

# Radiofrequency Wire & New Technique for the Treatment of Coronary Chronic Total Occlusion

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**NG ET AL.: Radiofrequency Wire & New Technique for the Treatment of Coronary Chronic Total Occlusion.** *Treatment of coronary CTO remains a technical challenge in contemporary PCI. The major limitation of the procedure is the inability to pass a guidewire across the CTO. A new OCR guidewire system has demonstrated clinical potential for navigating through CTO; in addition, the system is now coupled with RF energy for facilitating guidewire crossing through highly resistant hard total occlusive lesions. This device might offer new horizon for PCI to CTOs which would not have been attempted before. (J HK Coll Cardiol 2003;11:22-26)*

*Chronic total occlusion, optical coherence reflectometry, radiofrequency energy*

## 摘要

治療冠狀動脈慢性完全性阻塞中同步協定信號控制仍然是技術上的一項挑戰。在操作過程中最大的限制在於導線無法通過慢性完全性阻塞段。一種新型的光學聯接反射性導線系統在臨床應用中顯示出通過慢性完全性阻塞段導向的優越性。此外，這套系統還配備了射頻能量，由此能夠使導線通過非常堅硬的完全性阻塞段。這一裝置為治療冠狀動脈慢性完全性阻塞中協定信號的控制提供了新的方向，而這在以前是沒有嘗試過的。

關鍵詞：慢性完全性阻塞 光學聯接反射計 射頻能量

## Introduction

Percutaneous coronary interventions (PCI) are routine procedures in today's Cath Labs. However, PCI for chronic total occlusion (CTO), defined as a total occlusion of more than three months' duration, presents a number of technical challenges. A successful procedure represents a better long-term outcome for patients with CTO,<sup>1</sup> however, its success rate remains unsatisfactory. Successful recanalization is achieved in less than 65% of attempted procedures, with an inability to cross the lesion with a guidewire being the reason

for failure in about 80% of unsuccessful attempt.<sup>2</sup> To facilitate guidewire crossing of CTO, new guidewires have been developed, including a ball-tipped wire, the laserwire, guidewires with hydrophilic coating, and stiff wires with high-torque control; however, these have failed to improve the success rate of PCI to CTO significantly.<sup>3</sup> The lack of visualization to navigate safely the guidewire through the occlusion site is a major cause of failure. To overcome this limitation, a new guidance system, the Safe-Cross™ wire, has been developed that uses both optical coherence reflectometry (OCR) for proper direction within the lesion and radiofrequency ablation energy (RF) delivered at the wire tip to traverse hard total occlusions.

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## Materials and Methods

The principles and set-up of OCR technology in the Safe-Steer™ wire has been described in the literature.<sup>4-7</sup> In brief, it is a forward-looking optical guide

wire system that utilizes near-infrared light and optical coherence reflectometry (OCR) techniques to discern if it is safe to proceed in the current path of the guide wire in the total occlusion or, more importantly, if the guidewire is approaching the normal artery wall (media or adventitia tissue) and has to be redirected. Moreover, the Safe-Cross™ is the said new guidewire system that carries both the OCR in the Safe-Steer™ wire (as a forward-looking fiberoptic guidance technology to navigate CTO) and the ability to deliver RF energy at the distal tip of the guide wire. As the presence of organized, calcified plaque in CTO remains a major obstacle for guidewire to negotiate through even though it is in proper direction; to overcome this limitation, the Safe-Cross™ system incorporates the ability to deliver RF energy to the distal tip of the guidewire. A 125 µm single mode fiber with a polyimide jacket is used with an outer diameter of approximately 0.0065" for the optics. The proximal portion of the guidewire is commercially available 0.013" hypodermic tubing that serves as a conduit for the fiber. The distal tip is a custom wound coil spring with a platinum end as a radiopaque marker. The fiber terminates at the distal end of the wire with a polished surface flushed with the guidewire tip. Polyimide coating is used to electrically isolate the wire except for the ablative region of the distal tip. The delivery of low frequency (250 kHz), short-duration (20 ms) RF energy is used to create a lumen slightly larger than the wire itself. The initiation of RF energy is gated by the permission from the OCR and the delivery will be interrupted automatically if the path of wire advancement is toward the arterial wall. Coupled with the OCR guidance, the RF ablation enables the guidewire to pass through highly organized and calcified CTO that would not be easily traversed by conventional guidewires (Figure 1).

