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SURGICAL TECHNIQUE

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Minimal access left ventricular reconstruction

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Abstract

The Revivent TC™ Transcatheter Ventricular Enhancement System (BioVentrix Inc.) is intended for use in heart failure with cardiac dysfunction a previous myocardial infarction. The resultant increased left ventricular systolic volume and discrete, contiguous, noncontractile (akinetic and/or dyskinetic) scar located in the anteroseptal, apical (may extend laterally) region of the left ventricle (LV) lends itself to Revivent. The procedure, called Less Invasive Ventricular Enhancement, consists of the implantation of a series of micro-anchors pairs to exclude the scarred myocardium, to reduce and reshape the LV. We present the procedure step-by-step, as team coordination between the cardiac surgeon and the interventional cardiologist is essential to ensure good procedural outcomes. This is a novel and new technique to address heart failure secondary to myocardial infarction.

KEYWORDS

heart failure, LIVE, Revivent TC™, ventricular restoration

1 | INTRODUCTION

At present, over 15 million people are living with heart failure (HF) in Europe. HF is responsible in most westernized economies for 1%–2% of all healthcare expenditures and is the leading cause of hospitalization in people over the age of 65. The prognosis for patients with HF has remained alarmingly poor over the last 20 years. Despite some notable improvements in survival rates, approximately one in three patients admitted to a hospital with HF still die within 1 year. This places a huge financial burden on the healthcare system and signals the typical downward spiral of the course of this disease. Due to this fact, there has been a significant paradigm shift in the focus of cardiac treatment worldwide in the last two decades.

Ischemic cardiomyopathy is the leading HF cause in the Western World. It is frequently associated with left ventricle (LV) scarring where viable heart tissue has been damaged and is replaced by fibrotic scar, which results in left ventricular dysfunction. The loss in left ventricular function most often results in angina, significant dyspnea, ventricular arrhythmias, and an increased risk of thromboembolism and death.

Surgical treatment is an option in advanced ischemic HF. Patients with significantly enlarged LV end-systolic and end-diastolic volume indices (LVESVI and LVEDVI) appear to benefit most from surgical intervention. Relative contraindications to surgery include excessive anesthetic risk, impaired function of residual myocardium, severely diminished cardiac index, and lack of a discrete scar with indistinct margins. Left ventricular surgical treatment usually requires a median sternotomy, cardiopulmonary bypass, and left ventriculotomy on either a beating or an arrested heart. Adoption of the surgical technique for correction of this condition has been limited by both the invasiveness of the procedure and potential for significant subsequent perioperative morbidity and mortality. BioVentrix™ has developed the Revivent TC™ System to provide devices for the treatment of a left ventricular scar, utilizing a less invasive, beating heart approach.

Less Invasive Ventricular Enhancement (LIVE) procedure with Revivent TC™ reshapes and resizes LV without sternotomy or extracorporeal circulation through direct plication of the scarred myocardium. The procedure consists in the implantation of a series of internal (right ventricular septum) and external titanium

microanchors (5 mm × 25 mm) which are brought together through a poly-ether-ether-ketone tether (1.7 mm × 1.0 mm) to approximate LV free wall and the anterior septum, consequently excluding the scarred myocardium (Figure 1). Septal right ventricle (RV) anchors are deployed by a transcatheter technique, through a venous access on the neck—right internal jugular (RIJ) vein.

First-in-human LIVE procedures were performed in September 2013. Since the device obtained CE mark approval in June 2016, the multicentric observational BioVentrix™ Registry Assessment of Ventricular Enhancement for the Revivent TC™ system trial has been ongoing in Europe.[1] In total, 230 cases have been performed with an overall mortality of 18 (7.8%). Twelve cases of mortality occurred during the CE mark trial and four before changing the procedure to apical snaring (described below).

In fact, the procedure went through some simplification initiatives and improvements throughout the years. It originally required a sternotomy, then moved to a left minithoracotomy. To deliver the internal anchors, wire snaring was originally done in the right ventricular outflow tract, is now done in the right ventricular apex. We are presenting here the surgical technique and the latest results of this latest iteration.

