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Stepwise visualization of a provisional bifurcation stenting procedure—multimodal visualization within a reanimated human heart utilizing Visible Heart® methodologies

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Short title: Provisional bifurcation stenting procedure

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Classifications: Bare metal stent; Other technique; Stent enhancement

Abbreviations

IVUS: Intravascular ultrasound

KBT: Kissing Balloon Technique

LV: Left ventricle

OCT: Optical Coherence Tomography

POT: Proximal Optimization Technique

RCA: Right coronary artery

Introduction

Stenting procedures for bifurcation lesions can be complex, yet are often necessary with percutaneous coronary interventions. There are few resources and clinically applicable models for practitioners to visualize stenting techniques (1). Optical Coherence Tomography (OCT) and Intravascular Ultrasound (IVUS) are beneficial for real-time procedural visualization, yet reconstructions of the left main are difficult with OCT and often IVUS produces artifacts (2). Evaluations of implantable cardiac devices require innovative and critical testing during the design process and for understanding procedural outcomes. **Other benchtop models for bifurcation stenting are valuable (3,4), however Visible Heart® methodologies offer the unique capability to demonstrate these procedures within physiologic anatomy with analogous compliance and flow human anatomy** (5).

We describe direct endoscopic visualization of a coronary bifurcation stenting procedure in a human heart with sub-clinical coronary disease. Multimodal visualizations provide critical stepwise education for patients, clinicians, and device design engineers, as well as insights relative to the device-tissue interface within a human heart (Figures 1,2; Moving Image 1).

Methods

This heart, not viable for transplantation, was procured from a 78-year-old female organ donor via LifeSource (St. Paul, MN, USA). **Research was approved by the University of Minnesota's Institutional Review Board and LifeSource's research board, and consent from the donor's family was obtained.** Upon reanimation with a clear modified Krebs-Henseleit buffer, according to previously described methodologies (5), the heart elicited an intrinsic normal rhythm that was sustained with viable hemodynamic function. The right coronary artery (RCA) was accessed with a guide catheter and visualized (Figure 1A-1E). Images were simultaneously captured with endoscopic footage from the ascending aorta and right coronary artery via 4.0mm and 2.4mm videoscopes (IplexFX, Olympus, Tokyo, Japan), and fluoroscopy.

Results

Endovascular visualizations are paired with fluoroscopic imaging to describe steps of a provisional stenting technique within a human's coronary anatomy.

1. Wiring side and main branches

The main branch was wired with a 0.014 Cougar™ and the side branch (**small acute marginal branch**) was also wired, as seen under fluoroscopy and direct visualization with the 2.4mm videoscope (Figure 2, Panels 1A-C). A stenotic lesion location was not identified in this heart, yet a "typical" location where a provisional technique is identified with visible vessel calcification is shown in Figure 2, Panels 2A-B. This location was utilized for demonstrating the stenting procedure; the main vessel just proximal to this bifurcation (crux at the RCA) elicited multiple plaques and fatty streaks, and minor calcified nodules.

2. Contrast bolus and main branch stent deployment

A contrast bolus was delivered through the guide catheter and stenting was sized to the main branch utilizing estimation under fluoroscopy. The **Integrity™ stent** (Medtronic, Minneapolis, MN, USA) was deployed with 16atm of balloon pressure to ~3.5mm (Figure 2, Panels 2A-C).

3. Proximal Optimization Technique

A Proximal Optimization Technique (POT) was performed on the proximal end of the stent with a short non-compliant balloon sized 1:1 according to proximal main branch size (Figure 2, Panels 3A-D). This technique ensured proper apposition of the stent to the vessel wall. Consensus data suggest this reduces risk of the stent overlaying the side branch or disrupting the neo-carina (1).

4. Wiring side branch through main branch stent

To gain access to the side branch, a wire was crossed through the main branch struts (Figure 2, Panels 4A-B). It is important to aim for one of the distal stent struts that covers the side branch ostia.

5. Final Kissing Balloon Technique and visualization of formed neo-carina

A second balloon was placed over the side branch wire; the main and side branch balloons were inflated simultaneously (10atm each) to perform the Kissing Balloon Technique (KBT) (Figure 2, Panels 5A-C). This produces an optimally opposed main branch stent while opening struts to generate a neo-carina at the ostia of the side branch. The overall technique was finalized by performing a POT of the main branch stent—inflating short non-compliant balloon in the main branch stent proximal to bifurcation area to ensure proper stent apposition and correct proximal potential or changed geometry (bottleneck) in the proximal stent segment after potential KBT misalignment.

