Title slide for presentation on Pacemaker Diagnostics, a comparison of the various diagnostic features available from multiple different manufacturers. This series will NOT present absolutely every possible iteration and feature of every device as this is simply not feasible but it will provide an overview of the major features and capabilities of the larger manufacturers. Where possible, I have attempted to use recent printouts from the current devices but this will quickly become outdated.

These slides were all obtained from patients whom I have cared for. The commentary reflects the author's understanding of the various capabilities of these systems. Any inaccuracies are mine alone. These printouts are provided as a service to individuals with an interest in this field simply to increase an awareness of the various diagnostic capabilities that presently exist. Some of the commentary reflect my personal experience with the various diagnostic feature and counters. It is rare that a single diagnostic is adequate for the patient. Each has its own strengths and weaknesses - each tend to compliment the others and are best used in conjunction with one another to facilitate an understanding of the behavior of the pacing system in each patient.

Slide series 1998\98040706.ppt

Slide # PAL\980101

Indications for CRT

- Symptomatic congestive heart failure, NYHA Functional Class III-IV
- Maximal medical therapy
- End-diastolic LV dimension > 55 mm
- Intraventricular conduction defect (usually LBBB) with QRS > 130 ms

In all the major studies and in general clinical practice 20-30% of patients do not respond to CRT

What is Cardiac Resynchronization?

- **Optimize the Left Atrial-Left Ventricular synchrony**
  - **to maximize ventricular filling and eliminate diastolic regurgitation**
- **Improve coordination of mechanical contraction of the Left Ventricle**
  - **Stimulating LV septum (from RV) and LV posterior-lateral wall either simultaneously or sequentially**
    - We will NEVER totally normalize LV contraction
  - **CRT is NOT to coordinate RV and LV contraction**
    - Mis-interpretation of “biventricular pacing”

Differential Diagnosis of Non-Responders

- Lack of mechanical dyssynchrony despite LBBB
- Poor LV lead location
- Large area of scar from prior M.I.
  - Myocardium in the area of the LV lead must be able to contract
- Pacemaker inhibited a significant portion of the time
  - Atrial fibrillation with intact conduction
  - Automatic mode switch
  - Sinus rate > Maximum Tracking Rate
- Inappropriate AV and VV delays
- LV lead dislodgment or loss of capture

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Inappropriate Patient Selection

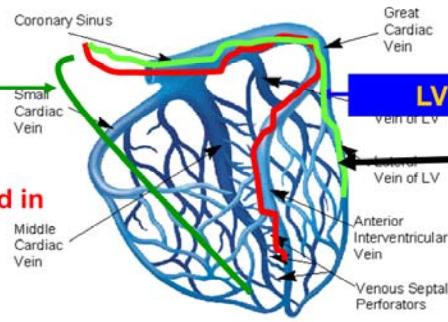
- While the ECG (LBBB) is a good screening tool, not all patients have mechanical dyssynchrony
- Large scar due to prior MI, remainder of myocardium may be hypercontractile
- Predominant diastolic rather than systolic dysfunction

No options available for these patients; potential placebo effect (30% of control patients had beneficial effect)!

- **Lead placed in CS and advanced to anterior cardiac vein**
  - **This is biventricular but not CRT**

RV Lead

Preferrably want lead in the area of latest contraction



LV Lead

LV Lead should be in Posterior or Lateral vein

LV Lead problems

- The majority of patients who receive a CRT system have an intact rhythm and AV nodal conduction
  - This is likely to change in the future
- Failure to deliver CRT will result in a return of the intrinsic conduction pattern
  - While the etiology of a malfunction will be the same as other pacing system malfunctions, the symptomatic presentation will differ as heart rate will continue to be supported by the other ventricular lead
    - Some clinicians (Prof. J.J. Blanc) have suggested that LV pacing alone works as well as BiV
    - This is being evaluated by SJM in the B-Left Study in Europe

Pacing System Malfunction

- Changes in capture threshold
  - Loss of capture
- Alterations in sensing
  - Undersensing
  - Oversensing
- Lead dislodgment
- Timing considerations
  - Paced and sensed AV delays
    - Optimize
  - Refractory periods
    - As short as possible
  - Maximum tracking rate
    - As high as possible

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Signs & Symptoms

Standard Pacing System

- Syncope, Presyncope
- Fatigue, Low C.O.
- Pre-implant Symptoms
- Loss of Capture - asystole
- Pauses in paced rhythm

Biventricular Pacing System

- Exacerbation of CHF
- Intact rhythm on ECG
- Classic paced complexes
- Return of intrinsic PR interval

Pacing system malfunction in a CRT system may be subtle and difficult to identify from the ECG

Baseline Data

- 12 lead ECGs
  - Native rhythm and conduction
  - RV paced rhythm
  - LV paced rhythm
  - Biventricular paced rhythm
- Intracardiac electrograms
- Telemetered event markers

Loss of Capture

CRT System
- **Wider or subtle change in paced QRS morphology**

Standard pacing system
- **Pacing stimulus fails to elicit a cardiac depolarization**

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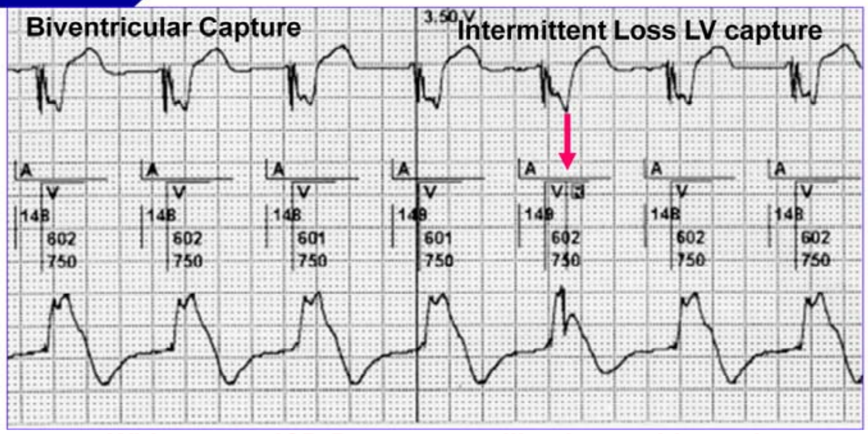
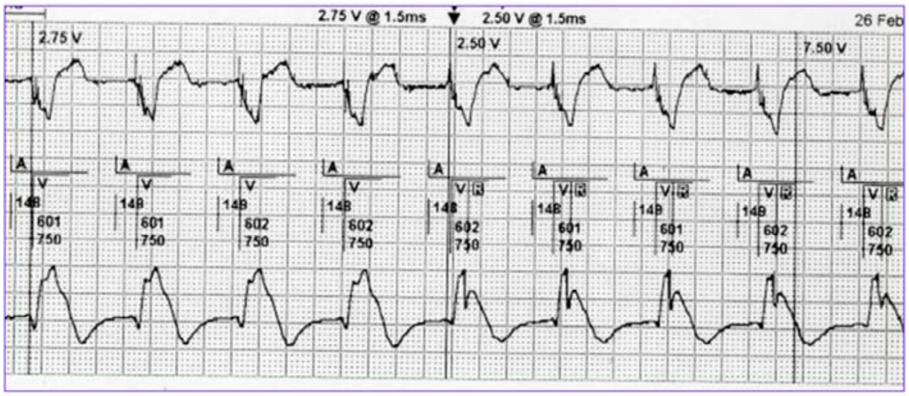
Loss of Capture: Utility of Event Markers and EGM



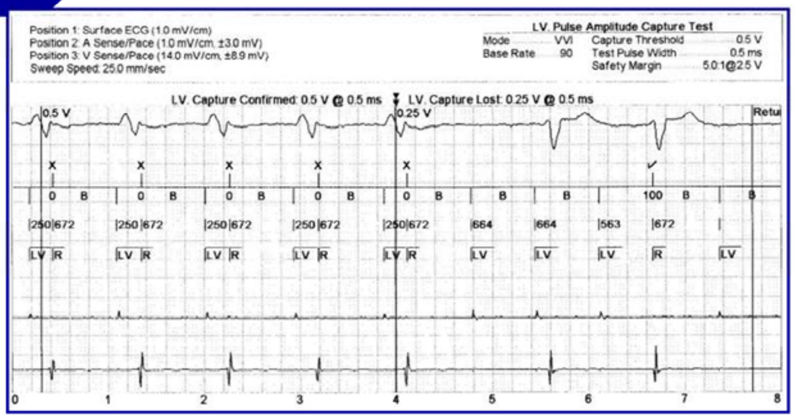
With current ICD-D systems, will only see this marker pattern with loss of RV capture since sensing has been disabled in the LV channel

Ventricular Capture Threshold



True biventricular AutoCapture is currently under-development.

Ventricular Capture Threshold



With LV capture, there is conduction to the RV with "R" sense. Loss of LV capture results in the intrinsic rhythm.

