

ROSS PROCEDURE FACTS FOR AORTIC VALVE PATIENTS



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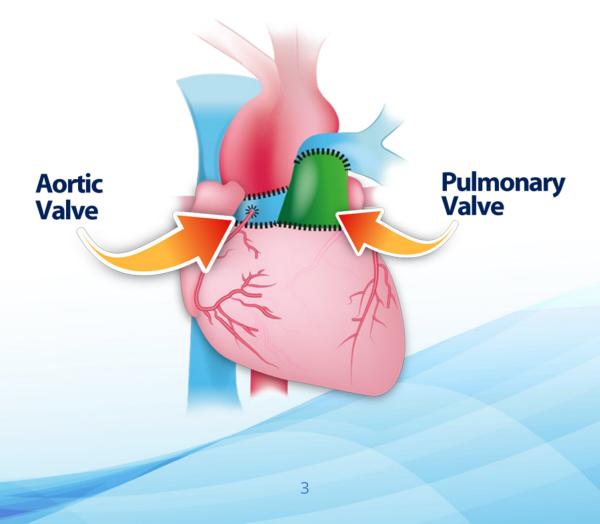


Introduction:

The Ross Procedure: A Transformative Therapy for Aortic Valve Disease

Cardiac surgery continues to evolve as new techniques, devices and research enhance patient outcomes and patient experiences. In particular, the Ross Procedure stands out as a transformative approach for aortic valve reconstruction.

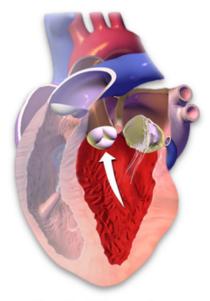
This innovative operation, which was developed by Dr. Donald Ross in 1967, has experienced a "renaissance" in recent years as new research demonstrates that the Ross Procedure provides patients a durable and effective alternative to traditional aortic valve replacement treatment options.



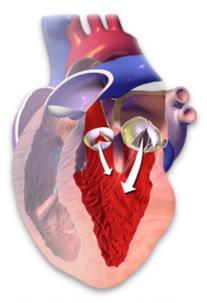


Aortic valve disease is a common cardiac condition that impacts millions of people around the world. Aortic stenosis (a narrow valve) and aortic regurgitation (a leaky valve) are debilitating and deadly diseases. In fact, 50% of patients with severe aortic stenosis die just 24 months after the onset of symptoms if left untreated. ¹





Aortic Stenosis (A narrow valve)



Aortic Regurgitation (A leaky valve)

Traditional surgical methods typically involve mechanical or bioprosthetic valve replacement for aortic valve disease. While effective, each of these approaches has limitations such as the need for lifelong blood thinners and/or frequent reoperations.

The Ross Procedure offers several benefits compared to traditional aortic valve replacement therapies.



Fact 1: There Are Many Patient Advantages of the Ross Procedure

The Ross Procedure offers several benefits that distinguish it from other aortic valve replacement options. These advantages make it an attractive choice for many patients, including younger individuals, who seek a long-term solution without the drawbacks of traditional mechanical or biological valve replacements.

- Long-Term Durability: The Ross Procedure switches the patient's own pulmonary valve (also known as the autograft) to the aortic valve position. Autografts have been shown to last for decades and are often more durable than biological valve and mechanical valves.
- **Superior Hemodynamics:** The autograft mimics the natural function of the aortic valve resulting in better blood flow and reduced heart strain.
- No Lifelong Anticoagulation: Unlike mechanical valves, the Ross Procedure eliminates the need for lifelong blood thinners thereby reducing bleeding risks.
- Improved Quality of Life: Patients can return to normal activities with fewer restrictions that often create higher energy levels and promote overall health.



• **Growth Potential in Younger Patients:** The autograft may grow with the patient thereby making the Ross Procedure ideal for children and young adults.



"I have performed over 650 Ross Procedures during the past 30 years. For the right patient, the operation provides favorable, long-term outcomes and excellent quality-of-life."

