

Complex Coronary Interventions with the Novel Mozec™ CTO Balloon: The MOZART Registry



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ABSTRACT

BACKGROUND: Mozec™ CTO is a novel semicompliant rapid-exchange PTCA balloon catheter with specific features dedicated to treat complex coronary lesions like chronic total occlusions (CTOs). However, no data have been reported about the performance of this device in an all-comers population with complex coronary lesions.

METHODS: We evaluated the safety and success rate of Mozec™ CTO balloon in 41 consecutive patients with chronic stable angina and complex coronary lesions (15 severe calcified coronary stenoses, 15 bifurcation lesions with planned two-stent intervention, and 11 CTOs). Safety was assessed reporting the balloon burst rate after inflation exceeding the rated burst pressure (RBP) according to the manufacturer's reference table. Success was defined as the possibility to advance the device further the target lesion.

RESULTS: The Mozec™ CTO balloon showed an excellent performance with a 93.3% success in crossing tight and severely calcified lesions (14/15 pts), a 93.3% success in engaging jailed side branches after stent deployment across bifurcations (14/15 pts), and a 90.9% success in crossing CTO lesions (10/11 pts). The burst rate at RBP of the Mozec™ CTO balloon was 6.7% (1/15 balloons) in the tight and severely calcified lesions, 6.7% (1/15 balloons) when dilating jailed vessels, and 9.1% (1/11 balloons) in CTOs.

CONCLUSIONS: The novel Mozec™ CTO balloon dilatation catheter showed promising results when employed to treat complex lesions in an all-comers population. Further studies should clarify if this kind of balloon might reduce the need of more costly devices like over-the-wire balloons and microcatheters for complex lesions treatment.

KEYWORDS: balloon catheter, coronary angioplasty, chronic total occlusion, bifurcation, calcified coronary artery disease

CITATION: Lupi et al. Complex Coronary Interventions with the Novel Mozec™ CTO Balloon: The MOZART Registry. *Clinical Medicine Insights: Cardiology* 2015;9:91–96 doi: 10.4137/CMC.S25552.

TYPE: Technical Advance

RECEIVED: March 04, 2015. **RESUBMITTED:** May 25, 2015. **ACCEPTED FOR PUBLICATION:** May 27, 2015.

ACADEMIC EDITOR: Thomas E. Vanhecke, Editor in Chief

PEER REVIEW: Five peer reviewers contributed to the peer review report. Reviewers' reports totaled 574 words, excluding any confidential comments to the academic editor.

FUNDING: Authors disclose no funding sources.

COMPETING INTERESTS: Authors disclose no potential conflicts of interest.

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Background

Complex coronary interventions in patients with tight and severely calcified coronary stenoses and chronic total occlusions (CTOs) are frequent in the all-comers population from the daily clinical practice.¹ In such patients, dedicated guide wires, over-the-wire (OTW) balloons, and microcatheters are often needed to treat these difficult lesions,² but these devices are more difficult to use and more expensive. Thus, the availability of workhorse rapid-exchange balloons with excellent crossing profiles, great pushability, and reduced costs can simplify the treatment of complex lesions, reducing the need for less user-friendly and more expensive equipment.

Study device. Mozec™ CTO (Meril Life Sciences Pvt. Ltd.) is a novel PTCA semicompliant rapid-exchange balloon dilatation catheter manufactured with specific features to facilitate complex coronary interventions. Its soft and laser-bonded distal tip of 5 mm with an entry profile of 0.016" for the 1.25 mm and 1.50 mm measures favor the deep engagement in the tight lesions or the CTO microchannels

with a smooth atraumatic lesion entry. Moreover, a novel Novalon™ balloon material ensures overall low wrapping profile and the short abrupt balloon shoulder design allows for crossing profiles as low as 0.022". Distal shaft coating of MeriGlide™, a biocompatible, hydrophilic, lubricious coating of the distal balloon base up to the rapid-exchange port, is another feature that can improve trackability of the device across long, tortuous, and calcified lesions. It is less than 4 μm thick and is nonthrombogenic, as it resists to fibrin adsorption and platelet adhesion. This is important to reduce thrombus formation during PCI, which is strongly correlated with postprocedural neointimal proliferation and subsequent restenosis.³

The seamless single-tube transition to the hypotube improves pushability allowing for superior force transmission without any loss during navigation.

These characteristics make the device virtually competitive, in terms of penetration power, crossing profile, and pushability, with the best available microcatheters and OTW balloons.