2 | PATIENT SELECTION

Any patients suffering from HF symptoms with cardiac dysfunction caused by a previous myocardial infarction resulting in increased LV systolic volume and in a discrete, contiguous, noncontractile, (akinetic and/or dyskinetic) scar located in the anteroseptal, and apical (may extend laterally) region of the LV.

Transthoracic echocardiography is utilized to assess for LV dilatation, diminished ejection fraction (EF), LVESVI, and LVEDVI, regional wall akinesis or dyskinesis. It is a useful imaging modality to guide further investigation to determine suitability for Revivent TC™ and to plan the LV reconstruction.

Cardiac magnetic resonance (CMR) with late gadolinium enhancement (LGE) gives a higher resolution image, clearly indicating scar thickness, extent, and anatomy. It also gives an excellent

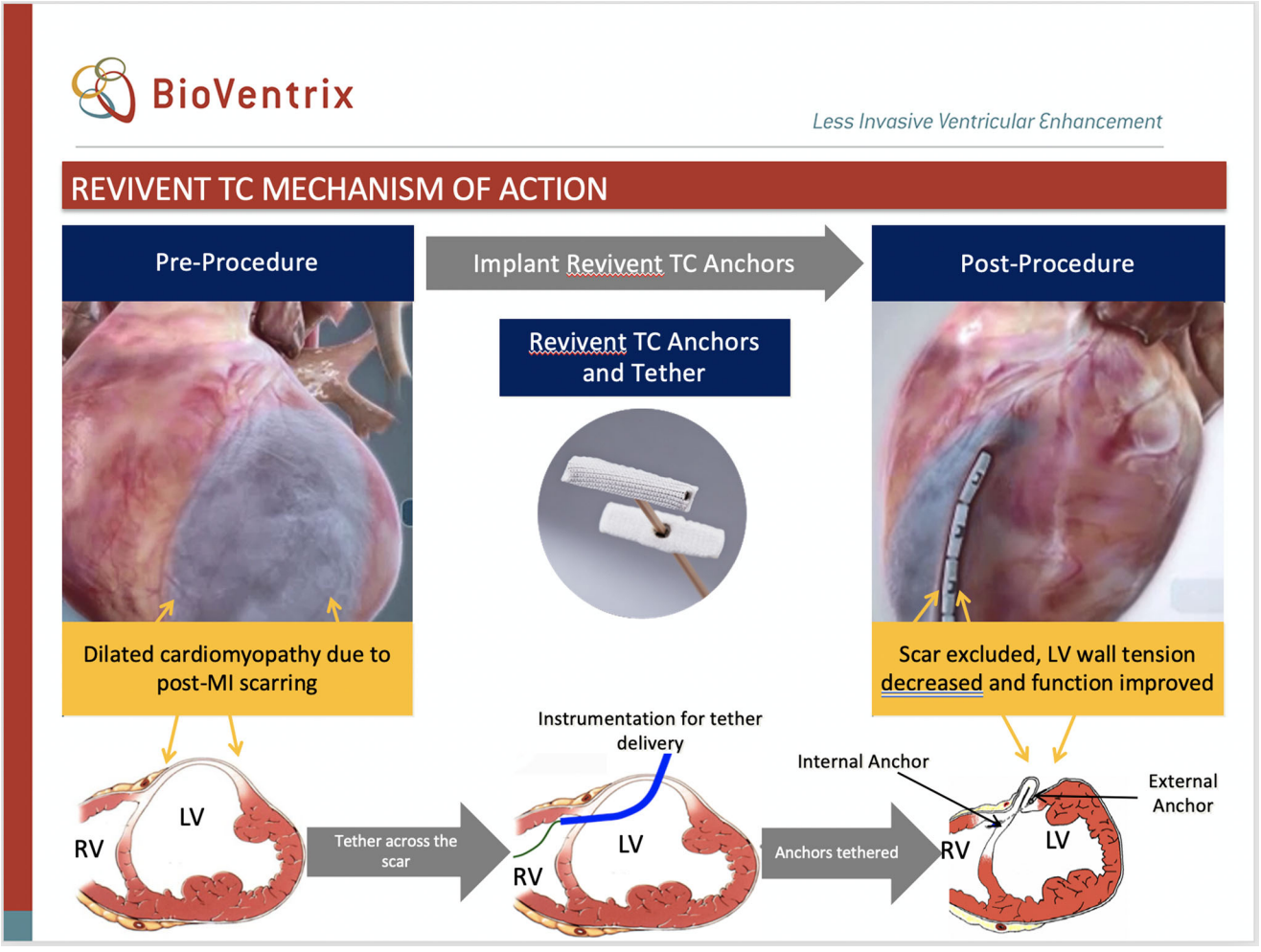

FIGURE 1 The Revivent TC™ System consists of titanium anchors and delivery instrumentation for the anchor placement. LV, left ventricle; MI, myocardial infarction; RV, right ventricle; TC, transcatheter

indication of LVESVI, LVEDVI, and EF. LGE is the gold standard for scar determination.

A four-dimensional cardiac computed tomography scan carried out with a triphasic injection of contrast media is a suitable alternative to CMR for patients unable to undergo the latter.

3 | IMPLANT PROCEDURE

The patient shall be prepared for cardiac hybrid procedure according to hospital's standard procedures. Intraoperative transoesophageal echocardiography (TEE) is required to provide procedural assistance, monitor LV and valve function, and evaluate myocardial anchor implant placement.

A cell salvage system, standby cardiopulmonary bypass, external defibrillator pads, meticulous control of activated clotting time (ACT), and serum K^+ and Mg^{2+} add to patient safety.

We are describing the procedure step-by-step:

1. Percutaneously access the vein.
2. Insert a 14F Introducer into RIJ and advance into the superior vena cava or right atrium (Figure 2).
