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Transcatheter approximation of papillary muscles

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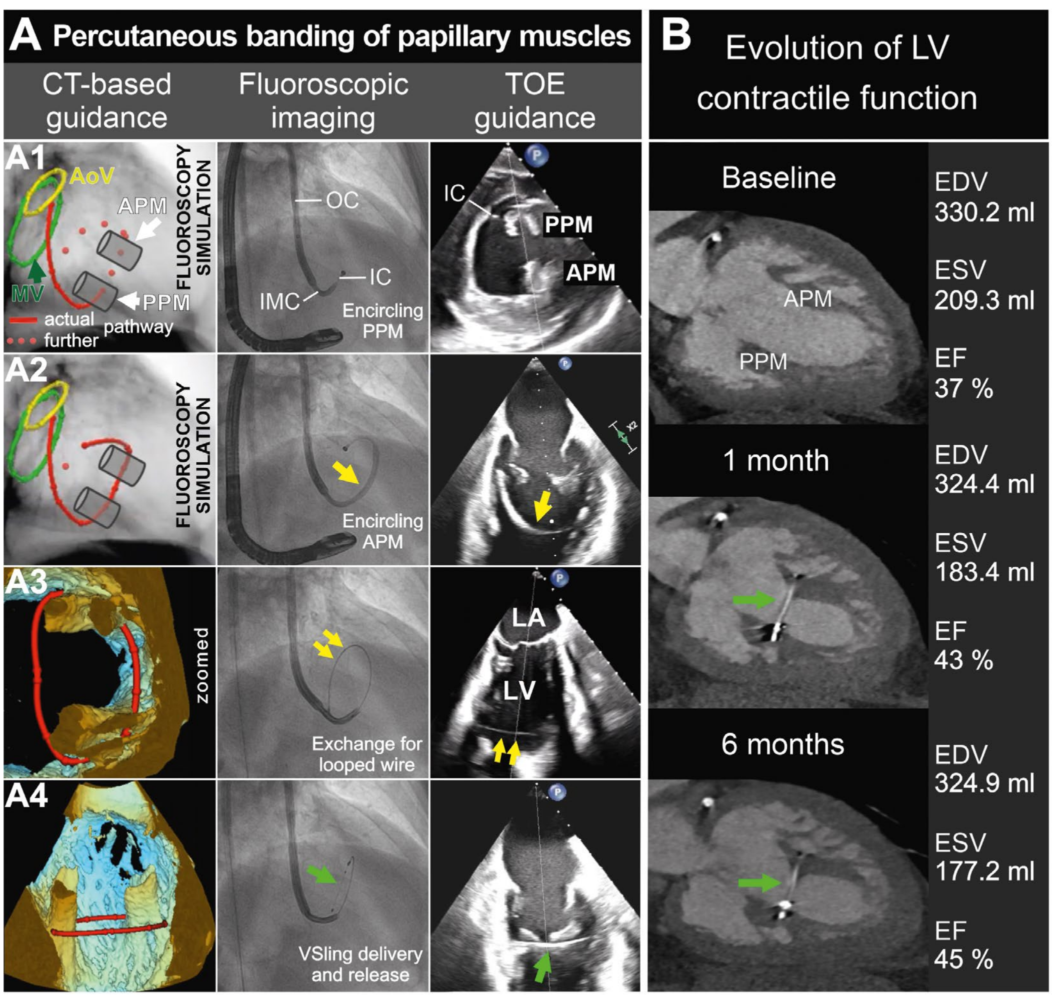

