CASE REPORT

First Recanalization of a Coronary Artery Chronic Total Obstruction in an 11-Year-Old Child with Kawasaki Disease Sequelae Using the CROSSER Catheter

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Abstract This is a case of an 11½-year-old diagnosed with Kawasaki disease at 6 months of age. Distal left main coronary aneurysm involving the proximal anterior descending and circumflex had progressed into a chronic total occlusion. We report the first application of a novel percutaneous technique using the CROSSER catheter system in a child. The CROSSER is a high-frequency mechanical vibration catheter-based technology developed to safely penetrate through calcific and noncalcific coronary artery occlusions. This is also the first Kawasaki disease patient to benefit from this technology; in this disease, coronary artery stenosis is typically associated with heavy calcification.

Keywords Kawasaki disease · Coronary aneurysm · Coronary calcification · Chronic total occlusion · Catheter intervention

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Kawasaki disease (KD) is an acute inflammatory illness of childhood affecting essentially preschool children. Although there is no known etiology of this disease, it is well established that KD triggers a vasculitis affecting medium-sized vessels, specifically the coronary arteries (CAs) [14]. In severely affected individuals, CA aneurysm may develop, leading to CA stenosis in nearly 20% in a 10- to 21-year angiography follow-up series [7]. The incidence of CA stenosis is directly linked to the location and the extent of CA dilatation during the acute phase of the disease [16]. Stenotic sequelae appear to be unlikely if CA dilatation is <6 mm in diameter. The incidence of CA stenosis is 58 and 74% when initial CA aneurism is 6–8 or ≥8 mm, respectively. On the other hand, aneurism regression is more likely to occur and less likely to cause stenosis or obstruction when it is located on a bifurcation compared to branch lesions.

In this report, we present an 11½-year-old girl who had developed a chronic total occlusion (CTO) of her left main CA and the percutaneous approach that was used to revascularize her major left CA territory. We utilized a novel investigational technique using the CROSSER system (FlowCardia, Inc., Sunnyvale, CA, USA), a high-frequency mechanical vibration catheter-based technology developed to safely penetrate through calcific and noncalcific CTO.

Case Report

This patient (weight, 31 kg; height, 140.5 cm) was diagnosed with KD at 6 months of age. Despite appropriate intravenous immune globulin therapy at initial presentation, she developed aneurismal dilata-
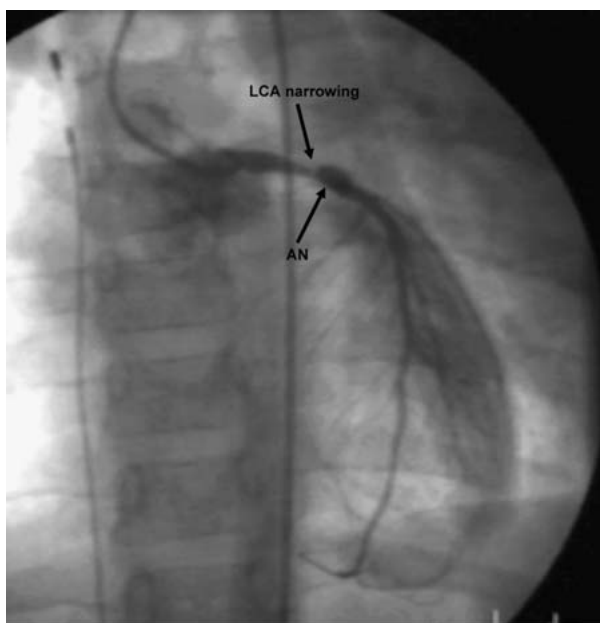
Fig. 1 Narrowing between the proximally dilated left coronary artery (*LCA*) and the aneurism (*AN*)

tion of the left CA as diagnosed by echocardiography. Since then, she received daily antiplatelet PO aspirin. Warfarin was not pursued due to marginal compliance.

A first diagnostic coronary angiography at 14 months of age showed a giant 8-mm aneurysm at the distal left main CA involving the bifurcation at the origins of the anterior descending and the circumflex segments. The right CA was normal.

