

**Frequency, Accurate  
Diagnosis, and  
Treatment Strategies  
for Carotid Stent  
Restenosis**

**Mark H. Wholey, MD  
TCT 2009**

# Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

## Consultant, Investor Cofounder

- Abbott Inc., Courdis, Boston Scientific, MedRad, Setagon, Covidien, Square One, Access Closure, Therawire Inc., Neuro Interventional Technology

# Predictive Factor for ISR

- Post CEA Restenosis 7%
- Post Operative Infection
- Prior Radiation
- Pre-dilation
- Vessel size 4mm or <

# Carotid Stent Restenosis

**PRECISE/SAPPHIRE**

**2.4%**

**3 YEAR F/U**

**WALLSTENT/BEACH**

**6.0%**

**3 YEAR F/U**

**NEVTSTENT/CAREDNET**

**4.0%**

**3 YEAR F/U**

**ACCULINK/ARCHER**

**3.0%**

**3 YEAR F/U**

# ISR – 5 Year F/U

> 40%	Diameter Reduction	<b>42%</b>
> 60%	Diameter Reduction	<b>16%</b>
> 80%	Diameter Reduction	<b>6.4%</b>

**418 Patients**

**21 mo.**

# ISR - Incidence

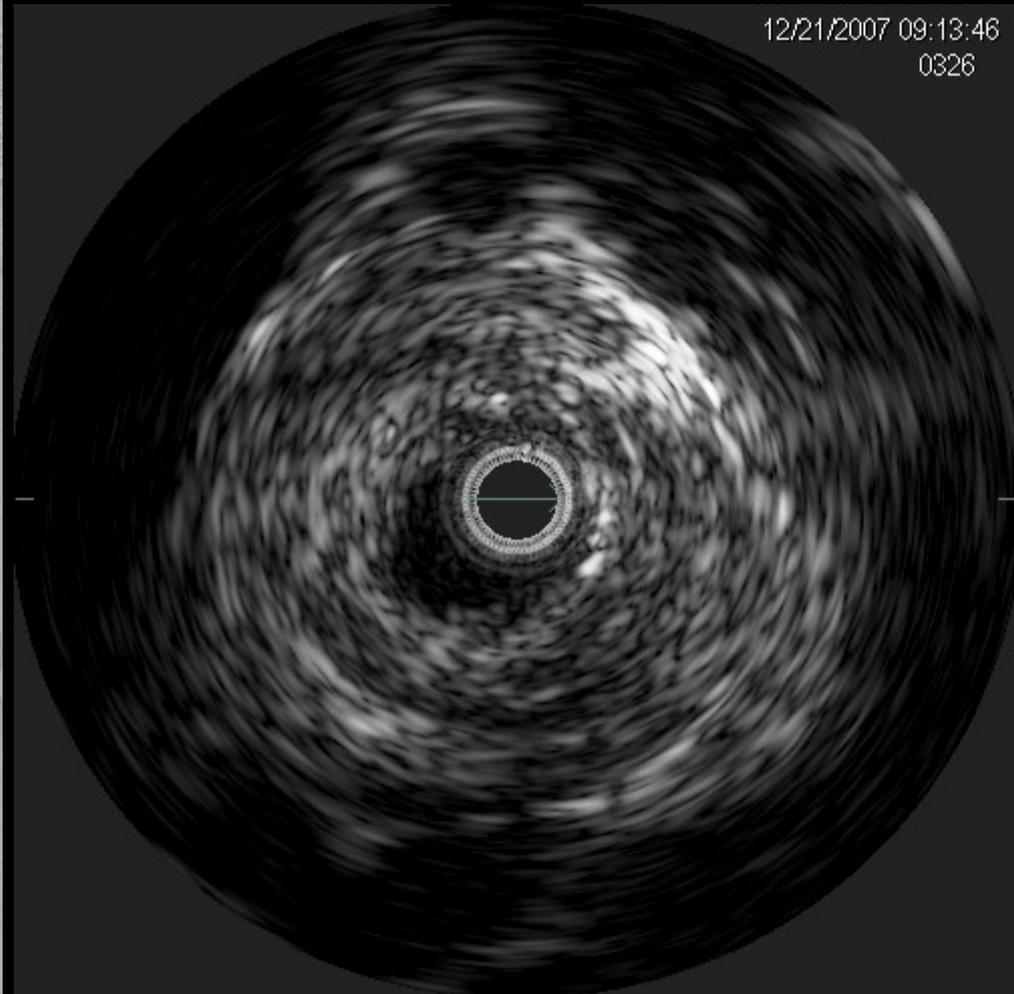
Type of cell – Open vs Closed

**ISR: Did not vary**

Wallstent vs Acculink

**ISR: Tapered Stent > Non-Tapered**

# Pre-Stenting Assessment



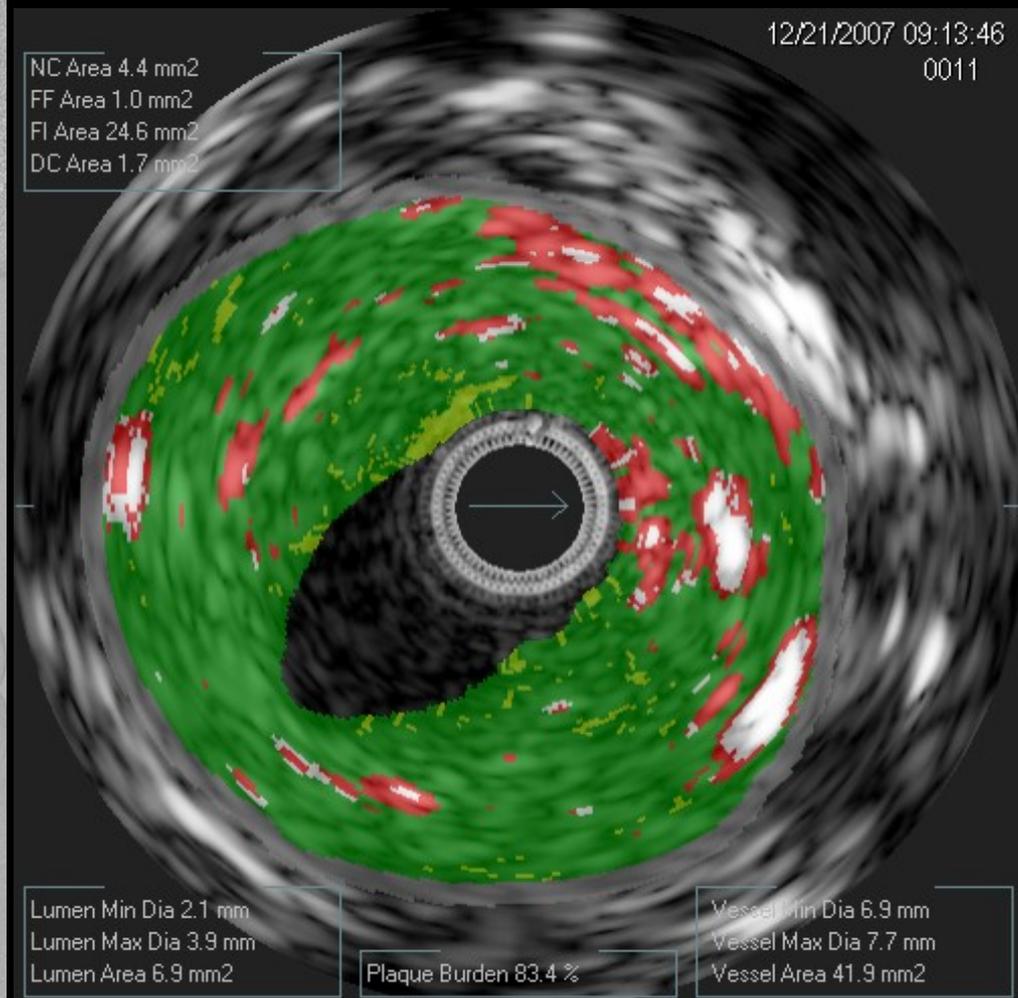
# ISR – Onset Characteristics

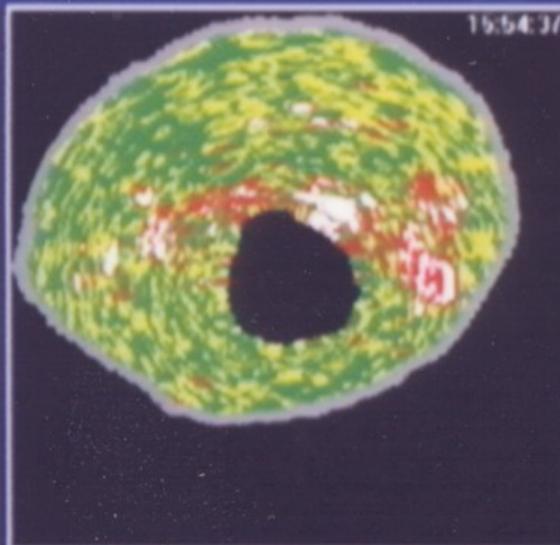
- Early < 2 yrs – fibro intimal hyperplasia
- Later > 2yrs – recurrent atherosclerosis
  - Distal Embolization more likely