Methods

Trial design and patient population. The MOZec™ CTO balloon in complex coronary interventions (MOZART) study is a prospective, nonrandomized, single-arm registry aimed to evaluate the performance of the novel Mozec™ CTO balloon dilatation catheter for the treatment of complex coronary lesions in an “all-comers” stable coronary artery disease (CAD) patient population. The objective of the registry was to test the safety and the efficacy of this new device in treating stable patients with complex coronary anatomy at a single tertiary level clinical institution (“Maggiore della Carità Hospital”, Novara, Italy).

Key inclusion criteria were:
patients >18 years of age;

1. Symptoms of stable angina or silent ischemia with a positive functional test for ischemia and indication to coronary angiography;
2. Presence of a type C coronary lesion, according to the ACC/AHA coronary stenosis classification, with one of the following characteristics: (a) severe calcium with narrowing >80% and length >15 mm at visual estimate; (b) bifurcation lesion with planned two-stent treatment (culotte or mini-crush technique) and the need for recrossing packed struts encroaching side branch ostia; and (c) CTO according to the Euro CTO club definition¹ with planned antegrade approach; and
3. Agreement to participate in the study and in personal data management.

Key exclusion criteria were:

1. Acute coronary syndrome and
2. Left main stem involvement.

Procedure. PCI procedure was performed according to current standard guidelines.⁴ Pretreatment of the target lesion with any device other than the Mozec™ CTO balloon was not allowed. For this study, the Mozec™ CTO device was available in the following range of sizes: 9 mm and 15 mm in length for diameters of 1.25 mm and 1.5 mm. The choice of the device length and diameter was left to the operator choice. The device was considered successful if it was possible to track the balloon to the end of the stenosis or the occlusion. After an unsuccessful attempt to cross the lesion with the study device, angioplasty was performed with other devices according to the operator preference.

A routine 12-lead electrocardiogram was obtained before procedure, immediately postprocedure, and 24 hours later. Blood sample laboratory analysis included high sensitivity cardiac troponin I before procedure (<24 hours), 24 hours after procedure, and then daily thereafter until hospital discharge.

During the procedure, intravenous heparin (70–100 units/kg) was administered after sheath insertion to maintain

an activated clotting time >250 seconds (or >200 seconds if glycoprotein IIb/IIIa inhibitors were used, at the operator's discretion). Regarding DAPT, aspirin 100–325 mg was given >24 hours prior to procedure if not already taken; for thienopyridine (clopidogrel), a loading dose of 600 mg at least two hours prior to procedure, if not already taken (75 mg daily). After the procedure, all the patients received aspirin (100–325 mg) daily indefinitely, and clopidogrel 75 mg was prescribed daily for at least one month in case of bare metal stent deployment and up to one year in case of drug eluting stent deployment.

Quantitative coronary angiography. As a routine for our center, standard image acquisition of the treated stenosis was performed using two or more angiographic projections, intracoronary nitroglycerine to provide maximum coronary dilation, and repetition of identical angiographic projections of the lesion at baseline and final angiography. Angiograms were analyzed on site by two independent reviewers (AL and GGS). Using the contrast-filled injection catheter as the calibration source, quantitative angiographic analysis was performed using a validated automated edge detection algorithm (QAngio XA Medis).⁵ Selected images for analysis were identified using angiographic projections that demonstrated the stenosis in an unforeshortened view and minimized the degree of vessel overlap. The best angiographic projection that minimized lesion foreshortening was used for analysis. The length, minimal lumen diameter, and the percentage of diameter stenosis at the site of intervention were evaluated for each lesion before PCI.

Endpoints and clinical follow-up. The primary safety endpoint was the rate of balloon bursting after inflation at an inflation pressure higher than the rated burst pressure (RBP). The primary efficacy endpoint was the rate of successfully crossing the target lesion allowing the first lesion dilation. Baseline, procedural, and clinical FU data were collected by dedicated clinical research nurse; data monitoring was performed physically at the participating clinical site.

Statistical analysis and ethical issues. Categorical data were presented as frequencies (percentages of the total). Data sets with continuous variables were tested for normal distribution with the Shapiro–Wilk normality test. In case of normal distribution, data were presented as mean values ± standard deviation (SD); when non-normal distribution was evidenced, data were presented as median values with interquartile range (25%, 75%). The study was approved by the local ethical committee, and each patient signed a written informed consent to be included in the study. The study was conducted according to the principles of the Declaration of Helsinki.

