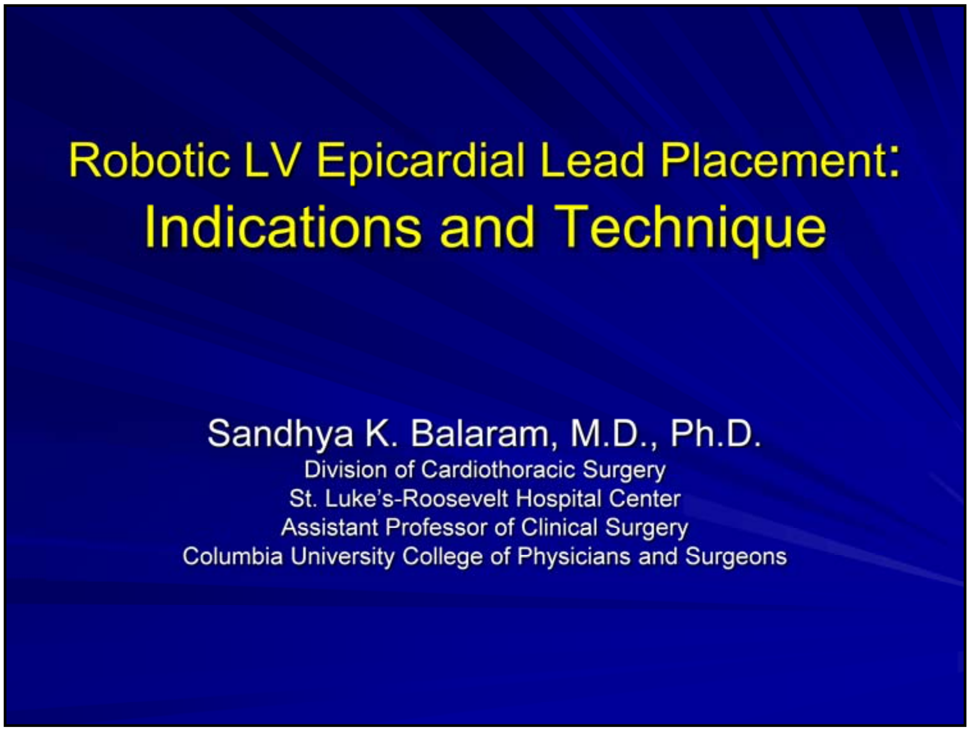
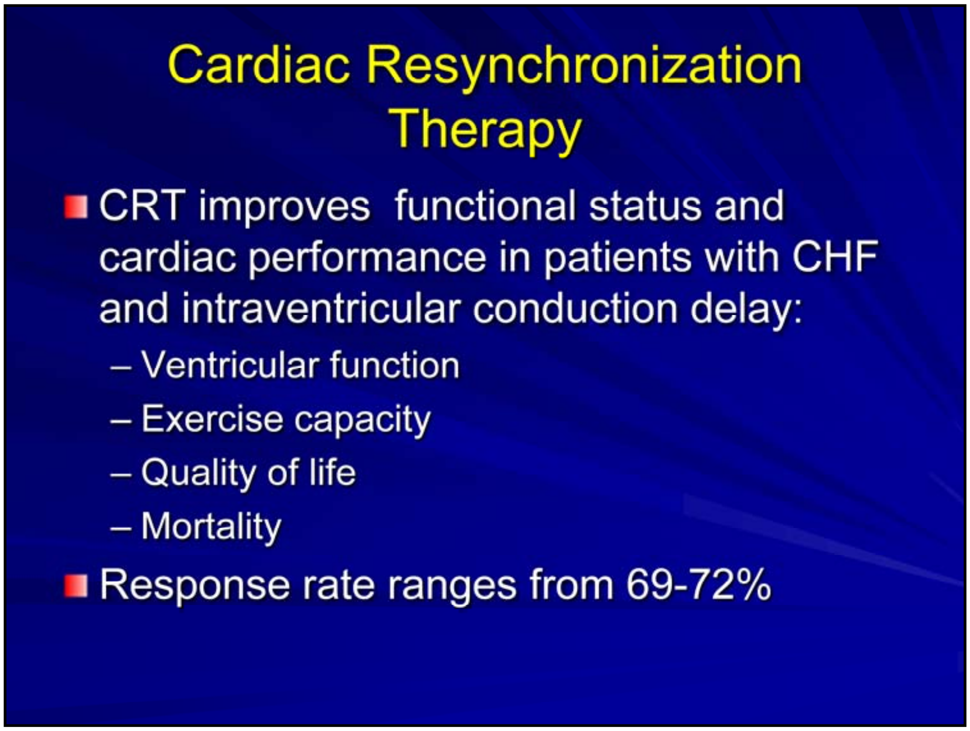
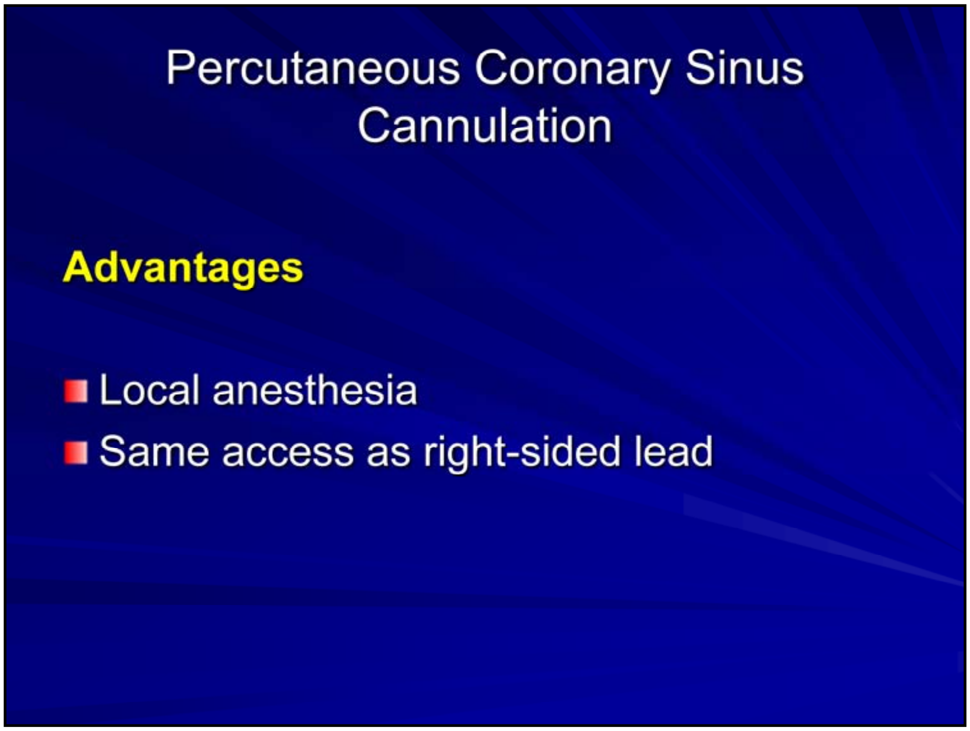


For the past several years, numerous clinical trials have proven the benefits of cardiac resynchronization therapy in the treatment of chronic heart failure. Surgically implanted left ventricular leads have typically been used as a last option after failure of percutaneous lead placement.

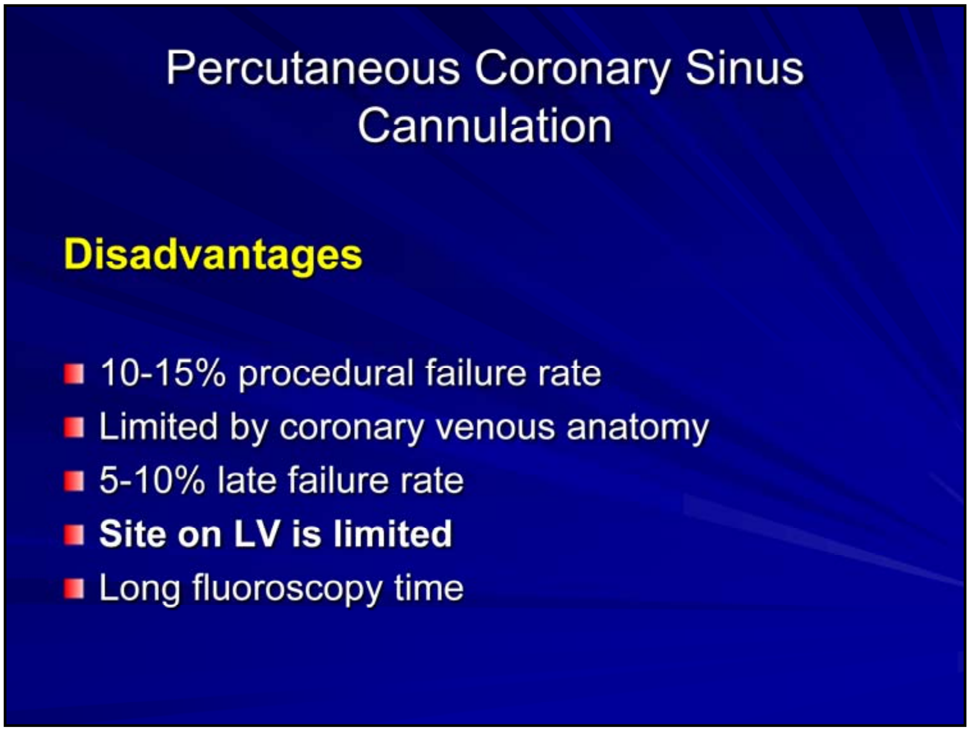
I will be speaking about the use of robotic technology which allows precise movements with excellent visualization within a closed chest, establishing a minimally invasive option to lead placement that allows for short procedural and recovery times as well as site-direction to optimize outcomes.