# Complication Despite VH IVUS

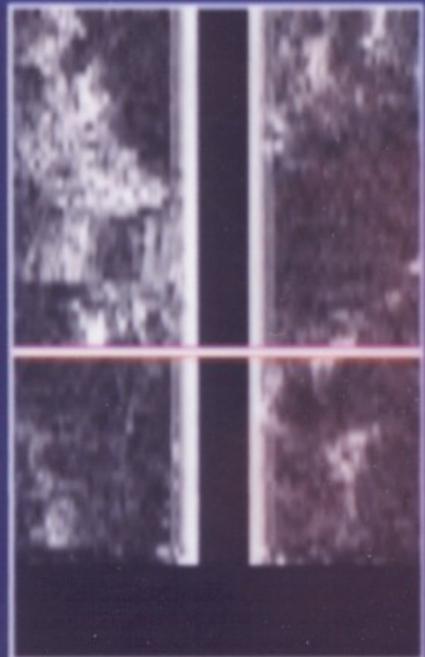
- 77 year old female with a preocclusive stenosis distal to a site of prior endarterectomy 3 years prior in the L ICA.
- Uneventful CAS

# Pre-Stenting Assessment





VL A, Segment: 1



Lumen Area	4.5 mm <sup>2</sup>	
EEL Area	52.5 mm <sup>2</sup>	
Plaque Area	47.9 mm <sup>2</sup>	
% Plaque Burden	91 %	
Fibrous Area	22.3 mm <sup>2</sup>	53 %
Fibro-Fatty Area	13.3 mm <sup>2</sup>	32 %
Dense Calcium Area	2.0 mm <sup>2</sup>	5 %
Necrotic Core Area	4.4 mm <sup>2</sup>	10 %



