

## State of art: 40 years of interventional cardiology Angelo Sante Bongo



### Aforisma di Winston Churchill



"Il successo è la capacità di passare da un insuccesso all'altro senza perdere l'entusiasmo"

"L'ottimista vede l'opportunità in ogni pericolo ,il pessimista vede pericolo in ogniopportunità

### First cardiac catheterization in a horse by Chauveau and Marey



Etienne Jules Marey (1830–1904)



Auguste Chauveau (1827–1917)



### Curves recorded by Chauveau and Marey

Cette figure 6 représente les tracés (n° 1) de l'oreillette, (n° 2) du ventricule, (n° 3) de la pulsation cardiaque.—Les mouvements son egistrés pendant quatre révolutions du cœur. — Les tracés se lisent de gauche à droite, comme l'écriture ordinaire. Nous don



# • Catheter introduced by Chauveau and Marey into the left ventricle via the left carotid



### Werner Forssmann (1904-79)



The first vessel catheterization was performed in 1929

### The Nobel Prize in Medicine or Physiology: October 1956





### André Cournand (1895-1988)







### Sven-Ivar Seldinger (1921-98)





#### Mason Sones Jr (1918-85)







### Preformed coronary catheters: design, shapes and techniques



### First X-ray picture obtained by Roentgen: the hand of his wife



• First coronary angiography in a dog, obtained during cardiac arrest through an anaesthetic accident (Arnulf 1956)





(1921-2016)



Fig. 16 – A) Frontespizio della monografia nella quale è stato pubblicato per la prima volta (1952) l'aspetto radiologico delle arterie coronarie visualizzate con mezzo di contrasto. B) Alcune immagini contenute nel volume.

ACTA RADIOLOGICA SUPPLEMENTUM 97

#### A ROENTGENOLOGIC STUDY OF THE CORONARY ARTERIES IN THE LIVING

LUCIO DI GUGLIELMO and MARIANO GUTTADAURO

STOCKHOLM 1952



### René Favaloro (1923–2000)



#### **Charles Theodore Dotter (1920-85)**



His first arterial recanalization was unintentionally performed in 1963. Using an abdominal aortography to assess a renal artery stenosis, he saw, with shock and awe, that he had actually –involuntarily– recanalized an

PHILIPPE GASPARD

The first intentional transluminal angioplasty was performed on **January 16, 1964** on an 82year-old female patient suffering from a left leg ulcer with gangrenous toes who refused amputation.

Charles Dotter and Bill Cook met at the annual meeting of the Radiological Society of North America (RSNA), which took place that year in Chicago and Bill Cook began manufacturing a "Dotter dilatation kit", consisting of two stiff coaxial Teflon catheters, size 8 Fr (2.7 mm) and 12 Fr (4.0 mm).

### Eberhard Zeitler (1930-2011)



He contributed to the development of Dotter's method in Europe, which allowed Andreas Grüntzig to create a balloon catheter in 1974 and to perform the first coronary dilatation in 1977

### He performed the first peripheral angioplasty in Germany in 1968.



He organized the first international angioplasty meeting in Nürnberg, where **he met Charles Dotter and Andreas Grüntzig**. Unlike his colleagues Werner Forssmann and Charles Dotter, Eberhard Zeitler was recognized and appreciated for his clinical activities and his influence on interventional radiology during his lifetime. **He contributed to the development of Dotter's method in Europe**, which allowed Andreas Grüntzig to create a balloon catheter in 1974 and to perform the first coronary dilatation in 1977



#### THE HISTORY OF CORONARY ANGIOPLASTY PHILIPPE GASPARD

### Andreas Roland Gruentzig (1939–1985)







**ANDREAS GRÜNTZIG AND THE CONCEPT OF A BALLOON CATHETER** Andreas Roland Grüntzig (1939-85) was born in Dresden, Germany, the provincial capital of Saxony. Dresden is a beautiful baroque city on the banks of the river Elbe, referred to as the "Venice of the North" for its cultural life and art collections. As were Werner Forssmann and Eberhard *Zeitler, he was a man originally from the* east of Germany. Three key periods can be identified in his life: **P***An itinerant youth related to the* consequences of World War II (1939-69) The Zurich years (1969-80)

Departure to America (1980-85).

