

# Where Are We Now?

## Current Scientific Evidence from Clinical Trials and Upcoming New Horizons

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THE UNIVERSITY OF  
**TOLEDO**  
HEART AND VASCULAR CENTER

# Where Were We Then?



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# The First Patient in Toledo

*November 25, 1997*

- Critical LICA stenosis
- Severe LV dysfunction
- Severe mitral regurgitation
- Prior CABG, SVG stent
- Evaluation for heart transplant



# The First Patient in Toledo

*November 25, 1997*

- No Institution Review Board Approval
- No clinical trial
- No hospital privileges for carotid stenting
- No confirmation of insurance coverage
- A phone call



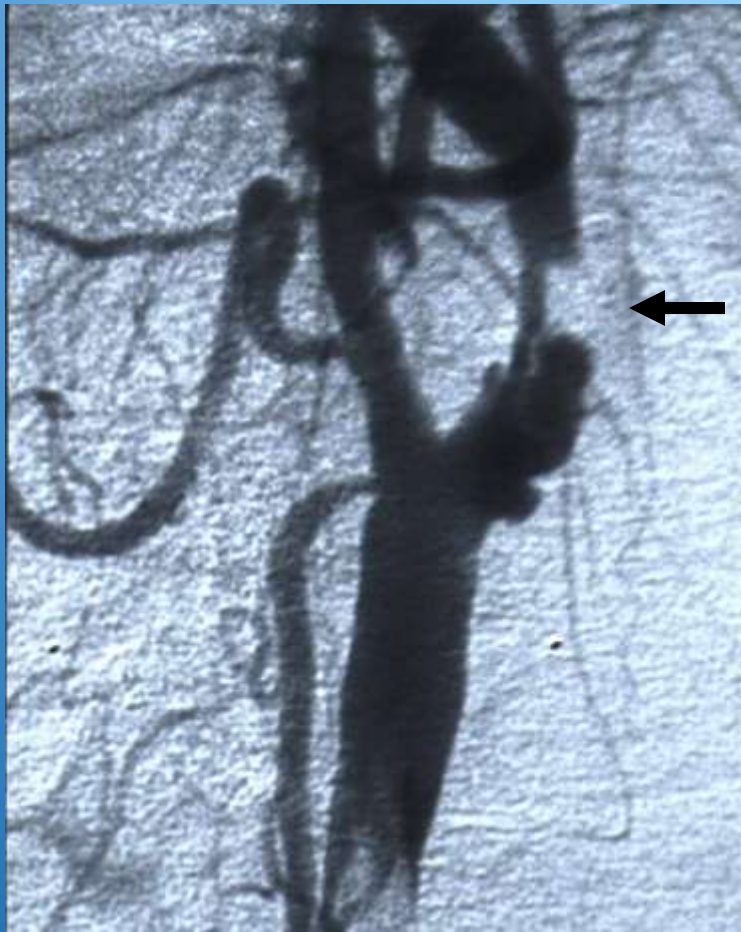
# The First Patient in Toledo

*November 25, 1997*

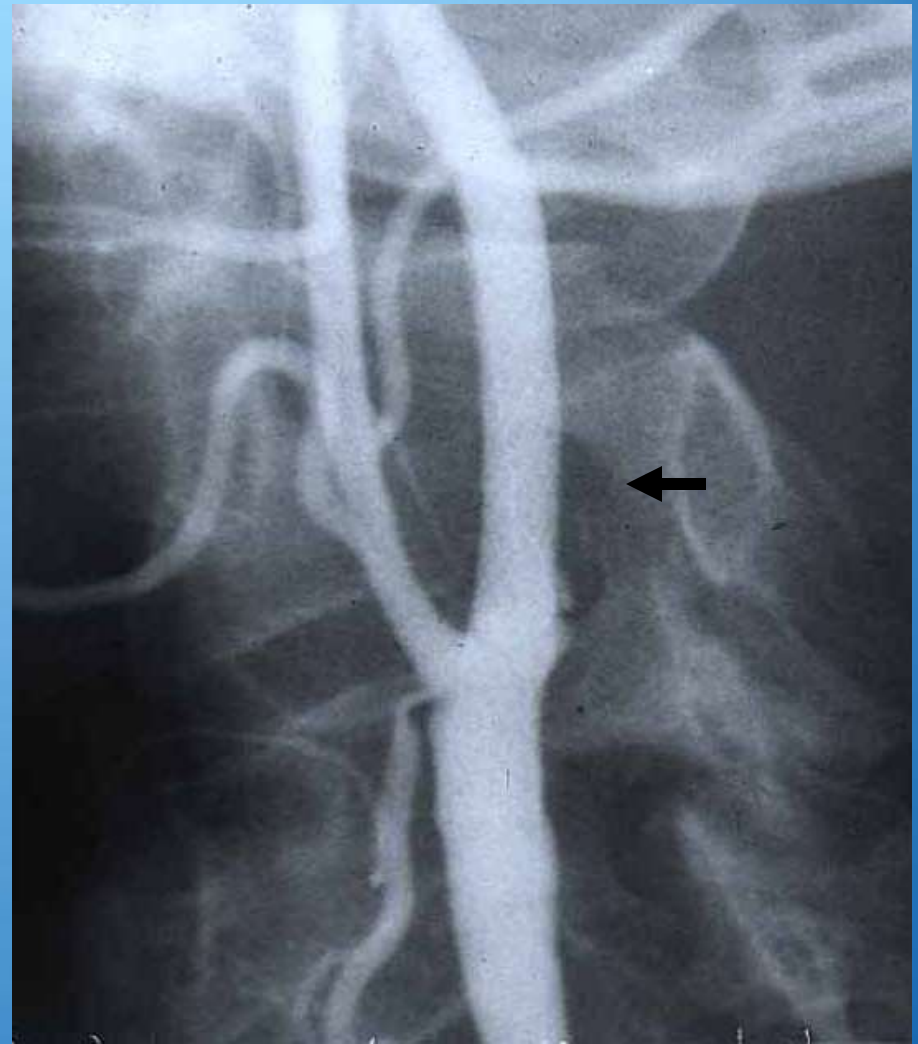
- Done in collaboration with Neurology and Neuroradiology
- 9 French guiding catheter
- No embolic protection
- Wallstent over a 0.018" guidewire
- Aspirin and ticlopidine



