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Achieving Metrics during Beating-Heart Ex-Maze Procedures Improves Outcomes

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ABSTRACT

Background: Current surgical treatments for atrial fibrillation (AF) lack intraoperative metrics that predict long-term outcomes. The extracardiac maze (Ex-Maze) procedure is a beating-heart maze procedure that causes spontaneous conversion to sinus rhythm (SR) during lesion creation. Spontaneous conversion and confirmation of pulmonary vein exit block are 2 important predictors of long-term freedom from AF.

Methods: A beating-heart Ex-Maze procedure was performed in 54 AF patients (paroxysmal, n = 2; persistent, n = 11; longstanding persistent, n = 41) undergoing concomitant cardiac surgery (mitral valve replacement [MVR] = 23, aortic VR [AVR] = 7, coronary artery bypass graft [CABG] = 17, CABG + AVR = 3, CABG + MVR = 2, atrial-septal defect = 2). The Ex-Maze lesion set is a comprehensive, biatrial ablation pattern created epicardially with unipolar, radiofrequency energy applied by a vacuum-integrated device. Electrocardiogram data were collected during the procedure and at 1, 3, 6, and 12 months postoperatively; 24-hour Holter monitors data were also obtained 12 month postprocedure.

Results: Mean left atrial size was 5.4 cm. Average procedure time was 39 minutes. There were no device- or procedure-related complications. At the time of surgery 48 patients were in AF; 32 (67%) patients spontaneously converted to SR during lesion creation. At a mean follow-up of 262 days, 42 of 48 patients (88%) were free from AF, 39 of 48 (81%) were in SR; and 35 of 47 (74%) were free from AF and had discontinued class I and III antiarrhythmic drugs. In 32 of 33 patients (97%), exit block at 15 mA was confirmed, in which pulmonary vein isolation was tested. Follow-up was completed for 30 of the exit-block patients; freedom from AF was observed in 29 of 30 (97%), SR in 26 of 30 (87%), and freedom from AF and class I/III antiarrhythmic drugs in 25 of 29 (86%).

Conclusions: Recent advances in techniques and technologies permit the creation of a comprehensive biatrial lesion pattern on the epicardium of a beating heart. Observation of spontaneous conversion and confirmation of pulmonary vein exit block are important metrics that predict improved long-term outcomes.

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INTRODUCTION

Cox et al [1991] described a comprehensive biatrial pattern of continuous transmural lesions as an effective surgical treatment for all patients with atrial fibrillation (AF). Conversion to sinus rhythm (SR) during lesion creation indicates that existing and clinically significant macroreentrant circuits have been interrupted. Intraoperative confirmation of pulmonary vein isolation provides an indication of the completeness of the lesion pattern and lesion transmurality. Therefore, arrested-heart surgery is limited by the inability to monitor atrial rhythms during AF therapy. In addition, most surgical treatments for AF lack standard and reliable intraoperative indicators for predicting the long-term success of the procedure. Moreover, partial or incomplete lesion patterns limited to the left atrium may not sufficiently disrupt the bi-atrial reentry pathways that lead to AF.

Although conversion to SR and confirmation of electrical isolation of the pulmonary veins may provide an indication of the long-term success of the ablation procedure, visual confirmation that left and right atrial lesion patterns are connected and contiguous is also an essential requirement for creating an effective electrical barrier within the atrial walls. Therefore, the definition for a comprehensive bi-atrial lesion pattern should meet the following criteria:

- The pattern should be contiguous and include lesions on the left and right atria which are interconnected.
- The lesion pattern should ensure isolation of the pulmonary veins by demonstrating exit block at >15 mA.
- Lesions should be full thickness, without gaps of viable myocardium.

MATERIALS AND METHODS

Patients

Study participants were 54 patients with documented AF (paroxysmal = 2, persistent = 11, longstanding persistent = 41) [HRS/EHRA/ECAS 2007] who underwent nonemergent

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cardiac surgery during the period August 2006 to November 2007 via median sternotomy with a concomitant open-chest, beating-heart Ex-Maze procedure. Informed consent was obtained from all patients in accordance with local institutional review board and ethics committee regulations. Surgeons at participating sites were certified in performance of the Ex-Maze procedure by demonstrating the ability to create the complete lesion pattern and demonstrate exit block.

