</sup> creating an overabundance of patients with indwelling filters. Even with heightened awareness and closer follow-up for removal, up to 40% to 60% of filters implanted for over 1 year cannot be removed using standard methods.<sup>8,10</sup> Based on earlier

**Table 3. Major Procedure-Related Complications**

CX #	Study Year	Major Complication	Filter Type	Cause	Related to Laser	Successfully Treated	Alleviated Filter-Related Morbidity
1	1	IVC thrombus	Optease	Excess force*	No	Yes, thrombolysis	Yes, recurrent VTE
2	1	IVC hemorrhage	Trapease <sup>†</sup>	Excess force*	No	Yes, IVC stent graft	Yes, PTS
3	2	IVC hemorrhage	Celect	Excess laser along embedded filter apex	Yes	Yes, IVC stent graft	Yes, pain
4	2	Right renal infarction	Celect	Removal of existing penetrating filter apex from renal artery	No	Yes, medical management	Yes, pain
5	4	Delayed IVC thrombus (>1 wk post-procedure)	Simon-Nitinol <sup>†</sup>	Recurrent caval stenosis and thrombophilia	No	Yes, thrombolysis and angioplasty	Yes, pain
6	6	IVC hemorrhage	Optease	Existing filter fractures causing asymmetric lasing along cylindrical components	Yes	Yes, IVC stent graft	Yes, anxiety
7	7	Sepsis	Günther-Tulip	Removal of filter leg from existing SB penetration	No	Yes, IV antibiotics and medical management	Yes, pain
8	7	Likely IVC hemorrhage with suspected GDA branch hemorrhage	Option	Existing filter fractures causing asymmetric lasing along conical components. Removal of existing penetrating filter leg from vicinity of GDA	Yes	Yes, IVC stent graft along with GDA embolization	Yes, PTS
9	7	Sacral artery branch hemorrhage	Titanium Greenfield <sup>†</sup>	Removal of existing penetrating filter leg near sacral artery	No	Yes, endovascular sacral artery occlusion	Yes, pain
10	7	High-flow right renal arteriovenous fistula	Option	Removal of existing penetrating filter apex from renal artery and IVC wall	No	Yes, renal artery stent graft placement with preservation of renal perfusion	Yes, cessation of filter-related anticoagulation

GDA indicates gastroduodenal artery; PTS, post-thrombotic syndrome; SB, small bowel; and VTE, venous thromboembolism.

\*Before routine protocol of force gauge use. Complications related to high force were identified within the first 25 cases in study year 1. Following introduction of the force gauge protocol, there were no further complications related to excess force. All complications were successfully treated with percutaneous endovascular therapy and/or medical management without the need for open surgery.

<sup>†</sup>Permanent-type inferior vena cava (IVC) filter.

estimates,<sup>15</sup> if >2.2 million filters are implanted over a 20-year period and if 50% are not removed because of lack of follow-up or failed retrieval, then >1.1 million patients would end up with an embedded filter in the United States alone regardless of whether a filter is still indicated.

The use of advanced retrieval techniques in specialized centers has the potential to improve retrieval success among patients with chronically embedded filters, but these cases are often complex, and prior studies have shown a risk of major vascular injury, thrombosis, and device fracture<sup>7-9</sup> with advanced retrieval methods. In a 2014 study comparing 231 routine versus 57 advanced retrieval attempts (mean dwell time=277 days) (advanced attempts), the use of advanced techniques was associated with a higher success rate of 95% versus 73%, but also a significantly higher complication rate of 5.3% versus 0.4%.<sup>7</sup> However, there were no force gauge assessments in that study to avoid overexertion and no laser technique available to permit low-force removal, so we assume the use of aggressive force resulted in major vessel injury. Therefore, we hypothesized that careful force-gauge use to avoid overexertion, along with a new laser-assisted technique, would allow retrieval of >95% of embedded filters with a <5% risk of major complications. Our study achieved both of these end points with a 99.4% retrieval success and a 2.0% overall major complication rate, with only 0.6% complications from laser. Furthermore, our study was much larger than earlier studies,<sup>7-9</sup> had a mean filter dwell time of over 4 years (versus average dwell times of <1 to 1.5 years in prior studies<sup>7-9</sup>), encompassed a wider variety of filters including many permanent types (Table 2), and is the only trial to include data on objective force assessments during advanced filter retrieval.