# First Toledo Case



Initial



Post Stent

# First Patient

- No procedural complications
- Discharged following day
- Event-free survival until October 2001



November 26, 1997

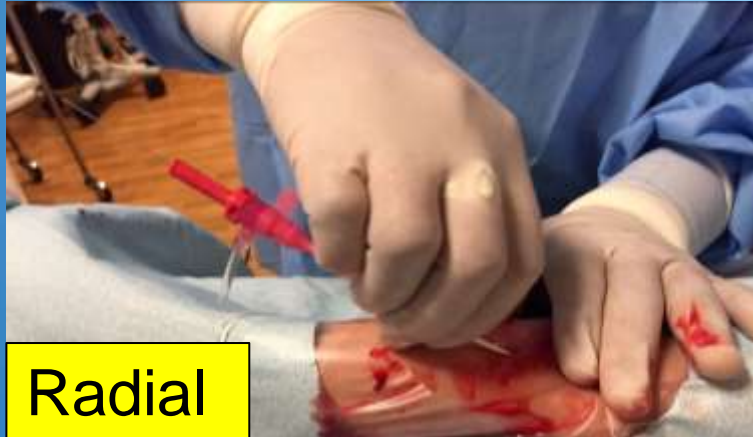
# Where Are We Now?

- *All* procedures must be financially covered
  - Part of a clinical trial
  - Meet Medicare criteria
  - Insurance coverage
- *All* physicians must have hospital privileges
- *All* procedures include embolic protection



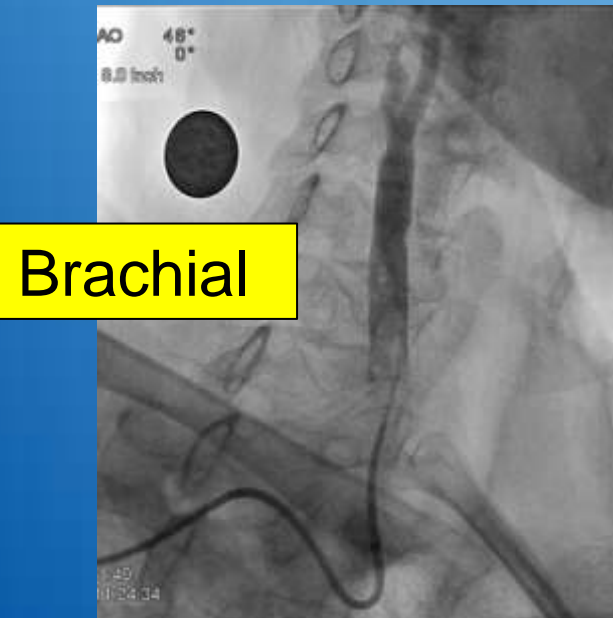
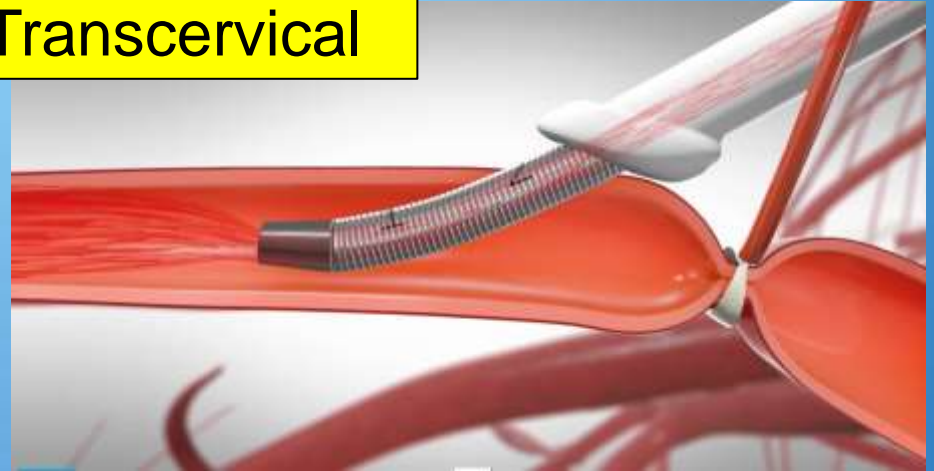