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Etiology of Loss of LV Capture

- Lead dislodgment
- Massive increase in capture threshold
- Poor position requiring high outputs
- Mechanical problem with LV lead
- Pharmacologic / metabolic factors

Management of Loss of Capture

- Increase output
- Correct metabolic abnormalities
- Withdraw recently introduced pharmacologic agents
- Program to unipolar output and sensing configuration
  - Possible with CRT-P but not CRT-D
- Operative intervention to reposition or replace lead

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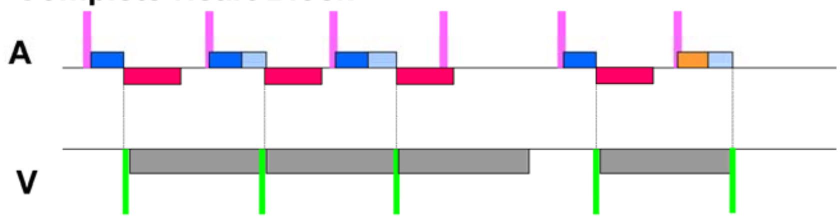
Maximum Tracking Rate

- **Limiting the MTR is NOT the appropriate way to limit the highest heart rate**
  - IF the sinus rate can exceed MTR and there is intact AV nodal conduction, when the patient has a physiologic need for a high rate, there will be loss of CRT
  - In presence of AV block, sinus > MTR will cause a loss of appropriate AV synchrony even though Ventricular CRT is still present

Timing: Maximum Tracking Rate

Complete Heart Block



Sinus rate > MTR

AV interval

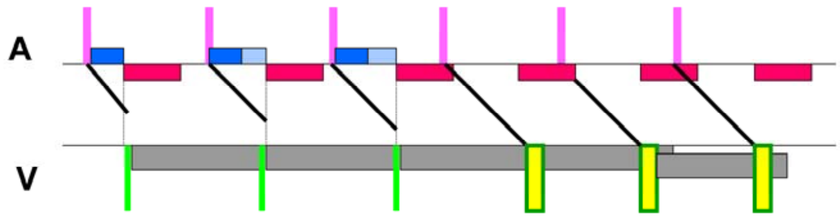
AV interval extension

PVARP

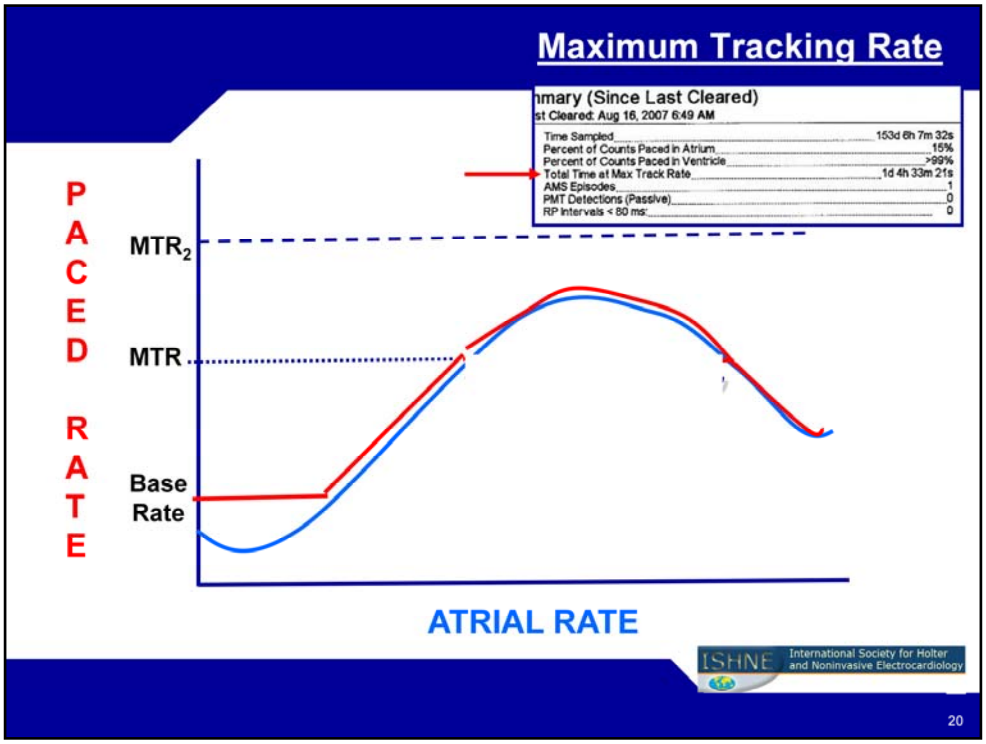
MTR interval

Sinus > Maximum Tracking Rate

Congestive Heart Failure - CRT Pacing



Sinus rate > MTR; PV < PR interval


Maximum Tracking Rate
nmary (Since Last Cleared)
st Cleared: Aug 16, 2007 6:49 AM
Time Sampled 153d 6h 7m 32s
Percent of Counts Paced in Atrium 15%
Percent of Counts Paced in Ventricle >99%
Total Time at Max Track Rate 1d 4h 33m 21s
AMS Episodes 1
PMT Detections (Passive) 0
RP Intervals < 80 ms: 0
PACED RATE
MTR_2
MTR
Base Rate
ATRIAL RATE
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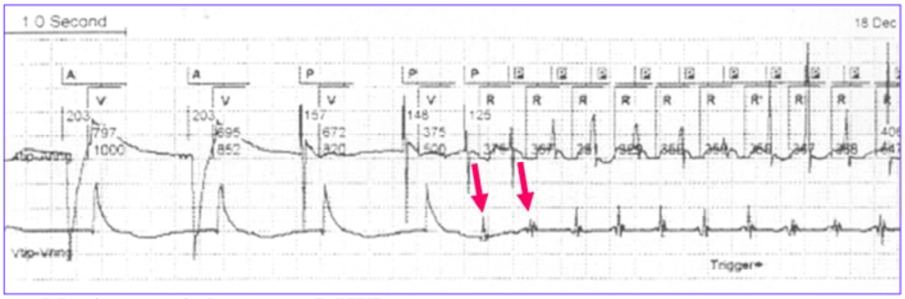
20

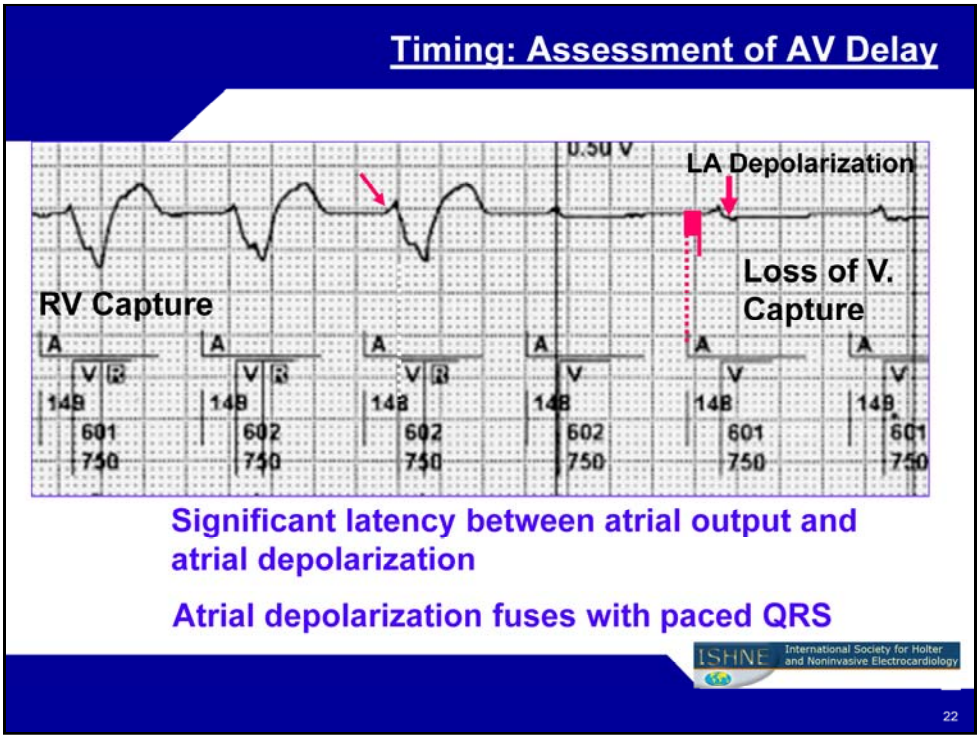
Stored EGMs



Native atrial rate > MTR

P wave in PVARP - hence not tracked but is conducted

In a CRT pacing system, set MTR >> maximum anticipated sinus rate



Observations with respect to AV delay

First examine the complexes associated with loss of ventricular capture. The atrial output induces an atrial depolarization. However, there is significant latency between the atrial stimulus and the atrial evoked response. It measures almost 80 ms. At a programmed AV delay of 150 ms, that means that the P wave effectively starts 70 milliseconds in front of the paced QRS.

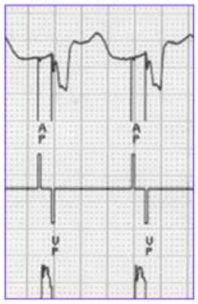
Now turn to the left side of the rhythm strip. The up-slope of the QRS complex that would normally be labeled an initial R wave is identified by a red arrow . This is really the first part of the P wave. The blue line aligning with the ventricular output marker identifies the start of the QRS which occurs after this “R” wave.

