How to select guide-wires for challenging CTO crossing?

Dr. Sven Bräunlich

Department of Interventional Angiology
University Hospital Leipzig
Germany

Disclosure

Speaker name:

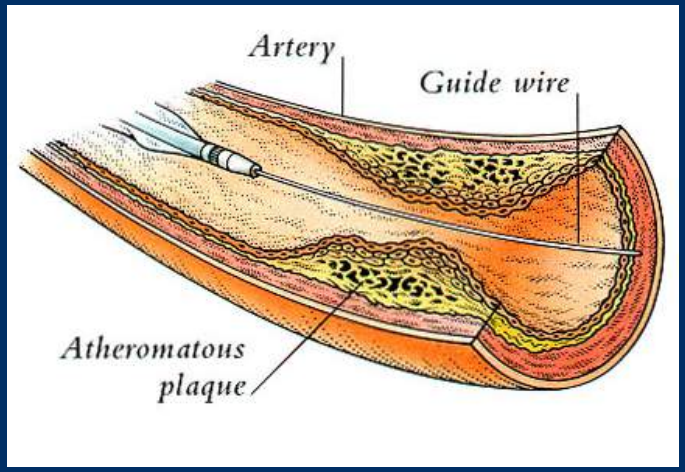
Sven Bräunlich

I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

Guide Wire Usage



Guide wire are used to

Reach treatment area
Access lesion
Cross lesions
Deliver and provide support for devices

If you **can't:**

Access the lesion
Cross the lesion
Deliver devices to and across the lesion

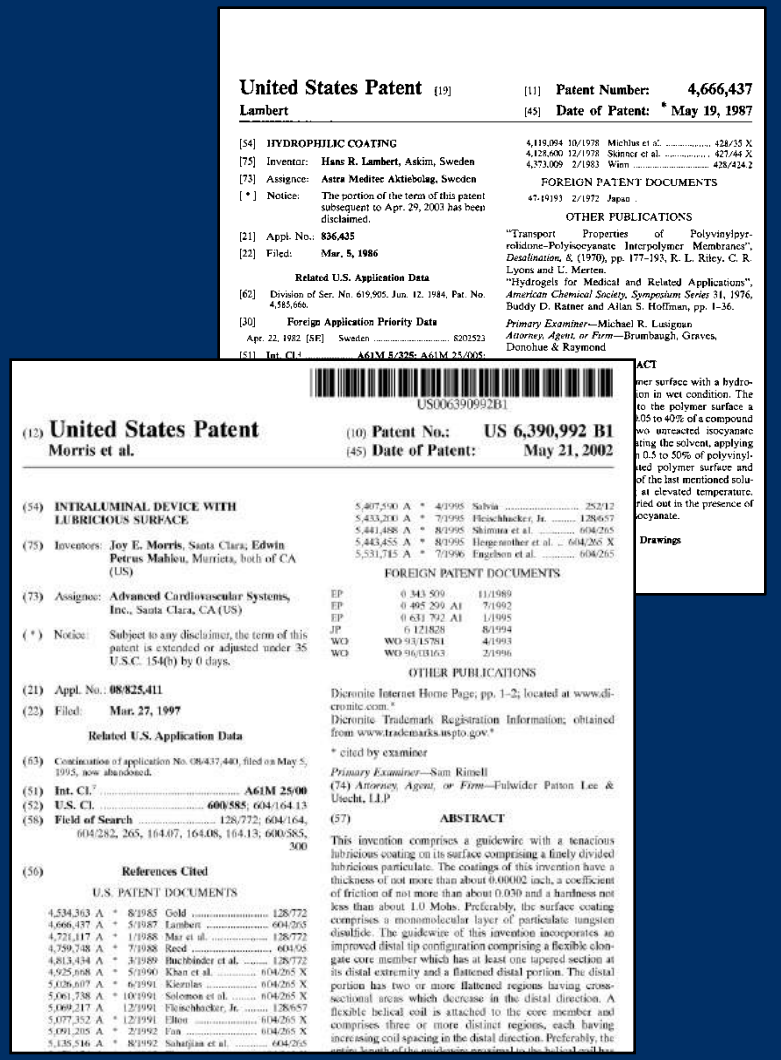
You can't treat the patient!

History

1977: Grüntzig performed 1st coronary angioplasty using a guidewire – balloon unit

1982: Simpson reported 1st independently movable flexible tipped guidewire

Guidewire technology has since advanced with a wide selection for different lesions and vessel anatomies



United States Patent [19]
Lambert

[11] Patent Number: 4,666,437
[45] Date of Patent: * May 19, 1987

[54] HYDROPHILIC COATING
[75] Inventor: Hans R. Lambert, Askim, Sweden
[73] Assignee: Astra Meditec Aktiebolag, Sweden
[*] Notice: The portion of the term of this patent subsequent to Apr. 29, 2003 has been disclaimed.
[21] Appl. No.: 836,435
[22] Filed: Mar. 5, 1986

Related U.S. Application Data
[62] Division of Ser. No. 619,905, Jun. 12, 1984, Pat. No. 4,585,666.

