Conclusions. (1) Short term results and restenosis rate after Wiktor stent implantation without subsequent anticoagultion is encouraging. (2) Mild or significant structural deformity was found in 13 (16%) of stents.

967-20 Reduced Thrombogenicity of Nitinol vs Stainless Steel Slotted-Tube Stents in Rabbit Carotid Arteries

Sushil Sheth, Vishva Dev, Michael C. Fishbein, James S. Forrester, Frank Litvack, Neil L. Eigler. *Cedars-Sinai Medical Center, Los Angeles, CA*

The thrombogenicity of slotted-tube stents made of nitinol or stainless steel (Palmaz Schatz) was assessed in a rabbit carotid artery model. Fourteen nitinol and 8 stainless steel stents (7 mm long single segment stents) were deployed in a carotid artery of 22 NZW rabbits with a 3.0 mm balloon inflated twice at 6 atm for 1 min. No antiplatelet or antithrombotic drugs were given. Eight rabbits with nitinol and 8 with stainless steel stents were euthanized after 4 days. The remaining 6 rabbits with nitinol stents were euthanized after 14 days. At sacrifice, both carotids (stented and control) were exposed and resting blood flow measured. The amount of thrombus on each stent was assessed by a semi-quantitative grading scale (I: no lumen encroachment; II: lumen encroachment; III: subocclusive thrombus; and IV: occlusive thrombus) and by the weight of the dry thrombus. *Results:* All nitinol were patent at 4 and 14 days whereas 6 out of 8 (75%) stainless steel stents had total thrombotic occlusion at 4 days ($p < 0.0001$).

Parameter	Stainless Steel 4 day	Nitinol 4 day	Nitinol 14 day	ANOVA p-value
n	8	8	6	
Carotid flow (ml/min)	1.5 ± 2.8	24.0 ± 2.0	25.5 ± 1.9	<0.000001
Thrombus grade	III = 2, IV = 6	I = 8	I = 6	<0.0001
Thrombus weight (mg)	20.0 ± 5.9	2.5 ± 0.6	2.7 ± 0.3	<0.000001

Histologic examination of stented arterial segments showed that although the depth of strut penetration was similar in all 4 day rabbits, the group with stainless steel stents consistently had evidence of diffuse medial necrosis and thinning (8/8 vs 1/8; $p = 0.0004$). *Conclusions:* Nitinol stents developed significantly less thrombus in comparison to stainless steel stents of similar design as measured by thrombus weight, thrombus grade and degree of blood flow reduction at 4 days in the rabbit carotid artery model. For nitinol stents there was no worsening of these thrombotic parameters at 14 days, compared to 4 days. More severe vascular injury may contribute to the thrombogenicity of stainless steel stents.

967-21 Long Term Results of Balloon Expandable Slotted-Tube Nitinol Stents in Canine Coronary Arteries

Kenneth Mahrer, Bruce Samuels, Huai Luo, Michael C. Fishbein, James S. Forrester, Frank Litvack, Neal Eigler. *Cedars-Sinai Medical Center, Los Angeles, CA*

This study evaluated delivery performance, quantitative angiographic parameters, intravascular ultrasound appearance, long term patency and vascular histology of radio-opaque, slotted-tube nickel titanium (nitinol) stents permanently implanted in canine coronary arteries. Dogs were treated with aspirin for 1 month. Follow-up angiography and histology were performed at 0.5, 1, 3, and 6 months (number of vessels = 2, 4, 6, and 26, respectively). *Results:* Thirty-eight of 39 (97%) stents were successfully implanted in the mid LAD and LCX of 20 dogs. One stent, which was undersized, was successfully removed by thermal recovery. Tandem stents were placed in 2 dogs without difficulty. Intravascular ultrasound of 6 stents showed symmetrical expansion with good wall contact. Acute angiographic parameters:

	nominal stent size (mm)			ANOVA p
	3.0	3.5	4.0	
number	4	22	12	–
inflation pressure (atm)	5.5 ± 0.5	6.1 ± 1.4	5.9 ± 1.6	0.47
minimal diameter (mm)	2.93 ± 0.07	3.24 ± 0.14	3.48 ± 0.16	0.0003
balloon to artery ratio	1.23 ± 0.03	1.25 ± 0.10	1.25 ± 0.08	0.65
stent to artery ratio	1.09 ± 0.03	1.14 ± 0.09	1.13 ± 0.07	0.30
percent recoil	11.0 ± 1.8	8.4 ± 1.8	9.9 ± 1.8	0.05

