# Original Articles

# Automatic Remote Monitoring of Implantable Cardioverter-Defibrillator Lead and Generator Performance
## The Lumos-T Safely RedUceS RouTine Office Device Follow-Up (TRUST) Trial

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*Background*—Monitoring performance of implantable cardioverter-defibrillator (ICD) generators and leads is important. Methods available are with in-person evaluations or by automatic remote home monitoring (HM). These were prospectively evaluated and compared in the TRUST trial. The HM technology tested performed daily self-checks and databasing with rapid event notifications for out-of-range (including asymptomatic) conditions.

*Methods and Results*—Patients (n=1339) were randomly assigned after ICD implant 2:1 to HM or to conventional groups. Both groups underwent scheduled checks every 3 months and were followed for 15 months. In HM, in-person office visits were scheduled at 3 and 15 months. At 6, 9, and 12 months, HM only was used with subsequent office visits if necessary. Between these time points, ICDs triggered event notifications for system integrity problems. Patients randomly assigned to conventional follow-up were evaluated with office visits only. HM and conventional patients were similar (age, 63.3±12.8 versus 64.0±12.1 years; 72.0% versus 73.1% male; New York Heart Association II class, 55.9% versus 60.4%; left ventricular ejection fraction, 29.0±10.7% versus 28.5±9.8%; coronary artery disease, 64.8% versus 71.7%; primary prevention, 72.2% versus 73.8%; DDD devices, 57.8% versus 56.6%). Four patients crossed over from conventional to HM because of advisories. Scheduled checks were more successfully accomplished in HM (92.7% versus 89.2% in conventional, $P<0.001$). Sixty-two device-related events (53 in HM versus 9 in conventional) were observed in 46 patients (40 [4.4%] in HM versus 6 [1.39%] in conventional, $P=0.004$). Forty-seven percent were asymptomatic. HM detected generator and lead problems earlier (HM versus conventional: median, 1 versus 5 days; $P=0.05$). A total of 20 device problems (eg, lead fracture, elective replacement indicators) requiring surgical revision (0.012 per patient-year) were found, 15 in HM and 5 in the conventional groups. Other events were managed nonsurgically (eg, reprogramming, initiation of antiarrhythmics).

*Conclusions*—ICD lead and generator malfunction was infrequent and often asymptomatic. Only a minority of detected events required surgical intervention. Automatic HM enhanced discovery, permitted prompt detection, and facilitated management decisions. Longitudinal parameter trending, with component function evaluated daily by remote monitoring, may enable long-term performance assessment.

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**Key Words:** defibrillators ■ monitoring ■ follow-up ■ remote monitoring

The implantation of cardiac electronic devices has increased exponentially over the last decade in response to widening indications.[1] Assessment of post–implant system performance is a recognized responsibility for both physicians and industry (stated in position statements[2–4]) but is challenging in view of increasing volume and device complexity. Recent advisories have heightened awareness for the need for intensive surveillance mechanisms. Remote monitoring may satisfy these difficult monitoring demands, but technologies differ in application. Earlier systems demanded patient-activated transmissions on a calendar basis. Short, small-scale prospective studies demonstrated patient acceptance and ability to detect device malfunction.[5,6] Contemporary systems may maintain near-

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continuous surveillance and use automatic device-triggered transmissions for rapid problem notification. Technical feasibility has been published for one such system.[7] However, until recently, the clinical application of this form of remote

technology had not been tested prospectively in a large scale trial.

The TRUST (Lumos-T Safely RedUceS RouTine Office Device Follow-Up) multicenter trial prospectively tested and compared both conventional in-office follow-up to remote home monitoring (HM) with automatic daily surveillance for the treatment of patients receiving implantable cardioverter-defibrillators (ICDs).[8] HM self-tests system performance daily with notification of deviations in generator and/or lead function (eg, elective replacement indicators [ERI], out-of-range impedances).[7,9] All collected data are automatically databased and important parameters trended for review. We hypothesized that HM would enable intensive longitudinal device follow-up and enhance ability to identify system problems, especially when asymptomatic, compared with conventional 3-monthly checks.

## Methods

TRUST was a prospective, randomized, multicenter clinical trial comparing the safety and utility of automatic remote monitoring in recipients of ICDs with standard in-clinic follow-up.[8] The study was an investigator-initiated clinical trial designed by a steering committee consisting of physicians (who also served as investigators) in collaboration with the sponsor. The protocol was written by the principal investigator and sponsor. TRUST was conducted in 102 US centers. The institutional review board at each site approved the study, and all patients gave written informed consent. Enrollment of patients commenced in August 2005 and was completed in February 2008. The follow-up period ended in May 2009. Recipients of single- and dual-chamber ICDs with HM implanted for class I/II indications who were not pacemaker-dependent were eligible. HM was based on a low-power wireless transmitter within the pulse generator transmitting stored data daily to a bedside communicator for relay telephonically (cellular and/or landline) to a service center for automatic processing and online review.[7] Critical event data and specified "out-of-bounds" conditions were transmitted immediately without patient interaction and flagged for attention, suiting this remote technology for discovery of silent problems.[9,10]