Results

A total of 41 consecutive patients were enrolled between November 2014 and March 2015, 11 with a CTO with planned antegrade approach, 15 with a tight and severely calcified lesion, and 15 with a 1.1.1 Medina classification bifurcation



intended to treat with a two-stent strategy. Clinical features are summarized in Table 1, angiographic and interventional characteristics in Table 2, specific clinical and angiographic features of CTO lesions in Table 3. Mean age was 69.8 ± 11.2 years, 26.8% were diabetics (noninsulin dependent only), and 17.1% had previous MI or PCI intervention in the six months before (Table 1). Right coronary artery was the most prevalent target vessel (48.8%), and all the lesions were type C according to the AHA/ACC stenosis classification. Procedural outcomes are depicted in Table 1. Radial access was used in 68.3% of cases; all the lesions were predilated, and the first dilation was attempted with a 1.25 or 1.5 Mozec™ balloon. The Mozec™ balloon was highly effective in crossing such very complex lesions, with an overall success rate of 95.1% (39/41 lesions) and similar high success rates across different lesion types (Table 2). Balloon rupture was rare in the consideration of complexity of the lesions, with an overall burst rate of 7.3% (3/41) at a mean inflation pressure of 16.5 ± 0.8 ATM (Table 2).

In case of unsuccessful Mozec™ balloon advance, crossing of the lesion was accomplished with other devices according to the choice and the experience of the interventionalists.

Only in one case (a CTO patient), it was not possible to cross the lesion regardless the device used. In four cases (9.8%), the procedure was completed with the aid of a Guideliner™ catheter, and in two cases (4.9%), rotational atherectomy was employed.

No patient of the study population died during the hospital stay and/or suffered from stent thrombosis. Seven patients developed a small periprocedural myocardial infarction, according to the Third Universal Definition,⁶ without developing new Q waves.

Discussion

The present study demonstrates the feasibility and safety of crossing and dilating tight and complex coronary lesions with the novel Mozec™ CTO balloon, a balloon catheter engineered specifically to tackle CTOs and other complex coronary interventions.

CTOs represent about 10% of lesions usually encountered in an “all-comers” cath lab population¹ and other complex lesions like severely calcified stenosis are also very frequent, especially in the presence of comorbidities like dia-

Table 1. Clinical characteristics of the study population.

	CHRONIC TOTAL OCCLUSIONS (11 pts)		SEVERE CALCIFIED LESIONS (15 pts)		2-STENT TREATED BIFURCATIONS (15 pts)	
	COUNT	MEAN \pm SD	COUNT	MEAN \pm SD	COUNT	MEAN \pm SD
Age (years)		69.0 \pm 10.9		70.6 \pm 9.2		65.1 \pm 13.2
Male sex	9	81.8%	7	47.6%	8	53.3%
Hypertension	10	90.9%	12	80.0%	8	53.3%
Diabetes	4	36.4%	4	26.7%	3	20.0%
Tobacco (active/quitted >2 years)	5	45.4%	3	20.0%	5	33.3%
Dyslipidemia	4	36.4%	5	33.3%	5	33.3%
BMI >30 kg/m ² BSA	3	27.3%	3	20.0%	3	20.0%
PAD	3	27.3%	3	20.0%	1	6.7%
Previous CABG	0	0.0%	1	6.7%	0	0.0%
Previous MI and/or PCI	4	36.4%	3	20.0%	0	0.0%
eGFR <30 ml/min	1	9.1%	3	20.0%	1	6.7%
Dialysis	0	0.0%	1	6.7%	0	0.0%
Baseline LVEF%		41.8 \pm 11.9		50.9 \pm 6.6		47.3 \pm 10.2
Radial access	5	45.5%	11	73.3%	12	80.0%
Baseline troponin I (ng/dL)		0.016 \pm 0.004		0.018 \pm 0.009		0.015 \pm 0.006
Postprocedural troponin I (ng/dL)		0.10 \pm 0.14		0.12 \pm 0.20		0.13 \pm 0.10
Baseline CRP (mg/dL)		0.11 \pm 0.18		0.13 \pm 0.20		0.10 \pm 0.08
Baseline fibrinogen (mg/dL)		367.2 \pm 88.4		395.1 \pm 99.9		302.7 \pm 86.5
Baseline platelet count ($\times 10^3/\text{mm}^3$)		206.5 \pm 101.9		266.7 \pm 112.8		211.52 \pm 99.6
Baseline mean platelet volume (fL)		9.45 \pm 0.22		9.96 \pm 0.47		9.86 \pm 0.59

Abbreviations: BMI, body mass index; BSA, body surface area; PAD, peripheral artery disease; CABG, coronary artery bypass graft; MI, myocardial infarction; PCI, percutaneous coronary intervention; eGFR, estimated glomerular filtration rate; LVEF, left ventricular ejection fraction; CRP, C-reactive protein.

