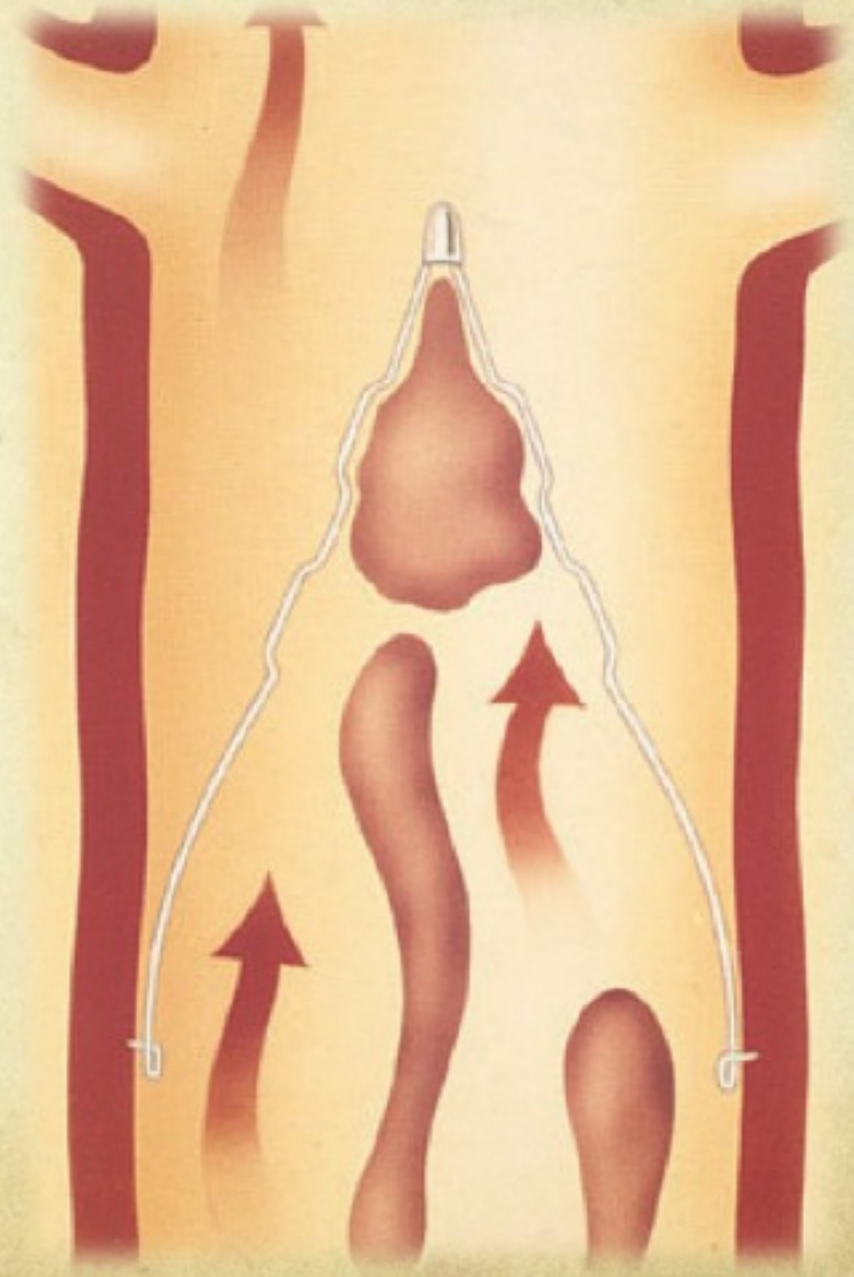
IVC Filters and the Trauma Patient



Stuart M Lyon
Injury 2011

Trauma and venous thromboembolism (VTE)

- Trauma patients have the highest VTE rate of all hospital patients
  - » Geerts WH, *Chest*. 2001;119:132S–175S
- Fatal Pulmonary Embolism (PE) is 3rd most common cause of death in trauma patients who survive >24hrs after injury
  - » Anaya DA, *Surg Clin North Am*. 2005 ;85(6):1163-77

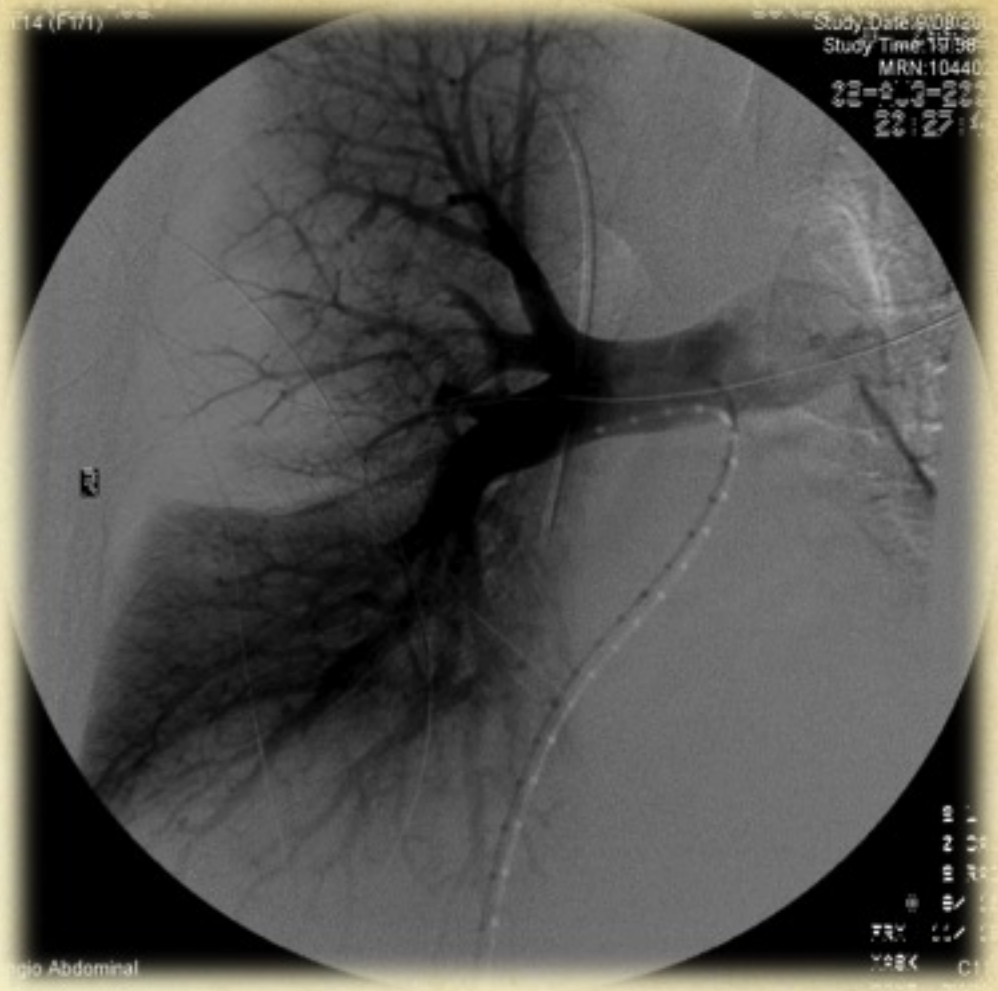
Why high VTE in trauma?

- Hypercoaguable
  - increased thromboplastin
  - reduced fibrinolytic activity
  - circulating catecholamines
  - compliment activation
  - reduced clearance of clotting factors
- Venous endothelium
  - -extrinsic coagulation mechanism from direct endothelial trauma
  - remote endothelial trauma ?
- Venous stasis
  - -prolonged bed rest
  - -altered flow dynamics, etc
- Don't forget to add the medical culprits
  - Co morbidities/ age/ obesity/ pregnancy
  - 1in 14 trauma patients have a genetic clotting defect

VTE prophylaxis after trauma

- Chemoprophylaxis
  - Low Molecular Weight Heparin often contraindicated
    - Delay of 4 days in 50% of trauma patients
    - Delay of 1 week in 25% of trauma patients
    - 3 fold increase in VTE with delay to LMWH over 4 days
      - » Nathens AB, *J Trauma*. 2007;62:557-562
- Sequential compression devices
  - Efficacy questioned
    - » Knudson MM, *J Trauma*. 1996;41:446-459
  - Contraindicated in 35% due to lower limb injuries
    - » Agudelo JF, *Orthopedics*. 2005;28(10):1164-71
- Monitoring
  - Duplex, clinical, etc
  - Efficacy questioned

What is aim of IVC filter Rx?



Prevent PE!

?Reduce morbidity and mortality of PE with acceptable safety and cost benefit profiles?

IVC and Trauma

- PREPIC
- Filter development
  - Birth of the retrievable filter
  - Prophylactic indications/ filters
  - Future directions
- State of play IVC filters in Trauma
- Conclusions??
- Where to from here

INDICATIONS

- Contraindication to anticoag.
- Anticoag. failure (10%)
  - Recurrent PE
  - Progressive DVT
- Anticoag. Complication:
  - Major hemorrhage-approx 10-26% risk
  - Heparin induced thrombocytopenia- 5-15%
  - Heparin induced osteoporosis
- Failure of existing filter

ONE RCT

- 400 patients with prox DVT, mean age 72
- Randomised to filter + AC or AC alone

Time	Filter grp	AC grp
Day1	1.1% PE	4.8% PE
2yrs	20.8% DVT	11.6% DVT
8yrs	6.2% PE	15.1% PE
8yrs	35.7% DVT	27.5% DVT
8yrs	50.3% PTS	69.7% PTS

- No difference in mortality at 8 yrs
  - Decousus et al. NEJM 1998;338:409
  - PREPIC Study Group. Circulation 2005;112:416-22

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PREPIC

' IVC filters in patients with DVT +/- PE protect against longterm development PE without favouring development of PTS'

'Their insertion is associated with a significant increase in DVT'

IVC filters

- Difficult to deny that filters have a role to play in preventing PE in proximal DVT.
- Can we take high risk groups and give them the advantage of caval interruption without the risks?