The trial design has been reported previously.[8] Briefly, ICD patients were randomly assigned before implant in a 2:1 scheme to HM or conventional care with remote monitoring disabled and followed with in-clinic follow-up sessions. Both groups underwent scheduled checks every 3 months and were followed for 15 months. In HM, in-person office visits were scheduled at 3 and 15 months. At 6, 9, and 12 months, HM was used with in-office visits only if necessary. Between these time points, ICDs triggered event notification for system integrity problems. Conventional patients were evaluated with office visits only. Scheduled and unscheduled evaluations were tracked in both study groups. The trial's primary and secondary objectives were safety (stroke, death, and need for a cardiovascular procedure), efficacy (reduction in health care utilization), and early detection. The trial prespecified that scheduled and unscheduled physician evaluations, including those resulting from event notification in HM, would be assessed for time to detection, presence of accompanying symptoms, and actionability. Protocol-required event notifications were system-related (end of service (EOS), elective replacement indicator (ERI), atrial impedance <250 or >1500 Ohm, ventricular impedance <250 or >1500 Ohm, daily shock impedance <30 or >100 Ohm, shock impedance <25 or >110 Ohm); arrhythmia related events (detection of atrial fibrillation, supraventricular tachycardia [SVT], ventricular tachycardia [VT], and ventricular fibrillation [VF]), and ineffective ventricular maximum energy shock (notified on first shock of any sequence in a given episode). Event detection time was measured as the time from onset of the episode or event to its subsequent evaluation. Events without symptoms were classified as silent events. Events were categorized as "actionable" if system revision, reprogramming

changes, or change in antiarrhythmic medications were performed in response. Invasive procedures during the study involving generator and/or lead revision (which formed a component of the primary safety end point) were defined as actionable, surgical events. Nonsurgical management plans were derived from case report forms. All system-related (ie, lead and generator) problems were identified and compared in both groups.

An independent clinical events committee comprising 3 physicians, not participating in the trial and blinded to investigational sites, patient identities, and randomization assignment, adjudicated all deaths and cardiovascular adverse events and disputed classifications of actionable versus nonactionable office device interrogations between the physician and the prespecified protocol definition.

## Analysis and Statistics

Only patients completing at least 1 in-office follow-up were used for analysis. Pacing threshold changes were not followed by HM in studied devices. Actionable interactions requiring change in antiarrhythmics or generator reprogramming for atrial fibrillation or VT/VF events that did not elicit "30-J ineffective" event notifications were excluded. Four patients in the conventional group with the Sprint Fidelis lead crossed over to the remote monitoring arm on receipt of the advisory notice,[11] but these patients were analyzed as conventional patients (intention-to-treat analysis). Continuous variables were summarized as means and standard deviations unless otherwise noted. Categorical variables were summarized in frequency distributions. Group differences were compared with Student *t* tests and Mann–Whitney tests. Median times from onset to evaluation for the detected event of a given type between groups were compared with nonparametric Mann–Whitney tests (distributions). Proportions were compared with Fisher exact tests. Kaplan–Meier analysis was done to compare the time to first system event in the 2 study groups, with the difference evaluated using a log-rank test. A probability value of 0.05 was considered evidence of statistical significance.

## Results

A total of 1339 patients had at least 1 in-clinic follow-up visit (908 in HM, 431 in conventional) and formed the group for analysis. HM and conventional patients were similar at enrollment: age, $63.3 \pm 12.8$ versus $64.0 \pm 12.1$ years ($P=0.37$); sex, 72.0% versus 73.1% male ($P=0.70$); New York Heart Association class II, 55.9% versus 60.4% ($P=0.12$); primary prevention indication, 72.2% versus 73.8% ($P=0.60$); left ventricular ejection fraction, $29.0 \pm 10.7$ versus $28.5 \pm 9.8$ ($P=0.50$); ischemic etiology, 64.8% versus 71.7% ($P=0.01$); dual-chamber implants, 57.8% versus 56.6% ($P=0.68$); β-blocker usage, 34.3% versus 30.2% ($P=0.15$); and amiodarone in 13.2% versus 12.5% ($P=0.79$). Systems implanted comprised Biotronik generators capable of HM (Lumax 300 DR-T (1.3%), Lumax 300 VR-T (1.1%), Lumax 340 DR-T (22.2%), Lumax 340 VR-T (11.9%), Lumos DR-T (33.9%), Lumos VR-T (29.5%) coupled to the following leads: Biotronik (94.5%), Guidant (2.2%), St Jude Medical (2.5%), Medtronic (1.7%), and Oscor (0.06%).