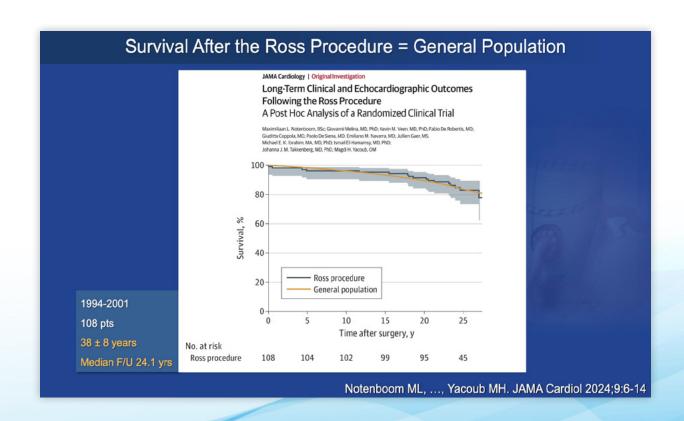
Dr. Vaughn StarnesExecutive Director, USC Cardiac and Vascular Institute (Los Angeles, California)



Fact 2: New Durability Research For The Ross Procedure Is Encouraging

In 2024, new research was published in Journal of the American Medical Association (JAMA) specific to the durability of the Ross Procedure. In this unique study, researchers looked at a group of aortic valve patients who had the Ross Procedure in the 1990s.

There were several highlights from the study which tracked patients that, on average, had the Ross Procedure performed 25 years ago. Most importantly, the study found that the survival of these patients mirrored that of the general population. This means that Ross Procedure patients had the same life expectancy as people who did not have aortic valve disease. ²





The Ross Procedure is providing excellent outcomes for select patients. For example, Adam Pick, the founder of HeartValveSurgery.com and a Ross Procedure patient, has returned to all the activities he enjoyed prior to surgery including SCUBA diving and surfing. Plus, Adam has not had any type of reoperation since his Ross Procedure was performed by Dr. Vaughn Starnes in 2005.



"Over 19 years ago, I had a successful Ross Procedure by Dr. Vaughn Starnes at USC. Since then, I have had no problems with my heart. Plus, I'm SCUBA diving and surfing again."

Adam Pick

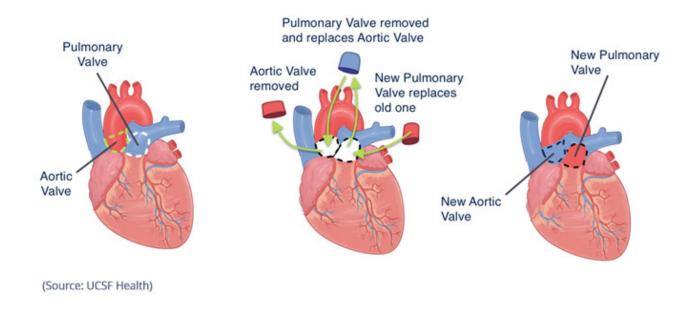
Ross Procedure Patient of Dr. Vaughn Starnes
Patient Advocate & HeartValveSurgery.com Founder



Fact 3: The Ross Procedure Is A Two-Valve Operation

One of the big questions about the Ross Procedure is, "How does it work?".

During the Ross Procedure, also known as the "Switch Procedure", a cardiac surgeon removes the diseased aortic valve of the patient. Then, the surgeon moves the patient's own pulmonary valve into the aortic valve position. Lastly, a donor valve (or bioprosthetic valve) is sutured into the patient's pulmonary position within the heart. For this reason, the Ross Procedure is a two-valve operation.



The Ross Procedure is different from traditional surgical aortic valve replacement procedures because it uses the patient's own valve (the autograft) instead of a manufactured biological or mechanical valve.



After the Ross Procedure, similar to traditional surgical aortic valve replacement operations, patients may stay in the hospital for up to one week which may include one to two days in the intensive care unit (ICU) and three to four days in a recovery room. It can take several weeks to fully recover from cardiac surgery and patients should avoid lifting heavy items during this time.



