the stent without adjunctive balloon dilation. The Palmaz-Schatz stents were implanted using a non-compliant balloon with a mean inflation pressure of 12 ATM. The cross sectional area of the stent and lumen were measured by intravascular ultrasound immediately and at 28 days after implant.

| | Stent area ($mm^2$) | |
|---|---|---|
| | Implant | 28 Days |
| Nitinol | 7.75 ± 1.40 | 9.10 ± 0.99* |
| Palmaz-Schatz | 6.94 ± 1.47 | 6.82 ± 1.19 |

*p = 0.01 versus Palmaz-Schatz

At 28 days, the lumen area ($mm^2$) in the nitinol stents (7.22 ± 0.89) was significantly greater than the Palmaz-Schatz stents (5.54 ± 1.32, p = 0.046). On histology, the vessel injury score was similar for the nitinol (0.6 ± 0.3) and the Palmaz-Schatz (0.5 ± 0.1, p = 0.73) stents. The mean neointimal area (1.07 ± 0.44 $mm^2$ versus 2.07 ± 0.26 $mm^2$, p = 0.002) and percent area stenosis (17.0 ± 7.3 versus 35.2 ± 6.0, p = 0.003) were significantly less in the nitinol versus the Palmaz-Schatz stents.

This nitinol self-expanding stent exerts a more favorable effect on vascular remodeling and neointimal formation than a balloon expandable tubular slotted stent, thus optimizing the effects of stent placement in this experimental model.

## 921-38 Quantitative Angiographic Evaluation of the New Micro Stent

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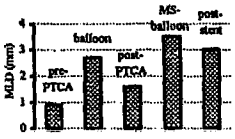
Since October 1994, 113 AVE Micro Stents (MS) were implanted for treatment of 95 lesions (out of 100) in 94 patients (pts), 69 male, mean age 62 ± 10 (range 36–86). Five lesions could not be stented because of poor guiding support (1), calcification (2) or angulation (2). Target vessels were LAD (38%), circumflex (17%), RCA (39%), LM (1%) and vein graft (5%). MS of 4 (13%), 8 (43%) and 16 mm (44%) with diameters of 3.0 (60%), 3.5 (34%) and 4.0 mm (6%) were delivered through 7F guiding catheters. High pressure inflation (mean 11 ± 2 bar, range 5–18) was used to fully expand the MS by fluoroscopy and angiography. Indications were: elective (22%), optimization after PTCA (25%), non occlusive dissection (41%), bail-out after PTCA (7%) and bail-out after use of another stent (4%). Quantitative coronary angiography (QCA) was performed in 58 lesions pre-PTCA, during balloon inflation, post-PTCA, during MS-balloon inflation and post-stent (Figure). The reference diameter was 2.9 ± 0.6 mm and the final diameter stenosis was 9 ± 12%. No anticoagulation was used in 87% of the pts (aspirin, fractionated heparin for 2 weeks and ticlopidine for 1 month). There were no access site complications (transfusions in 2 pts). Subacute stent thrombosis occurred in 1 pt 72 hours after MS implantation. There were no death, myocardial infarction or CABG.




Thus, no anticoagulation is required following MS implantation, even in pts at higher risk for (sub) acute stent thrombosis. Optimal stent deployment can be achieved with QCA on-line, but without intravascular ultrasound given the radiopacity of MS.

## 921-39 Initial Clinical Experience With a New Handmade Coronary Stent

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To reduce the cost of coronary stenting we handmade a balloon expandable stainless steel coil stent. Preliminary comparison with the Palmaz-Schatz stent in porcine iliac arteries revealed no differences in the acute thrombosis rate nor in the 6 weeks follow-up angiographic and morphometric restenosis rate. Subsequently, 73 stents were implanted in coronary arteries of 52 pts (for bail-out in 28 pts and to improve a suboptimal angiographic result in 24 pts). Before stent implantation aspirin 500 mg IV and oral ticlopidin 500 mg was given in addition to heparin to maintain the activated clotting time > 300 sec. After the stents were mounted by hand on the balloon catheter used for predilation, all implantations were successful except for 2 : 1 stent was lost but could be retrieved and in a second pt emergency bypass grafting was indicated. In the other pts ticlopidin was continued for 2 months and aspirin 320 mg for 6 months. There was no in-hospital stent thrombosis but 2 pts developed a groin hematoma, 1 necessitating blood transfusion.