3. Determine the location of incision by placing an instrument under fluoroscopy at the desired location and ensure that the position allows access to the LV apex and placement of the most basal anchor pair. The incision should be placed over the intercostal space that gives a direct line from the anterolateral wall 5–6 cm above the apex of the LV and 1–2 cm above the very apex of the RV; in general, the medial aspect of the incision should be at the level of the patient's areola.
4. Identify aneurysm (scar) margins and epicardial landmarks including LAD and cardiac apex.
5. Place a "leash" or tethering mechanism to manipulate the heart. The "leash" consists of a 2-0 double pledgeted, horizontal mattress polypropylene suture with a tourniquet. Suture should be placed in the scar tissue of the heart using suture and pledgets appropriately deep in the scar to prevent pulling through the wall of the heart. Additional leashes may be placed in the scar as necessary to allow appropriate cardiac manipulation. Leashes should be placed only in scar intended for exclusion.
6. Heparinize the patient maintaining an ACT of 300 s or greater. Float a Swan–Ganz catheter through the 14Fr sheath up to the pulmonary artery (PA).
7. Advance a 0.025 Jagwire™ through the Swan–Ganz catheter and keep it on the PA.
8. Advance a 7-Fr multipurpose (MP) catheter with an EnSnare™ endovascular snare system inside and open it in the RV apex (Figure 3).
9. Perform an RV gram to confirm the position of the EnSnare™.
10. Place a 7-cm 18 gauge straight needle on the scarred epicardium to identify landmarks and needle puncture direction.
11. Puncture the needle through the epicardial surface and redirect it towards the selected septal site as directed by the EnSare™ in the RV apex; (confirm LV wave form with pressure measurement). Confirm needle is in the RV using injection of contrast within the needle (Figure 4).
12. Advance a 0.032'' wire through the needle and snare it with the EnSnare™ under fluoroscopy.
13. At this point, the 14Fr sheath is advanced to the RV, near the interventricular septum. The 0.025'' Jagwire™ can be also removed.
14. Remove the straight needle and advance a 6Fr Brite tip™ catheter through the 0.032'' wire and into the RV (confirm scar location). Tactile feedback should reinforce the catheter's

