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Mapping the maze: advancing atrial fibrillation models and therapies

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Part One

Outcomes of thoracoscopic ablation in long-standing persistent atrial fibrillation

Chapter 2

Clamping versus nonclamping thoracoscopic box ablation in long-standing persistent atrial fibrillation

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Abstract

Objective: To compare clinical outcomes of clamping devices and linear nonclamping devices for isolation of the posterior left atrium (box) in thoracoscopic ablation of long-standing persistent atrial fibrillation.

Methods: Eighty patients who underwent thoracoscopic pulmonary vein and box isolation using a bipolar clamping device (42 patients) or bipolar nonclamping device (38 patients) to create the roof/inferior lesions for box isolation were included from 2 centres. Follow-up consisted of 24-hour Holter at regular intervals. Freedom from AF during 1-year follow-up and catheter repeat interventions were compared between groups.

Results: Acute intraoperative electrical isolation of the box compartment was significantly higher in the clamping group than in the nonclamping group (100% and 79%, respectively, $P < 0.01$). At 1-year follow-up, 91% of the clamping group and 79% of the nonclamping group were in sinus rhythm. During 1-year follow-up, recurrence rates did not significantly differ between the 2 groups ($P = 0.08$). Repeat catheter interventions were required in 10% of the clamping group and 21% of the nonclamping group ($P = 0.15$). Conduction gaps in the roof or inferior lesions were found in 1 patient (2%) in the clamping group versus 4 patients (11%) in the nonclamping group ($P = 0.13$).

Conclusions: Thoracoscopic pulmonary vein and box isolation are highly effective in restoring sinus rhythm in long-standing persistent atrial fibrillation on short-term follow-up. Comparison of clamping and nonclamping devices revealed lower rates of intraoperative exit block of the box in the nonclamping group. However, this did not translate into a significant difference in atrial fibrillation freedom at short-term (1-year) follow-up.

Introduction

Totally thoracoscopic ablation has been increasingly accepted for the treatment of patients with long-standing persistent atrial fibrillation (AF) because of its high efficacy compared with percutaneous ablation and minimally invasive character (1,2). The left atrial posterior wall has been suggested to play a major role in the initiation and the maintenance of AF, and therefore complete isolation of this area is desired (3). The most common lesion set consists of pulmonary vein (PV) antrum isolation combined with left atrial posterior wall (box) isolation. To create the box lesions, current thoracoscopic techniques mainly rely on 2 types of bipolar radiofrequency (RF) ablation devices, that is, ablation clamps and linear nonclamping devices. Thus far, no study has compared these devices in terms of their clinical efficacy. Histologic studies suggest that clamping devices create more durable lesions compared with nonclamping devices (4-6). Because durable isolation of the PVs and posterior wall is crucial for freedom from AF, we compared the 1-year outcomes of these 2 common devices in patients with long-standing persistent AF.

Materials and Methods

Patients and Data Collection

Consecutive patients with symptomatic long-standing persistent AF undergoing thoracoscopic ablation at the Leiden University Medical Centre (October 2009 to December 2016) and Catharina Hospital (December 2013 to November 2016) were included. Patients were refractory to 1 or more class I/III antiarrhythmic drugs or had failed catheter ablation. Clinical data were prospectively collected in the electronic patient information system of the Cardiothoracic Surgery/Cardiology departments of both hospitals and were retrospectively analysed. Definitions of long-standing persistent AF and clinical outcomes were based on the Heart Rhythm Society expert consensus statement on catheter and surgical ablation of AF (7). This study was conducted with approval of the institutional review boards of the Leiden University Medical Centre (LUMC, G17.101) and Catharina Hospital Eindhoven. Patient data in the LUMC were collected after written informed consent, whereas data in the Catharina Hospital were collected as part of a quality improvement initiative, waiving the need for individual informed consent. All data were handled in accordance with the European General Data Protection Regulation.

Surgical Techniques

In both thoracoscopic approaches, PV isolation was performed using ablation clamps, whereas isolation of the posterior left atrium (box) was performed using a clamping or a linear nonclamping device (**Figure 1**). In each of the 2 centres, one technique was performed exclusively. The clamping box lesion set was performed only in the Leiden University Medical Centre by 2 surgeons (J.B./T.J.v.B.), whereas the nonclamping box lesion set was performed in the Catharina Hospital by 1 surgeon (N.J.V.).

