Evolution of Endovascular Aneurysm Treatment: The Good, the Bad and the Ugly

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Disclosures

Consultant, Stryker Neurovascular, Inc
Educational Speaker, Covidien
Core Reading Lab, Microvention, Inc
History of Endovascular Aneurysm Treatment, B.C.

- Werner, 1941: silver wire insertion through the orbit
- Lussenhop and Velasquez, 1964: carotid navigation with silastic tubing
- Kessler and Wholey, 1970: carotid occlusion with balloon catheter
- Hilal, 1974: magnetic-tipped microcatheter used to navigate intracranial vessels
Meanwhile in the USSR... 

- 1962: non-detachable balloon catheter 
- 1964: TBO of ICA 
- 1969: txd CCF with N-D BC 
- 1974: first English paper on use of detachable balloons 

Balloon catheterization and occlusion of major cerebral vessels 

F. A. Serbinenko, M.D. 

N. N. Burdenko Institute for Scientific Research in Neurosurgery, USSR Academy of Medical Sciences, Moscow, USSR
Latex Balloons
Parent Artery Occlusion
Reconstructive Therapy

- Reconstructive therapy
  - Intrasaccular occlusion of aneurysm with preservation of parent artery
  - Requires supple microcatheter to reach the aneurysm
  - Requires embolic device that is pliable but stable, and detachable

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GOLDBALLOON

We must remember that, in 1974, Pr. Fedor Serbinenko, neurosurgeon in Moscow, invented the latex detachable balloon. At this time, the balloon introduction was performed via direct carotid puncture with coaxial catheters. This approach, uncomfortable for the patient and inducing high radiation dose for the operator, has been replaced by the femoral approach.

In 1980, Balt in association with Pr. Serbinenko, was one of the first companies to develop and to produce detachable latex balloons and associated delivery catheters. The know-how and the experience, acquired over 25 years of continuous production and development, allows the Goldballoon to be positioned as having the highest quality and effectiveness. Deployment is by way of single catheter or coaxial overtube.

5 BALLOON SIZES ARE AVAILABLE:

- GOLDBAL1
- GOLDBAL2
- GOLDBAL3
- GOLDBAL4
- GOLDBAL5
Endovascular detachable balloon embolization therapy of cavernous carotid artery aneurysms: results in 87 cases

Randall T. Higashida, M.D., Van V. Halbach, M.D., Christopher Dowd, M.D., Stanley L. Barnwell, M.D., Ph.D., Bill Dormandy, B.S., Julie Bell, M.S., and Grant B. Hieshima, M.D.

Departments of Radiology and Neurological Surgery, Interventional Neuroradiology Section, University of California Medical Center, San Francisco, and Interventional Therapeutics Corporation, South San Francisco, California
Cavernous Aneurysm
Development of the Guglielmi Detachable Coil (GDC)

- Guido Guglielmi, MD (Univ of Rome)
- Developed 1988-1991 in conjunction with Ivan Sepetka, Target Therapeutics, and Fernando Vinuela, MD (UCLA)
GDC: Design

• Design considerations
  – Radiopaque
  – Low profile (for use in 0.018” systems)
  – Flexible (navigate carotid siphon)
  – Soft (minimize perforation risk)
  – Retrievable
  – Size-matched to aneurysms
GDC: Original Design
Special Article

Electrothrombosis of saccular aneurysms via endovascular approach

Part 1: Electrochemical basis, technique, and experimental results

GUIDO GUGLIELMI, M.D., FERNANDO VIÑUELA, M.D., IVAN SEPETKA, M.S., AND VELIO MACELLARI, M.S.

Department of Neurological Sciences, Therapeutic Neuroangiography, University of Rome Medical School, Rome, Italy; Department of Radiological Sciences, Endovascular Therapy, University of California Medical Center, Los Angeles, California; and Target Therapeutics, San Jose, California

Special Article

Electrothrombosis of saccular aneurysms via endovascular approach

Part 2: Preliminary clinical experience

GUIDO GUGLIELMI, M.D., FERNANDO VIÑUELA, M.D., JACQUES DION, M.D., AND GARY DUCKWILER, M.D.