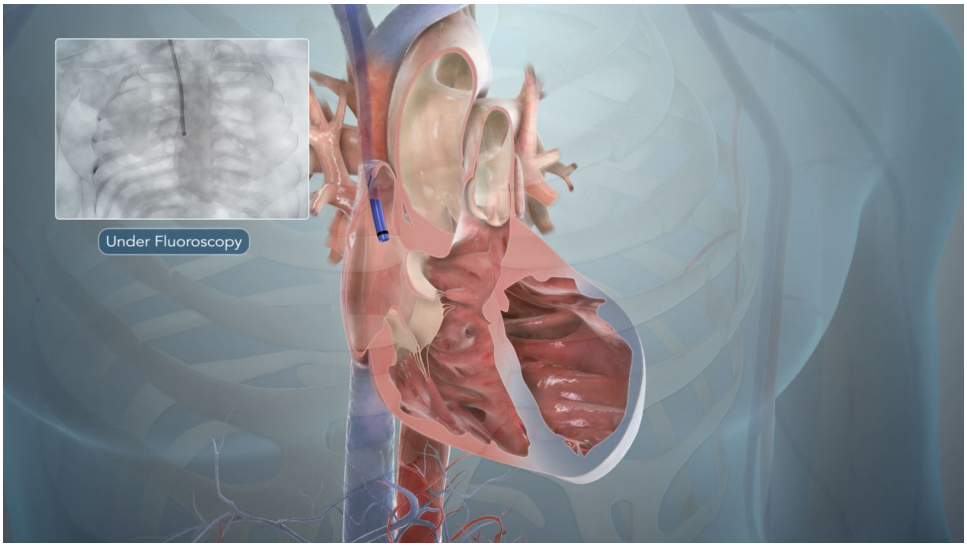

FIGURE 2 Step 2: Insert a 14-F Introducer into right internal jugular and advance into the superior vena cava (SVC) or right atrium (RA)

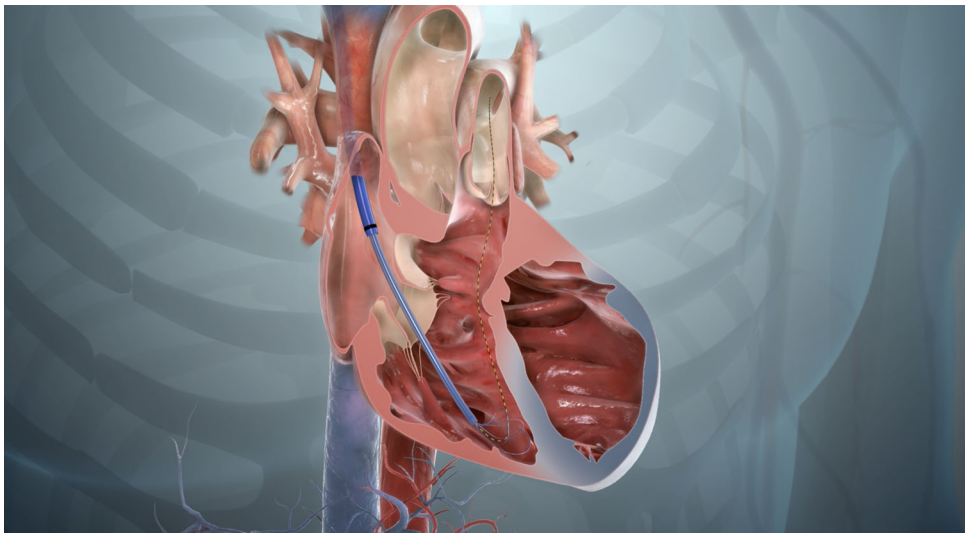

FIGURE 3 Step 8: Advance a 7-Fr multipurpose (MP) catheter with a EnSnare™ endovascular snare system inside and open it in the right ventricle apex

passage through scar. This is done under fluoroscopy and TEE should be continuously looking at any changes in tricuspid regurgitation change from baseline (Figure 5).