#### Maria Schlumpf





The **first angioplasty in Zurich using the Dotter technique was performed** by Eberhard Zeitler with Andreas Grüntzig **in December 1971**. .....In front of skeptical radiologists, the procedure ended abruptly due to an embolization of atheromatous plaque into the popliteal artery. It confirmed the opinion of the radiologists present that this method had no place for use in humans.

Maria removed every obstacle she possibly could, and anyone criticizing him was met with tremendous opposition from her. Andreas's charisma and personality allowed him, once again, to resist adversity and skepticism. When anyone told him: **"Don't go there!"**, the man who had dedicated his life to vascular disease responded: **"Just stop me!"** 

#### THE HOME-MADE CATHETER BALLOON



From left to right: Michaela Gruentzig, Walter Schlumpf, Maria Schlumpf, Andreas Gruentzig



the Swiss company of Hugo Schneider (which employed Helmuth Schmid, and who would later be fired for doing freelance work with Andreas Grüntzig) agreed to manufacture Andreas Grüntzig's **balloon catheters starting in the second half of 1976.** 



• Initial site of Schneider Medintag in the late 1970s, at the time the only producer of coronary angioplasty balloons



 Initial single lumen balloon catheter used by Gruentzig for peripheral angioplasty





•Macroscopic (left) and microscopic (right top) aspect of the first coronary angioplasty performed in a dog in 1975. One month later: inner healing but potential for restenosis by intimal proliferation (right bottom)



 First coronary balloon catheter as used in the initial series of patients

### Documentation of the first coronary angioplasty procedure



**In September 1977**, a 38-year-old man (the same age as Andreas Grüntzig), suffering from unstable angina with a positive stress test due to an isolated stenosis of the left anterior descending coronary artery (LAD), enthusiastically accepted to be the first patient treated with this new therapeutic approach, an approach which promised to allow him to avoid coronary bypass graft surgery

• First coronary angioplasty lesion (circles) two days before (A), immediately after (B), and one month after (C) balloon dilatation

The first coronary angioplasties in Zurich





• Final live course in Zurich with about 200 participants

• Follow-up at 20 years of the first patient of Andreas Gruentzig with a live exercise test during a primetime Swiss television show





•Maximal exercise test of the first patient 23 years after the procedure during work-up of some ill-defined chest discomfort at rest in the morning

### Coronary angiogram of the first patient on 10 April 2000



• Sixth coronary angiogram of the patient on 7 December 2000 showing severe in-stent restenosis of the new site, with the initial site of Gruentzig still looking perfect (left upper panel)



### •Andreas Roland Gruentzig a few days before his fatal plane crash in October 1985










## Geoffrey Hartzler (1946–2012)



BEFORE DISTAL test BALLOON J 20-30 AFTER

World's first balloon angioplasty for a myocardial infarction –Kansas City, MO, USA –Geoffrey Hartzler, August 1980 (Courtesy Barry Rutherford) ♥ In 1982, Geoffrey Hartzler shared his experience with **multivessel disease patients**. The dilatation of several lesions **in one session** yielded immediate results that were comparable to bypass surgery.

♥ In 1983, following Peter Rentrop and Jürgen Meyer, Geoffrey Hartzler recommended coronary angioplasty be performed immediately as the treatment of choice in acute myocardial infarct patients – this would later be called ST-segment Elevation Myocardial Infarction (STEMI).

♥The "genius Prophet", Geoffrey Hartzler had envisaged the invaluable contribution of angioplasty for the treatment of heart attacks, resolving the problem simply and effectively as well as drastically reducing the hospital stay.

He also thought that coronary angioplasty could be carried out immediately after coronary arteriography.

