

## The Completely Endoscopic Treatment of Atrial Fibrillation: Report on the First 14 Patients with Early Results

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### ABSTRACT

We report the early results of a new completely endoscopic technique for the treatment of atrial fibrillation (AF).

**Methods:** Fourteen patients underwent surgery solely for the treatment of AF. The thoracoscopic technique delivered microwave energy to the epicardial surface of the beating heart. Access was obtained through 3 right-sided and 3 left-sided thoracic ports. The AFx/Guidant Flex-10 catheter was employed to produce a box lesion around the pulmonary veins along with additional right- and left-sided lesions. The left atrial appendage was amputated.

**Results:** Ten patients had paroxysmal fibrillation, 1 had persistent fibrillation, and 3 were in permanent AF. Mean age of the group was 60 years, and their mean duration of AF was 74 months. Half had undergone unsuccessful attempts at chemical and/or electrical cardioversion. There were no deaths. Two patients required conversion to open procedure to control bleeding from the left atrial appendage. Average procedure time was 221 minutes, with the last 2 procedures taking less than 2 hours. Median length of hospital stay was 6 days, with 7 patients staying less than 3 days. Seventy-one percent of patients were in sinus rhythm at discharge, 100% at 6 months follow-up, and 67% at 12 months.

**Conclusion:** Totally endoscopic microwave ablation of atrial fibrillation appears to be safe and truly minimally invasive. It is associated with a short length of stay, short procedure time, and acceptable rhythm results. This procedure has the potential to greatly expand the indications for surgery in patients suffering from AF and deserves longer-term investigation.

### INTRODUCTION

Atrial fibrillation (AF) is the most common cardiac arrhythmia and the most difficult to treat. Overall success at maintaining sinus rhythm with nonsurgical therapies varies but is usually no greater than 60%, with multiple failures due to drug intolerance [Roy 2000, Singh 2000, AFFIRM 2002]. Surgical treatment of AF has been more successful. Cure

rates with the traditional cut-and-sew Cox-Maze III procedure have ranged from 80% to 97% in published trials [Arcidi 2000, Kosakai 2000, McCarthy 2000, Schaff 2000]. Unfortunately, this operation requires a sternotomy, cardiopulmonary bypass, and cardiac arrest, and so its complexity and morbidity have prevented widespread application. Attempts to develop a more widely applied surgical treatment for AF have concentrated on using alternative energy sources and less invasive approaches without cardiopulmonary bypass [Autschbach 2000, Sie 2001, Mazzitelli 2002, Shake 2002, Damiano 2003]. We report our early results on a series of patients who were treated with a totally thoracoscopic technique [Saltman 2003] to deliver epicardial microwave ablation for the treatment of AF. Our operation is simple, safe, and quick and is performed without cardiopulmonary bypass or sternotomy. It also appears to be quite effective during early follow-up.

### METHODS

Fourteen patients underwent surgery solely for the treatment of AF. All patients underwent treatment with a completely thoracoscopic approach using the Flex 10 microwave antenna (Guidant, Santa Clara, CA, USA) as previously described [Saltman 2003]. Briefly, the patient was positioned supine under general anesthesia with arms abducted 90 degrees. A transesophageal echocardiogram was performed to measure left atrial size and to confirm the absence of thrombus in the left atrial appendage. After deflation of the right lung, 3 ports were created in the right pleural space: 5 mm at the third intercostal space, midaxillary line; 5 mm at the fourth or fifth intercostal space, midaxillary line; and 10 mm at the fifth intercostal space, anterior axillary line. For the last 10 patients, CO<sub>2</sub> insufflation at 10 cm H<sub>2</sub>O pressure was used to quicken the appearance of the pneumothorax.

The pericardial sac was opened longitudinally from the superior vena cava (SVC) to the inferior vena cava (IVC), approximately 2 cm anterior to the phrenic nerve. Blunt dissection was performed underneath the SVC and IVC to establish access to the transverse and oblique sinuses, respectively. Two 14-French red rubber catheters were then guided through the sinuses with the aid of stylets (Figure 1). The red rubber catheters were exited through the inferior right chest port and the right lung was reinflated.