There is normally a delay between electrical activation of the atrium and mechanical contraction. In addition, with pacing from the Right Atrium, there is a further delay associated with the need to conduct the atrial depolarization from the RA to the LA. In all likelihood, at very short AV delays, the left atrial contraction will coincide with the LV contraction precluding any benefit from atrial transport. Although patients with a failing heart function on a flattened Starling or Ventricular Function curve, they commonly need every little bit of help that we can provide. In this case, it is to maintain optimal atrial transport to maximize ventricular filling.

Programming AV / PV Delay Multisite Fusion

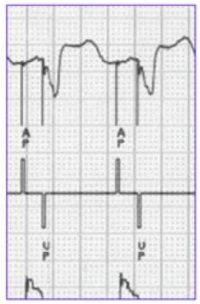
AV Delay

100 ms



Fusion due to CRT Pacing

160 ms

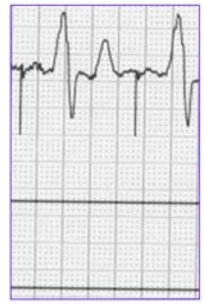


Fusion due to CRT Pacing

210 ms

Fusion due to CRT Pacing and Native Conduction

Native



Intrinsic Conduction

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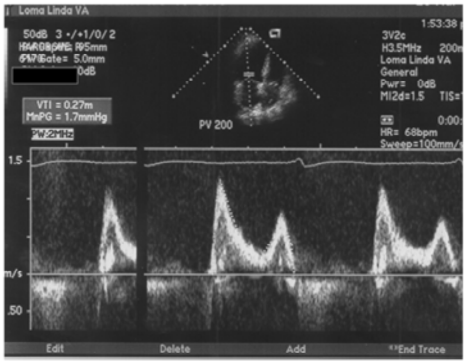
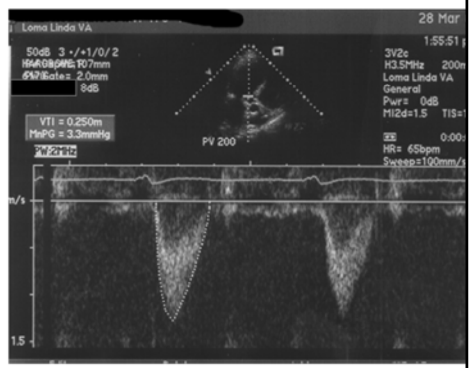
Programming AV / PV Delay using Echo-Doppler at PV 200 ms





LV Inflow tract

VTI 0.27 m

V 1.26 m/s

LV Outflow tract

VTI 0.250 m

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Limitations of Echo-Doppler

- Needs to be scheduled
- Time consuming
- 10-15% error between sequential measurements and between interpreters
- There is no consensus as to the best technique or measurement
  - Standard M mode (transthoracic or transesophageal)
  - Tissue Doppler Imaging (TDI)
  - Echo strain

Although Echo-Doppler is the current gold-standard, it is not convenient and it cannot be done at each follow-up visit to adjust AV and VV intervals with reverse remodeling.

Background for QuickOpt

- QuickOpt is an algorithm incorporated in the SJM programmer to adjust paced and sensed AV delays and VV delays based on EGM measurements
- Contraction cannot occur until the muscle has been depolarized
- Measurement of the time to depolarization in each chamber from atrial depolarization and between chambers will provide a guide towards programming paced and sensed AV delays

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Timing Cycle Optimization

In an analysis of 11 separately published studies, 440 out of 550 patients (80%) showed statistically significant improvement from sequential biventricular pacing over simultaneous pacing.[1-11]

[1]Chan, et al. "Tissue Doppler Guided Optimization of A-V and V-V Delay of Biventricular Pacemaker Improves Response to Cardiac Resynchronization Therapy in Heart Failure Patients" *J of Cardiac Failure 2004; 10, 4 (suppl.): S72 (abstract 199).*

[2]Bordachar, et al. "Echocardiographic Parameters of Ventricular Dyssynchrony Validation in Patients with Heart Failure Using Sequential Biventricular Pacing" *JACC 2004 Dec 7; 44 (11): 2157-2165.*

[3]Vanderheyden, et al. "Tailored echocardiographic interventricular delay programming further optimizes left ventricular performance after cardiac resynchronization therapy" *Heart Rhythm, Volume 2, No. 10, Oct 2005 1066-1072.*

[4]VanGelder, et al. "Effect of Optimizing the VV Interval on Left Ventricular Contractility in Cardiac Resynchronization Therapy" *American Journal of Cardiology 2004; 93, 1500-1503.*

[5]Sogaard, et al. "Sequential Versus Simultaneous Biventricular Resynchronization for Severe Heart Failure: Evaluation by Tissue Doppler Imaging" *Circulation 106: 2078-2084 (2002).*

[6]Rosanio, et al. "Non-Simultaneous Pacing of the Right and Left Ventricles for Heart Failure: Is It Worth It?" *AHA Abstract: 1618 (2003) AHA 76th Scientific Sessions, Orlando, Nov. 9-12, 2003.*

[7]O'Cochlain, et al. "The Effect of Variation in the Interval Between Right and Left Ventricular Activation on Paced QRS Duration" *PACE 2001; 24: 1780-1782.*

[8]Perego, et al. "Simultaneous vs. Sequential Biventricular Pacing in Dilated Cardiomyopathy: An Acute Hemodynamic Study" *The European Journal of Heart Failure 2003; 5: 305-313.*

[9]Bracke, et al. "Importance of Interventricular Delay to Optimize Cardiac Resynchronization Therapy" *JACC 41: (2003) ACC 52nd Annual Scientific Sessions March 30*-April 2nd, 2003, Chicago*

[10]Mortenson, et al. "Sequential Biventricular Pacing: Evaluation of Safety and Efficacy" *PACE 2004; 27: 339-345.*

[11]Leon, et al. "Effect of Cardiac Resynchronization Therapy with Sequential Biventricular Pacing on Doppler-Derived Left Ventricular Stroke Volume, Functional Status and Exercise Capacity in Patients with Ventricular Dysfunction and Conduction Delay" *PACE 25: 141 (2002) NASPE 23rd Annual Scientific Sessions, May 8-11, 2002, San Diego.*

Timing Cycle Optimization

- Three studies comprising 350 patients studied patient quality of life (QoL) and all showed improvement on QoL scores[1-3]

- In addition, two studies specifically address non-responder rates and both showed a reduction in non-responder rates[1,4]

[1]Chan, et al. "Tissue Doppler Guided Optimization of A-V and V-V Delay of Biventricular Pacemaker Improves Response to Cardiac Resynchronization Therapy in Heart Failure Patients" *J of Cardiac Failure 2004; 10, 4 (suppl.): S72 (abstract 199).*
[2]Bordachar, et al. "Echocardiographic Parameters of Ventricular Dyssynchrony Validation in Patients with Heart Failure Using Sequential Biventricular Pacing" *JACC 2004 Dec 7; 44 (11): 2157-2165.*
[3]Leon, et al. "Effect of Cardiac Resynchronization Therapy with Sequential Biventricular Pacing on Doppler-Derived Left Ventricular Stroke Volume, Functional Status and Exercise Capacity in Patients with Ventricular Dysfunction and Conduction Delay" *PACE 25: 141 (2002) NASPE 23rd Annual Scientific Sessions, May 8-11, 2002, San Diego.*
[4]Vanderheyden, et al. "Tailored echocardiographic interventricular delay programming further optimizes left ventricular performance after cardiac resynchronization therapy" *Heart Rhythm, Volume 2, No. 10, Oct 2005 1066-1072.*

Timing Cycle Optimization

- Seven studies used NYHA class improvement as a surrogate for patient response to optimized therapy
- All seven studies resulted in improvements in NYHA functional class status[1-7]