As a specialized center that accepts complex filter cases, our patients were often referred after failed retrieval attempts or when other centers refused to attempt filter removal because of high procedural risks. Indeed, we noted increased variety and complexity of cases encountered throughout the study period. We believe this helps to explain why 10 different combinations of major complications and causes were encountered without duplication (Table 3). For instance, we accepted cases involving severe filter fractures and penetrations that increased the risk of injury to the IVC and/or adjacent arteries during filter removal. In attempting these cases, we learned that severe filter fractures may lead to asymmetric lasing of fibrous tissue along the vessel wall causing major venous hemorrhage. We also learned that filter components may penetrate through the cava and into adjacent arteries predisposing to organ infarction, major arterial hemorrhage, and arteriovenous fistula formation during filter removal. Tracking these data throughout the study

allowed us to perform subsequent protocol modifications to anticipate, mitigate, and manage these complications. For instance, in our later experience, we were able to anticipate an existing renal artery penetration with early arteriovenous fistula and repair this immediately during concomitant filter removal to avoid renal infarction, something that we were unable to anticipate in our earlier experience (Table 3). Essentially, we learned from this larger experience that venous vascular injury and thrombosis are just a few of the complications that may occur as previously described,<sup>5,10</sup> and that retrieval of penetrating filter components may also be associated with major arterial hemorrhage, organ injury, and sepsis.

A potential alternative to the laser technique is sole use of endobronchial forceps. Although we believe forceps use to free an embedded filter apex is generally safe, the safety and efficacy of forceps use for removal of embedded filter legs and filter struts has not been established in large numbers relative to the laser method. The largest study to date by Tavri et al<sup>9</sup> was a retrospective review that included only 55 patients with embedded filter legs/struts. Their success rate was 96.3% (53/55),<sup>9</sup> a lower rate versus 99.4% (498/500) in the current study, despite relatively fewer filter types and shorter dwell times. The study by Tavri et al included only 6 filter types (versus 11 types in our study) with average dwell times of only 565 days (versus >1500 days in our study). Despite the lower case complexity encountered by Tavri et al, their forceps-specific major complication rate was 7.3% (4/55)<sup>9</sup>—more than 12 times higher than our laser-specific complication rate of 0.6% (3/500). Furthermore, Tavri et al reported several forceps-related fractures resulting in an 18% (10/55) iatrogenic filter fracture rate,<sup>9</sup> which included embolization of fragments into the heart and lungs,<sup>9</sup> and we observed no such complications at 0% (0/500) with laser use.

This study has limitations. The results were acquired in a single center that specializes in advanced filter removal. Therefore, it is unclear whether the overall safety and efficacy of removing embedded filters as described here would translate into similar outcomes when performed elsewhere. Although we assumed that filter removal would reduce the risk of future filter-related complications among patients who were physically asymptomatic, it is possible that some or all of these patients could have remained asymptomatic from their indwelling filters. However, among these patients who were physically asymptomatic, none developed any major procedure-related complications, and all achieved cessation of filter-related anticoagulation (if previously prescribed) following filter removal. Although all patients with anxiety reported relief of this symptom, we did not obtain formal psychiatric evaluations or use scoring systems to quantify their anxiety



relief postprocedure, so future studies should address this. Another limitation is the lack of cost analysis. Although the laser sheath apparatus carries additional device cost, successful filter removal in a single session may decrease overall expense by eliminating the high cost of multiple failed procedures that we routinely observed before successful laser retrieval, and these issues warrant further study. Finally, the laser sheath apparatus is currently not FDA-approved for IVC filter removal and this may limit proper technique dissemination. Nevertheless, the current study represents the largest prospective trial to date of patients undergoing laser-assisted filter removal, and it now validates the original experimental protocol<sup>5</sup> in a much larger cohort.

## CONCLUSIONS

This 8.5-year prospective study supports a new indication for excimer laser sheath use in experienced centers for removal of embedded vena cava filters refractory to high-force retrieval attempts. This percutaneous technique was overall safe and effective in removing a variety of filter types regardless of implantation length, using a minimally invasive protocol that avoids excessive force, thereby avoiding the need for invasive open surgery. In a patient population experiencing an epidemic of filter-related complications, laser-assisted retrieval has the potential to prevent and alleviate filter-related morbidity by safely removing embedded IVC filters in tens of thousands of patients per year.

## ARTICLE INFORMATION

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### Disclosures

None.

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