= the birth of non permanent filters and prophylactic indications.

INDICATIONS

- High risk PE
- Standard prophylaxis ineffective or CI

Explosion in use of filters

Trends in vena caval interruption

Phillip S. Moore, MD,[a] Jeanette S. Andrews, MS,[b] Timothy E. Craven, MSPH,[b] Ross P. Davis, MD,[a] Matthew A. Corriere, MD,[a] Christopher J. Godshall, MD,[a] Matthew S. Edwards, MD,[a] and Kimberley J. Hansen, MD,[a] *Winston-Salem, NC*

(J Vasc Surg 2010;52:118-26.)

- NIS database
- VCF increased from 52,680 (98) to 104,114 (05)
- Prophylactic VCF for head injury and morbid obesity increased significantly
- Hospitalizations with DVT and PE rose 14% and 59%

"The findings that rates of DVT and PE in hospitalized patients increased significantly form 1998 to 2005 was unexpected."

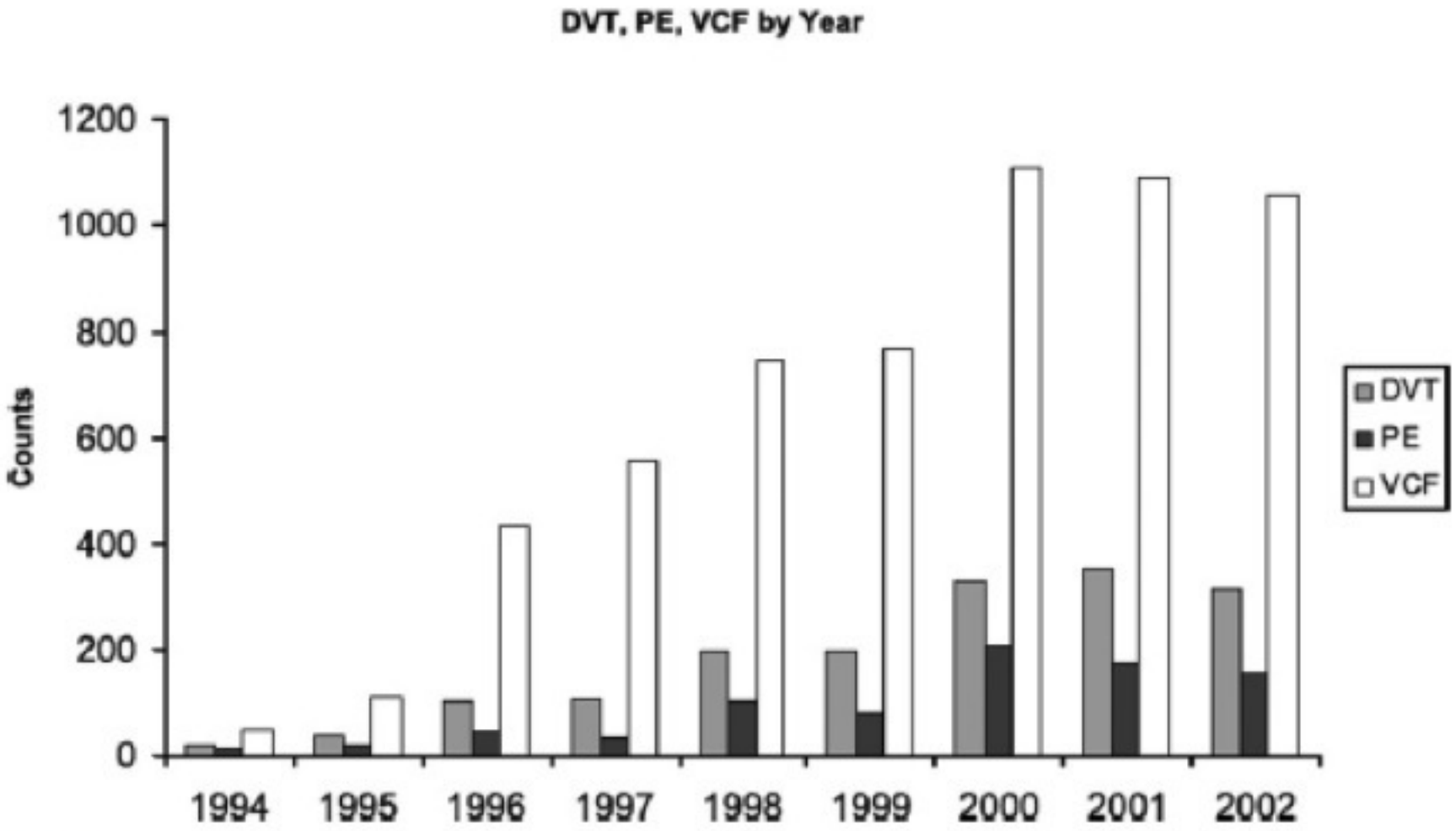


FIG 2. Bar graph demonstrating the number of patients reported to the NTDB who had a VCF placed during the interval 1994-2002. Also shown are the number of patients reported to the NTDB who had either a DVT or a PE. When these numbers are divided by the total number of patients reported to the NTDB in each of the years shown, the number of VCF placed annually has increased 340%, whereas the number of DVT or PE reported has increased 246% (Shackford SR, Cook A, Rogers FB, et al. The increasing use of vena cava filters in adult trauma victims: data from the American College of Surgeons National Trauma Data Bank. J Trauma 2007;63:764-9. Reproduced with permission).

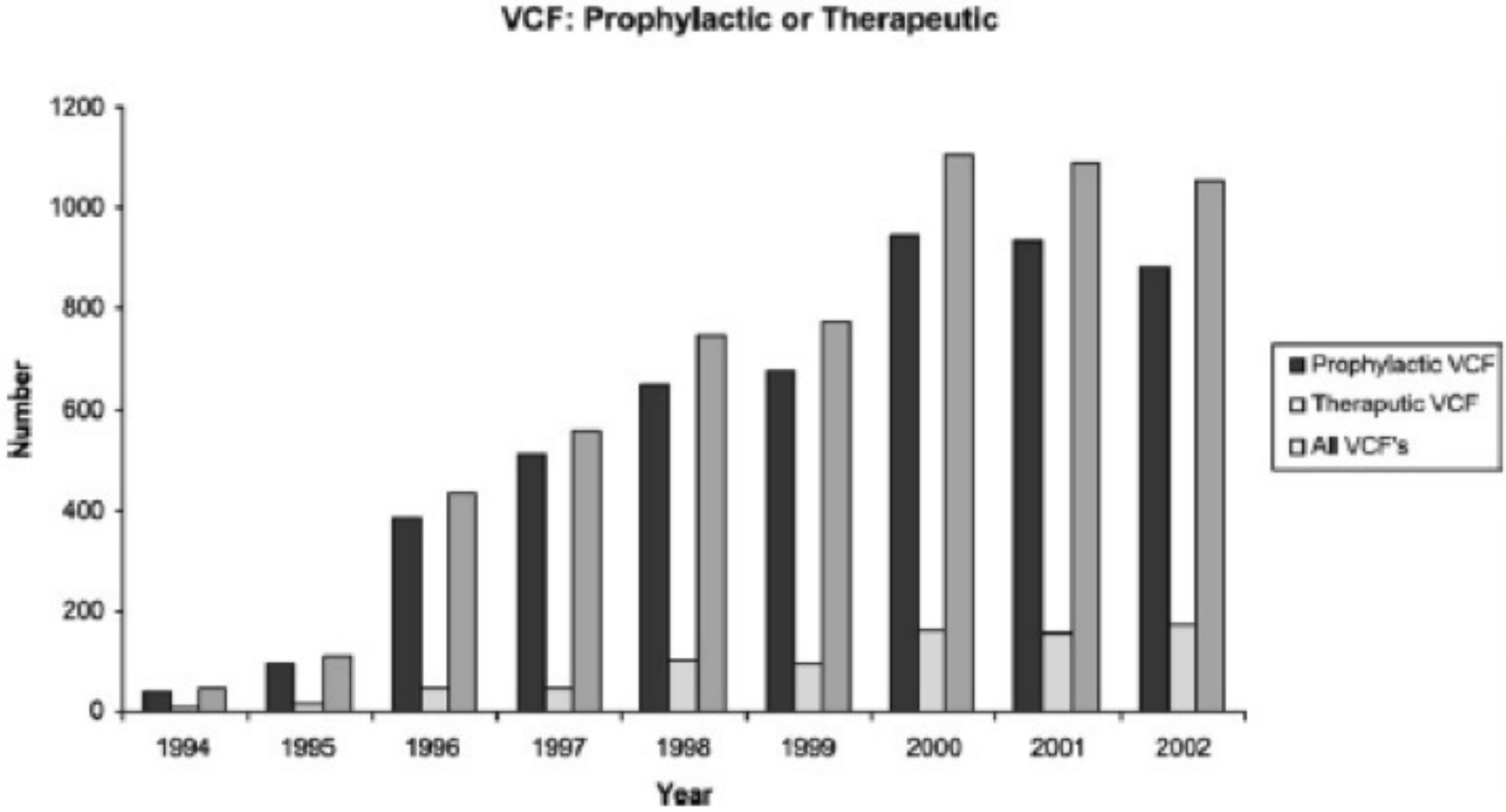


FIG 3. Bar graph demonstrating the total number of VCFs placed as reported to the NTDB during the interval 1994-2002. Also shown are the number placed in patients with a diagnosis or complication of either DVT or PE (considered a therapeutic filter) and the number placed in patients without DVT or PE as a complication or diagnosis (considered a prophylactic filter) (Shackford SR, Cook A, Rogers FB, et al. The increasing use of vena cava filters in adult trauma victims: data from the American College of Surgeons National Trauma Data Bank. J Trauma 2007;63:764-9. Reproduced with permission).