## **PAMI trial**

The direct (immediate angioplasty) approach for acute myocardial infarction was investigated in the PAMI[88] (Primary Angioplasty in Myocardial Infarction) trial in **1997.** Compared with thrombolytic therapy (t-PA), primary balloon angioplasty reduced inhospital mortality from 7.2% to 2.3% (p=0.03). So coronary angioplasty cut the acute myocardial infarction mortality compared with intravenous thrombolytic therapy by two thirds.



### **TABLE IV** Progress in Balloon Angioplasty

1977	Andreas GRÜNTZIG	5 mm fixed wire tip	
1980	Peter RENTROP	Intracoronary thrombolysis	
1981	John SIMPSON	Steerable guide wire	
1983		8F Guiding catheter	
1984	Martin KALTENBACH	Long-wire technique	
	Bernhard MEIER	Kissing balloon	
1985	Richard STACK	Reperfusion catheter	
1986	Tassilio BONZEL	Monorail system	
	Raimund ERBEL	Perfusion balloon	
	Jacques PUEL	Bare metal stent	

### Tassilo Bonzel, inventor of the monorail system

First freehand sketch of the sliding rail balloon coronary dilatation catheter (later "monorail"), drawn in 1983





## Directional atherectomy catheter of John Simpson

### Atherectomy and las



• Proximal LAD lesion before (above) and after (below) DCA





## • Treatment of saphenous vein graft lesions with the TEC

## Rotablator



## Alexis Carrel (1873-1944)



. He was awarded the **Nobel Prize in Physiology or Medicine at the age of 40.** What he predicted in 1910 came true: **"I am a creator of techniques,** 

it's up to others to use them"..

**BALLOON ANGIOPLASTY LIMITATIONS** 

After the first experimental canine coronary dilatations of Andreas Grüntzig on October 22, 1975, the two pitfalls of coronary angioplasty were clearly identified with regard to histological findings:

 occlusive dissection was observed in 2 to 10% of cases,

 and restenosis was observed in 20 to 57% of cases.

To prevent these two problems, an intraluminal scaffolding sustaining a **permanent radial force** was proposed in order to treat dissections and prevent elastic recoil of the arterial wall.

Stenting also appeared interesting for stabilizing the plaque of the culprit lesion in acute coronary syndromes and to prevent thrombus formation, allowing for myocardial protection. **Charles Theodore Dotter** (14 June 1920 – 15 February 1985)



The inappropriate use of the term "stent" to the design of an endoprosthesis is attributed to an English dentist, Charles Thomas Stent (1807-85), who had improved a dental impression compound in order to fill gaps caused by treating root canals

## Concept of arterial scaffolding for the treatment of dissections and subsequent coronary thrombosis



• The self-expanding Wallstent constrained by a doubled-over membrane on the delivery device and half-way through delivery



The meeting in **1980** between two Swedish expatriates in Switzerland marked the beginning of the "Saga of the Stent". Ake Senning, who had supported Andreas Grüntzig in his project to dilate coronary arteries, was trying to find a device to treat aortic dissections. He came in contact with the engineer **Hans Wallsten**, who had made his fortune in a printing factory. Hans took up the challenge and proposed producing a double helix metal device which would provide support to the artery



The world's first human implantation of a coronary artery endoprosthesis, March 28, 1986, Toulouse, France– Hervé Rousseau, Francis Joffre and Jacques Puel (Courtesy Hervé Rousseau)



Angiographic pre- (A), immediately post- (B) and at 12-year follow-up (C) of the first patient to undergo a Wallstent implantation (Courtesy Jacques Puel)



World's first stenting for acute occlusion during PTCA: before PTCA, during PTCA, after stenting – The agony and the ecstasy (Courtesy Ulrich Sigwart)

**June 12, 1986** 



## Balloon-expandable Palmaz-Schatz stent



In May of 1987, the first Palmaz stent, designed for peripheral vessels, was implanted in a human iliac artery by Julio Palmaz and Goetz Richter, a radiologist in Freiburg, Germany. This was 17 months after the implantation of the first Wallstent in an iliac artery. On December 10, 1987, the first Palmaz-Schatz stent, designed for coronary vessels, was implanted in a human coronary artery by Eduardo Sousa, Julio Palmaz and Richard Schatz in Sao Paulo, Brazil – 21 months after the implantation of the first coronary Wallstent



### Angiographic follow-up after placement of a self-expanding coronary-artery stent.

Serruys PW1, Strauss BH, Beatt KJ, Bertrand ME, Puel J, Rickards AF, Meier B, Goy JJ, Vogt P, Kappenberger L, et al.