Figure 1. *Transcatheter banding of papillary muscles. A) The key procedural steps are illustrated: (A1) PPM encircling with a telescopic 3D-steerable catheter system, (A2) encircling the APM (followed by snaring the inner catheter/wire), (A3) wire looped around the papillary muscles, and (A4) VSling band delivery, tightening and release. B) The evolution of LV volumes and contractile function over 6 months. Yellow arrow – the catheter system encircling papillary muscles; yellow double arrow – looped wire; green arrow – VSling. 3D: three-dimensional; AoV: aortic valve; APM: anterior papillary muscle; CT: computed tomography; EDV: end-diastolic volume; EF: ejection fraction; ESV: end-systolic volume; IC: inner catheter; IMC: intermediate catheter; LA: left atrium; LV: left ventricle; MV: mitral valve; OC: outer catheter; PPM: posterior papillary muscle; TOE: transoesophageal echocardiography*

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Left ventricular (LV) spherical remodelling is the hallmark of heart failure with reduced ejection fraction (EF); it limits the efficacy of established pharmacological and non-pharmacological therapies and is associated with poor prognosis[1,2]. Physical LV geometry improvement (physical reverse remodelling) can reduce LV wall stress, promoting biological reverse remodelling[1,2]. The approximation (banding) of papillary muscles (PMs), performed during open-chest cardiac surgery, reduces the interpapillary distance and results in a more physiological (elliptical) LV shape[3], with randomised study evidence showing long-term improvement in cardiac function[3]. A percutaneous PM banding system (VSling [Cardiac Success])[1] has undergone testing in animal models and human cadavers[4], paving the way for clinical evaluation. The VSling system consists of (1) a steerable 14 Fr outer catheter with a snare; (2) a system of two telescopic, three-dimensional (3D)-steerable, PM-encircling catheters (an intermediate catheter, providing support, and an atraumatic-tipped inner catheter, "paving the way"); (3) a delivery wire forming a loop around the PMs; and (4) the VSling itself (PM band), a looped wire-deliverable permanent implant whose circumference is adjustable prior to device locking and detachment from the delivery system.

Herein, we share procedural imaging **(Figure 1)** from the first ischaemic cardiomyopathy patient in a European multicentre study of transcatheter PM approximation: a 58-year-old male (with a history of two myocardial infarctions, a dilated LV and chronic heart failure refractory to established therapies), in whom we performed percutaneous VSling band **(Supplementary Figure 1)** implantation.

Procedure preparation involved, first, precise determination of the PM encircling pathway using computed tomography (CT)-based simulation of fluoroscopy and transoesophageal echocardiography (TOE; MrTEEmothy [Medical Simulation Technologies]) **(Figure 1A, Moving image 1)**. Then, the encircling route was physically verified in a 3D print of the patient's heart **(Supplementary Figure 2)**. Finally, VSling delivery (transfemoral transaortic access using a steerable three-catheter system), tightening, and implantation were performed **(Supplementary Figure 3, Supplementary Figure 4, Moving image 2, Moving image 3)** under real-life fluoroscopy, with navigation support from CT-simulated fluoroscopy and TOE **(Figure 1A)**. The procedure reduced the interpapillary distance from 27 mm to 12 mm **(Supplementary Figure 4, Moving image 4)**; this resulted in a more conical LV shape **(Supplementary Figure 5)**. Clinical improvement (an increase in the 6-minute walk test and New York Heart Association Functional Class improvement from III to II) and EF increase were maintained in follow-up **(Figure 1B, Moving image 5, Moving image 6)**.

