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Dual Lumen Microcatheters for Recanalization of Chronic Total Occlusions: A EuroCTO Club Expert Panel Report

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Short Title: DLMC in CTO-PCI

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ABSTRACT

Dual lumen microcatheters (DLMC) have become indispensable tools in the setting of percutaneous coronary intervention (PCI) of chronic total occlusion (CTO). Other than allowing preservation and treatment of bifurcated coronary branches within or in the proximity of the CTO-body, they enable the use of modified parallel wiring, antegrade dissection and re-entry, collateral selection and retrograde negotiation of the distal CTO-cap. This Euro-CTO consensus document describes current DLMCs and suggests a practical guide to anatomies and techniques in which these devices are applicable.

Classifications: Bifurcation; Chronic coronary total occlusion; Other technique

ABBREVIATIONS:

CTO: chronic total occlusion

Cx: circumflex artery

DLMC: dual lumen microcatheter

GC: guiding catheter

IVUS: intravascular ultrasound

LAD: left anterior descending coronary artery

MC: microcatheter

MV: main vessel

OTW: over-the-wire

PCI: percutaneous coronary intervention

RCA: right coronary artery

SB: side branch

INTRODUCTION

Microcatheters (MC) are indispensable for contemporary chronic total occlusion (CTO) percutaneous coronary intervention (PCI).[1, 2] DLMCs have been introduced more recently but have found multiple clinical applications in CTO recanalization. This consensus document of the Euro-CTO Club describes the technical characteristics of available DLMCs and makes recommendations based on an in-depth discussion of their role during the 2020 EuroCTO Club annual meeting in Berlin.

AVAILABLE DEVICES

All DLMCs except the ReCross catheter (IMDS, Roden, Netherlands) consist of a monorail (rapid exchange) delivery system (distal exit port), combined with an OTW lumen (proximal exit port). Radiopaque markers are used to identify the exit ports (**Figure 1**). An overview of available devices and their characteristics is presented in **Figure 1** and in **Table 1**.

The TwinPass (Teleflex Medical, Limerick, PA-USA) (**Figure 1A)** is 135 cm long and has a tip-to-OTW-lumen distance of 20 mm. A modification of this catheter (TwinPass Torque, **Figure 1B)** has been introduced with a tip-to-OTW-exit port distance of 7 mm and a 10-degree deflection. The main technical innovation of the TwinPass Torque is braiding along the catheter. This should theoretically facilitate torquing towards the desired direction (proximal cap, distal true lumen, side-branches), however this feature is limited in practice by the ability of the operator to control the direction of the distal port.

The FineDuo/Crusade (Terumo/Kaneka, Japan) (**Figure 1C**), is a hydrophilic coated DLMC with an OTW lumen and a rapid exchange lumen, with a 1 mm radiopaque marker on the rapid exchange lumen, positioned at a 0.5 mm distance from the distal tip.

The NHancer Rx (IMDS, Roden, Netherlands) (**Figure 1D)** has the smallest crossing profile (2.3 F) and uses a removable stylet in the OTW lumen to facilitate advancement.

The ReCross (IMDS, Roden, The Netherlands) (**Figure 1E)** has the unique characteristic of having two OTW lumens with the proximal exit port at 12 mm from the tip, positioned opposite to the distal exit port.

The Sasuke (Asahi Intecc, Aichi, Japan) (**Figure 1F)** is the longest DLMC (145 cm) and is intended to be used both for antegrade and retrograde procedures, taking advantage of the hydrophilic coating of the distal 38 cm. It has an oval design with the OTW exit port having a 20-degree deflection positioned at 6.5 mm from the tip.

Insertion of DLMC is straightforward but removal can be cumbersome as co-ordination is required between two operators to ensure that the over-the-wire and monorail wires both remain in position within the coronary arteries. Balloon trapping is highly recommended to facilitate this manoeuvre but requires a 7 Fr guide catheter except for the Nhancer Rx and the Sasuke.

RECOMMENDATIONS OF USE, CLINICAL INDICATIONS AND TECHNIQUES (Table 2 and Figure 1)

Major side-branch near the proximal CTO-cap (Figure 1A' and Supplemental Video 1)

Many CTO proximal caps occur at or close to side-branches (SB). In this case, the use of a standard microcatheter may be limited by wire prolapse into the open SB, either as a result of unfavourable angulation or the wire following a lower resistance pathway (where the proximal cap is fibrotic or calcified). Under these circumstances, a DLMC placed on a workhorse wire that is sited distally in the SB provides a stable platform for proximal cap

penetration, as the operator can better control the wire direction towards the CTO cap whilst also augmenting penetration force in this direction[3]. After successful penetration of the proximal cap the DLMC should be exchanged to a conventional MC.