# A World of Choices: Access

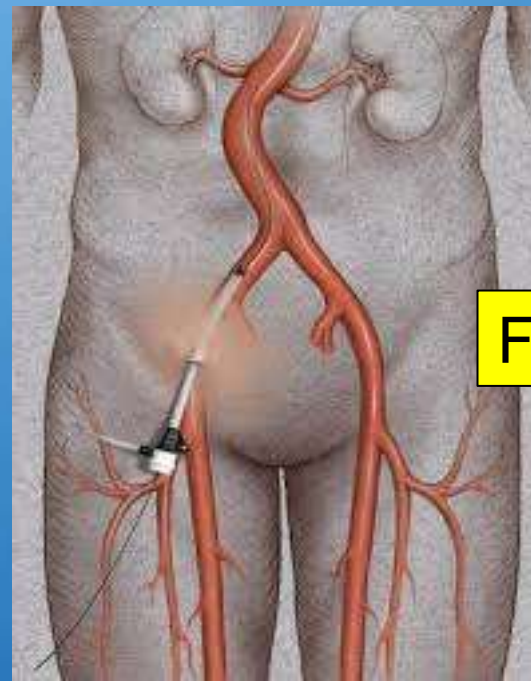


Radial

Transcervical



Brachial



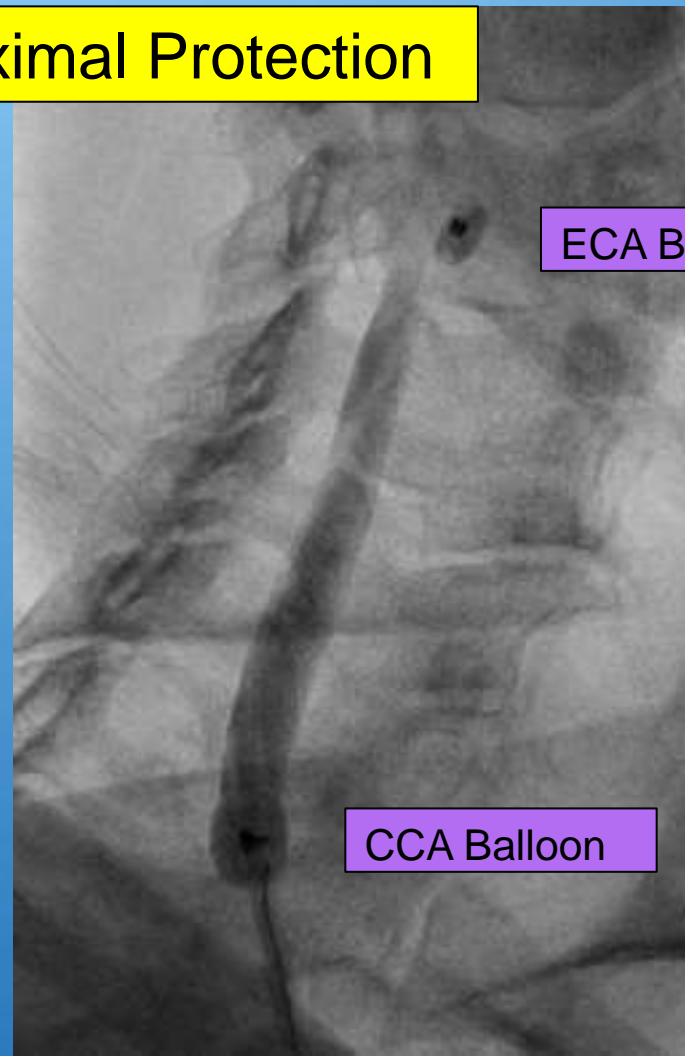
Femoral

# A World of Choices: Embololic Protection



Embololic Protection Filter

## Proximal Protection



ECA Balloon

CCA Balloon

# Not a Choice

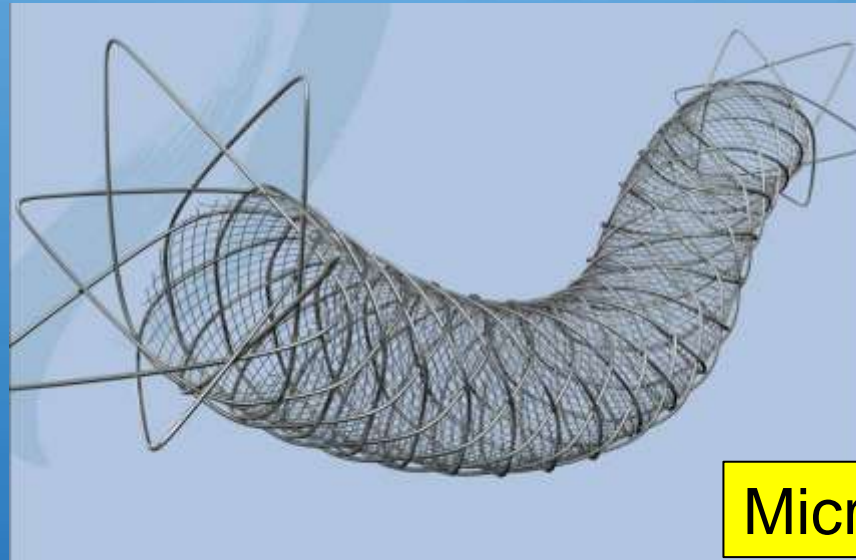


# A World of Choices: Stents



Closed Cell

Open Cell



Micromesh

A photograph of a desert landscape. In the foreground, a two-lane asphalt road with a yellow dashed center line and white edge lines curves slightly to the right. The road is flanked by sparse, dry vegetation and small green shrubs. In the middle ground, there are rolling hills with patches of reddish-brown and light-colored soil. In the background, a large, prominent red sandstone cliff face rises against a clear blue sky. The cliff has vertical erosion patterns and a flat top. The overall scene is bright and sunny.

**Where is This Going?**

# 2017 and Beyond

*Having Great Equipment...That We Can't Use!*

- Interventional equipment (stent, embolic protection, etc) not approved for sale in country
- Equipment approved, but not purchased by hospital
- Equipment available in hospital, but insurance won't cover procedure
- Equipment available in hospital, but cost-prohibitive for most patients

# 2017 and Beyond

*Are You Better Off Without a Stent?*



CREST-2  
Coordinating Center



CREST-2 Statistical and  
Data Coordinating Center



Funded by:



National Institute of  
Neurological Disorders  
and Stroke