Description of the Device

The monopolar radiofrequency device (Visitrax™, nContact Surgical, Morrisville, NC, USA) incorporates a thin, flexible electrode with silastic tubing through which vacuum is applied to maintain consistent contact with the epicardial surface during energy delivery [Kiser 2008]. The vacuum further pulls saline through the electrode to cool the device and the epicardial surface, inhibiting excessive heating and allowing optimal energy penetration into the tissue. The resulting lesions are precisely located and avoid damage to adjacent structures. Lesions are clearly visible on the myocardium, allowing the surgeon to directly visualize and connect lesion patterns.

Description of the Ex-Maze Procedure

All patients underwent preoperative transesophageal echo imaging to rule out left atrial thrombus. After sternotomy, the Ex-Maze surgical ablation procedure was performed on the beating heart prior to cross-clamp and the concomitant cardiac procedure. [Kiser 2007] Continuous electrocardiogram monitoring was performed throughout the procedure. Spontaneous conversion to SR during lesion creation was recorded. After completion of the Ex-Maze lesion pattern (Figure 1), those patients remaining in AF were electrically cardioverted to SR. Left and right pulmonary vein isolation was verified by pacing the pulmonary veins at 15 mA and demonstrating exit block through the inability to capture the atria.

Postoperative Management and Follow-Up

Antiarrhythmic and anticoagulant drugs were discontinued prior to the procedure. Postoperative antiarrhythmic therapy was directed by the referring physician but generally included avoiding class I or III antiarrhythmic drugs postoperatively unless AF recurred. If AF recurred in the early postoperative period, amiodarone was administered and maintained for 2 weeks; if SR was restored amiodarone was discontinued. In 3 patients, prophylactic antiarrhythmic drug use was prescribed by the referring physician even though the patient remained in SR postoperatively throughout the entire follow-up period. Anticoagulation was reinitiated postoperatively and continued for at least 3 months.

Patients were monitored until discharge and at 1, 3, and, 6 months with a 12-lead electrocardiogram and at 12 months with a 24-hour Holter monitor.

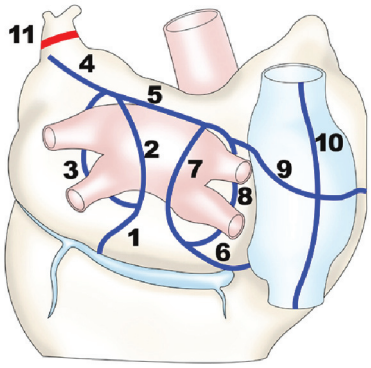

Figure 1. Diagram of the Ex-Maze lesion pattern.

Statistical Analysis

Baseline values and follow-up periods are reported as mean ± SD. Comparisons of freedom from AF, restoration of SR, and freedom from AF and antiarrhythmic drugs for patient segments were calculated by χ^2 analysis.

RESULTS

Fifty four patients (23 males, 31 females) underwent an Ex-Maze procedure in combination with other cardiac procedures (mitral valve repairs or replacements [MVR] = 23, aortic valve replacements [AVR] = 7, coronary artery bypasses [CABG] = 17, CABG + AVR = 3, CABG + MVR = 2, and atrial-septal defect repair = 2). The mean age of the patients was 68 ± 9 years (range 50-85 years). The mean left atrium size was 5.4 ± 1.0 cm and the mean additional operative time was 39 ± 16 minutes. There were no device- or procedure-related complications. Figure 2 shows the breakdown of study patients according to their follow-up status. There were 2 deaths <30 days postoperatively (end-stage renal disease and heart failure), and 2 deaths >30 days postoperatively (multisystem organ failure and renal failure). There was 1 intraoperative exclusion, and 1 patient elected not to travel for follow-up visits.

Overall results for 48 patients were available. At mean ± SD follow-up of 262 ± 104 days, 42 of 48 patients (88%) were free from AF, 39 of 48 (81%) were in SR, and 35 of 47 (74%) were free from AF and class I/III antiarrhythmic drugs (Figure 3) Three patients continued taking class I or III antiarrhythmic drugs despite remaining in stable SR throughout the follow-up period.