Discussion

Visible Heart® methodologies have enabled our laboratory to reanimate 85 human hearts and directly observe critical steps involved in complex bifurcation stenting procedures, and offering valuable insights on the dynamics and effects of different procedural techniques. **This approach is closer to native human physiology and/or pathophysiology than utilizing silicon tubes or other bench testing techniques due to dynamic compliance, flow, and capacity for visualization within real anatomies.**

Limitations

Stenting procedure was performed in a reanimated human heart with minimal coronary artery disease, thus is considered an idealized outcome.

Conclusion

We provide educational still and movie images of a provisional stenting technique in a reanimated human heart.

Impact on Daily Practice

Our unique ability to reanimate human hearts offers educational visualization of bifurcation procedures that is valuable for patients, clinicians, and device design engineers.

Acknowledgements

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Conflict of interest: Iaizzo, Medtronic research contract; Burzotta, Medtronic, Abbott, and Abiomed speaker fees; Lassen, Medtronic, Abbott, Biosensors, and Boston Scientific speaker fees; Iles, no conflicts of interest.

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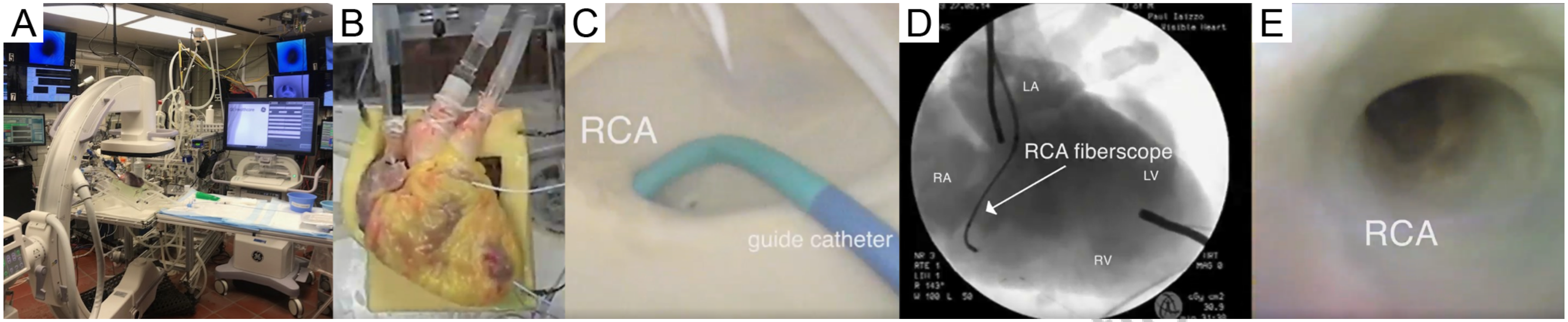
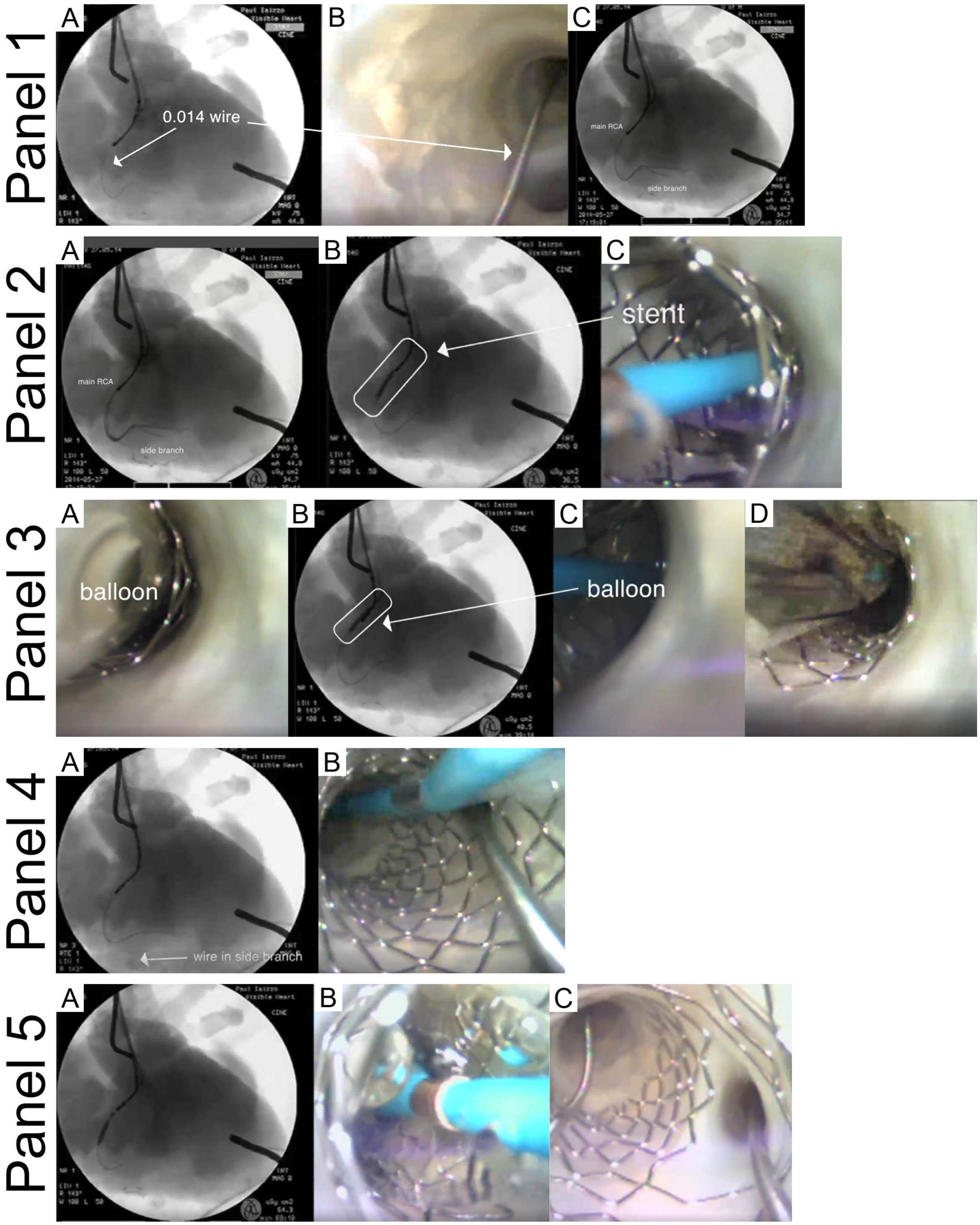
Figure Legends