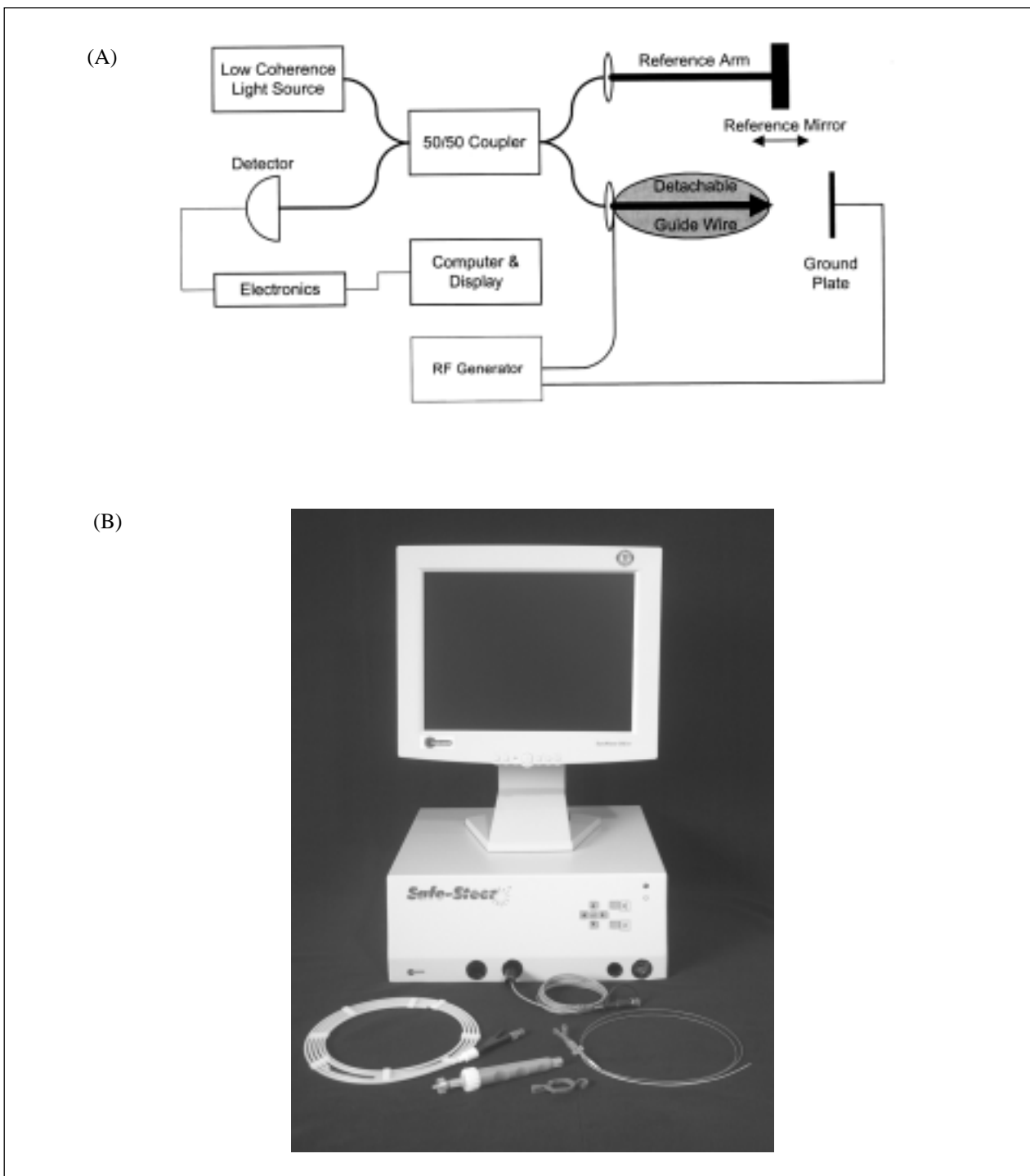
## Patients

Successful PCIs in two patients with long-standing CTO had been performed using the new Safe-Cross™ wire and described as below.