Parallel-wire technique (Figure 1B' and Supplemental Video 2)

The parallel-wire technique is an integral part of the modified hybrid algorithm recently proposed by the Euro-CTO Club[4]. This technique may be an option in cases where, during antegrade wiring, subintimal tracking occurs. Alternatively to a single-wire negotiation to gain access to the true lumen beyond the distal CTO-cap, parallel wiring advocates the use of a second wire to gain distal luminal wiring, while the first wire remains as visual reference and material that occupies the proximal entry in the subintimal space. In this context, a DLMC can be used over the first guidewire (placed subintimally). Of note, there are no data that support one strategy or device over another. Individual operators need to consider the balance among safety, physician experience, equipment availability and the overall cost of the procedure. The presence of the potential for the loss of distal side branches should still prompt assessment by intravascular imaging to clarify the intravascular course of the second wire after it has reached the distal lumen.

Distal Re-entry (Figure 1C' and Supplemental Video 3)

Some operators have been using DLMCs in a Stingray-like technique, inserting the DLMC beyond the distal CTO-cap, in order to allow re-entry by puncturing the true lumen using the OTW guidewire. We do not encourage this practice because there is a dedicated device that allows a more precise and safer re-entry (Stingray, Boston Scientific, USA) directing the wire towards the distal true lumen. We acknowledge however that there are some special

circumstances that DLMC use can be considered as an alternative. These are namely: (i) failure of Stingray delivery; (ii) unavailability of the technology; and (iii) clinical-investigational purposes.

Access of SB at the distal occlusion cap (Figure 1D' and Supplemental Video 4)

In case of antegrade wiring, particularly in longer CTO lesions, the guidewire may re-enter beyond a bifurcation. Subsequent stenting will seal a tissue flap over the alternate branch resulting in its closure and making rescue highly unlikely. Once the CTO is crossed with confirmed lumen entry at the bifurcation, a DLMC can allow safe wiring of the second branch. This will allow kissing inflation or 2-stent techniques as clinically indicated to manage the bifurcation itself.

Selective engagement of angulated collaterals (Figure 1E' and Supplemental Video 5)

This application of DLMC is not limited to CTO but it is especially helpful in retrograde recanalization whenever it is necessary to engage septal or epicardial collaterals originating with retrovert angles. Following wire engagement, the DLMC can be removed and exchanged to a conventional MC in order to cross the collateral, minimizing the risk of trauma. An optimal entry-view is recommended and the use of gentle lubricious guidewires is recommended. Occasionally, the angulated collateral can be engaged using in combination a DLMC and the so-called "hairpin" guidewire technique [180-degree reverse angulated polymer jacket guidewire (Sion black, Asahi Intecc, Japan) that is being pulled back, until its tip engages the ostium of the collateral][5]. Whilst DLC may be helpful, pre-shaped MCs (angled tip SuperCross, Teleflex, USA) or the Venture catheter may prove more helpful in extreme angulation.

Retrograde crossing and retrograde puncture of the distal CTO cap (Figure 1F')

Dual lumen microcatheters are often useful for a distal cap bifurcation, in exactly the same manner as they are for solving proximal cap crossing. They can be considered for this use provided that it is safe to pass them through the collateral (septal with or without dilation with a small balloon and especially in bypass grafts). Their use retrogradely via epicardial collaterals is strongly discouraged. Indeed, the latter can lead to trauma of the collaterals due to the direct contact of the monorail guidewire with the collateral lumen. Retrograde parallel wiring is unreasonable, considering that a retrograde dissection-re-entry technique is by far more efficient and safer for the patient.

CONCLUSION

There is growing interest in the application of DLMCs, especially in CTOs with proximal or distal caps at large bifurcations, and for parallel wiring. A systematic approach is required to exploit all the potential of this important addition to the CTO armamentarium.

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Conflict of interest statement

Dr. Pyxaras reports proctorship and consultancy fees from Boston Scientific, speaker honoraria from Abiomed and Astra-Zeneca. Dr. Levefre report proctorship fees from Boston Scientific and Terumo. Dr. Goktekin reports proctorship and consultancy fees from Boston Scientific, Asahi, Terumo, Boston Scientific, Medtronic, Abbott. Prof. Carlo Di Mario receives research or educational grants from Abbott, AMGEN, Asahi intecc, Astra-Zeneca, Boston Scientific, Cardinal Health, Behring, Chiesi, Daiichi Sankyo, Edwards, Medtronic, Menarini, Pfizer, Sanofi, Shockwave, Teleflex, Volcano-Philips. Dr. Mashayekhi received consultancy fees and speaker honoraria from Abbott, Abiomed, Asahi Intecc, Astra-Zeneca, Biotronik, Boston Scientific, Cardinal Health, Daiichi Sankyo, Medtronic, Schockwave, Teleflex, Terumo. All other authors have no conflicts of interest to report.