Figure 1. Visible Heart® methodologies. A) C-arm, backtable, and Visible Heart® apparatus and monitoring capabilities. B) Reanimated human heart from 78-year-old female donor. C) Guide catheter placed in right coronary artery (RCA). D) 2.4mm fiberscope placed in RCA. E) Direct visualization of RCA. LA: left atrium; LV: left ventricle; RA: right atrium; RV: right ventricle

Figure 2. Steps of provisional stenting technique. ***Panel 1***. A) Fluoroscopic image of guide catheter positioned in right coronary artery (RCA) and placement of 0.014 wire in main branch. B) Direct visualization of target bifurcation and 0.014 wire within main branch. C) Fluoroscopic image of main and side branches wired. ***Panel 2.*** A) Fluoroscopic image of contrast injection via guide catheter in RCA. B) Fluoroscopic guidance of stent deployment within main RCA branch. C) Direct visualization of stent deployment in main branch vessel. ***Panel 3.*** A) Short balloon (sized 1:1) positioned to cover proximal edge of main branch stent; one can visualize mal-apposition of stent struts to vessel wall. B) Balloon inflation under fluoroscopy. C) Balloon expanding the stent within main branch. D) Direct visualization of balloon deflation and properly apposed stent struts onto vessel wall. ***Panel 4.*** A) Fluoroscopic image of wire advanced into side branch. B) Direct visualization of wire through distal strut of main branch stent covering side branch ostia. ***Panel 5.*** A) Fluoroscopic image obtained during Kissing Balloon dilation. B) Direct visualization of Kissing Balloon Technique. C) Direct visualization of final result of provisional stenting technique (result of final Proximal Optimization Technique not shown).


A
B
C
RCA
guide catheter
D
LA
RCA fiberscope
RA
LV
RV
E
RCA


Panel 1
A
0.014 wire
B
C
main RCA
side branch
Panel 2
A
main RCA
side branch
B
stent
C
Panel 3
A
balloon
B
balloon
C
D
Panel 4
A
wire in side branch
B
Panel 5
A
B
C