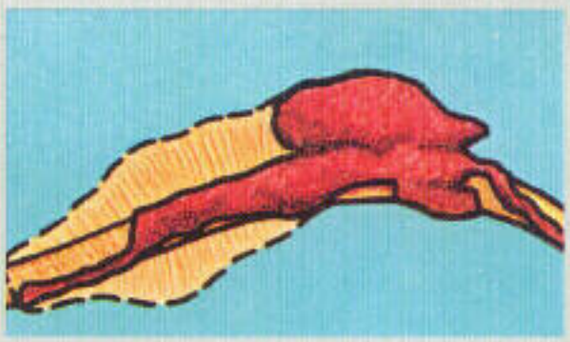
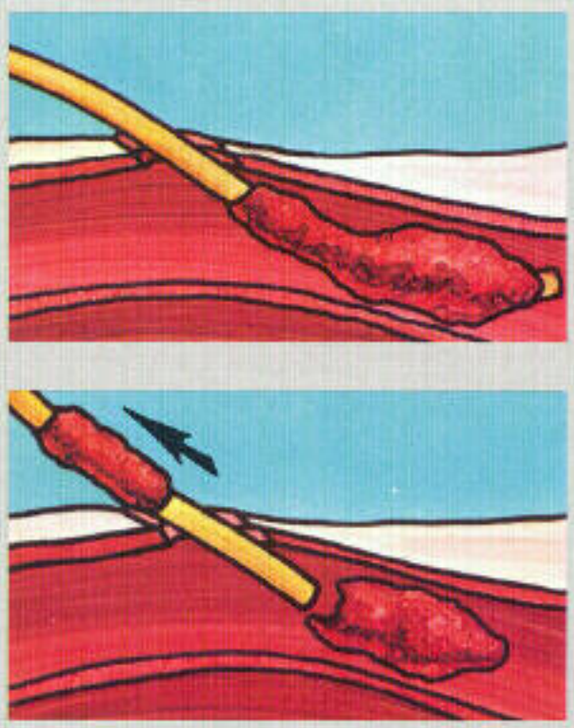
Catheter-Induced Thrombosis: a rising concern

Until recently, thrombosis resulting from the use of catheters was not regarded as a significant problem. Clinical attention focused more on other effects, such as the risk of septicaemia or complications of catheter insertion itself.

But studies over the past few years demonstrate a rising concern over platelet affinity for catheters and the potential risks of thromboembolic complications that may be catheter



The extruded thrombus poses the threat of complications.



How does it happen? The thrombus can be freed from the catheter by the stripping effect of catheter removal.

In this test, catheters were exposed to platelet suspensions, then measured by scintillation counting a minimum of three times to allow an average value to be calculated.

In two separate experiments, groups of materials were immersed for 10, 30, and 60 minutes.

Results: Exhibit 2 illustrates the scintillation counts for the various materials tested in the experiments. High counts indicate that the material has a tendency to attract platelets in greater numbers and is thus more likely to be thrombogenic.

Conclusions: ... Hydromer-coated materials tend not to attract platelets in great numbers and are considered less thrombogenic than the other materials tested.

