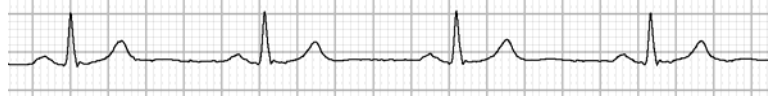


Advanced Therapy for Cure of Atrial Fibrillation

Surgical Maze, Catheter Ablation and Minimally Invasive Surgery for AF

Most patients with atrial fibrillation (AF) are best treated by antiarrhythmic medications, or with a “heart rate control plus blood thinners” approach, as maintaining normal heart rates (most often by medications such as beta blockers) usually takes care of symptoms, and

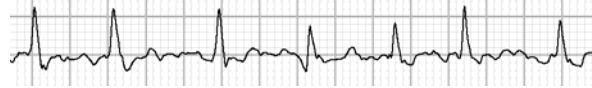


Normal Rhythm

the blood thinners (warfarin, Coumadin) minimize the risk of stroke. Together, these treatments address the main problems of AF, which are:

- Stroke Risk: Up to several percent per year in some patients
- Symptoms: Palpitations, fatigue, shortness of breath and others
- Cardiomyopathy: Weakening of the heart muscle

Some people, however, may do best with advanced therapy, directed at permanently maintaining normal heart rate and rhythm by curing the AF itself. The best candidates for this are those with intermittent (“paroxysmal”) AF, moderate or severe symptoms from the AF, poor response to medicines, and little or no other heart disease such as leaky valves, enlarged heart, or previous heart attack.



Atrial Fibrillation

Patients who get AF mostly at night, or after gulping down a cold drink, or while recovering from hard exercise may have a type of AF due to excessive nerve stimulation of the upper chambers (“vagally-mediated AF”) and may also respond to advanced therapy. Benefits of successful elimination of AF could include reduction or elimination of symptoms such as palpitations or fatigue, reduction or elimination of some of the medications required for AF (although blood thinners are often still required), and improved pumping function of the heart.

A Brief History of Procedures for Cure of Arrhythmias

Surgical Maze: James Cox and colleagues developed an open-heart surgical procedure, called the “Maze” procedure, during the 1970’s and 1980’s, modifying and improving upon it over the years, settling on the “Maze III” procedure in 1992. “Maze” refers to the series of incisions made in the upper chambers of the heart, which are arranged in a “maze-like” pattern. These incisions were intended to stop AF by interrupting by blocking the irregular electrical activity by the scars of the incisions. It has long been considered the “gold standard” for effective surgical cure of AF.

Dr. Cox was able to show that the procedure was successful for eliminating AF. He showed that in patients who had the Maze III procedure with other heart

surgery at the same time, 84% were free from AF, with no medications for AF, even five years later; this is quite good. However, complications were frequent. 2% of their patients died during surgery or shortly thereafter, and 19% required pacemakers.

More recently, Dr. Cox and associates published long-term results in 112 patients receiving the Maze III procedure without other heart surgery at the same time, and 86 who were getting other surgery. Nearly 80% of the patients who received the Maze III procedure alone were free of AF

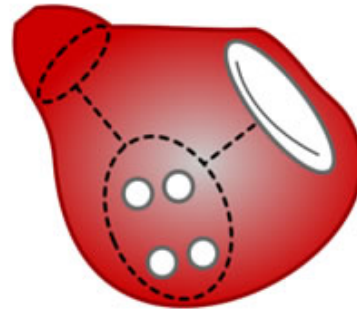
without antiarrhythmic medicines about 5 years later, but 3.6% of the patients died or had a stroke during surgery, and 8% required pacemakers. They stayed in the hospital about 10 days, and nearly 19% had a major complication of some sort. This was better than previous results, but still too much for most doctors and their patients to accept. In addition, the surgery was long, complex, and difficult, and was never widely adopted by heart surgeons. However, it is still sometimes performed, and both success and complications are thought to be better than in years past.

Perhaps the most important aspect of the Maze III procedure is that it has become the benchmark for success to which all other procedures for eliminating AF have been compared. A great deal of effort has been made to equal the success of the Maze III, while reducing the complexity and likelihood of complications. These efforts led to the development of the Mini-Maze procedures.