15. Exchange the 0.032'' wire with a 0.014'' through a 6Fr standard MP catheter. This is done on the surgical side.
16. At this point, the 6Fr Brite tip™ catheter must be inside the 14Fr sheath.
17. Place the internal anchor assembly over the 0.014'' guidewire, advance it through the 14Fr. During this maneuver, the 14Fr introducer must be kept in contact with the right side of the septum, with the tip of the 6Fr Brite tip™ inside the 14Fr lumen. The 0.014" guidewire and guiding catheter may be removed as soon as any part of the wire becomes exposed outside the 6Fr Brite tip™ at the epicardial location (Figure 6).

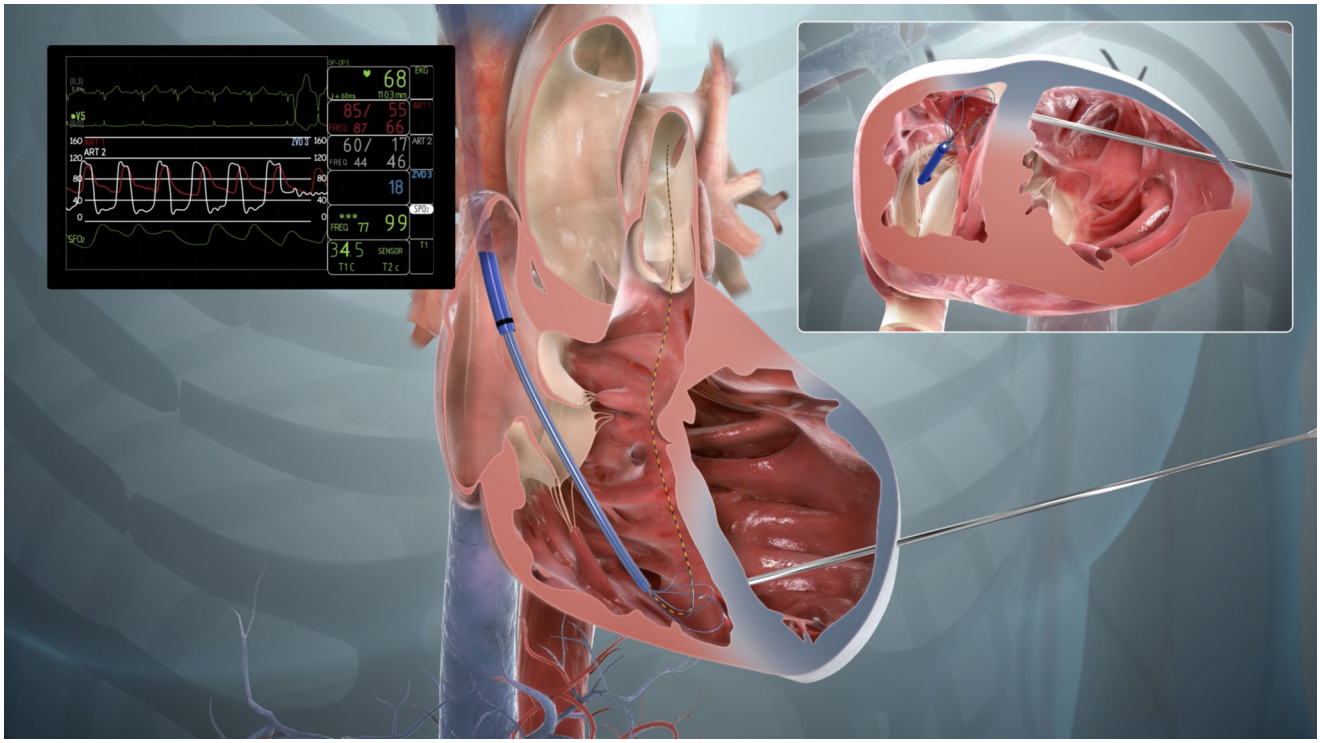

FIGURE 4 Step 11: Puncture the needle through the epicardial surface and redirect it towards the selected septal site as directed by the EnSare™ in the right ventricle apex