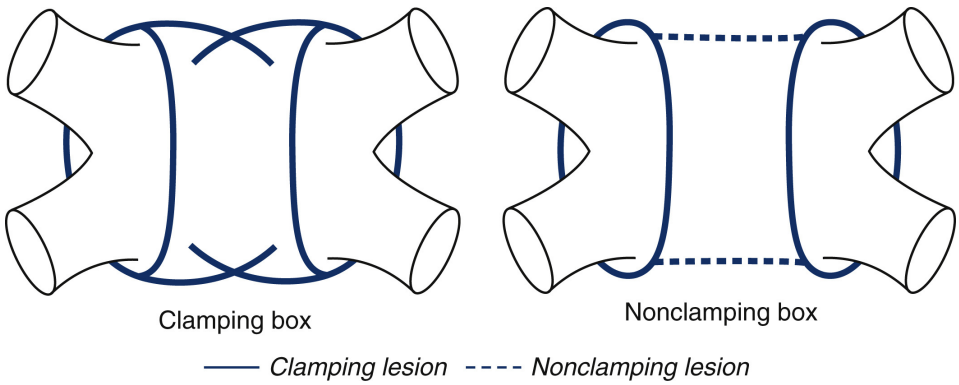

Figure 1. Schematic overview of the PV and box ablation lesions placed with clamping and nonclamping devices in the 2 groups. Solid lines represent lesions ablated with a clamping device, and dotted lines represent lesions placed with a nonclamping device.

The clamping box lesion set was created by using a single device, a bipolar saline-irrigated RF clamp (Cardioblate Gemini-s, Medtronic). Starting ablation from the left, the clamp was applied 4 times with the convexity of the clamp facing toward the atrial myocardium to apply left PV antrum lesions and 4 times with the concavity of the clamp facing toward the myocardium to create the roof/inferior lesions. This clamping across the left atrial posterior wall is shown in **Figure 2**. For each application, energy was delivered until impedance measurements indicated transmurality (based on the generator algorithm). Between applications, the ablation clamp was repositioned to ensure overlap of the lesions at the hinge point of the Gemini Clamp. The same lesions were repeated from the right side to create the right PV antrum lesion and to close the box. This procedure has been described previously in detail (8) and can also be seen in **Supplemental Video 1**.

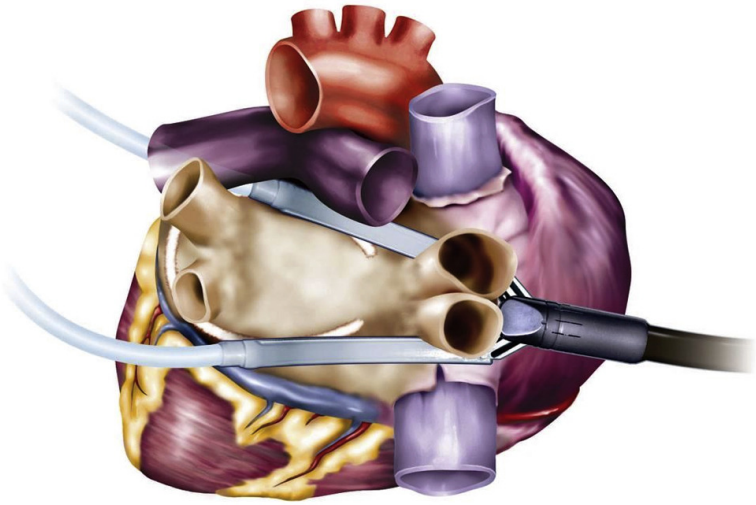

Figure 2. Illustration of the Gemini-s device clamping across the left atrial posterior wall to create the roof and inferior lesions in the clamping group.

The nonclamping box lesion set consisted of creating a circumferential right antral PV lesion using a nonirrigated bipolar RF clamp (EMR2, AtriCure). During a minimum of 5 applications, the clamp was repositioned each time when impedance measurements (based on the generator algorithm) indicated transmurality. Continuing on the right, starting from the PVs, the roof and inferior lesion were created using a linear nonclamping device (Coolrail Linear Pen, AtriCure) by overlapping an average of 20 lesions connecting with the left PV antrum thereby closing the box. Then, the left PV antrum was isolated using a bipolar RF clamp again (EML2, AtriCure). This procedure has also been described in detail (9) and can be seen in **Supplemental Video 2**.