Department of Neurological Sciences, Therapeutic Neuroangiography, University of Rome Medical School, Rome, Italy; and Department of Radiological Sciences, Endovascular Therapy, University of California Medical Center, Los Angeles, California
GDC: Clinical Trial

- First patient treated in March, 1990
- 20 centers participate in clinical trials, 1992-1995
- Non-surgical candidates
- FDA approval September, 1995
Clinical Results
(Vinuela, ASNR 1995)

• 715 patients as part of FDA trial
  – 48% SAH, 25% mass effect; 15% giant
  – 58% ant circulation, 42% post circulation

• Radiographic outcomes
  – Complete occlusion seen in 62% of small aneurysms with small neck
  – 35% for aneurysms with broad neck
  – 37% of large aneurysm with small neck
FDA Approval Sept 1995

• Only for non-surgical or high-risk patients
  – GOOD
    • First safe and effective reconstructive device for EVT of aneurysms
    • Required training and proctoring
  – BAD
    • Limited coil sizes and shapes
    • ? Durability
    • Few trainers/proctors
  – UGLY
MUD WRESTLING

Yeah, we ALL imagined it would be a lot sexier than this.

- Wide-necked and fusiform aneurysms difficult
- Delicate system
  - coil unraveling, fracture, migration
- Coil compaction
  - neck remnants
  - regrowth
Better Coils (2000)

- Different sizes/lengths (2 mm - 20mm)
- Different stiffnesses (GDC 10 and GDC 18)
- Different shapes (2D coils, framing coils)
- Stretch resistance
New Companies

- More variety, more products
  - Cordis/Codman: Trufill DCS Orbit (2002)
Transition Zones

GDC Delivery steel wire

GDC 10 US SR SynerG Delivery Wire

TRUFI LL DCS ORBIT™ Delivery soft polymer tube

MICRUS MicruSphere Delivery Wire

MTI Sapphire Delivery Wire

Microvention V-Trak

Photos taken at Cordis Neurovascular and owned by CNV.
Surface Coatings

• Can we increase “biological activity” of platinum by adding surface coatings?
• Can this be done without changing
  – thrombogenicity
  – softness
  – radiopacity
• How much can be delivered?
  – 50µ thickness coating = 3% of aneurysm volume
• Will it cause complications?
Coil Coatings: PGLA

Coming Soon...
Coil Coatings: Hydrogel

HydroSoft®
HydroCoil® Embolic System
Explanted Aneurysm Close-Up of Neck Area
12 y.o. in MVA with CHI and Proptosis/Bruit
Fistula closed with Hydrocoil/Bare Platinum

82% by length, 91% by volume of hydrocoil
Five Days and 2 M Post
Trial Outcomes of Coated Coils

- **Cerecyte Trial**
  - Bare platinum vs Cerecyte
    - No benefit of Cerecyte over BP
    - Increased complications (5.4% vs 0.8%) in ruptured

- **Matrix and Platinum Coil Trial**
  - No difference in recurrence with similar rates of reintervention (10%)

- **Hydrocoil Endovascular Aneurysm Occlusion and Packing Study**
  - Rate of major angiographic recurrence was slightly lower in HC group (24 v 34%; p=0.049)
New Techniques:
Balloon Remodeling

Cordis Commodore (left) and Boston Scientific Sentry (top) silicone balloons
Stent-Assisted Coil Embolization
Differences Between Stents

- **Neuroform**
  - Open cell design
  - Follows wall contour
  - Scales may open into neck
  - Cannot recapture

- **Enterprise**
  - Closed cell design
  - Kinks along curves
  - Better coverage of neck
  - Able to recapture before 70% of stent delivered
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Stent “Scale” Lassoed By Coil
Expansion of the Field

• GOOD
  – More variety
  – More competition (?)
  – More ideas (no matter how crazy!)