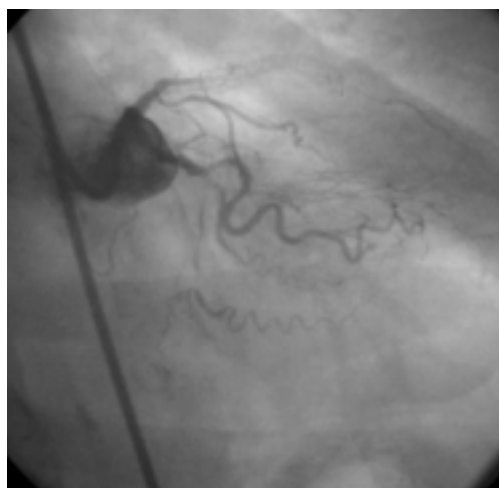
### Case 1

A 57-year-old woman suffered from diabetes mellitus, hypertension, hypercholesterolemia and

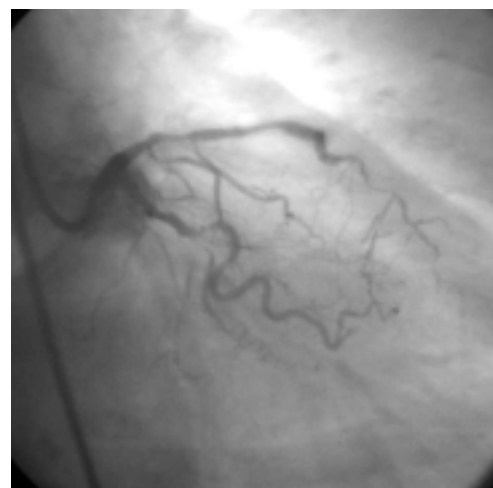
ischemic heart disease. She has undergone repeated angioplasty & stenting to the proximal left anterior descending artery before (3.0 x 40 mm Gianturco-Roubin (GR) II stent) (Cook, Bloomington, IN). Coronary angiography in April 1999 revealed occlusive in-stent restenosis starting from the proximal part of the GR II stent. The total occlusion could not be crossed using the 0.014" Choice PT wire (Boston Scientific Corp, Natick, MA) and 0.014" Intermediate wire (Guidant, Santa Clara, CA). The patient declined coronary artery bypass graft (CABG) surgery and had class II stable angina with medical treatment. She underwent another coronary angiography in April 2002 because of worsened angina. The LAD was occluded as before, with faint left-to-left collaterals (Figure 2). Since the patient still refused CABG and the Safe-Cross™ became available in our institution, PCI was arranged in August 2002. Using a 7F AL1 guide (Cordis, Johnson and Johnson Interventional Systems, Warren, NJ), a Maverick 1.5 x 9 mm balloon (Boston Scientific Corp, Natick, MA) was advanced proximal to the LAD occlusion after sending an All Track Wire (ATW; Cordis, Johnson and Johnson Interventional Systems, Warren, NJ) to the lesion. The ATW was exchanged for the Safe-Cross™ guidewire. After confirming the wire tip was pointing in the correct intraluminal direction seen as green light in the OCR display, RF energy was applied and the Safe-Cross™ guidewire was advanced distally. At positions where the Safe-Cross™ guidewire could not be steered to point away from the vessel wall, the guidewire was exchanged for the 0.014" Shinobi wire (Cordis, Johnson and Johnson Interventional Systems, Warren, NJ). With better steerability, the wire could be manipulated to point in the correct direction. Then the balloon was advanced as distal as possible over the Shinobi, followed by exchange for the Safe-Cross™ guidewire. By alternating the use of the Safe-Cross™ guidewire and conventional PCI guidewire, about two-third of the length of the occlusion was recanalized. The remaining segment of occlusion was crossed using the Shinobi wire alone. The Shinobi wire was exchanged for the Balance Middle Weight (BMW; Guidant, Santa Clara, CA) wire. After dilating the lesion with the 1.5 x 9 mm Maverick balloon, a 3.0 x 10 mm cutting balloon (Boston Scientific Corp, Natick, MA) was used to optimize the angiographic result. Vascular brachytherapy (VBT)



**Figure 1.** Optical coherence reflectometry guide wire system combined with radiofrequency ablation for navigating a guidewire through a CTO. (A) Schematic representation of the system. (B) The Safe-Cross™ console with the wire.



**Figure 2.** Left coronary artery angiography in the RAO caudal view showing total occlusion of the LAD at the inlet of the Gianturco-Roubin II stent.



**Figure 3.** Final angiographic result in the LAO caudal view after recanalization using the Safe-Cross™ and conventional guidewire, balloon angioplasty, and brachytherapy.

using a GALILEO™ centering catheter (Guidant, Santa Clara, CA) was performed for this occlusive in-stent restenosis. Final result revealed 30% residual stenosis in the proximal part of the stent, a type B dissection in the distal LAD beyond the stent, and TIMI-3 flow (Figure 3). The patient was discharged one day after the PCI without any complications.