Mean time from implant to first office visit was $104 \pm 65$ in HM versus $99 \pm 44$ days in conventional ($P=0.205$). Mean follow-up durations were $407 \pm 103$ (range, 21 to 617) days for the HM group and $399 \pm 111$ (range 32 to 582) days for conventional ($P=0.17$). Mean follow-up times were less than 15 months because of the allowable window around the 15-month visit and subjects who withdrew during the study. Scheduled checks were completed more successfully in the HM than the conventional group (92.7% versus 89.2%,
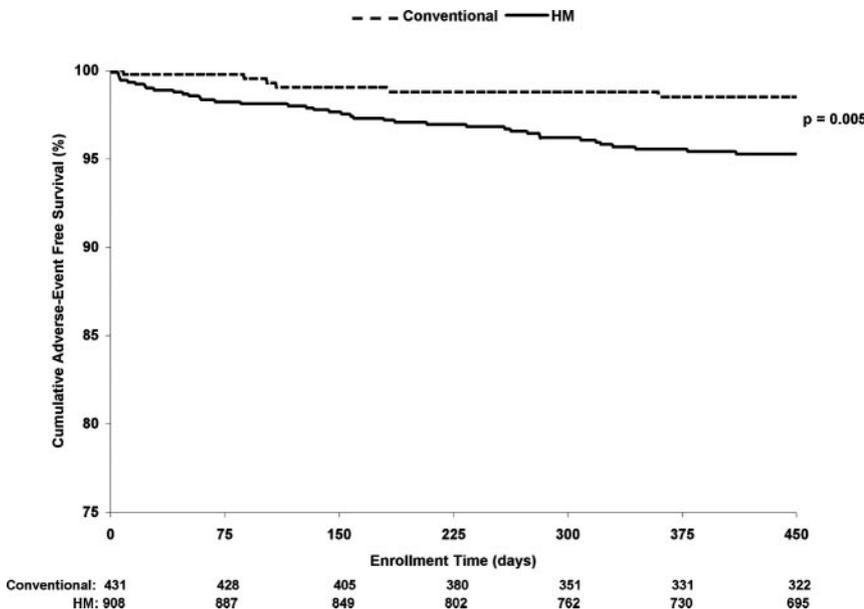
**Table 1.  Device-Related Events**

| Category | Event Detections | Remote Monitoring | | Conventional | |
|---|---|---|---|---|---|
| | | Events Detected (n=2784) | Patients Having Event (n=908) | Events Detected (n=1099) | Patients Having Event (n=431) |
| System | Shock impedance <25 or >100 Ohm | 9 (0.3%) | 6 (0.7%) | 2 (0.2%) | 1 (0.2%) |
| | Atrial impedance <250 or >1500 Ohm | 6 (0.2%) | 5 (0.6%) | 2 (0.2%) | 2 (0.5%) |
| | ERI | 1 (0.04%) | 1 (0.1%) | 0 | 0 |
| | Ventricular impedance <250 or >1500 Ohm | 2 (0.07%) | 2 (0.2%) | 0 | 0 |
| | VT/VF detection off | 1 (0.04) | 1 (0.1%) | 0 | 0 |
| Other | 30-J ineffective | 25 (0.9%) | 20 (2.2%) | 2 (0.2%) | 1 (0.2%) |
| | T-wave oversensing | 8 (0.3%) | 7 (0.8%) | 3 (0.3%) | 2 (0.5%) |
| | Electromagnetic interference | 1 (0.04%) | 1 (0.1%) | 0 | 0 |
| Total | | 53 (1.9%) | 40 (4.4%) | 9 (0.8%) | 6 (1.4%) |

$P<0.001$). In the conventional group, 1 patient demonstrated lead noise on interrogation during in-clinic evaluation within 3 months of implant. A few days later, he presented with a shock. At surgical revision, loose-set screws were discovered as the cause for inappropriate ICD discharge. Pacing threshold increases (increased pulse width or pacing output >1.0 V) at in-office follow-up were reported in 28 of 908 (3.1%) of HM versus 12 of 431 (2.8%) in conventional patients ($P=0.86$, Fisher exact test). Primary and secondary end points have been reported separately: HM reduced in-office evaluations by 45% safely and permitted early (median, 1 day) physician evaluation of significant events.[12] Most events resulted from arrhythmias (n=2784 in HM; n=1099 in conventional).[10]

A total of 46 patients demonstrated device-related issues during follow-up. These occurred in 20 of 570 (3.5%) subjects with single-chamber and 26 of 769 (3.4%) with dual-chamber devices ($P=1$). Events originated from 40 (4.4%) patients followed by HM compared with 6 (1.39%) in conventional care ($P=0.004$). These 46 patients contributed a total of 62 device-related events during the study. Fifty-three

device-related events occurred in HM and 9 in conventional (Table 1). This represented a rate of 0.055 per patient-year in HM and 0.027 per patient-year in conventional. Events were captured progressively during follow-up in both groups but with a higher incidence in HM (Figure 1). In HM, 43 of 53 events (81%) were notified by automatic event triggers. The remainder was detected by in-person evaluations. Average time from onset to physician evaluation of these events was 4.4±9.2 in HM versus 23.6±40.2 days in conventional (median, 1 [range, 0 to 39; interquartile range, 0 to 4] versus 5 [range, 0 to 126; interquartile range, 1 to 27] days, respectively, $P=0.05$, Mann–Whitney); 46.8% of these system-related events were clinically silent. Clinical actions were taken in 27 of 62, representing a rate of 0.017 per patient-year.

