

Catheter Cardiovasc Interv (2005);64:146-52

Preliminary experience with the frontrunner coronary catheter: Novel device dedicated to mechanical revascularization of chronic total occlusions

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The novel device Frontrunner coronary catheter (FCC), dedicated to recanalization of chronic total occlusions (CTOs), relies on blunt microdissections inside the plaque, allowing passage of guidewire through the lesion and adjunctive angioplasty. In order to evaluate efficacy and safety of recanalization using the FCC device, we included patients with de novo or restenotic CTOs in a native coronary artery with prior failure using a guidewire or considered unsuitable for guidewire attempt in which the FCC was attempted first. Between October 2000 and June 2003, 50 patients with 50 CTOs were included in the study. Thirty-two patients had prior failure with a mechanical wire. Device and angiographic success were obtained in 25 (50%) occlusions: 53% in lesions with prior guidewire failure and 44% when FCCs were attempted first ( $P = 0.8$ ). During the first year of experience, angiographic success was 42% (5 occlusions) and in the third year 75% (12 occlusions;  $P = 0.12$ ). Coronary perforation occurred in nine (18.0%) patients, leading to tamponade in two (4%) patients. Perforations occurred in 5 out of 12 attempted patients during the first year and in 4 out of 38 patients in the following period (41.7% vs. 10.5%;  $P = 0.04$ ). Serious adverse events occurred in five (10%) patients within 30-day follow-up. Four non-Q-wave myocardial infarctions occurred in hospital (clinical success 42%) and one death 7 days after the index procedure. The use of FCC increases the success to open chronic total occlusions refractory to mechanical guidewires or that were considered unsuitable for an attempt with a guidewire. The risk of coronary perforation due to FCC use is relatively high and it can decrease with experience. Catheter Cardiovasc Interv 2005;64:146-152. (c) 2005 Wiley-Liss, Inc. [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list\\_uids=15678451](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15678451)

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Impact of sirolimus-eluting stent on the outcome of patients with chronic total occlusions  
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Several randomized trials have demonstrated that stent implantation after successful recanalization of long-term total occlusions decreases restenosis and reocclusion rates. The sirolimus-eluting stent (SES) has recently proved its efficacy to decrease restenosis in selected patients. However, the efficacy of SES implantation in patients who have chronic total occlusions is currently unknown. Therefore, we investigated procedural and 6- and 12-month angiographic outcomes (analyzed by quantitative coronary angiography) and left ventricular function in 60 patients who received SESs and 120 patients who received bare metal stents (BMSs). Minimum luminal diameter did not differ immediately after recanalization (SES group 3.04 +/- 0.50 mm vs BMS group 3.12 +/- 0.48 mm). After 6 months, the SES group still had significantly larger luminal diameters (3.04 +/- 0.44 mm vs 1.94 +/- 0.98 mm) and significantly lower restenosis and reocclusion rates (2% and 0%, respectively) than did the BMS group (32% and 6%, respectively). Late loss was significantly smaller in the SES group than in the BMS

group. At follow-up, the SES group had fewer cardiac events, including target lesion revascularization ( $p < 0.001$ ), than did the BMS group. In conclusion, SES implantation after recanalization of chronic total occlusion provides a better clinical outcome with less restenosis and target lesion revascularization after 6 months than does BMSs.

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Value of preprocedure multislice computed tomographic coronary angiography to predict the outcome of percutaneous recanalization of chronic total occlusions

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We performed multislice computed tomographic coronary angiography in 45 patients who had chronic total occlusions and were scheduled for percutaneous recanalization. Multivariate analysis identified a blunt stump (by conventional angiography), occlusion length  $> 15$  mm, and severe calcification (by multislice computed tomographic coronary angiography) as independent predictors of procedural failure.