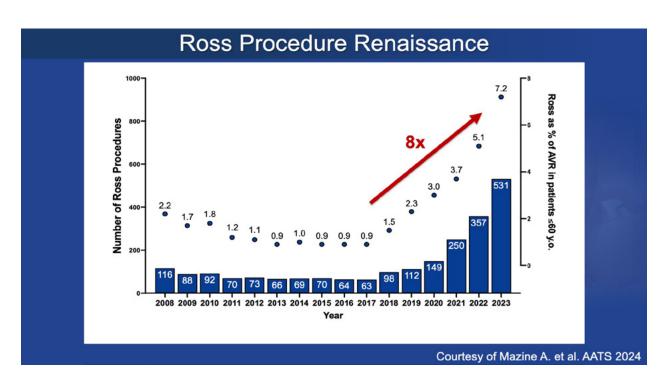
"During the Ross Procedure, we move the pulmonary valve to the aortic position because that provides the best, long-term durability for patients."

Dr. Joanna ChikweChair, Cardiac Surgery, Cedars-Sinai Medical Center (Los Angeles, California)



Fact 4: A Ross Procedure Renaissance Is Happening

Given the long-term durability and lifestyle benefits of the Ross Procedure, patient interest in the Ross Procedure has amplified during the past 10 years. The number of Ross Procedures performed in the United States has increased from 63 in 2017 to 531 in 2023, a 742% increase. ³



In particular, this "Ross Procedure Renaissance" is happening for younger patients. According to the cardiac surgery database managed by The Society of Thoracic Surgeons, approximately 7 percent of patients under the age of 60 are getting a Ross Procedure in the United States. This compares to less than 1 percent of aortic valve patients in that same age range just seven years ago.



Fact 5: The Ross Procedure is Not For Every Patient

It is critical for patients with aortic valve disease to understand that the Ross Procedure is not for every patient. That said, you and your medical team should discuss the opportunities and risks of this procedure given your specific anatomy, your lifestyle, and your health goals.

Select guidelines for patients to qualify for the Ross Procedure include:

- An adult typically 50 years old or less with aortic valve disease that requires surgical replacement
- A patient with no chronic conditions that may affect long-term survival such as chronic renal disease or severe coronary artery disease
- Patients considering getting pregnant in the future
- · Patients who have active lifestyles
- Select pediatric patients

A patient may not be a candidate for the Ross Procedure if they have the following conditions:

- Connective tissue disorders (e.g. Marfan syndrome, Loeys-Dietz syndrome)
- Autoimmune diseases (e.g. rheumatoid arthritis, lupus erythematosus)
- Pulmonary valve disease
- · Multi-vessel coronary artery disease





"I do not typically think about the Ross Procedure for patients unless the patient 50 years of age or younger. Even then, it might not be the right choice."

Dr. Eric RoselliChief of Adult Cardiac Surgery, Cleveland Clinic (Cleveland, Ohio)



Fact 6: Patients Must Find An Experienced Ross Procedure Team

The success of the Ross Procedure heavily depends on the expertise and experience of the surgical team. The Ross Procedure is a very complex procedure that requires a high level of precision and skill which can only be achieved by surgeons who have performed the Ross Procedure many times.

For that reason, the North American Ross Consortium (NARC) and Ross Procedure Reference Centers have been established to provide patients optimal care while sharing best surgical practices for this unique operation. The use of advanced surgical techniques requires training and experience to maximize the benefits of the Ross Procedure.

To determine if a Ross Procedure is the best treatment option for you, a Ross Procedure team may conduct a series of diagnostic tests including angiograms, echocardiograms, computer tomography (CT) scans, and magnetic resonance imaging (MRIs).



"Our team at USC has done over 650 Ross Procedures. It's very important that patients find an experienced Ross Procedure team."

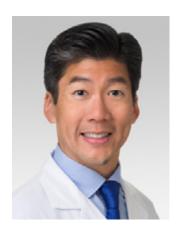
Dr. Craig Baker Chief of Cardiac Surgery, Keck Medicine of USC (Los Angeles, California)



When meeting with your medical team, it's essential to feel empowered and ask questions specific to your condition and your treatment options.