Distal Frame	---	37
Current Frame	---	37
Proximal Frame	---	37

< Back **Step #4: Frame Results**

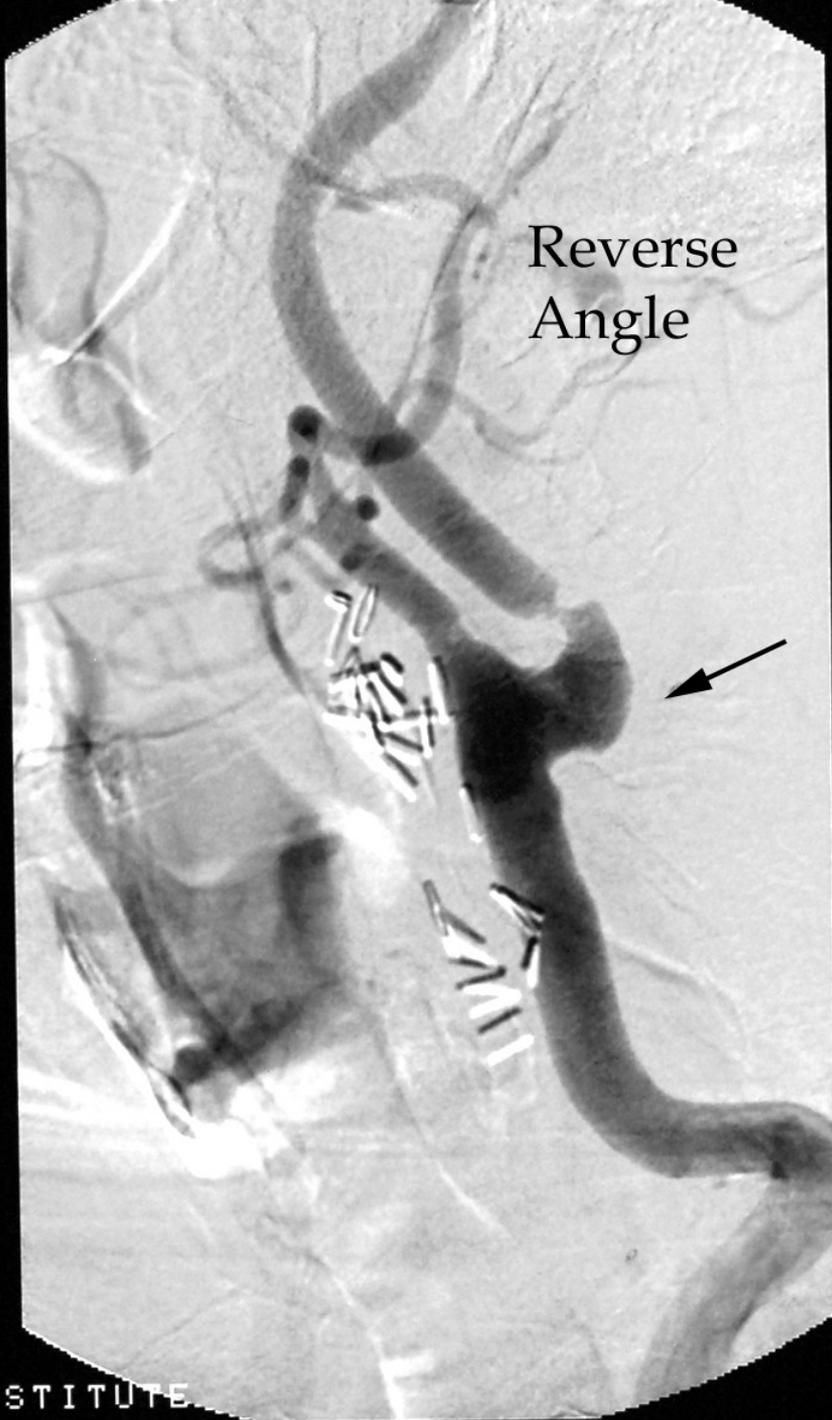
HOME

PLAY LOOP

REW / FWD

BORDERS ON/OFF

GO TO SEGMENT



# Recurrent Stenosis Following CEA

- As high as 15%
- Nascet 7%

# ISR Options for Treatment

- Surgical Removal of Stent
- Endovascular

**Restenosis rates  
that warrant re-  
intervention are not  
well defined.**

# Aim

To develop customized duplex ultrasound velocity criteria for evaluating in-stent stenosis at clinically relevant thresholds

# Data Collection

## Patients:

- 605 carotid stent patients reviewed

## Selection criteria:

- Carotid angiography and DUS performed within 30 days of each other

## Data: DUS Parameters

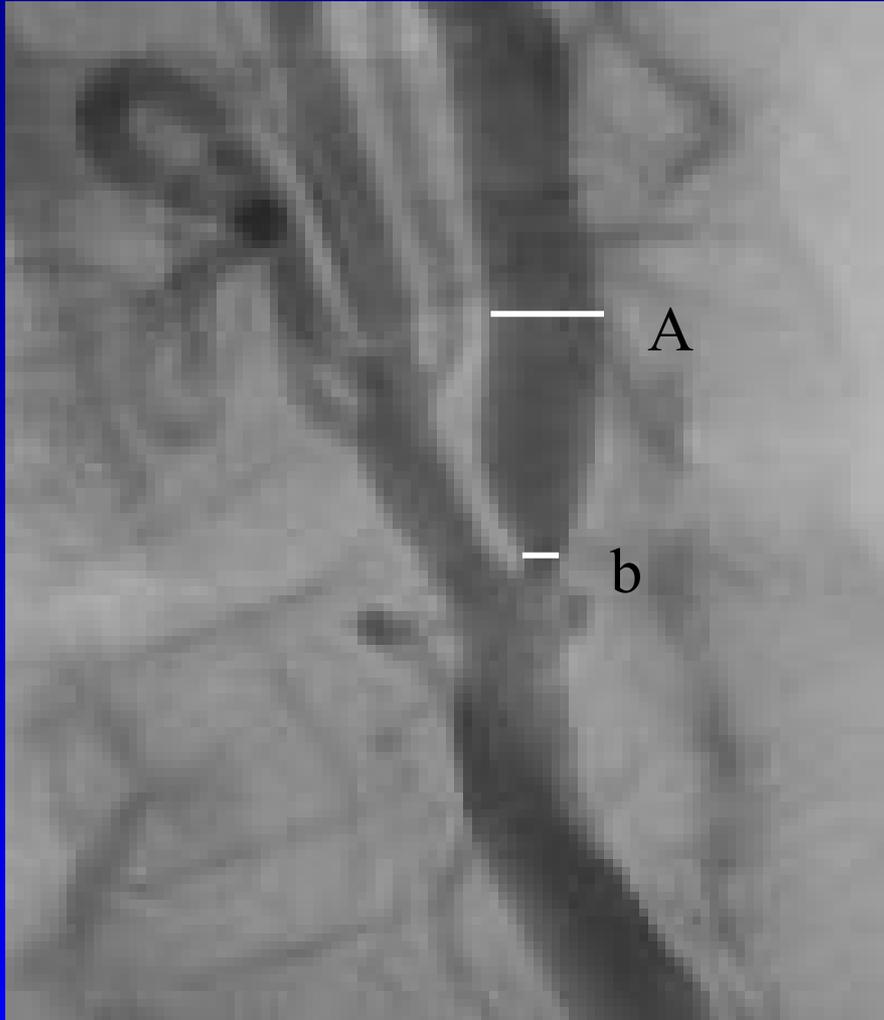
PSV  
ICA/CCA ratio  
EDV

## • Angiographic Stenosis

NASCET method

# NASCET Method

## *Determining % Stenosis*



$$\% \text{ Stenosis} = \left(1 - \frac{b}{A}\right) \times 100\%$$

# Example: Stented Carotid Artery

## Parameter

## Result

Peak Systolic Velocity (PSV)

275 cm/s

Internal/Common Carotid Artery (ICA/CCA)

4.45

End Diastolic Velocity (EDV)