**Table 2.** Angiographic and interventional characteristics of the study population.

	CHRONIC TOTAL OCCLUSIONS (11 pts)		SEVERE CALCIFIED LESIONS (15 pts)		2-STENT TREATED BIFURCATIONS (15 pts)	
	COUNT	MEAN ± SD	COUNT	MEAN ± SD	COUNT	MEAN ± SD
Radial access	5	45.5%	11	73.3%	12	80.0%
Syntax score		23.6 ± 2.2		22.7 ± 3.1		24.5 ± 2.7
Left main CAD	4	36.4%	0	0.0%	0	0.0%
Multivessel CAD	10	90.9%	9	60.0%	8	53.3%
Euroscore		4.5 ± 0.6		3.7 ± 0.9		4.4 ± 0.8
Need for IABP	2	18.2%	0	0.0%	1	6.7%
Treated vessel/pt		1.8 ± 0.6		1.7 ± 0.8		2.4 ± 0.7
Stent deployed/pt		2.0 ± 1.1		1.9 ± 0.9		2.7 ± 0.6
Treated vessel						
LAD	5	45.5%	3	20.0%	7	46.7%
LCx	2	18.2%	1	6.7%	1	6.7%
RCA	3	27.3%	10	66.7%	7	46.7%
MO/Dia/PL/PDA	0	0.0%	1	6.7%	0	0.0%
SVG	0	0.0%	0	0.0%	0	0.0%
Reference vessel diameter (mm)		3.3 ± 0.3		3.4 ± 0.4		3.4 ± 0.4
Lesion length (mm)		24.0 ± 10.9		25.2 ± 14.7		21.7 ± 12.0
Baseline MLD		0.0 ± 0.0		0.6 ± 0.1		0.8 ± 0.1
Baseline stenosis degree (%)		100.0 ± 0.0		82.2 ± 4.4		77.0 ± 2.8
Mozec™ CTO balloon success in crossing the target lesion	10	90.9%	14	93.3%	14	93.3%
Ballon rupture	1	9.1%	2	13.3%	0	0.0%
In hospital death	0	0.0%	0	0.0%	0	0.0%
In hospital MI	2	0.0%	2	13.3%	3	20.0%
Acute/subacute stent thrombosis	0	0.0%	0	0.0%	0	0.0%

Abbreviations: IABP, intra-aortic balloon pump; LAD, left anterior descending; LCx, left circumflex; RCA, right coronary artery; Mo, obtuse marginal; Dia, diagonal; PL, posterolateral; PDA, posterior descending artery; SVG, saphenous vein graft; CAD, artery disease; MLD, minimum luminal diameter; ARC, Academic Research Consortium.

betes, renal impairment, and peripheral vascular disease.⁷⁻⁹ Moreover, these kinds of lesions are common in the elderly¹⁰ and are expected to become even more frequent with aging of patient populations.

Another clinical subset of patients who are difficult to treat with workhorse apparatuses and usually benefit from dedicated devices are those with coronary bifurcation lesions treated with a two-stent strategy. In these patients, encroachment of heavily packed stent struts can make extremely difficult the recrossing of the side branch ostium with even low profile balloon catheters.¹¹ Usually CTOs require dedicated devices like OTW balloon catheters or microcatheters,^{1,2} but this expensive technology is also used in the daily practice to approach complex cases of calcified or bifurcation coronary lesions.

Mozec™ CTO is a novel PTCA semicompliant balloon catheter engineered with specific features to facilitate complex coronary interventions. It has a distal tip of 5 mm with an entry profile of 0.016" favoring deep engagement in the tight lesions or the CTO microchannels. Moreover, the novel Novalon™

hydrophilic balloon material ensures the overall low wrapping profile with crossing profiles as low as 0.022". Finally, distal shaft hydrophilic coating with MeriGlide™ polymer and the seamless single-tube transition to the hypotube improve pushability and trackability of the device across long, tortuous, and calcified lesions. These characteristics might make the device virtually competitive, in terms of penetration power, crossing profiles, and pushability, with the best available microcatheters and OTW balloons.