Figure 4 shows the results by AF type based on the previously published definitions [HRS/EHRA/ECAS 2007]. One patient was classified postprocedure as paroxysmal; this patient remained in SR without taking class I or III antiarrhythmic drugs. All 11 patients with persistent AF were free from AF postprocedure; 10 of 11 (91%) were in SR and 9 of 11 (82%) were free from AF without class I/III antiarrhythmic drugs. For the long-standing persistent AF patients, 30 of 36 (83%) were free from AF, 28 of 36 (78%) were in SR, and 25 of 35 (71%) were free from AF without class I or III antiarrhythmic drugs.

A total of 48 patients were in AF at the beginning of the procedure; 6 arrived in the operating room in SR. Of these, 32 of 48 (67%) spontaneously converted into SR during Ex-Maze lesion creation. All patients who entered the operating room in SR remained in SR throughout the follow-up period. Of the patients who spontaneously converted during lesion creation, 25 of 30 (83%) were free from AF and class I/III

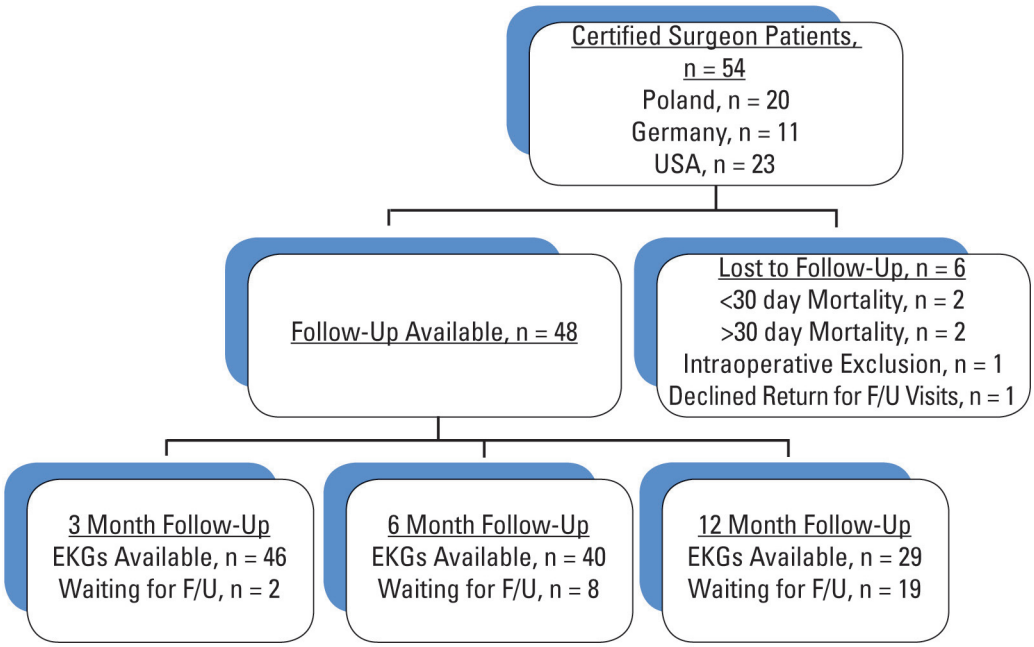

Figure 2. Breakdown of Study Patients.

antiarrhythmic drugs at mean follow-up. That compares to only 7 of 13 (54%) for patients who did not convert during lesion creation; $\chi^2 = 4.14$, degrees of freedom (df) = 1, $P < .05$ (Figure 5).

Conduction block was tested at 15 mA and verified in 32 of 33 patients (97%). Of these patients, 29 of 30 (97%) were free from AF and 25 of 29 (86%) were free from AF and class I/III antiarrhythmic drugs. These outcomes were higher than in patients in whom exit block was not tested; 13 of 18 (72%) had freedom from AF, $\chi^2 = 6.14$, df = 1, $P = .013$; and 10 of 18 (56%) freedom from AF and antiarrhythmic drugs, $\chi^2 = 5.49$, df = 1, $P = .019$ (Figure 6).