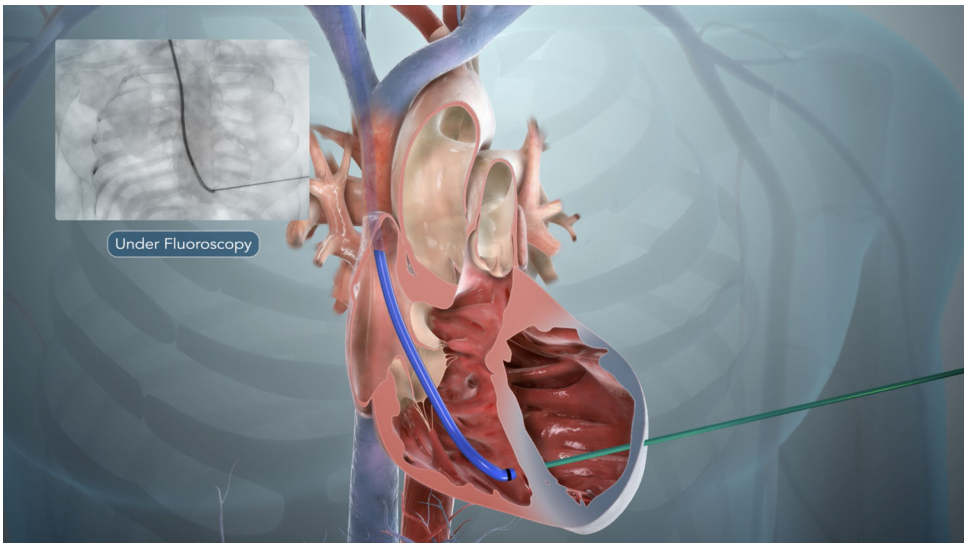

FIGURE 5 Step 14: Remove the straight needle and advance a 6-Fr Brite tip catheter through the 0.032'' wire and into the right ventricle (confirm scar location)

18. The tip of the 14Fr introducer, which has been essentially in contact with the septum, is retracted to reveal the anchor when it is into immediate proximity of the septum, delivering it pushing the hinging mechanism.
19. Remove the 6Fr Brite tip™. The external anchor is placed over the tether and advanced to the epicardial surface. Then use the force gauge to bring the two walls of the LV into apposition (Figure 7).
20. Assess hemodynamics, LV configuration (by TEE), and tricuspid valvular function (by TEE); if appropriate, release anchor, leaving it in position against the right side of the septum.
21. Repeat steps 11–20 for each LV–RV anchor pair.
22. When it is determined that the next anchor should be LV–LV (i.e., at the LV apex with no further space in the RV apex), retract the introducer from the RV, then oppose the walls with existing anchor pairs into contact plus 1–2 Newtons, (thus rendering the geometry of the final, reshaped LV except for the apex). Caution: Using excessive force could lead to tissue erosion or anchor migration, it is critical to use the force gauge to ensure proper force to the anchors is being applied.
23. Using the LV apical needle in a standard surgical needle holder, load the needle such that it is at a 10–15-degree angle from the needle holder shaft.
24. With visibility gained from manipulation of previous anchor pairs, drive the LV needle across the cardiac apex from right-to-left.
25. Retrieve the needle tip. Lay down the hinged anchor on the right side of the apex and cut the tether at or near the needle to allow