[1]Chan, et al. "Tissue Doppler Guided Optimization of A-V and V-V Delay of Biventricular Pacemaker Improves Response to Cardiac Resynchronization Therapy in Heart Failure Patients" *J of Cardiac Failure 2004; 10, 4 (suppl.): S72 (abstract 199).*
[2]Bordachar, et al. "Echocardiographic Parameters of Ventricular Dyssynchrony Validation in Patients with Heart Failure Using Sequential Biventricular Pacing" *JACC 2004 Dec 7; 44 (11): 2157-2165.*
[3]Vanderheyden, et al. "Tailored echocardiographic interventricular delay programming further optimizes left ventricular performance after cardiac resynchronization therapy" *Heart Rhythm, Volume 2, No. 10, Oct 2005 1066-1072.*
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[5]Rosanio, et al. "Non-Simultaneous Pacing of the Right and Left Ventricles for Heart Failure: Is It Worth It?" *AHA Abstract: 1618 (2003) AHA 76th Scientific Sessions, Orlando, Nov. 9-12, 2003.*
[6]Mortenson, et al. "Sequential Biventricular Pacing: Evaluation of Safety and Efficacy" *PACE 2004; 27: 339-345.*
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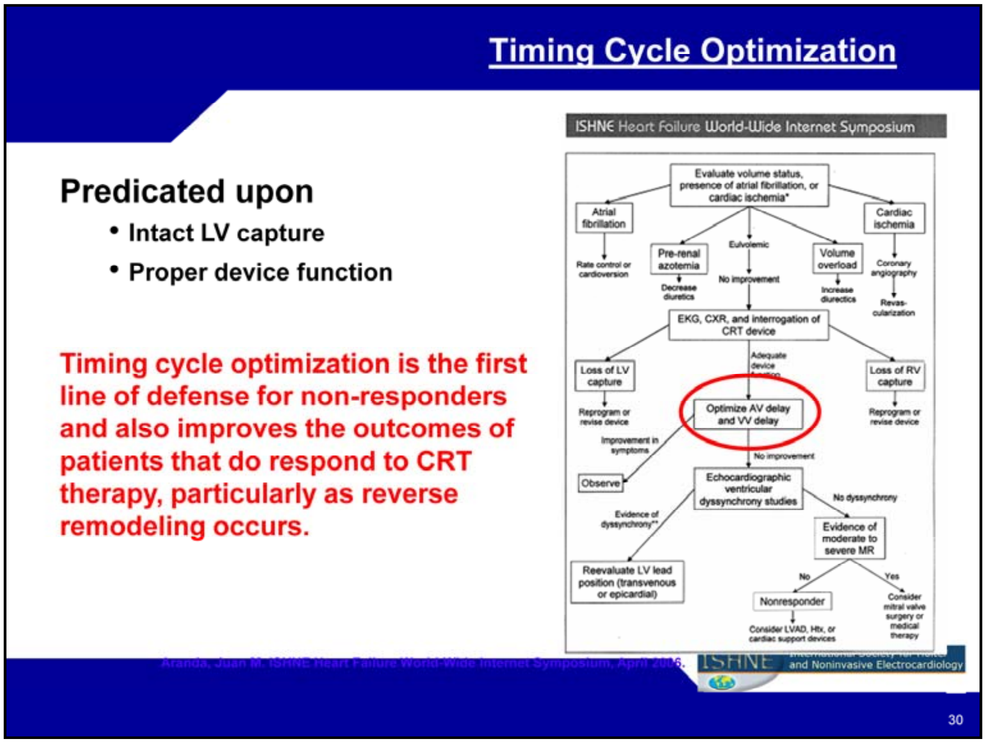
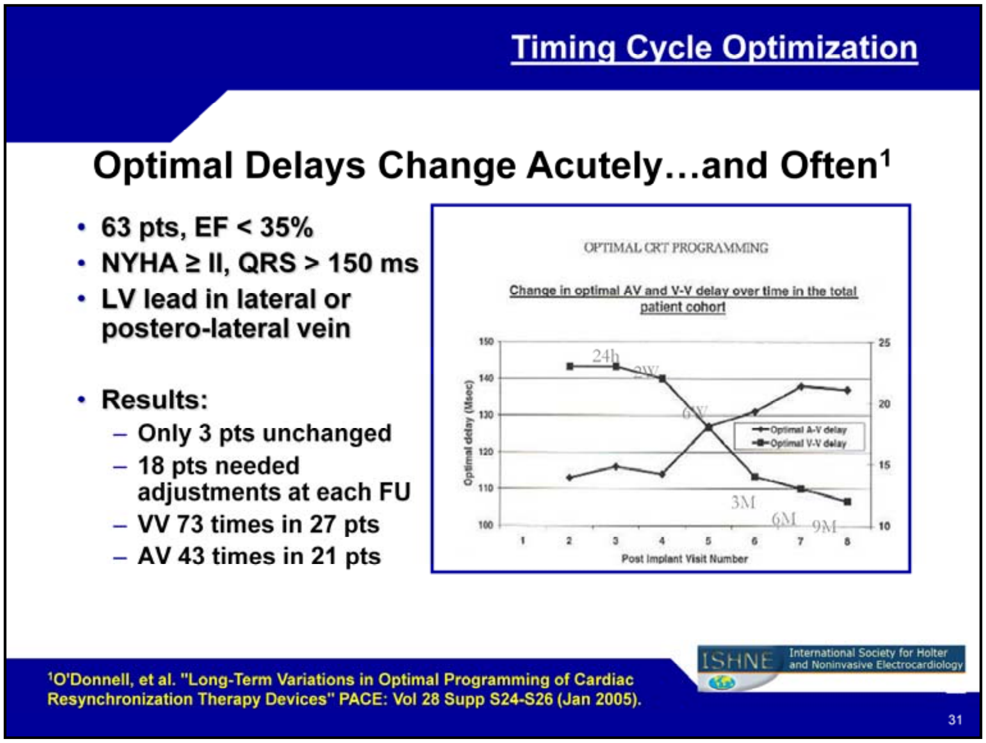


Assuming that LV capture is maintained and the device is functioning properly, QuickOpt is your opportunity to convert non-responders and to improve the outcomes of patients who do respond to CRT therapy



In this study by O'Donnell, appearing in PACE in 2005, you can see that the question of whether timing cycles change over time is answered.

In some patients, the timing cycles began to change in a little as 24 hours and as often as every two to three weeks. As you can see, the VV delays appear to get shorter while the AV delays tend to get longer.

In this group of 63 patients, only three (less than 5%) of the patients were unchanged. 18 patients needed adjustment at every follow up with VV delays being changed 73 times in 27 patients and AV delays being changed 43 times in 21 patients over a 9 month period.

QuickOpt™ Timing Cycle Optimization

- **QuickOpt™ optimization is clinically-proven to correlate with echo based methods:**
  - **Prospective 11-patient pilot study presented at Cardiostim 2004[1]**
  - **Retrospective 61-patient study conducted in the U.S.[2]**
  - **IDE clinical trial with 115 patients conducted in the U.S.[3]**

[1] Meine, et al. "IEGM Based Method for Estimating Optimal VV Delay in Cardiac Resynchronization Therapy." Europace Supplements, Vol. 6, June 2004 (#149/2).
[2] Meine, et al. "An Intracardiac EGM Method for VV Optimization During Cardiac Resynchronization Therapy" *Heart Rhythm Journal 3 (5) May 2006 [abstract AB30-5].*
[3] Porterfield, et al. "Device based intracardiac delay optimization vs. echo in ICD patients (Acute IEGM AV/PV and VV Study)" Europace Vol 8 Supp 1 July 2006 [abstract #6178].

QuickOpt™ Optimization

Study Method[1-3]

- Echo-derived Optimization
  - Aortic VTI measured at several AV and VV delay settings
  - Optimal delay determined by the maximum aortic VTI (Max AVTI)
- SJM IEGM-derived VV Optimization
  - SJM IEGM formula used to determine optimal AV and VV delay
  - Aortic VTI measured at IEGM-derived delay
- Aortic VTI at IEGM-derived VV delay compared to Max AVTI from echo optimization
- Correlation measures how closely IEGM VTI matches echo VTI
- Aortic VTI measures forward flow!

[1] Meine, et al. "IEGM Based Method for Estimating Optimal VV Delay in Cardiac Resynchronization Therapy." Europace Supplements, Vol. 6, June 2004 (#149/2).
[2] Meine, et al. "An Intracardiac EGM Method for VV Optimization During Cardiac Resynchronization Therapy" *Heart Rhythm Journal 3 (5) May 2006 [abstract AB30-5].*
[3] Porterfield, et al. "Device based intracardiac delay optimization vs. echo in ICD patients (Acute IEGM AV/PV and VV Study)" Europace Vol 8 Supp 1 July 2006 [abstract #6178].

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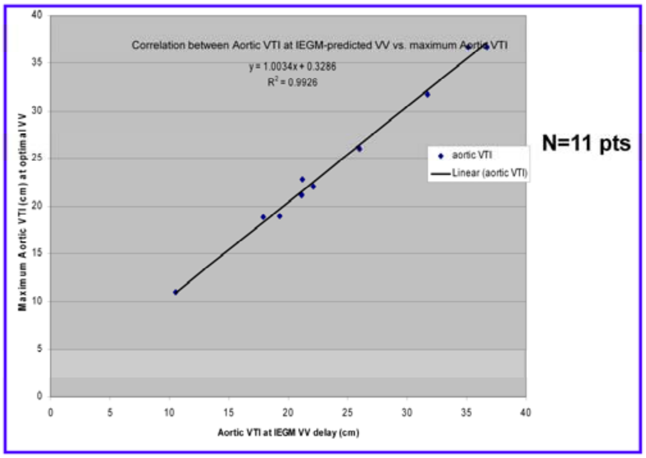
A Pilot Prospective Study - Cardiostim 2004[1]



N=11 pts

[1]Meine, et al. "IEGM Based Method for Estimating Optimal VV Delay in Cardiac Resynchronization Therapy." Europace Supplements, Vol. 6, June 2004 (#149/2).

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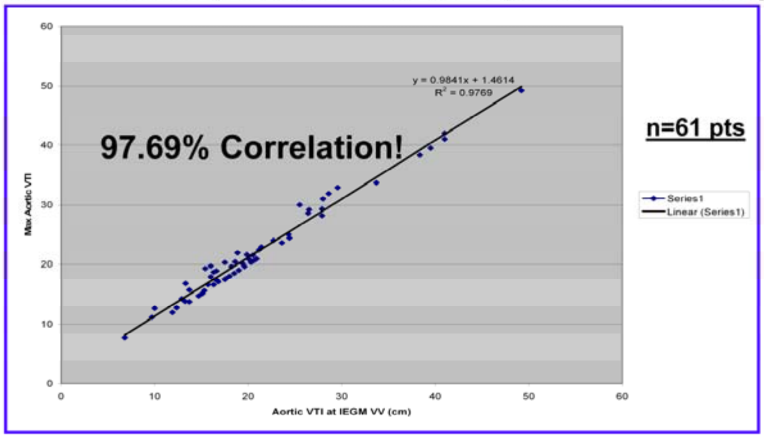
Results of Retrospective IEGM VV Optimization Study[1]



[1]Meine, et al. "An Intracardiac EGM Method for VV Optimization During Cardiac Resynchronization Therapy" Heart Rhythm Journal 3 (5) May 2006 [abstract AB30-5].