Conclusions: Implantation of a low cost self made coronary stent gives excellent in-hospital results. The 6 months clinical and quantitative coronary angiographic follow-up results will be presented.

## 921-40 Treatment of Long Lesions in Small Tortuous Coronary Vessels With a New Intravascular Rigid-Flex (NIR) Stent

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Stent designs favoring radial support and plaque scaffolding are necessary to reduce restenosis but confer decreased flexibility, limiting use in complex lesion/vessel anatomy. The balloon-expandable stainless steel NIR stent employs a continuous uniform multicellular design which has superior flexibility prior to expansion, but also achieves excellent support and scaffolding after deployment. To assess the utility of this advanced stent design, 42 NIR stents of various lengths (10 = 9 mm, 17 = 16 mm, and 15 = 32 mm) were implanted in 28 lesions (11 LAD, 10 LCX, and 7 RCA) in 15 patients. Twenty-five lesions (89%) were considered by two experienced operators difficult to treat with the conventional tubular slotted stent due to vessel tortuosity (n = 7), distal lesion location (n = 6), lesion length (mean stenter segment = 37 mm), and/or < 2.5 mm reference diameter (n = 11, mean reference diameter = 2.72 ± 0.56 mm). Deployment success was 98% (42/43 stents). High pressure stent expansion (17 ± 4 atm) was guided by intracoronary ultrasound (ICUS) in all cases. After final stent expansion, minimum lumen diameter was 2.47 ± 0.5 mm (mean % stenosis 9.2%) and minimal cross-sectional area (ICUS) was 6.4 ± 0.2 $mm^2$ (distal reference area = 6.2 ± 0.2 $mm^2$). Post-procedure, all patients were treated with aspirin alone and at 30-day follow-up, there has been no stent thrombosis. *In conclusion:* Despite complex lesion/vessel anatomy, early experiences with the NIR stent indicate favorable deployment success, acute angiographic results, and 30-day clinical outcomes. This new stent design has the potential to expand clinical indications and simplify the technique of coronary stent implantation.

## 921-41 Comparison of Initial and Late Angiographic Results After AVE Micro and Palmaz-Schatz Stent Implantation

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To evaluate the initial and late outcome of AVE introcoronary micro stent implantation, we compared the results of 20 patients (23 lesions; *AVE*) of the implantation with those of 294 patients (324 lesions; *PS*) of elective Palmaz-Schatz stent implantation. Angiographic follow up was done 3 months (3M) after stent implantation. There were no significant differences in their age, gender, lesion types, extents of diseased vessels or left ventricular ejection fraction between the 2 groups.

| | *AVE* (N = 23) | *PS* (N = 324) | *p* |
|---|---|---|---|
| Delivery success | 22 (96%) | 296 (91%) | NS |
| Stent thrombosis | 0 | 0 | NS |
| Reference diameter (mm) | 3.14 ± 0.34 | 3.24 ± 0.78 | NS |
| MLD before stenting (mm) | 0.87 ± 0.33 | 0.89 ± 0.54 | NS |
| MLD after stenting (mm) | 3.01 ± 0.40 | 3.24 ± 0.73 | NS |
| MLD at 3M (mm) | 1.70 ± 1.05 | 2.42 ± 1.18 | <0.001 |
| % Stenosis at 3M | 45.6 ± 31.4 | 27.6 ± 24.2 | <0.001 |
| Restenosis rate | 9 (39%) | 50 (20%) | <0.01 |
| Reintervention/CABG | 6 (28%) | 38 (13%) | 0.06 |

MLD; minimum lumen diameter

Thus, the long-term results of AVE stent implantation, although its initial results are acceptable, are inferior to those of Palmaz-Schatz stent. We conclude that AVE stent implantation should be considered, only when Palmaz-Schatz stent is not feasible.

## 921-42 First Use of the Second-Generation Gianturco-Roubin Stent Without Coumadin

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The second generation Gianturco-Roubin stent (GR II) has a lower profile, is available in longer lengths, and has a radioopaque marker at each end. To perform initial evaluation of the modified stent, 27 GR II stents in 20 or 40 mm lenghts were implanted in 18 patients between May 23 and June 2, 1995. All procedures were planned, although 3 patients experienced acute closure following the initial angioplasty. A femoral approach (16 patients) or

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