Prospective randomized trials have demonstrated improvements in ventricular function, exercise capacity, quality of life, and mortality, among patients undergoing cardiac resynchronization therapy (CRT) via biventricular pacing [1–5]. Although the response from percutaneous biventricular pacing can be dramatic, the overall response rate in previous large, prospective randomized trials ranges from 69% to 72%. The reason for this incomplete response is likely multifactorial and remains incompletely defined. LV site stimulation appears to play a critical role in LV resyncrhnoization,



LV leads placed by percutaneous coronary sinus cannulation are inserted in anterior sites, lateral sites, and posterolateral sites in fairly equal distribution and are primarily determined by the presence or absence of acceptable coronary sinus venous tributaries.



Disadvantages of percutaneous LV pacing include a number of limitations:
Dependent on inconsistent venous anatomy

Success of coronary sinus cannulation and LV lead placement are limited by technical challenges and coronary venous anatomy

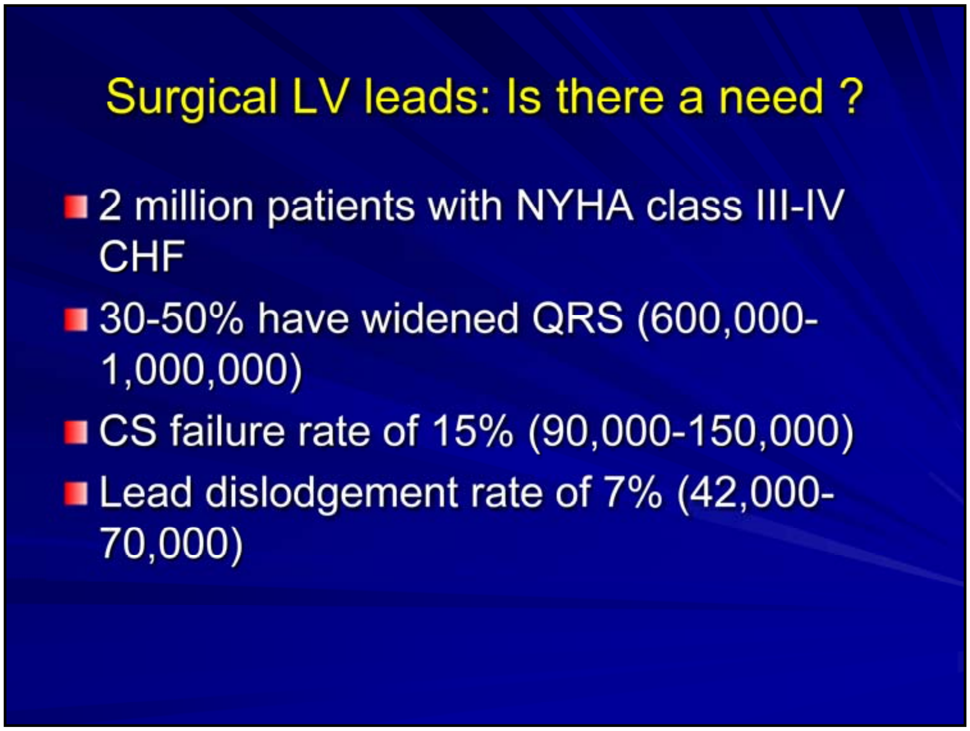
Technical limitations owing to individual coronary sinus and coronary venous anatomy result in a 10–15% failure rate of LV lead placement when performed in this manner.

tortuous coronary venous anatomy, distortion of a large coronary sinus ostium that may occur with enlarged atria, presence of postoperative scarring and stenosis, and potentially long implant times with radiation exposure.

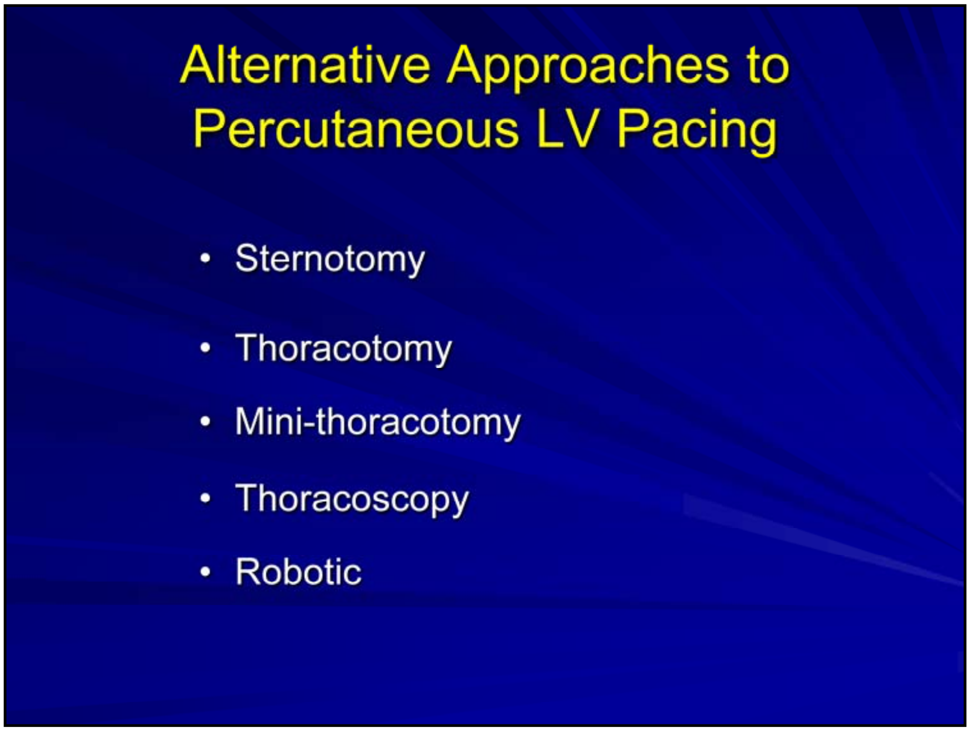
Large coronary veins can be associated with changes in pacing thresholds

Small coronary veins may not accept the lead

Potential for coronary sinus perforation.



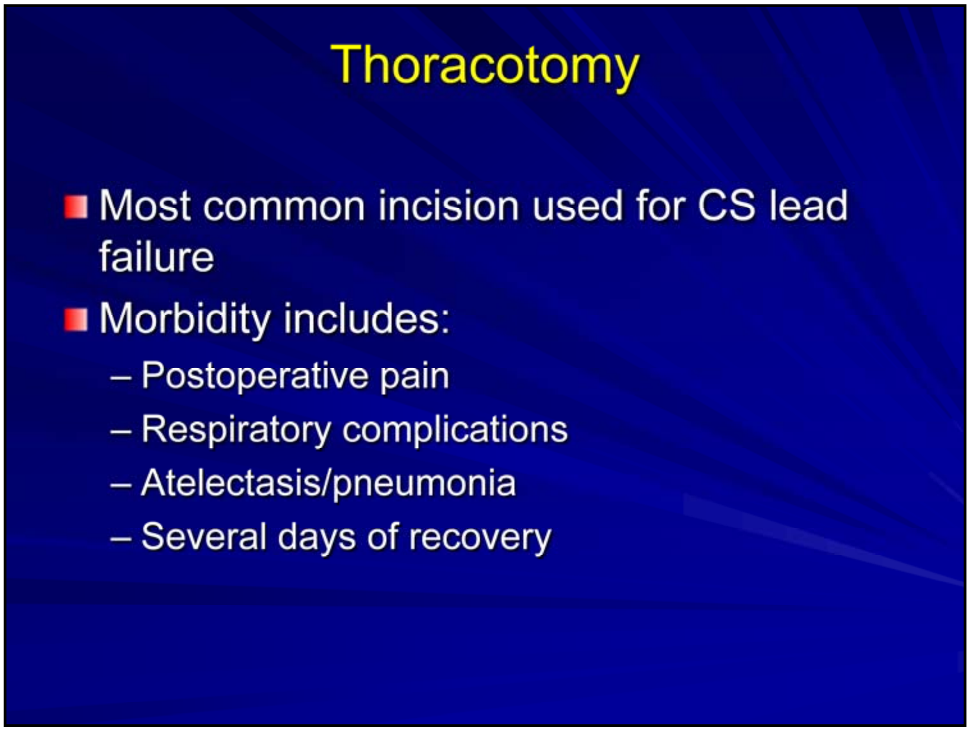
When percutaneous lead placement is unsuccessful, rescue therapy has typically involved direct surgical approaches to the LV epicardial surface. Although used predominantly in the setting of coronary sinus (CS) lead failure, these approaches do offer direct access to the LV surface, and reliable LV lead insertion can be performed with a near 100% success rate. Placement of these leads was considered to carry a high morbidity among patients that are otherwise debilitated, increasing hospital costs, and recovery times.



