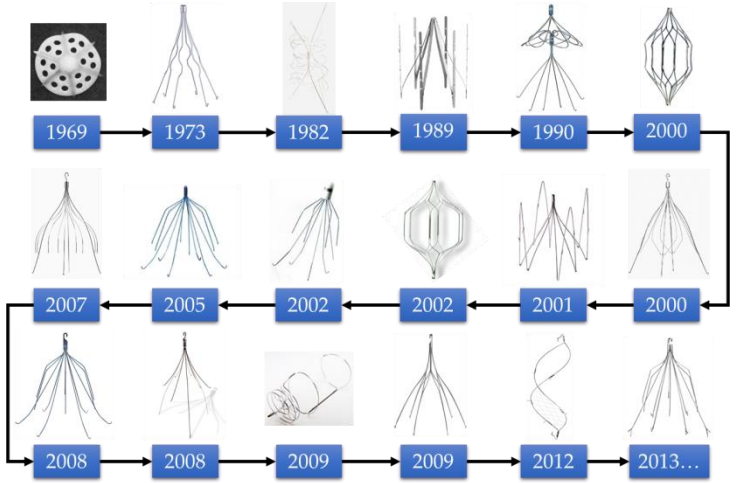
FDA Critical Path Project

"Generation and Review of Regulatory-Grade Computational Evidence Using a Generic Inferior Vena Cava Filter"

Summary of Preliminary FEA

The objectives of this project are to…

- **Develop** a **generic** IVC filter



- **Predict** & **demonstrate**:
  - **fatigue** resistance
  - embolus-trapping efficiency
- Ideally,
  - single strut shape (simplify fatigue simulation/testing)
  - resist tilt, migration, and vein wall perforation

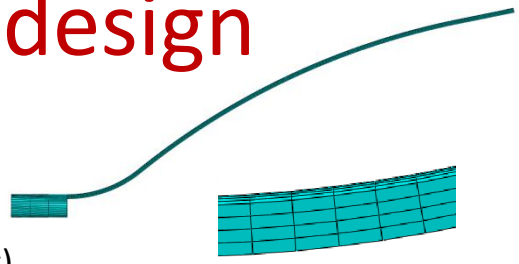
???

*designs investigated in previous FEA simulations

FEA performed to evaluate filter design

Setup:

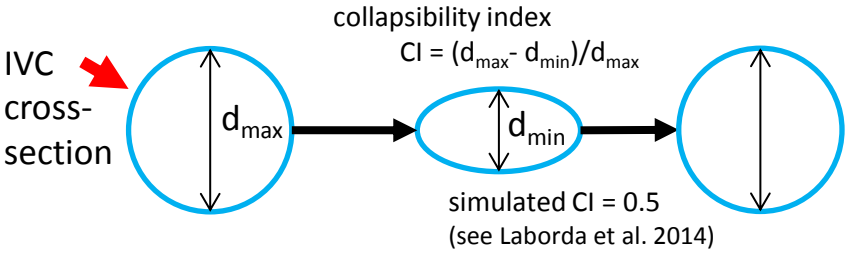
- ABAQUS Dynamic/Implicit (quasi-static); 10x mass scaling
- C3D8I elements (4 per strut thickness & width; ~3,000 to 6,000 per strut)
- SE508 nitinol (material properties from Craig Bonsignore's example on GitHub)

