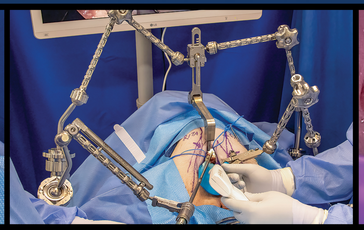
A New Technology Platform and Technique for Sternal Sparing Coronary Revascularization Surgery

Eric Ndikumana, MD[1], Kyle C. Purrman, MD[1,2], Hossein Amirjamshidi, MD[1], Peter A. Knight, MD[1], Jude S. Sauer, MD[1,2]

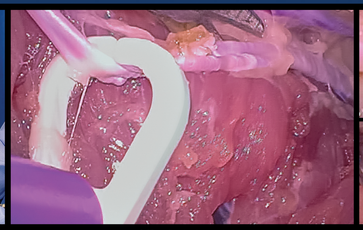
[1]Division of Cardiac Surgery, University of Rochester Medical Center, Rochester, NY, USA, [2]LSI SOLUTIONS®, Victor, NY, USA



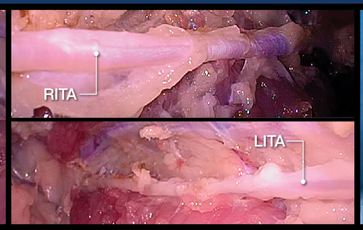
1A: Subxiphoid incision



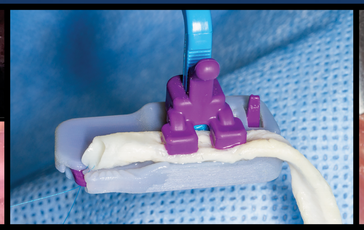
1B: Modular table-mounted retractor system



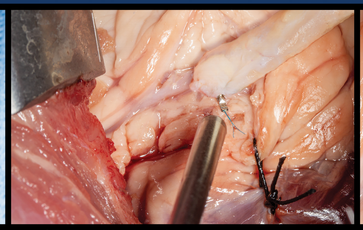
1C: Axial guide



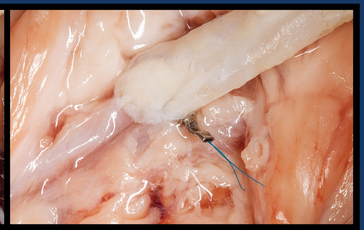
1D: BITA dissection



1E: Adjustable tissue pedestal



1F: Tiny titanium fastener deployment



1G: Fastener securing anastomotic suture

OBJECTIVE

Less invasive coronary artery bypass graft (CABG) surgery is underused despite more than 25 years of interest from surgeons and growing patient demands for less pain and rapid, full recovery. To advance surgical coronary revascularization, a dedicated innovation effort was undertaken with 2 critical technical objectives: uncompromised subxiphoid bilateral internal thoracic artery (BITA) harvest and the ergonomic creation of durable anastomoses through small thoracotomy access. Patients deserve the proven benefits of multiarterial coronary bypass grafting through soft tissue access.

METHODS

This evolving novel technology platform currently comprises 4 main categories of devices: modular table-mounted retractor system with task-specific features (e.g., retrosternal retractors customized for LITA and RITA exposure, readily adjustable cannulas, additional tissue positioning accessories, etc.) optimized for videoscopic assisted subxiphoid BITA harvest; malleable shafted axial guide device for gentle distraction of ITAs for clipping and energy dissection; adjustable tissue pedestal for atraumatically orienting the ITA cobra head adjacent to the coronary target site for accurate anastomotic suturing through remote access; and automated manually powered 3 mm shaft device for crimping a tiny titanium fastener to secure and trim 6-0, 7-0, or 8-0 polypropylene suture. After extensive testing in ex vivo porcine heart, porcine carcass, and cadaver models, initial evaluation of technology platform components in patients undergoing CABG surgery was safe and encouraging.

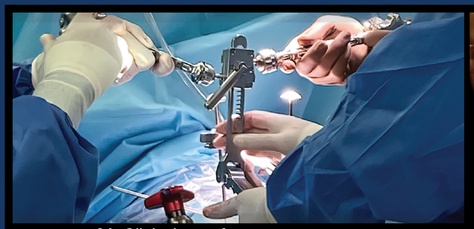
Disclosures:

Dr. Sauer is the president and CEO of LSI SOLUTIONS®.

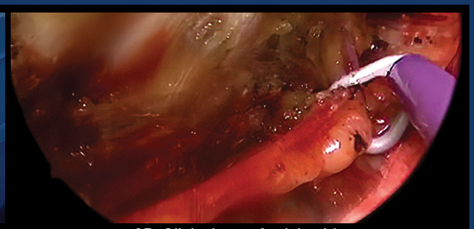
Drs. Knight, Purrman, and Ndikumana received grant funding from LSI SOLUTIONS® for participation in this research.



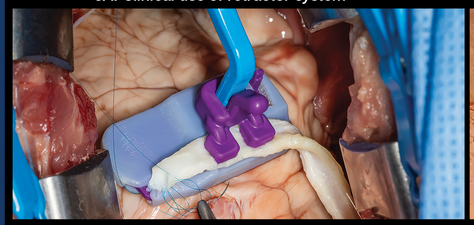
Fig 2: New technology platform devices



3A: Clinical use of retractor system



3B: Clinical use of axial guide



3C: Use of tissue pedestal



3D: Clinical use of tiny titanium fastener

RESULTS

Successful BITA harvest: 53/53 porcine carcasses and 11/11 cadavers with 127 total ITAs harvested to date. ITA to coronary artery anastomoses in 27 explanted porcine hearts and 23 porcine carcasses provided 50/50 successful anastomoses during development. Recently, partial ITA harvests were achieved via subxiphoid access in two MIDCAB patients. The axial guide demonstrated usefulness for BITA harvest in 4 full-sternotomy CABG patients. More than 300 tiny titanium fasteners have been successfully deployed by more than 55 surgeons in approximately 100 CABG patients since its June 2021 clearance for use in the United States.

CONCLUSION

Initial evaluations offer early encouragement for this new evolving technology platform and its associated techniques for multi-arterial coronary revascularization through small soft tissue access. For patients with coronary artery disease, widespread adoption of this approach may provide the proven benefits of CABG surgery without many of its current drawbacks.

UNIVERSITY of ROCHESTER MEDICAL CENTER