Thirty four patients had a left atrial size (transthoracic echocardiogram; parasternal view) <6.5 cm, and a complete Ex-Maze lesion pattern (group A). Of these patients, 30 of 31 (97%) were free from AF, 28 of 31 (90%) were in SR, and 25 of 30 (83%) were free from AF and antiarrhythmic drugs (Figure 7). Of the 20 patients with a left atrium >6.5 cm or an incomplete lesion pattern (group B), only 12 of 17 (71%) were free of AF, 11 of 17 (65%) were in SR, and 10 of 17 (59%) were free of AF and antiarrhythmic drugs (Figure 7). Freedom from AF and restoration of SR were statistically different between group A and group B, $\chi^2 = 6.88$, df = 1, $P < .01$, $\chi^2 = 4.73$, df = 1, $P = .03$, respectively.

DISCUSSION

AF is a complex, multifactorial disease that affects more than 5 million people in the US [Miyasaka 2006].The treatment outcomes for AF have been correlated with atrial size, duration of AF, degree of structural heart disease, and

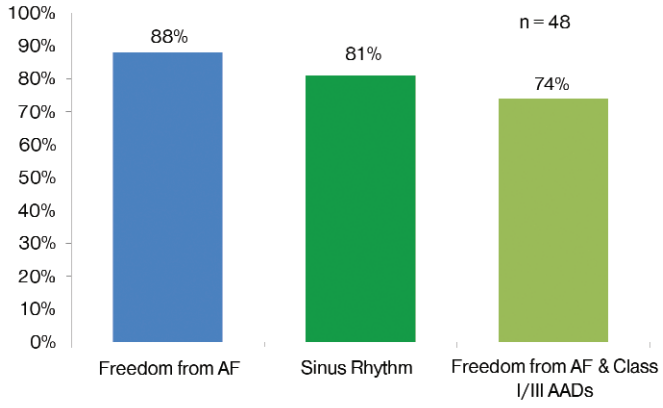

Figure 3. Outcomes at last follow-up (mean: 262 days).

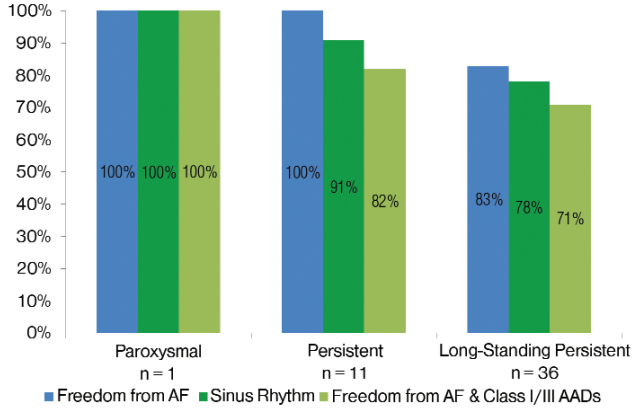

Figure 4. Outcomes according to AF type at last follow-up.

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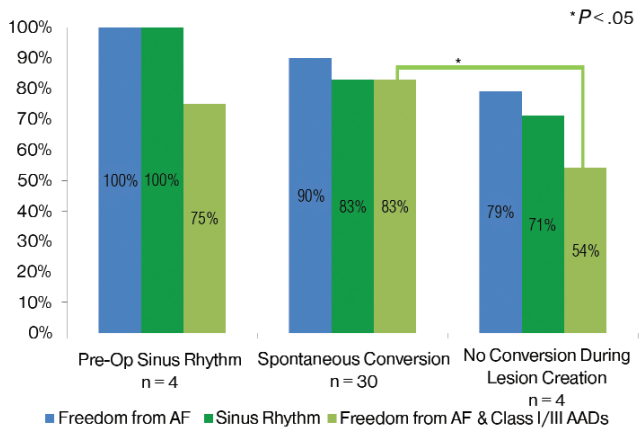

Figure 5. Impact of spontaneous conversion during lesion creation.