The left lung was then deflated and the same ports established as on the right side. The pericardium overlying the left atrial appendage was opened sharply, revealing the 2 red rubber catheters. They were retrieved and delivered outside the

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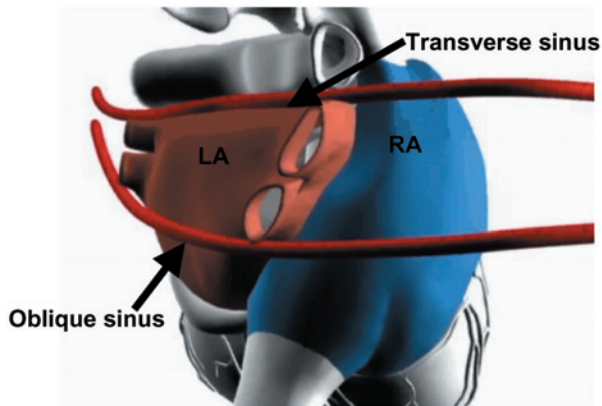


Figure 1. Artist's rendition of the posterior aspect of the heart. The right atrium (RA) and the left atrium (LA) are indicated. The red rubber guide catheters are positioned in the transverse and oblique sinuses as shown, coursing posterior to the superior and inferior vena cavae, respectively.

chest through the inferiormost port. The catheters were sutured together tip to tip, placed back in the chest, and drawn around the pulmonary veins with gentle traction from the right side. Once position was confirmed posterior to the left atrial appendage, the tip of the Flex 10 probe was sutured to the end of the transverse sinus catheter and the entire assembly guided around the pulmonary veins with gentle traction on the inferior catheter (Figure 2). Position was confirmed again by reinflating the left lung, collapsing the right lung, and observing from the right side.

Ablation around the pulmonary veins was then performed at 90 seconds per lesion and 65 watts per application. Most patients required 8 to 10 lesions to complete the encirclement. An additional lesion was then placed to connect the pulmonary vein box lesion to the left atrial appendage. For permanent and persistent fibrillation patients, additional right-sided lesions were also performed laterally from the SVC to the IVC along the sulcus terminalis, onward toward the coronary sinus over the IVC, and finally to the tip of the right atrial appendage.

When all the ablations were completed, the Flex 10 was withdrawn, the right lung reinflated, and the left lung collapsed. A 45-mm endoscopic stapler (Endo-GIA; Ethicon, New Brunswick, NJ, USA) was introduced into the inferiormost left port and the LA appendage removed with a single application of the stapler.

A single 28-French chest tube was placed in each pleural space through the inferiormost ports. The patient was then awakened, extubated, and transferred to the intensive care unit for recovery. The tubes were removed either that evening or on the first postoperative day. Discharge took place when patients were in either sinus rhythm or rate-controlled AF.

Patients were maintained on amiodarone or their preoperative antiarrhythmic, as well as oral anticoagulation for 3 months. Electrocardiographic follow-up was undertaken at 1, 3, 6, 9, and 12 months. Antiarrhythmic and anticoagulant

drugs were discontinued after sinus rhythm was documented on 2 consecutive visits at least 3 months apart.

## RESULTS

Patient demographics are summarized in Table 1. Mean patient age was  $60 \pm 4$  years (range, 39-82 years). Ten patients were paroxysmal fibrillators, 1 was a persistent fibrillator, and 3 had permanent AF. Average duration of AF preoperatively was  $74 \pm 17$  months (range, 24-240 months). The average left atrial diameter was  $4.9 \pm 0.4$  cm (range, 2.7-10.0 cm). Half the patients had undergone unsuccessful attempts at cardioversion with drugs and/or countershock. Antiarrhythmics used include amiodarone, sotalol, procainamide, and dofetilide.

Overall results are summarized in Table 2. There were no deaths. Two patients (3 and 6) required conversion to open procedure to control bleeding from the left atrial appendage (LAA). Five patients did not have the LAA excised, owing to technical difficulties with either the stapler or the positioning of the appendage. Average procedure time was 221 minutes, with the last 3 procedures being completed in less than 2 hours. Median length of stay was 6 days, with 9 patients (64%) experiencing perioperative AF. In general discharge was not delayed in an attempt to reestablish sinus rhythm; 4 patients were discharged in rate-controlled AF, adequately anticoagulated.