Our pilot study demonstrated the feasibility of using the Mozec™ CTO balloon as a workhorse first choice device to cross and begin dilation of complex coronary lesions. To this end, we selected complex cases from an all-comers population of a tertiary center catheterization laboratory. In particular, three subsets of interest were identified: CTOs, tight and calcified stenoses, and bifurcations treated with a two-stent strategy. The Mozec™ CTO balloon showed a fair performance in each of these challenging situations, with a high rate of success in engaging and crossing the target lesions. The Mozec™ CTO balloon success rates, all above 90%, are

**Table 3.** Clinical and angiographic characteristics of CTO patients.

PATIENTS	11
CTO duration, months, (mean ± SD)	9.4 ± 2.4
CTO length ≥20 mm, (%)	4 (36.5%)
CTO diameter ≤3mm, (%)	5 (45.5%)
In stent CTO, (%)	1 (9.1%)
Blunt stump, (%)	3 (27.3%)
Severe calcification, (%)	5 (45.5%)
Severe tortuosity, (%)	4 (36.5%)

Abbreviations: CTO, chronic total occlusion; SD, standard deviation.

substantially similar to those reported for more costly CTO dedicated catheters. Obata et al reported antegrade CTO treatment with a success rate of 62.5% with the Finecross™ microcatheter¹² and with a success rate of 85.3% with the Corsair™ septal dilators device.^{12,13} The even more specialized and costly Tornus™ dilator catheter showed similar procedural success rates in antegrade CTOs.^{14–16} Thus, the availability of a rapid-exchange balloon with excellent crossing profiles, great pushability, and low cost (Table 4) has the potential for simplifying the treatment of complex lesions reducing the need for less user-friendly and more expensive equipment.

Moreover, the Mozec™ CTO balloon was a safe device. In fact, even when inflated with pressures far exceeding the RBP, balloon disruption was rare. This is an important safety point, because the adverse consequences of balloon rupture during coronary angioplasty are well known.¹⁷ In fact, balloon ruptures have been linked with potentially life-threatening complications like vagal baroreflexes, perforations, dissections, and embolizations leading to ischemia and hemodynamic instability.^{18,19} Moreover, coronary ruptures might affect negatively long-term prognosis of CAD patients treated with PCI.^{20,21} However, in our series, we observed a few balloon ruptures that were not associated with perforation, temporary or permanent no-reflow, or type 4a MI. No substantial danger may originate from the use of the device as the first choice, as if the device fails to pass through the lesion it can be easily removed like other minirail devices and substituted by other microcatheters OTW balloon catheters.

Table 4. Cost comparison of different common CTO support devices.

DEVICE	TYPE	US \$
Mozec™ CTO	rapid exchange balloon	150
Finecross	OTW microcatheter	800
Corsair	OTW microcatheter	1000
Tornus	OTW microcatheter	1200
Sapphire CTO	OTW balloon	150
MiniTrek OTW	OTW balloon	140

Abbreviations: CTO, chronic total occlusion; OTW, over the wire.

Limitations

First of all, the present study is a prospective registry, without a randomized comparison with other similar devices; thus no conclusion about the advantage of using this balloon in complex lesions in comparison to other existing devices can be drawn from this study.

Moreover, in the current analysis, the relatively low number of patients precludes any definite conclusions regarding the efficacy and the safety beyond the perspective of a preliminary single-center feasibility study. However, our success rate for Mozec™ CTO balloon trended to be higher in the severely calcified stenoses and in bifurcation lesions than in CTOs. This observation reflects the peculiar anatomy of CTO lesions, which still leads to less favorable results even in the era of retrograde approach.¹ On the other hand, we observed a few type 4a MI occurring in severely calcified lesion and in bifurcation lesions, probably related to incomplete stent expansion and apposition because of diffuse calcium deposition and unfavorable bifurcation angles, in fact in none of these cases.

Conclusions

The novel Mozec™ CTO balloon demonstrated a good performance in approaching complex coronary lesions in stable “all-comers” CAD patients, with a high procedural success. Moreover, there were no safety concerns in this preliminary evaluation, as burst rate was rare even at pressures well further the RBP.

Author Contributions

Conceived and designed the experiments: AL. Analyzed the data: AL, AS. Wrote the first draft of the manuscript: AL. Contributed to the writing of the manuscript: ASB, AR, GGS. Agree with manuscript results and conclusions: AL, ASB, AR, GGS, AS. Jointly developed the structure and arguments for the paper: AL, GGS. Made critical revisions and approved final version: AL, ASB, AR, GGS, AS. All authors reviewed and approved of the final manuscript.

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