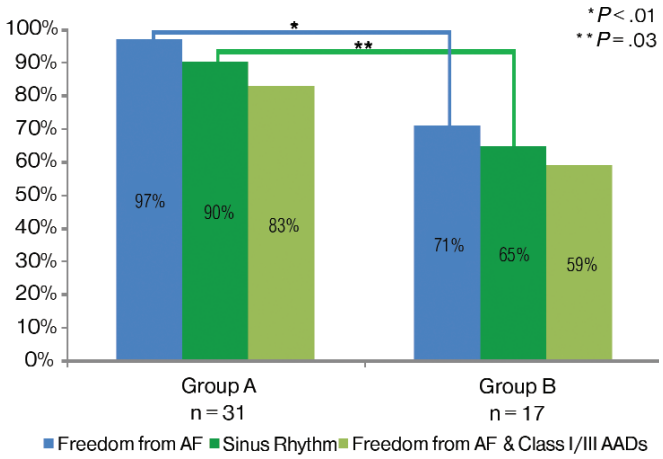

Figure 7. Impact of adhering to protocol on midterm outcomes.

age [Feinberg 1995; Gillinov 2002; Hynes 2003; Liu 2004]. More than 80% of AF patients have nonfocal, wavelet AF that may be due to degenerative changes within the myocardium resulting in the development of new reentrant circuits [Cox 2003]. Such structural remodeling promotes a progression to persistent AF. This sustained AF requires the presence of an atrial substrate of sufficient mass capable of maintaining reentrant circuits [Falk 2001; Natale 2007]. Once initiated, the risk of continued AF increases for patients with atria that have become dilated, damaged, or scarred. For these reasons, the success rate is low for treating AF with therapies that do not completely disrupt reentrant conduction pathways early in the disease process. Therefore, a successful ablation procedure must segment the atria into small enough sections to break existing and prevent new reentry circuits from forming within the myocardium and must be performed before there has been significant structural change in the heart tissues.

The Cox-Maze III procedure provides effective long-term treatment of AF because it interrupts macroreentrant circuits affecting both atria. Barnett et al performed a metaanalysis based on 69 studies involving 5885 surgically treated AF patients. Freedom from AF after biatrial procedures

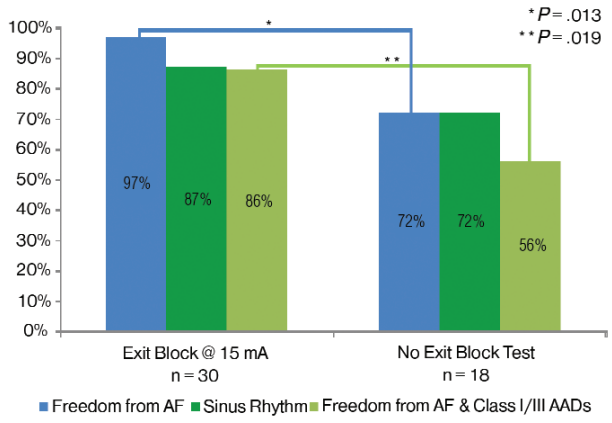

Figure 6. Impact of confirming exit block on midterm outcomes.

was significantly higher than that for left atrium–only procedures at 3 months, 1 year, 2 years, and 3 years postoperatively [Barnett 2006]. Biatrial lesions can block the transmission of ectopic pulmonary vein foci that can initiate AF and interrupt the macroreentrant atrial pathways that perpetuate AF. The cut-and-sew maze procedure provides the highest rate of freedom from AF in cases with and without structural heart disease. However, even the gold standard cut-and-sew maze procedure has limitations. Kosakai et al showed that restoration of SR decreased from >90% if the AF duration prior to surgery was <5 years to approximately 60% if the duration was >10 years and 0% if the duration was >32 years. Restoration of SR was also dependent on left atrial size; at left atrium size <4.5 cm, SR was observed in >95% of patients compared to <80% if left atrial size exceeded 6 cm, 50% at >7 cm, and 0% at >8.7 cm [Kosakai 2000].