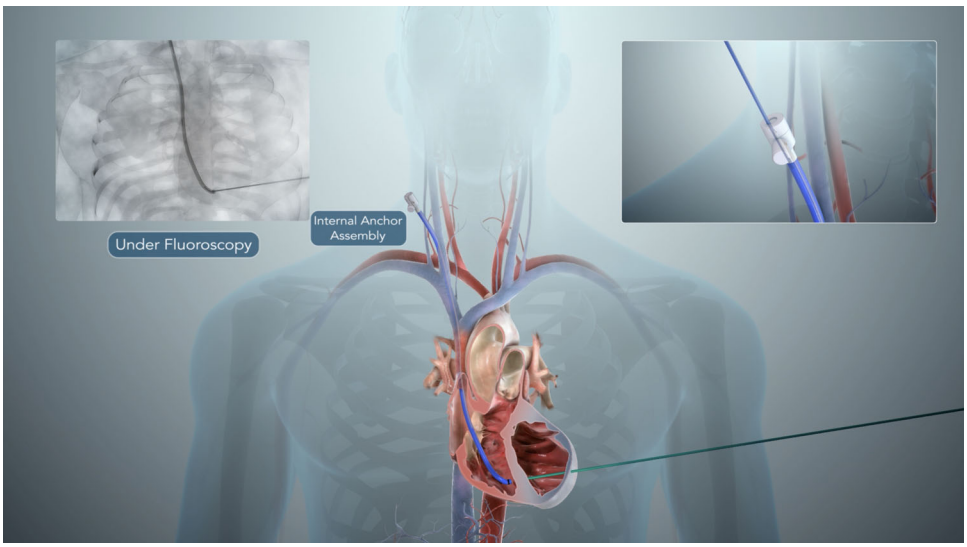

FIGURE 6 Step 17: Advance the OWTI/guiding catheter combination through the 14Fr, and then through the 6Fr Brite tip, which is tranversing two walls of the left ventricle

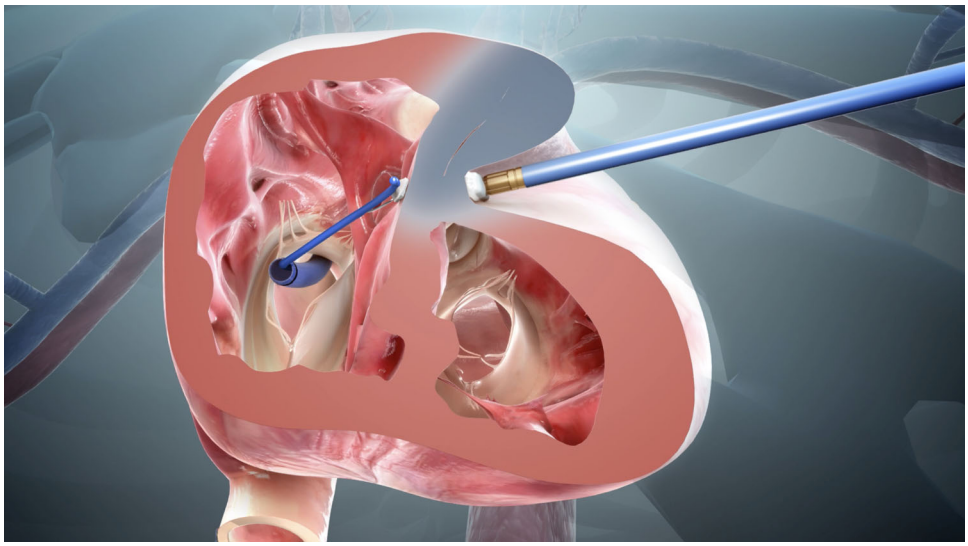

FIGURE 7 Step 19: The external anchor is placed over the tether and advanced to the epicardial surface. Then use the force gauge to bring the two walls of the left ventricle into apposition

placement of an external anchor for hemostasis. Check all anchor positions fluoroscopically for alignment (Figure 8).

4 | RESULTS

Between July 2018 and January 2020, 47 patients (84.4% men; mean age 61 ± 12.5 years) were submitted to the LIVE procedure in 16 Institutions in Europe, North America, and Asia. Procedural success was 100%. There was no intrahospital mortality. There was no case of ventricular septal defect, right ventricular perforation or sternotomy conversion. New-onset tricuspid valve regurgitation was observed in one patient, but after 3 months the degree of regurgitation came down to baseline. In the mean follow-up period of 9.8 months, New York Heart Association Class improved a median of 1 grade and there was no late mortality.

