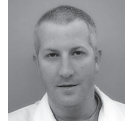


QUICKOPT™ TIMING CYCLE OPTIMIZATION

Clinicians' Perspectives:

Interviews with Avi Fischer, M.D., F.A.C.C., Marie-Noelle Suzanne Langan, M.D., F.R.C.P, F.A.C.C., Luigi Padeletti, M.D., Eugene Rhim, M.D.



Four physicians provide insight about their use of St. Jude Medical's QuickOpt™ Timing Cycle Optimization feature.

How would you describe QuickOpt™ Timing Cycle Optimization?

Dr. Fischer: It is a simple tool for individualizing CRT settings based on the individual characteristics of the patient. It is easy to use, quick and can be repeated as needed.

Why did you choose to use QuickOpt Timing Cycle Optimization?

Dr. Rhim: QuickOpt is the only available one-touch CRT optimization algorithm that has been proven to be as effective as echocardiogram-guided optimization.

What benefits have you experienced?

Dr. Langan: The real benefit is that it is a programmable response for each individual patient that allows, in a very short period of time, – a minute to two minutes – a clinician to investigate what would be the best parameters and actually apply those parameters so that the cardiac output is maximized.

Dr. Fischer: We saw some improved patient outcomes, not just clinical but psychological, as patients feel that they have significant adjustments made to their complex devices when we discuss what we are doing with QuickOpt.

How much time does it take to utilize QuickOpt Timing Cycle Optimization during a patient follow-up visit?

Dr. Langan: It takes about a minute to two minutes to program — to interrogate it, find out the parameters and then deliver those parameters to the device.

Dr. Rhim: The QuickOpt algorithm allows for measurement of intracardiac intervals and suggested programming changes within a minute or two.

Has QuickOpt Timing Cycle Optimization streamlined follow-up visits and are patients experiencing any benefits?

Dr. Rhim: QuickOpt has definitely streamlined follow-up visits. Many electrophysiologists do not have echocardiograms in their offices, and therefore echo-guided optimization has to be scheduled separately in different locations. In the past, QuickOpt has improved patients' symptoms post implant. Currently, I use QuickOpt during initial implantation with excellent results.

Dr. Langan: The benefit to the patient is really that it is very quick. Beyond that, it is standardized so that it is a very efficient and successful way to reprogram the device. This allows patients to be interrogated by the Merlin™ Patient Care System and programmed for what fits them best. That is in contrast to what we used to have to do, which was to take pictures of that individual and change the parameters and re-picture, which would often take 45 minutes to two hours, as well as require you to be in another lab to do it.

How long have you been using QuickOpt Timing Cycle Optimization in your practice?

Dr. Padeletti: QuickOpt has been used in our hospital since its launch in the Italian market, or two years. We were involved in the preliminary evaluation and we became early adopters of this method.

Within your practice, what percentage of your CRT patients are non-responders?

Dr. Padeletti: In our experience, we found that 40 percent of CRT patients are non-responders; the main causes are related to patient selection, technical issues or programming issues.



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Has QuickOpt™ Timing Cycle Optimization made an impact with your CRT non-responders?

Dr. Rhim: Yes, we have had several patients with initial implants who have been able to avoid lengthy echo-guided optimization with excellent clinical success.

Do you believe QuickOpt Timing Cycle Optimization is as effective as echo to optimize AV and VV delays?

Dr. Padeletti: QuickOpt optimization is clinically proven to be as effective as echo-based optimization. We evaluated the performance of QuickOpt using Real-Time 3-D Echo and we found excellent results, with a significant improvement in ejection fraction, stroke volume, ejection time, filling time, and myocardial performance index.

During your patient follow-up visits, how frequently do you utilize QuickOpt Timing Cycle Optimization?

Dr. Padeletti: We found that the QuickOpt feature is so easy and effective that now it is used for 100 percent of patient follow-up visits.

What impact has QuickOpt Timing Cycle Optimization made on your practice, in either practice efficiency or patient outcomes?

Dr. Rhim: QuickOpt has mainly impacted our practice in terms of patient convenience. Since our office is 100 percent electrophysiology and does not use echocardiograms, echo-guided optimization requires referral to an imaging center.

Do you believe QuickOpt could be considered “standard of care” for timing cycle optimization?

Dr. Padeletti: QuickOpt represents an important step forward in timing cycle optimization, being characterized by automaticity, simplicity and quickness. It can also be applied to all patients and not only to a restricted category of them. Other clinical studies are currently being performed; if their results are validated, QuickOpt should be considered as a standard optimization method.

Guest Clinicians

Avi Fischer, M.D., F.A.C.C., is Director of the Pacemaker and Defibrillator Therapy Section of Electrophysiology at Mount Sinai Medical Center in New York City. His current faculty appointments include Assistant Professor of Medicine and Director of the Medical Student Elective in Cardiology, both at Mount Sinai School of Medicine. Dr. Fischer is a frequently invited lecturer, is actively involved in clinical trials, and has authored many peer-reviewed journal articles.

Marie-Noelle Suzanne Langan, M.D., F.R.C.P., F.A.C.C., and Eugene Rhim, M.D., have a successful private EP practice at Manhattan Cardiac Arrhythmia Consultants in New York City. Both are actively involved in clinical post-market research studies to further enhance the advancement of device technology.

Luigi Padeletti, M.D., is Professor of Cardiology at the University of Florence, Italy. He is also Director of the Post Graduate School of Cardiology and Director of the EP Lab Faculty of Medicine, both at the University of Florence. Dr. Padeletti has extensive publication experience and frequently speaks at major scientific meetings.

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Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

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