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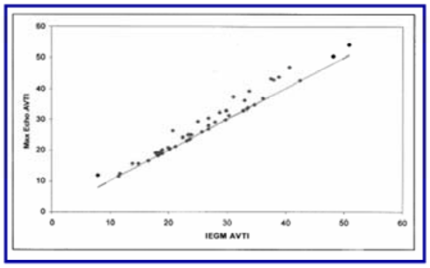
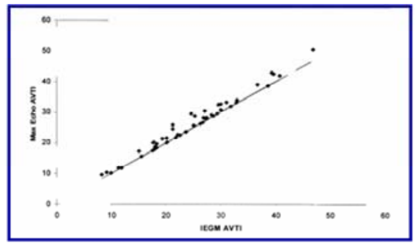
ACUTE IEGM AV and PV (Sensed AV) Study[1]

- **PV Delay Group (n=56)**
  - CCC = 96.1%
- **AV Delay Group (n=56)**
  - CCC = 97.5%

Plot of Max Echo AVTI for the PV Delay on 52 Analyzable Patients with the Identity Line Superimposed



Plot of Max Echo AVTI for the PV Delay on 52 Analyzable Patients with the Identity Line Superimposed



[1]Porterfield, et al. "Device based intracardiac delay optimization vs. echo in ICD patients (Acute IEGM AV/PV and VV Study)" Europace Vol 8 Supp 1 July 2006 [abstract #6178].

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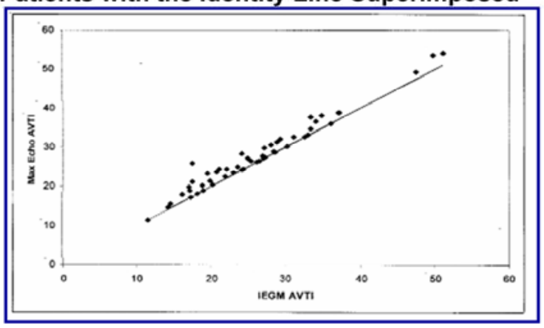
QuickOpt™ Optimization

ACUTE IEGM-CRT VV Study[1]

- **VV Delay Group (n=54)**
  - CCC = 96.6

Plot of Max Echo AVTI for the PV Delay on 52 Analyzable Patients with the Identity Line Superimposed



[1]Porterfield, et al. "Device based intracardiac delay optimization vs. echo in ICD patients (Acute IEGM AV/PV and VV Study)" Europace Vol 8 Supp 1 July 2006 [abstract #6178].

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QuickOpt™ Timing Cycle Optimization

- **QuickOpt™ optimization is clinically-proven to correlate with echo based methods:**
  - **Prospective 11-patient pilot study[1]**
    - 99.2% correlation
  - **Retrospective 61-patient study[2]**
    - 97.6% correlation
  - **Prospective multi-center IDE clinical trial[3]**
    - 96.1% correlation for Sensed AV (PV) delay[3]
    - 97.5% correlation for Paced AV delay[3]
    - 96.6% correlation for VV Delay[3]

Special Caution: Leads in RV Apex and Rt. Atrial Appendage, other lead locations have not yet been studied!

[1] Meine, et al. "IEGM Based Method for Estimating Optimal VV Delay in Cardiac Resynchronization Therapy." Europace Supplements, Vol. 6, June 2004 (#149/2).
[2] Meine, et al. "An Intracardiac EGM Method for VV Optimization During Cardiac Resynchronization Therapy" *Heart Rhythm Journal 3 (5) May 2006 [abstract AB30-5].*
[3] Porterfield, et al. "Device based intracardiac delay optimization vs. echo in ICD patients (Acute IEGM AV/PV and VV Study)" Europace Vol 8 Supp 2006 [abstract #6178].

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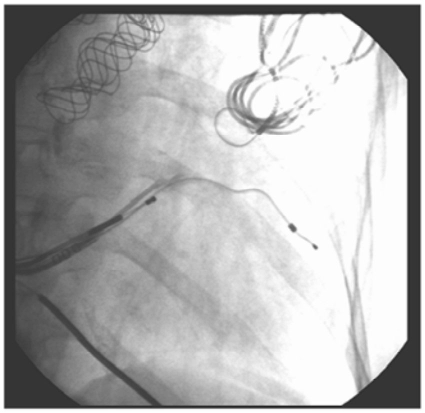
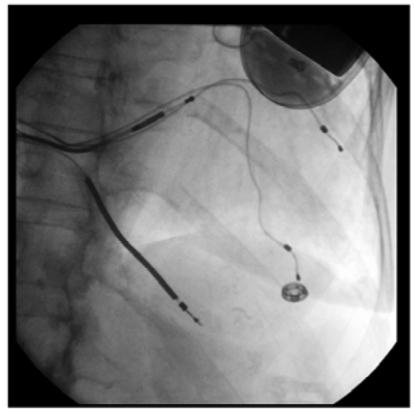
What if non-invasive adjustments do not improve response rate?

- **Detailed echo study (TDI, strain, speckle) looking for area of latest contraction**
- **Placement of a second lead in the area of latest contraction**
  - **Transvenous if possible**
  - **Epicardial**

Addition of a second LV lead via the CS



Baseline



Following revision

Courtesy – George Eisinger, FCE – SJM (2007)

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Summary: CRT Non-responders

- If patient presents with exacerbation of CHF - pacing system malfunction is now part of differential diagnosis
- Baseline 12 lead ECGs provide valuable templates for initial screening
- Change in QRS morphology or inhibition of pacing system suggests a problem necessitating further evaluation and may allow a return of CHF symptoms

Summary (continued): CRT non-responders

- For patients who do not respond to CRT or who, after a period of response, deteriorate

- Keep refractory periods as short as possible and MTR as high as possible

- Optimize AV and VV intervals
  - Echo-Doppler
  - QuickOpt (can be done at each visit)

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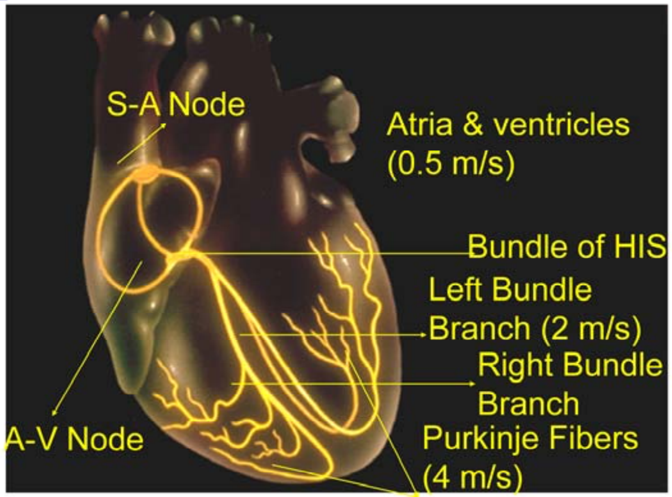
Supplemental Slides on QuickOpt™

Electrical Conduction Pathway



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Key Principles

- Mitral valve closure can be estimated by measuring the interatrial conduction time (P-wave duration)[1]
- Onset of isovolumic contraction can be measured using the peak of the R wave[2]
- Interventricular conduction delays can be measured by evaluating simultaneous RV & LV IEGMs and measuring the time between the peaks of the R waves[3]

[1]Worley, et.al "Optimization of cardiac resynchronization: left atrial electrograms measured at implant eliminates the need for echo and identifies patients where AV optimization is not possible" *Journal of Cardiac Failure Aug. 2004 Vol. 10, Issue 4, Pg S62.*

[2]Koglek, et al. "Eine einfache methode zur bestimmung des AV-intervalls bei zweikammerschrittmachern." Herzschrittmacherther Eleklrophysiol 2000; 11:244-253.

[3]Meine, et al. "IEGM Based Method For Estimating Optimal VV Delay in Cardiac Resynchronization Therapy" Europace Supplements, Vol. 6, June 2004 (#149/2).

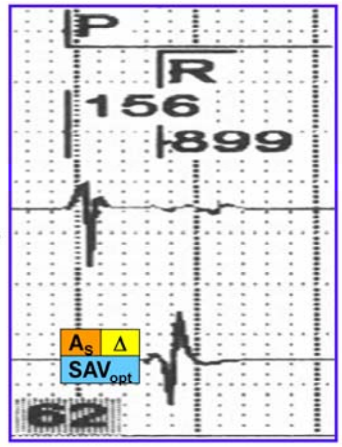
Goals

- Characterize interatrial conduction patterns in order to:
  - Maximize preload
  - Allow proper timing of mitral valve closure
- Characterize intrinsic and paced interventricular conduction patterns so that:
  - Pacing stimuli and the resultant LV & RV conduction (paced wave fronts) meet midway between the two stimulation sites

Electronic Optimization of Sensed AV Delays

The IEGM estimates inter-atrial conduction delay by measuring the width of the P wave. The QuickOpt™ algorithm utilizes this measurement to calculate the optimal sensed and paced AV delays, with the goal maximizing preload and allowing for proper timing of mitral valve closure.

