Comparative Clinical Evaluation of Trackmaster Coronary Stent with new generation Everolimus Stent (USFDA approved), in all comers performed at BLK MAX Hospital, New Delhi.

Presentor:

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This was a single-center, single-arm prospective observational study carried out at a tertiary care center.

Disclosure

- I do not have any potential conflict of interest to declare

Methods:

- **Trackmaster Stent:** The study population included a registry of 58 patients who underwent single or multi vessel revascularization with clinical presentations such as stable/unstable angina and acute coronary syndrome in period between April 2022 and September 2022 who completed Six months follow-up period.

- **Comparative device (US FDA approved):** The study population included a registry of 58 patients who underwent single or multi vessel revascularization with clinical presentation such as stable/unstable angina and acute coronary syndrome in period between April 2022 and September 2022 who also completes Six months follow-up period.

- All the patients enrolled were implanted with at least one Trackmaster stent &/or Comparative device (market available USFDA approved everolimus stent) and responded to follow-up. Individual Patient was implanted with one type of stent only, which means one patient was not implanted with both devices. i.e Trackmaster stent & comparative device. The endpoint of the study was the incidence of major adverse cardiac events (MACE) defined as cardiac death, Myocardial infarction, repeat coronary revascularization and stent thrombosis. Clinical and telephonic follow-up was performed and MACE was analysed at 180 days.

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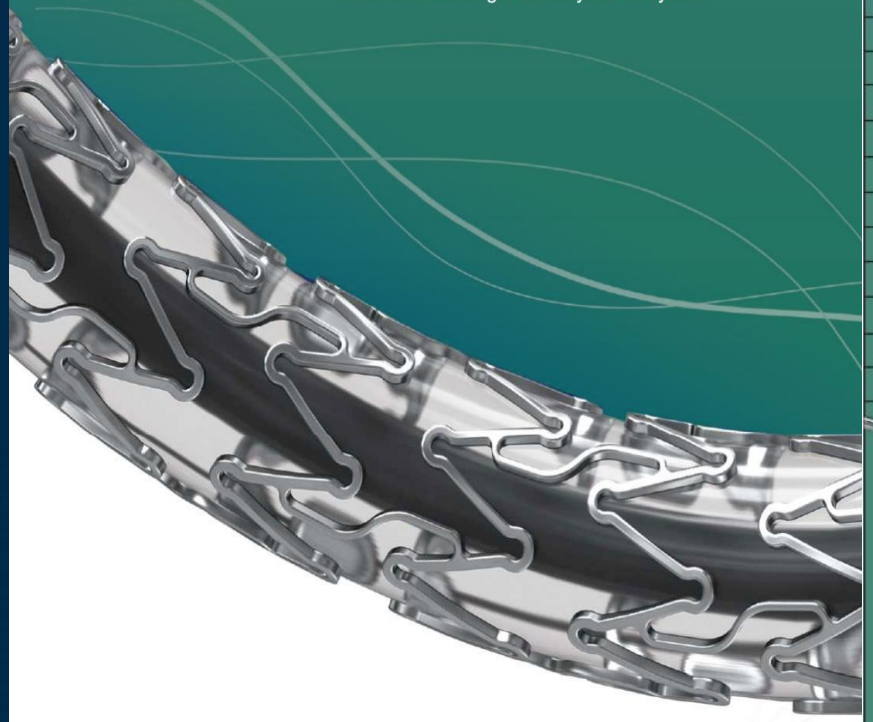
trackmaster

Everolimus Eluting Coronary Stent System



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THE STENT WITH
EXCEPTIONAL FLEXIBILITY &
ULTRA-THIN STRUT THICKNESS (65µm)

STENT SPECIFICATION

Design:	Open Cell Stent Design
Material:	Cobalt Chromium (CoCr) L605
Length (mm):	8, 13, 16, 20, 24, 28, 32, 36, 40, 43 & 47
Diameter (mm):	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00 & 4.50
Strut Dimensions:	Thickness 65 µm | Strut 70 µm | Connectors 50 µm
Nominal Pressure (NP):	9 atm
Rated Burst Pressure (RBP):	16 atm
Foreshortening:	Nearly Zero
Recoil:	≤ 5 %
Crossing Profile:	Nearly 1.00 mm
Min. Guidewire Diameter:	0.014"
Min. Guiding Catheter I.D.:	5 Fr Compatible
Radial Strength:	Excellent
Flexibility:	Excellent