[30] Foreign Application Priority Data
Apr. 22, 1982 [SE] Sweden 8202523

[51] Int. Cl.4 ..... A61M 5/325; A61M 25/005

4,119,094 10/1978 Michlue et al. ..... 428/35 X
4,128,600 12/1978 Skinner et al. ..... 427/44 X
4,373,009 2/1983 Winn 428/424.2

FOREIGN PATENT DOCUMENTS
47-19193 2/1972 Japan .

OTHER PUBLICATIONS
"Transport Properties of Polyvinylpyrrolidone-Polyisocyanate Interpolymer Membranes", *Desalination*, 8, (1970), pp. 177–193, R. L. Riley, C. R. Lyons and U. Merten.
"Hydrogels for Medical and Related Applications", *American Chemical Society, Symposium Series* 31, 1976, Buddy D. Ratner and Allan S. Hoffman, pp. 1–36.

Primary Examiner—Michael R. Lusignan
Attorney, Agent, or Firm—Brumbaugh, Graves, Donohue & Raymond

ACT
...ner surface with a hydro-...ion in wet condition. The ...to the polymer surface a ...0.05 to 40% of a compound ...wo unreacted isocyanate ...ating the solvent, applying ...n 0.5 to 50% of polyvinyl-...ated polymer surface and ...of the last mentioned solu-...at elevated temperature. ...ried out in the presence of ...ocyanate.

Drawings

US006390992B1

(12) United States Patent
Morris et al.

(10) Patent No.: US 6,390,992 B1
(45) Date of Patent: May 21, 2002

(54) INTRALUMINAL DEVICE WITH LUBRICIOUS SURFACE

(75) Inventors: Joy E. Morris, Santa Clara; Edwin Petrus Mahieu, Murrieta, both of CA (US)

(73) Assignee: Advanced Cardiovascular Systems, Inc., Santa Clara, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 08/825,411

(22) Filed: Mar. 27, 1997

Related U.S. Application Data

(63) Continuation of application No. 08/437,440, filed on May 5, 1995, now abandoned.

(51) Int. Cl.7 ..... A61M 25/00
(52) U.S. Cl. 600/585; 604/164.13
(58) Field of Search 128/772; 604/164, 604/282, 265, 164.07, 164.08, 164.13; 600/585, 300

(56) References Cited

U.S. PATENT DOCUMENTS

4,534,363 A * 8/1985 Gold 128/772
4,666,437 A * 5/1987 Lambert 604/265
4,721,117 A * 1/1988 Mar et al. 128/772
4,759,748 A * 7/1988 Reed 604/95
4,813,434 A * 3/1989 Buchbinder et al. 128/772
4,925,668 A * 5/1990 Khan et al. ..... 604/265 X
5,026,607 A * 6/1991 Klemles ..... 604/265 X
5,061,738 A * 10/1991 Solomon et al. ..... 604/265 X
5,069,217 A 12/1991 Fleischhacker, Jr. 128/657
5,077,352 A * 12/1991 Elton ..... 604/265 X
5,091,205 A * 2/1992 Fan ..... 604/265 X
5,135,516 A * 8/1992 Sahatjian et al. 604/265
5,407,590 A * 4/1995 Salvia 252/12
5,433,200 A * 7/1995 Fleischhacker, Jr. 128/657
5,441,488 A * 8/1995 Shimura et al. 604/265
5,443,455 A * 8/1995 Hergenrother et al. ..... 604/265 X
5,531,715 A * 7/1996 Engelson et al. 604/265

FOREIGN PATENT DOCUMENTS

EP 0 343 509 11/1989
EP 0 495 299 A1 7/1992
EP 0 631 792 A1 1/1995
JP 6 121828 8/1994
WO WO 93/15781 4/1993
WO WO 96/03163 2/1996

OTHER PUBLICATIONS

Dicronite Internet Home Page; pp. 1–2; located at www.dicronite.com.*
Dicronite Trademark Registration Information; obtained from www.trademarks.uspto.gov.*

* cited by examiner

Primary Examiner—Sam Rimell
(74) *Attorney, Agent, or Firm*—Fulwider Patton Lee & Utecht, LLP

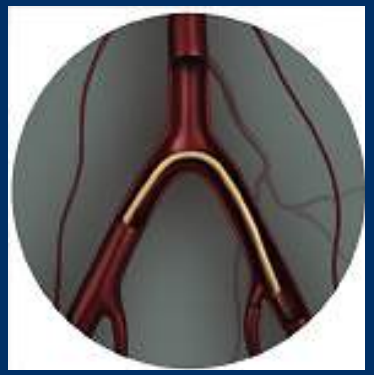
(57) ABSTRACT

This invention comprises a guidewire with a tenacious lubricious coating on its surface comprising a finely divided lubricious particulate. The coatings of this invention have a thickness of not more than about 0.00002 inch, a coefficient of friction of not more than about 0.030 and a hardness not less than about 1.0 Mohs. Preferably, the surface coating comprises a monomolecular layer of particulate tungsten disulfide. The guidewire of this invention incorporates an improved distal tip configuration comprising a flexible elongate core member which has at least one tapered section at its distal extremity and a flattened distal portion. The distal portion has two or more flattened regions having cross-sectional areas which decrease in the distal direction. A flexible helical coil is attached to the core member and comprises three or more distinct regions, each having increasing coil spacing in the distal direction. Preferably, the

Benefits of Understanding Guide Wire Design

There are many different guide wires available for use

Appropriate guide wire selection can make it easier to overcome difficult clinical scenarios



Remember: User experience and familiarity with the guide wire also plays an important role in clinical success!