In total, 20 device-related adverse events requiring surgical revision occurred during the course of the study, representing an incidence of 0.012 per patient per year (Table 2). Seven of 15 complications in HM were directly related to device-related event notifications/detections listed in Table 1. Notification of non–device-related events (such as ventricular arrhythmias) sometimes indirectly led to detection of lead



**Figure 1.** Event-free survival rates in HM compared with conventional care. The observed time to the first event was shorter in HM.

## Table 2. Patients With Device-Related Complications

| Category | Remote Monitoring (HM) | | Conventional Group | |
|---|---|---|---|---|
| | Patients (n=908) | Complications/Patient-Year (n=1013 Years) | Patients (n=431) | Complications/Patient-Year (n=471 Years) |
| Lead-related complications | | | | |
| Lead revision | 10 | 0.010 | 2 | 0.004 |
| Lead explant | 1 | 0.001 | 0 | 0.000 |
| Lead replacement | 3 | 0.003 | 2 | 0.004 |
| System explanted because of lead fracture | 0 | 0.000 | 1 | 0.002 |
| Generator-related complications | | | | |
| ERI from twiddling (replaced ICD and lead) | 1 | 0.001 | 0 | 0.000 |
| Total complications | 15 | 0.015 | 5 | 0.011 |

problems that were managed by lead revision or replacement. The remainder was detected during in-person evaluation, for example, an elevated pacing capture threshold that resulted in lead revision. These device complications occurred in 13 of 656 (2%) patients receiving implants for primary prevention compared with 7 of 252 (2.8%) for other indications ($P=0.46$, Fisher exact test). These were attributable to 15 in HM compared with 5 in conventional ($P=0.63$) from a total of 16 subjects (13 in HM versus 3 in conventional, $P=0.30$). These patients accounted for 1.57 recorded events per patient year.

### Leads

Lead problem notification, comprising out-of-range atrial and ventricular lead impedance, T-wave oversensing, electromagnetic interference, and out-of-range shock impedance are listed in Table 1. A total of 33 lead problem notifications were observed in 21 (2.31%) HM and 5 (1.16%) conventional group patients. HM lead notifications were 6 atrial impedance out of range, 2 ventricular lead impedance out of range (Figure 2), 8 T-wave oversensing, and 1 electromagnetic interference (Figure 3). Lead problems detected in conventional were 2 events each of atrial impedance and shock impedance out of range and 3 episodes of T-wave oversensing. Of these, 36.4% were actionable (n=12). Out-of-specification shock impedance values were reported in 6 (0.7%) patients declaring 9 events in the HM group and 2 events were detected on interrogation in 1 (0.2%) patient in the conventional group (Figure 4). Actionable causes were surgical lead revision in a minority (n=4, 33.3%), for example, fracture (Figure 2). Otherwise, management entailed reprogramming changes only (n=8, 66.7%) (Figure 3).

### Generators

One HM patient reached the point of elective replacement indication (ERI, Figure 4), but this was due to twiddling with retraction of the ventricular lead into the pectoral pocket followed by shocks that caused high-voltage circuitry failure and premature battery depletion. One alert was received for a device set with disabled ventricular arrhythmia detection.

Twenty patients (2.2%) in HM and 1 patient (0.2%) in conventional care had 27 episodes of "ineffective maximum-energy shock": 25 in HM and 2 in conventional care (9 in dual-chamber and 18 in single-chamber devices). Five were

reported to occur for VF. The majority of remaining events related to SVTs or T-wave oversensing; 48% were followed with continued monitoring. The remainder was actionable (n=14, 51.9%), largely managed conservatively with reprogramming (n=9, 64.3%) and/or, initiation/change in antiarrhythmic medications (n=4, 28.6%). Surgical lead revision was required in only 2 cases (14.3%). In 1 case, this resulted from twiddler syndrome, resulting in numerous (asymptomatic) therapies without shock delivery, prematurely depleting the battery (Figure 4). In the other, the lead was revised and the device upgraded to a high-energy generator. No deaths were attributable to system malfunction.

## Discussion

To the authors' knowledge, this is the first prospective, randomized study evaluating the efficacy of remote surveillance of ICD performance. HM, by automatic daily evaluation, enhanced discovery of system issues (even when asymptomatic) and enabled prompt clinical decisions regarding conservative versus surgical management. Performance problems were often asymptomatic and required system revision infrequently. A high reliability of implanted systems was observed.