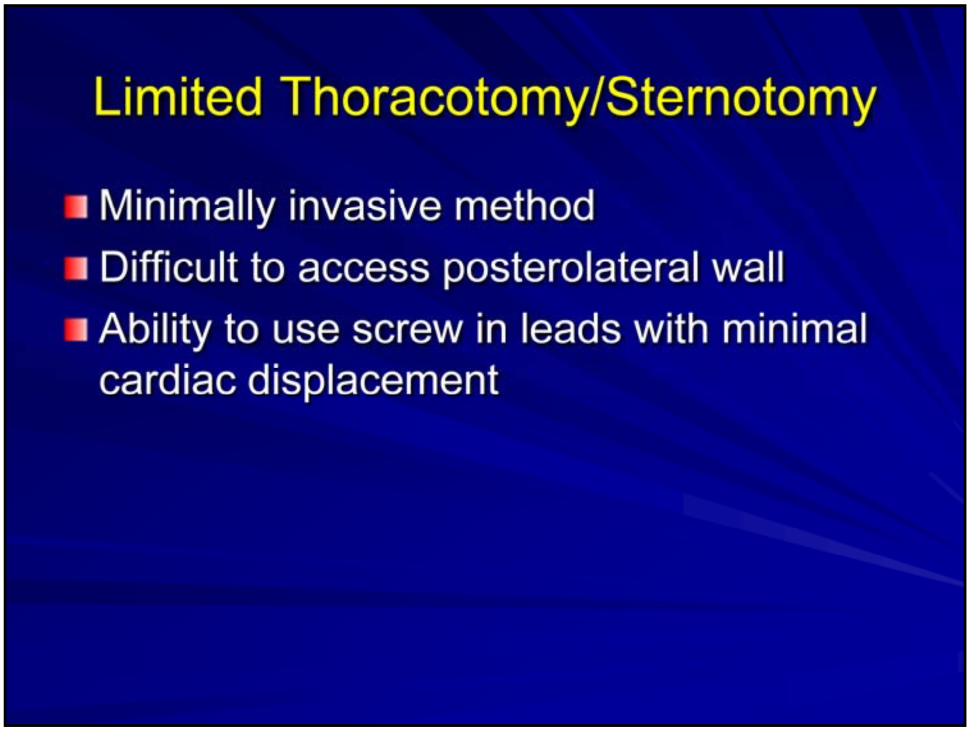
The range of procedures has included approaches as invasive as median sternotomy or thoracotomy to a totally endoscopic procedure with the use of robotic technology Access to the entire LV surface provides a unique opportunity for detailed LV mapping and precise site-directed resynchronization

Sternotomy has been a particularly helpful approach in patients with congenital or surgically corrected anatomy (i.e. Fontan) who do not have endovascular access to the right atrium or right ventricle. Access to the left ventricle through a sternotomy, however, does require significant cardiac manipulation. The techniques for accessing the posterolateral surface of the heart through a sternotomy are well known to cardiac surgeons versed in off pump coronary bypass grafting. Nonetheless, the morbidity of this approach, especially in the setting of prior cardiac surgery, may be restrictive in these sometimes frail heart failure patients who warrant CRT

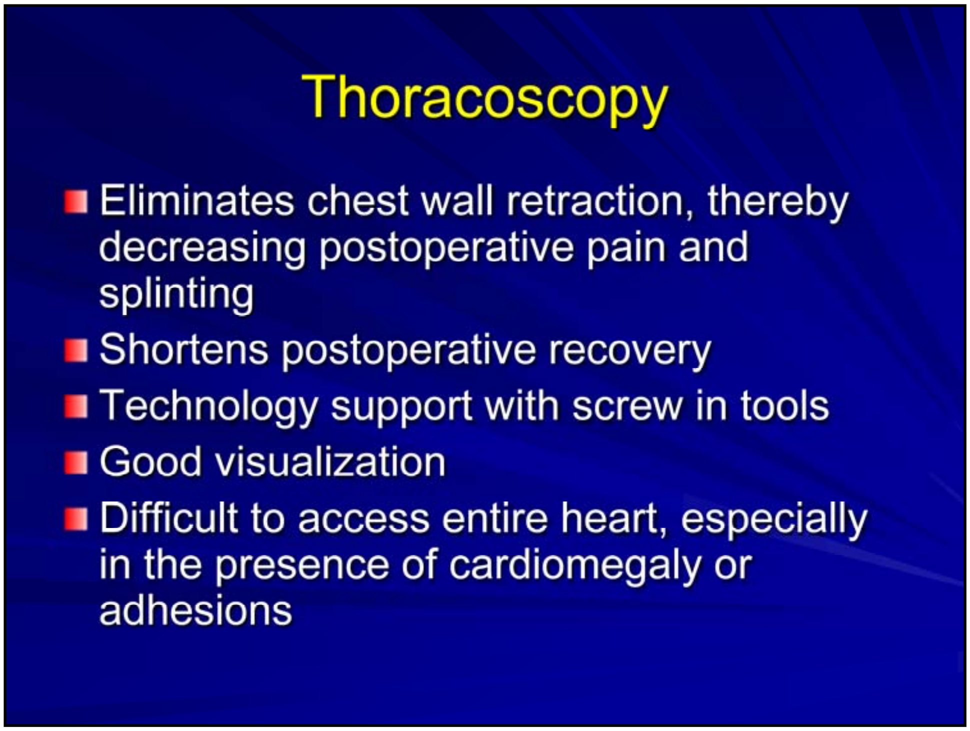
A limited lower hemisternotomy with unilateral division of the sternum into the 3rd or 4th interspace, can be used to access the left ventricle in a more minimally invasive fashion. However, the surgical approach to the posterolateral surface of the left ventricle is very difficult through this exposure, especially in reoperative situations.



Thoracotomy incisions have been used most commonly for LV epicardial lead implantation. These incisions provide more direct access to the left ventricle without significant cardiac manipulation. A formal rib spreading thoracotomy can be used in all situations for the fullest exposure to the posterolateral wall. However, this approach does carry a significant morbidity with a real recuperative phase. These patients, often frail and debilitated, are at risk for respiratory complications resulting from a decreased pulmonary functional residual capacity and postoperative pain; these include atelectasis and pneumonia.

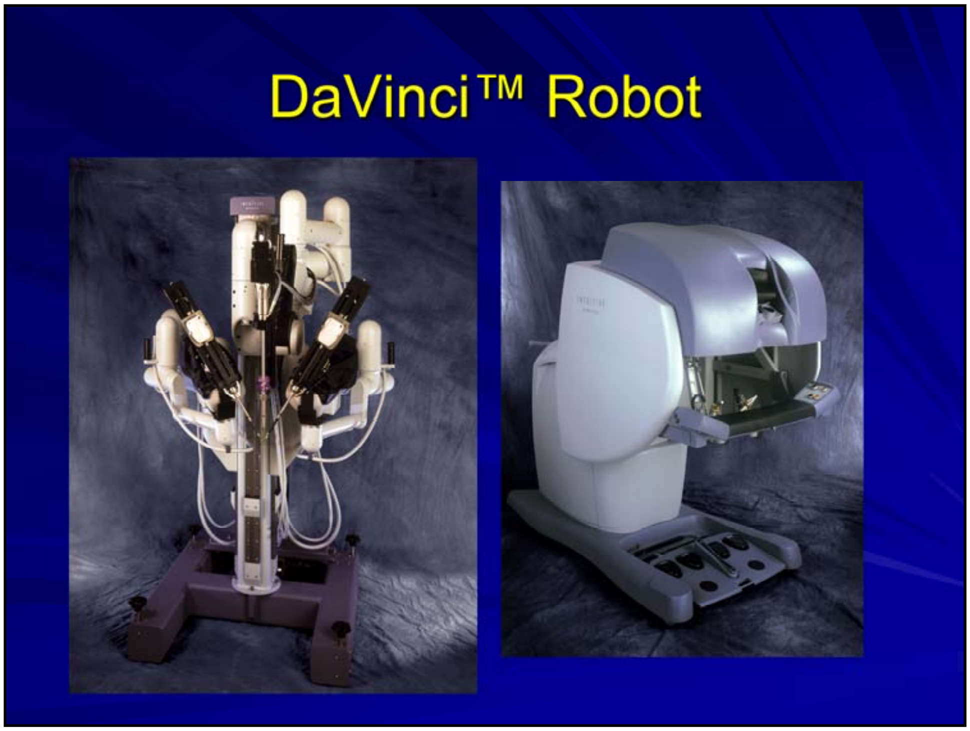


In order to minimize the trauma of a formal thoracotomy, minimally invasive cardiac surgeons have developed limited thoracotomy approaches to access particular parts of the LV surface. Limited anterior or lateral thoracotomy with or without rib spreading is an excellent minimally invasive approach for exposure of the anterior wall and is used commonly for minimally invasive revascularization of the left anterior descending artery.The incision is made below and just lateral to the nipple and a soft tissue retractor can be used in some patients for adequate exposure without the use of a rib spreader (The use of special screw-in tools has helped lead placement through these small thoracotomy incisions. Although access to the lateral wall and posterolateral wall is possible with some cardiac displacement, these patients often have significant cardiomegaly that makes true posterolateral exposure difficult.



<u>Endoscopic approaches to left ventricular lead placement</u>

Totally endoscopic approaches to the LV surface have the advantage of eliminating chest wall retraction and rib spreading and, therefore, shortening post-operative recovery and significantly decreasing post-operative pain. More importantly, however, these video-assisted approaches also allow access to the entire LV surface with excellent visualization. Thoracoscopy for LV lead placement has been championed by many groups [10, 12, 21, 22]. A number of different approaches exist, including placement of the ports in anterolateral and posterolateral positions. The dexterity with which surgery can be performed is variable and suturing fine leads on the LV surface can be challenging. As such, the placement of screw-in leads with the use of introducing tools is the preferred implantation technique when thoracoscopy is performed. Similarly, fine dissection necessary to free the heart and lung from surrounding structures in the re-operative setting can also be difficult. These limitations are often due to range of motion in the setting of cardiac movement. Nonetheless, global LV access and LV mapping are facilitated with the endoscopic approach and site-directed lead placement can be easily accomplished. The technical demands for reops and massive cardiomegaly may cause conversion, meanshile, robotic technology allows for 3D vision, wcaled motion and complete wrist like motion for delicate dissection and limited working space.