In both techniques, electrical isolation of the PVs and box was confirmed after completion of the lesion set. Patients who did not achieve sinus rhythm during the procedure underwent electric cardioversion. Entrance block was defined as the absence of sharp electrograms in each of the PVs and box compared with baseline measurements (Cardioblate MAPS Device, Medtronic or Max 5 Pen, AtriCure). Exit block was defined as the absence of left atrial capture when pacing in all PVs and the box. In the event that entrance or exit block had not been achieved after lesion set completion, a series of additional RF applications were performed and entrance/exit block measurements were

repeated. Although additional RF applications entrance or exit block could not be achieved, it would be regarded as failed entrance/exit block.

Left atrial appendage (LAA) management varied between centres. Preoperatively, transesophageal echocardiography was used in all patients to exclude the presence of a left atrial thrombus. Management was performed by 60-mm stapler exclusion (Endo GIA Universal Stapler, Medtronic) or clip closure (AtriClip, AtriCure) when deemed feasible.

Antiarrhythmic drugs were started or continued after the procedure throughout the 3-month blanking period and discontinued after the first follow-up if the patient was in sinus rhythm. Oral anticoagulation was resumed until (a minimum of) 6 months after the procedure and discontinued, based on rhythm and CHA_2DS_2-VASc score (congestive heart failure, hypertension, age, diabetes, stroke, vascular disease and sex score), at the discretion of the cardiologist.

Follow-up

Follow-up consisted of 24-hour Holter monitoring at regular intervals (3, 6, and 12 months). Recurrence was defined as any episode of AF, atrial flutter (AFL), or atrial tachycardia (AT) lasting 30 seconds or more on 24-hour Holter, electrocardiography, or pacemaker/implantable cardioverter defibrillator interrogation after the 3-month blanking period. Patients were asked to visit the hospital in case of symptoms suggestive of arrhythmia for additional electrocardiography or 24-hour Holter monitoring. Patients with suspected reconnection due to the presence of AF/AFL/AT were invited for an endocardial electrophysiologic evaluation and ablation. All patients who completed the 1-year 24-hour Holter recording were included in the analysis.

Statistical Analysis

Categoric data are presented as counts and percentages, whereas numeric data are expressed as mean ± standard deviation for normally distributed data or as median [interquartile range] for non-normally distributed data. Numeric data were compared using the independent sample t test or Mann–Whitney U test, and categoric data were compared using the chi-square test or Fisher exact test. A mixed-effect logistic regression model was fitted to model the probability of atrial arrhythmia recurrence. Time and surgical technique effect were fitted as fixed effects. Time was included as a categoric covariate, contrasting follow-up moments at 6 and 12 months versus 3 months, to account for nonlinearity of effect at log-odds scale. Time points represented

rhythm status measured at the follow-up moment plus any recurrences detected in the preceding interval. A normally distributed within-person effect was added to the model to account for within-person correlation in longitudinally observed recurrence of atrial arrhythmias. Statistical analysis was performed using SPSS (v23.0, IBM), and graphs were plotted in GraphPad Prism (v7.0, GraphPad Software Inc).

Results

Baseline Demographics

Eighty patients with long-standing persistent AF underwent thoracoscopic ablation between 2009 and 2016. A total of 42 patients underwent box ablation using a clamping device, whereas 38 patients underwent nonclamping device box ablation. In the clamping group, mean age was 59 ± 8 years with a median duration of AF of 4 (2-6) years. Median left atrial volume index was 42 (38-52.3) mL/m^2, and 7 patients (17%) had previously undergone catheter ablation. In the nonclamping group mean age was 61 ± 9 years, median AF duration was 3 (2-7) years, median left atrial volume index was 36.5 (31.5-51.3) mL/m^2, and 12 patients (32%) previously underwent catheter ablation. During follow-up, 6 patients (14%) in the clamping group and 6 patients (16%) in the nonclamping group had continuous rhythm monitoring through an implanted device. Between the 2 groups, the median CHA_2DS_2-VASc score was significantly higher in the nonclamping group (1 [0-2], 2 [1-2], P = 0.01) as well as the body mass index (29.6 ± 4.3 vs 26.9 ± 3.1, P < 0.01). An overview of baseline characteristics is shown in **Table 1**.