The optimal sensed AV delay is the sum of A_S (sensed P wave) and Δ (an added interval that allows for ventricular filling). The interval added is from 30 to 60 ms, depending on the measured P Wave. A short P wave would have a longer interval added, while a longer P wave would have a shorter interval added.



$$SAV_{opt} = A_S + \Delta$$

$$30 \leq \Delta \leq 60$$

SAV is Sensed AV Delay
A_S is sensed P wave
Δ is added interval

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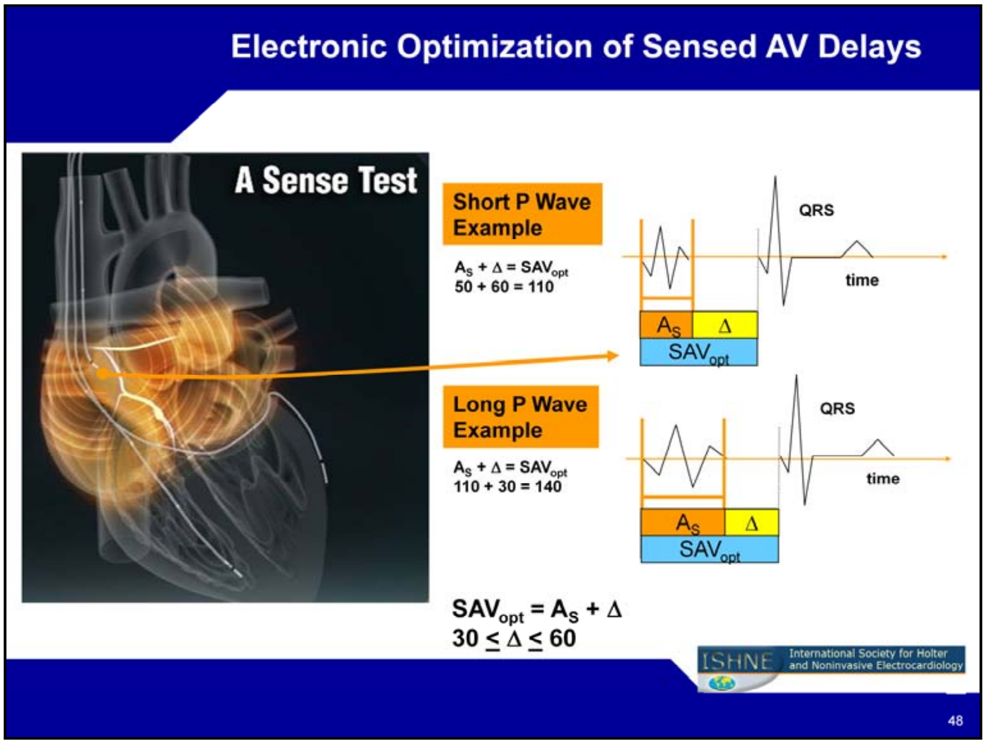
Electronic Optimization of Sensed AV Delays
A Sense Test
Short P Wave Example
$A_S + \Delta = SAV_{opt}$
$50 + 60 = 110$
QRS
time
A_S
Δ
SAV_{opt}
Long P Wave Example
$A_S + \Delta = SAV_{opt}$
$110 + 30 = 140$
QRS
time
A_S
Δ
SAV_{opt}
$SAV_{opt} = A_S + \Delta$
$30 \leq \Delta \leq 60$
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Electronic Optimization of Paced AV Delays

The optimal paced AV delay is the sum of A_S (sensed P wave) and Δ (an added interval that allows for ventricular filling). The interval added is from 80 to 110 ms, depending on the measured P Wave. A short P wave would have a longer interval added, while a longer P wave would have a slightly shorter interval added.

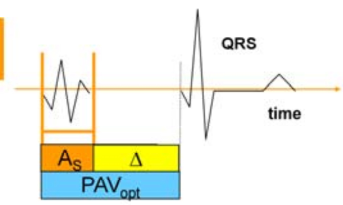
$$PAV_{opt} = A_S + \Delta$$

$$80 \leq \Delta \leq 100$$

PAV is Paced AV Delay
A_S is sensed P wave
Δ is added interval

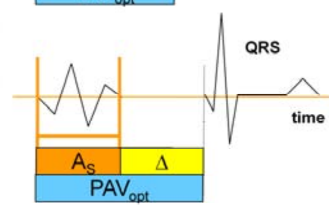
Short P Wave Example

$A_S + \Delta = PAV_{opt}$
$50 + 110 = 160$



Long P Wave Example

$A_S + \Delta = PAV_{opt}$
$110 + 80 = 190$



$$PAV_{opt} = A_S + \Delta$$
$$80 \leq \Delta \leq 110$$

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V-V optimization

Paced and sensed tests are performed to characterize the conduction properties of the ventricles. The goal is to time the right and left ventricular activation so that the paced wavefronts meet near the ventricular septum. The V Sense test measures the intrinsic interventricular delay (Δ). The RV Pace and LV Pace tests are used to measure the difference in interventricular conduction delays (ε). All of these measurements are used to optimize the VV Delay (Interventricular Pace Delay).

$$VV_{opt} = 0.5 \times (\Delta + \varepsilon)$$

Δ is related to the intrinsic depolarization
ε is a correction term depending on wave front velocity

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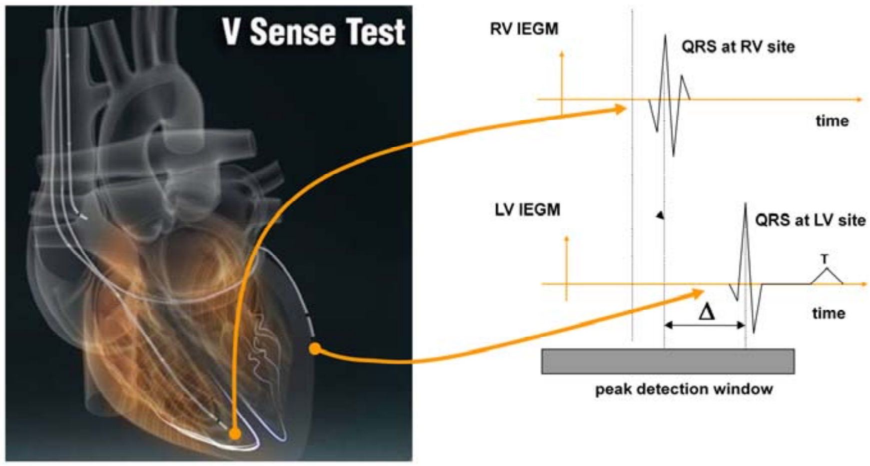
V-V optimization: Intrinsic depolarization term (Δ)



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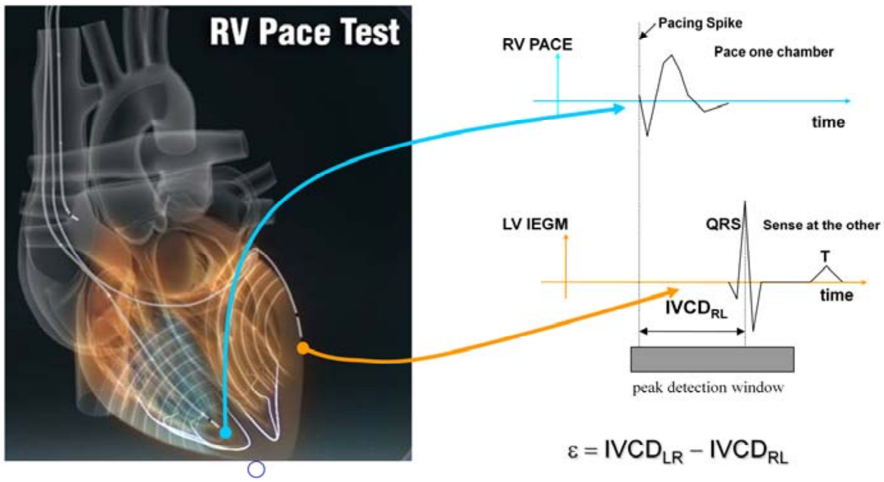
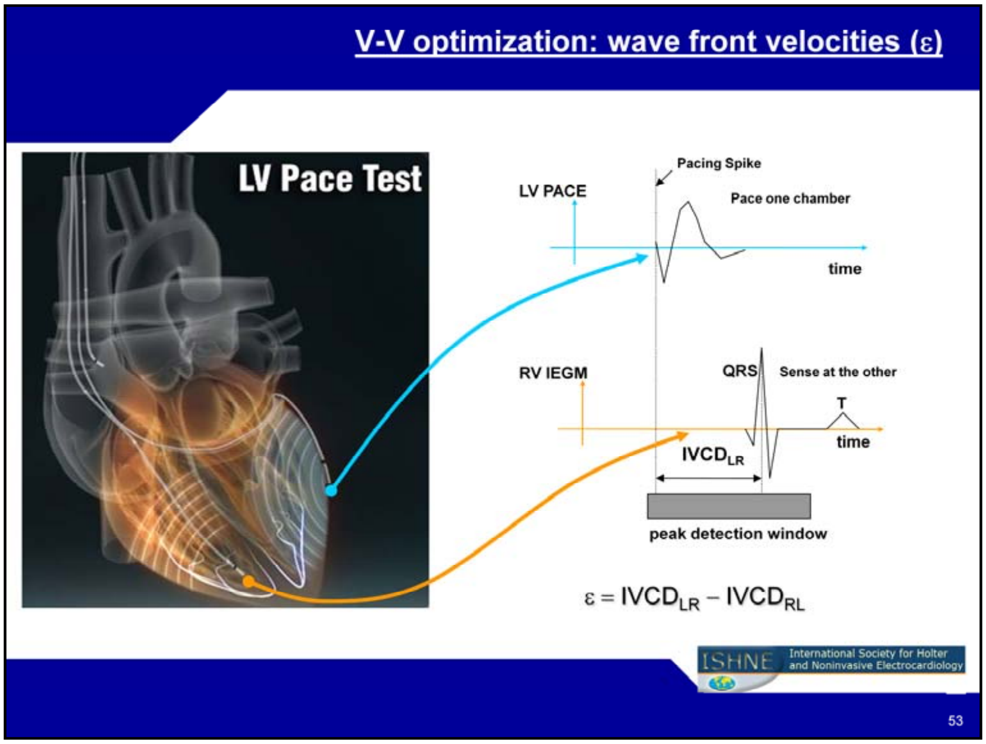
V-V optimization: wave front velocities (ε)