Societal guidelines

- EAST = consideration of very high risk patients who are immobilized and cannot receive anticoagulation.
- AC Chest physicians = recommend against primary prophylaxis in trauma patients.
- SAGES = consideration of VCF in morbid obesity undergoing laparoscopic surgery.

Where to stand?

- No RCT for prophylactic filters
- Great variation in societal guidelines
- Fundamentalists on both sides
- Rest of us in a very wide middle

High risk PE, standard prophylaxis ineffective or CI

- Permanent filters?
- Temporary filters?
- Retrievable filters?
- No filters?
- Which patient cohorts?

Who?

Alfred

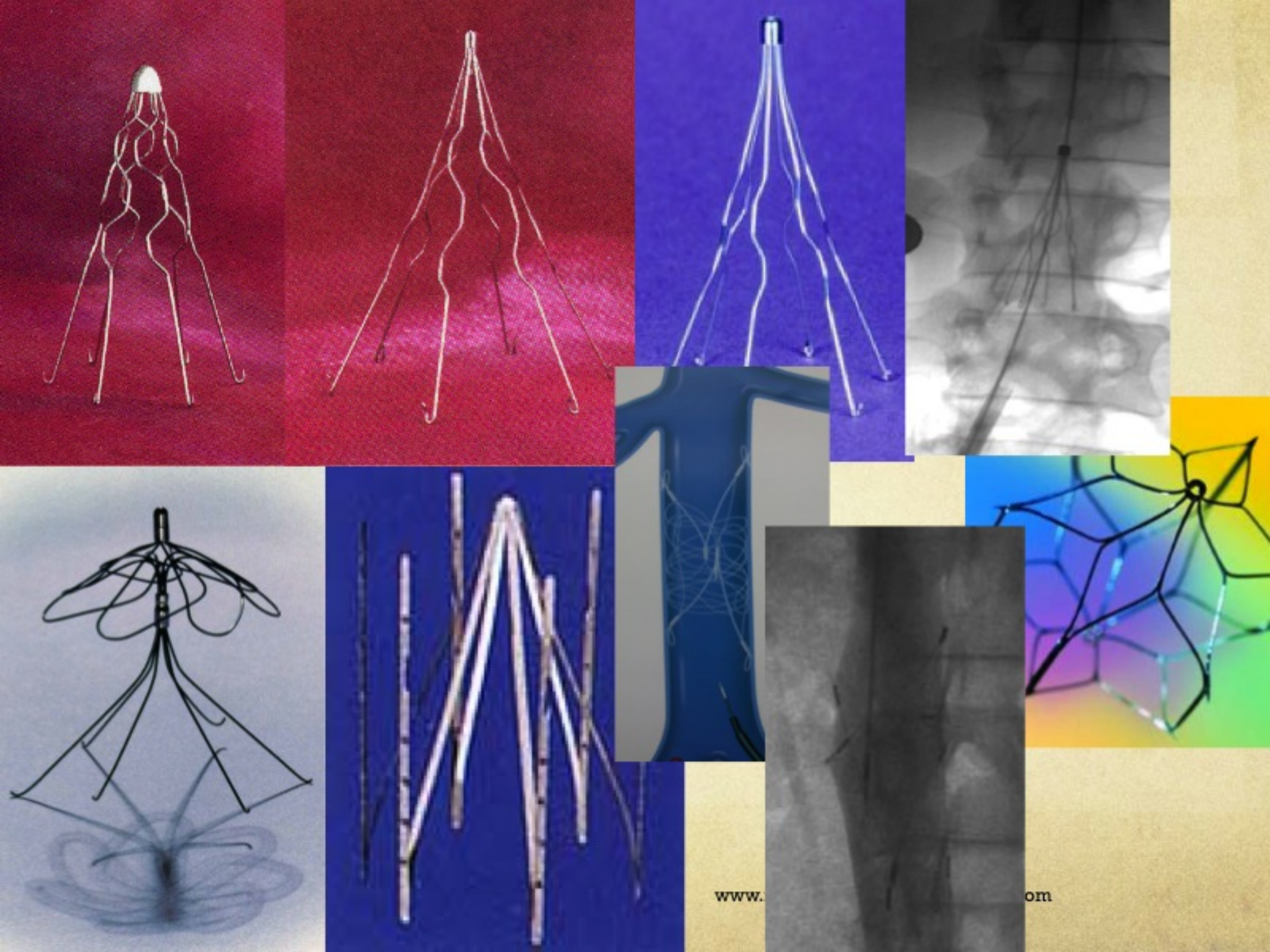
- CI to clexane > 72 hours and CI to IPC , with one of the following
  - Spinal injury
  - Multiple lower limb fractures
  - Pelvic fractures
- Duplex proven above knee DVT and CI to full anticoagulation

The Alfred hospital Trauma Service Unit Handbook, Feb 2011

History

Surgical

- Ligation
- Plication
- Clipping
- Stapling
- Filter 1967 –Mobin Udin



Current Filters

Filter	Sheath size	Max IVC diam	MRartifact
SS Gr	28Fr	28mm	+++
Tit Gr	15Fr	28mm	-
OTW-SSGr	15Fr	28mm	++
Bird's Nest	14Fr	40mm	+++
VenaTech LGM	13Fr	28mm	+
Vena Tech LP	9Fr	30mm	+
Simon Nitinol	9Fr	28mm	+
Gunther Tulip	8.5Fr	30mm	+
Trapease	8Fr	30mm	+

Temporary Filters

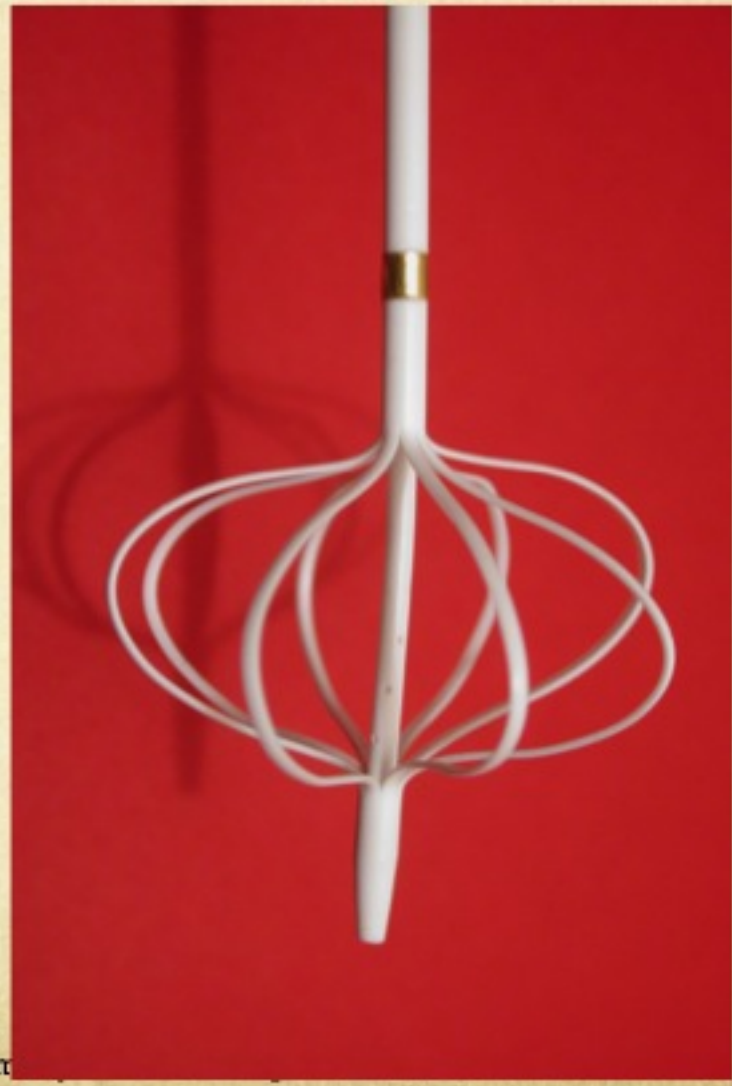
- Three types: recently five
  - **Tethered**: filter is attached to a catheter.
    - Günther Temporary filter (Cook)
    - Tempofilter® II (Braun)
  - **Retrievable/Permanent**: the filter is totally implanted.
    - Günther Tulip (Cook)
    - Recovery (Bard)
  - ***in-situ* Thrombolysis**: IVC clot lysis
    - ProLyser (Cordis)
    - Antheor (Medi.tech)
    - Protect (BARD)
    - Lysofilter (Braun)
  - **Convertible**
  - **Dissolvable**

Tempofilter II

- B. Braun
- 6 wks implantation
- Totally implanted
- Subcut anchoring device
- Migration to RA reported
  - 1 death

