Laser Sheath-Assisted IVC Filter Retrieval

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Disclosures

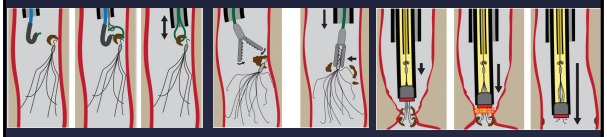
- Speaker's bureau/consulting: Cook Medical, Boston Scientific, Becton Dickinson, Medtronic, Penumbra, Tactile Medical, Philips
- Consulting: W.L. Gore, Asahi Intecc, Veryan, Cordis, Surmodics, Abbott, EnVVeno, Varian, Terumo

FDA Safety Communication 2014

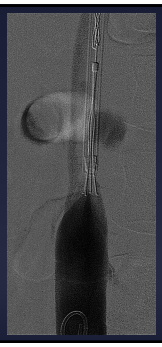
Implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed.

Advanced Techniques

- Advanced techniques have had a significant impact on retrieval success
- Techniques include loop wire snare, rigid endobronchial forceps, and Excimer laser sheath-assisted ablation

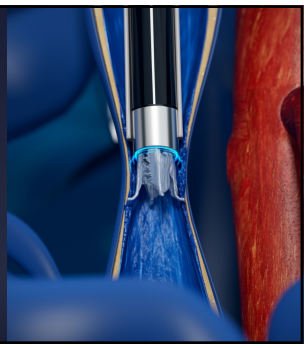


- IVC filter struts incorporated into caval wall from extended implantation
- Would require large forces to detach with standard sheath/snare technique

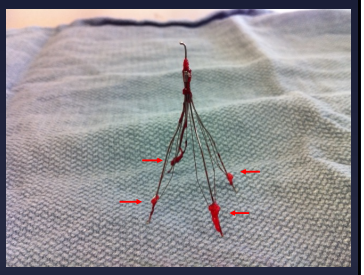


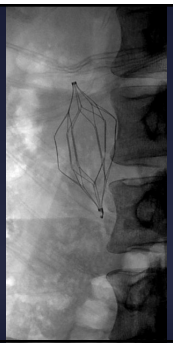
Excimer laser technology

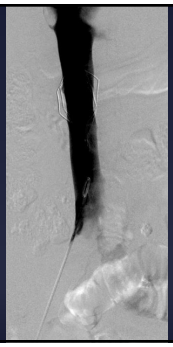
- Philips Laser System or CVX-300 is an ultraviolet cool laser
- Philips laser technology uses photothermal issue ablation
- Laser mechanism of action does not damage the IVC filter[1]
- Laser has the penetration depth of 50 microns, less than the width of a human hair[2]
- Most effective when equal traction / counter traction is applied
- Application of laser allows reduction of forces needed to retrieve the foreign body

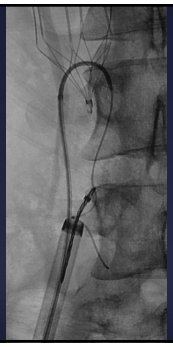


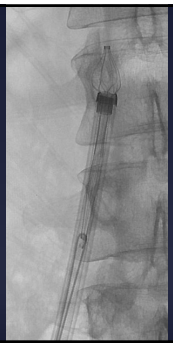
- Note fibrin at filter implantation site; laser used to ablate this tissue and permit release of the filter

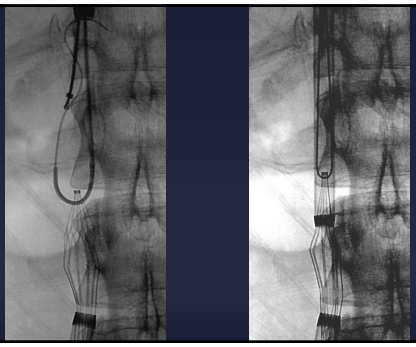


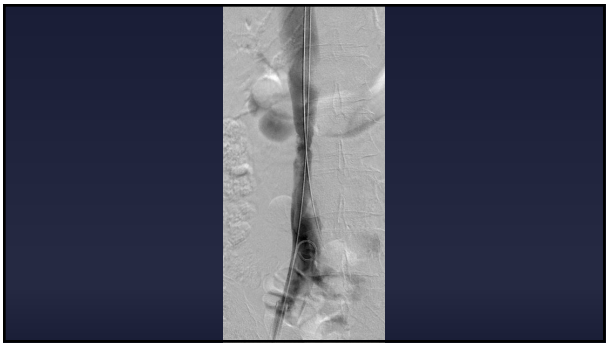


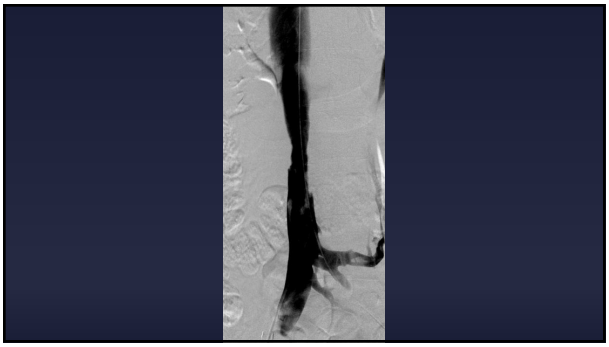








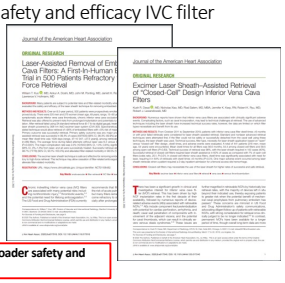




Single-center studies demonstrate safety and efficacy IVC filter removal with excimer laser sheath