$$\varepsilon = IVCD_{LR} - IVCD_{RL}$$



V-V optimization: wave front velocities (ε)
LV Pace Test
Pacing Spike
LV PACE
Pace one chamber
time
RV IEGM
QRS
Sense at the other
T
time
$IVCD_{LR}$
peak detection window
$\varepsilon = IVCD_{LR} - IVCD_{RL}$
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$VV_{opt} = 0.5 \times (\Delta + \varepsilon)$

Δ is related to the intrinsic depolarization
ε is a correction term depending on wave front velocity

Example:

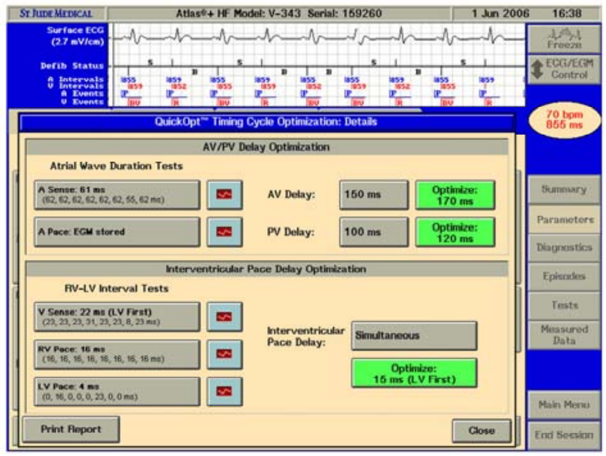
Δ=40ms (RV sensed before LV)

IVCD_LR=60ms IVCD_RL=50ms
In this case, it takes longer to depolarize from Left to Right
ε = IVCD_LR – IVCD_RL = 60 – 50 = 10 ms

VVopt = 0.5 x (Δ + ε) = 0.5 x (40 + 10) = 50/2= 25
We get: LV first, V-V=25ms

How QuickOpt™ Optimization Works

QuickOpt™ Optimization electrically characterizes the conduction properties of the heart and uses an innovative formula to calculate the optimal AV and VV delays.



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How QuickOpt™ Optimization Works

AV Optimization:

1. QuickOpt™ optimization measures the total P-wave duration of eight IEGM events for the A-Sense test

2. Measured P-wave durations are averaged

3. The QuickOpt™ algorithm uses an innovative formula to calculate the optimal AV and PV delays
   - A variable delta is added to the measured P-wave duration
   - Delta added is dependent on the measured events

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How QuickOpt™ Optimization Works

VV Optimization:

1. QuickOpt™ optimization measures eight IEGM events for each of the V Sense, RV Pace and LV Pace tests.
   - V Sense – measures intrinsic interventricular delay
   - RV Pace – measures conduction speed from right to left
   - LV Pace – measures conduction speed from left to right

2. Measurements from each test are averaged

3. The QuickOpt™ algorithm uses an innovative formula to calculate the optimal VV delay
   - Difference in conduction speeds between RV Pace and LV Pace tests used as correction term for the intrinsic delay measurement

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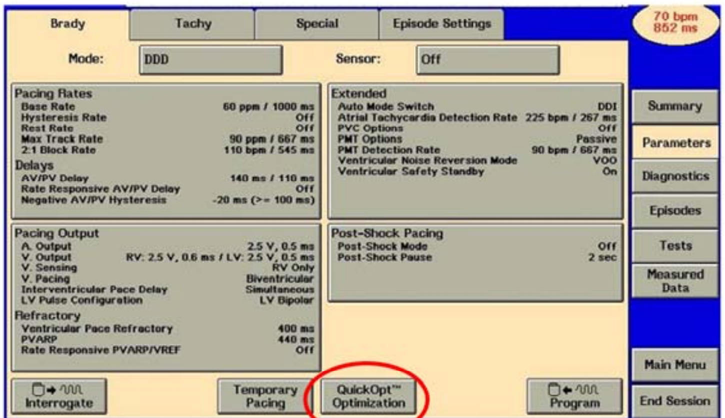
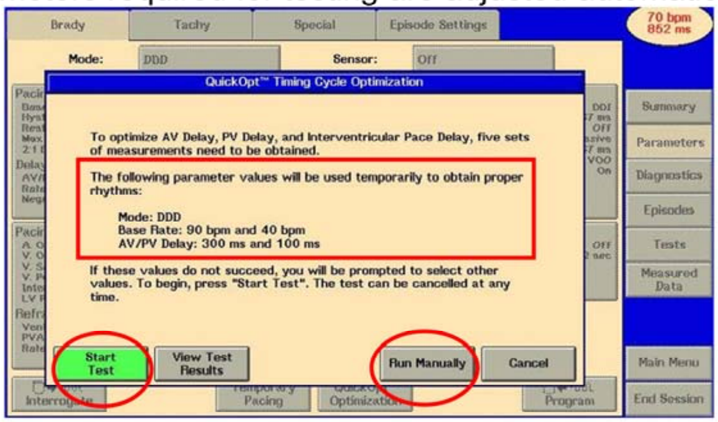
QuickOpt™ – Brady Parameters Screen

QuickOpt™ Optimization is found on the brady parameters screen



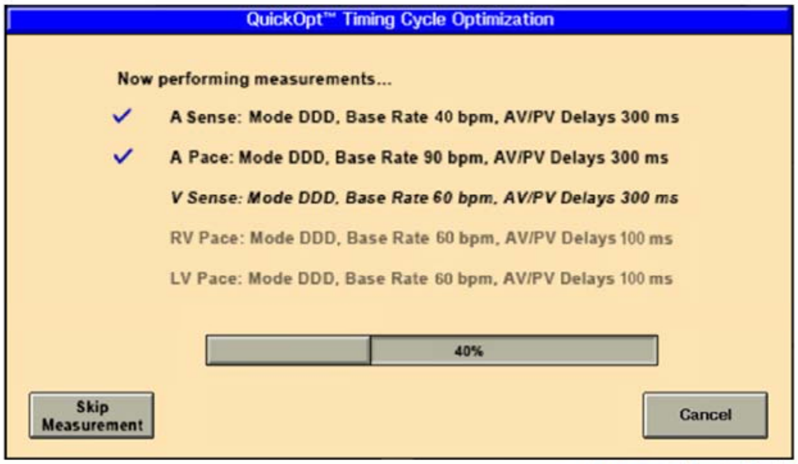
QuickOpt™ – Start Test Screen

Tests can be run automatically or manually
Parameters required for testing are adjusted automatically



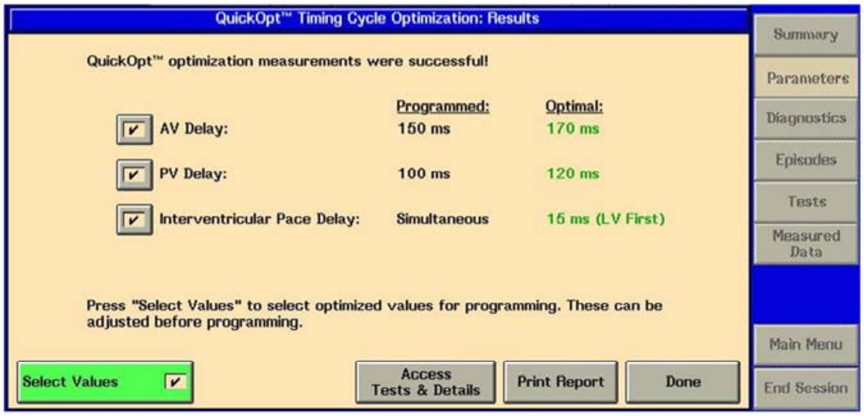
QuickOpt™ – Test in Progress

Automatic testing performs all relevant tests



QuickOpt™ – Results

Results are displayed in about a minute[1]



[1]AV Optimization in dual-chamber devices take approximately 30 seconds.
AV and VV Optimization in CRT-D devices take approximately 90 seconds.