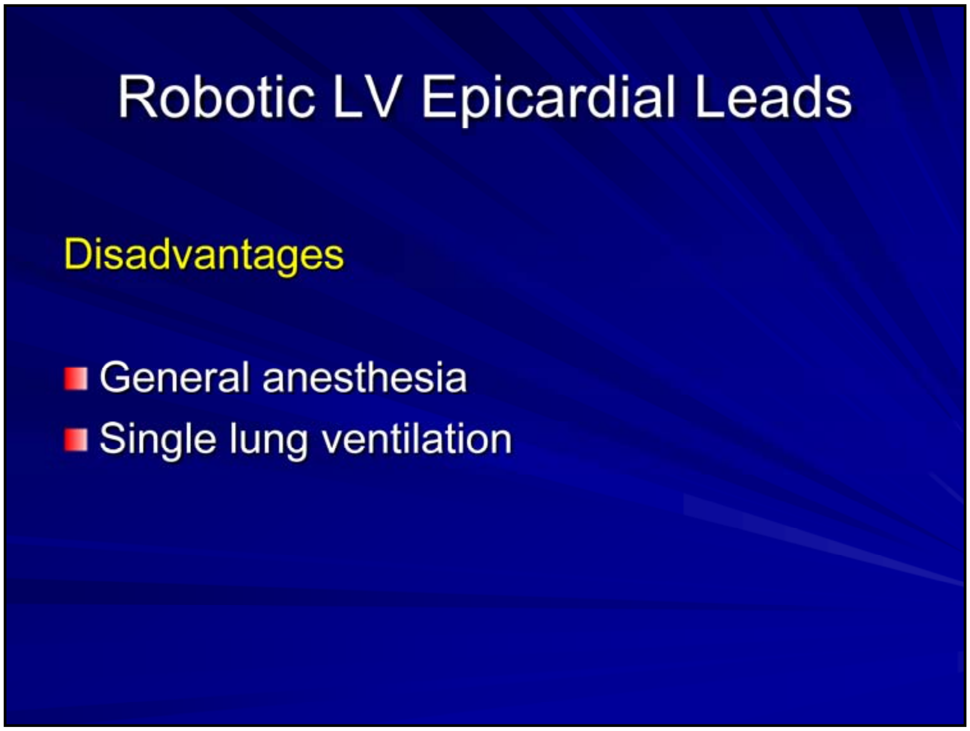


Robotically assisted approaches to biventricular pacing aim to combine the dexterity advantages of open surgery with the minimally invasive and exposure advantages of thoracoscopic surgery. The daVinci robotic system (Intuitive Surgical Incorporated, Sunnyvale, California, USA) is composed of a surgeon control console and a surgical arm unit that positions and directs the micro-instruments. Unlike standard thoracoscopic instruments, these specialized “EndoWrist” instruments have a full 7 degrees of freedom, simulating the motion of a human wrist at the operative site . Insertion of the instruments into the chest cavity is performed through two 8 mm ports. A third 10 mm port is used to insert the endoscope. The instruments are controlled by a surgeon who sits at the operating console away from the operative field. Computer interfacing allows for scaled motion, eliminating tremor, and providing for incredibly accurate surgical precision through these small ports. The surgeon views the surgery through the eyepiece in the surgical console which provides high-definition, magnified, real three-dimensional vision.

Robotic LV Epicardial Leads

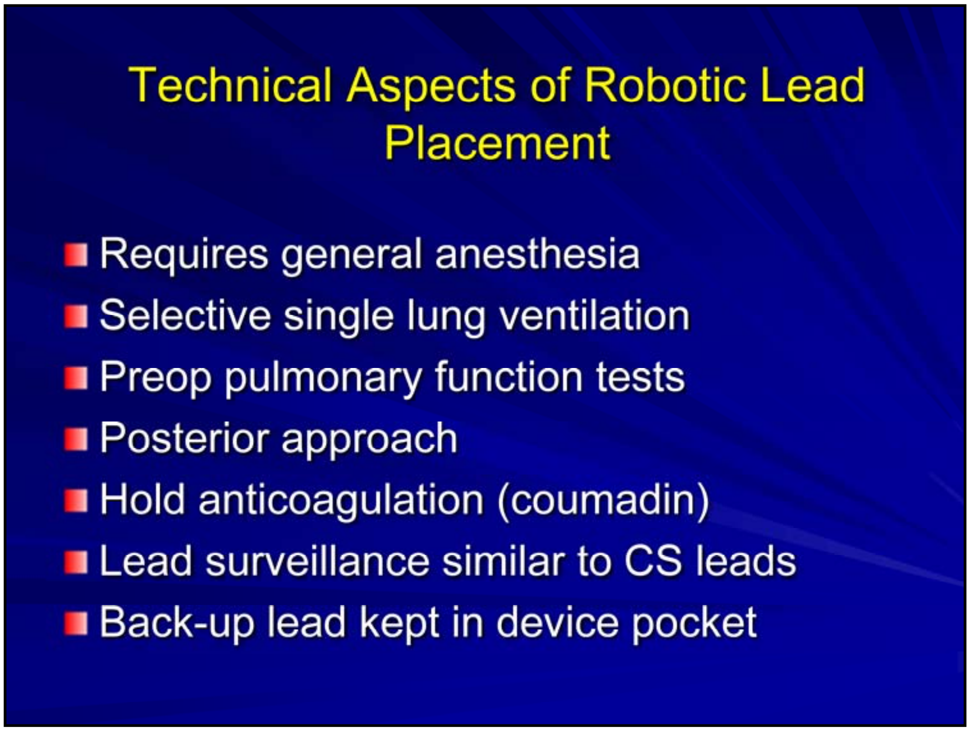
Advantages

- Direct placement on any portion of the LV
- Minimally invasive
- Site-directed approach


Robotic LV Epicardial Leads
Disadvantages
General anesthesia
Single lung ventilation

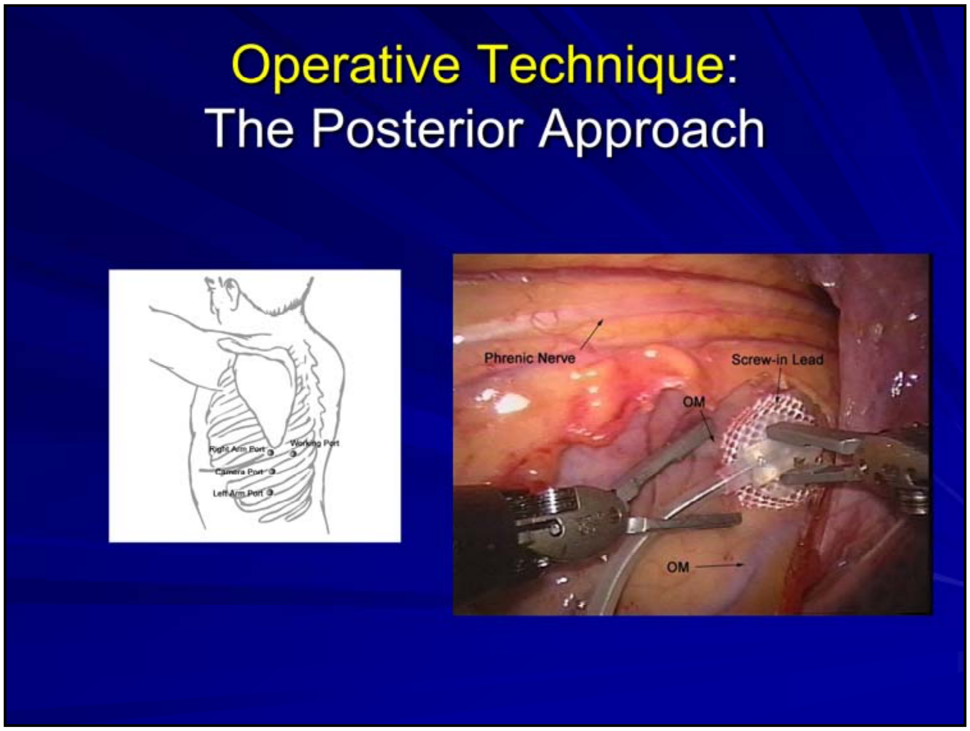
Indications For Robotic LV Lead Placement

- Inability to cannulate CS
- Small CS venous tributaries
- Prior perforation
- Lead fracture or dislodgement
- High pacing threshold
- Primary implant