The Mini-Maze procedures

A series of procedures have been developed based on the Maze procedure, which were intended to be less invasive or complex. Unfortunately, nearly all of the originators of these techniques used the term “mini-Maze”, “mini-maze”, or “minimaze” to denote their procedure. There are now at least four procedures in use, all of which have been called “mini-maze” or similar. Detailed descriptions are beyond the scope of this document; brief descriptions follow:

Concomitant mini-Maze: For many years, this was the only kind of minimaze, and it's still by far the most commonly performed of the minimaze procedures. It is done at the time of other heart surgery, such as during a heart valve replacement. This is quite common, most adding only a few minutes to the surgery, and has been routinely done at most institutions for several years now. It generally requires both a median sternotomy (incision through the breastbone) and cardiopulmonary bypass (heart-lung machine).



Some of the incisions required in the Left Atrium for the Cox-Maze III surgery

Microwave minimaze: In 2003, Saltman and others published their experience with “a completely endoscopic approach to microwave ablation for atrial fibrillation”, sometimes referred to as the “microwave minimaze”. This was the first publication of the surgical procedures to eliminate AF without requiring a median sternotomy or cardiopulmonary bypass. It continues to be performed today, and has the benefit of small incisions and relatively quick recovery.



Clamp used for Minimally Invasive Surgery of AF
(Wolf mini-Maze)

HIFU mini-Maze: This procedure using High Intensity Focused Ultrasound to destroy parts of the atrium responsible for AF.

Wolf mini-Maze: In 2005, Wolf and others published this technique. The surgeon places clamp-like tool on the left atrium near the pulmonary veins, and ablation is performed by heating the atrial tissue between the jaws of the clamp, cauterizing the area, much like a catheter ablation. In some institutions, the surgeon and the electrophysiologist work closely together to ensure that the ablation is complete. In addition, the part of the Left Atrium (the “appendage”) in which most clots form is removed, which may reduce the long-term likelihood of stroke even if AF were to return.

In some institutions, such as Sacred Heart Medical Center, this procedure has been modified to also eliminate some of the nerves to the heart that are thought to be important in AF; some have called this the “*Oklahoma Wolf Procedure*” in order to give credit to those at the University of Oklahoma who have been instrumental in adding this to the procedure. A video of this procedure is available online at www.minimaze.org.

We believe that this procedure is a reasonable one, as it addresses the causes of the AF itself as currently understood: abnormalities near the pulmonary veins, and excessive activity or the autonomic nerves on the heart. It also may address the main consequence of AF (stroke) by removing the Left Atrial Appendage. Unlike some other mini-Maze procedures, this particular type of mini-Maze may require certain things that some other types of mini-Maze do not, such as longer incisions and the presence of an electrophysiologist during surgery, but we believe that this trade-off is a good one. This is because the long-term success of the surgery is thought to depend on certain things that can generally be done using this approach:

- Electrically isolating the pulmonary veins, *proving it* by electric stimulation
- Reduction or elimination of nerve input to the heart, *proving it* by stimulation
- Removal of the Ligament of Marshall, which is known to be a problem in AF
- Removal of the Left Atrial Appendage, from which most strokes originate

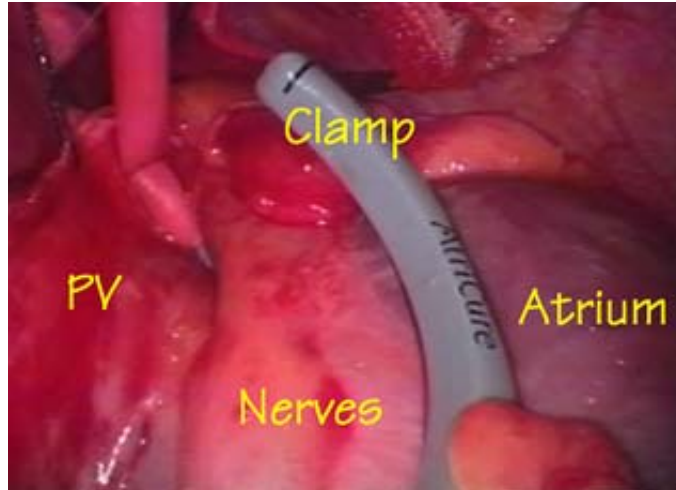
Recent Advancements in Understanding and Treatment of AF:

