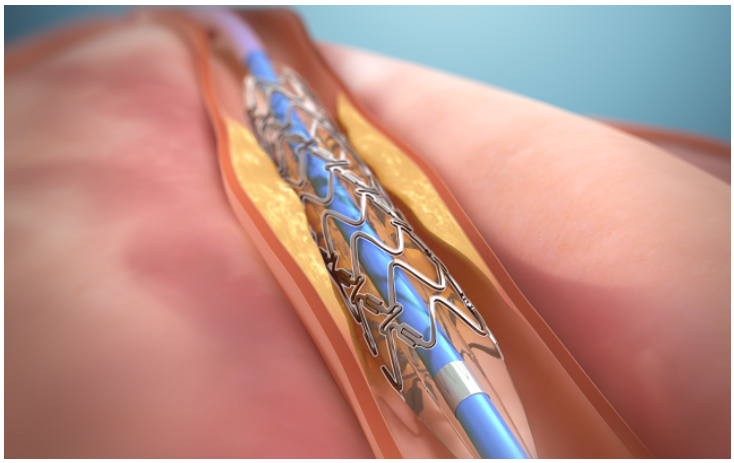
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Elixir Medical reveals a strong clinical safety profile for DynamX Bioadaptor

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The bioadaptor is the first coronary artery implant that adapts to vessel physiology



Elixir Medical, a developer of innovative, drug-eluting cardiovascular devices, on Jan 27th, 2021 announced the 24-month clinical results for the DynamX™ Coronary Bioadaptor System, recently presented at 30th Annual Live Interventions in Vascular Endotherapy conference organised by the National Heart Centre of Singapore (Singapore LIVE). The bioadaptor is the first coronary artery implant that adapts to vessel physiology.

Coronary artery disease (CAD) is a common form of heart disease. It occurs when the arteries to the heart become narrowed or blocked with plaque, depriving the heart muscle of needed oxygen and nutrients. Doctors traditionally have recommended using a drug-eluting stent (DES) to open up the narrowed arteries. Drug-eluting stents do an efficient job supporting the coronary artery but they permanently cage the vessel, which has been associated with major adverse cardiac events (MACE). These adverse events continue to build year-over-year without end.

The DynamX Bioadaptor is a new class of treatment for CAD. Unlike DES, which are rigid and constrain the artery, the bioadaptor is designed to move more naturally with the artery wall in response to the needs for more oxygen demanded by the heart (such as during exercise). It also allows the artery to expand to accommodate any new plaque build-up, maintaining the diameter of the treated area for good blood flow over time.

Dr. Antonio Colombo, MD, co-principal investigator of the study, Professor of Cardiology at Humanitas Medical School, Senior Consultant in Interventional Cardiology at Humanitas Research Hospital, Rossano, Milan, and Director of the Cardiac Catheterisation Laboratory in Columbus Hospital, Milan, Italy, revealed that the 24-month results from the clinical study showed:

- excellent safety profile for the bioadaptor
- no target vessel revascularisation
- no device thrombosis (blood clotting)

Previously published data on the bioadaptor demonstrated:

- the ability of the bioadaptor and artery to expand and keep the vessel open, which preserves good blood flow over time,
- normal artery motion with each heartbeat, enabling the artery to provide more blood flow in response to the body's needs during physical activity,
- the ability of the device and its drug coating to inhibit disease progression and support the vessel during healing.

Dr. Colombo said, "Coronary arteries naturally have the ability to expand with disease progression in order to maintain blood flow to the heart. Drug-eluting stents cage the coronary arteries and hinder this physiological response. DynamX is the first metallic coronary artery implant to demonstrate positive adaptive remodelling of the vessel. At 24 months, the bioadaptor continued to show no thrombosis and no target vessel revascularisation, which demonstrates a strong safety profile and excellent performance."

In Singapore, The National Heart Centre of Singapore is currently using the DynamX Bioadaptor for its patients. At the Singapore LIVE conference, Prof. Lim Soo Teik performed a live patient case from the National Heart Centre using the DynamX Bioadaptor.

Prof. Jack Tan, Deputy Head and Senior Consultant, Department of Cardiology, National Heart Centre of Singapore, and Head of Cardiology, Sengkang General Hospital, said: "Drug-eluting stents are the current gold standard treatment, but there is an opportunity to improve upon that technology. The promise of the bioadaptor is in addressing the 2-3% adverse event rate that occurs with DES each year, which may improve long-term patient outcomes. We are pleased to offer latest technology with the potential to provide greater benefits to patients."

Prof. Lim Soo Teik, Deputy Medical Director and Senior Consultant, Department of Cardiology, and Director of the Cardiac Catheterisation Laboratory, National Heart Centre Singapore, said, "DynamX Bioadaptor has demonstrated excellent clinical results, and performed well in the procedure presented at the Singapore LIVE conference. We are hopeful that allowing the artery to expand, preserving blood flow, and restoring artery motion may result in better outcomes for our patients."

Conclusion: The 24-month clinical study results demonstrated the positive safety profile features of the DynamX Bioadaptor, the first coronary artery implant that adapts to vessel physiology.