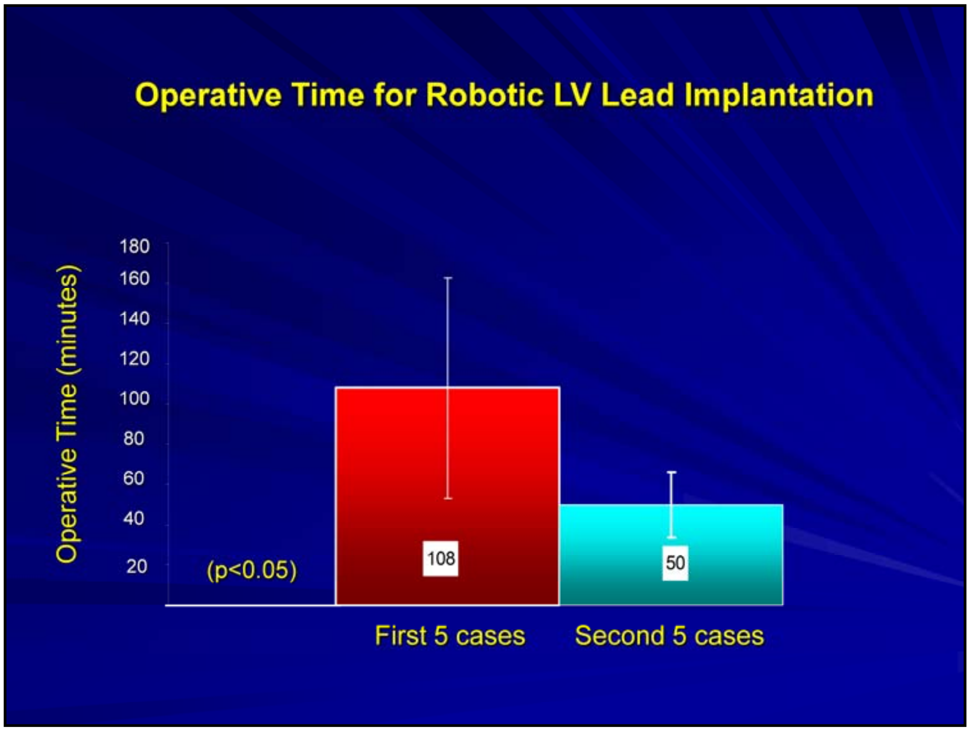


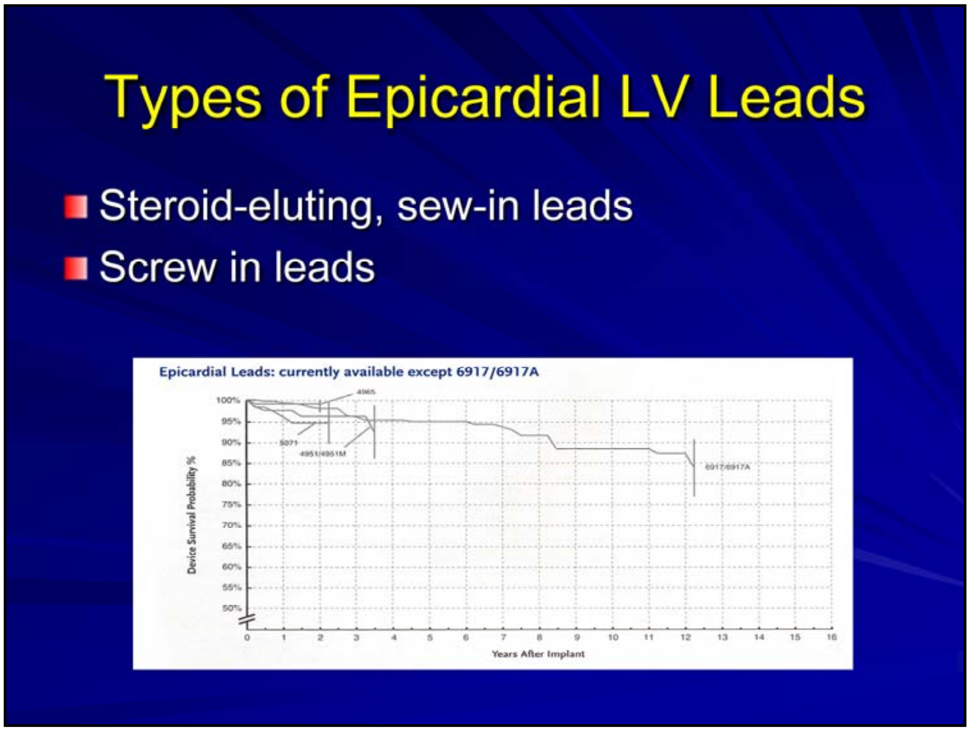
All minimally invasive surgical options for LV lead placement require general endotracheal anesthesia. Selective single lung ventilation allows for complete cardiac access and is a requirement for thoracoscopic or robotic lead insertion. As such, all patients requiring surgical LV lead placement with underlying pulmonary disease require pulmonary function tests in order to determine their suitability for single lung ventilation. A history of prior cardiac surgery including the arrangement of coronary bypass grafts should be obtained in order to allow for safe cardiac dissection. A posterior approach with the robot is especially helpful in this re-operative situation. Anticoagulation should be held prior to either endoscopic or open approaches as hematoma is prone to develop along the path of lead tunneling when the patient is anticoagulated.

Lead surveillance is performed in a similar manner as for CS leads. However, the presence of a back-up LV lead in the device pocket should allow for rapid lead exchange should LV lead failure be a concern. Pocket and device infections should be dealt with aggressively. All intravascular hardware should be removed and epicardial leads can easily be extracted endoscopically.



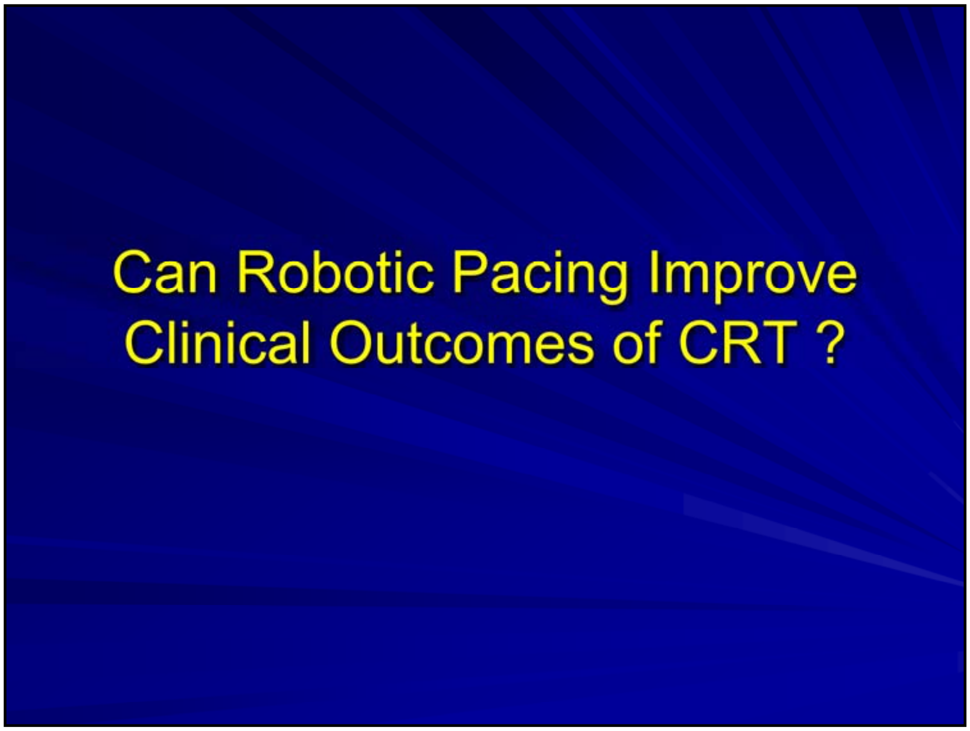
For LV lead insertion, the patient is positioned in a full, left posterolateral thoracotomy position and the robot is introduced in the posterior axillary line. A separate working port is used for introduction of the leads. The fine, scaled motion of the robotic arms allows for facile dissection of the pericardium from the epicardium as well as easy identification of bypass grafts when prior cardiac surgery has been performed. The robotic facilitation similarly allows for implantation of all types of leads as suturing is easily done. The three-dimensional endoscopic view gives the surgeon complete access to all surfaces of the LV for mapping and implantation.


Operative Time for Robotic LV Lead Implantation
Operative Time (minutes)
180
160
140
120
100
80
60
40
20
(p<0.05)
108
50
First 5 cases
Second 5 cases