It is important to note that handling of the mitral subvalvular apparatus is not without risks, and potential chordal interactions with the PM band need to be avoided[5]. For this reason, PM morphology[5] and their vascularisation[6] need to be considered when assessing the feasibility of PM percutaneous realignment. The procedure reported herein involved type I PMs (i.e., each forming a single uniform unit)[5] in a patient with a history of myocardial infarctions arising from left anterior descending coronary artery atherosclerotic disease in the absence of ischaemic lesions in the left circumflex and right coronary arteries. The realignment of PMs may present a particular challenge for type III and IV PMs, i.e., in case of partial separation of the PM heads[5]. These types are more prevalent in the posterior PM (PPM), while their occurrence in the anterior PM (APM) is rare. In type V PMs (in which the heads are anatomically separated), it is imperative that both heads are fully included in the encircling loop in order to prevent the "seagull sign" phenomenon. Furthermore, the segmental nature of the PM's blood supply may require consideration, particularly in type IV and V PMs, in which the apex is more susceptible to ischaemic complications due to the fragility of its truncal blood supply and the degree of physical stress involved[5,6]. While the APM has dual blood supply, the PPM (supplied exclusively by the circumflex branch of the left coronary artery in case of predominant left circulation and exclusively by the posterior descending branches of the right coronary artery in case of predominant right circulation) is in general more susceptible to ischaemia[6]. These considerations are important for patient selection to avoid potential peri- and postprocedural mechanical complications that might arise from anatomy-related chordal interactions and PM ischaemia.

In conclusion, transcatheter approximation of the papillary muscles in the beating human heart is feasible, and, in suitable anatomy, it can be performed safely and with structural and functional benefits. Percutaneous PM banding does not obstruct other established or investigational therapeutic approaches to chronic heart failure[1,7].

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Conflict of interest statement

The authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Figure 1. VSling papillary muscle band (photograph).

Supplementary Figure 2. Physical verification of the papillary muscle encircling pathway in a 3D print of the patient's heart (photographs).

Supplementary Figure 3. The role of CT-based simulation of fluoroscopy (Mr TEEmothy) in intraprocedural navigation.

Supplementary Figure 4. Fluoroscopic images of the key steps in the transcatheter banding of papillary muscles to improve LV shape and mechanical function in LV failure.

Supplementary Figure 5. 3D visualisation of the left ventricle (CT imaging) with a focus on papillary muscles and the PM band (VSling).

Moving image 1. CT-based simulation of the role of fluoroscopy in determining optimal procedural C-arm angulation.

Moving image 2. Transcatheter banding of papillary muscles using the VSling System – fluoroscopy cine images.

Moving image 3. Intraprocedural navigation using live transoesophageal echocardiography imaging.

Moving image 4. Transthoracic echocardiography – focus on the papillary muscles before (left) and after (right) banding.

Moving image 5. Transthoracic echocardiography imaging at baseline, and 1 and 6 months after percutaneous papillary muscle banding.