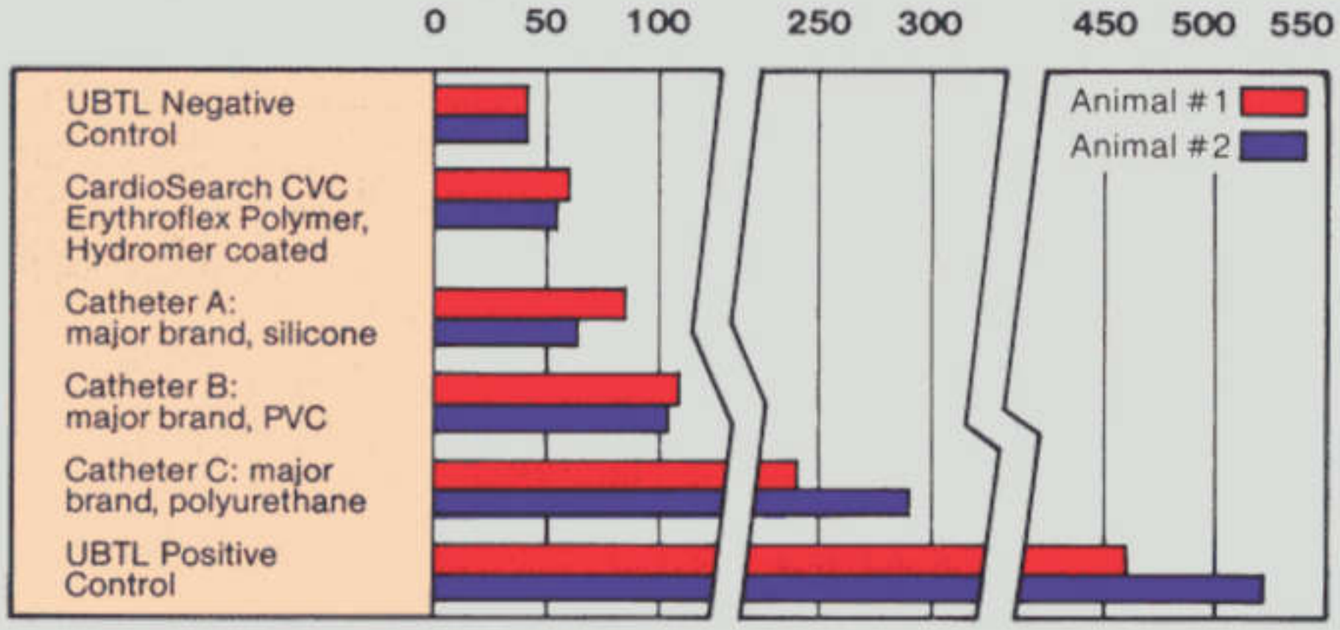
NO. 3: In vivo implant study at Rutgers [3]

In association with Rutgers University, Crowley and Borow also conducted in vivo studies using dogs. In this study, competitive catheters were cut to 30mm lengths at the distal end, then implanted simultaneously into test animals for periods ranging from one to four weeks. Four instruments were inserted on the arterial side, and four on the venous side.

Results: Exhibit 3, which visually summarizes the overall test results, shows instruments removed from one test animal after 14 days.

Conclusions: Erythrocath provides greater thromboresistance than competitive catheters.

EXHIBIT 1: Average Thrombus weight (mg) per catheter in Acute Canine Intra-arterial Implantation Study