• BAD
  – More expensive devices with only theoretical benefit
  – More elaborate treatments
  – More marketing

• UGLY
It's not personal. It's just business.
International Subarachnoid Aneurysm Trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomised trial

International Subarachnoid Aneurysm Trial (ISAT) Collaborative Group*

International subarachnoid aneurysm trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomised comparison of effects on survival, dependency, seizures, rebleeding, subgroups, and aneurysm occlusion

Andrew J Molyneux, Richard S Kerr, Ly-Mee Yu, Mike Clarke, Mary Sneade, Julia A Yarnold, Peter Sandercock, for the International Subarachnoid Aneurysm Trial (ISAT) Collaborative Group*

Risk of recurrent subarachnoid haemorrhage, death, or dependence and standardised mortality ratios after clipping or coiling of an intracranial aneurysm in the International Subarachnoid Aneurysm Trial (ISAT): long-term follow-up

Andrew J Molyneux, Richard S Kerr, Jacqueline Birks, Najib Ramzi, Julia Yarnold, Mary Sneade, Joan Rischmiller, for the ISAT collaborators

- Coil vs clip in 2143 pts with aSAH
- At 1 yr, 23.7% coil and 30.6% clip pts were dead or dependent
- Trial stopped prematurely b/c disability-free survival at one year was better in coiled pts
- Risk of seizures lower in coiled group
- Risk of late rebleeding is low (0.2%)
- GDC approved for all indications in 2003
Trends of Utilization of Coiling vs Clipping, 2000-2006

Alshekhlee A; Stroke 41:1471;2010
Widespread Adaptation

• GOOD
  – More patients being treated endovascularly with lower complication rates
  – Field advances

• BAD
  – “Turf wars”
  – “Hurry up” training programs
  – Little cooperation amongst subspecialties
    • Took one year for Radiology and Neurosurgery to agree to ACGME fellowship name: “Endovascular Surgical Neuroradiology”
Coil Focus

- Longer coil lengths
- Different primary winds
- Larger diameter coil cross-section
- Delivery wire/detachment zone modifications
Onyx Aneurysm Treatment
Flow Diversion

Meta-analysis of UIA and PED Literature (Murthy et al J Clin Neurosciences 2013)

- 13 studies; 905 pts, 1043 aneurysms
- Mean aneurysm diameter = 11.1 mm
- 37% large; 10% giant
- Cumulative mortality rate: 2.3%
- Stroke = 1.9%
- TIA = 2%
- ICH = 2.3%
- 6 m cumulative event rate: 16.7%
- 6 m aneurysm occlusion rate: 79.7%
NICE Recommendations (Nat’l Institute for Clinical Effectiveness)

• Evidence supports its use in pts with giant or complex aneurysms unsuitable for surgery, where large number of coils would be needed for stent-assisted coiling

• Only becomes cost beneficial in cases where >32 coils would be used

• Discussions with clinical experts suggested the number of patients estimated by Covidien to be suitable for treatment with PED was excessively high
Blister Aneurysm of Basilar Artery
Treatment with PED

PRE-PIPELINE

IMMEDIATE POST
Unsubtracted Image of Device
DynaCT With Good Wall Apposition
10 Days Post Pipeline
Day 18 Post Treatment

- Pt awoke with L hemiparesis
- Emergent CTA shows device open, no filling of aneurysm
- Emergent DWI shows R paramedian pontine infarct
35 Days Post Pipeline
35 Days Post Pipeline
35 Days Post Pipeline
Post Stenting with Enterprise
28 and 22
2x1 HS and 8 D Post
With Increased Complexity Comes Increased Risk!
Comparison of NF and ENT Stents in UIA