Key questions to ask your doctors about the Ross Procedure include:

- Is the Ross Procedure a good treatment option for my condition? Why or why not?
- For my specific anatomy, how effective is the Ross Procedure compared to other treatment options?
- What are the risks associated with the Ross Procedure? How does your team manage those risks?
- How many Ross Procedures have you and your team performed?
- What are your patient outcomes for the Ross Procedure for patients with my specific aortic valve disease?



"The Ross Procedure is complex. Patients should seek out experienced cardiac centers that specialize in the Ross Procedure."

Dr. Chris Malaisrie Co-Director, Heart Valve Center, Northwestern Medicine (Chicago, Illinois)



Fact 7: The Ross Procedure May Provide Patients A Lifelong Fix

One of the most significant benefits of the Ross Procedure is its potential to provide patients a life-long solution for aortic valve disease thereby eliminating the need for future aortic valve surgeries.

There are several reasons for this:

Durable Solution: When the pulmonary valve (also known as the autograft) is switched into the aortic valve position, it may last for decades thereby reducing the likelihood of additional reoperations compared to mechanical or bioprosthetic valves.

Natural Adaptation: The living tissue within the autograft adapts and functions like a natural aortic valve which provides a lasting and effective solution in which the body recognizes its own tissue - unlike the foreign substances of a mechanical valve (made from pyrolytic carbon) or biological valves (made from pigs or cows).

Reduced Reoperation Rates: Studies show that patients who undergo the Ross Procedure have lower reoperation rates thereby offering patients a potential one-time surgical solution.

Growth Benefits: The autograft's ability to grow with the patient, particularly in younger individuals, ensures that the valve remains functional and effective over a long period unlike a mechanical or biological valve.



"New research shows Ross Procedure durability going out to the third decade. There are no aortic valve treatment options that have demonstrated similar, long-term outcomes."

Dr. Christopher Burke
Director, Thoracic Aorta Program
UW Medicine Heart Institute (Seattle, Washington)

Given the benefits of the Ross Procedure, many patients are evaluating the Ross Procedure as a safe, effective and long-lasting alternative to traditional aortic valve replacement options which may require the lifelong use of blood thinners (e.g. warfarin).



"I did a lot of research on my aortic valve replacement options. The Ross Procedure provided me a normal quality-of-life without blood thinners. Plus, new studies show the Ross Procedure can last a very long time."

Andy Dial, Ross Procedure Patient of Dr. Christopher Burke



Fact 8:

Normal Life Expectancy is Achieved Even After A Ross Procedure Reoperation

A key concern of patients considering the Ross Procedure is, "What if my aortic valve or pulmonary valve replacement fails after a Ross Procedure?".

This is an important question that has been researched. For example, Dr. William Brinkman and a team of medical professionals at Baylor, Scott & White The Heart Hospital - Plano recently published, "Outcomes of Redo Operations After The Ross Procedure."

The conclusions of this research, which followed 225 Ross Procedure patients, were:

- Reintervention after Ross Procedure is not associated with worse survival.
- Even if patients require a reintervention, normal life expectancy is maintained.
- The possibility of reoperation should not be a reason to avoid the Ross Procedure if you are an appropriate candidate.

According to this research, patients that require a Ross Procedure reoperation continue to benefit from normal life expectancy. According to Dr. Brinkman, patients stay on the same survival curve after a Ross Procedure reoperation, which is superior to a bioprosthetic valve and a mechanical valve





"Our research shows that normal life expectancy is achieved from the Ross Procedure even if a reoperation is needed."

Dr. William Brinkman
Director, Aorta Program, Baylor Scott & White The Heart
Hospital - Plano (Plano, Texas)

As for the different types of Ross Proceedure reoperations, those therapies may include a surgical heart valve replacement or a transcatheter heart valve replacement (which does not require an incision to the patient's chest or ribs).



"After 15 years, only about 30% of Ross Procedure patients require a reoperation that may utilize surgical or transcatheter techniques."

Dr. Michael Ibrahim Director, Reconstructive Valve Surgery, Penn Medicine Heart & Vascular Center (Philadelphia, Pennsylvania)



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For more information, please visit:

www.MyRossProcedure.org

To find medical teams that specialize in the Ross Procedure, please <u>click here.</u>

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