At 8 years old, a treadmill stress test was performed (Bruce protocol). Performance duration was up to 8:56 (10 METs) with no symptoms or abnormal ECG changes. Concomitant stress echocardiography and myocardial perfusion scan did not show segmental dysfunction or perfusion defects. Coronary angiography showed that the aneurismal dilatation of the left CA had regressed in size to 5.5 mm. The distal portion of the left main CA showed a mild tapered narrowing (Fig. 1).

The patient, who remained asymptomatic, was reinvestigated recently per routine and standard recommendations. Exercise stress testing triggered significant ST depression starting at the end of stage 2, accompanied by a decrease in blood pressure, pallor, and extreme fatigue. Myocardial perfusion scan did not show significant territorial perfusion defects. The next day, a diagnostic coronary angiography was performed, which showed complete obstruction of the left CA. The left main CA could be opacified only proximally. The aneurysm was heavily calcified on plain fluoroscopy. Distally, the circumflex and the left anterior descend-

ing CA were only opacified via right CA angiography, which showed a heavy collateral network irrigating retrogradely the left territory. Attempts to cross the lesion using standard wire techniques were fruitless. Therefore, the patient was started on atorvastatin and bisoprolol, in addition to aspirin, and scheduled for an interventional catheterization after consideration of a double coronary bypass surgery as a second option or a backup plan. Our decision to undertake the interventional option was based essentially on a recently published paper describing an innovative technique and initial results of a clinical investigation using the CROSSER catheter system [4].

The FlowCardia System consists of reusable electronics (generator and transducer) and the single-use CROSSER catheter. The CROSSER catheter is connected to the generator and the generator converts AC line power into high-frequency current. This current is then delivered to piezoelectric crystals contained within the transducer resulting in crystal expansion and contraction, which propagates high-frequency mechanical vibration down a Nitinol core wire to the stainless-steel tip of the CROSSER catheter at approximately 20 kHz or 20,000 cycles per second. This vibrational energy provides mechanical impact and cavitational effects that aid in the recanalization of an occluded artery.
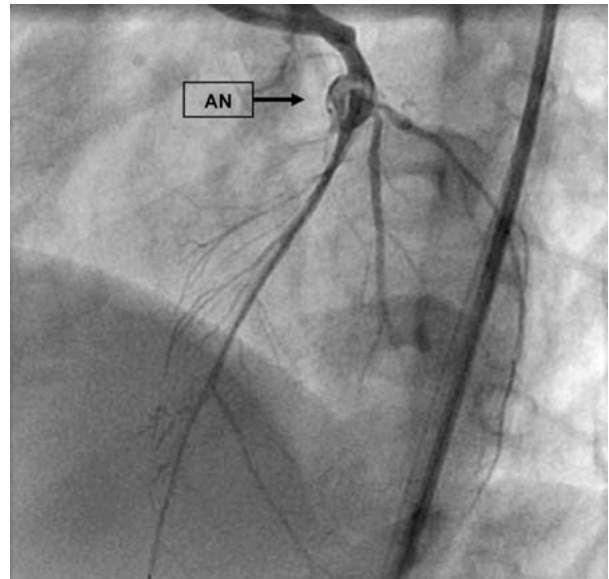
Procedure

