

Longevity of Implantable Cardioverter Defibrillators: A Comparison Among Manufacturers and Over Time

KEY TAKEAWAYS

First, a new independent study conducted with data from two large European centers confirms Boston Scientific as the longevity leader across VR, DR, and CRT ICDs. Second, this is the largest study to investigate multiple manufacturer ICD longevity to date and the first study showing our advantage across the ICD platform. Third, this is the eighth study supporting our longevity advantage in CRT-Ds.

STUDY DESIGN

- 3,436 patients, a total of nearly 5,000 devices (4,881) with a fairly equal distribution across the four largest manufacturers : St Jude Medical 31.5%; Biotronik 25.0%; Boston Scientific 19.4%; Medtronic 18.4%; Sorin 3.2%; Cameron Health 2.0%; Intermedics 0.4%
- Devices implanted over nearly 20 years, March 1994 to January 2014, with a median follow-up of 53 months
- 1,339 ICDs were replaced for ERI
- Study includes representation of both early and modern devices—cutoff of 2006

PRIMARY ENDPOINTS

- Time from implant to ERI
- All other reasons for device removal were excluded (upgrade, infection, advisory) from this analysis

DESCRIPTION

Study aim: Determine device longevity using very large databases of two teaching hospitals with a high number of implants and replacements and a homogeneous distribution among manufacturers.

- St. Jude Medical: 1,539 devices (31.5%) with 295 replacements
- Biotronik: 1,219 devices (25%) with 298 replacements
- Boston Scientific: 947 devices (19.4%) with 311 replacements
- Medtronic: 898 devices (18.4%) with 356 replacements

IMPORTANT OUTCOMES

- Post-2006, Boston Scientific was the overall leader in VR, DR, and CRT-D device longevity—lasting significantly longer than all other manufacturers
- Boston Scientific device survival at 6 years was 100% for VR, 93.3% for DR and 97.6% for CRT-Ds, compared to Medtronic device survival which was 85.9% for VR, 76.5% for DR and 46.3% for CRT-D

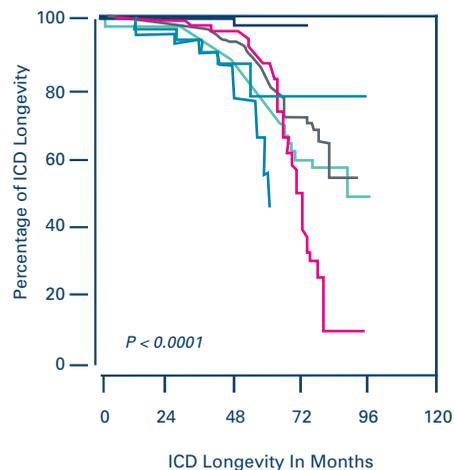
Get the facts and cut the risk.

Boston Scientific offers ICDs and CRT-Ds designed to be the world's longest lasting—with up to 80% more battery capacity than other available models.³ Better CRT-D longevity could mean a reduced risk of exposure to complications and infections for your patients.^{4,5,6}

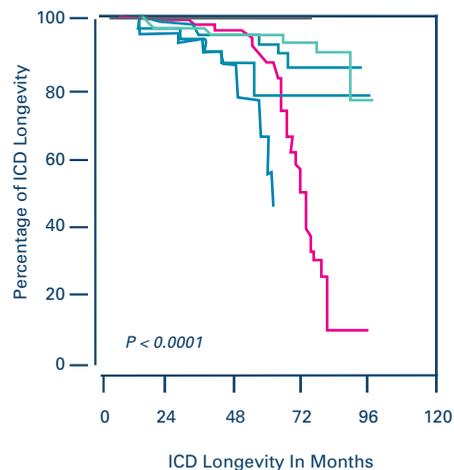
For more information, visit www.devicelongevity.com.