Cordis - ProLyser

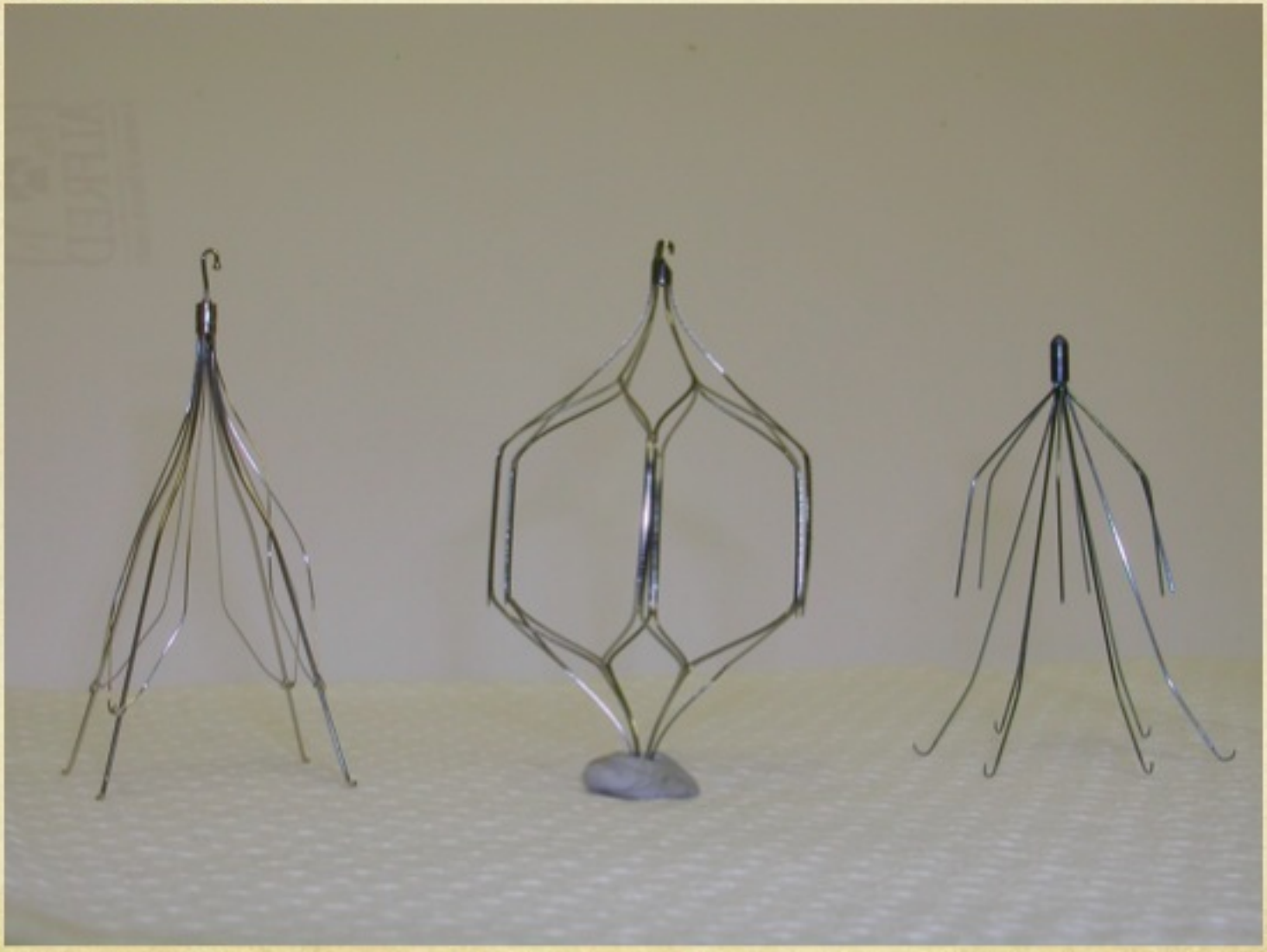
- Permits in-situ thrombolysis with 3F catheters
- Material: Fluoropolymer
- Dimensions:
  - Filter Diameter
    - Maximum Vena Cava = 35 mm
  - Introducer system
    - Diameter = 7 F / 8,5 F
    - Length = ?
- Access
  - Brachial / Jugular / Femoral



www.minim

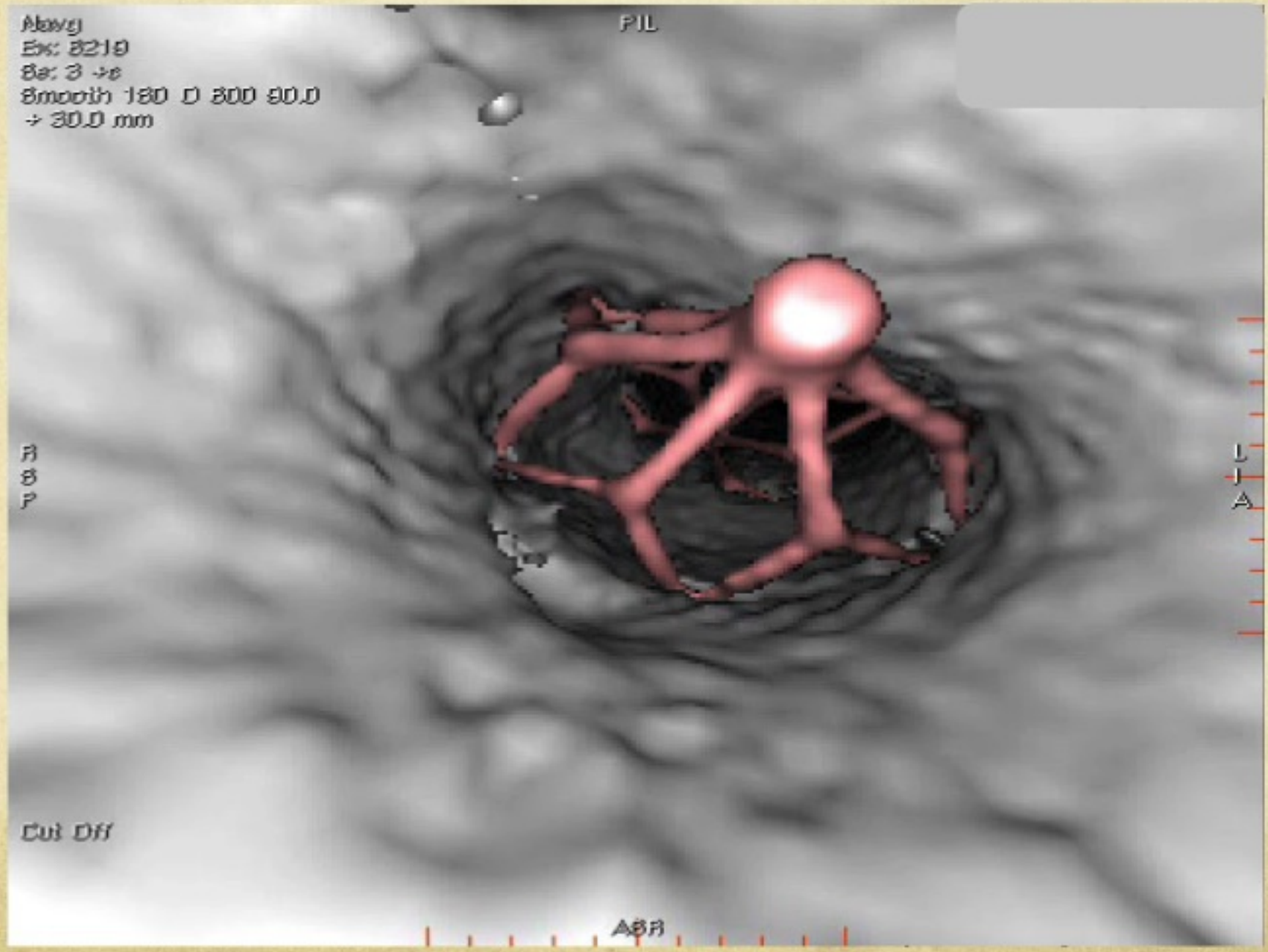
Courtesy Dr Ian Kelly
Wexford, IR

Temporary Vena Cava Filters



Retrievable/Permanent

Endothelialization



Short- and Long-term Retrievability of the Celect Vena Cava Filter: Results from a Multi-institutional Registry

Stuart M. Lyon, MD, Guillermo Elizondo Riojas, MD, Raman Uberoi, MRCP, FRCR, Jai Patel, MRCP, FRCR, Mario Enrique Baltazares Lipp, MD, Graham R. Plant, MBBS, FRCR, Miguel A. De Gregorio, MD, Rolf W. Günther, MD, William D. Voorhees, PhD, and Jennifer A. McCann-Brown, PhD

J Vasc Interv Radiol 2009; 20:1441–1448

Abbreviations: CEC = clinical events committee, IVC = inferior vena cava, PE = pulmonary embolism