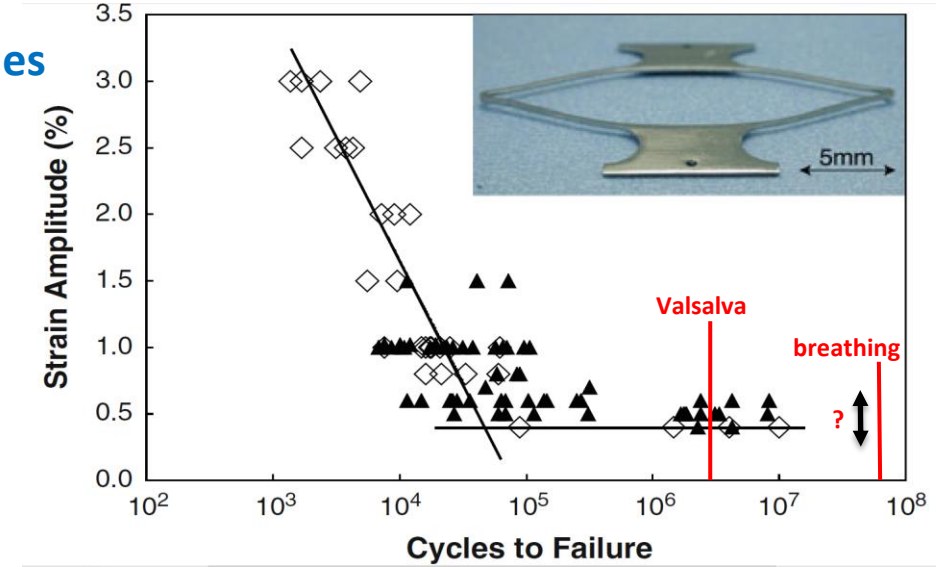


4 elements through strut

Simulated conditions → extracted quantities

1. Sheathing → prestrain
2. Filter placement → contact force/area
3. Valsalva → mean/amplitude strain





Pelton, A. R. (2011). *J. Mater. Eng. Perform.*, 20(4-5), 613–617

Two IVC diameters considered (human variability):

1. 14mm (3.5mm wall displacement during Valsalva)
2. 28mm (7.0mm wall displacement during Valsalva)

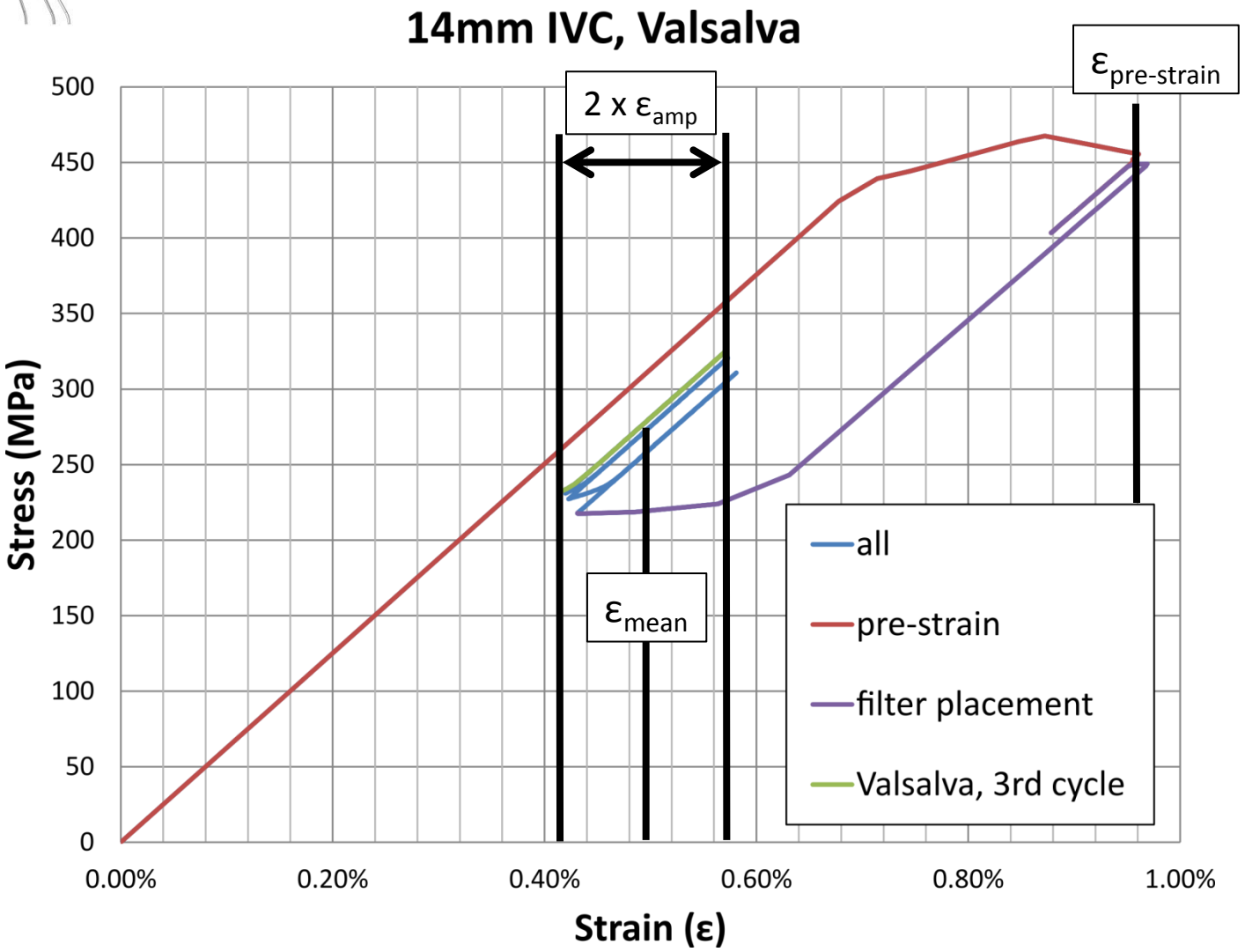
We assume Valsalva is the limiting loading scenario for fatigue life