As for complications, patient 6 suffered pneumonia and was discharged home in sinus rhythm on the 17th postoperative day. Patient 12 experienced a pulmonary embolism and was sent home in sinus rhythm on the 14th postoperative day. Patient 2 underwent successful percutaneous ablation for typical right atrial flutter 3 months after surgery, patient 1 received a permanent pacemaker for sick sinus syndrome approximately 9 months postoperatively, and patient 6 underwent successful percutaneous ablation for an atypical left atrial flutter 6 months after surgery.

The success at maintaining either a paced or sinus rhythm is shown in Figure 3. Average follow-up at this point is 6 months (range, 1-12 months). Eighty-six percent of patients left the operating room in a sinus or paced rhythm.

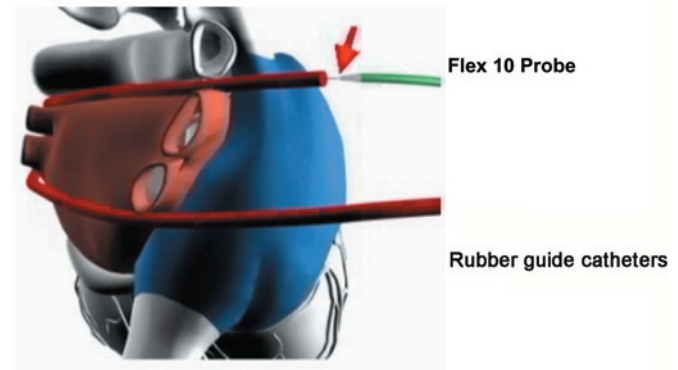


Figure 2. The 2 guide catheters have been connected and drawn around the pulmonary veins. The AFx/Guidant Flex 10 microwave ablation catheter is attached to the superior catheter and drawn around the veins by traction.

Table 1: Demographics of Patient Population\*

Patient No.	Sex	Age, y	AF Duration, mo	AF Type	LA Diameter, cm	Previous Cardioversion	Ejection Fraction, %	Preoperative AADs
1	Female	72	24	Paroxysmal	4.5	False	50	True
2	Male	72	120	Paroxysmal	4.8	False	60	True
3	Male	70	120	Paroxysmal	4.4	False	60	True
4	Female	66	96	Paroxysmal	4.1	False	65	False
5	Female	56	48	Persistent	4.4	False	10	True
6	Male	54	120	Permanent	4.8	False	25	False
7	Female	61	48	Paroxysmal	4.4	False	60	False
8	Male	74	240	Permanent	5.7	False	65	False
9	Male	39	36	Paroxysmal	4.5	False	65	True
10	Female	44	24	Paroxysmal	3.5	False	65	True
11	Male	42	36	Paroxysmal	4.5	True	65	True
12	Male	82	120	Paroxysmal	10	True	65	False
13	Male	65	108	Permanent	6.2	False	41	False
14	Male	41	24	Paroxysmal	2.7	True	40	False

\*AF indicates atrial fibrillation; LA, left atrium; AADs, antiarrhythmic drugs.

At the time of discharge, 71% were out of AF; at 1 month the success rate was 69%, at 3 months it was 73%, at 6 months 100%, at 9 months 100%, and at 12 months 67% (Figure 3).

## DISCUSSION

In this report we describe the first series of patients to have undergone a completely thoracoscopic approach to surgical treatment for AF. This report is not meant to address long-term efficacy but rather to provide confirmation of feasibility and safety. We have demonstrated that this new procedure is safe and reproducible and may be effective in the short term. To prove efficacy we will clearly need more rigorous and longer-term follow-up in a larger number of patients. We are quite optimistic based on the results presented here, as well as the results of others performing similar lesion sets via open approaches [Gillinov 2002, Damiano 2003]. Furthermore and most importantly, the minimally invasive nature of our technique may allow application of surgical ablation to a wider patient population than previously thought to be candidates for ablation.

### Procedural Details

Our lesion sets were somewhat limited by our minimally invasive approach. Although we could isolate the pulmonary veins as a "box," similar to the classic Cox-Maze III operation, the area behind the posterior mitral valve annulus would also have been difficult and likely unsafe to ablate thoracoscopically, especially from the epicardial aspect. Studies are currently underway in our laboratory to quantify the impact of lesion choice on the ultimate efficacy of the procedure at curing AF and to determine whether certain lesions such as those behind the mitral valve can safely be performed from the epicardium with microwave energy.