The study demonstrates that HM may provide a stringent method of postimplant ICD evaluation in which system components are tested daily and out-of-range values reported rapidly. Previously used techniques have been inconsistent in both follow-up method and definition of failure, reflecting limitations of available techniques. For example, meta-analysis of device registries was used to determine ICD generator malfunction. Rates were low (0.003 per patient-year) but still an order of magnitude higher than for pacemakers, enforcing the need for monitoring.[14] Lead malfunction is more frequent, but independent studies report sharply varying rates from 0.6% at 1 year[15] and 2.5% to 15% at 5 years.[16,17] This variation exists even when a single component is being tracked, such as the Fidelis lead,[18] highlighting the weakness of detection based on conventional in-person follow-up and symptomatic patient presentation or analysis of voluntary return of products, which is vulnerable to reporting bias.[19] Inconsistent definitions of failure also augment this problem. For example, in one study,[16] problems were discovered during routine face-to-face follow-up and reprogramming
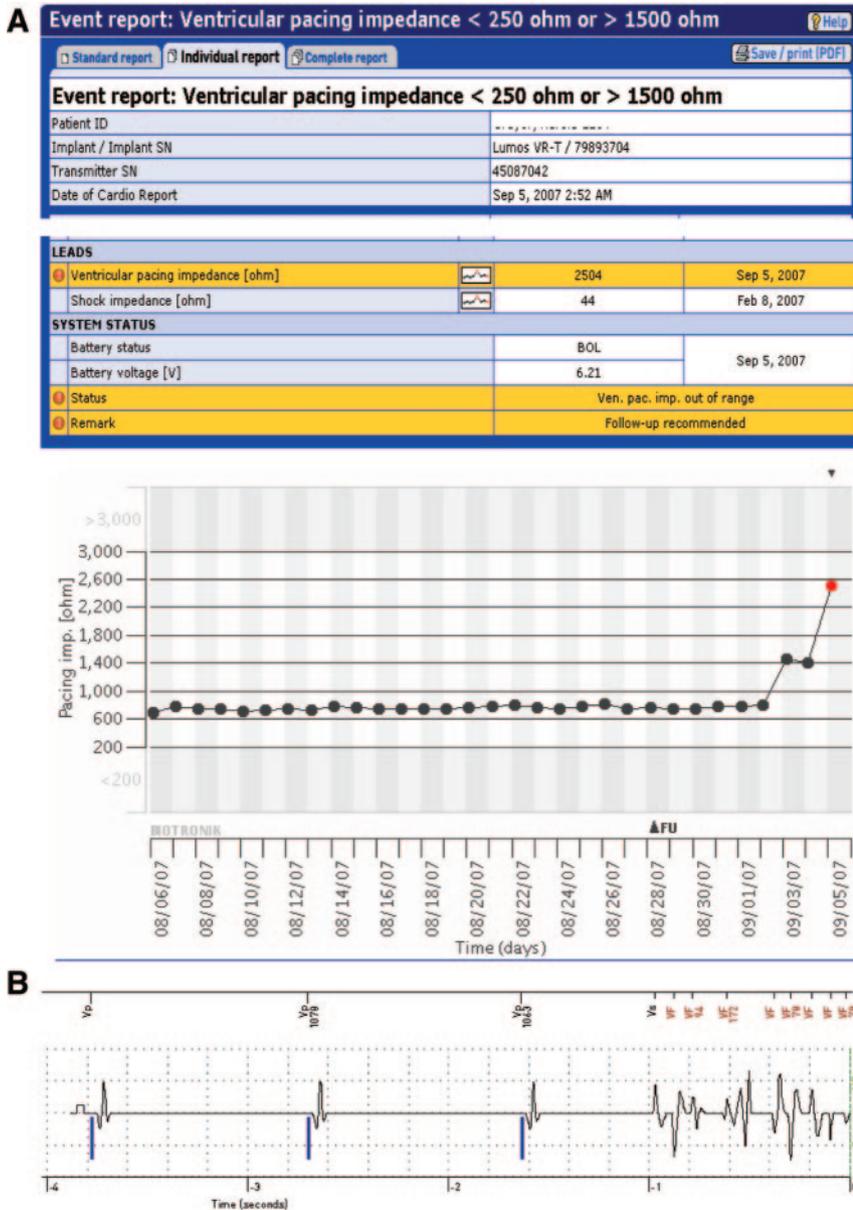
**Figure 2.** Lead fracture. A, Front page of this HM patient's web page shows flagged event notification indicating a lead impedance alert (red exclamation mark on yellow background). The graph shows that the lead impedance trend (plotted daily: black dots) was stable but then increased suddenly. Deviation from baseline trend triggered an event notification (red dot). This patient who had presented with VT had received an ICD implant for secondary prevention and was randomly assigned to the remote monitoring arm of TRUST. After his 3-monthly in-office evaluation (marked FU 8/28/07), he was discharged with remote follow-up. However, 8 days later, his device flagged the alert (top) for ventricular lead impedance "out of range." This was asymptomatic, and the patient received no shocks. The patient was unaware of this event until called. The lead was extracted and replaced. Without HM prompt notification, this may have remained unidentified until next scheduled device check months later, putting the patient at interim risk for failed detection/therapy for life-threatening ventricular arrhythmia. B, Lead artifact with extremely short coupling intervals from patient with lead fracture. Electrograms with noise from fractured leads were wirelessly transmitted automatically because irregularly sensed events elicited VF detection criteria (even though shock was not delivered in this case). The transmission terminated with VF detection. HM notifies cancelled shock therapy.[13] The wireless intracardiac electrogram transmission (intracardial electrogram with markers) is sufficient to enable a clinical decision, although electrogram definition was modest in this first-generation device (Lumos-T). Current-generation devices (Lumax-T) transmit electrograms with improved resolution and longer duration including postdetection sequences identical to the view on the programming device (eg, in Figure 3).