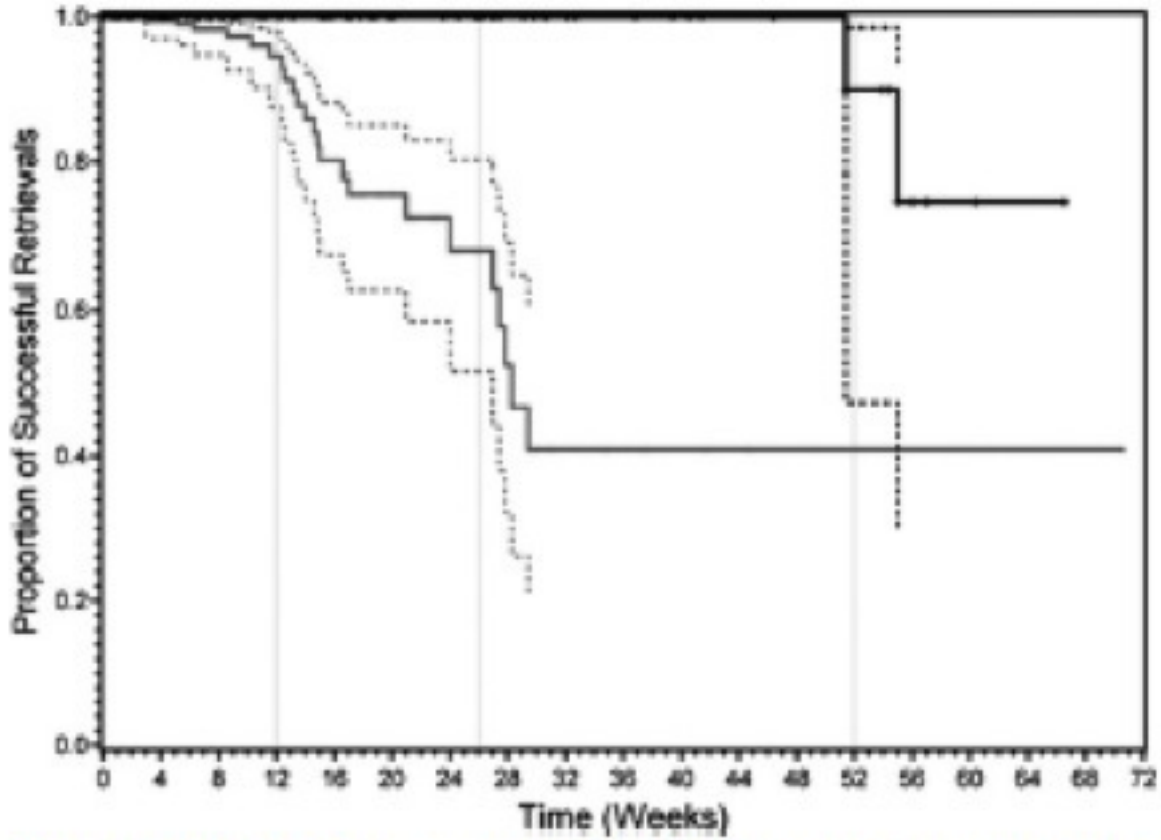


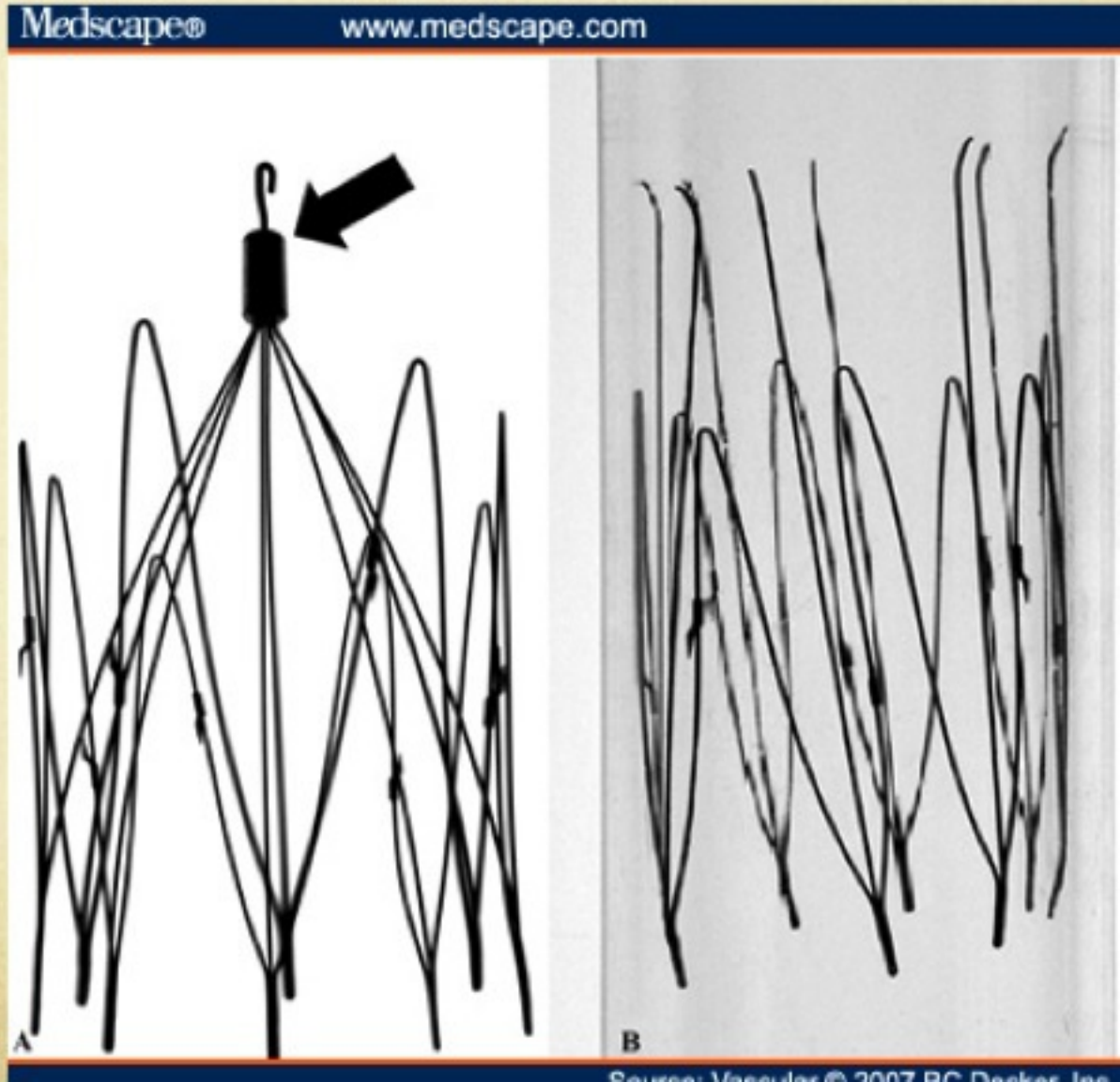
Figure 4. Kaplan-Meier analysis comparing the successful retrieval rate profile of the Celect filter to that of the Günther Tulip filter. The probability of successful filter retrievals at time points beyond 12 weeks is greater when the Celect filter is placed (black) versus when the Günther Tulip filter is placed (gray).

