Carotid Artery Angioplasty and Stenting: Current Status

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Carotid Angioplasty and Stenting

First time percutaneous intervention has “attacked” a surgical procedure which is so successful and with so little morbidity and mortality

Carotid Angioplasty and Stenting
Current Status

Currently….

Still an Experimental Procedure

Stroke

Undergoing intense investigation

October, 2002

"Controversies in Stroke"

?

Clinical Trials
Design Concepts

- Case Report
- Case Series
- Database Analysis
- Observational Study
- Controlled Clinical Trial
- Replicated Clinical Trials

Clinical Trials: A Methodologic Perspective. S Piantadosi, MD, PhD. 1997

Case Series
Carotid Stenting

First Single Center Trial

- Yadav et al
  University of Alabama
  Circulation, 1997

107 patients / 126 carotid lesions

Case Series

Carotid Stenting

Yadav et al. Circulation, 1997

First Single Center Trial

Immediate to 30 days

minor strokes	7 (7%)
major strokes	2 (2%)
deaths	1 (1%)

combined incidence overall	7.9%
ipsilateral major stroke/death	1.6%

Not much has really been published to change this

Case Series/ Database Analysis

- Single Center Studies
- Multicenter Studies

Registry

Manufacturer sponsored

Case Series/ Database Analysis

Stent only

- Cordis/Johnson & Johnson Co.
  SMART™
- Boston Scientific Corp.
  Integra™
- C. R. Bard, Inc.
  Memotherm™
- Advanced Cardiovascular Systems, Inc.
  ACCULINK™

Case Series/ Database Analysis

Stent/Protection Device

Surgically “high risk” patients

- Cordis/Johnson & Johnson Co.
  - SAPPHIRE/AngioGuard™
- Boston Scientific Corp.
  - SHELTER/Percusurge ™
  - BEACH/EpiWire ™
- Advanced Cardiovascular Systems, Inc.
  - ARCHeR/ACCUNET ™

Controlled Clinical Trial

Cordis/Johnson & Johnson Co.
SAPPHIRE/AngioGuard™

On-going
multicenter, randomized trial
carotid angioplasty/stenting
versus
carotid enarterectomy
in surgically “high-risk” patients

Controlled Clinical Trial

SciMed/Boston Scientific Corp.

Wallstent® trial

The object was to statistically evaluate equivalence of data from patients undergoing stent therapy compared with control data from a similar patient population randomized to carotid endarterectomy

Controlled Clinical Trial

"Wallstent® Trial"

SciMed/Schneider (USA) Inc.
Boston Scientific Corporation

Randomized 600 patients/arm to CAS/CEA
symptomatic patients 70% → 50%

Began enrollment January, 1997

Controlled Clinical Trial

"Wallstent® Trial"

31 centers

221 patients randomized (phase II)

stent	108
surgery	113

Data only began presented in abstract form

Investigators have been given IDE Final Study Report

Controlled Clinical Trial

"Wallstent ® Trial"

Event	Stent	Surgery
study related deaths	5 (4.6%)	2 (1.8%)
ipsilateral stroke, minor	3 (2.8%)	0
ipsilateral stroke, major	4 (3.7%)	0
ipsilateral TIA	2 (1.9%)	0

Controlled Clinical Trial

"Wallstent® Trial"

Could not prove the 1º hypothesis

Under review by the DSB

- stroke in surgery arm lower than expected
- stroke in stent arm was higher than expected

Trial suspended enrollment July, 1999

Controlled Clinical Trial

Things learned from the “Wallstent® Trial”