A 500-patient single-center study showed Laser-assisted retrievals have low major complication rate (2.0%) and high success rate (98.7%) [1]

441-patient single-center study[2] showed low major adverse event rate (0.6%) and high technical success (96%) [2]



No multi-center studies to date have evaluated the broader safety and success, limiting the generalizability of the technique

1. Kuo WT, Oschi AA, Ponting JM, Rosenberg JK, Liang T, Hofmann LV. J Am Heart Assoc. 2020.
2. Desai KR, Kiss N, Salem R, Kerp JK, Ryu RK, Lewandowski RJ. J Am Heart Assoc. 2020.

Results: demographics, medical history, filter characteristics

	Single-Center N=139	Multi-Center N=126
Mean Age (years)	52±16	52±16
Female	56.1%	59.5%
Deep Vein Thrombosis	85.2%	89.7%
Pulmonary Embolism	62.6%	62.1%
Prophylactic filter placement	26.6%	57.1%

Filter model	Single-Center	Multi-Center
Retrievable	89.2%	83.3%
Gunther Tulip (Cook Medical)	65	56
OptEase (Cordis)	32	35
Option (Rex Medical)	15	9
Celect (Cook Medical)	11	2
ALN (ALN)	1	1
Meridian (Bard)	None	1
Recovery (Bard)	None	1
Permanent	10.8%	16.7%
Simon Nitinol (Bard)	6	3
TrapEase (Cordis)	7	15
Greenfield (Steel/Titanium, BSC)	2	3

	Single-Center	Multi-Center
Mean Filter Dwell Time (months)	57.1±51.8	69.7±62.0
Median Filter Dwell Time (min, max)	40 (1.0, 186.0)	64 (1.0, 261.0)
Prior Failed Retrieval Attempts	100.0%	42.1%
Pre-procedural imaging evaluation of filter	84.1%	88.9%
Filter Malfunction	8.8%	40.5%
Filter Tilt >15 degrees	31.4%	39.7%
Penetration of the IVC	14.0%	54.8%
Whole device Embolization/Migration	3.7%	1.6%
IVC Occlusion	0.7%	13.6%

Results: primary endpoints

Efficacy target performance: ≥ 89.4%

Primary Efficacy Endpoints	Single-Center N=139	Multi-Center N=126
Technical success rate	**95.7%**	**95.2%**
Reasons for procedural failure	**p=0.007**	**p=0.016**
Failure to capture filter apex	None	1
Failure to ablate tissue/free filter from caval wall	None	4
Other	6	1

p-value is 1-sided for comparison against the efficacy performance goal of 89.4%

Safety target performance: ≤10%

Safety Endpoints	Single-Center N=139	Multi-Center N=126
Device Related Major Complication	**2.9% (4/139)**	**4.0% (5/126)**
One subject reported multiple complications/SIR grades – Multi-Center	**p=0.001**	**p=0.011**

p-value is 1-sided for comparison against the safety performance goal of 10%.
Major Complications include C. Require therapy, minor hospitalization (<48 hours); D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours) ; E. Permanent adverse sequelae; F. Death.

Safety endpoints

Safety Endpoints	Single-Center N=139	Multi-Center N=126
Device Related Major Complication	2.9% (4/139) p=0.001	4.0% (5/126) p=0.011
Procedure related Major Complication	3.6%	4.0%
Filter fracture with embolization	2	0
Filter penetration	1	0
IVC perforation	1	0
Access site hematoma	1	0
IVC injury with extravasation	0	2
Hematoma, major	0	2
Hemorrhage	0	1
Device related Minor Complication	15.8% (22/139)	11.1% (14/126)
Procedure related Minor Complication	26.6%	15.1%

One subject reported multiple complications/SIR grades – Multi-Center

p-value is 1-sided for comparison against the safety performance goal of 10%.
Major Complications include C. Require therapy, minor hospitalization (<48 hours); D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours) ; E. Permanent adverse sequelae; F. Death.
Minor Complications include A. No therapy, no consequence; B. Nominal therapy, no consequence;
includes overnight admission for observation only.

Conclusions

- First multicenter "real-world" of safety and effectiveness of excimer laser sheath for IVC filter retrieval
- The technical success rate for laser sheath assisted IVC filter retrieval was >95% for both cohorts in the setting of prolonged dwell times (average of > 4.5 yrs)
- Major complication rates were low for both single and multi-center data at 2.9% and 4.0%, respectively → **no major complications scored as "definitely related"** to the use of the laser
- Broader generalizability of laser sheath assisted retrieval with appropriate training in centers with variable case volume and experience