changes without surgical intervention were included in the "failure" rate. In contrast, in another study, 76% of lead malfunction came to clinical attention because of inappropriate ICD therapies and the need for surgical revision defined failure.[17] Both reports may underestimate the true incidence of lead failure if malfunctions are asymptomatic, occur intermittently, or result in death (only a minority of devices are interrogated postmortem). Hence, inaccurate follow-up methods may undermine the important task of ICD component surveillance.

The present study differs significantly from all previous reports. It prospectively followed a single patient cohort with freshly implanted ICD systems, tested a detection method (remote monitoring) independent of symptoms or follow-up schedule, used a uniform definition for out-of-range behavior, and assessed clinical actions taken, differentiating these between surgical or nonsurgical. HM detected more device-related issues and earlier compared with those following

calendar-based or symptom-driven in-person interrogations. The results confirmed that conventional in-person follow-up methods underreport device malfunctions (Figure 1), although monitoring guidelines indicate that patients may be followed either in person or remotely.[4]

## Remote Monitoring

Feasibility studies with earlier remote monitoring technologies requiring patient activation demonstrated ability to detect lead and generator problems, for example, T-wave oversensing or battery ERI.[5,6] These systems demand coordination with a device clinic on a calendar-based schedule. Absence of interim monitoring (ie, the majority of the time) conceals diagnostic data for extended periods and risk overwriting (since device diagnostics have finite memory), especially relevant for asymptomatic problems. This form of remote monitoring essentially substitutes for conventional in-person evaluation and is likely to yield similar data transfer and

**A**

**B**

| General | | Therapy | |
|---|---|---|---|
| Episode number | 12 | ATP in VT/VF delivered | 0 |
| Episode type | VF | ATP One Shot delivered | NO |
| Detection | Dec 19, 2008 12:42:13 PM | Shocks delivered | 0 |
| Termination | Dec 19, 2008 12:42:28 PM | Shocks aborted | 1 |
| Duration | 15s | Maximum energy [J] | 36 |
| Implant settings no. | 11 | **Termination** | |
| **Detection** | | Mean PP at termination [ms] | 505 |
| Mean PP at initial detection [ms] | 481 | Mean RR at termination [ms] | 505 |
| Mean RR at initial detection [ms] | 305 | **Remark** | |
| Onset [%] | 37, fulfilled | none | |
| Stability [ms] | 183 | | |
| Redetection | ... | | |

**Figure 3.** Nonphysiological signals. Asymptomatic detections meeting VF detection criteria resulted in immediate event notifications. Wireless electrogram transmission automatically accompanies detections in VF zone even if shock therapy is aborted.[13] Left panels: A, Electromagnetic interference. Event notification received for an aborted shock detected at 7:16 PM. The accompanying automatic wirelessly transmitted electrogram shows gross artifact on both atrial and ventricular leads. The subject was asymptomatic but in response to the notification was seen in-office within 24 hours. Right panels: B, Event notification for VF detected. Accompanying wirelessly transmitted electrograms demonstrate T-wave oversensing. Time from onset to detection within 24 hours. Channel electrograms: FF indicates far field; A, atrial; and RV, right ventricular. Markers: As indicates atrial sensed; Vp, ventricular paced; VT1, sensed electrogram occurring at short interval within VT detection zone; and VF, sensed electrogram occurring at interval short enough to be classed as VF.

problem discovery rates. Thus, when used to follow up a pacemaker population, clinically actionable events took several months for discovery, and only 66% of data were transmitted.[20] HM, in contrast, relies on automatic device-triggered communication independent of schedule or patient or physician interaction. In pacemakers with HM, 90% of transmitted data were received within 5 minutes with >99% data fidelity and ICD generators self-declared problems promptly irrespective of interrogation schedules or associated symptoms.[7,12] Several alerts may be triggered for a single problem until resolution occurs, improving probability of detection.