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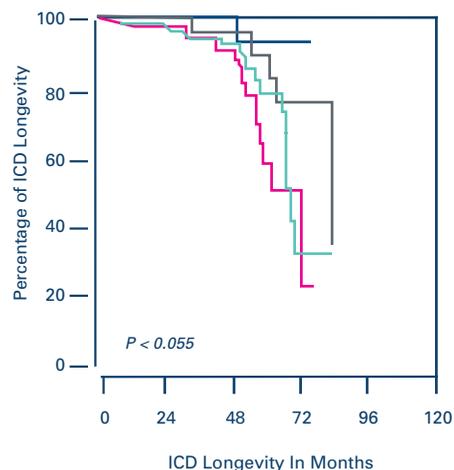
Overall Longevity Comparison Post 2006



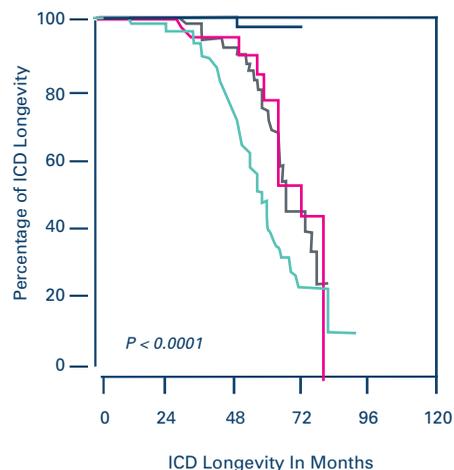
VVI Longevity Comparison Post 2006



DDD Longevity Comparison Post 2006



CRT-D Longevity Comparison Post 2006



Devices Implanted Post 2006

Device Type	BSC Device Survival at 6 years	MDT Device Survival at 6 years	SJM Device Survival at 6 years	BIO Device Survival at 6 years
VR	100%	85.9%	92.6%	45.6%
DR	93.3%	76.5%	35.3%	26.3%
CRT-Ds	97.6%	46.3%	26.5%	44.9%

Even more remarkable was that the survival for BSC VR, DR and CRT was identical between 5 and 6 years (VR = 100%, DR = 93.3 %, CRT-D = 97.6%). All other manufacturers had increasing rates of ERI for all device types (except St. Jude VR which stayed the same).

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INCLUSION CRITERIA

- Replacement due to battery depletion was performed for 1,339 ICDs. Patient survival at 5 years was 80.1 %

EXCLUSION CRITERIA

- Replacements due to upgrade, advisory, or removal for infection were censored at the date of the procedure
- Devices out of service due to patient death or transplant were censored at the date of these events

PRINCIPLE INVESTIGATORS

Simon von Gunten, Beat A. Schaer, Sing-Chien Yap, Tamas Szili-Torok, Michael Kuhne, Christian Sticherling, Stefan Osswald, and Dominic A.M.J. Theuns

¹ Alam M, Munir B, Rattan R, Flanagan S, Adelstein E, Jan S, Saba S. Battery Longevity in Cardiac Resynchronization Therapy Defibrillators. 2013; Europace (2013) doi: 10.1093/europace/eut301. First published online: October 6, 2013. Kaplan Meier curves depicting survival of CRT devices free from battery depletion by device manufacturer. Battery Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators is an independent, single-center, retrospective observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from January 1, 2008 to December 31, 2010 at University of Pittsburgh Medical Center hospitals. The initial study population included 746 patients; 94 were excluded at the onset because they were lost to follow-up within a month of implant, 6 others were excluded because they had a Biotronik CRT-D and that number of devices precludes meaningful comparison.

² Survival rate calculated using device replacements for battery depletion as indicated by ERI.

CRT-D Systems from Boston Scientific – DYNAGEN™ EL ICD, DYNAGEN™ MINI ICD, INOGEN™ EL ICD, INOGEN™ MINI ICD, ORIGEN™ EL ICD, ORIGEN™ MINI ICD

INDICATIONS AND USAGE

Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

CONTRAINDICATIONS

Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.

WARNINGS

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias.)

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks /pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.
(Rev A)

CRT-D Systems from Boston Scientific – DYNAGEN/INOGEN/ORIGEN

INDICATIONS AND USAGE

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:

Moderate to severe heart failure (NYHA Class III-IV) with EF \leq 35% and QRS duration \geq 120 ms; or left bundle branch block (LBBB) with QRS duration \geq 130 ms, EF \leq 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

CONTRAINDICATIONS

There are no contraindications for this device.

WARNINGS

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Do not kink, twist, or braid the lead with other leads. Do not use defibrillation patch leads with the pulse generator system. Do not use this pulse generator with another pulse generator. Ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. Once the PTM feature has been triggered and the magnet response set to Inhibit therapy the patient should not reapply the magnet. For DF4–LLHH or DF4–LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, hospital and medical environments, home and occupational environments, environmental and medical therapy hazards, follow-up testing, explant and disposal, supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks /pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

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(Rev A)

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