The patient was brought to the catheterization laboratory on June 16, 2006. Given the investigational status of the device used in this case report, approval was obtained from an institutional government-designated pediatric ethics committee and from the Canadian Special Access Programme of the Therapeutic Products Directorate, Health Canada. Parental written informed consent was obtained prior to the intervention. The CROSSER system was provided to the institution by FlowCardia.
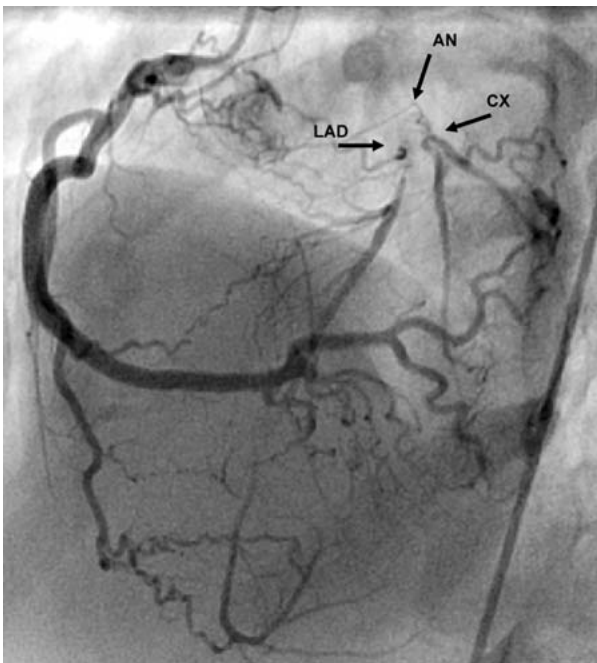
The intervention was performed under general anesthesia due to the young age of the patient. After right and left femoral arterial accesses were obtained, a 7-Fr guiding JL catheter (Cordis) was advanced for left CA manipulations and a 5-Fr diagnostic JR catheter (Cordis) for right CA anterograde and left CA retrograde opacification. Left CA angiography confirmed the thread-thin communication between the midportion of the left main CA segment and the aneurysm, which remained dye-free (Fig. 2). Right CA angiography showed a heavy collateral network irrigating retrogradely the left territory up to the origins of the anterior descending and the circumflex arteries

Fig. 2 Total obstruction of the left main coronary in a ''cul-de-sac'' proximal to any identifiable branching (*arrow*)

Fig. 3 Right coronary artery angiography demonstrating a heavy collateral network irrigating retrogradely the left territory up to the origins of the anterior descending (*LAD*) and the circumflex (*CX*) arteries. Note the circular calcified aneurism (*AN*)

Fig. 4 Left coronary artery angiography demonstrating adequate perfusion of the anterior descending and the circumflex segments across the calcified aneurism (*AN*)

(Fig. 3). The proximal segment of the anterior descending artery also showed a long segment stenosis, and the aneurysm remained dye-free. Initially, a 0.014-in. HI-TORQUE Balance Middleweight UNIVERSAL (BMW) guidewire (Guidant) failed to advance beyond the midportion of the CA aneurysm. Special care was taken in order to avoid wall dissection. Subsequently, a 0.014-in. Shinobi guidewire (Cordis) was manually shaped to give it a distal curve in order to support the CROSSER catheter and to facilitate its tip orientation during activation. The CROSSER was advanced over the Shinobi wire to the occlusion; then it was activated and it began to make visual progress into the occlusion. Advancing over the Shinobi, the CROSSER traversed the CA between the midportion of the left main segment and the aneurysm and created a channel within the aneurysm and out of the aneurysm into the anterior descending CA. Afterwards, the Shinobi guidewire was advanced distally into the true lumen of the anterior descending artery and exchanged for a 0.014-in. ExtraSPORT guidewire (Guidant). Subsequent advancement of an intravascular ultrasound catheter was not possible across the proximal end of the aneurysm due to heavy calcification. Therefore, primary balloon dilatation was performed at both the proximal and the distal ends of the aneurysm using noncompliant balloons (1.5-, 2.0-, 2.5-, and 2.5-mm diameter). Intravascular ultrasound was utilized for segmental coronary measurements. Subsequently, a Cypher Sirolimus-eluting stent, 3.0 mm in diameter and 30 mm in length (Cordis), was deployed covering the proximal stenosis on the distal left main CA, the CA aneurysm, and the distal stenosis on the proximal anterior descending CA. Immediate anterograde perfusion of the anterior descending artery and the circumflex CA was documented by left CA angiography (Fig. 4). The circumflex and the obtuse marginal branches represented 70% focal proximal stenoses, which were not addressed during the procedure.