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FIGURE LEGENDS

Figure 1.

Left Panel: Principal dual lumen microcatheters on use and their dimensional characteristics; (A) Twin Pass (Teleflex); (B) Twin Pass Torque (Teleflex); (C) FineDuo (Terumo); (D) NHancerRX (IMDS); (E) ReCross (IMDS); (F) Sasuke (Asahi Intecc).

Right Panel: Graphical representation of anatomical scenarios and relative techniques of use for dual lumen microcatheters; (A'): Major side-branch near the proximal CTO-cap; (B'): Parallel-wire technique; (C'): Distal re-entry; (D'): Access of SB at the distal occlusion cap; (E'): Selective engagement of angulated collaterals, using the reverse wire technique; (F'): Retrograde crossing and retrograde puncture of the distal CTO cap.

Acknowledgment: *images of the Sasuke microcatheter, as depicted in the right panel, were made by VP Medical and used upon proprietary permission from Asahi Intecc.*

SUPPLEMENTAL MATERIAL

Video 1. Case example of a major side-branch near the proximal CTO-cap: Ostial occlusion of an LAD with retrograde filling over the RCA. A DLMC was used to antegradely puncture the proximal CTO-cap using a stiff guidewire.

Video 2. Case example of parallel wiring using a DLMC: the first wire is subintimal (rapid-exchange port), while the second wire (OTW port) find its way to the distal true lumen of the LAD.

Video 3. Case example of distal re-entry using DLMC: initially, subintimal tracking of the distal RCA. The wire is left in place and – over a DLMC – the second wire performs a puncture into the distal true lumen of the vessel.

Video 4. Case example of access of SB at the distal occlusion cap: the distal CTO-cap consists of a bifurcated segment of the Cx; after antegrade wiring of the first marginal branch, a DLMC is positioned over the first guidewire and, subsequently, a second wire passes safely to the second major side branch.

Video 5. Case example of selective engagement of angulated collaterals using the "hairpin" technique, as well as retrograde crossing and retrograde puncture of the distal CTO cap.

Legend. *CTO: chronic total occlusion; Cx: Circumflex artery; DLMC: dual lumen microcatheter; LAD: left anterior descending coronary artery; OTW: over-the-wire; RCA: right coronary artery.*

Table 1. Dual lumen microcatheters – dimensional/positional characteristics

	Length (cm)	Proximal O.D. (F)	Dual lumen O.D. (F)	Tip entry O.D. (F)	Distal marker distance from tip (mm)	Inner lumen O.D. (in.)	Distal tip length* (mm)	Distance of OTW lumen port from tip (mm)	Hydrophilic coating length (cm)	Guiding catheter compatibility	Guiding catheter minimal luminal dimensions for trapping
TwinPass	135	2.9	3.4 x 2.7	2	1	0.016 in. (RX) 0.0165 in. (OTW)	20	20	18	6F	7F
TwinPass Torque	135	3.1	3.5 x 3.5	2.1	1	0.015 in. (RX) 0.0155 in. (OTW distal) 0.0165 in. (OTW proximal)	7	7	25	6F	7F
FineDuo/Crusade	140	3.2	3.1**	1.3	0.5	0.014 in.	1.5	6.5	21	6F	7F
NHAncer Rx	135	2.6	3.3 x 2.3	1.5	0 (radiopaque tip)	0.019 in. tip and shaft lumen	5	6.5	18	6F	6F

ReCross	140	3.4 x 2.6***	3.3 x 2.3	1.5	0 (radiopaque tip)	0.019 in. tip and shaft lumen	5	8 / 12	25	6F	7F
Sasuke	145	3.2	3.3 x 2.5	1.5	0 (radiopaque tip)	0.016 in. (tip) 0.017 in. (shaft)	4	6.5	38	6F	6F

Legend. *O.D.: outside diameter; OTW: over-the-wire; RX: rapid-exchange*

** Defined as Length of the distal tapered part of the microcatheter*

*** The Crusade/FineDuo is circular, not oval, and as such has only one dimension*

**** The ReCross dual lumen microcatheter has a proximal cross-section which is oval, therefore two dimensions are used.*