Follow-up

At the end of the blanking period, 100% of patients in the clamping group and 95% of patients in the nonclamping group were in sinus rhythm, whereas at 1 year, 91% of patients in the clamping group and 79% of patients in the nonclamping group were free from atrial arrhythmias (**Figure 3**). After correction for time effect in random-effect logistic regression, we found no significant difference in AF/AFL/AT recurrence during 1-year follow-up between the 2 groups (F-test = 3.05, P = 0.08, **Table 2**). At 1 year, 12% of the clamping group and 16% of the nonclamping group were continuing to use antiarrhythmic drugs (P = 0.61). During the 1-year follow-up period, repeat catheter ablation was performed in 4 of 42 patients (10%) in the clamping box group and in 8 of 38 patients (21%) in the nonclamping box group (P = 0.15).

Table 1. Baseline clinical characteristics

Characteristic	Clamping box (n = 42)	Non-clamping box (n = 38)	
Age (years)	59 ± 8	61 ± 9	*P = 0.21*
Female	10 (24%)	11 (29%)	*P = 0.60*
Duration of AF (years)	4 [2-6]	3 [2-7]	*P = 0.64*
Left atrial volume index (ml/m^2)	42 [38-52.5]	36.5 [31.5-51.3]	*P = 0.05*
CHA_2DS_2-VASc score	1 [0-2]	2 [1-2]	*P = 0.01*
0	15 (36%)	6 (16%)	
1	15 (36%)	11 (29%)	
2	7 (16%)	12 (32%)	
≥ 3	5 (12%)	9 (24%)	
Body Mass Index (kg/m^2)	26.9 ± 3.1	29.6 ± 4.3	*P < 0.01*
Hypertension	17 (41%)	22 (58%)	*P = 0.12*
Diabetes mellitus	0 (0%)	2 (5%)	*P = 0.13*
Prior stroke	1 (2%)	4 (11%)	*P = 0.13*
Prior transient ischemic attack	2 (5%)	1 (3%)	*P = 0.62*
Prior catheter ablation	7 (17%)	12 (32%)	*P = 0.12*
Pacemaker/ICD monitoring	6 (14%)	6 (16%)	*P = 0.85*

Data are presented as *n* (%), mean ± SD or median [ICR]
AF: atrial fibrillation, ICD: implantable cardioverter defibrillator, ICR: interquartile range, SD: standard deviation

Catheter Repeat Ablations

During repeat catheter procedures, gaps in the lesion set were regularly found as source of recurrence. PV lesion gaps were found in 2 patients (5%) in the clamping group versus 3 patients (8%) in the nonclamping group (P = 0.56). Gaps in the roof or inferior box lesions were present in 1 patient (2%) in the clamping group versus 4 patients (11%) in the nonclamping group (P = 0.13). Cavotricuspid isthmus ablation for the presence of typical AFLs was performed in 1 patient in the clamping group and in 5 patients in the nonclamping group (P = 0.07). In both groups, 1 patient underwent posterior mitral isthmus ablation for the presence of a mitral isthmus dependent flutter. After repeat catheter ablation, all 4 patients in the clamping group regained sinus rhythm, whereas in the nonclamping group 4 of 8 patients returned to sinus rhythm, 2 of 8 patients

remained in AF, and 2 of 8 patients continued to experience AFLs. A complete overview is presented in **Table 3.**

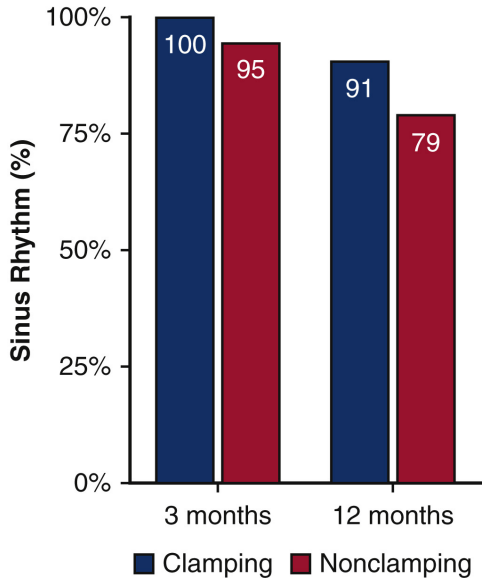

Figure 3. Percentage of patients in sinus rhythm after the blanking period (3 months) and at maximal (12 months) follow-up in the clamping and nonclamping box isolation groups.