Patients randomly assigned to HM in the TRUST trial were evaluated in-office once within 6 to 12 weeks of implant, and this did not differ from those in conventional care. HM does not supplant this first postimplant in-person evaluation,[4] important for assessment of wound healing, determination of chronic thresholds, and setting of final pacing parameters.

Problems such as lead perforations or failures requiring revision (eg, loose set screws in this study) and symptomatic reactions to implantation (eg, pacemaker syndrome, diaphragmatic pacing, and pocket infection) cluster in this early postimplant and occur more frequently with dual-chamber or resynchronization units.[21–23] After this 3-month period, HM surveillance was demonstrated to be superior to regular office checks in this study. The utilization of HM for monitoring system performance was strengthened by the quality of transmitted information and its timely delivery. Event triggers cover an extensive range of potentially lethal (and asymptomatic) system problems and permit prompt intervention either surgically, for example, for lead failure[9,14,19,24,25] (Figure 2), or conservatively, for example, to prevent potential inappropriate therapies (Figure 3). The nonsustained ventricular arrhythmia notification may be triggered by system issues such as lead electric noise artifacts caused by fracture or nonphysiological electric signals. Identification of patients

**A** **Status - Implant:**

| Battery | |
|---|---|
| Status | ERI |
| Voltage [V] | 6.20 |
| Voltage measured on | Nov 20, 2006 |

| Transmitter | |
|---|---|
| Transmitter SN | 45086371 |
| Last transmission received on | Nov 20, 2006 10:50:41 AM |
| Message type | event triggered |

EOS    ERI    MOL2    MOL1    BOL

**Ven. shocks**

● Shocks started   ◆ Shocks aborted   ▲ Shocks successful

**B**

Shocks

3.90
3.00
2.00
1.00
0

Oct 20, 2006  21   24   27   30   Nov   05   08   11   14   17   Nov 20,

Time [days]
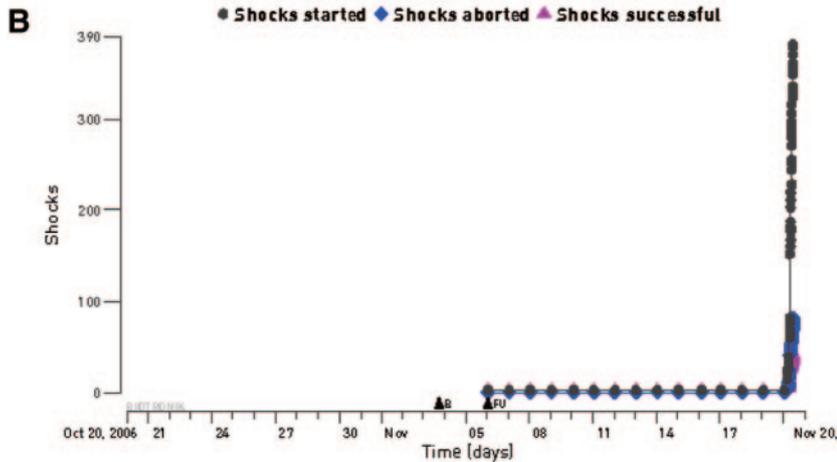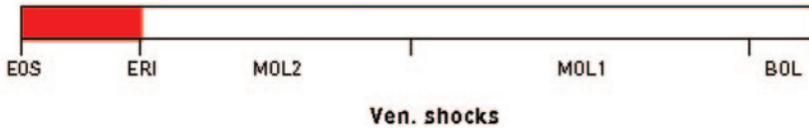
**C** **Status - Lead:**

| RV lead | | Measured on |
|---|---|---|
| Pacing impedance [ohm] | 420 | Nov 20, 2006 |
| Shock lead | | |
| Impedance of last delivered shock [ohm] | < 25 | Nov 20, 2006 |

**Figure 4.** Generator malfunction with event notifications of ERI (A), shock history (B), and disintegration of high voltage (HV) circuitry (C). Event notifications were transmitted for delivered and aborted VF therapies, shock impedance <25 Ohm, and ERI. Notification showed 381 shocks started, 82 aborted, and 250 ineffective maximum energy shocks that contributed to battery depletion. These occurred in a short span leading to the near-vertical ascent in the cumulative shock score. Lead dislodgment and fracture as the result of twiddling was the cause.

with a high burden of these may facilitate intervention to preempt premature battery depletion.[13] The potentially alarming notification of ineffective maximum-energy shock may mark increased defibrillation thresholds, the probabilistic nature of defibrillation, or inappropriate deliveries, which was the dominant cause in this study. In 1 case, notification was received for disabled VF detection. This potentially lethal occurrence may be encountered more often as patients with different comorbidities undergo procedures in different departments.