• 130 UIA
  – 53 ENT, 77 NF
  – 94% technical success rate

• Morbidity
  – 15% ENT, 3% NF (p=0.020)

• Multivariate analysis
  – Use of NF predictive of retreatment (p=0.034)
  – Type of stent was not predictive of clinical outcome as measured by mRS

Durst et al Clinical Radiology 2013
Dual Catheter Technique

• Technique used for wide-necked aneurysms
  – “Weaving” of two coils concurrently
  – Placement of framing coil without detaching followed by filling from second catheter

• Advantages
  – No need for balloon catheter or stent
  – No need for antiplatelet agents
Basilar Tip Aneurysm
Working Projections
1st and 2nd Positions 7 x 20 Penumbra and After Removal of 5 x 9 Penumbra
Coil Retrieval with 4 mm Alligator Snare
Dual Catheter Technique with Stryker XL Coils
Pre 1 (XL 7 x 20)/2(5 x 20 S); 1/4 (3x8 US); 1/5 (2x6 US)
8M Gd MRA MIPs
Dual Catheter Technique

• 100 consecutive pts with wide-necked aneurysms
• Technical success rate: 91%
• Morbidity: 1%, mortality: 2%
• Clinical outcomes
  – 93% demonstrating mRS 0-2 regardless of score at presentation
• Retreatment rate: 18%

Durst et al J Neurosurg Aug 2014
Treatment of Very Small Aneurysms
64 yo F with Ruptured Basilar Tip Aneurysm

2.25 H X 1.8 W X 1.8 D WITH 1.8 NECK
39 yo F with Ruptured Basilar Tip Aneurysm
Follow-Up Study 10 Days Later
Post 18 Months Tx MRA
Corresponding Angiogram
52 yo Male with Ruptured AComA
Dual Catheter Technique
Coil Ball Impingement

3 x 8, 2 x 6 360

1.5 x 3 360
Non-Occlusive Thrombus
Eight Days and Six Months Post Treatment
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Coil Retrieval with 4 mm Alligator Snare
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Dual Catheter Technique
Coil Ball Impingement

3 x 8, 2 x 6 360

1.5 x 3 360
Non-Occlusive Thrombus
Eight Days and Six Months Post Treatment
69 yo F with SAH

5 coils: 5 – 2.5 360 US
Six Month F/U
Progressive Filling

4 x 10 360 US
3 x 6 360 US/2.5 X 4 HEL US
2 X 3 360 US
55 yo F with Recurrence Following Coiling for SAH
“Weaving” of Two Coils
Final Post
Observations

• New tiny, softer coils fills the niche of a complex shape in very small diameter
  – Treat small aneurysms more effectively
    • Prevents multiple manipulations of the aneurysm while trying to find a 2 mm that fits
    • Stable complex neck coverage
    • More robust construct because of radial support
Observations

• Very soft
  – Pack densely within the coil ball in a precise location

• “Plays well with others”
  – Does not displace other coils while packing or retrieving
  – Works well for “weaving” with dual catheter technique
Potential Drawbacks

• “Snaking” in catheter
  – May jam against RHV on guide, injuring the coil
  – More common with longer coils
Take Home Messages

• "Nihil simul inventum est et perfectum" (Nothing is invented and perfected at the same time)
  – Don’t be too eager to “be the first”

• Keep it simple
  – Don’t start with the complex plan
  – Be patient and work that coil

• Recognize that you cannot be all things to all people
  – Have a command of at least one coil system before “trying out” new devices
56 yo M with Strong Family Hx of Ruptured Aneurysms
Working Projections
Pre 1A, Pre 1B
Take Home Messages

• Being involved with a new technology is exhilarating
  – Opens doors to collaboration, publication and invention
  – Protect yourself, your work, your institution and your patients

• Technology isn’t disruptive—people are
Take Home Messages

• Public actions can have personal consequences
  – Working with industry
  – Working with government panels
  – Working with societies

• Be kind to everyone—you never know when you might need their help