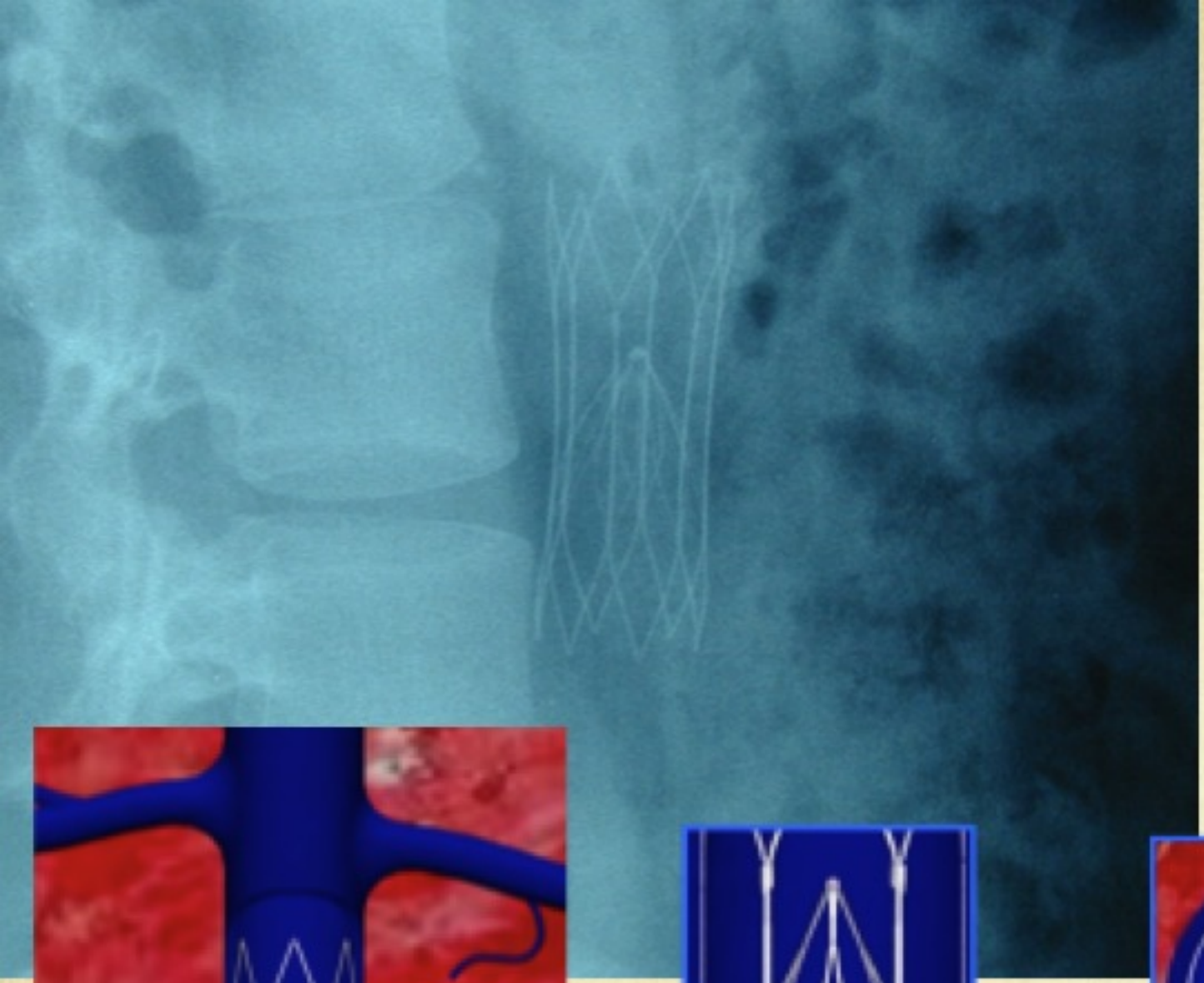
Retrieval window

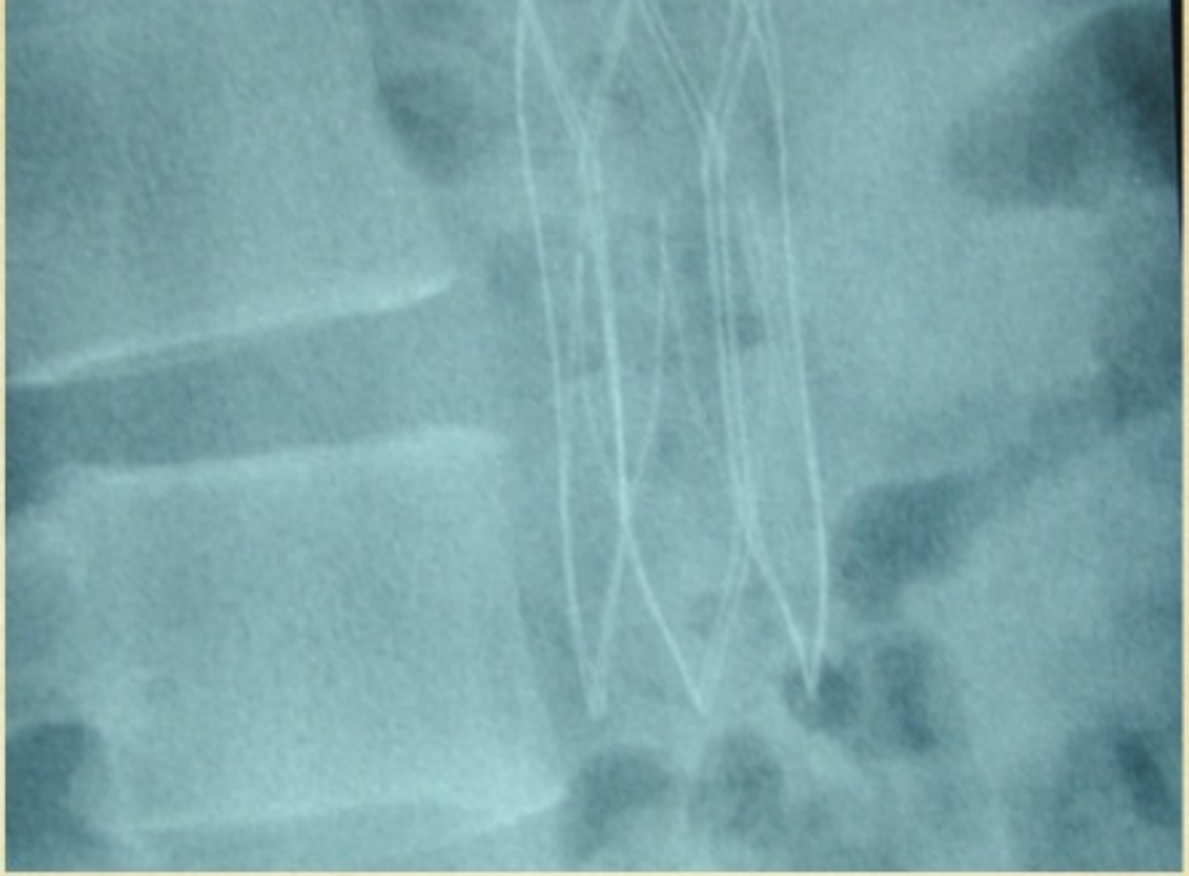
Early GT clinical and experimental published studys 14 day max recommendation. 1997-2001	14 days max.
Extended interval for retrieval of Gunther-Tulip filters.. JVIR 2004	Mean 43.6 days (1-126) Success 84%
Retrievable Gunther Tulip inferior vena cava filter: experience in 317 patients. JMIRO 2008	Mean 77 days Success 92%
Initial experience in 115 patients with the retrivable Cook Celect vena cava filter. JMIRO 2009	128 days (14-267) Successful 93.4%
Short and Long term retrievability of the Celect Vena Cava Filter: Results from a multi-institutional Registry. JVIR 2009	Mean 179 days (5-466) Success 96.6%

In situ temporary interruption devices

- Convertible
  - Braun
  - Mednova
- Dissolvable

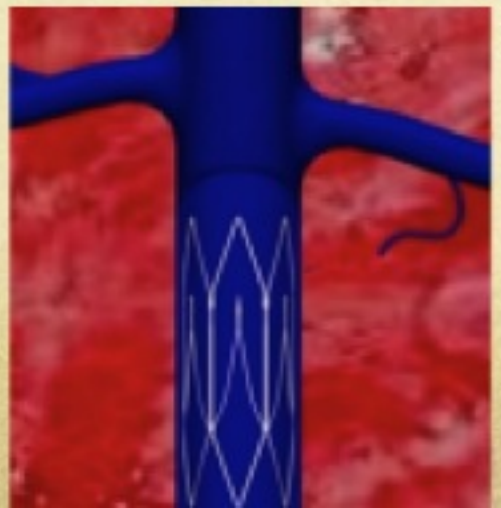


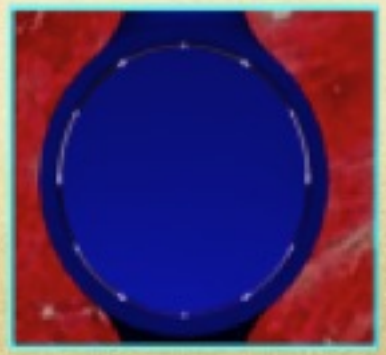




90 days in situ

The Novate IVC filter is not approved for commercial distribution and is currently under clinical investigation in Australia





Efficacy of VCFs in trauma

Data supporting prophylactic VCFs after trauma is limited to historical and/or non-randomised controls

Decrease In number and severity of PE

Khansarina, J Vasc Surg. 1995;22:231-236
Greenfield, J Vasc Surg. 2000;32:490-5
Velhamos, J Trauma. 2000;49:140-144
Sekhran, J. trauma. 2001; 51:1087-1090

" Most studies demonstrate successful efficacy of IVC filetrs to reduce the incidence of all PE and fatal PE but lack rigorous control groups for comparison."
Martin, Current Problems in Surgery 2010; 47(7):524-618

Efficacy of prophylactic VCFs

Data supporting prophylactic VCFs after trauma is limited to historical and/or non-randomised controls

Increase in PE with increasing prophylactic VCF use

» McMurty, J Am Coll Surg. 1999 Sep;189(3):314-20

No change in PE rate with increasing use of prophylactic VCFs

» Antevil, J Trauma. 2006 Jan;60(1):35-40
» Cherry, J Trauma. 2008 Sep;65(3):544-8

Study aim

To investigate the effect of prophylactic VCFs on the incidence of PE after major trauma

Methods

- Prospectively collected data
  - The Alfred Hospital Trauma Registry
  - Dept. Radiology VCF Database

- Inclusion criteria:
  - Major trauma patients
    - Injury Severity Score (ISS) > 15
    - Death following injury
    - ICU admission >24hrs requiring mechanical ventilation
    - Injury requiring urgent surgery on admission
  - July 2001- July 2008

- Multivariate logistic regression
  - Covariates derived from a literature review

Results - demographics

- 6,344 patients met inclusion criteria

Patient Characteristics	
	Mean (SD)
Age (years)	44.2 (21.0)
Injury Severity Score (ISS)	24.3 (12.0)
	n (%)
Male	4645 (73.2)
Blunt injury	5724 (90.2)

- 511 VCFs (8.1% of total major trauma population)
  - Prophylactic -
  - With DVT -

Results - incidence of PE

- 45 PE (0.71%)
  - 2 fatal PE (0.03%)
- 42 (94%) symptomatic, 3 (6%) incidental findings
- Median time to PE: 9 days (range 0 - 48)

Results - univariate analysis, PE vs no-PE, significant results

Covariate	*Odds ratio*	*95% CI*	*p-value*
Age > 40 years	2.28	1.21 – 4.28	p=0.010
Injury severity score (ISS) > 20	2.37	1.23 – 4.59	p=0.010
Number of injuries to lower extremity	1.25	1.13 – 1.38	p<0.001
Injury severity to lower extremity	1.31	1.08 – 1.59	p=0.005
Number of pelvic fractures	1.73	1.05 – 2.86	p=0.031
Number of lower limb fractures	1.42	1.16 – 1.73	p<0.001
Number of major operations (>2 hrs)	1.11	1.04 – 1.19	p=0.003
Central venous catheterisation	3.30	1.84 – 5.93	p<0.001
Blood transfusion	2.79	1.54 – 5.05	p<0.001
Hospital length of stay hours	1.00	1.00 – 1.01	p<0.001
Mechanical ventilation hours	1.00	1.00 – 1.002	p=0.012
Intensive care unit hours	1.00	1.00 – 1.01	p<0.001

Results - multivariate analysis, PE vs. no-PE

Covariate	*Odds ratio*	*95% CI*	*p-value*
Prophylactic vena cava filter	0.28	0.088 – 0.890	p=0.031
Number of injuries to lower extremity (AIS)	1.31	1.174 – 1.469	p<0.001
Central venous catheterisation	3.41	1.879 – 6.172	p<0.001

AIS: Abbreviated Injury Scale

“Breakthrough” PE?

