Long Term Results of Biodegradable Igaki-Tamai Stent

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Background: We developed a new biodegradable self-expanding coil stent (Igaki-Tamai Stent) made of high molecular weight poly-*l*-lactic acid (PLLA). After the favorable results of this stent in the porcine coronary artery, we started the first human coronary application. **Methods:** From September 1998 through April 2000, 63 lesions in 50 patients electively underwent the stent implantation for coronary artery stenoses. There were 44 male and 6 female, and the mean age was 61 ± 13 yrs. All target lesions were AHA/ACC type B and C. Coronary angiography was performed before and immediately after the procedure. Additional assessment by quantitative coronary angiography was done 1 day, 3, 6 and 12 months (Mo) after the procedure. Restenosis was defined as the percent diameter stenosis (%DS) ≥ 50% at follow-up. **Results:** The reference vessel diameter was 2.95 ± 0.46 mm. The minimal lumen diameter (MLD) was 0.91 ± 0.39 mm and the lesion length was 13.5 ± 5.7 mm before procedure. The %DS decreased from 69% before stenting to 12% after stenting. All PLLA stents were successfully implanted. Subacute thrombosis occurred in one patient (2.0%) at day 5 who had been treated with inadequate heparinization because of gastrorrhagia. No other MI, CABG or death developed within the follow-up period. Seven patients had repeat angioplasty within 6 months and 1 patient had repeat angioplasty at 12 months. Twenty-five patients received 18-month follow-up angiography and 21 patients received 24-month follow-up angiography. There was no restenosis in 18-month and 24-month follow-up angiograms. The interim follow-up results are shown in the table. **Conclusions:** Our preliminary experience suggests the feasibility, safety, and efficacy of the Igaki-Tamai biodegradable stent in humans.

	Pre (n=63)	Post (n=63)	6 Mo (n=60)	12 Mo (n=53)
MLD (mm)	0.91±0.39	2.68±0.43	1.76±0.74	2.01±0.54
%DS (%)	69±13	12±8	38±22	29±13
Restenosis Rate			20% (12/60)	17% (9/53)
TLR Rate		11% (7/63)	13% (8/63)	