#### Author information

#### Abstract

**BACKGROUND:** The placement of stents in coronary arteries after coronary angioplasty has been investigated as a way of treating abrupt coronary-artery occlusion related to the angioplasty and of reducing the late intimal hyperplasia responsible for gradual restenosis of the dilated lesion.

**METHODS:** From March 1986 to January 1988, we implanted 117 self-expanding, stainless-steel endovascular stents (Wallstent) in the native coronary arteries (94 stents) or saphenous-vein bypass grafts (23 stents) of 105 patients. Angiograms were obtained immediately before and after placement of the stent and at follow-up at least one month later (unless symptoms required angiography sooner). The mortality after one year was 7.6 percent (8 patients). Follow-up angiograms (after a mean [+/- SD] of 5.7 +/- 4.4 months) were obtained in 95 patients with 105 stents and were analyzed quantitatively by a computer-assisted system of cardiovascular angiographic analysis. The 10 patients without follow-up angiograms included 4 who died.

**RESULTS:** Complete occlusion occurred in 27 stents in 25 patients (24 percent); 21 occlusions were documented within the first 14 days after implantation. Overall, immediately after placement of the stent there was a significant increase in the minimal luminal diameter and a significant decrease in the percentage of the diameter with stenosis (changing from a mean [+/- SD] of 1.88 +/- 0.43 to 2.48 +/- 0.51 mm and from 37 +/- 12 to 21 +/- 10 percent, respectively; P less than 0.0001). Later, however, there was a significant decrease in the minimal luminal diameter and a significant increase in the stenosis of the segment with the stent (1.68 +/- 1.78 mm and 48 +/- 34 percent at follow-up). Significant restenosis, as indicated by a reduction of 0.72 mm in the minimal luminal diameter or by an increase in the percentage of stenosis to greater than or equal to 50 percent, occurred in 32 percent and 14 percent of patent stents, respectively.

CONCLUSIONS: Early occlusion remains an important limitation of this coronary-artery stent. Even when the early effects are beneficial, there are frequently late occlusions or restenosis. The place of this form of treatment for coronary artery disease remains to be determined.



The results of the first **105 patients** in the first six centers implanted with a Wallstent between March 1986 and January 1988 were published in 1991. **Stent occlusion occurred in 24%** of the patients. The total restenosis rate was 32%, but only 14% of the cases remained patent at angiographic followup.

### Rusty in retirement, as a pet of Julio Palmaz



In December 1993, the FDA would not approve the Palmaz-Schatz stent without a randomized trial, even though this had not been required for the Gianturco-Roubin 10 months earlier, nor for two different additional types of devices: laser and rotational atherectomy. **The "Stent war" would finally be won by Julio Palmaz and Johnson & Johnson in August 1994 with the final FDA approval for the Palmaz-Schatz coronary balloon-expandable stent**.

## First stent trial(s)

1989, two randomized multicentre studies (STRESS and BENESTENT) comparing POBA to elective Palmatz-Schatz stenting. In these studies, 20% to 30% reduction in clinical and angiographic restenosis compared with POBA. Palmatz-Schatz stent approved by the FDA in 1994



Due to its high rates of restenosis, the Cook Gianturco-Roubin stent failed equivalency to the Palmaz-Schatz

## **Gianturco-Roubin stent: Outdated**



Cesare Gianturco and Gary Roubin developed a balloon-expandable coil stent consisting of a wrapped stainless steel wire resembling a clamshell

Particular mention should be given to the Cook Gianturco-Roubin stent, which was the first balloon-expandable stent implanted in a human coronary artery by Gary Roubin This took place in Atlanta, on **September 3**, **1987**, **three months before the first Palmaz-Schatz stent**.