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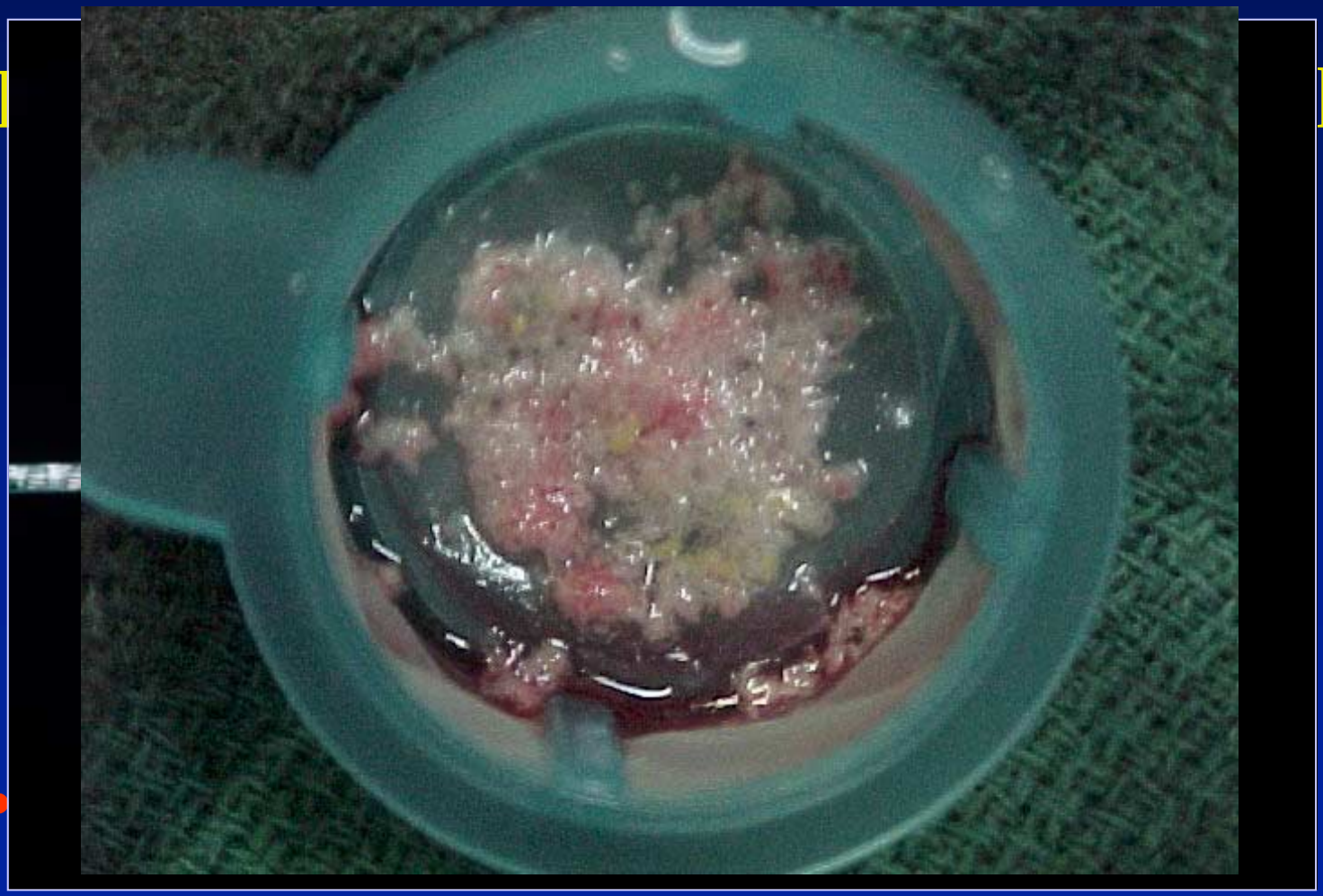
- 

Controlled Clinical Trial

Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS)

504 patients with carotid stenosis randomized

endarterectomy	253
endovascular treatment	251

Stents used in	55 (26%)
Angioplasty alone	158 (74%)

Lancet 2001; 357:1729-1737

Controlled Clinical Trial

Carotid Angioplasty/Stenting
CAVATAS

No difference in the major outcomes between the two arms at 30 days.