86 cm/s



# Example: Non-Stented Carotid Artery

<u>Parameter</u>	<u>Result</u>
Peak Systolic Velocity (PSV)	276 cm/s
Internal/Common Carotid Artery (ICA/CCA)	4.82
End Diastolic Velocity (EDV)	74 cm/s



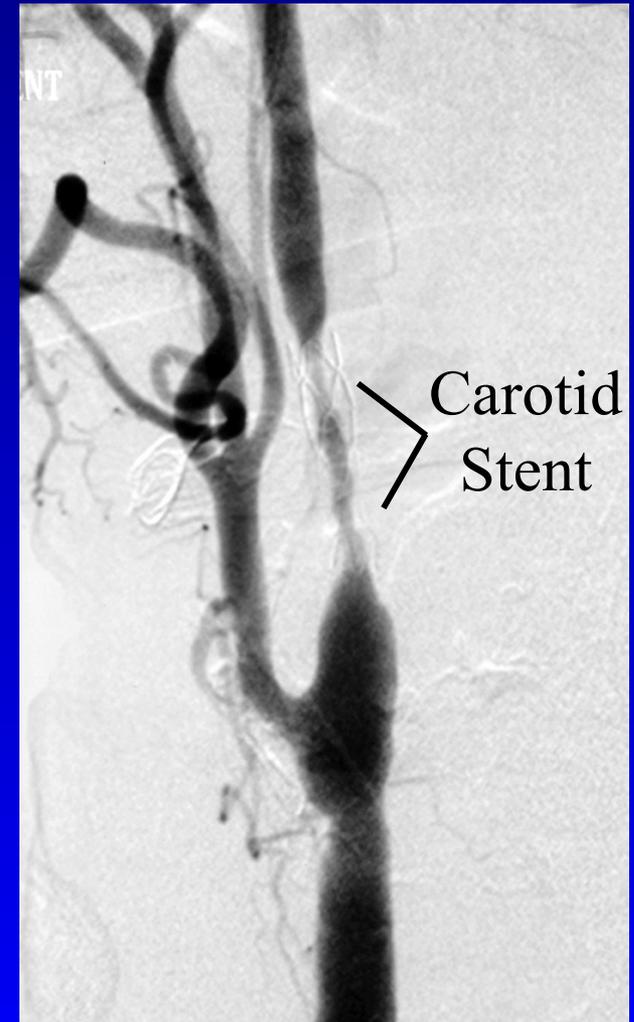
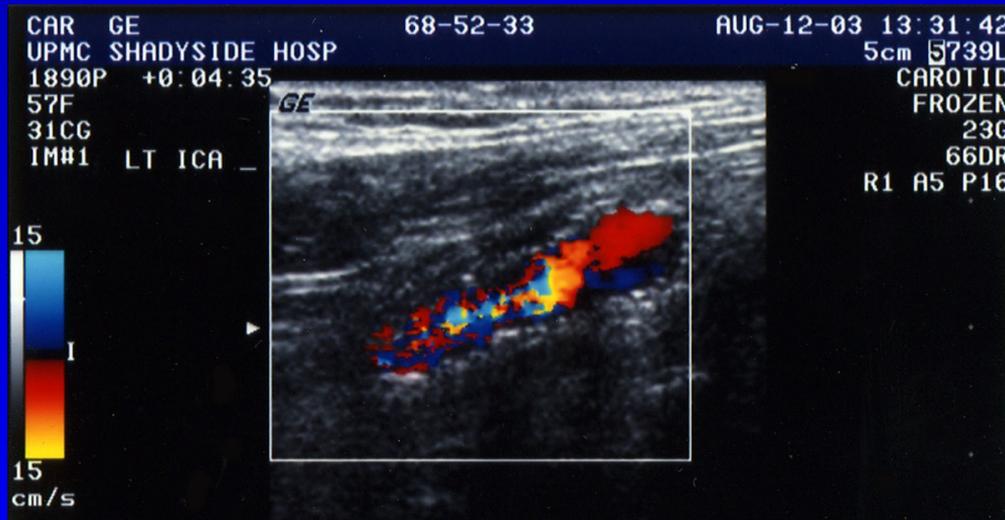
# Stented Carotid Artery