Questions to Consider

For a select clinical situation…

What guide wire characteristics would be most useful?
Why are those characteristics useful?

What guide wire design features would help provide those characteristics?

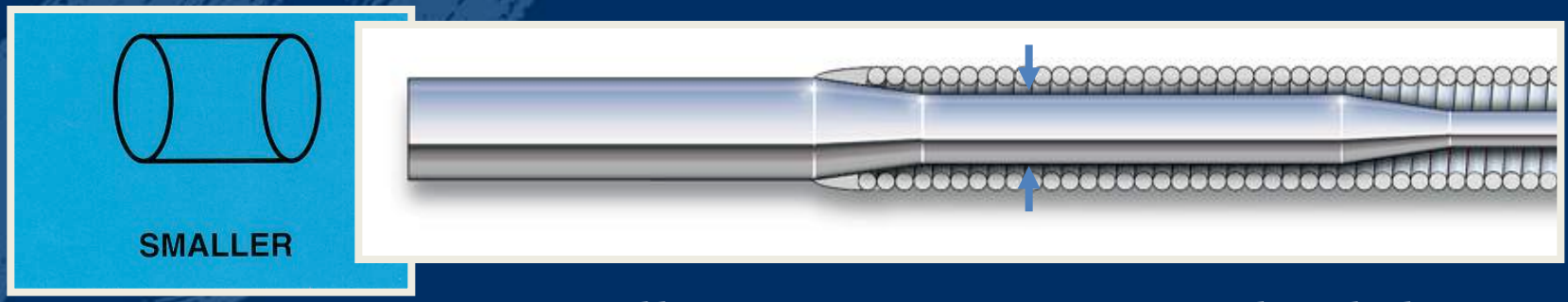
Link between Design Features and Performance Characteristics

PERFORMANCE CHARACTRISTICS	DESIGN FEATURES ("BUILDING BLOCKS")					
	CORE MATERIAL	CORE DIAMETER	CORE TAPER	TIP DESIGN	COVERS & COILS	COATINGS
Flexibility	X	X				
Support	X	X				
Pushability	X	X		X		
Trackability	X	X		X	COILS	X
Steering / Torque Response	X	X			COVERS	X
Tip Shapeability / Reshapeability	X			X		
Tip Visibility					X	
Tactile Feedback				X	X	X

Guidewire Components lead to ***Technical Characteristics*** that affect ***Performance Properties***

Core Diameter

- Diameter affects flexibility, support and torque



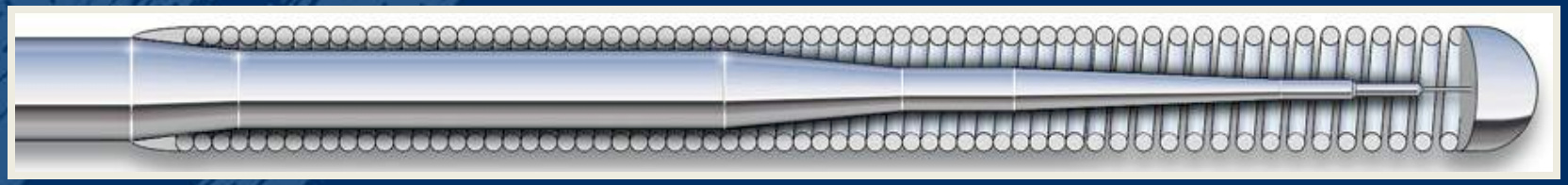
Smaller Diameter = More Flexibility

Larger Diameter = More Support & Torque

Lanzer, P., (2006) Mastering Endovascular Techniques: A Guide to Excellence. Lippincott W. & W., 8: 226-235; Kähler J. et al. Initial Experience With a Hydrophilic-Coated GW for Recanalization of Chronic Coronary Occlusions. Catheterization and Cardiovascular Interventions 49:45–50 (2000)

Core Material

- Affects flexibility, support, steering and tracking



Stainless Steel

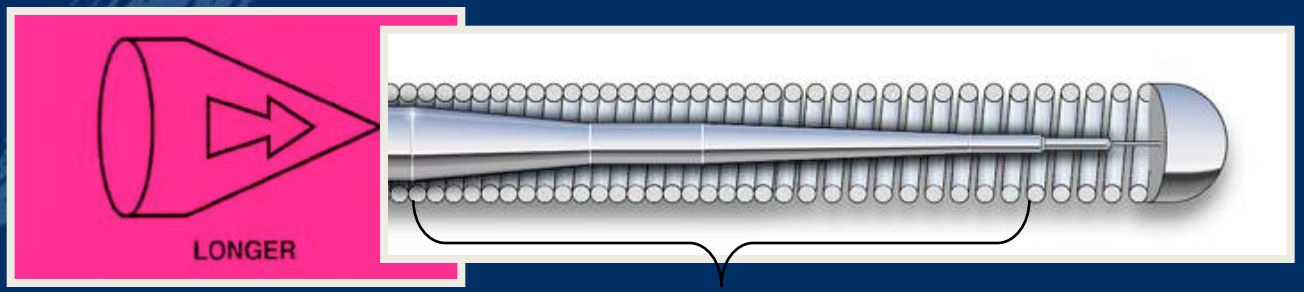
Nitinol

High Tensile Strength Stainless Steel

Lanzer, P., (2006) Mastering Endovascular Techniques: A Guide to Excellence. Lippincott W. & W., 8: 226-235; Kähler J. et al. Initial Experience With a Hydrophilic-Coated GW for Recanalization of Chronic Coronary Occlusions. Catheterization and Cardiovascular Interventions 49:45–50 (2000)