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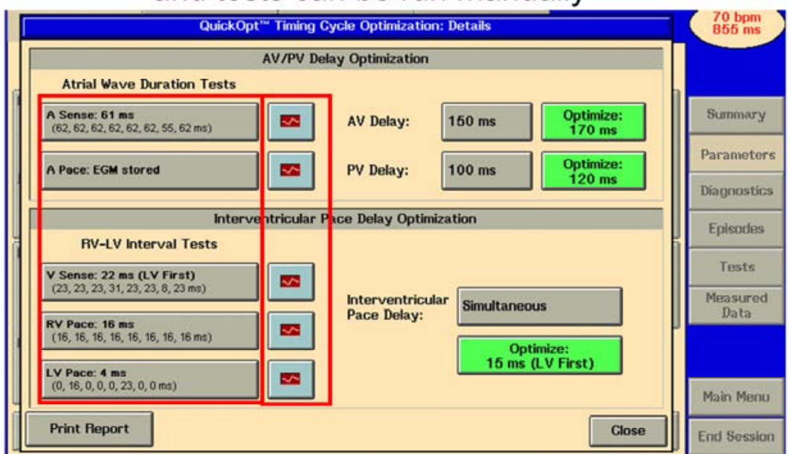
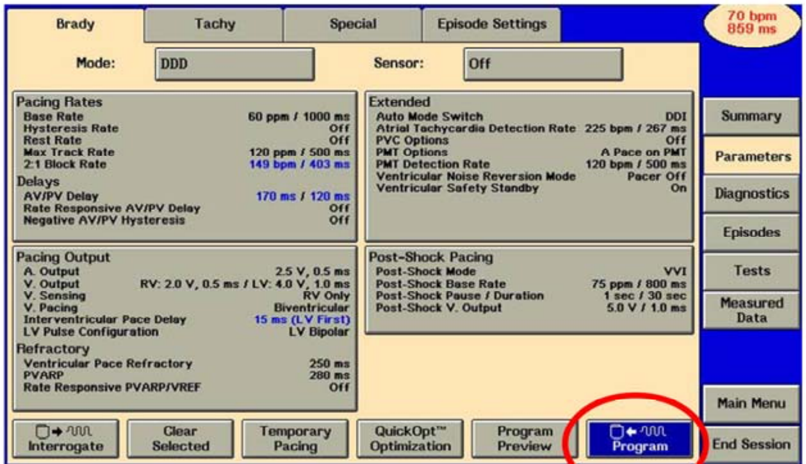
QuickOpt™ – Details

Test details and electrograms can be viewed individually and tests can be run manually



QuickOpt™ – Program

Once values are determined, programming is easy



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QuickOpt™ Timing Cycle Optimization

Additional Data
Supporting the Effectiveness
of Timing Cycle Optimization

Additional Data Supporting the Effectiveness of Timing Cycle Optimization

- 45 patients classified as "non-responders" following implant
- A-V & V-V delay optimized using Echo TDI
- 85% of patients improved significantly after optimization as shown by QoL and EF

Chan et al. "Tissue Doppler Guided Optimization of A-V and V-V Delay of Biventricular Pacemaker Improves Response to Cardiac Resynchronization Therapy in Heart Failure Patients" J of Cardiac Failure 2004; 10, 4 (suppl.): S72 (abstract 199).

Additional Data Supporting the Effectiveness of Timing Cycle Optimization

- 41 HF patients with CRT device implantation
- Echo w/ TT & pulsed Doppler tissue imaging performed
  - Pre-CRT implantation
  - Post-CRT implantation w/ AV Optimization
  - 3 months post AV & VV optimization
- Results (After 3 mos. Optimized Therapy)
  - NYHA functional class improved (1.7 ± 0.6 vs. 3.2 ± 0.5 $p<0.01$)
  - QoL scores Improved (24 ± 14 vs. 45 ± 17 $p<0.01$)
  - Exercise Capacity Improved (389m ± 65m vs. 264m ± 73m $p<0.05$)
  - LVEF Increased (34% ± 6% vs. 28% ± 6% $p=0.035$)
  - 85% of patients were optimized at a V-V delay other than zero
- Individually optimized sequential CRT provided a significant hemodynamic improvement compared with simultaneous CRT

Bordachar et al. "Echocardiographic Parameters of Ventricular Dyssynchrony Validation in Patients with Heart Failure Using Sequential Biventricular Pacing" *JACC 2004 Dec 7; 44 (11): 2157-2165.*

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Additional Data Supporting the Effectiveness of Timing Cycle Optimization

	Simultaneous CRT	Optimized V-V	% Improvement	P value
VTI (mm)	122 ± 31	154 ± 42	26%	<.001
LVFT (ms)	404 ± 102	472 ± 110	17%	.001
LVFT/HR (ms/bpm)	6.0 ± 2.0	7.1 ± 2.2	18%	.001
IVD	35 ± 33	13 ± 25	63%	.013
VD	51 ± 34	34 ± 18	33%	.010
SUM dyssynchrony (ms)	86 ± 49	47 ± 31	45%	.002

Non-responder rate at 6 months = 10%

Vanderheyden, et al. "Tailored echocardiographic interventricular delay programming further optimizes left ventricular performance after cardiac resynchronization therapy"
Heart Rhythm, Volume 2, No. 10, Oct 2005 1066-1072.

Additional Data Supporting the Effectiveness of Timing Cycle Optimization

53 patients

- **41 patients in sinus rhythm**
  - 26 patients w/ischemic cardiomyopathy (IC)
  - 15 patients w/idiopathic dilated cardiomyopathy (IDC)
- **12 patients in AF (23%)**

Maximum dP/dt measured

- **Baseline (prior to CRT implant)**
- **Simultaneous CRT pacing**
- **V-V Optimized**

	n	Baseline	Simultaneous	% Increase	Optimized V-V	% Increase
AF	12	941 ± 240	1,142 ± 207	21	1,180 ± 196	25
Sinus Rhythm	41	814 ± 178	952 ± 271	17	1,027 ± 297	26
IDC	15	754 ± 220	890 ± 245	18	955 ± 267	27
IC	26	846 ± 249	987 ± 232	17	1,069 ± 252	26
All Patients	53	842 ± 231	995 ± 247	18	1,061 ± 259	26

Van Gelder, et al. "Effect of Optimizing the VV Interval on Left Ventricular Contractility in Cardiac Resynchronization Therapy" *Am J Cardiol 2004; 93, 1500-1503*

Additional Data Supporting the Effectiveness of Timing Cycle Optimization

In the van Gelder study, Simultaneous-CRT was compared to Sequential-CRT measuring LV dP/dt as the acute endpoint[1]

Rhythm	Disease	Baseline	Simul-taneous	Sequential	Relative Improve-ment	Simul-taneous	LV First	RV First
Sinus 15 pts	DCM	754+220	18%	27%	48%	4	10	1
Sinus 26 pts	ICM	846+249	17%	26%	58%	1	25	0
AF 12 pts		941+240	21%	25%	17%	2	9	1

87% of all patients were optimized at a V-V delay other than simultaneous.

[1]van Gelder, et al. Effect of optimizing the V-V interval on LV contractility in cardiac resynchronization therapy. Am. J Cardiology 2004, vol. 93: 1500-1503.

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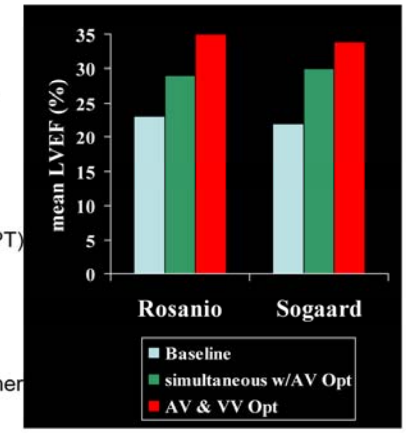
Additional Data Supporting the Effectiveness of Timing Cycle Optimization

- **Both Studies:**
  - Single center studies of consecutive patients with NYHA III/IV HF, QRS >130
  - Trans-mitral flow optimized with AV delay post implant
- **Rosanio, et al.** AHA Abstract; 1618 (2003)
  - N=22
  - V-V Delay of 0 for first 2 months
  - Echo based optimization of V-V delay (OPT) at 2 months
- **Sogaard, et al.** Circ. 2002; 106:2078-84
  - N=20
  - Optimal V-V Delay based on Echo TDI
  - Acute data shown. After 3 mo. LVEF further improved to 39% (P<0.01)



Additional Data Supporting the Effectiveness of Timing Cycle Optimization

Bordachar, Rosanio and Sogaard studied SQ-CRT comparing EF, NYHA and 6 MWT[1-3]

Author	# pts	Baseline: % EF	Baseline: NYHA	Baseline: 6 MWT	3 months: % EF	3 months: NYHA	3 months: 6 MWT	Optimal Sequence of Activation: LV	Optimal Sequence of Activation: RV	Optimal Sequence of Activation: Sim
Bordachar Improvement	41	28%	3.2	264 m	34% 21.4%	1.7 46.9%	369 m 39.8%	25	6	10
Rosanio Improvement	22	22.5 %	3.4	349 m	35% 55.5%	1.9 44.1%	441 m 26.4%	18	1	3
Sogaard Improvement	20	22.4 %	3.45	222 m	38% 30%	1.9 45%	401 m 80%	9	11	

84% of all patients were optimized at a V-V delay other than simultaneous.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