## Carotid Duplex Ultrasound

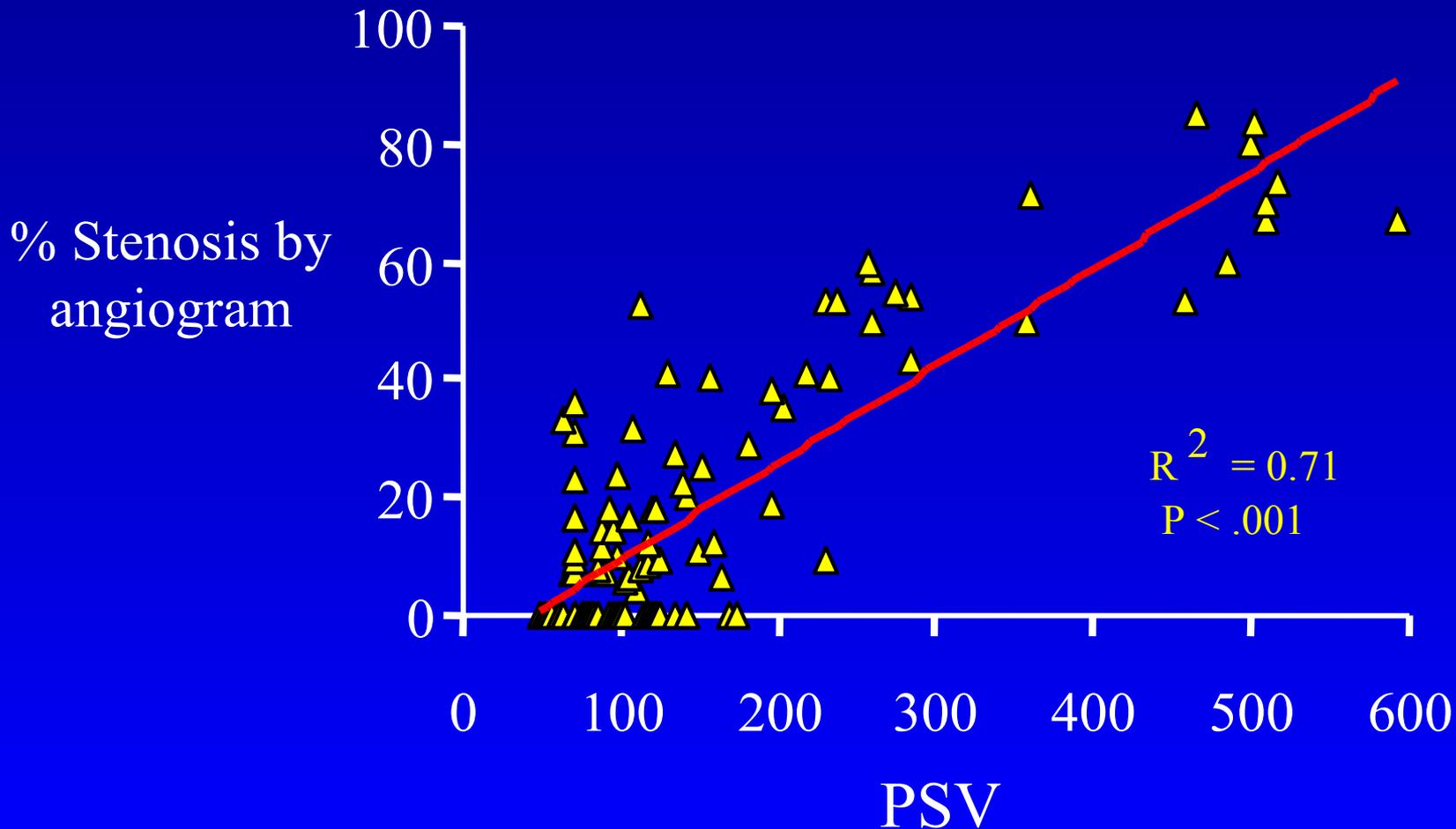
PSV 457 cm/s

ICA/CCA 5.2

EDV 101 cm/s



# Distribution of PSV Measurements vs Angiographic In-Stent Stenosis



To detect  $\geq 70\%$  angiographic stenosis:  $PSV \geq 350$  cm/sec

Had:

100% Sensitivity

96% Specificity

55% PPV

100% NPV

ICA / CCA ratio of  $\geq 4.75$  had

100% Sensitivity

95% Specificity

50% PPV

50% NPV

## Limitation:

Large number of restenosis  
but only 19 were  $\geq 50\%$  only 6  $\geq 70\%$ .

Reflects either low recurrence  
or poor detection.

# Take home message

- PSV, ICA/CCA ratio and EDV increase with stenosis to a greater extent in stented carotid arteries
- To predict > 50% stenosis:

	Non-stented	Stented
PSV	$\geq 125$	$\geq 225$
ICA/CCA	$\geq 2.0$	$\geq 2.50$

- To predict > 70% stenosis:

	Non-stented	Stented
PSV	$\geq 250$	$\geq 350$
ICA/CCA	$\geq 3.5$	$\geq 4.75$

- 85 year old male with bilateral carotid artery occlusive disease stented in Stages in 2006. Returned in 2008 with color flow duplex studies suggesting restenosis of the left internal carotid. Angiography demonstrated migration of the previously positioned stent to the common carotid with recurrent stenosis of the original lesion. Additional stent placed to fix the stent migration as well as the recurrent lesion at the ostium of the left internal carotid.