Core Taper / Grind

- Tracking
  Ability of wire body to follow tip around bends
- Degree of support



Longer taper = More Support

Shorter taper = More Flexibility

Lanzer, P., (2006) Mastering Endovascular Techniques: A Guide to Excellence. Lippincott W. & W., 8: 226-235; Kähler J. et al. Initial Experience With a Hydrophilic-Coated GW for Recanalization of Chronic Coronary Occlusions. Catheterization and Cardiovascular Interventions 49:45–50 (2000)

Coatings

Polymer or plastic
Provide lubricity
Smooth tracking through tortuosity
Radiopacity for visualization
Can be put over coils

Polymer Cover

Covers

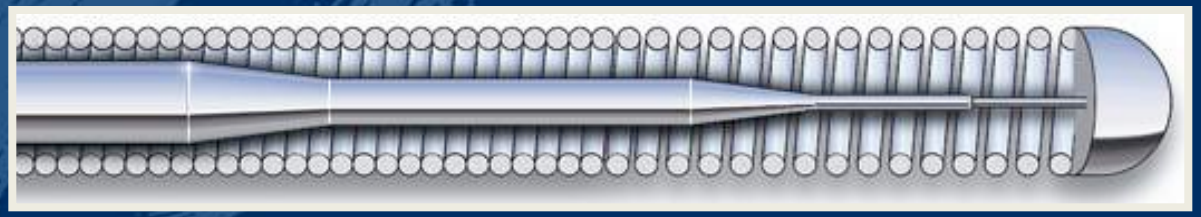
- Affect lubricity and tracking
- Facilitate smooth movement
- Different lengths and location in body of wire
- Types:

Glidewire® Polymer Tip

Lanzer, P., (2006) Mastering Endovascular Techniques: A Guide to Excellence. Lippincott W. & W., 8: 226-235; Kähler J. et al. Initial Experience With a Hydrophilic-Coated GW for Recanalization of Chronic Coronary Occlusions. Catheterization and Cardiovascular Interventions 49:45–50 (2000)

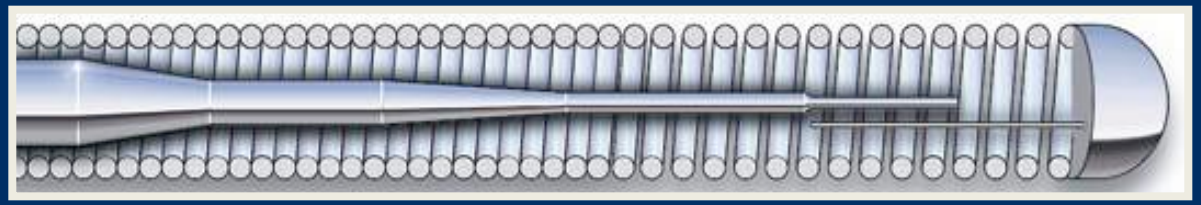
Tip Style

Affects steering
Design options



Core-to-tip

- Precise steering and tip control
- Stiffer to assist with resistant lesions



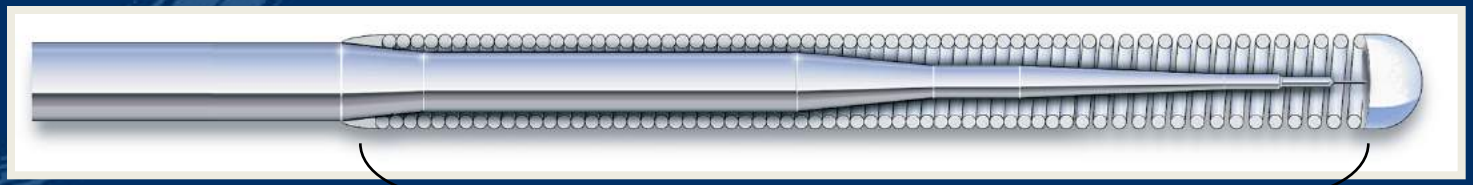
Shaping Ribbon

- Flexible
- Softer tip, gentle
- Allows shape retention

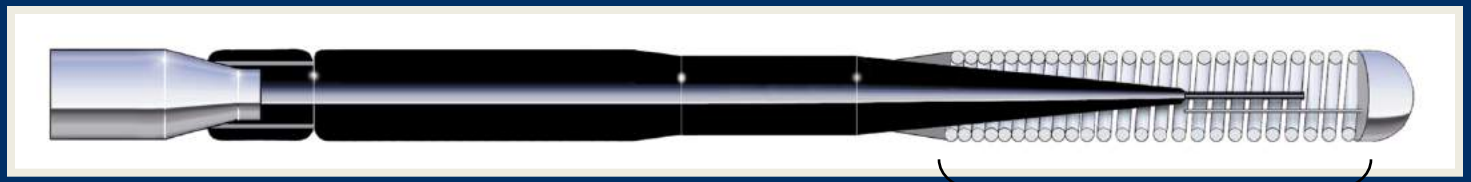
Lanzer, P., (2006) Mastering Endovascular Techniques: A Guide to Excellence. Lippincott W. & W., 8: 226-235; Kähler J. et al. Initial Experience With a Hydrophilic-Coated GW for Recanalization of Chronic Coronary Occlusions. Catheterization and Cardiovascular Interventions 49:45–50 (2000)