5 | DISCUSSION

Revivent TC™ approach is essentially less invasive than conventional SVR. Therapeutic volume reduction was achieved regardless of the delivery method. Interestingly, there was no additional benefit of adding coronary revascularization to the procedure. This data compare favorably with the STICH subanalysis, which established a survival benefit in patients realizing more than 30% reduction in LVESVI and/or postoperative LVESVI less than 60 ml/m^2.[2]

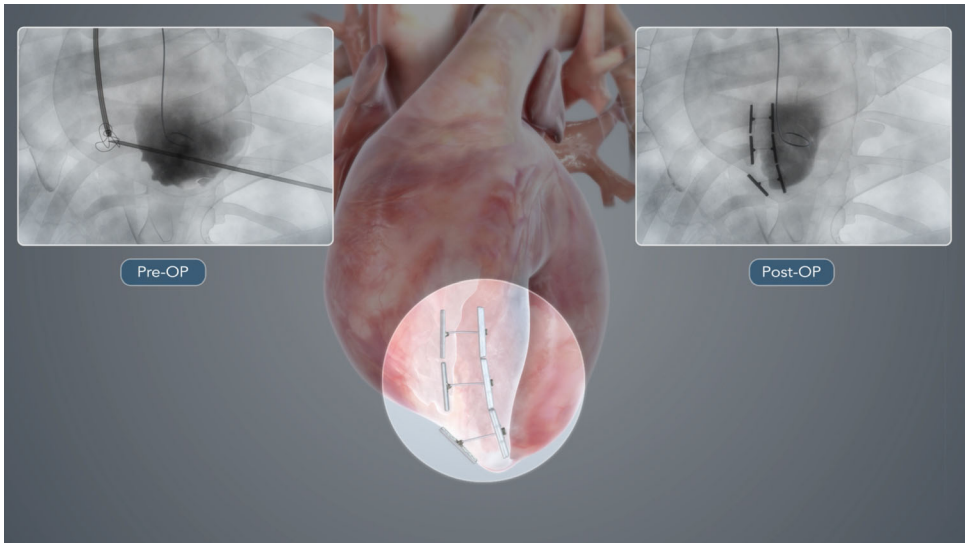

FIGURE 8 Final step: Final left ventricle gram assessment and preoperative comparison

SVR improves HF symptoms and long-term survival for patients with ischemic cardiomyopathy.[3] The majority of cases in these studies underwent standard open-heart surgery via sternotomy with cardiopulmonary bypass, cardioplegic myocardial arrest, and ventriculotomy. Implantation of the Revivent TC™ System device does not require cardiopulmonary bypass, cardioplegic arrest, or a ventriculotomy.

Initial experience with LIVE latest iteration shows no mortality. By comparison, the reported mortality rate from the international Reconstructive Endoventricular Surgery returning Torsion Original Radius Elliptical shape to the LV registry of 1198 postanterior infarction SVR cases was 5.3%.[4] Improvement in outcomes after implantation of the Revivent TC™ System should be possible through application of experience gained in selecting candidates and in the technique of implantation. This might also offer an alternative in patients at high risk of perioperative complications or with a frail preoperative condition.

6 | CONCLUSION

With Revivent Transcatheter™, Left Ventricular Reconstruction is highly feasible, safe and efficacious. The avoidance of median sternotomy, cardiopulmonary bypass and cross-clamping with cardioplegia allows for immediate hemodynamic improvement and shorter recovery and return to normal activities. The volume reduction is comparable with most surgical series and fares much better than the STICH values. Ongoing studies will further demonstrate the value of this approach in this sick group of patients with HF.

INSTITUTIONAL REVIEW BOARD AND INFORMED CONSENT

Revivent TC™ is a CE marked device. All implants were approved by Institutional Review Boards.

A written informed consent was obtained for every patient treated with Revivent TC™ device.

AUTHOR CONTRIBUTIONS

Thasee Pillay and Paulo Neves did article drafting and revision. Federico Benetti did critical revision of the article. Kevin van Bladel, Andrew Wechsler, and Lon Annest were involved in device development and proctoring the majority of the procedures.

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