### Development

## • First stents by EDM

For Michael Poon, [90] four phases could be distinguished in the vascular response to balloon dilatation:

> The mechanical phase of elastic recoil expansion of the vessel;



The thrombogenic phase of mural thrombus formation due to local hemorrhage; DAP

The proliferative phase of neointimal hyperplasia due to smoothmuscle cell proliferation;

The constrictive remodeling phase due to change of the cellular and protein content in the vessel wall.

### Intracoronary Stenting Without Anticoagulation Accomplished With Intravascular Ultrasound Guidance

by Antonio Colombo, Patrick Hall, Shigeru Nakamura, Yaron Almagor, Luigi Maiello, Giovanni Martini, Antonio Gaglione, Steven L. Goldberg, and Jonathan M. Tobis



*Conclusions* The Palmaz-Schatz stent can be safely inserted in coronary arteries without subsequent anticoagulation provided that stent expansion is adequate and there are no other flow-limiting lesions present. The use **of high-pressure final balloon dilatations** and **confirmation of adequate stent expansion** by intravascular ultrasound provide assurance that anticoagulation therapy can be safely omitted. This technique significantly reduces hospital time and vascular complications and has a low stent thrombosis rate.

*Circulation* Volume 91(6):1676-1688 March 15, 1995



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### Example of intravascular ultrasound-guided coronary stent implantation.



Antonio Colombo et al. Circulation. 1995;91:1676-1688



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### A, Baseline angiogram demonstrates a proximal right coronary artery stenosis (arrow).



Antonio Colombo et al. Circulation. 1995;91:1676-1688



## Antiplatelet therapy and stent thrombosis

In reviewing the chronology of events, it appears that:

The idea of a loading-dose was proposed by Carl White in 1985; The efficacy of ticlopidine was identified by Paul Barragan in 1986; The superior efficacy of dual antiplatelet therapy in stable coronary artery disease was demonstrated by Raffaele de Caterina in 1991; The systematic dual antiplatelet therapy for stent thrombosis prevention was implemented from 1992 in the French study, directed by Marie-Claude Morice, and was validated in 1996.

Ticlopidine (250 mg) was replaced by **clopidogrel (75 mg) from 1999** onwards, as it was more effective in the reduction of major cardiac events (including deaths) and better tolerated. **The combination of clopidogrel with aspirin became the standard of care and was used for all stent implantations.** We just excluded patients allergic to aspirin, or intolerant to clopidogrel. The arrival of prasugrel and ticagrelor changed the situation.



BMJ VOLUME 326 17 MAY 2003 bmj.com

**Evoluzione degli stent DES** 

- 1. THE FIRST-GENERATION WITH A DURABLE POLYMER: CYPHER AND TAXUS
- 2. THE TWO FAMILIES OF ANTIPROLIFERATIVE AGENTS (Sirolimus Paclitaxel)
- 3. "STORM AT ESC 2006": LATE-STENT THROMBOSIS
- 4. THE SECOND-GENERATION DES WITH THIN STRUTS AND THIN DURABLE POLYMERS
- 5. THE THIRD-GENERATION DES WITH BIODEGRADABLE POLYMERS
- 6. THE FOURTH-GENERATION DES WITH POLYMER-FREE DRUG CARRIER SYSTEM
- 7. THE FIFTH-GENERATION WITH NOVEL STENT COATING

### **TABLE IX** Results Achieved with Durable Polymer Coated Stents

	ANGIOGRAPHIC RESULT	CLINICAL EFFICASY	STENT THROMBOSIS	
SES/PES	SUPE	RIOR		BMS
SES	SUPE	RIOR		PES
EES	SUPE	RIOR		BMS
EES		PES		
EES	NON IN	FERIOR	NO DIFFERENCE	SES
ZES	INFERIOR			SES/PES
ZES		NO DIFFERENCE		PES
R-ZES	NO DIFFERENCE	NON INFERIOR		EES

Left hand column is compared to right hand column

BMS = Bare metal stent

EES = Everolimus-eluting stent

PES = Paclitaxel-eluting stent

SES = sirolimus-eluting stent

ZES = Zotarolimus-eluting stent (Endeavor)