Our lesions were not assessed for transmural or conduction block. In lieu of in vivo confirmation of transmural, we relied on dosimetry—delivering microwave energy for a spe-

cific duration (90 seconds) and at a specific power (65 watts), which has been shown to produce conduction block in the laboratory [Watanabe 1999, Thomas 1999, Williams 2002]. The lack of methods for in vivo confirmation is a problem that currently plagues all unipolar ablation technologies and is a topic of intense investigation and development.

We chose to amputate the atrial appendage in all patients to eliminate a likely source of thrombus for patients who failed to achieve sinus rhythm. Intraoperative TEE was used initially to exclude preexisting thrombus in the appendage, and later to confirm complete removal. We were successful in 64% of cases and declined to attempt removal in the remainder. In the 2 patients who required open conversion to control bleeding, which occurred as a retraction injury in one and as a torque injury in the other. These cases point out the

Table 2. Intraoperative and Early Postoperative Results\*

Patient No.	LAA Excision	Postoperative AF	Postoperative Cardioversion	Postoperative LOS, d
1	False	True	False	2
2	True	True	True	7
3	True	True	False	17
4	True	False	False	8
5	True	True	False	6
6	False	False	False	7
7	False	True	False	8
8	True	True	False	2
9	False	False	False	2
10	False	True	False	3
11	True	False	False	2
12	True	True	True	14
13	True	True	True	3
14	True	False	False	1

\*LAA indicates left atrial appendage; AF, atrial fibrillation; LOS, length of hospital stay.

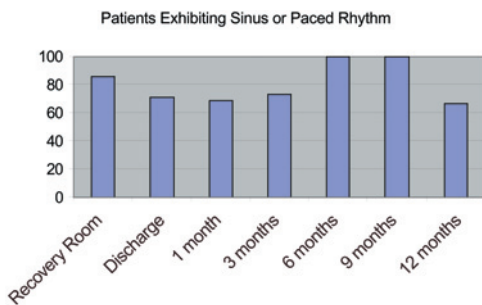


Figure 3. Percentage of patients exhibiting either sinus or paced rhythm at follow-up.

limitations of current stapling technologies: the location of the lowest left-sided 10-mm port is critical. We found that placing the port more posteriorly allowed the stapler to approach the appendage parallel rather than perpendicular to its origin. With increasing experience, modified port placement, and less traumatic staplers, we expect safe amputation of the left atrial appendage to become more routine.

#### Future Directions

At this point, further technical innovation of our thoracoscopic maze procedure focuses on 2 areas. The first is the development of a simpler steering and rotating system to place the microwave probe around the pulmonary veins and orient it correctly. Currently red rubber catheters are used to guide the Flex 10 through the transverse and oblique sinuses as the probe alone is too flexible and not steerable. Although this procedure has proved reliable, it requires time to retrieve the catheters from the left side, tie them together, and replace them appropriately. In addition, sometimes the Flex 10 is placed in the wrong orientation. Rotation to the correct orientation can be quite time-consuming. A steerable and rotatable probe that could surround the veins at once would obviate these extra steps. Although fluoroscopic imaging has been suggested to us, we have been reluctant to introduce this technique as it would increase the complexity of the procedure and the clutter in an already crowded operating room.

The second area for innovation is in our ability to safely and reproducibly obliterate the left atrial appendage. We would envision a more flexible or even a remotely controlled stapler that would allow the surgeon to approach the appendage from almost any port location and accommodate almost any physiognomy. We are currently evaluating a new stapling technology that appears to offer exactly this type of control and flexibility, and early results are encouraging.

#### Study Limitations

Because our first procedure was performed in late 2002, the longest follow-up is only 12 months, making it difficult to determine long-term efficacy. In addition, because we assess rhythm only with outpatient “spot” electrocardiograms, we may be contaminating our data with observation bias and missing clinically silent episodes of AF, particularly for patients with paroxysmal fibrillation. To address these issues for a future report, we are currently undertaking a longer follow-up study

that incorporates Holter monitoring of all patients who have undergone microwave ablation at least 6 months in the past.

In summary, we present for the first time a new completely thoracoscopic minimally invasive method for treating patients with AF. This procedure is safe and appears to be effective in short-term follow-up. Although our thoracoscopic approach will undergo further refinement and follow-up to prove efficacy over the longer term, we believe that this procedure represents a true breakthrough in the treatment of AF. Further innovation will allow us to treat a broader scope of patients and may even lead to the possibility of surgery as primary treatment for atrial fibrillation.

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