Great strides have recently been made in our understanding of AF. Among the things we've learned are that most AF comes from the left upper chamber of the heart (Left Atrium). It usually originates from within or near the areas where the veins bringing oxygenated blood back from the lungs to the heart ("pulmonary veins") meet the Left Atrium. Nerve fibers connect to the heart in this area as well.

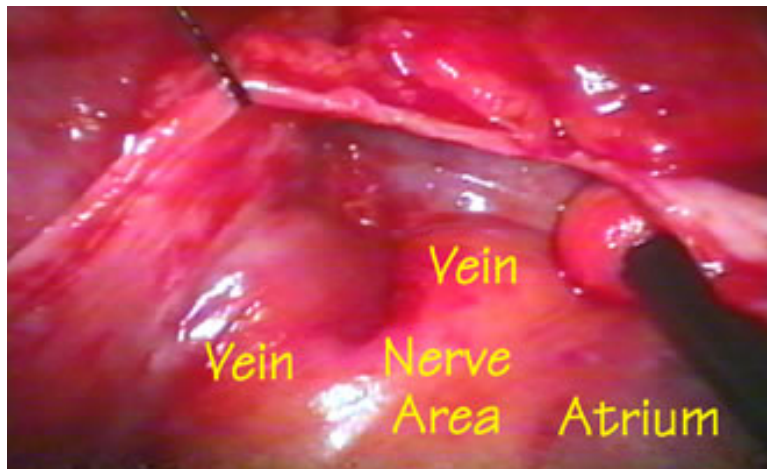
Nerves and the Heart: Most people with AF have it because of some other problem, such as longstanding high blood pressure, or a leaky heart valve. But some people have no apparent reason for AF – so why would they have an arrhythmia?

Experiments have shown that excessive vagus nerve activity (the nerves to the heart that the body uses to slow the heart down) can make AF much more likely to occur, and that eliminating these nerves makes AF less likely to occur. Interestingly, many of these nerves are right at the spots that the surgeons cut during the Maze procedure, and where electrophysiologists cauterize during catheter ablation of AF.

Procedures for Elimination of Atrial Fibrillation: Abnormal electrical impulses from these *pulmonary veins*, or from the *nerves* to the heart, cause AF in some patients. Better understanding of the pulmonary veins, the nerves to the heart, surgery such as the Maze procedure, and catheter ablation have recently converged to bring us advanced procedures for elimination of AF. Now, advanced therapy for AF involves a multidisciplinary approach, involving both the electrophysiologist and the surgeon. The goal is to eliminate AF with the very high success rate of the surgical Maze III procedure and the very low complication rate of the catheter ablation procedure. Two separate procedures have been



Positioning of clamp to electrically isolate the pulmonary veins from the atrium, reducing the action of nerves on the heart at the same time.



Left Atrium, Pulmonary Veins, Nerves to Heart

developed and may approach that goal; they are *Catheter Ablation of AF* and the *Minimally Invasive Surgical Procedure for AF*.

Catheter Ablation of Arrhythmias (other than AF): *Catheter ablation* eliminates arrhythmias by advancing catheters (Teflon-coated wires) to the heart, putting the catheter tip on the spot causing the arrhythmia, and cauterizing and eliminating it by heating the tip of the catheter. This procedure was developed during the 1980's, and has been standard therapy for many arrhythmias since 1990. It is performed by cardiologists who specialize in management of heart rhythm disturbances (electrophysiologists). Even the earliest reports showed this procedure to be extremely successful (almost 100%), with few complications (less than 1%); it revolutionized the management of many common arrhythmias.