Coils

Affect support, steering, tracking and visibility
Impact dimension of wire
Affect tactile feedback



Outer Coils



Tip Coils Only

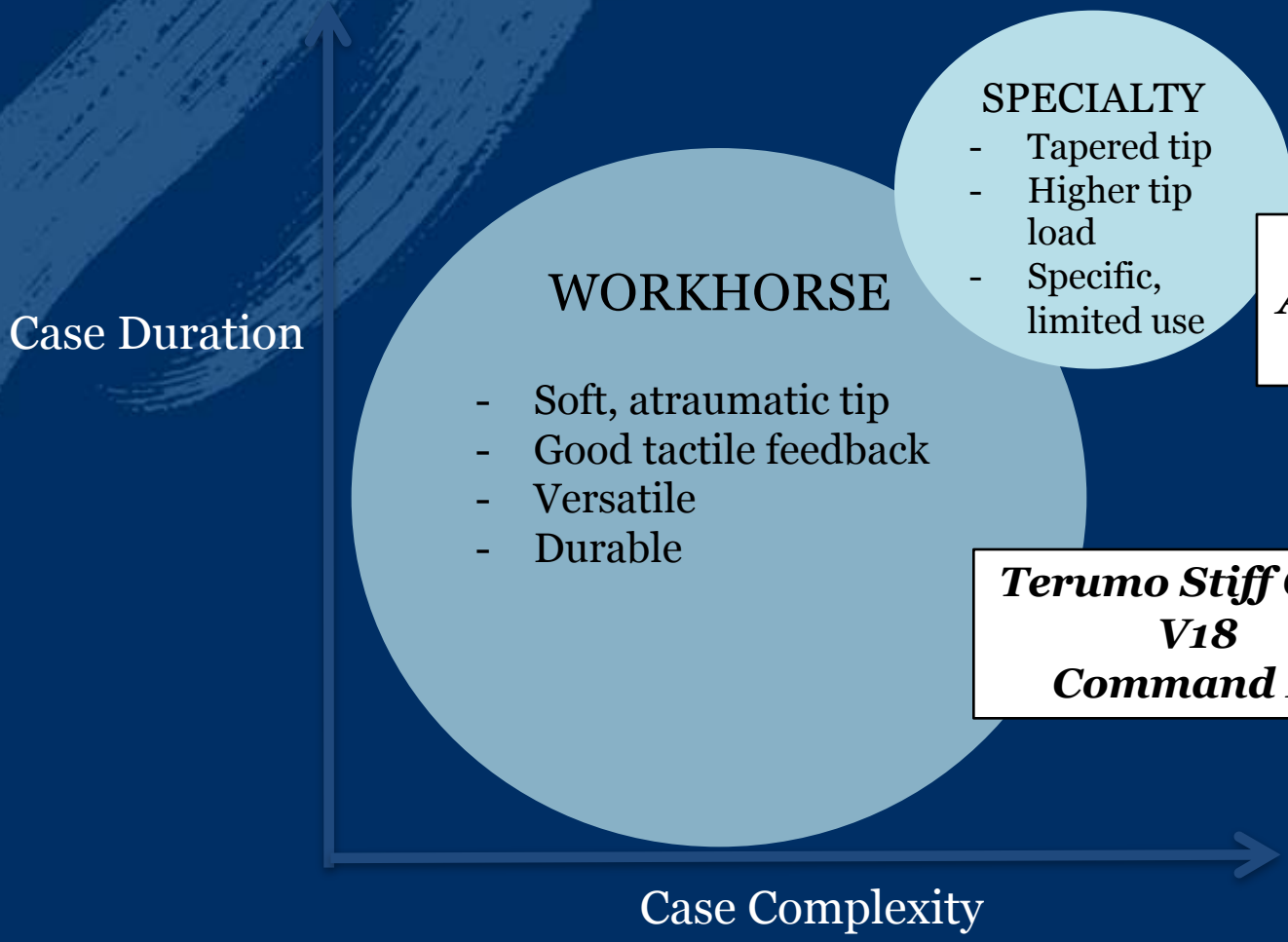
Lanzer, P., (2006) Mastering Endovascular Techniques: A Guide to Excellence. Lippincott W. & W., 8: 226-235; Kähler J. et al. Initial Experience With a Hydrophilic-Coated GW for Recanalization of Chronic Coronary Occlusions. Catheterization and Cardiovascular Interventions 49:45–50 (2000)

Sounds like a lot of wires, but easiest way to think about them is to break them into (1) CATEGORIES and (2) PLATFORMS