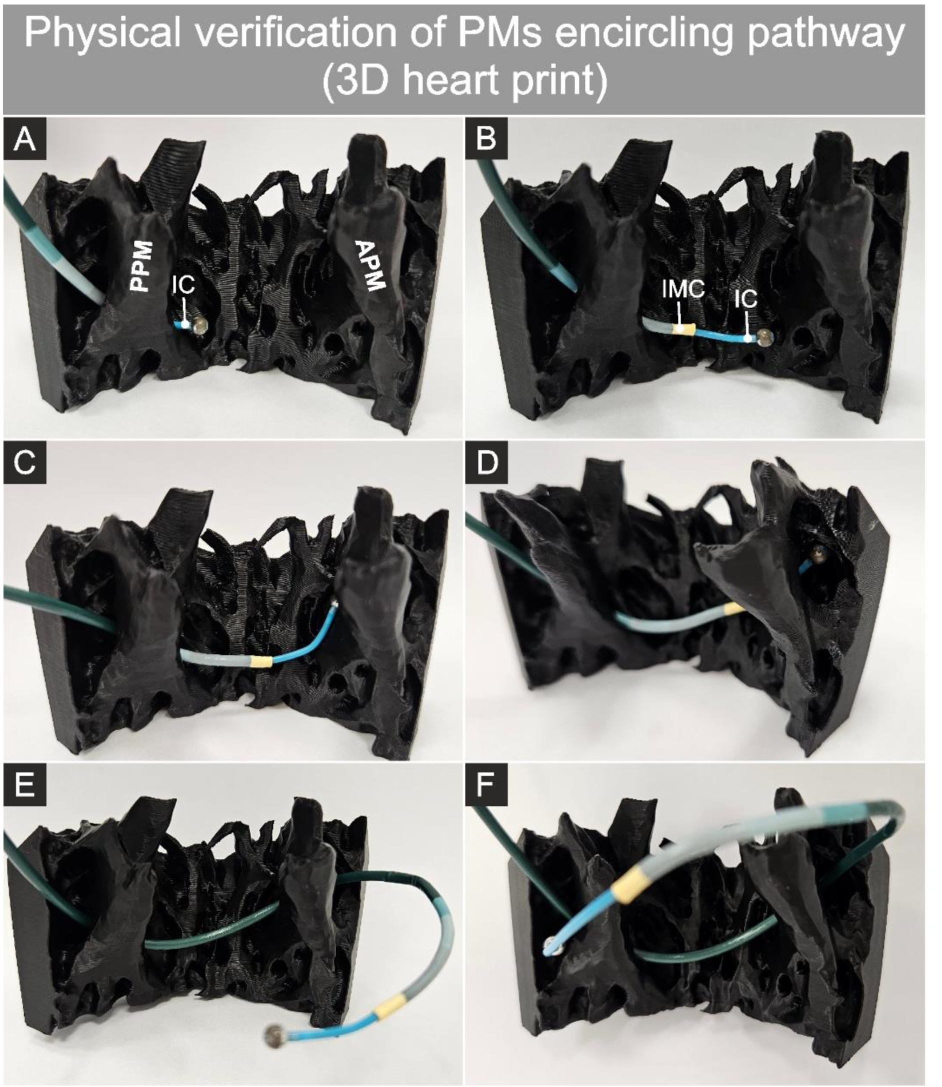
Moving image 6. Dynamic CT imaging (papillary muscles – aortic valve plane) at baseline, and 1 and 6 months after the transcatheter banding of papillary muscles.

The supplementary data are published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-25-01353

Supplementary data

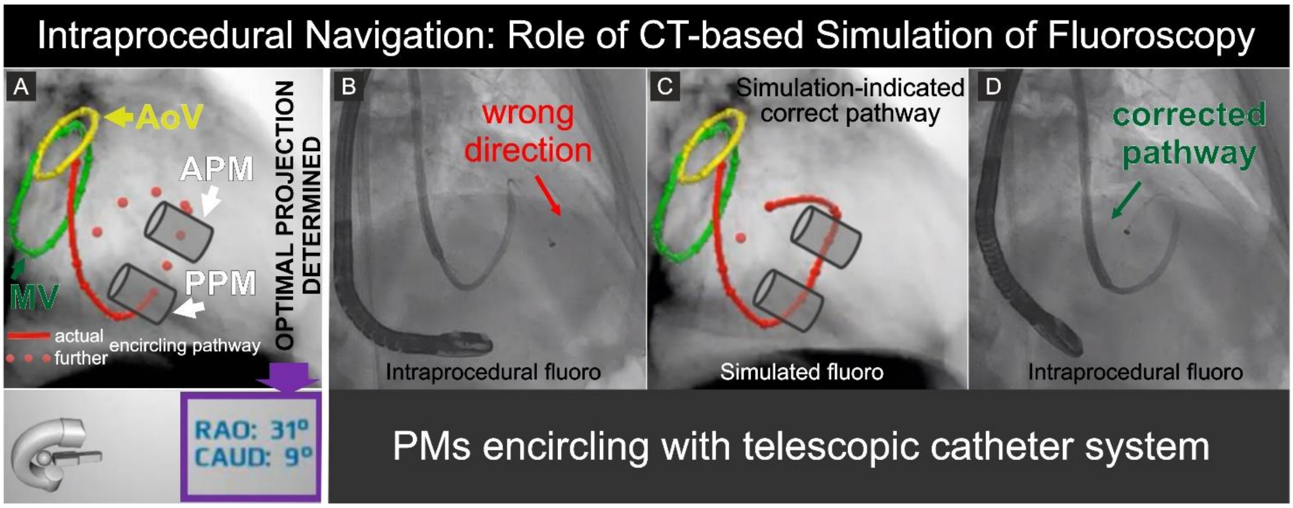
VSling Band

Supplementary Figure 1. VSling papillary muscle banding device (photograph).