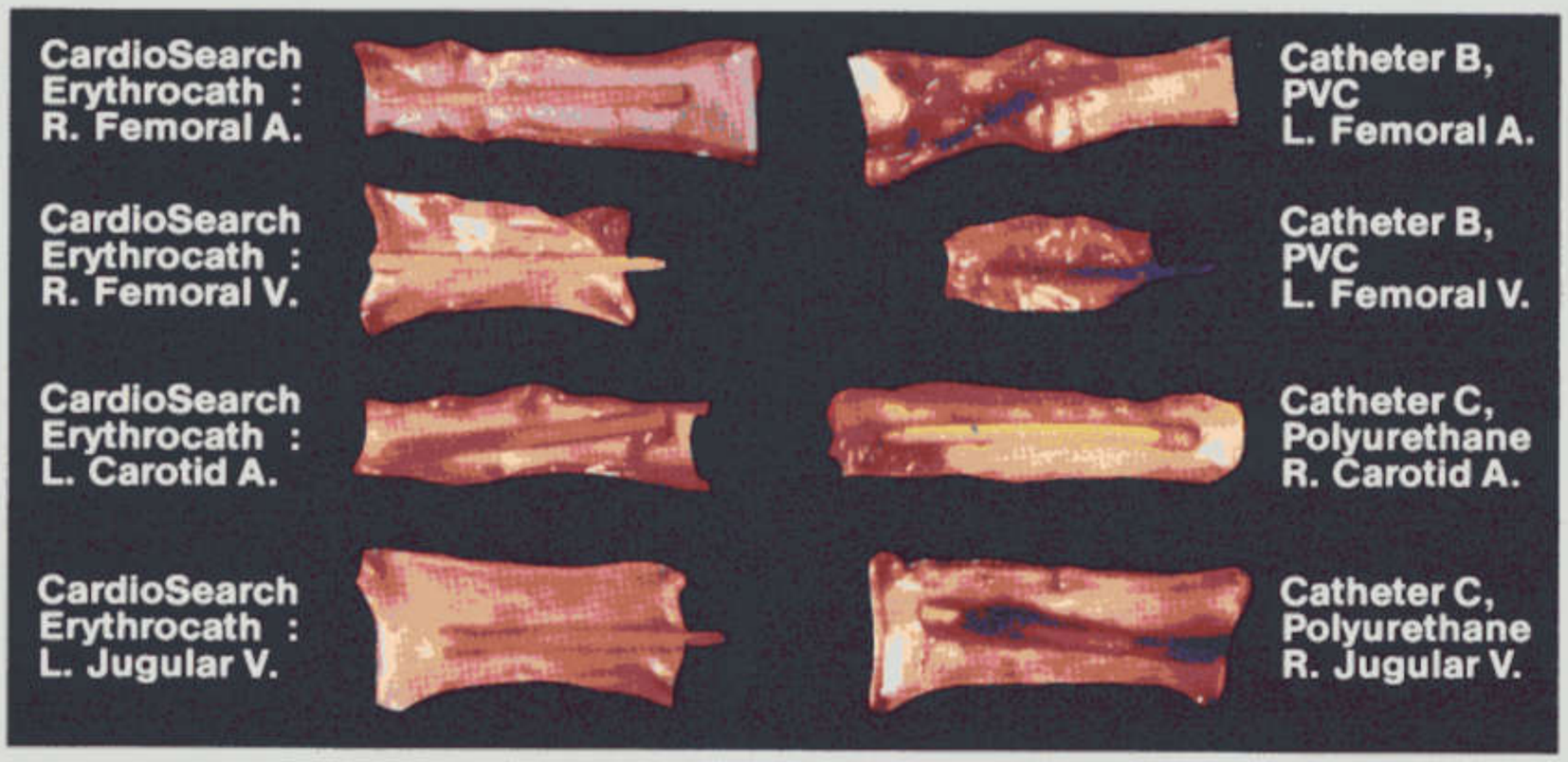
Note: The above chart displays Thrombus weights, including extruded Thrombus, averaged from six instruments in each case. Figures have been normalized to factor out differences in catheter surface areas.

EXHIBIT 2: Scintillation counts for catheters tested in Platelet Suspensions

	Experiment 1			Experiment 2*		
	Low	Avg	High	Low	Avg	High
Hydromer on Erythroflex	1.3	25.5	82.0	<10.0	91.0	460.0
Hydromer/Heparin Complex	2.6	26.5	52.0	11.0	115.0	310.0
Catheter A: major brand, PVC	13.0	31.0	43.0	10.5	275.0	1500.0
Catheter B: major brand, PVC	6.5	36.0	101.0	13.0	400.0	1150.0
Catheter C: major brand, Teflon†	9.5	36.5	69.0	16.5	440.0	1450.0
Experimental catheter material	15.2	42.0	84.0	11.2	430.0	1550.0
Catheter D: major brand, silicon	10.0	50.0	120.0	25.0	650.0	2100.0
Catheter E: major brand, polyurethane	3.0	54.0	130.0	20.0	470.0	1650.0
Scarified PVC	60.0	160.0	360.0	95.0	1800.0	3100.0

*Values are higher than those in experiment 1, due to a suspension richer in platelets and different lots of tagging agent; also due to correction factors for catheter surface area and background radiation.

EXHIBIT 3: Selected test devices from Rutgers In Vivo Study



RUTGERS DOG STUDY

In vivo Implant: 8 Days

Clot Size 0 (No Clot)-5

Deseret
Left Femoral Artery

Thickened Vessel: Yes
Clot Size: 3-4
Notes: Clot at One End
Pressure to Clear Lumen: 1
Notes: Proximal Clot

Deseret
Left Femoral Vein

Thickened Vessel: --
Clot Size: 1
Notes: Floating Clot
Pressure to Clear Lumen: 5
Notes: --

Pressure to Clear Lumen 0 (Clot Slides Out)-5

Hydromer coated
Right Femoral Artery

Thickened Vessel: No
Clot Size: 0
Notes: Clean
Pressure to Clear Lumen: 1
Notes: --

Hydromer Coated
Right Femoral Vein

Thickened Vessel: --
Clot Size: 0-1
Notes: --
Pressure to Clear Lumen: 0-1
Notes: Clot Slid Out On Its Own