# CREST-2

## *The Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial*

- Landmark surgical trials (NASCET, ACAS) compared endarterectomy to *minimal* medical therapy
- CREST compared CEA to stenting *with no medical arm*
- Multiple stent registries *without control group*
- Medical therapy more substantial now



# CREST-2

## *The Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial*

CREST-2 offers three

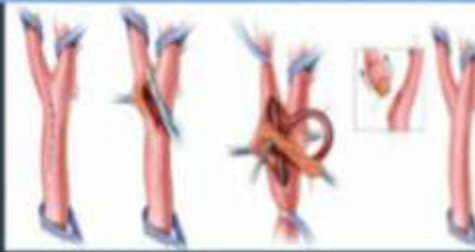
### **STROKE PREVENTION OPTIONS**

1



Medical Management

2



Carotid Endarterectomy  
+ Medical Management

3



Carotid Artery Stenting  
+ Medical Management

# CREST-2

## *Medical Management*

- Aspirin
- Blood pressure optimization
- Lipid management
- Lifestyle modification
  - Smoking
  - Physical activity
  - Weight management

# Lipid Management and Stroke

- Numerous meta-analyses
- 83,000 – 267,000 patients
- Statin versus control
- ~20% relative risk reduction for stroke
- Effective in primary and secondary prevention
- Effective with or without coronary artery disease
- Protection increases as LDL decreases

Corvol. Arch Intern Med 2003;163:669-676

Amarenco. Stroke 2004;35:2902-2909

Briel. Am J Med 2004;117:596-606

O'Regan. Am J Med 2008;121:24-33

DeCaterina. J Am Coll Cardiol 2010;55:198-211

Lipid-Lowering and Stroke

## Cholesterol-Lowering Interventions and Stroke

Insights From a Meta-Analysis of Randomized Controlled Trials

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# Conclusions

- Carotid interventions are reaching a plateau
- Current limitations are often non-technical
- Medical therapy may be a better option