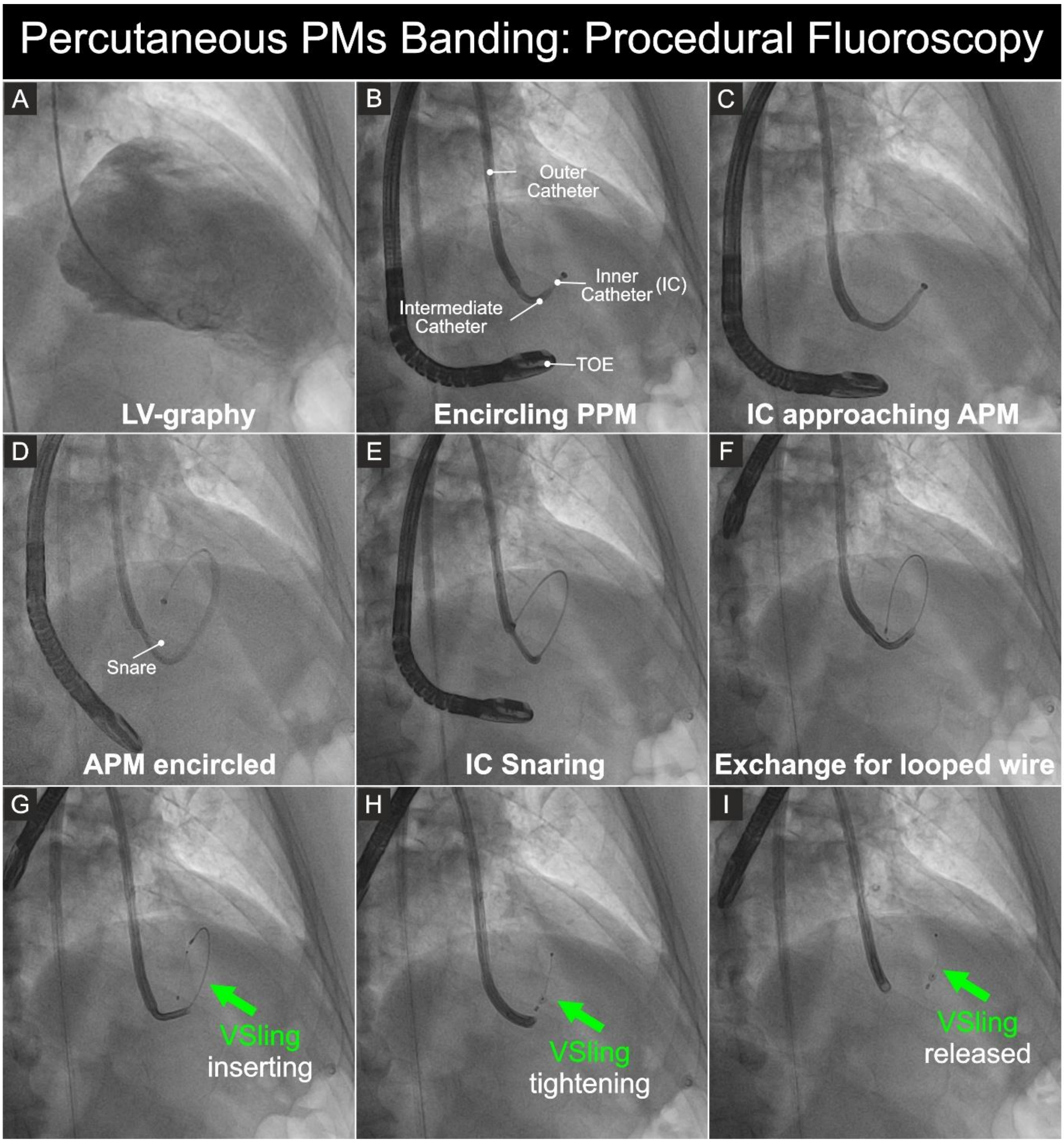
Supplementary Figure 2. Physical verification of the papillary muscle encircling pathway in a 3D print of the patient's heart (photographs).