### Databasing and Advisories

Automatic parameter trending of performance data retrieved daily (without errors associated with manual data entry) permits long-term longitudinal evaluation of system survival. Additionally, HM may facilitate management of advisories. These largely encompass disintegration of high-voltage circuitry, battery depletion, and lead failure, all of which are captured by currently evaluated event triggers.[26,27] Conventional detection methods, such as increasing the frequency of office visits,[11] are impractical, onerous, and likely to miss dangerous interim problems. Patient alert mechanisms such as beeps are insensitive and prone to false-positive evaluations.[28,29] In contrast, HM generators trigger immediate alerts

on deviation from established trends. This reduces the burden both for patients to monitor their own devices frequently and for clinics responsible for large populations with a low incidence of typically silent problems. Identification of the small number of affected devices may permit elective replacement of these few and avoid unnecessary large-scale elective replacement. Continuous monitoring may aid balanced management decisions because a similar malfunction may confer different risks in different patients. For example, elective replacement of a lead under advisory may be unnecessary in patients who are not pacemaker-dependent. These attributes of remote management collectively have the potential to diminish morbidity/mortality and reduce associated hospital admissions with significant implications for cost reduction.

### Limitations

The low incidence of system-related complications requiring surgical correction in this study may reflect ICD components used and should not be extrapolated to alternative choices from the same or different manufacturers (manufacturing methods are proprietary). Of studied leads, only 4 were under advisory notices. A relatively short follow-up occurred in this study, and most device-related problems are anticipated to

manifest several years after implant, primary examples being battery depletion and lead failure.[15] Some may accelerate rapidly with time.[18] These are all appropriately detected and rapidly notified by HM as illustrated in the current study. Significant changes in pacing threshold occurred infrequently, although pacemaker-dependent patients were excluded because devices did not have the ability for automatic threshold assessment. However, current-generation HM devices have this feature and automatically notify significant threshold changes, permitting remote management of such patients. HM may have increased benefit for resynchronization devices (not assessed in the present study) because these have a higher incidence of performance problems.[23]

HM technology may notify within seconds,[7,9] but, in this study, the mean time to physician evaluation exceeded 4 days. This may be because not all device-related events in patients assigned to remote follow-up were detected by HM. The trial protocol required HM checks to be performed daily and before any in-office evaluations, but, in some cases, these were not performed because of oversight from the following physician/device specialist.[12] Despite being categorized as protocol deviations, events detected by this pathway would have been "charged" to HM during analysis. This probably reflects evolving familiarity with a new technology, and further improvement may require a change in work flow patterns in device clinics. Although HM has demonstrated capability for early detection, in some cases, the time between the occurrence of event and patient morbidity may be too short to permit intervention. For example, one third of patients with Fidelis lead failure receive inappropriate shocks within 3 hours.[28] Future technology may incorporate an ability to adjust programming to respond to failures detected during monitoring. Nonsurgical actionable events may have been incompletely reported because case report forms may not have detailed all management plans. This study addressed events related to ICD performance. Clinical actions taken in response to other events, such as the percentage pacing and atrial or ventricular arrhythmias, were not assessed. Furthermore, early detection ability may permit effective use of hemodynamic sensors incorporated into implantable units in patients with heart failure.[30] These form the objectives of future studies.[31]

## Conclusion

The present study presents a device management model in which near-continuous remote surveillance of ICD performance is combined with automatic self-declaration of system problems, enabling prompt medical decisions. The ability to collect detailed device-specific data, with component function assessed daily, sets a precedent for establishing norms for lead and generator performance and for longitudinal evaluation in an era of advancing device (and patient) complexity. These characteristics have significant ramifications for implantable cardiac electronic devices in general and patient safety.

## Acknowledgments

## References

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## CLINICAL PERSPECTIVE

The implantation of cardiac electronic devices has increased exponentially over the last decade in response to widening indications. Assessment of post–implant system performance is an important responsibility but challenging in view of increasing volume, device complexity, and advisory notices. Remote monitoring may satisfy these difficult monitoring demands. This was tested in the TRUST trial in which remote home monitoring (HM) with automatic daily surveillance was compared with conventional in-office follow-up after implantable cardioverter-defibrillator implant. The results demonstrated that conventional monitoring underreported device-related problems. HM, in contrast, enhanced discovery of system issues (even when asymptomatic) and enabled prompt clinical decisions regarding conservative versus surgical management. Performance problems were often asymptomatic and required system revision infrequently. A high reliability of implanted systems was observed. The present study presents a device management model in which near-continuous remote surveillance of implantable cardioverter-defibrillator performance is combined with automatic self-declaration of system problems, enabling prompt medical decisions. The ability to collect detailed device-specific data, with component function assessed daily, sets a precedent for longitudinal evaluation of lead and generator performance. These characteristics have significant ramifications for implantable cardiac electronic devices in general and patient safety.

## Automatic Remote Monitoring of Implantable Cardioverter-Defibrillator Lead and Generator Performance: The Lumos-T Safely RedUceS RouTine Office Device Follow-Up (TRUST) Trial

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