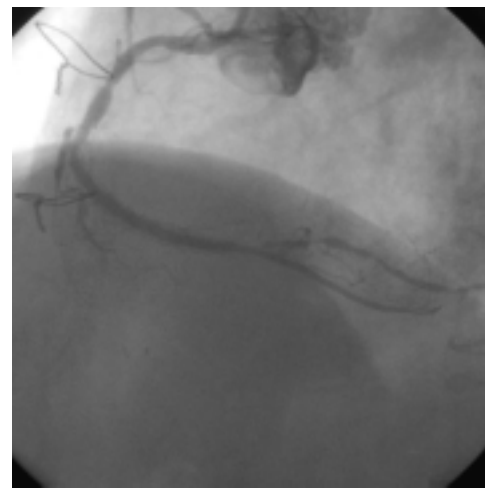
## Case 2

A 66-year-old man, an ex-smoker, with hypertension, hypercholesterolemia, and coronary artery disease underwent CABG in July 1996 with left internal mammary artery (LIMA) graft to LAD, sequential saphenous vein graft (SVG) to the superior and inferior branches of the ramus, individual SVG to first obtuse marginal (OM) and R-PLV respectively. The patient experienced recurrent angina 6 months later. Cardiac catheterization performed in February 1997 showed occluded SVG to the PLV while the other grafts were all patent. The RCA was totally occluded at the distal segment, which was revascularized by deployment of a 3.5 x 48 mm Magic Wallstent (Schneider, Zurich, Switzerland). Another cardiac catheterization was arranged in September 1998 because of recurrent angina. The RCA was occluded at the proximal part of the Magic Wallstent. The occlusive in-stent restenosis (ISR) could not be crossed using the 0.014" Sport (Guidant, Santa Clara, CA), Shinobi, or Standard (Guidant, Santa Clara,

CA) wires. The patient refused a second CABG operation and had class II to III angina with medical therapy. With the availability of the Safe-Cross™ in our institution, an attempt to recanalize the occlusive ISR was arranged in August 2002. Diagnostic shots showed occlusive ISR as before (Figure 4) with right-to-right and left-to-right collaterals. Using a 7F Zuma II FR4 guide (Medtronic AVE, Santa Rosa, CA), a Maverick 1.5 x 20 mm balloon was advanced proximal to the RCA occlusion after sending a 0.014" BMW wire to the lesion. Similar to the strategy in the first case, a channel was created by using the Safe-Cross™ guidewire and conventional guidewire. At positions where the Safe-Cross™ guidewire could not be steered to point to an intraluminal direction, the wire was exchanged for the Shinobi wire which was manipulated to point away from the vessel wall. Approximately two-third of the length of the occlusion was recanalized using this method while the remaining was crossed using the Shinobi wire alone. The Shinobi wire was sent to the R-PLV branch and exchanged for the BMW wire. The lesion was dilated with the 1.5 x 20 mm Maverick balloon followed by the 3.5 x 15 mm FX Minirail balloon (X Technologies, Inc., Tustin, CA). VBT using a GALILEO™ centering catheter was then performed for the same reason as above. Final result revealed 20% residual stenosis, no dissection, and TIMI-3 flow (Figure 5). The patient had an uneventful recovery and discharged.



**Figure 4.** Right coronary angiography in the LAO view showing total occlusion of the RCA at the inlet of the Magic Wallstent.



**Figure 5.** Final angiographic result in the LAO view after recanalization using the Safe-Cross™ and conventional guidewire, balloon angioplasty, and brachytherapy.

## Discussion

In our two patients with chronic (>3 years), long (40 and 48 mm respectively) occlusive ISR and history of unsuccessful recanalizations because of inability of conventional guidewires to cross the lesions, the Safe-Cross™ allowed us to create a path through these highly resistant CTO. One of the shortcomings of the Safe-Cross™ guidewire is relatively inferior steerability compared with conventional guidewires. We overcome this problem by exchanging the Safe-Cross™ guidewire for a conventional guidewire (Shinobi for our cases), which has better steerability. After manipulating the Shinobi wire to point away from the vessel wall, the over-the-wire balloon was advanced as distal as possible to secure the position such that after exchanging back to the Safe-Cross™ guidewire, the position was maintained. With repeated maneuvers, more than half the length of the CTO was crossed and it happened that in both cases the remaining occlusion could be traversed without the need of the Safe-Cross™ guidewire.

Apparently, the approach for both native & ISR CTOs are the same, though the latter has the advantage of providing better fluoroscopic guidance. Finally, although there is no data from the literature commented on the success rate, cost-effectiveness of the procedure; more patients need to be gathered for the procedure in order to provide more information

about the feasibility of this system (including signal stability & reliability).

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