UPMC Shadyside  
WHOLEY



4136798  
Feb 23 2006  
14:56:04

RIGHT

(Filt. 3)  
(Shut.)

depart. RAO: 29  
depart. CAU: 2  
depart. L: -7  
Mag = 1.00  
FL: ROT:  
WW: 2599WL: 1928  
XA 1000x1000

Seq: 2  
FRAME = 12 / 19  
MASK = 4

55068488  
Feb 21 2008  
11:30:49



**STENT  
MIGRATION**

depart. LAO: 59  
depart. CRA: 1  
depart. L: -3  
Mag = 1.00  
FL: ROT:  
WW: 4096 WL: 2048  
XA 1000x1000

Seq: 9  
FRAME = 10 / 19  
MASK = 1



depart. LAO: 89  
depart. CRA: 1  
depart. L: -3  
Mag = 1.00  
FL: ROT:  
WW: 4096WL: 2048  
XA 1000x1000

Seq: 7  
FRAME = 18 / 26  
MASK = 1



LEFT 7X40 STENT  
POST DILATION

(Filt. 3)

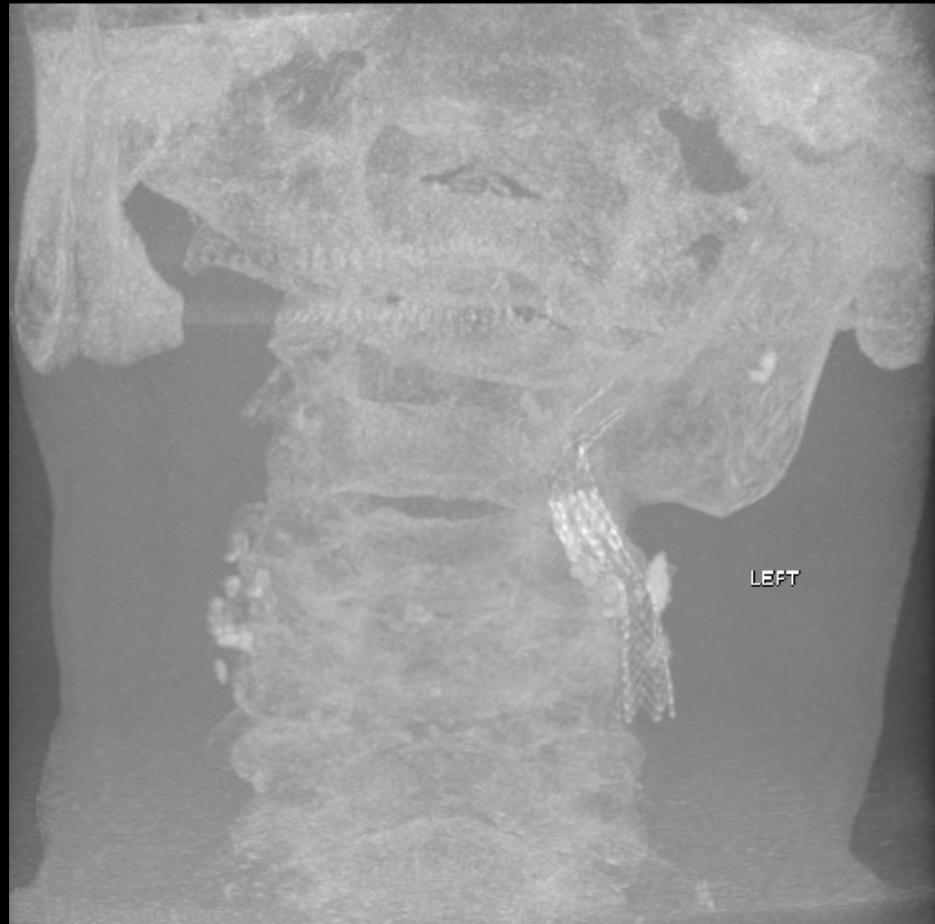
depart. RAO: 43  
depart. CRA: 0  
depart. L: 0  
Mag = 1.00  
FL: ROT:  
WW: 4096 WL: 2048  
XA 1000x1000

Seq: 5  
FRAME = 77/10  
MASK = 1

Post angio  
and additional  
stent

- 85 year old female with prior left carotid endarterectomy. Right internal carotid is totally occluded. Vertebral basilar responsible for most of the collateralization to the right hemisphere. Non-functioning ACOM. Post endarterectomy high restenosis in the left internal carotid managed with endovascular stenting (2007). Dystrophic calcification noted at the adventitial level of the left internal carotid adjacent to the stent. Managed by conventional balloon angioplasty.