(1) Main Categories

Workhorse	**Specialty**
• Access wire • "Go-to" wires • Soft tip atraumatic wires	• CTO wires • Device delivery wires

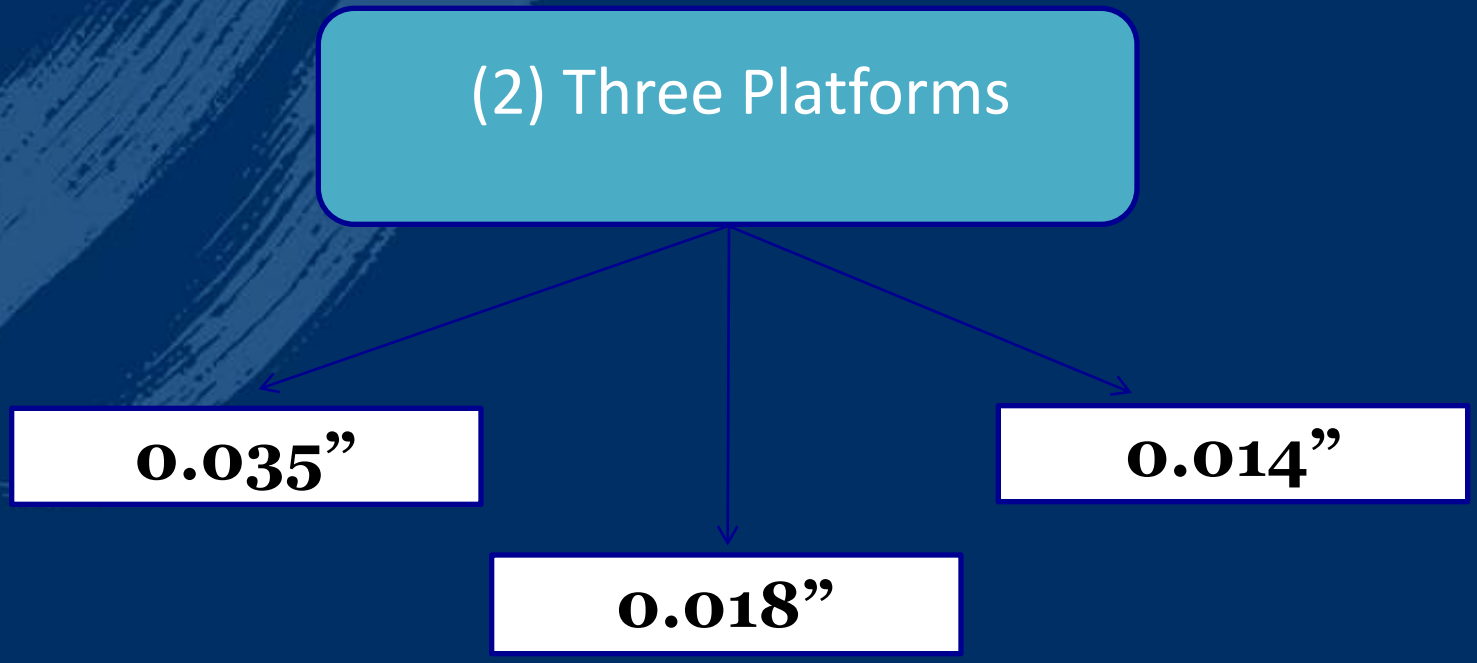
Guidewire Selection Strategy :
Dependent on procedural steps and complexity



Terumo Stiff Glide
V18
Command ES

Connect 250T
Asahi Treasure/Astato
Victory

Sounds like a lot of wires, but easiest way to think about them is to break them into (1) CATEGORIES and (2) PLATFORMS



Personal preference vs. different wire for different purposes?

Platform Usage by Anatomy

ILIAC

0.035" PLATFORM

- Designed to provide highest support and stability
- Compatible with iliac treatment platforms

SFA

0.035" PLATFORM

- Designed to provide highest support & stability
- Compatible with most SFA balloons/stents

0.018" PLATFORM

- Less traumatic
- Well suited to distal SFA/popliteal
- More steerable and flexible
- Supports lower profile devices
- Supports Supera

0.014" PLATFORM

- Least support
- May be useful in some situations e.g., re-entry

BTK

0.014" PLATFORM

- Most suitable for small vessels
- Compatible with lowest profile balloons

0.018" PLATFORM

- Specific feature needed, i.e., high support, good device crossing

Example of a Case-Based Wire Selection Strategy

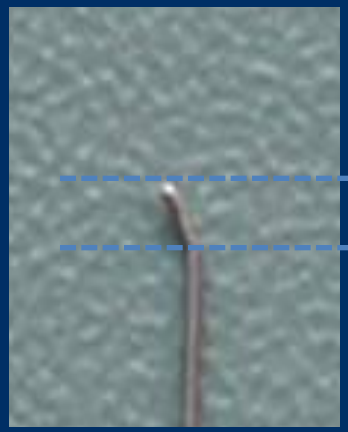
Intraluminal GW-Passage
to avoid problems with reentering

Start with 0.018“ work-horse GW
(V18, Command 18)
for intraluminal passage

More drilling than
pushing the GW

In case of failure of the work horse GW: CTO-Guidewires are used (high tip load/penetration power)