Catheter Ablation of AF: AF is more complex than those arrhythmias, however, and catheter ablation of AF was not attempted until nearly 10 years later, when our understanding of AF improved and advanced therapy such as catheter ablation became practical. This procedure now goes by several names, including the Pulmonary Vein Isolation Procedure, Catheter Maze, Pappone Technique, Wide Area Circumferential Ablation, and Catheter Ablation of AF. Catheters are maneuvered from the leg into the left atrium, and ablation of the connections between the Left Atrium and the Pulmonary Veins is performed. Because the connections are quite extensive, AF ablation is much more complex than a standard ablation procedure, and the procedure can be long. Success rate is lower and the potential for complications higher than standard ablations, due to the large amount of ablation that is required, and the proximity of the pulmonary veins, the esophagus, and other structures. Nevertheless, catheter ablation for AF is successful in many cases, and has been an important part of the management of AF at Sacred Heart Medical Center since 1998.

How do the Catheter and Surgical approaches compare?

Comparing catheter ablation to surgery is difficult. Both procedures continue to evolve and improve, so direct comparisons can never accurately reflect current methods. Widely varying ways of reporting success and complication rates from various institutions have made interpretation of these claims very difficult. Some institutions claim even higher success rates than the full Maze procedure (83% complete success even after ten years), but we know that procedures such as catheter ablation, which are less thorough than the surgical Maze, are unlikely to improve on the success of the full Maze III. The best we can probably hope for is to equal that success rate, with a reduction in risk.

Worldwide results of catheter ablation of AF in more than 8000 patients from 1995 to 2002 are available. 52% of patients had a complete success (no AF; no medications), and 76% were successful if those who still required medications to maintain normal rhythm were included. About 25% of patients had required a second procedure, and there were complications in 6% of patients. These results probably underestimate success of catheter ablation using current techniques, which have improved since 2002, when that study ended.

Success rates of the catheter ablation and minimally invasive surgery are likely similar, perhaps in the 75% range for certain carefully selected patients. Types of

complications differ between the two procedures. Rare but potentially serious complications of catheter ablation, including death due to perforation of the esophagus, about 1.5% incidence of stroke, and pulmonary vein stenosis (scarring and closure of the vein, which can cause shortness of breath) have been reported with the catheter ablation approach. Complications have been very infrequent with the surgical approach, but because only several hundred of these procedures have been performed to date, this must be interpreted cautiously.

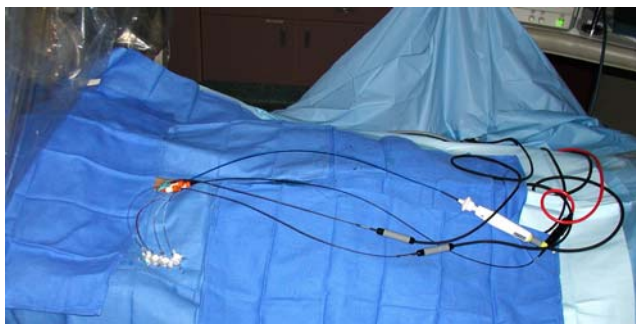
	Catheter Ablation	Minimally Invasive Surgery
Success	70%?	Same or higher?
Days in the hospital	2	4
Pain/discomfort	Minimal	Moderate
Mortality	Very rare	Very rare
Pulmonary Vein Stenosis	Several percent	Very rare
Stroke during procedure	1 – 1.5%	Very rare
X-ray exposure	Moderate	none

Each approach appears to have a role. As of the time of publication of this guide, the surgical procedure seems to be associated with more discomfort (incisional pain for several days, and complete recovery may take two to three weeks) and a longer hospital stay, but may also be associated with higher likelihood of success and a lower likelihood of serious complications. You will need to discuss with your physician which approach, if any, seems appropriate for you.

What is it like to have a catheter ablation of Atrial Fibrillation?

You would come to the hospital on the morning of your procedure, to be admitted to the Cardiac floor. From there, you would be taken to the Electrophysiology Laboratory, where these procedures are performed. They can be long, taking at least 3 hours, but sometimes quite a bit longer than that.