3D2  
UPMC Shadyside  
Seq: 5

SLP

Jan 22 2007  
10:34

Volume Rendering No cut

DFOV 11.6cm

WHOLEY

P  
L  
I

A  
R  
S

No VOI

Voxel size: 0.2 mm

W = 4095 L = 2048

Angles

0 L 130 RAO 1 CRA

IRA



UPMC Shadyside  
WHOLEY

Oct 24 1921

52128330  
Jan 22 2007  
10:26:28

PTA 5mm  
Balloon only.  
Lesion would not  
efface



LEFT

(Filt. 3)  
(Shut.)

depart. RAO: 10  
depart. CRA: 4  
depart. L: 0  
Mag = 1.00  
FL: ROT:  
WW: 4096WL: 2048  
XA 1000x1000

Seq: 4  
FRAME = 11 / 19  
MASK = 1

3D2  
UPMC Shadyside  
Seq: 7

S 57

Jan 22 2007  
10:38

Volume Rendering No cut

DFOV 9.3cm

WHOLEY

R  
A



L  
P

**LEFT CAROTID**  
Angles

0 L 35 LAO 0 CRA

No VOI

Voxel size: 0.2 mm

W = 4095 L = 2048

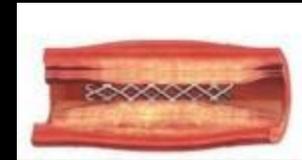
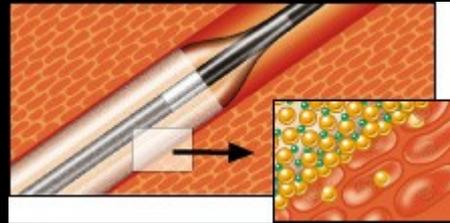
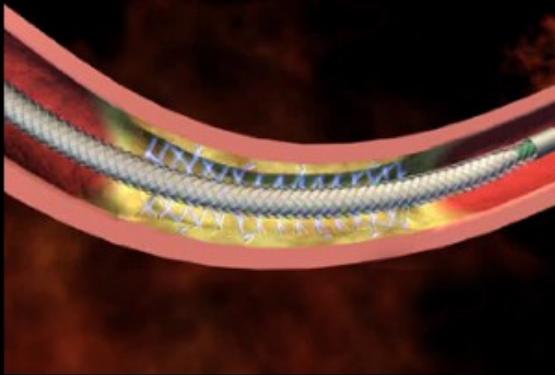
# ISR – Treatment Options

- PTA – conventional or cutting balloon
- Drug eluting balloon
- Drug eluting wire
- Additional Stenting

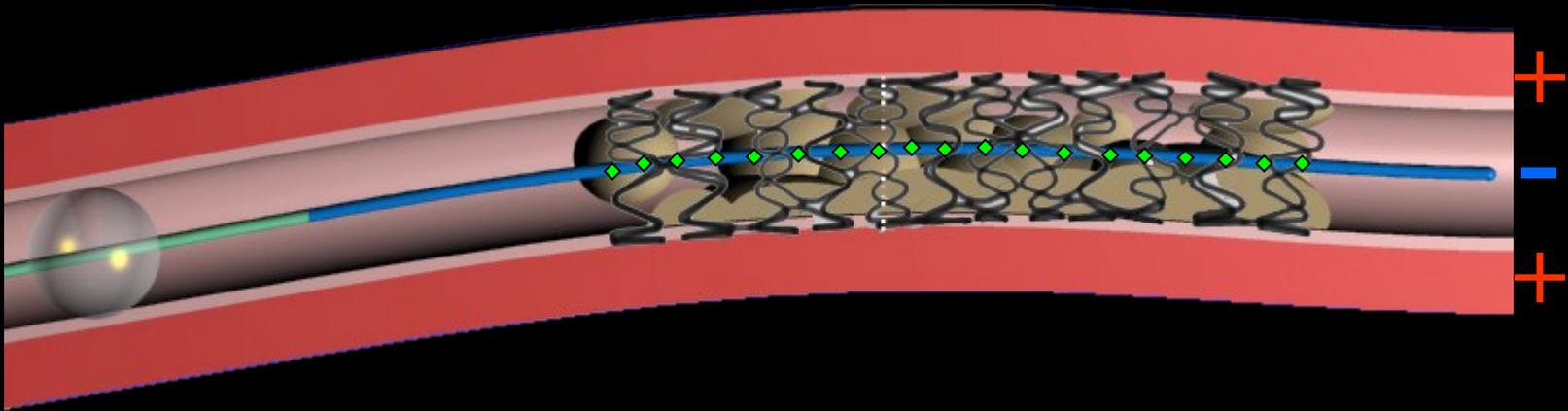
# Future

- Drug Eluting Stents
- Biodegradable stents
- Antiproliferative Therapy

# PACCOCATH BALLOON DRUG ELUTION



# Drug Elution Wire



- Restore patency with balloon/cutting balloon/stent
- Treat with iontophoretic guidewire.
- Use stent as guidance/positioning aid.
- Drug delivered through interstices of stent struts.
- Lipophilic absorption and redistribution to achieve uniform tissue concentration.

# The End