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Prevention of distal embolization and no-reflow in patients with acute myocardial infarction and total occlusion in the infarct-related vessel: A subgroup analysis of the cohort of acute revascularization in myocardial infarction with excimer laser-CARMEL multicenter study

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To overcome the adverse complications of percutaneous coronary interventions in thrombus laden lesions (i.e., distal embolization, platelet activation, no-reflow phenomenon), mechanical removal of the thrombus or distal embolization protection devices are frequently required. Pulsed-wave ultraviolet excimer laser light at 308 nm can vaporize thrombus, suppress platelet aggregation, and, unlike other thrombectomy devices, ablate the underlying plaque. The following multicenter registry was instituted to evaluate the safety and efficacy of laser ablation in patients presenting with acute myocardial infarction (AMI) complicated by persistent thrombotic occlusions. Patients with AMI and complete thrombotic occlusion of the infarct-related vessel were included in eight participating centers. Patients with further compromising conditions (i.e., cardiogenic shock, thrombolysis failures) were also included. Primary endpoint was procedural respective laser success; secondary combined endpoints were TIMI flow and % stenosis by quantitative coronary analysis and visual assessment at 1-month follow-up. Eighty-four percent of all patients enrolled ( $n = 56$ ) had a very large thrombus burden (TIMI thrombus scale  $\geq 3$ ), and 49% were compromised by complex clinical presentation, i.e., cardiogenic shock (21%), degenerated saphenous vein grafts (26%), or thrombolysis failures (5%). Laser success was achieved in 89%, angiographic success in 93%, and the overall procedural success rate was 86%. The angiographic

prelaser total occlusion was reduced angiographically to 58% +/- 25% after laser treatment and to 4% +/- 13% final residual stenosis after adjunctive balloon angioplasty and/or stent placement. TIMI flow increased significantly from grade 0 to 2.7 +/- 0.5 following laser ablation ( $P < 0.001$ ) and 3.0 +/- 0.2 upon completion of the angioplasty procedure ( $P > 0.001$  vs. baseline). Distal embolizations occurred in 4%, no-reflow was observed in 2%, and perforations in 0.6% of cases. Laser-associated major dissections occurred in 4% of cases, and total MACE was 13%. The safety and efficacy of excimer laser for thrombus dissolution in a cohort of high-risk patients presenting with AMI and total thrombotic occlusion in the infarct-related vessel are encouraging and should lead to further investigation. *Catheter Cardiovasc Interv* 2005;64:67-74. (c) 2004 Wiley-Liss, Inc.

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Primary stenting of occluded native coronary arteries: final results of the Primary Stenting of Occluded Native Coronary Arteries (PRISON) study

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**BACKGROUND:** Primary intracoronary stent placement after successfully crossing chronic total coronary occlusions may decrease the high restenosis rate at long-term follow-up compared with conventional balloon angioplasty. **METHODS:** In a prospective, randomized trial, balloon angioplasty was compared with stent implantation for the treatment of chronic total occlusions. Patients were followed for 12 months with angiographic follow-up at 6 months. Quantitative coronary analysis was performed by an independent core lab. **RESULTS:** A total of 200 patients were enrolled. Baseline characteristics were evenly distributed. After the procedure the mean minimal luminal diameter in the conventional group was 2.34 +/- 0.46 mm versus 2.90 +/- 0.41 mm in the stented group ( $P < .0001$ ). The 6-month angiographic follow-up showed a mean minimal luminal diameter of 1.57 +/- 0.74 mm in the conventional group versus 1.93 +/- 0.85 mm in the stented group ( $P = .009$ ) and a mean diameter stenosis of 44.7% +/- 25.0% versus 35.5% +/- 26.5% ( $P = .036$ ). Binary angiographic restenosis (>50% diameter stenosis) was seen in 33% in the conventional group versus 22% in the stented group ( $P = .137$ ). The reocclusion rates were 7.3% and 8.2%, respectively ( $P = 1.00$ ). At 12 month follow-up, the rate of target lesion revascularization was significantly higher in the conventional group (29% versus 13%,  $P < .0001$ ). **CONCLUSION:** These