- 4 patients with a VCF subsequently developed PE

	Fatal PE	***Chemoprophylaxis***	***Likely source of PE***	***Tilt***
Patient 1	No	LMWH	Thrombosed right subclavian vein	0
Patient 2	No	LMWH	Thrombosed left internal jugular vein	0
Patient 3	No	LMWH	Unknown	8
Patient 4	No	Nil	Thrombus trapped in filter - dislodged by retrieval catheter	0

LMWH: Low Molecular Weight Heparin

VCF complications

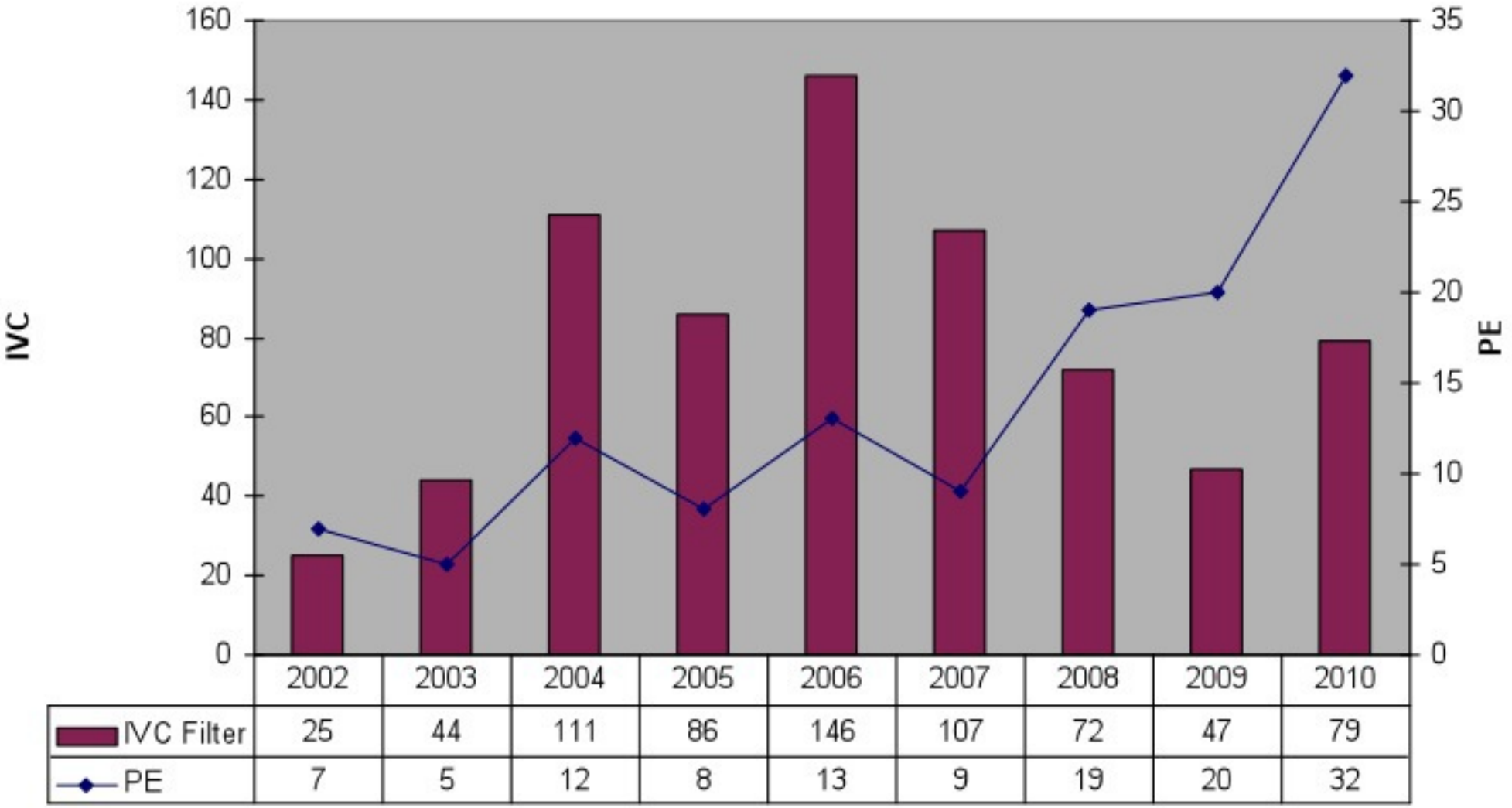
- Data available for 429 of 511 VCFs (84%)
- Major complications - 2.6% (n=11)
  - Non fatal PE (n=4)
  - Contrast reaction (n=1)
  - Filter damaged during deployment (n=1)
  - Deployment above renal veins (n=2)
  - Deployment in lumbar plexus (n=1)
  - Symptomatic vena cava thrombosis (n=1)
  - Post retrieval vena cava narrowing requiring balloon dilation (n=1)
- Minor complications - 21.2% (n=91)
  - Non-major complications
  - VCF tilt / mild vena cava narrowing post retrieval

VCF retrieval rates

- Technical success rate for retrieval - 92%
  - (279 retrievals from 302 attempts)

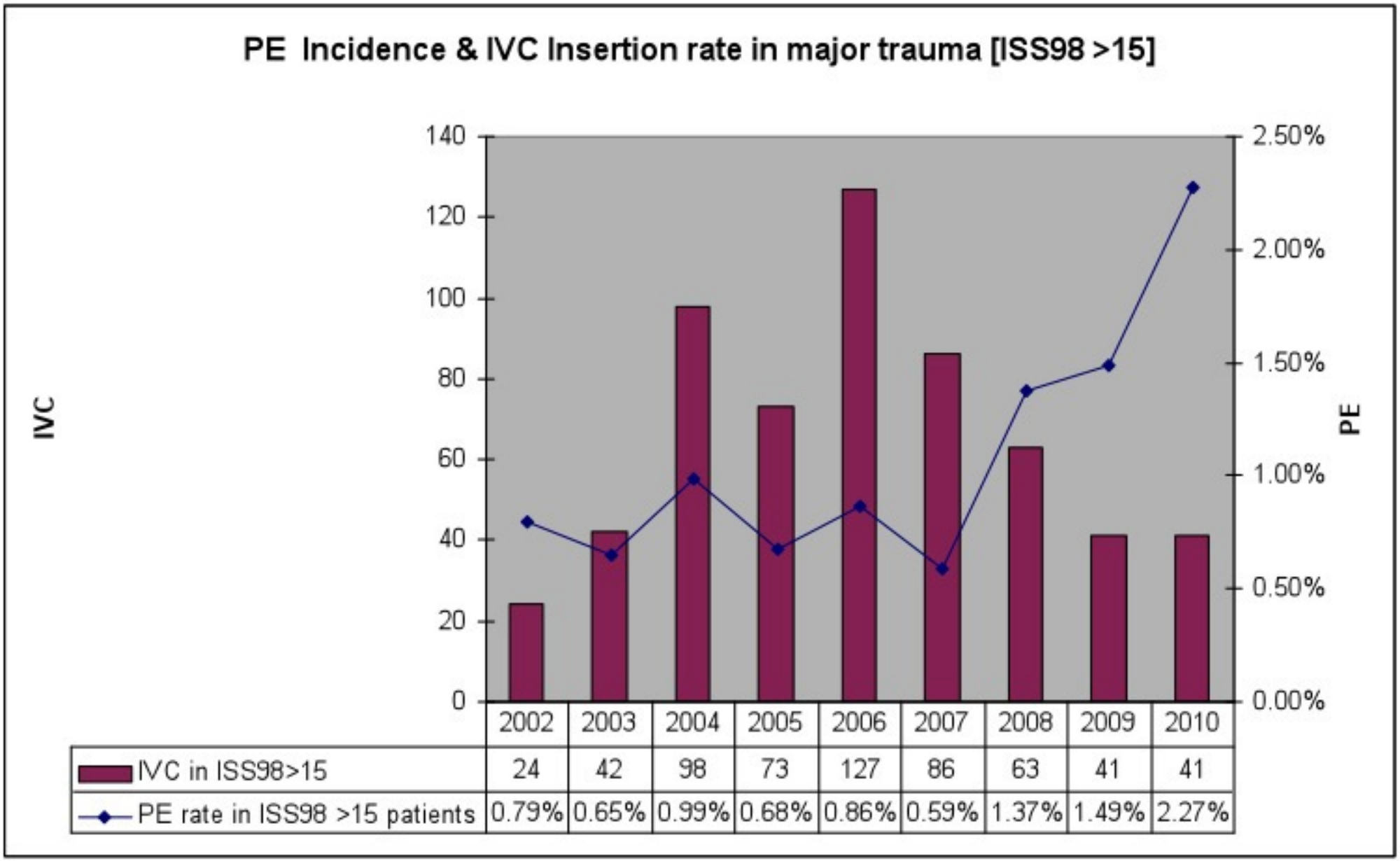
- Overall retrieval rate - 63% (to date)
  - (279 retrievals from 429 placements)

PE & IVC filter insertion rates in Trauma Patients
Trauma Database



	2002	2003	2004	2005	2006	2007	2008	2009	2010
IVC Filter	25	44	111	86	146	107	72	47	79
PE	7	5	12	8	13	9	19	20	32

Major Trauma ONLY



	2002	2003	2004	2005	2006	2007	2008	2009	2010
IVC in ISS98>15	24	42	98	73	127	86	63	41	41
PE rate in ISS98 >15 patients	0.79%	0.65%	0.99%	0.68%	0.86%	0.59%	1.37%	1.49%	2.27%