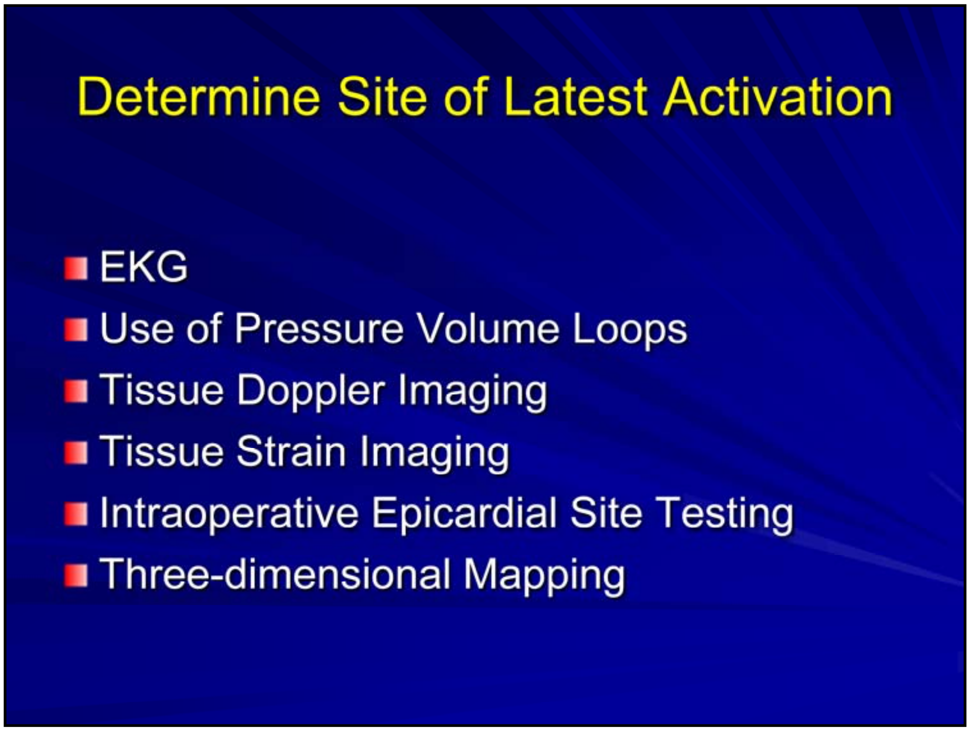
A number of different epicardial leads have been used for right ventricular (RV) pacing over the past 25 years. Historically, steroid eluting leads have had greater durability that non-steroid eluting “fish-hook” type leads or screw-in leads. Presently, the only steroid eluting epicardial leads for use in the United States are secured by sewing them onto the heart with fine sutures. These leads require exposure of bare myocardium in the target zone in order to achieve adequate pacing thresholds and do require finer dexterity when placed via an endoscopic approach.

The leads that can be placed without sutures are composed of a conducting screw that is secured into the myocardium with either an introductory tool or with robotic assistance. Historically, when these leads were used in the pediatric population long-term lead survival was not achieved past 10 years. However, when the screw-in and steroid eluting sew-on leads are examined for 10-year lead survival, the results are quite satisfactory. The 10-year lead survival of the screw-in lead is 92% and the steroid eluting lead nears 96%. These lead survivals far outlast the life expectancy of most elderly class III or IV heart failure patients and are very reasonable alternatives to epicardial coronary sinus leads. Nonetheless, the active development of steroid eluting screw-in leads promises to produce more durable epicardial leads for simple surgical epicardial lead placement.

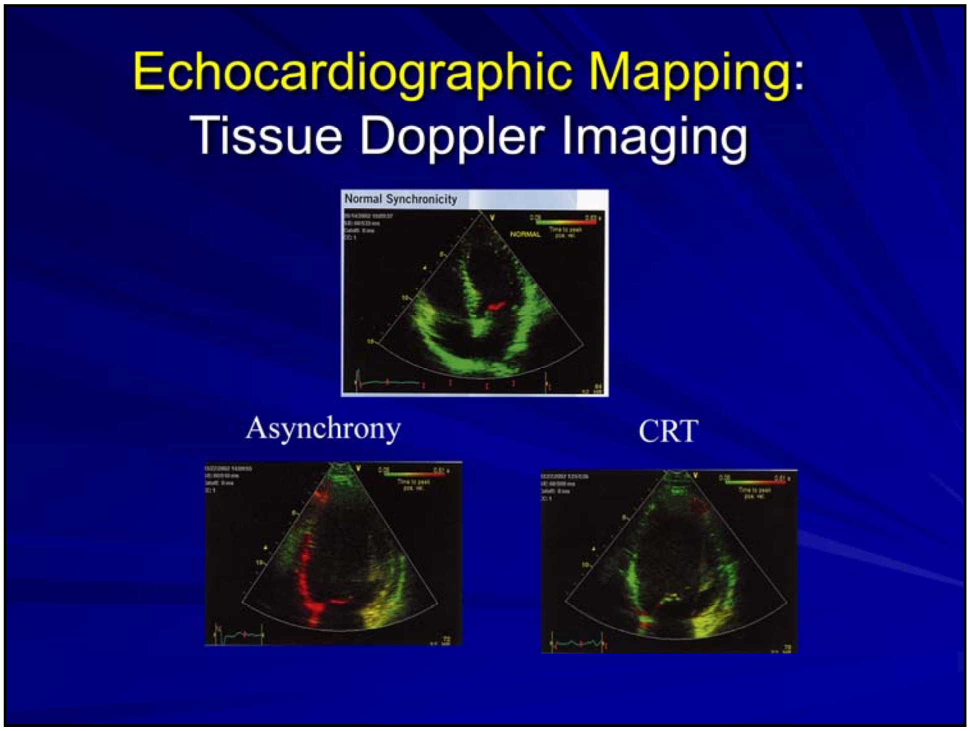


Outcomes of surgical left ventricular lead placement for cardiac resynchronization therapy

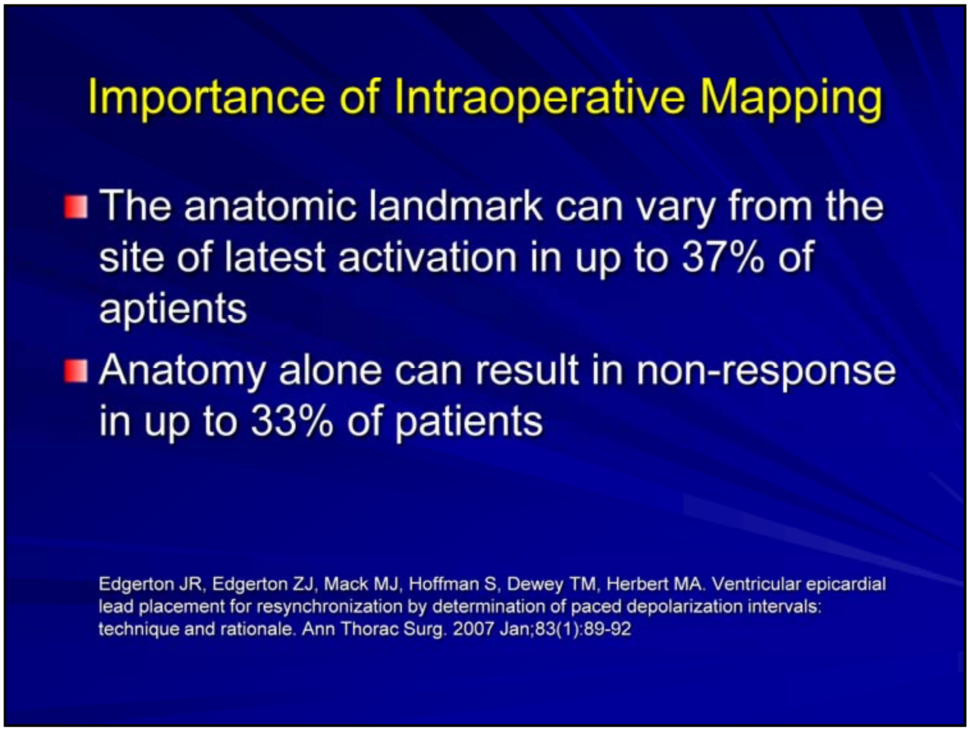
Most series of surgical epicardial lead placement have been reported in the setting of prior failure of CS lead insertion. As such, the majority of these patients are highly selected and represent a different population than the patients undergoing primary implantation. Nonetheless, a body of literature has been established over the past four years that accurately describes both peri-operative morbidity and short-term response rate with surgical epicardial lead placement through a variety of approaches.



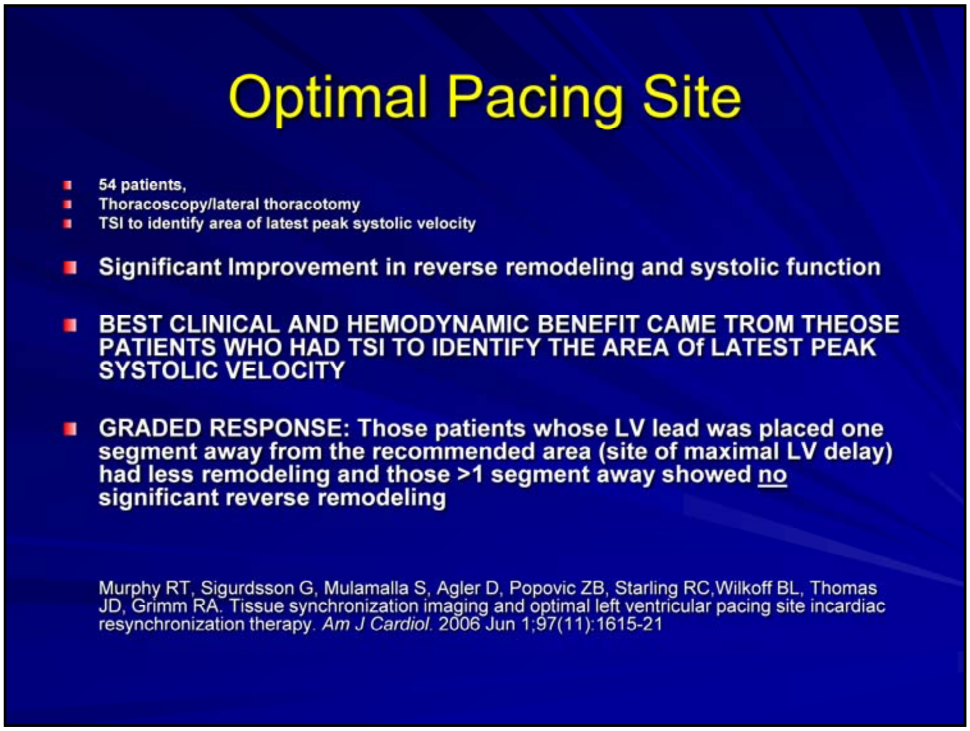
Recent literature has emphasized optimizing *site-directed* left ventricular lead placement using ventricular mapping [18]. The target zone for LV lead placement should correspond to the latest point of both electrical and mechanical activation. Historically, this has been labeled as the posterolateral wall midway between the base and the apex of the left ventricle. With pre-operative imaging, the area of latest mechanical activation can now be more accurately localized



The technique of tissue Doppler imaging (TDI) can be used to characterize the contraction of myocardial segments in time. By color-coding the segments, the target area of the left ventricle can be easily identified and more specifically defined.