R- ZES = Zotarolimus-eluting stent (Resolute)

### TABLE XI Angioplasty with the Stent

1992	Concern with arrival of bare metal stent					
	Occlusive dissections treatment					
	But disadvantage of anticoagulation					
	Frequency of sub-acute thrombosis					
	Bleeding complications					
	8 day hospital stays					
1996	Peace of mind with implantation of bare metal stent					
	6F guiding catheters					
	Dual antiplatelet therapy					
	Digital image optimization					
	Questioning of surgical stand-by					
2002	Arrival of drug-eluting stent					
	Autonomy					
	Restenosis becomes secondary					
	Optimization of bifurcation strategy					
	Comfort level in treating left main stenosis					
2006	Further advances					
	Thrombectomy					
	Retrograde approach to total chronic obstructions					
	FFR					
	OCT					
2012	Bioresorbable vascular scaffold					

### **TABLE XIII** Bioresorbable Scaffolds

NAME	PL	ATFORM	DRUG	POLYMER		COMPANY
	MATERIAL	STRUT THICKNESS		COATING	RESORPTION MONTHS	
Absorb BVS	PLLA	156	E	PDLLA	24-36	Abbott Vascular
ART PBS	PLLA	170	S	PLA	18-24	Arterial Remodeling Technologies/ Terumo
Biolute	PLLA	108	S	Nanocarrier	24	Envision Scientific
DESolve	PLLA	150	M/N	PDLLA	12-24	Elixir Medical
Fantom	TP	125	S	-	36	REVA Medical
Firesorb	PLLA	100-125	S	PDLLA		Microport Medical
Fortitude	PLLA	150	S	PDLLA	12-24	Amaranth Medical
ON-AVS	PLA	150	S	EPC capture	6	OrbusNeichMedical
Ideal Biostent	SAAA	200	S	Salicylate	6-9	Xenogenics
Igaki-Tamai	PLLA	170	none	non	24-36	Kyoto Medical
Magmaris	Mg	150	S	PLLA	12	Biotronik
Manli	PLA	120	S	PLA	12	Mirage
MeRes100	PLLA	100	S	PDLLA	24	Meril Life Sciences
Mirage	PLLA	125	S	_	14	Manli Cardiology
NeoVas	PLLA	160	S	PDLLA	36	Lepu
Xinsorb	PLLA	160	S	PDLLA	36	Huan Biotechnology

### **TABLE XIV** Stenting and other Advances in Coronary Angioplasty

YEAR	STENTS	ASSOCIATED TECHNIQUES	ACCESS		ANTITHROMBOTICS
1986	WALLSTENT	Directional atherectomy			Aspirin Coumadin
	Bare metal stent				
1988		Rotablator			
1989				IVUS	
1990					
1993		Cutting balloon	Radial Angioseal	FFR	
1994		Vascular brachytherapy	6 F		Anti-GP IIb/IIIa
			Perclose		
1995					
1996					Aspirin Ticlopidine
1998	IGAKI TAMAI				
	Bioresorbable stent				
1999	CYPHER	Coronary filters			Aspirin Clopidogrel
	Drug-eluting stent				
2000			5 F		
2001		Thrombectomy			
2002				OCT	
2005					
2006	BVS ABSORB	Retrograde approach to CTO			
	Drug-eluting bioresorbable stent	Drug-eluting balloon			
2007					Prasugrel
2009					Ticagrelor

# Conclusioni

- L'epoca pionieristica è finita da anni, oggi è l'epoca dei piccoli passi che debbono rendere la procedura il più appropriata possibile... es FFR, imaging, valutazione clinica attenta
- Resta indispensabile l'alleanza tra Cardiologi clinici ed interventisti, radiologi ed aziende
- Si deve ottimizzare la terapia antitrombotica post procedura es triplice T antitrombotica
- Non sono perse le speranze per gli stent bioasorbibili...