Performance goals are set for quantities extracted from FEA simulations

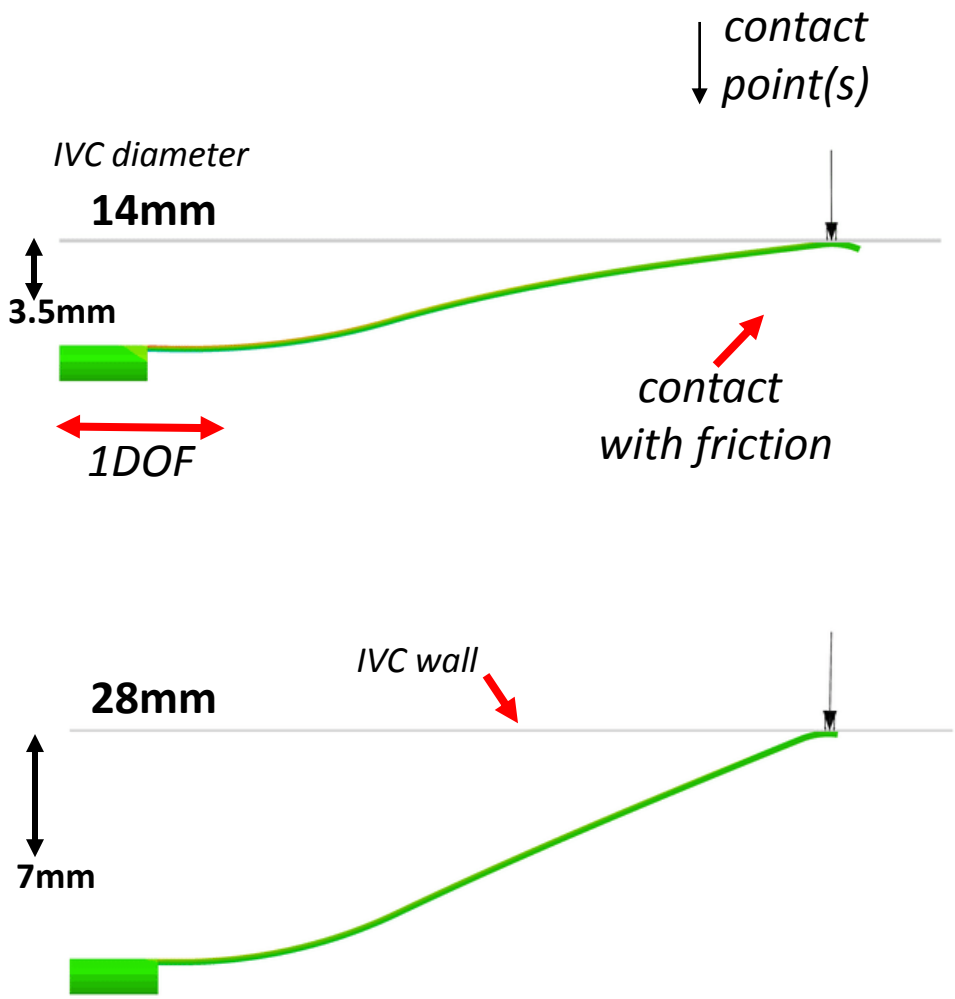
	distal end contacts wall?	prestrain (max/min prin. LE)	contact force (N) (per strut)	contact area (mm^2) (per strut)	ε amplitude, Valsalva (CI=0.5)	mean ε, Valsalva (CI=0.5)
target	***yes***	***<6%***	***0.010 to 0.100***	***>0.05?***	***<0.4%***	***<6%***

**to avoid plastic deformation during sheathing*

Stress-strain history diagram (Rev1)



Valsalva (fatigue loading) (Rev1)