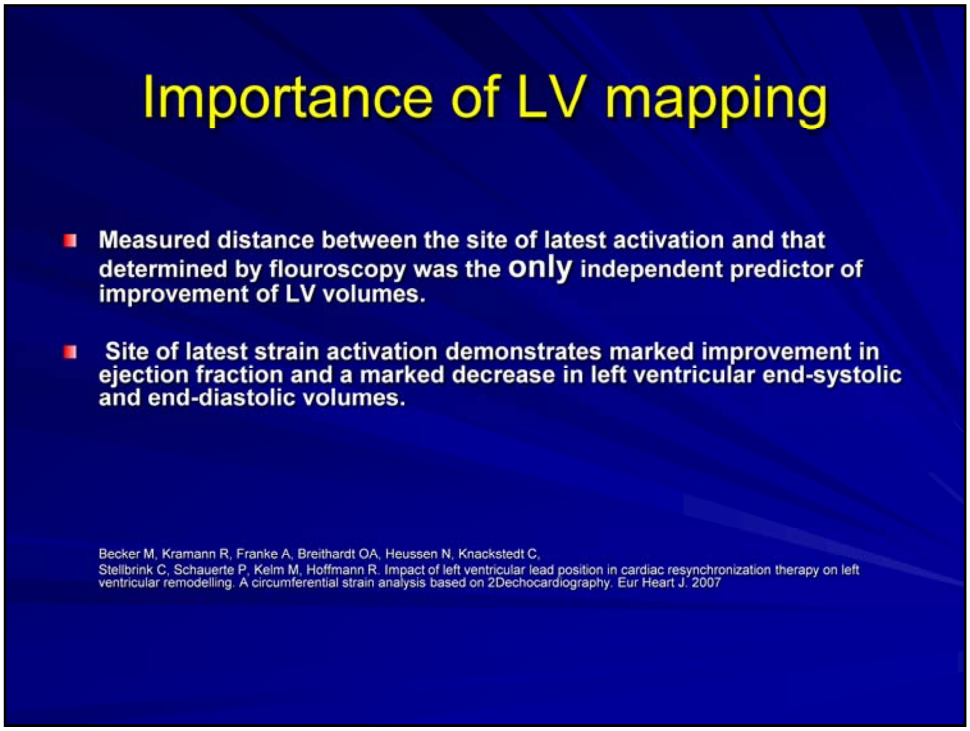


Edgerton et al. utilized intraoperative mapping with paced depolarization intervals to compare placement of the epicardial lead based on anatomic landmarks versus the site of latest activation. These two sites varied in 37% of patients. Placement of the LV lead based on anatomy alone resulted in nonresponse for 33% of patients. Determination of the individual patient's specific physiology appears critical in optimizing outomes.



The study: 54 patients,at cleveland clinic measured the site of maximal delay and looked at outcom4es , using thoracospopy or lateral thoracotomyTHE BEST CLINICAL AND HEMODYNAMIC BENEFIT CAME TROM THEOSE PATIENTS WHO HAD TSI IDENTIFY THE AREA OR LATEST PEAK SYSTOLIC VELOCITY

Use of the optimal pacing site of latest activation to determine exact placement of the epicardial LV lead was also recently shown to result in maximal reverse remodeling. Measurement of myocardial velocity with tissue strain imaging (TSI) provides information regarding the site of maximal LV delay. Use of this preoperative mapping technique demonstrated marked reverse remodeling and statistically significant improvements in systolic function. More importantly, those patients whose LV lead was placed one segment away from the recommended area had less remodeling and those >1 segment away showed no significant reverse remodeling. This data demonstrates the importance of individualized, targeted lead placement to maximize patient outcomes after CRT. The use of robotic epicardial lead insertion has capitalized on this preoperative determination of placement site to optimize left ventricular remodeling. In the future, the use of 3-dimensional mapping may provide still more information of the relationship between hemodynamics and resynchrony.

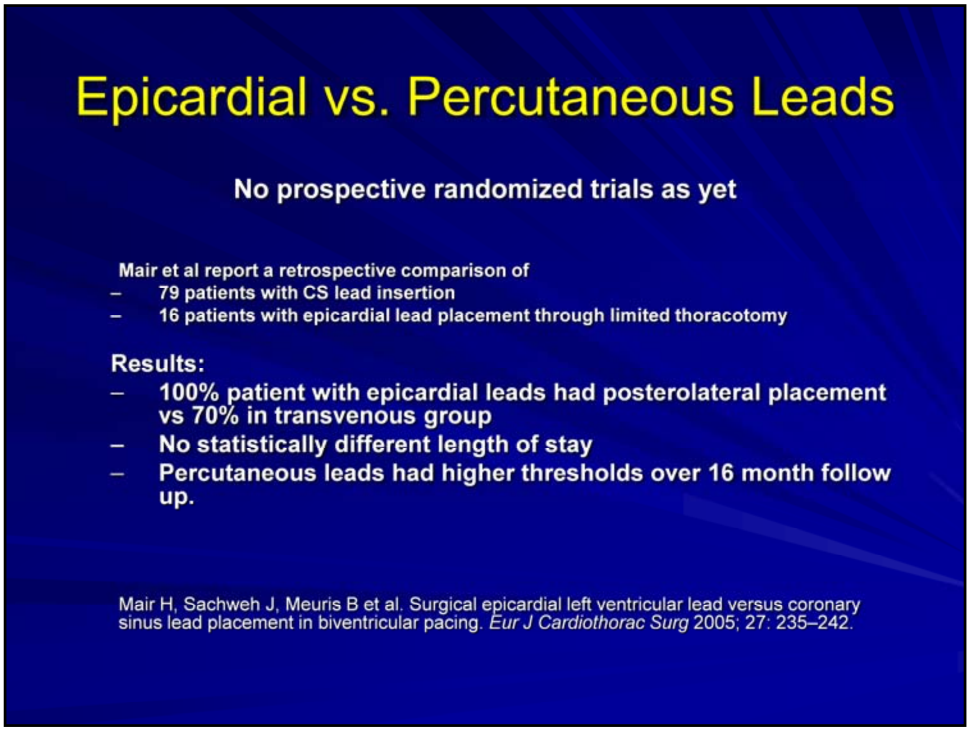


This was recently observed by Becker et al. . He used flluoursocopy to determine the site of lead placement

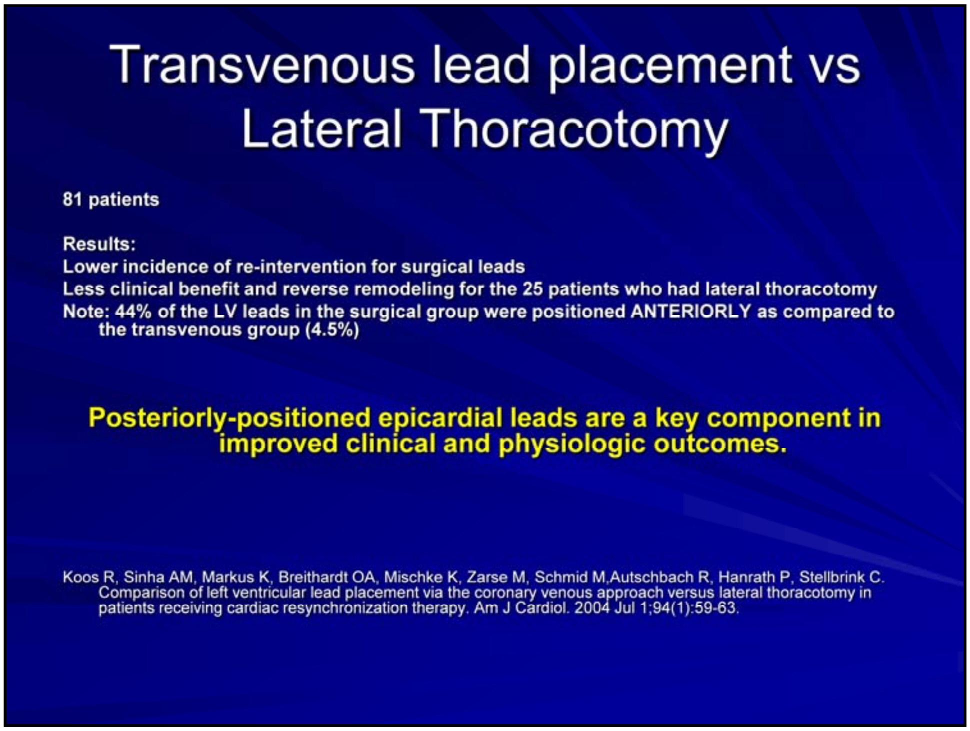
Others have utilized the site of latest strain activation to demonstrate improvement in ejection fraction and a marked decrease in left ventricular end-systolic and end-diastolic volumes. The measured distance between the site of latest activation and that determined by fluoroscopy was the only independent predictor of improvement of LV volumes.