Safety of IVC filters

- Caval thrombus

  Smoot et al, J Trauma April 2010

  Retrospective review 226 trauma patients with IVC filters

  27(12%) had documented thrombus within or below filter

  15(7%) clinically significant thrombus

- Access site thrombosis

  Molgaard et al, Radiology 1992 – femoral thrombosis 35%

  Rosenthal et al, J Vasc Surg 2004 – femoral thrombosis 1%

Long-Term Consequences of Pelvic Trauma Patients With Thromboembolic Disease Treated With Inferior Vena Caval Filters

Jose B. Toro, MD, Michael J. Gardeer, MD, Christian Hierholzer, MD, Domenico Sama, MD, Cagri Kosi, MD, William Ertl, MD, and David L. Helfet, MD

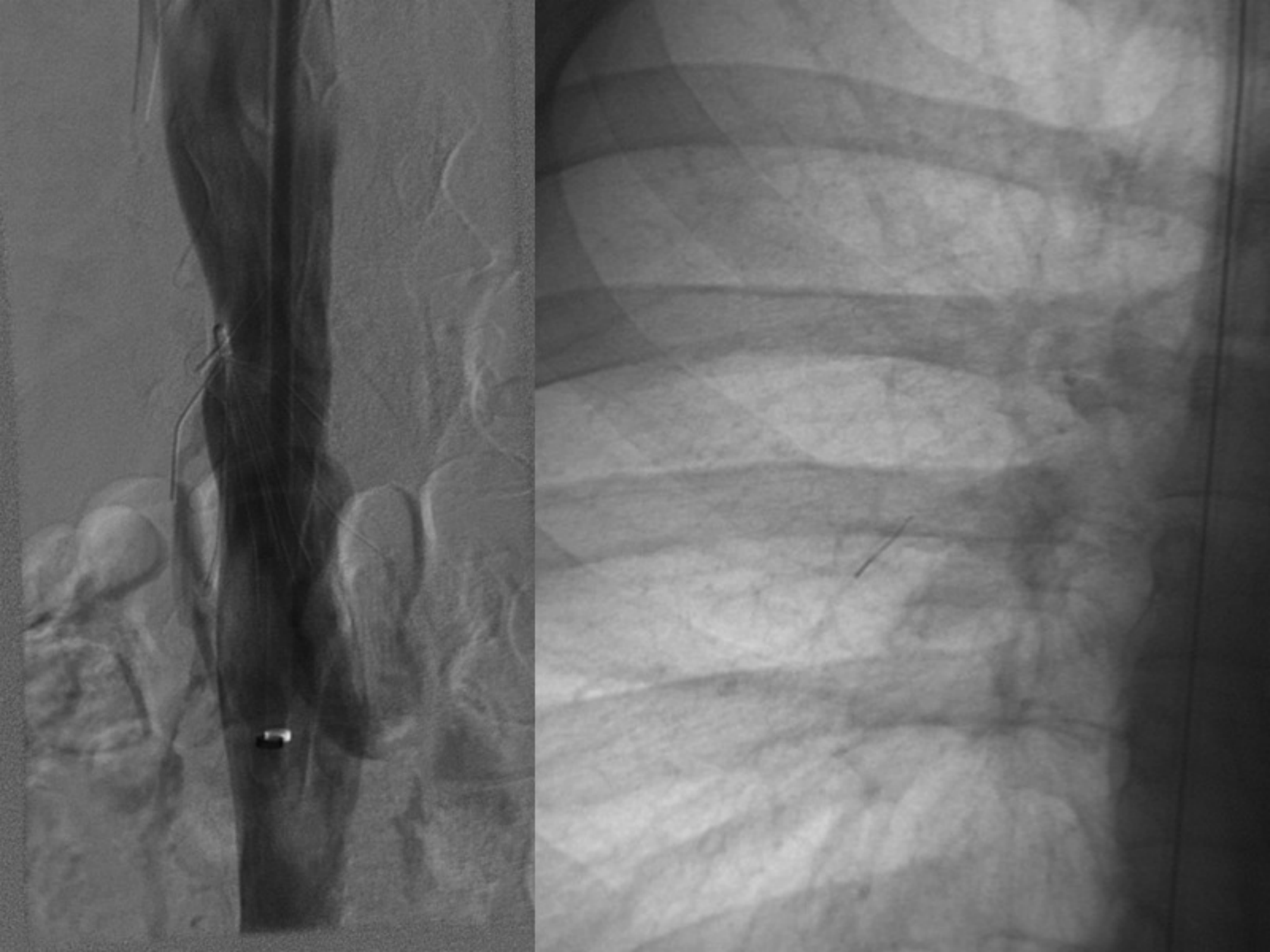
J Trauma [illegible]

- 88 / 102 consecutive patients followed up with average of 4 years
- Pelvic or acetabular fractures + preoperative DVT had IVC filters inserted.
- No patients readmitted with DVT or PE
- 7% lower extremity swelling, 1 patient PTS

" filter placement use is not associated with the same long term complications as in patients with thrombosis because of chronic medical comorbidities."

Filters have changed

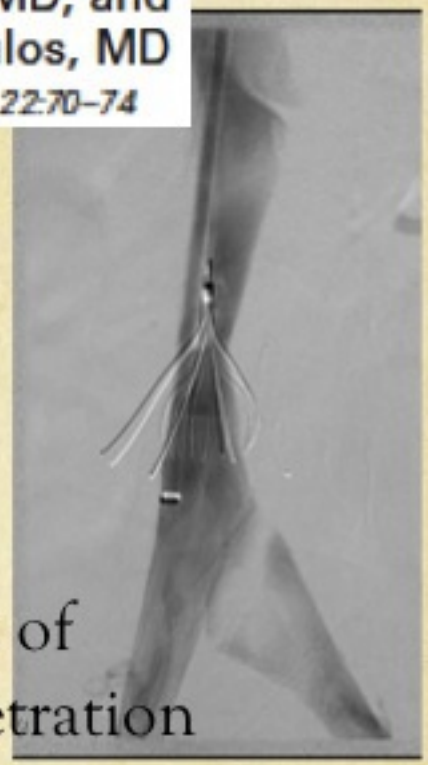
- Do we need to retrieve as aggressively as was the original intention?
  - PREPIC VCF's plagued by high DVT rates
  - But we do not seem to see the same complications
  - Recurrent DVT/ filter thrombosis/ access thrombosis uncommon
  - However, new problems
    - Filter penetration?
    - Filter fractures?
    - Filter migration?



Removal of Retrievable Inferior Vena Cava Filters with Computed Tomography Findings Indicating Tenting or Penetration of the Inferior Vena Cava Wall

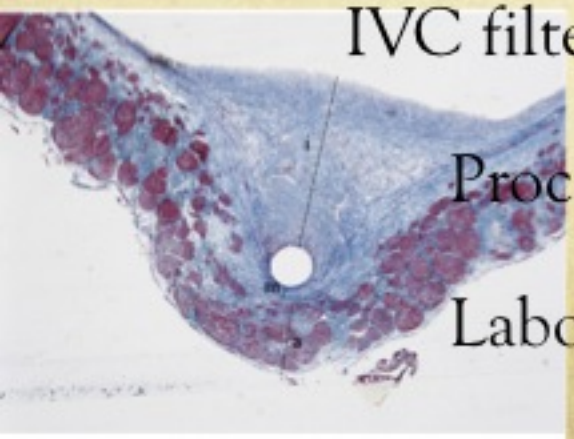
John C. Oh, MD, Scott O. Trerotola, MD, Mandeep Dagli, MD, Richard D. Shlansky-Goldberg, MD, Michael C. Soulen, MD, Maxim Itkin, MD, Jeffrey Mondschein, MD, Jeffrey Solomon, MD, and S. William Stavropoulos, MD

J Vasc Interv Radiol 2011; 22:70–74



- Filter struts outside the IVC wall on CT 85.9%
- 89.1% removed successfully
- No major complications

Animal models suggesting that CT caval penetration of IVC filter reflects a much lower rate of true penetration



Proctor et al, 1993 –all on CT: 0 at laparoscopy

Laborda et al, 2011 - 59.3% CT: 44% laparoscopy

IVC retrieval controversies

Retrievability and follow up

- Large variance (11% to 65%)
- Higher rates of retrieval in ANZ

FDA August 2010; " The FDA is concerned that these retrievable IVC filters, ..., are not always removed once patients risk for PE subsides."

The Deductive Argument for Retrievable IVC Filters

Deductive Reasoning #1

VTE* causes high mortality → YES

VTE* requires prophylaxis → YES

High-risk trauma patients are at high risk for VTE*→ YES

↓

Therefore: High-risk trauma patients require VTE prophylaxis

Deductive Reasoning #2

High-risk trauma patients require VTE prophylaxis → YES

Some high-risk trauma patients cannot have anticoagulation → YES

IVC filters are affective in prevention of PE^ → YES

↓

Therefore: Some high-risk trauma patients will require an IVC filter

Deductive Reasoning #3

Some high-risk trauma patients will require an IVC filter → YES

Permanent IVC filters cause long-term complications → YES

Retrieved IVC filters avoid long-term filter complications → YES

↓

Therefore: Retrievable IVC filters are indicated in high-risk

McLafferty; Disease a Month 2010; 56 (1): 619-627

- Which ones?
- Data?

IVC filters
what do we know?

- Safe
- Efficacy established in proximal DVT were anticoagulation is problematic.
- Probable efficacy in trauma for select groups

What do we not know?

- DVT/ PE
  - Increasing incidence?
  - Do PE's all come from our lower limb DVT?
  - Does ultrasound surveillance work in this cohort?
- Filters
  - Which trauma patients to put these in?
- Retrieval
  - What are the right retrieval rates and indications?
  - Dissolving filters?

Where to?

- Desperately need better data
  - RCT
  - Large registries
  - Other

- Dissolvable filters/ Convertible