The clinical evaluation of the da Vinci Surgical Systems (Models S1200, IS2000, IS3000) supporting its use for mitral valve repair was not performed totally endoscopically. Introduction and manipulation of the endoscopic instruments were controlled by the da Vinci Surgical Systems through port incisions (< 1 cm) while accessory technologies, e.g., atrial retractor and cardioplegia line, etc, were introduced through a mini-thoracotomy. Performance characteristics for conduct of totally endoscopic mitral valve repair using the da Vinci Systems have not been established.


Facing Mitral Valve Surgery?

Learn about minimally invasive da Vinci Surgery

Though it is often called a “robot,” da Vinci cannot act on its own. Surgery is performed entirely by your doctor. Together, da Vinci technology allows your doctor to perform complex procedures through just a few small openings, similar to thoracoscopic surgery. As a result, you may be able to get back to life without the usual recovery following major surgery. The da Vinci System has been used successfully worldwide in approximately 1.5 million various surgical procedures to date.

The Enabling Technology:
da Vinci Surgical System

The da Vinci Surgical System is designed to provide surgeons with enhanced capabilities, including high-definition 3D vision and a magnified view. Your doctor controls the da Vinci System, which translates his or her hand movements into smaller, more precise movements of tiny instruments inside your body.

The Condition:
Mitral Valve Prolapse

Your mitral valve separates the upper and lower chambers of the left side of your heart. Your mitral valve has two flaps that control blood flow. When the valve opens, it allows blood to flow into your heart’s main pumping chamber. When this chamber contracts to push blood out of your heart, your mitral valve closes to stop blood from flowing backwards. If your mitral valve flaps do not work properly, some blood flows backwards. This is called regurgitation or prolapse. It makes the heart work harder and can increase the risk of heart failure.

Mitral valve prolapse is a very common condition and occurs in women more often than men. It can occur over time or your mitral valve can be abnormal at birth. Many people have no symptoms at all and treatment is never needed. If you do have symptoms, they may include rapid heartbeat, chest pain, fatigue, difficulty breathing after activity, or shortness of breath.
The Surgery: Mitral Valve Surgery

Treatment and surgical options for mitral valve prolapse depend on how severe your symptoms are and your overall health. If your symptoms are mild, your doctor may suggest medication or lifestyle changes. If your symptoms become worse, your doctor may recommend mitral valve surgery. The goal of surgery is to allow your valve to open and close properly. There are two common types of mitral valve surgery: valve repair and valve replacement.

With valve replacement, your surgeon cuts out the damaged valve and replaces it with a new, artificial valve made of plastic or metal, or biological (from human or animal tissue). With valve repair, your surgeon rebuilds one or more of the valve flaps/leaflets using your own tissue. Your doctor will fully explain the pros and cons of replacing your valve versus repairing your valve.

During mitral valve surgery, a heart-lung machine is used. This machine temporarily takes over the function of your heart and lungs during surgery. It provides surgeons with a still surface.

Whether repairing or replacing your valve, surgery may be performed using open surgery through a large incision or minimally invasive surgery through a few small incisions.

During open surgery, doctors make a large chest incision and cut through your breastbone (sternum) to reach your heart. The incision must be large enough for your surgeon to fit his or her hands and surgical instruments inside your chest. Open surgery allows your surgeon to see and touch your heart and tissues. During minimally invasive surgery, specifically thoracoscopic surgery, doctors repair or replace your valve through one or more small incisions instead of a large incision. Long, thin surgical instruments and a tiny camera are inserted through the incisions to reach your heart. The camera sends images to a video monitor to guide surgeons as they operate.

Another minimally invasive option for patients facing valve surgery is da Vinci Surgery.

**da Vinci Surgery: A Minimally Invasive Surgical Option**

Using the da Vinci Surgical System, your surgeon makes a few small incisions between your ribs - similar to thoracoscopic (minimally invasive) surgery. The da Vinci System features a magnified 3D high-definition vision system and tiny wristed instruments that bend and rotate far greater than the human wrist. These features enable your doctor to operate with enhanced vision, precision, dexterity, and control.

As a result of da Vinci technology, da Vinci Mitral Valve Repair Surgery offers the following potential benefits compared to open surgery:

- Less blood loss and need for transfusions\(^3\)
- Less time in intensive care\(^4\)
- Shorter hospital stay\(^4,5,6\)
- Lower rate of atrial fibrillation after surgery (rapid/irregular heartbeat)\(^6\)
- Lower rate of pleural effusions after surgery (excess fluid around the lung)\(^6\)
- Faster recovery and return to normal daily activities, including work\(^6\)
- Faster improvement of physical & mental health following surgery\(^6\)
- Small incisions for minimal scarring

**Risks & Considerations Related to Mitral Valve Repair Surgery & da Vinci Surgery:**

Potential risks of mitral valve repair surgery include:
- Heart attack or stroke
- Heart rhythm problems
- Infection in the kidneys, chest, valves or bladder
- Fever and chest pain (together called post-pericardiotomy syndrome)
- Memory loss and/or loss of mental clarity

In addition to the above risks, there are risks related to minimally invasive surgery, including da Vinci Mitral Valve Repair Surgery, such as damage to nearby organs or nerves.\(^3\)

**Important Information for Patients:**

All surgery presents risk, including da Vinci Surgery. Results, including cosmetic results, may vary. Serious complications may occur in any surgery, up to and including death. Examples of serious and life-threatening complications, which may require hospitalization, include injury to tissues or organs; bleeding; infection; and internal scarring that can cause long-lasting dysfunction or pain. Temporary pain or nerve injury has been linked to the inverted position often used during abdominal and pelvic surgery.

Patients should understand that risks of surgery include potential for human error and potential for equipment failure. Risks specific to minimally invasive surgery may include: a longer operative time; the need to convert the procedure to other surgical techniques; the need for additional or larger incision sites; a longer operation or longer time under anesthesia than your surgeon originally predicts. Converting the procedure to open could mean a longer operative time, long time under anesthesia, and could lead to increased complications. Research suggests that there may be an increased risk of incision-site hernia with single-incision surgery. Patients who bleed easily, have abnormal blood clotting, are pregnant or morbidly obese are typically not candidates for minimally invasive surgery, including da Vinci Surgery. Other surgical approaches are available. Patients should review the risks associated with all surgical approaches. They should talk to their doctors about their surgical experience and to decide if da Vinci is right for them. For more complete information on surgical risks, safety and indications for use, please refer to http://www.davincisurgery.com/safety.

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