At 1 year, ipsilateral carotid stenosis
was more frequent in the endovascular arm (14%)
than the surgical arm (4%)
There was no difference in ipsilateral stroke

Lancet 2001; 357:1729-1737

Controlled Clinical Trial

Carotid Angioplasty/Stenting
CAVATAS

Wide confidence intervals...
Authors did not recommend
widespread introduction of
endovascular techniques
for the treatment of carotid stenosis
as an alternative to surgery

Lancet 2001; 357:1729-1737

Carotid Angioplasty/Stenting CAVATAS

Palmaz™ Balloon Expandable Stents
34% of stented patients

Lancet 2001; 357:1729-1737

Controlled Clinical Trial

NIH & Manufacturer sponsored

Carotid Revascularization Endarterectomy versus Stent Trial

CREST

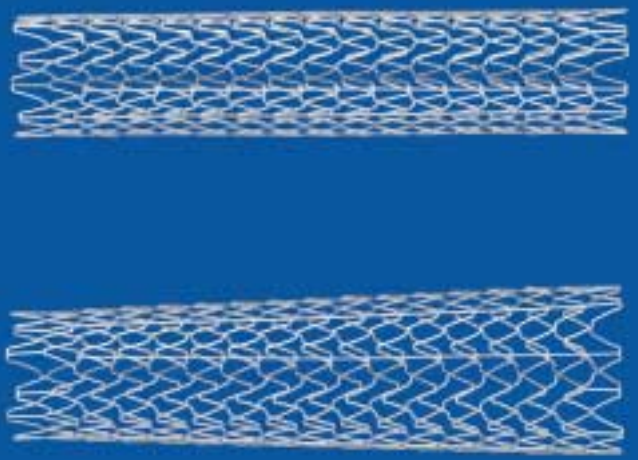
Controlled Clinical Trial

Purpose:
To contrast the relative efficacy of CAS versus CEA in preventing stroke, MI, and death during a 30 day peri-procedural period, and stroke ipsilateral to the study artery over the follow-up period in patients with symptomatic extracranial carotid stenosis

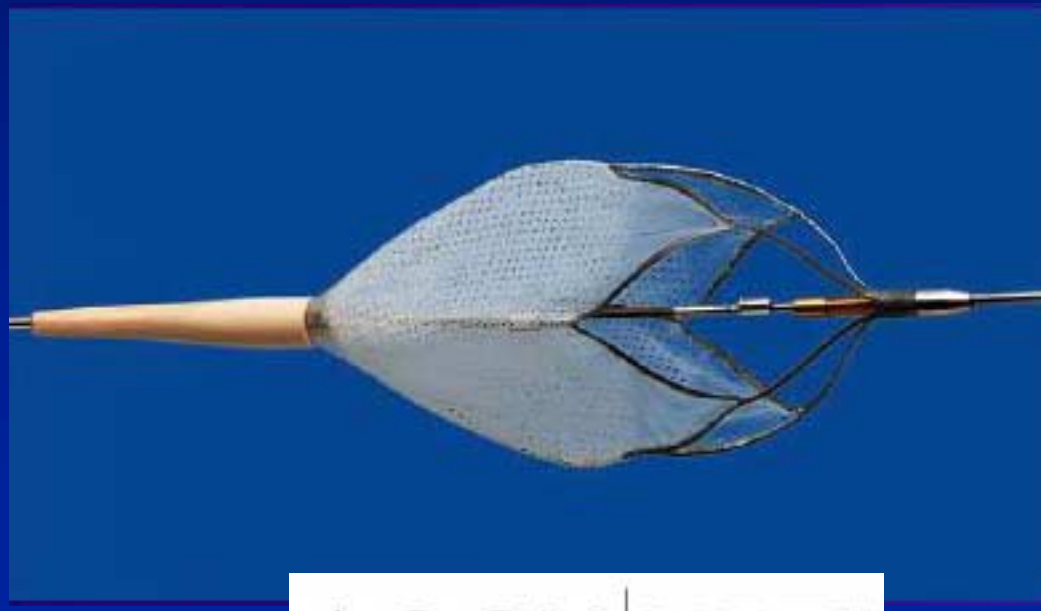
Controlled Clinical Trial

- ≥ 50% stenosis (symptomatic)
- ≈ 60 centers participating
- 2500 patients total planned enrollment
- distal protection is optional