Table 2. Mixed-effect logistic regression model of atrial arrhythmia recurrence including ablation technique and time effect

Variables	Estimate	SE	OR (95% CI)	P
Intercept	-4.497	0.838	0.011 (0.002-0.058)	0.000
Use of non-clamping technique*	0.971	0.556	2.640 (0.883-7.897)	0.082
Rhythm 6-months†	1.732	0.827	5.652 (1.108-28.822)	0.037
Rhythm 12-months†	2.312	0.804	10.099 (2.072-49.222)	0.004

*Reference = Use of clamping technique, †Reference = Rhythm 3-months
SE: standard error, OR: odds ratio, CI: confidence interval

Table 3. Characteristics of repeat catheter interventions

#	SVT type	Device of box isolation	Repeat intervention	Rhythm after
1	AF	Clamping	Reisolation of LPV/RPV/roof/inferior	SR
2	AF	Clamping	CFAE ablation + LAAI	SR
3	AF	Clamping	Reisolation of LPV + CFAE ablation + CTI	SR
4	AFL	Clamping	MI ablation	SR
5	AF/AFL	Non-clamping	CFAE ablation + CTI	AF
6	AF	Non-clamping	Reisolation of roof + CFAE ablation	SR
7	AFL	Non-clamping	CTI ablation	SR
8	AFL	Non-clamping	CTI ablation	AFL
9	AF/AFL	Non-clamping	Reisolation of RPV/roof/inferior + MI	SR
10	AFL	Non-clamping	CTI ablation	SR
11	AF/AFL	Non-clamping	Reisolation of LPV/roof/inferior + CTI	AF
12	AF	Non-clamping	Reisolation of RPV/roof + CFAE ablation	AF

AF: atrial fibrillation, AFL: atrial flutter, CFAE: complex fractionated atrial electrograms, CTI: cavotricuspid isthmus, LAAI: left atrial appendage isolation, LPV: left pulmonary veins, MI: mitral isthmus, RPV: right pulmonary veins, SR: sinus rhythm, SVT: supraventricular tachycardia

Discussion

This is the first study comparing outcomes of clamping and nonclamping devices for creation of the roof/inferior (box) lesions in addition to PV isolation in thoracoscopic long-standing persistent AF ablation. The main findings were 1) intraoperative electrical isolation of the clamping box lesions was significantly higher compared with the nonclamping box lesion (100% vs 79%, respectively); 2) repeat catheter interventions due to recurrence were required in 10% of the clamping group and 21% of the nonclamping group; and 3) resulting sinus rhythm rates at 1 year were 91% using clamping devices and 79% using nonclamping devices.

Thoracoscopic AF ablation has been established as a valuable therapy compared with catheter ablation in patients with long-standing persistent AF, in whom outcomes have generally been suboptimal and require multiple procedures to achieve sinus rhythm (10,11). The ablation outcomes in our

groups (91% and 79% freedom from AF at 1 year, on antiarrhythmic drugs) demonstrate that thoracoscopic ablation is effective in restoring sinus rhythm in long-standing persistent AF and are consistent with previous reports of thoracoscopic ablation in these populations (1,2).

In the 2 groups, we found that the acute electrical isolation of the box compartment as measured by exit block was significantly lower in the nonclamping group. However, this did not result in a significant difference in sinus rhythm rates during 1-year follow-up (P = 0.08). Because repeat procedures performed within the 1-year timeframe might influence the rates of sinus rhythm at 1 year, we also assed the frequency of repeat procedures and associated findings in both groups. Repeat procedures did not significantly differ between groups (10% in clamping vs 21% in nonclamping groups, P = 0.15), and neither did the amount of conduction gaps found in the box compartment (2% in clamping vs 11% in nonclamping groups, P = 0.13). However, in the present study, only part of the 2 groups were admitted for endocardial electrophysiologic testing, which likely underestimates the actual number of conduction gaps present. Bulava and colleagues (12) performed a staged hybrid procedure in a similar group with nonclamping roof/inferior lesions and found that 23% of the nonclamping box lesions versus 69% of the clamping PV lesions were electrically isolated 6 to 8 weeks after the surgical procedure.