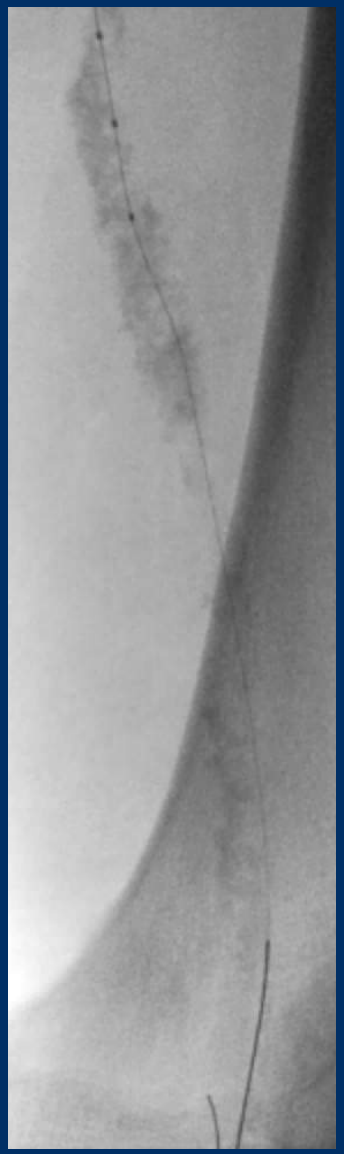
Tip-bending:



However,
after successfully
passing the GW through
calcified fempop
occlusions,

other problems
may be encountered
with intraluminal GW-passage

Impossible to follow with a balloon or support-catheter



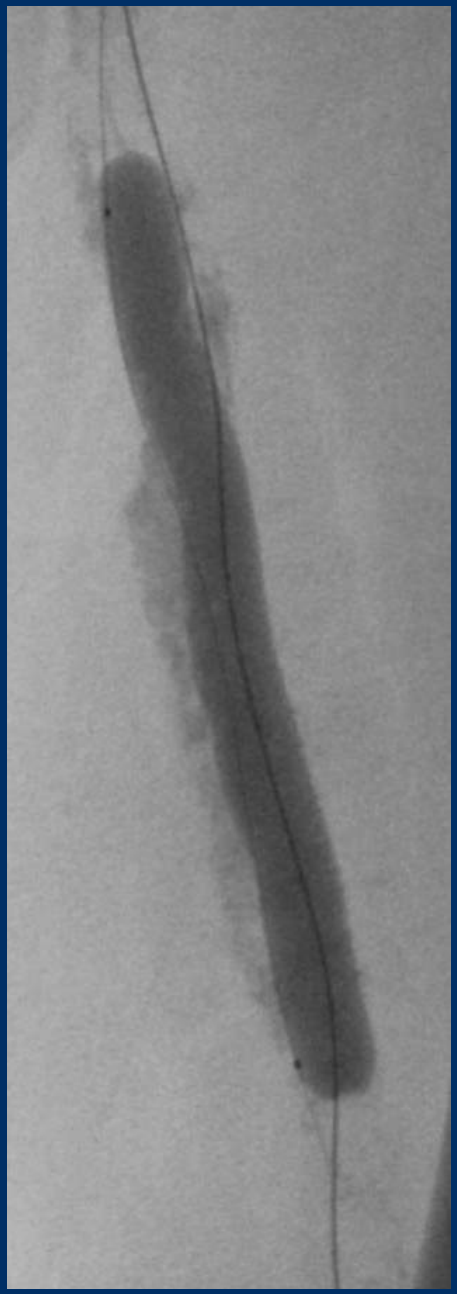
Exchange to a 0.014“ GW (through channel created by the 0.018“ GW)

for Ultra-low profile predilatation balloons

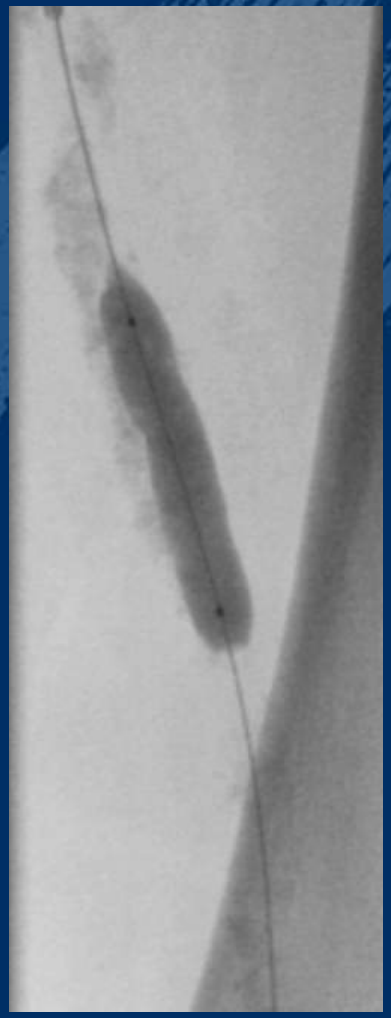
Followed by scoring balloon

Semi-compliant balloon with two external wires delivers focused force along the length of the balloon

Vessel preparation for further treatment



Intraluminal Recanalisation of Calcified = Complex Fempop-CTOs



After pre-dilatation and vessel preparation ...