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### NONOPERATIVE DILATATION OF CORONARY-ARTERY STENOSIS

### Percutaneous Transluminal Coronary Angioplasty

ANDREAS R. GRÜNTZIG, M.D., ÅKE SENNING, M.D., AND WALTER E. SIEGENTHALER, M.D.

Abstract In percutaneous transluminal coronary angioplasty, a catheter system is introduced through a systemic artery under local anesthesia to dilate a stenotic artery by controlled inflation of a distensible balloon.

Over the past 18 months, we have used this technic in 50 patients. The technic was successful in 32 patients, reducing the stenosis from a mean of 84 to 34 per cent (P<0.001) and the coronary-pressure gradient from a mean of 58 to 19 mm Hg (P<0.001). Twenty-nine patients showed improvement in cardiac function during follow-up examination. Because of acute deterloration in clinical status, emergen-

IN 1964, Dotter and Judkins<sup>1</sup> introduced the technic of transluminal angioplasty for the treatment of atherosclerotic obstruction of the femoral artery. Despite their enthusiasm, the technic has been largely ignored in the United States. In Europe, however, several physicians have used this technic to treat large numbers of patients.<sup>2</sup>

Because of the technical difficulties, complications and limited usefulness of transluminal angioplasty in the treatment of obstruction of the peripheral arteries, we sought to modify the original technic of Dotter and Judkins. A double-lumen dilatation catheter with a nonelastic balloon was developed.<sup>3</sup> Such catheters have been used since February, 1974, in patients with obstructions of the femoropopliteal and iliac arteries and have yielded low complication rates and no mortality.<sup>4</sup>

Recently, we modified this catheter to allow us to develop a technic for percutaneous dilatation of renalartery<sup>5</sup> and coronary-artery stenosis.<sup>6</sup> This technic was used in human beings' after preliminary trials in dogs and cadavers.<sup>8-10</sup> We present here preliminary results obtained with the technic in the past 18 months. cy bypass was later necessary in five patients; three showed electrocardiograpic evidence of infarcts.

Patients with single-vessel disease appear to be most suitable for the procedure, and a short history of pain indicates the presence of a soft (distensible) atheroma likely to respond to dilatation. We estimate that only about 10 to 15 per cent of candidates for bypass surgery have lesions suitable for this procedure. A prospective randomized trial will be necessary to evaluate its usefulness in comparison with surgical and medical management. (N Engl J Med 301:61-68, 1979)

#### MATERIALS AND METHODS

#### Technic

The basic equipment consists of two catheters (Firma H. Schneider, Zurich), the guiding catheter, which has an outer diameter of French 8-9, and the dilating catheter. The guiding catheter is inserted into the femoral artery according to the method of Seldinger or through a brachial arteriotomy under local anesthesia. The guiding catheter is advanced in a retrograde manner into the ascending aorta and positioned in the orifice of the coronary artery requiring dilatation. This catheter guides the dilating catheter into the stenotic arterial branch. The dilating catheter contains a double lumen to permit pressure measurements, contrast injection and inflation of the balloon. At the tip of this catheter, a short soft wire, 5 mm long, projects beyond the balloon (Fig. 1) and directs the catheter into the artery, thus avoiding injury to the arterial wall. By means of a fluoroscopic-image intensifier, the dilating catheter is advanced into the stenotic area. The balloon is filled with a liquid mixture of contrast medium and is inflated for three to four seconds at a pressure of 4 to 5 bar (400 to 500 kPa); the balloon is then deflated, blocking the artery for about 15 to 20 seconds (Fig. 2). Inflation and deflation of the balloon are controlled by a calibrated pressure pump (Firma H. Schneider).

To estimate the extent of coronary-artery disease and the effect of dilatation, coronary angiography is peformed immediately before and after transluminal angioplasty. It is important to obtain views laterally, from both oblique angles and hemiaxially.<sup>11</sup> The degree of stenosis is calculated from the mean stenosis seen in all projections and was determined by one of us (A. R. C.). In all cases, pressure wus monitored, and pressure gradients across the lesions were recorded. A pacemaker was readily available during the procedure.

From the Section of Cardiology, Medical Policlinic, Department of