The heterogeneity in acute lesion integrity can likely be attributed to a combination of factors. Mainly, thermal sinking proves to be a substantial obstacle when performing epicardial nonclamping ablation, as the endocardium is continuously cooled by circulating blood, thereby counteracting transmurality. Clamping devices are less affected by this phenomenon because of blood displacement between the 2 jaws. Moreover, epicardial fat presence significantly affects lesion transmurality, because fat is a poor conductor of energy (13,14). Particularly in chronic AF, epicardial fat volumes increase compared with both healthy patients and patients with paroxysmal AF (15), and thick epicardial fat pads have been described at the location of the roof lesion (16). With nonclamping devices, energy flows between the 2 electrodes of the device, possibly not reaching the endocardium when thick epicardial fat pads are present. This is in contrast to clamping devices, where energy flows from epicardium to endocardium, to the other endocardium and again to epicardium. Moreover, the need of nonclamping devices to overlap multiple applications to create linear lesions might prove to be a risk factor for the presence of conduction gaps.

The strategy toward LAA management was different in the 2 participating centres. Surgeons in the nonclamping group strived toward high LAA management rates, whereas surgeons in the clamping group were more conservative and managed the LAA on the basis of thromboembolic risk, LAA anatomy, and stapling safety. Which strategy is preferable remains under debate, because the risk–benefit ratio of empirical LAA exclusion is uncertain. Although not yet studied, safe closure of the LAA might be higher with the clip compared with stapling devices. Besides potentially reducing thromboembolic events, some electrophysiologic benefit might be expected when performing empirical LAA isolation as seen in percutaneous ablation studies (17). One patient in our group in whom the LAA was left *in situ* because of unfavourable anatomy for stapler excision required percutaneous electrical isolation of the LAA due to recurrence of AF. Whether there is an electrophysiologic benefit of empirical LAA isolation when performing thoracoscopic ablation remains to be determined.

Study Limitations

Several limitations of this study should be mentioned, which are mainly the relatively small group sizes and the nonmatched and nonrandomized retrospective nature. Because each centre performed 1 of the 2 techniques exclusively, differences in clinical baseline characteristics and risk factors (*e.g.* body mass index and CHA_2DS_2-VASc score), as well as clinical protocols and practice (*e.g.* follow-up patterns, medication regimens, and aggressiveness of treatment), could affect the clinical outcomes. These features prevent any definitive conclusions to be drawn regarding the efficacy of clamping and nonclamping box isolation. As mentioned earlier, the frequency of lesion gaps found during repeat procedures is likely underestimated because only part of the group underwent endocardial testing of the lesion integrity. Also, the 1-year freedom rates might be overestimated because some asymptomatic arrhythmia episodes may not have been detected by 24-hour Holter monitoring. Nonetheless, this study provides a first comparison of the efficacy of 2 types of ablation devices for box isolation currently used in clinical practice. Larger prospective studies with a longer rhythm follow-up should provide more definitive information on the ability of clamping and nonclamping devices to create continuous transmural roof/inferior lesions, as well as on their efficacy in treating long-standing persistent AF.

Conclusions

Thoracoscopic PV and box isolation following a structured approach and using intraoperative assessment of conduction block are highly effective in restoring sinus rhythm in long-standing persistent AF. Comparison of clamping and nonclamping devices for roof/inferior lesion ablation revealed lower rates of intraoperative conduction block in the nonclamping group. However, this did not translate into significant differences in AF freedom at short-term (1-year) follow-up in our groups.

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Supplemental Information

Supplemental Video 1. Overview of the thoracoscopic PV and box isolation procedure using a clamping device to isolate the box. Video available at: doi.org/10.1016/j.jtcvs.2019.07.104

Supplemental Video 2. Overview of the thoracoscopic PV and box isolation procedure using a linear nonclamping device to isolate the box. Video available at: doi.org/10.1016/j.jtcvs.2019.07.104