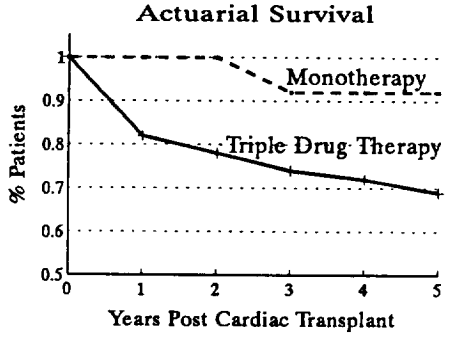
At follow-up, all vessels and 9 of 9 stented sidebranches were patent. The mean percent stenosis at 3 to 6 months was −1.6 ± 5.2 and the late loss was 0.2 ± 0.3 mm. All struts were covered with neointima at 2 weeks. At 6 months the maximal neointimal thickness was 260 ± 50 μm and was located adjacent to the struts. No thrombi and only occasional areas of granulation tissue with rare inflammatory cells were seen. *Conclusions:* A slotted tube nitinol stent has delivery performance characteristics and recoil similar to stainless steel slotted-tube stents. Nitinol stents endothelialize rapidly and intimal proliferation is insufficient to create a stenosis in this animal model. These data suggest that a slotted-tube, balloon expandable nitinol stent is sufficiently reliable and biocompatible to warrant clinical trials.

967-22 Thrombin Generation and Systemic Inflammatory Response After Coronary Stent Implantation

Ilka Ott, Franz-Josef Neumann, Meinrad Gawaz, Andreas May, Albert Schömig. *Medizinische Klinik der Technischen Universität München*

In patients with severe coronary artery disease a systemic inflammatory reaction (SIRS) occurs that contributes to thrombotic complications. To evaluate the systemic inflammatory response in patients with coronary stent implantation, serial venous blood samples were taken in 101 patients before and after stent implantation. Humoral and cellular inflammatory markers as well as the prothrombin-fragments F1 + 2 were analysed. An initial elevated thrombin generation was followed by an increased integrin surface expression (CD11b, FACScan) on monocytes (Mo) and granulocytes (PMN) (plateau after 2 days) and by an increase in plasma fibrinogen (fbg) and C-reactive protein (CRP) (plateau after 5 days).

The initial F1 + 2 peak correlated significantly with fbg and CRP at day 5 ($r = 0.07$ and 0.31, $p = 0.0001$) and with CD11b surface expression on Mo at day 2 ($r = 0.02$, $p < 0.05$) and on PMN by trend ($p < 0.1$).



Conclusion: After coronary stent implantation a systemic inflammatory reaction occurs. Its extend may have a causative relationship to the thrombin generation during stent implantation.

968 Molecular Aspects of Arterial Injury

Tuesday, March 21, 1995, 3:00 p.m.–5:00 p.m.
Ernest N. Morial Convention Center, Hall E
Presentation Hour: 4:00 p.m.–5:00 p.m.

968-23 Evaluation of Proliferation in Human Atherectomy Specimens Using In Situ Hybridization for Histone H3

Edward R. O'Brien, Simcha Urieli-Shoval, Michael R. Garvin, Earl P. Benditt, Douglas K. Stewart, Tomoaki Hinohara, John B. Simpson, Stephen M. Schwartz. *University of Washington, Seattle, WA; Sequoia Hospital, Redwood City, CA*

Previously, using immunocytochemistry for the proliferating cell nuclear antigen, we detected low levels of replication (≤1%) in 100 restenotic coronary atherectomy specimens. Histone H3 mRNA increases 30-50-fold as cells pass through S phase of the cell cycle and can be used as an independent marker of cell replication. Therefore, using *in situ* hybridization for histone H3 mRNA we examined the proliferative profile of: i) coronary atherectomy specimens (n = 12) obtained within the first 60 days after a previous interventional procedure, and ii) primary (n = 13) and restenotic (n = 10) peripheral atherectomy specimens because of their larger tissue sample size. For these respective tissue groups, the number of specimens that had any cells expressing histone mRNA on a slide were 2/12, 5/13 and 7/10. The total number of cells per slide expressing histone H3 mRNA ranged from 0 to 23, 0 to 82 and 0 to 118 for these 3 groups of specimens. Typical coronary and peripheral atherectomy specimens contain 4,500 and 10,200 cells per slide, respectively. Therefore, the highest replication profiles (0.5%, 1.2%) were seen in restenotic coronary and peripheral artery specimens obtained 1 and 2 days post-atherectomy, respectively. Smooth muscle and endothelial cells expressed histone H3 mRNA. *Conclusions:* These results suggest that: 1) replication is a modest event in human atherosclerosis and restenosis; 2) replication may be more prevalent in peripheral compared to coronary atherectomy specimens; and 3) anecdotally, an important time window for proliferation may be in the days immediately post-intervention.