You would be asleep at the time; most patients don't feel or remember much. Your right and left groin areas would be cleaned, sterile drapes would be put over you, and the doctor and his staff would insert sheaths (tubes) into the vein in the groin so that catheters (thin, flexible Teflon-coated wires) could be maneuvered into the heart. To get to the area causing the AF, a needle must be used to advance them from the right upper chamber to the left upper chamber (transseptal procedure). You will be given blood thinners by vein to reduce the risk of stroke during the procedure. The main part of the procedure involves your doctor finding and cauterizing the spots causing the AF.



Catheters positioned in the right groin for ablation

Afterward, you will return to your



*Incisions 3 months after
minimally invasive surgery*

room. The sheaths are usually still in place; they are removed when the blood thinners wear off several hours later. You will stay overnight, and go home the next day.

Some AF may persist for the next 4 to 6 weeks or so, while the healing process completes. You will be followed in clinic by the electrophysiologist and their staff following the procedure.

What is it like to have minimally invasive surgery for AF?

You would come to the hospital on the morning of your procedure, and be admitted to the Short Stay unit or the Cardiac Surgical floor. From there you would go to the operating room, where the anesthesiologist would put you asleep, and place you on a ventilator. Sometimes epidural anesthesia is also used. The cardiac surgeon performs the operation. It involves a three inch

incision between the ribs, with two smaller ones less than an inch long, on each side of your chest. The operation takes about 4 hours. When it is done, you would go to the Cardiac Surgical Floor, and likely stay in the hospital about four days. You would have tubes in the incisions in the chest to take care of any drainage for another day or so. There is some discomfort with the incisions.

Some AF may persist for the next 4 to 6 weeks or so, while the healing process completes. The recovery period varies, but most people would not resume work for at least two weeks. You will be followed in clinic by both surgical and electrophysiologic members of the team. A schedule of your visits is included at the end of this document.

What to expect from here:

If your physician believes you might benefit from advanced therapy of AF, you will be scheduled to see one of the electrophysiologists. Your records will be reviewed, and tests such as EKGs, Holter monitors, or an echocardiogram may be ordered. You will be seen in the office, and a medical history and physical examination will be performed. Therapeutic options and the pros and cons of each that are appropriate for you will be discussed. These may include:

- No change in your current management
- “Rate control plus blood thinner” strategy
- Cardioversion
- Antiarrhythmia medicines
- Pacemaker implantation with or without AV node ablation
- Catheter ablation of atrial flutter (a related rhythm disturbance that may accompany AF)
- Catheter ablation of AF
- Referral to a cardiac surgeon for minimally invasive surgery for AF

If your physician determines that you may be a good candidate for surgery for your AF, and you are a patient of Oregon Cardiology, please go to the website at www.minimaze.org and download and read and complete the following:

- Basic information about AF handout
- Advanced therapy for AF handout
- General new patient intake information form
- Atrial fibrillation new patient intake information form
- Review the minimaze website
- View the minimaze video
- Note that most patients at SHMC who undergo this procedure will be asked to enter the current research trial

Thank you.

We hope that this guide has been helpful.

Timeline for patients undergoing Minimally Invasive Surgery for AF

Time	Electrophysiology Office	Surgeon's Office	Hospital
10 weeks pre-op	Visit with Nurse Practitioner. Begin warfarin. Review handouts, video, research protocols, and www.minimize.org website		
6 weeks pre-op	Visit electrophysiologist; referred to the surgeon if appropriate.		
		Visit surgeon, schedule surgery and pre-op studies 1. Nuclear treadmill 2. Transesophageal echo 3. Studies for research	
1 week pre-op	Visit with EP Nurse Practitioner	Visit with surgical nurse	TEE Anesthesia consult Stop warfarin, begin LMWH
Day of Surgery			
Day 1 post-op			Remove chest tubes, restart anticoagulation
Day 3 post-op			Discharge to home
72 hours post discharge		Telephone check-up	Check INR; resume routine anticoagulation management
1 week post	Visit with EP nurse practitioner		
3 weeks post		Visit with surgical nurse	
6 weeks post		Visit with surgeon	
10 - 12 weeks post	Visit electrophysiologist; stop antiarrhythmics		
6 months post	Visit with electrophysiologist		
1 year post	Visit with electrophysiologist; one month of EKG monitoring		