A – crossing, with the inner catheter, through the 'tunnel' behind the posterior papillary muscle;
B – advancing the inner catheter and advancing – over the inner catheter – the intermediate catheter;
C – navigating the telescopic system towards anterior papillary muscle;
D – crossing, with the inner catheter, the 'tunnel' behind the anterior papillary muscle;
E – navigating the telescopic system towards the posterior papillary muscle;
F – closing the catheter system 'loop'; the papillary muscles encircling pathway - confirmed
Abbreviations: APM – anterior papillary muscle; PPM- posterior papillary muscle; IMC – intermediate (support) catheter; IC – inner catheter (note atraumatic tip)



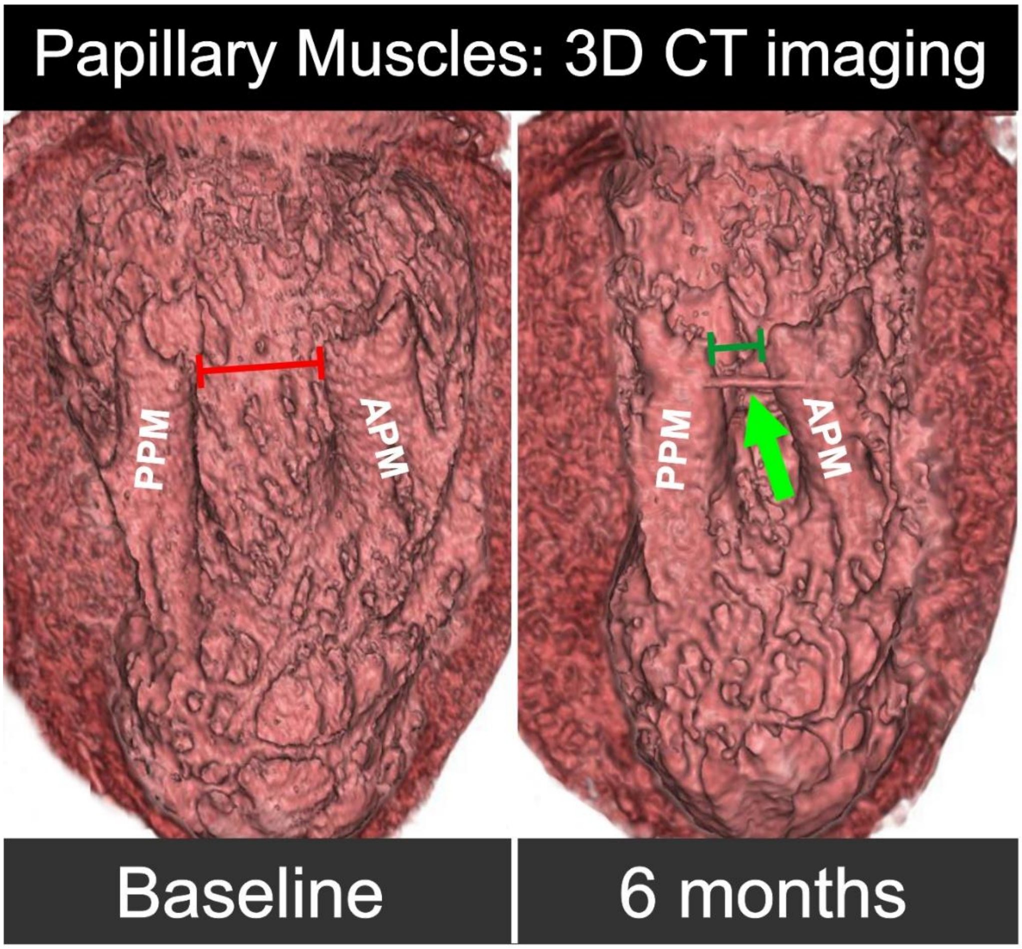
Supplementary Figure 3. The role of CT-based simulation of fluoroscopy (Mr TEEmothy) in intraprocedural navigation.