CREST
Carotid Revascularization Endarterectomy vs. Stent Trial



ACCU|LINK™
CAROTID STENT SYSTEM



ACCU|NET™
EMBOLIC PROTECTION SYSTEM

Controlled Clinical Trial

Currently

26 centers total

enrolled 372 patients

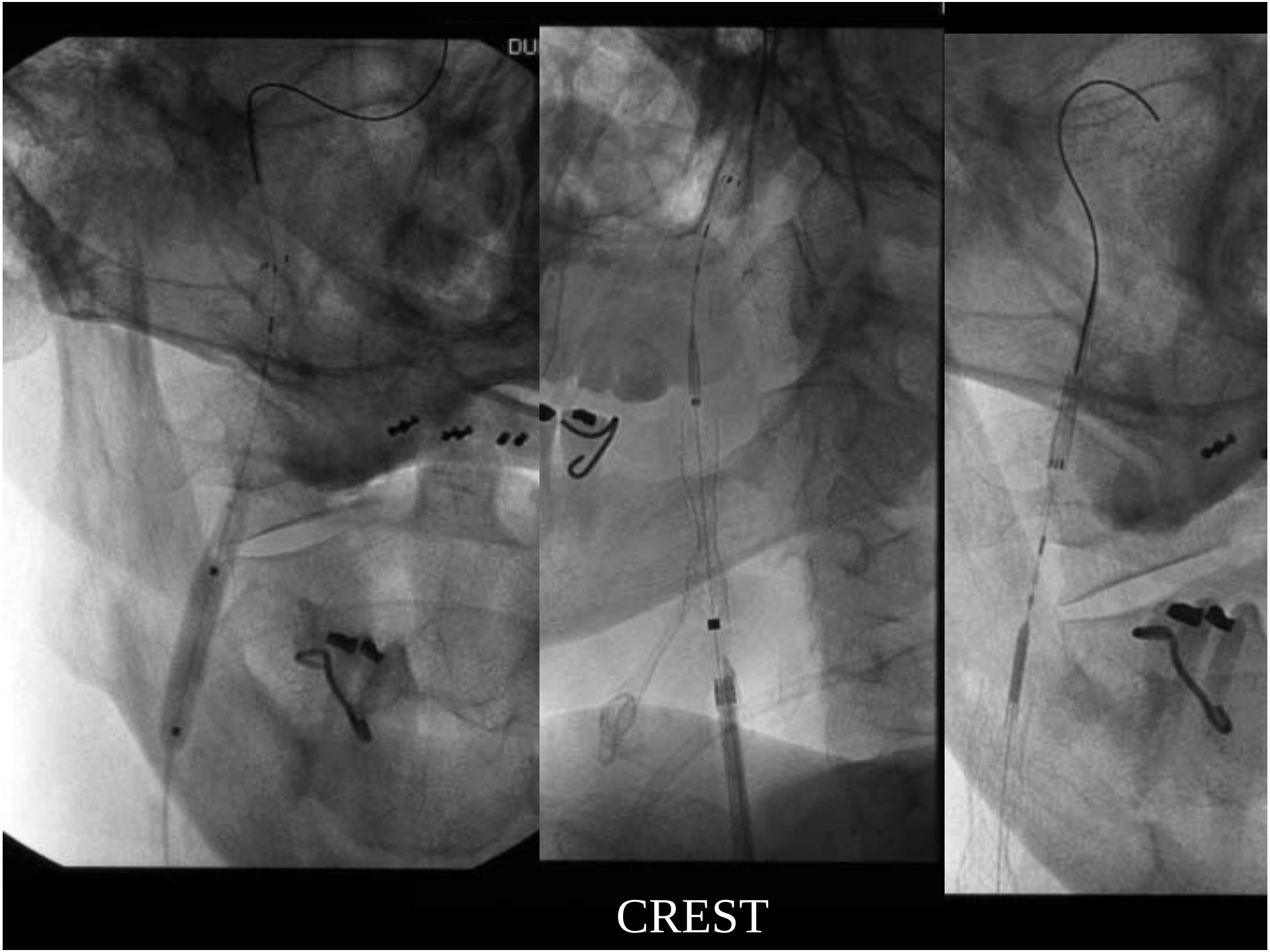
3 centers in randomization phase

enrolled 9 patients

Trial suspended enrollment February, 2002 due to problems with the ACCUNET™

Reactivation July, 2002


CREST


CREST


CREST

Carotid Angioplasty and Stenting

To be continued….