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ORDERING INFORMATION

Dia(mm)	8	13	16	20	24	28	32	36	40	43	47
2.00	TR20008	TR20013	TR20016	TR20020	TR20024	TR20028	TR20032	TR20036	TR20040	TR20043	TR20047
2.25	TR22508	TR22513	TR22516	TR22520	TR22524	TR22528	TR22532	TR22536	TR22540	TR22543	TR22547
2.50	TR25008	TR25013	TR25016	TR25020	TR25024	TR25028	TR25032	TR25036	TR25040	TR25043	TR25047
2.75	TR27508	TR27513	TR27516	TR27520	TR27524	TR27528	TR27532	TR27536	TR27540	TR27543	TR27547
3.00	TR30008	TR30013	TR30016	TR30020	TR30024	TR30028	TR30032	TR30036	TR30040	TR30043	TR30047
3.50	TR35008	TR35013	TR35016	TR35020	TR35024	TR35028	TR35032	TR35036	TR35040	TR35043	TR35047
4.00	TR40008	TR40013	TR40016	TR40020	TR40024	TR40028	TR40032	TR40036	TR40040	TR40043	TR40047
4.50	TR45008	TR45013	TR45016	TR45020	TR45024	TR45028	TR45032	TR45036	TR45040	TR45043	TR45047

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Results

58 Patients were enrolled. Total 63 Lesions were treated with 63 Trackmaster stents

Clinical characteristics	
Age(year) Mean ± SD	64 ± 12
Male	36(62.06%)
Female	22(37.93%)
Diabetes	13(22.4%)
Hypertension	23(39.6%)
Coronary disease	
Single vessel	10(17.24%)
Two vessel	23(39.65%)
Three vessel	25(43.10%)
Clinical presentation	
Stable angina	44(75.86%)
Unstable angina	14(24.13%)
Good LV function	24(41.3%)
Mild LV Dysfunction	15(25.86%)
Moderate LV Dysfunction	19(32.75%)

58 Paitents were enrolled. Total 67 Lesions were treated with 67 Comparative device

Clinical characteristics	
Age(year) Mean ± SD	65+/-10
Male	45(77.58%)
Female	13(22.41%)
Diabetes	27(46.55%)
Hypertension	31(53.44%)
Coronary disease	
Single vessel	10(17.24%)
Two vessel	26(44.82%)
Three vessel	22(37.93%)
Clinical presentation	
Stable angina	67(100%)
Good LV function	25(37.31%)
Mild LV Dysfunction	24(35.8%)
Moderate LV Dysfunction	7(10.44%)

Trackmaster - Baseline angiographic characteristics (n=58)

Lesion Bifurcation	
LAD	34(53.96%)
LCX	7(11.11%)
RCA	15(23.80%)
OM	7(11.11%)

Comparative Device Baseline angiographic characteristics (n=67)

Lesion bifurcation	
LAD	32(47.76%)
LCX	8(11.94%)
RCA	19(28.35%)
OM	8(11.94%)

Trackmaster Stent Characteristics of study patients (n=58)

Stent Diameter, MM	
≤2.5 mm	6(9.52%)
2.5 to 3.5 mm,	49(77.77%)
≥3.5 mm,	8(12.69%)
Stent length, MM	
< 15 mm	2(3.17%)
16 to 20 mm	13(20.63%)
21 to 26 mm	13(20.63%)
≥26 mm	35(55.55%)

Comparative Device Characteristics of study patients (n=67)

Stent Diameter, MM	
≤2.5 mm	8(11.94%)
2.5 to 3.5 mm,	52(77.61%)
≥3.5 mm,	7(10.44%)
Stent length, MM	
< 15 mm	7(10.44%)
15 to 20 mm	15(22.38%)
21 to 26 mm	7(10.44%)
≥26 mm	38(56.71%)

Results

Trackmaster	Comparative Device
At 180 days follow up, the efficacy endpoint MACE occurred in 1 (1.72%) of 58 patients consisting of stent thrombosis (ST) was observed in 1 patient. Other Clinical parameters were also assessed like MI, target lesion failures, target vessel failure, cardiac & non cardiac death, CABG etc.	At 180 days follow up, the efficacy endpoint MACE occurred in 2 (3.44%) of 58 patients consisting of stent thrombosis (ST) was observed in 1 patient & target vessel revascularization was observed in 1 patient. Other Clinical parameters were also assessed like MI, target lesion failures, target vessel failure, cardiac & non cardiac death, CABG etc.

Study Conclusion:

- The Baseline clinical & Cardiac characteristics, angiographic & Stent Procedural Characteristics, efficacy endpoint MACE were analysed by considering various clinical terms such as stent thrombosis, target lesion failure, target vessel failure, MI, cardiac & non cardiac death etc. in both devices & Comparision was made. The Study results indicates that Trackmaster stent was found to be non-inferior to Comparative device (new generation USFDA market available everolimus stent) in reducing risk and remains safe and effective at the end of 180 days follow up period in CAD patients after angioplasty.
- The outperformance of the Trackmaster stent which has bioresorbable polymer everolimus-eluting stent over the durable polymer everolimus-eluting stent in a complex patient population undergoing percutaneous coronary intervention suggests a new direction in improving next generation drug-eluting stent technology. The comparative device has durable polymer.

THANK YOU FOR ATTENTION