The patient was discharged the next day on previous cardiovascular medication with the addition of clopidogrel 75 mg PO. At the 10-day follow-up visit, the patient was completely asymptomatic, reporting improved tolerance of daily physical activities and improved sleeping time with no further shortness of breath, a symptom that the patient had not realized she had prior to the procedure. An exercise stress test was performed and showed excellent performance of 9:33 duration (10.9 METs), symptom-free, with no signs of electrical ischemia or decrease in blood pressure.

Discussion

The CROSSER catheter, which has a stainless-steel, smooth-edge tip, is designed to recanalize resistant or calcified obstructions in blood vessels via mechanical and cavitational effects. It may be used over a standard 0.014-in. coronary guidewire for debulking of very narrow stenoses or to recanalize CTO and therefore prepare the way for a 0.014-in. guidewire. From a safety perspective, once activated, the CROSSER catheter reciprocates longitudinally with a stroke depth of 20 μm or a couple of cell layers deep. This stoke distance on its own does not have the ability to perforate through the deeper elastic lamina. Furthermore, and as required by the Food and Drug Administration prior to human trial applications, several animal tests have been done to assess the safety of the CROSSER catheter in terms of risk of perforation. Canine coronary arteries were ligated with sutures and the operator manipulated the device (activated and not activated) utilizing extensive push and doddering and was unable to perforate the target artery (personal communication with FlowCardia staff). Among 300 adult coronary cases performed worldwide, there were no CROSSER-related complications. Two series of 53 [4] and 28 [11] patients have been reported so far, with one case of perforation in the latter series due to conventional dedicated CTO wire manipulation. The success rate was 76 and 64%, respectively, after failure with conventional dedicated CTO wires.

In this report, the CA aneurysm demonstrated heavy calcification that could be seen on plain chest x-ray. Intravascular ultrasound documented circumferential calcification. Unlike atherosclerotic CA disease of the adult, KD-related CA stenosis is associated with calcification in a much larger proportion, mainly in patients who develop giant aneurysms (CA aneurysm >8 mm) commonly visualized on plain chest x-rays or on fluoroscopy [9, 15]. Several interventional approaches to KD-related CA stenosis have been re-

ported in the literature, including the following separate or combined methods: percutaneous balloon angioplasty, transluminal rotational ablation, and stent implantation [5, 6]. Surgical treatment has also been offered to patients with significant stenosis or CTO. Although saphenous graft has been abandoned due to unsatisfactory long-term patency, favorable follow-up of pedicled internal thoracic artery bypass has been observed both with and without aneurismectomy/aneurismorrhaphy [8]. Nevertheless, long-term arterial graft patency in children who underwent internal thoracic artery graft before 12 years of age ($n = 146$) was 93, 73, and 65% at 1, 5, and 15 years postoperatively, respectively. This reported outcome was less favorable than that in a series in which the same type of graft operation was performed after age 12 years ($n = 156$), with reported patency rates of 95, 91, and 91% at identical intervals [17]. We believe that providing efficient percutaneous reperfusion of the CTO documented in our patient using the CROSSER system offers a unique alternative to surgery. The patency expectancy is yet to be determined, but we speculate that the use of a drug-eluting stent provides greater freedom from restenosis compared to previously reported cases in which bare metal stents have been utilized. There are no reliable data based on the KD population to support our argument. However, atherosclerotic CA disease in the adult clearly demonstrated a significant reduction of restenosis in general [3, 13], as well as in CTO cases [2, 12]. To our knowledge, there is one case report of CA aneurysm formation following sirolimus-eluting stent implantation in KD [10], but there are no other reports on drug-eluting stents in KD according to a recent Medline search. On the other hand, CA aneurysms secondary to high-pressure balloon dilatation (>10 mmHg) have been observed in KD patients [5] but appear to regress spontaneously with time [1].

In conclusion, current advances in coronary artery intervention provide a broader spectrum of nonsurgical therapeutic options for young children with severe, life-threatening KD-related CA sequelae. Specifically, this first successful experience with the CROSSER system is greatly encouraging for patients with CTO and heavy calcification typically found in KD.

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