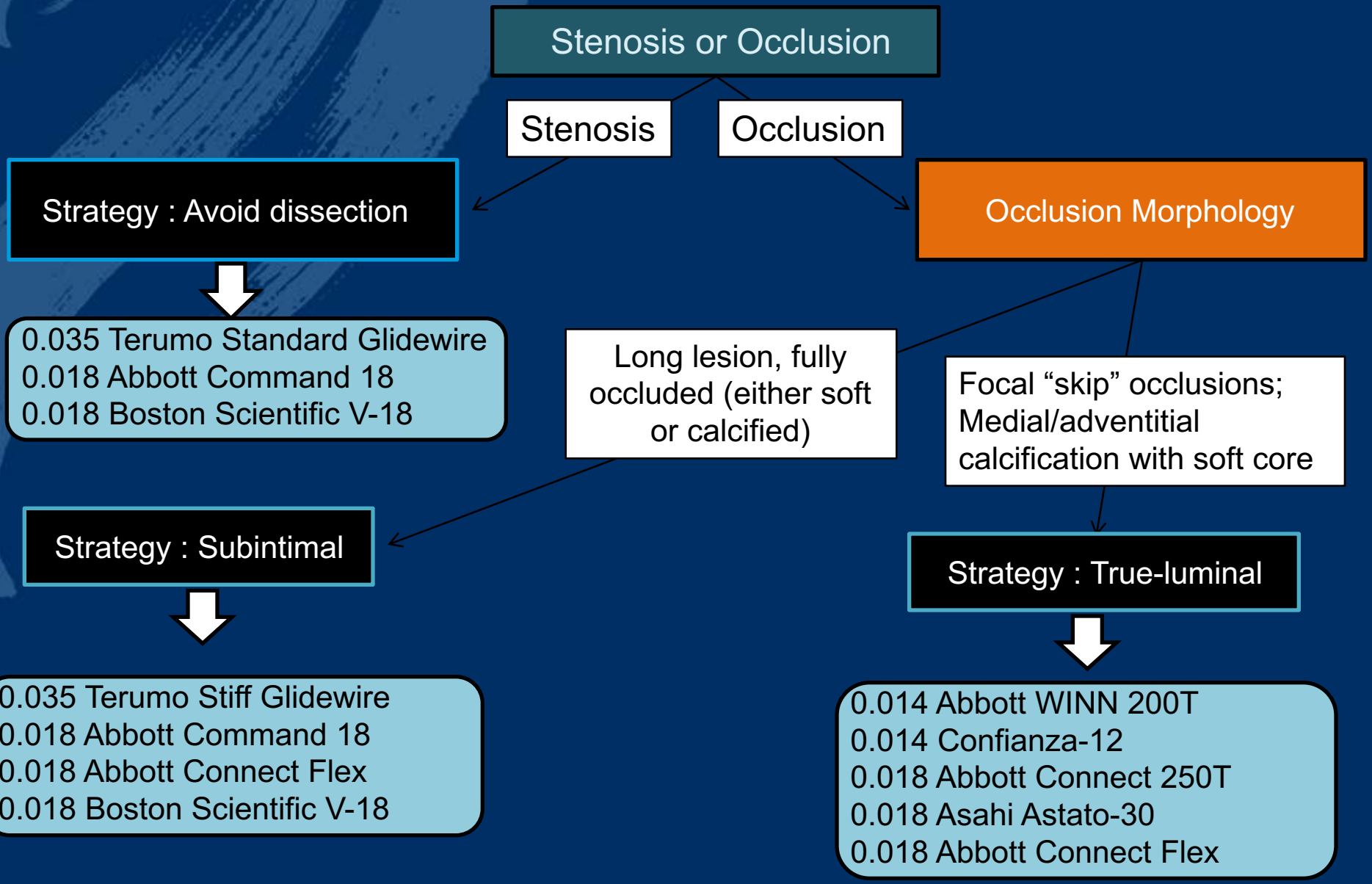
Ultra non-compliant high pressure PTA balloon

DCB

Supera

... on 0.018“ GW platform

Case/Lesion-Based Wire Selection Strategy Fem-Pop



Case-Based Wire Selection Strategy:
0.018 Guidewire Platform

Low profile tip + high gram tip load = increased penetration power and increased ability to exploit microchannels present in most CTOs

Wire	Make	Core	Tip Load	Support	Penetration
Victory®	Boston	Stainless	12, 18, 30gm	++	++/+++
HT Connect®	Abbott	Stainless	4gm	++	++
HT Connect® Flex	Abbott	Stainless	12gm	+	+
HT Connect® 250T	Abbott	Stainless	30gm	+++	+++
Astato® 30	Asahi	Stainless	30gm	+++	+++
Treasure® 12	Asahi	Stainless	12gm	++	++

Larger number of “specialty wires” in the 0.018” platform

Summary & Conclusions

- Guide wire selection depends on lesion, location, and strategy
- An increasing array of available wires has increased our ability to cross lesions and delivery therapy
- Understanding wire construction leads to an increased understanding of a specific wire's performance properties, and helps us choose the proper wire for the specific goal.