The Cox-Maze procedure is recognized as the most effective treatment for all types of AF [Cox 1991; Damaino 2007]. Long-term success rates with the Cox-Maze procedure have been reported to be as high as 98% [Cox 2000]. However, the complexity of the procedure, a reported procedural mortality of 2% to 10%, and associated morbidity, including the requirement for a permanent pacemaker in approximately 15% of patients, has limited the widespread adoption of this procedure [Cox 1991; Kosakai 2000; Damiano 2007]. Attempts to make the Cox-Maze procedure less invasive have led to the development of new technologies and procedures that have had limited success when compared to the Cox-Maze procedure [Sueda 2005]. Catheters, clamps, pens, and cinches have not reliably created comprehensive biatrial lesion patterns and are therefore predominately limited to the treatment of the left atrium. The success rate with pulmonary vein isolation reflects its use on a large percentage of paroxysmal AF patients, and successful outcomes include redo procedures and continued use of antiarrhythmic drugs. Cappato et al reported outcomes from 9370 patients, obtained through a questionnaire. Success was determined based on the recurrence of symptoms. The 6-month freedom from AF was reported to be

68%; the freedom from AF without antiarrhythmic drugs was reported at 34% [Cappato 2005]. At 24 months, freedom from AF was 70% but freedom from AF and antiarrhythmic drugs was 38% despite repeat ablation procedures performed in 26% of patients [Cappato 2005].

The Ex-Maze procedure is a comprehensive lesion pattern designed to closely mimic the Cox-Maze III pattern. The Ex-Maze pattern reduces the complexity of the Cox-Maze III procedure but still addresses the difficult-to-treat population with long-standing persistent AF. Patients treated with the Ex-Maze procedure (of which 76% had long-standing persistent AF) had 88% freedom from AF and 74% freedom from AF and class I or III antiarrhythmic drugs at a mean follow-up of 262 days. There were no repeat ablation procedures required.

Spontaneous conversion during lesion creation provides evidence that the lesion pattern has successfully disrupted existing macroreentrant circuits. It has been reported that conversion to SR during endocardial ablation procedures is an important marker for the success of the procedure [Oral 2004; Haissaguerre 2005; Jais 2006]. Intraoperative monitoring of heart rhythm during beating-heart epicardial ablation procedures allows the surgeon to observe conversion to SR. In this study, patients who spontaneously converted during lesion creation had a higher rate of freedom from AF without antiarrhythmic drugs compared to patients who did not convert, (83% vs 54%, $P < .05$). Similar to the finding of Kosakai et al, this study also confirmed that atrial dimension is an important to successful outcomes [Kosakai 2000]. Patients with an atrial dimension of <6.5 cm who received complete Ex-Maze patterns also had better midterm freedom from AF and restoration of SR than did older patients with large atria or incomplete lesion patterns (97% vs 71%, $P < .01$; and 90% vs 65%, $P = .03$, respectively). Patients with smaller atria who experienced either converion to SR or had confirmation of electrical isolation of the pulmonary veins at 15 mA at the time of surgery had a higher rate of SR. These relationships are important considerations in considering the best therapeutic approach to the AF patient, particularly for those patients with nonfocal, complex wavelet conduction patterns. To obtain conversion to SR, the physician must diligently work to obtain full-thickness lesions and ensure that the lesion pattern is complete and free of gaps of viable myocardium and that lesions intersect and connect both atria. Pulmonary vein isolation provides an additional metric of lesion completeness if exit block is verified at amplitudes of 15 mA. This assurance of exit block translated to more freedom from AF with and without antiarrhythmic drugs vs not testing for exit block (97% vs 72%, $P = .013$; and 86% vs 56%, $P = .019$, respectively).

CONCLUSIONS

Cox and others have established that a comprehensive ablation pattern that addresses both the left and the right atria provides a significant increase in long-term freedom from AF, especially for those patients with nonfocal, wavelet AF. Recent advances in techniques and technologies permit the creation of a Cox-Maze–like lesion pattern on the beating heart without the complexity of a cut-and-sew procedure. Observation of spontaneous conversion and confirmation of pulmonary vein exit block are important metrics that, when present, suggest a successful procedure and improved long-term outcomes. Further evaluation of the Ex-Maze lesion pattern and metrics of success during conventional cardiac surgery and translation of the lesion pattern into a minimally invasive, laparoscopic procedure are ongoing.

DISCLOSURES

Dr. Kiser is a stockholder in nContact Surgical, Inc. Drs. Kiser and Wimmer-Greinecker have consulted for nContact Surgical, Inc. The other authors report no conflicts of interest.

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