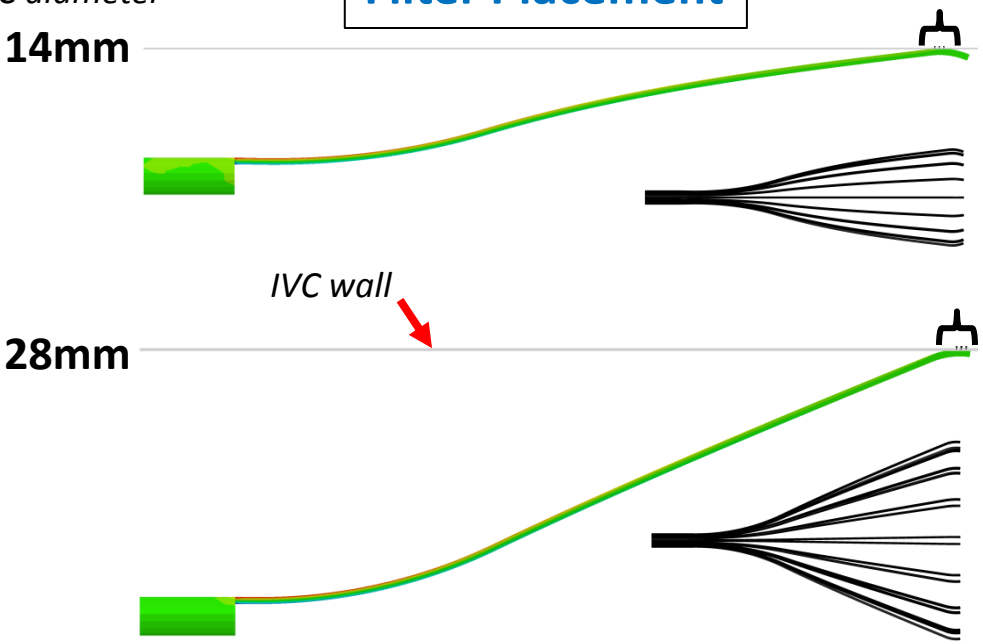


**FEA simulations of Valsalva shown for reference; note that the contact point between the IVC wall and the filter strut changes as the strut deforms*

Results summary (Rev1)

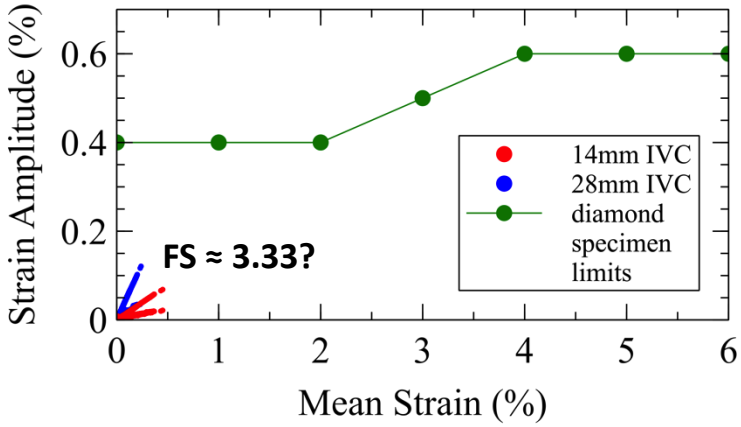
IVC diameter

Filter Placement



Valsalva

Strain Limit Diagram (SLD)



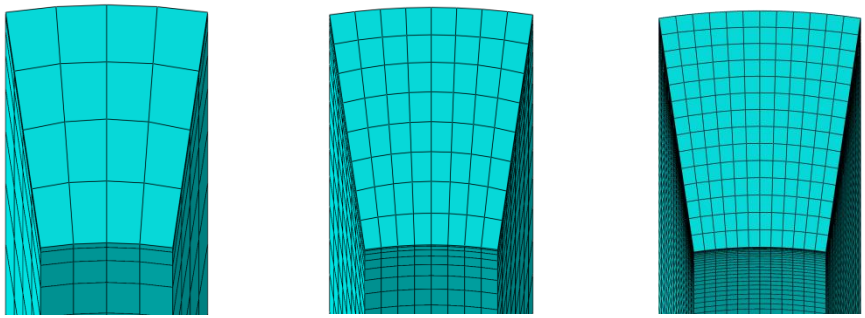
*results from third Valsalva cycle

IVC diamter	distal end contacts wall?	prestrain (max/min prin. LE)	contact force (N) (per strut)	contact area (mm^2) (per strut)	ε amplitude, Valsalva (CI=0.5)	mean ε, Valsalva (CI=0.5)
14mm	*yes*	*0.80%*	*0.028*	*0.018*	**0.07%**	*0.45%*
28mm	*yes*	*0.80%*	*0.010*	*0.018*	**0.12%**	*0.24%*