**OBJECTIVES:** The aim of this research was to assess the efficacy of paclitaxel-eluting stents in chronic total coronary occlusions (CTO). **BACKGROUND:** Percutaneous coronary interventions for CTOs are characterized by a high target vessel failure rate. **METHODS:** In 48 consecutive patients, paclitaxel-eluting stents (Taxus, Boston Scientific Corp., Natick, Massachusetts) were implanted after successful recanalization of a CTO (duration >2 weeks). Patients underwent an angiography after 6 months and were followed clinically for 12 months. They were compared with 48 lesion- and risk-matched patients with CTOs treated with bare metal stents (BMS). Primary clinical end point was the one-year incidence of major adverse cardiac events (MACE) (death, myocardial infarction, repeat revascularization); secondary end points were the rate of restenosis and re-occlusion. **RESULTS:** In-hospital MACE was 4.2% with Taxus, and 2.1% with BMS ( $p = \text{NS}$ ). The one-year MACE rate was 12.5% in the Taxus group, and 47.9% in the BMS group ( $p < 0.001$ ), which was due to a reduced need for repeat revascularization. The angiographic restenosis rate was 8.3% with Taxus versus 51.1% with BMS ( $p < 0.001$ ). There was only one late re-occlusion with Taxus (2.1%) as compared with 23.4% with BMS ( $p < 0.005$ ). The late loss was reduced in the Taxus group by 84% as compared with BMS. All nonocclusive restenoses in the Taxus group were focal and successfully treated by implanting an additional Taxus stent. **CONCLUSIONS:** The treatment of CTOs with a paclitaxel-eluting stent drastically reduces MACE and restenosis, and almost eliminates re-occlusion, which is typically frequent with BMS in CTOs. Chronic total coronary occlusion should be a preferred indication for drug-eluting stents.

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Growth factors in the collateral circulation of chronic total coronary occlusions: relation to duration of occlusion and collateral function

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**BACKGROUND:** Despite extensive animal experimental evidence, there are few data on the relation of growth factors and collateral function in humans. **METHODS AND RESULTS:** In 104 patients with a chronic total coronary occlusion (CTO; >2 weeks' duration), collateral function was assessed invasively during recanalization by intracoronary Doppler and pressure recordings. A collateral resistance index, R(Coll), was calculated. Blood samples were drawn from the distal coronary bed supplied by the collaterals and from the aortic root to measure basic fibroblast growth factor (bFGF), monocyte chemoattractant protein-1 (MCP-1), transforming growth factor-beta (TGF-beta), placenta growth factor (PIGF), and tumor necrosis factor-alpha (TNF-alpha). The bFGF concentration in the collateralized artery was higher than in the aortic root ( $34 \pm 20$  versus  $18 \pm 14$  pg/mL;  $P < 0.001$ ). bFGF was highest in recent occlusions (2 to 12 weeks) with the highest R(Coll). Higher collateral concentrations were also observed for MCP-1, TGF-beta, and PIGF, but without a close relation to the duration of occlusion. TNF-alpha was not increased in collaterals compared with the systemic circulation. MCP-1, PIGF, and TGF-beta were significantly increased in small collaterals with the highest shear stress. Diabetic patients had lower bFGF and higher MCP-1 levels than

nondiabetics. CONCLUSIONS: In CTOs, the continuous release of bFGF into collaterals showed a close relation to the duration of occlusion and collateral function, which underscores its therapeutic potential. Other factors influencing growth factor release appeared to be shear stress for MCP-1, TGF-beta, and PIGF and the presence of diabetes.

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Significant reduction in restenosis after the use of sirolimus-eluting stents in the treatment of chronic total occlusions

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OBJECTIVES: The aim of this study was to assess sirolimus-eluting stent (SES) implantation for the treatment of chronic total coronary occlusions (CTO).

BACKGROUND: Long-term results after percutaneous coronary intervention (PCI) in the treatment of CTOs is hindered by a significant rate of restenosis and reocclusion. In the treatment of relatively simple nonocclusive lesions, SESs have shown dramatically reduced restenosis rates compared with bare metal stents (BMS), but whether these results are more widely applicable is unknown. METHODS: From April 2002, all patients at our institution were treated with SES as the device of choice during PCI. During the first six months, 563 patients were treated solely with SES, with treatment of a de novo CTO in 56 (9.9%). This CTO cohort was compared with a similar group of patients (n = 28) treated in the preceding six-month period with BMS. RESULTS: At one year, the cumulative survival-free of major adverse cardiac events was 96.4% in the SES group versus 82.8% in the BMS group,  $p < 0.05$ . At six-month follow-up, 33 (59%) patients in the SES group underwent angiography with a binary restenosis rate (>50% diameter stenosis) of 9.1% and in-stent late loss of  $0.13 \pm 0.46$  mm. One patient (3.0%) at follow-up was found to have reoccluded the target vessel. CONCLUSIONS: The use of SESs in the treatment of chronic total coronary occlusions is associated with a reduction in the rate of major adverse cardiac events and restenosis compared with BMS.

can be a useful tool in addition to conventional wires in the treatment of CTO.

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