It does appear that appropriate LV site stimulation remains critical for complete LV resynchronization.

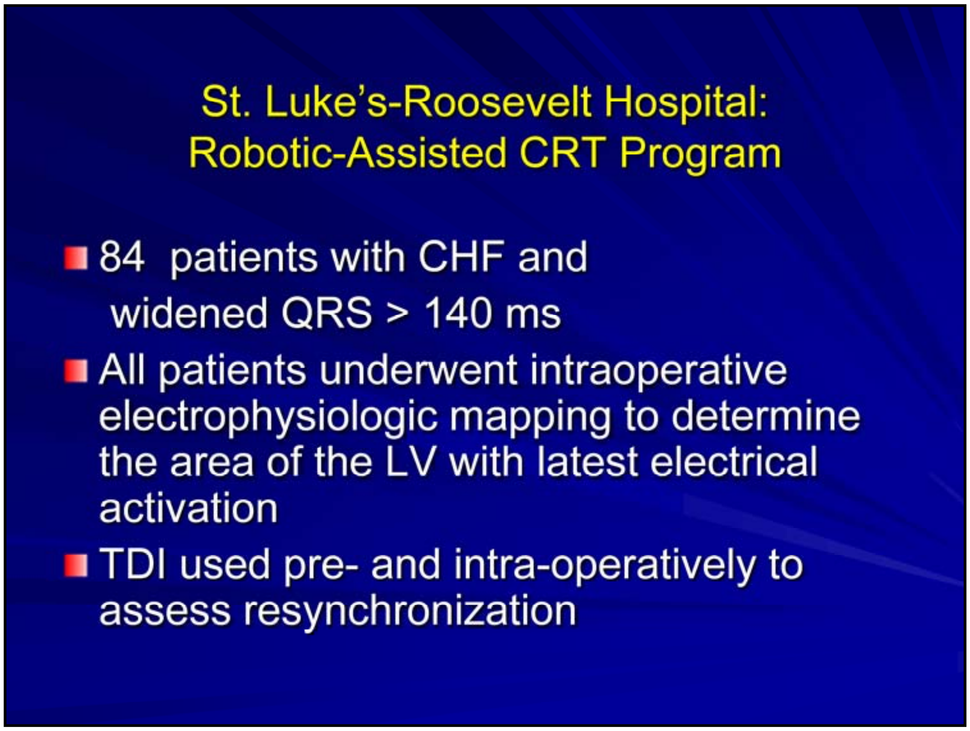
Three-dimensional echocardiography can also be used to evaluate 16–32 “voxels” of LV myocardium and to track their contraction in time. Multiple contraction waveforms can be imaged on line and the latest point of mechanical activation can be localized. These pre-operative imaging techniques allow for documentation of dyssynchrony in those patients evaluated for CRT with a widened QRS on baseline ECG. However, these techniques may also serve in the future to identify dyssynchrony in heart failure patients with no evidence of intraventricular conduction delay on baseline ECG.



Although no prospective, randomized comparison has yet been performed between surgical epicardial LV lead placement and CS lead placement, Mair *et al.* have reported results on a retrospective comparison. The study group included 79 patients undergoing CS lead insertion and 16 patients undergoing LV epicardial lead placement through a limited left lateral thoracotomy. The patients undergoing surgically placed LV leads included nine patients with failed CS leads and seven patients undergoing primary implant. All patients undergoing surgical placement of the epicardial LV lead achieved posterolateral lead placement as opposed to only 70% in the transvenous CS group. Length of stay was not statistically different between the two groups. Over a mean follow-up of 16 months, CS lead thresholds were significantly higher than surgically placed epicardial leads with seven CS leads having a pacing threshold of >4 V/0.5 ms versus no epicardial leads with a pacing threshold greater than 1.8 V/0.5 ms. In follow-up, 25 CS lead-related complications occurred, compared with one in the surgical group.



Koos et al. compared transvenous lead placement vs. lateral thoracotomy in 81 patients undergoing CRT. This study showed a lower incidence of re-intervention for surgical leads but also demonstrated less clinical benefit and reverse remodeling for the 25 patients who underwent lateral thoracotomy. The crucial feature of this study is that many of the LV leads in the surgical group were positioned *anteriorly* (44%) as compared to the transvenous group (4.5%). This study signifies the importance of posteriorly-positioned epicardial leads as a key component in improved clinical and physiologic outcomes.



Our group at St. Luke's-Roosevelt Hospital Center in New York has reported extensively on the short- and medium-term follow-up of robotic LV lead placement for biventricular pacing . Between 2002 and 2005, 60 patients have undergone robotic LV lead placement. The majority of these patients have had robotic LV lead implantation for a failure of CS lead placement (83%).

Patient Characteristics

N=84

- Age 73 ± 9 yrs (43-87)
- Inpatient 42%
- Ischemic CM 68%
- Idiopathic CM 32%
- Prior CABG 56%
- Multiple Re-op 17%

The operative results have been similar to those described by other groups with a 100% success rate for LV lead placement and a very low conversion rate to mini-thoracotomy (2.3%). All patients in this robotic series have been extubated in the operating room and median ICU and hospital lengths of stay have been 0.5 days and 1.5 days respectively. None of the patients required peri-operative inotropes. The last 20 patients in this series have undergone pre-operative TDI site localization and post-operative TDI pacing optimization. Post-operative morbidity has included one episode of pneumonia and two patients with intercostal neuropathy. No patients required re-intubation and there were no episodes of respiratory failure. Significant ventricular remodeling has been observed over the mean follow-up of 16.7 ± 9.5 months (range, 3–36 months) with statistically significant improvements in systolic LV internal dimension index and diastolic LV internal dimension index. Improvements in LV ejection fraction and New York Heart Association (NYHA) class have also been observed. The three-month clinical response rate has been 81%. Over the 36-month follow-up there have been four deaths (all of whom were initial non-responders). There have been three non-responders who remain alive with heart failure, one non-responder who underwent heart transplantation and four patients who worsened after an initial response for an overall response rate of 75% over the mean 17-month follow-up.

Complications

- Pneumonia
- Ischemic Colitis
- Intercostal Neuropathy
- Renal Insufficiency (transient)
- LV lead failure (6 mos)

Results

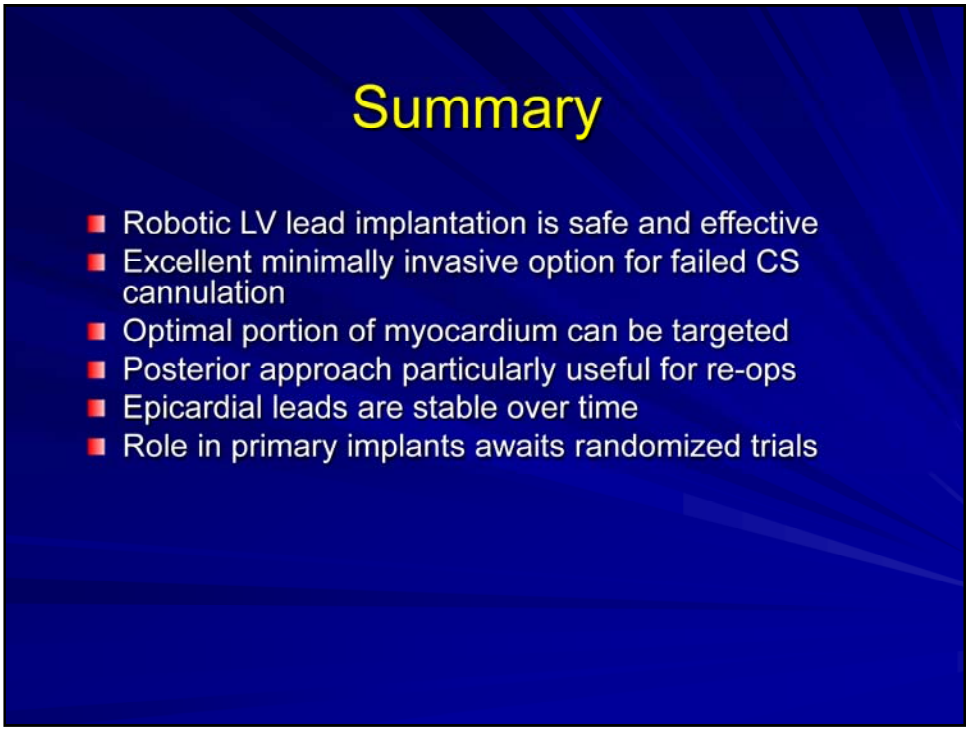
	Baseline	6 mos post-op	p
LVEF	11 ± 6%	23.4 ± 13.6%	<0.001
LVEDD	7.2 ± 1.2 cm	7.1 ± 1.0 cm	NS
NYHA class	3.5 ± 0.5	1.8 ± 0.8	<0.001
QRS duration	184 ± 29 msec	151 ± 20 msec	<0.01

Response Rate: 85%

Results- Lead Stability

F/U= 25 ± 8 months

	Threshold	Impedance
Intra-op	1.0 ± 0.5 V	1160 ± 248 Ω
Post-op	1.8 ± 1.1 V	310 ± 158 Ω
P value	NS	< 0.001



Robotic LV lead implantation is a valuable option

All patients have shown reproducible thersholds for LV pacing and sensing

The technique enables fine tuning of LV lead position, optimizing hemodynamic benefit

It avoids limitations of coronary anatomy with CS leads and deserves further prospective studies.