Mesh refinement (Rev1)

IVC diamter	distal end contacts wall?	prestrain (max/min prin. LE)	contact force (N) (per strut)	contact area (mm^2) (per strut)	ε amplitude, Valsalva (CI=0.5)	mean ε, Valsalva (CI=0.5)
coarse (4x4)	*yes*	*0.80%*	*0.0096*	*0.018*	**0.121%**	*0.24%*
medium (8x8)	*yes*	*0.92%*	*0.0096*	*0.0048*	**0.134%**	*0.26%*
fine (12x12)	*yes*	*1.04%*	*0.0102*	*0.0050*	**0.139%**	*0.27%*

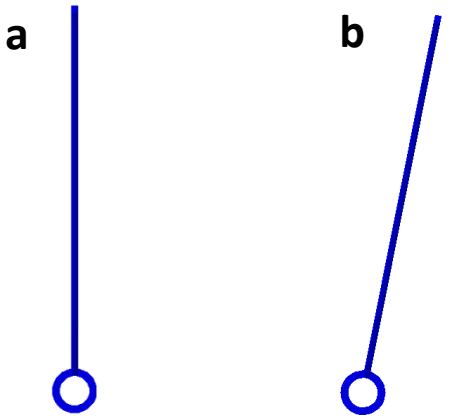
GCI: -2.81%



coarse **medium** **fine**

Eccentric loading of filter strut (Rev1)

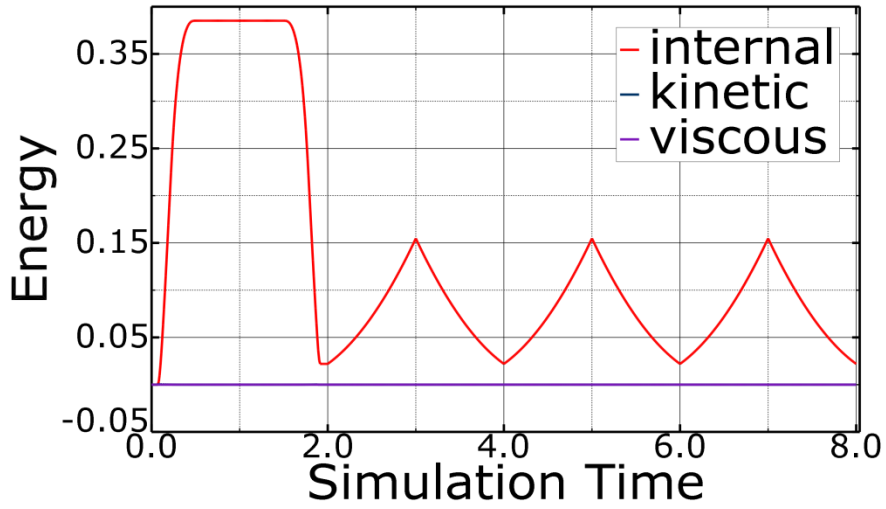
	IVC diamter	distal end contacts wall?	prestrain (max/min prin. LE)	contact force (N) (per strut)	contact area (mm^2) (per strut)	ε amplitude, Valsalva (CI=0.5)	mean ε, Valsalva (CI=0.5)
a	*28mm*	*yes*	*0.80%*	*0.010*	*0.018*	**0.12%**	*0.24%*
b	*28mm*	*yes*	*0.80%*	*0.0086*	*0.0091*	**0.14%**	*0.26%*



Static/Implicit vs. Dynamic/Implicit (Rev1)

	IVC diamter	distal end contacts wall?	prestrain (max/min prin. LE)	contact force (N) (per strut)	contact area (mm^2) (per strut)	ε amplitude, Valsalva (CI=0.5)	mean ε, Valsalva (CI=0.5)
Static/Imp	*28mm*	*yes*	*0.798%*	*0.00884*	*0.0182*	**0.122%**	*0.239%*
Dynamic/Imp	*28mm*	*yes*	*0.797%*	*0.00959*	*0.0182*	**0.121%**	*0.238%*

Dynamic/Imp



**Simulations were performed using Abaqus Standard, Dynamic/Implicit to increase stability of contact interactions. Simulations performed using Static/Implicit yield similar results, but do not converge in some cases.*