Mr TEEmothy, by Medical Simulation Technologies. The phases of planned progress in encircling the PPM and APM as per planned crossing pathway (to finally close the catheter system loop around the papillary muscles), is displayed on simulated fluoroscopic images in the selected C-arm angulation (examples in A, C, **Moving image 1**), in relation to the actual position of the catheter system (procedural fluoroscopic image frames in B and D). Wrong direction of the 3D-steerable inner catheter (B) is adjusted, according to the simulated fluoroscopy frame (C), resulting in the catheter system pathway correction (D). Note TOE probe in B and D – simultaneous TOE guidance **(Figure 1, Supplementary Figure 4, Moving image 1-Moving image 3)**.



Supplementary Figure 4. Fluoroscopic images of the key steps in the transcatheter banding of papillary muscles to improve LV shape and mechanical function in LV failure.

(NB. Image descriptions are embedded in consecutive procedural images A to I).



Supplementary Figure 5. 3D visualisation of the left ventricle (CT imaging) with a focus on papillary muscles and the PM band (VSling).

Note APM-PPM approximation by (now healed) band, resulting in a more conical LV shape. This has translated into improvement in LV volumes (LVESV more than LVEDV, **Figure 1**) and improved LV contractile function (note EF increase, **Figure 1**). For dynamic LV images see **Moving image 6**. *Abbreviations:* APM – anterior papillary muscle; PPM- posterior papillary muscle

Moving image 1. CT-based simulation of the role of fluoroscopy (Mr TEEmothy) in determining optimal procedural C-arm angulation.

Note superimposed papillary muscles encircling pathway (red) and aortic valve annulus and mitral valve annulus for operator orientation. CT-based simulation of fluoroscopy is an important addition, in procedural live fluoroscopic navigation, to live TOE imaging **(Figure 1, Supplementary Figure 3, Moving image 3)**. Optimal TOE imaging projections are pre-selected using MrTEEmothy (Medical Simulation Technologies) CT-based simulation of TOE.

Abbreviations: CT – computed tomography; TOE – transoesophageal echocardiography.

Moving image 2. Transcatheter banding of papillary muscles using the VSling System.

(Descriptions of fluoroscopic images are embedded in merged video clips). V-Sling system by CardiacSuccess.

Moving image 3. Intraprocedural navigation using live transoesophageal echocardiography imaging.

Note visualisation of the inner catheter crossing through the 'tunnel' behind the posterior papillary muscle (left and mid, yellow arrow) and part of the catheter system loop between the papillary muscles (yellow double arrow).

Moving image 4. Transthoracic echocardiography – focus on the papillary muscles before (left) and after (right) banding.

Note an effective reduction in the interpapillary distance.

Moving image 5. Transthoracic echocardiography imaging at baseline, and 1 and 6 months after percutaneous papillary muscle banding.

Top – short axis views, bottom – 4-chamber views (with focus on the left ventricle)

Note improvement in LV shape (this was associated with an increase in EF, consistent with CT imaging; **Figure 1** and **Moving image 6**). Green arrows depict the VSling band.

Moving image 6. Dynamic CT imaging (papillary muscles – aortic valve plane) at baseline, and 1 and 6 months after the transcatheter banding of papillary muscles.

Note an effective (and maintained at 6-months) reduction in the interpapillary distance, and improvement in LV shape in association with improved contractile function.