Detection of high-frequency artifact as a function of pulse generator algorithms and outer-insulation material

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BACKGROUND A high rate of malfunction, predominantly intermittent high-frequency artifacts (HFAs), has been recently reported in Abbott Medical Tendril pacing leads.

OBJECTIVE To investigate the factors associated with the occurrence of HFAs on Tendril leads using a commonly used comparator lead for a control.

METHODS We reviewed institutional data for Medtronic CapSureFix 5076 and Abbott Medical Tendril pace-sense leads retrospectively. Recordings deemed to be due to electromagnetic interference and far-field oversensing were not included in the classification of HFAs.

RESULTS A total of 7673 leads were analyzed: 1628 Optim-insulated Tendril leads, 825 non-Optim Tendril leads, and 5220 CapSureFix 5076. HFAs were seen in 212 leads and were more frequently observed in Tendril compared to CapSureFix leads during a mean follow-up of 4.1 ± 3.6 years. Lower age at implant, defibrillator systems, atrial position, and connection to an Abbott Medical generator were associated with increased HFA. In multivariable analysis, only connection to Abbott Medical generators (odds ratio 7.686, P < .001) and age (odds ratio 0.988 per year, P = .016) were independently associated with HFAs on pace-sense leads. In an Abbott-generator-only analysis, Optim-insulated Tendril leads were more likely to display HFAs than non-Optim Tendril leads but not Medtronic CapSureFix 5076 leads.

CONCLUSION Abbott Medical pulse generators independently predict HFA in Tendril and CapSureFix 5076 leads, likely the result of displaying short or low-amplitude noise episodes that other devices do not record. When restricted to Abbott generators only, Optim-insulated Tendril leads show an increased incidence of HFAs when compared to non-Optim Tendril leads but not CapSureFix 5076 leads.

KEYWORDS Autosensitivity; Generator algorithm; High-frequency artifact; Noise; Pacing lead

(Heart Rhythm 2019;16:1855–1861) Published by Elsevier Inc. on behalf of Heart Rhythm Society.

Each year, more than 1 million cardiovascular implantable electronic devices (CIEDs) are implanted worldwide. As the population ages and indications for pacemaker and defibrillator implantation increase, the total number of implanted components steadily rises, and the possibility for unintentional harm from suboptimal CIED components increases. A high rate of malfunction, predominantly oversensing of intermittent high-frequency artifacts (HFAs) in St. Jude/Abbott Medical Tendril 1688, 1888, and 2088 pacing leads (St. Jude Medical is now part of Abbott Laboratories, Chicago, IL), has been recently reported. With any higher-than-expected signal of CIED malfunction, questions arise as to whether the product in question should continue to be implanted and whether a product recall should be considered. However, within the same study, there seemed to be a relatively low incidence of objective lead failure and impedance abnormalities in leads with noise. We hypothesized that differences in pulse generator algorithms could lead to a lesser
or greater likelihood of recording HFAs across generator manufacturers, which could at least partially account for the high rate of HFAs seen in Tendril leads.

Methods
We retrospectively reviewed data for all patients implanted or followed at our institution with Medtronic (Minneapolis, MN) CapSureFix 5076 or Abbott Tendril (models 1688TC, 1888TC, 20888TC) pacemaker leads between January 2000 and September 2018 via a cardiac device electronic monitoring system (PaceArt, Medtronic). After lead implantation, all patients underwent periodic outpatient follow-up and/or remote device interrogations. All Tendril and CapSureFix 5076 leads were screened using the following search terms: noise, oversensing, artifact, insulation, and lead fracture. HFAs were defined as nonphysiologic artifacts on pacemaker leads detected at least twice in separate episodes and confirmed by the attending electrophysiologist. Transient arrhythmias or episodes only documented on a marker channel were not included as HFAs. Leads displaying clear electromagnetic interference (such as 60 Hz electrical artifact, sine wave pattern, perfectly regular, nonphysiologic pattern, and nonrecurring simultaneous signals on multiple leads) and far-field oversensing of T waves, R waves, or P waves were excluded from the criteria of HFA. Abnormal impedance was defined as below 200 ohms or above 2000 ohms. Leads that underwent a lead revision owing to rapidly rising or falling impedance were also included in the “abnormal impedance” group. Pacing/sensing failure was defined as a nonfunctional lead owing to loss of capture despite maximal output pacing and/or failure to reliably sense. The manufacturer of the generator for a given lead with HFAs was defined as the generator connected when HFAs were first detected, and the generator manufacturer connected to leads without HFA was defined as the most recent generator. Nominal sensing was bipolar. If leads were found to have had unipolar sensing at the time of HFA detection, these leads were excluded from the analysis. Patients with artifacts detected on device interrogation underwent isometric exercises per institutional protocol consisting of pectoral muscle contraction, reaching across the chest, and direct pocket manipulation. The study protocol was approved by the institutional review board at Vanderbilt University Medical Center.

Statistical analyses
Continuous variables are expressed as the mean ± standard deviation. Data were analyzed by a 1-way analysis of variance or Kruskal-Wallis test, with Tukey or Steel-Dwass post hoc test, as appropriate. Categorical variables, expressed as numbers or percentages, were analyzed using the $\chi^2$ test or Fisher exact test. A Kaplan-Meier analysis with the log-rank test was used to determine the probability of freedom from HFA. To analyze independent predictive factors of HFA, univariate factors with $P < .1$ were analyzed using the Cox proportional hazard regression model (multivariate analysis). All tests were 2-tailed, and a $P$ value of $<.05$ was considered to be significant. All statistical analyses were performed with EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). More precisely, it is a modified version of R commander designed to add statistical functions frequently used in biostatistics.$^3$

Results
A total of 7691 leads were identified in 5186 patients. HFAs were observed in 230 (3.0%) leads, of which 18 were excluded from analysis owing to being programmed to unipolar sensing at the time HFAs were detected (11 ventricular and 7 atrial). A total of 7673 leads, including 1628 Optim-insulated Tendril leads (models 1888 and 2088), 825 non-Optim Tendril leads (model 1688), and 5220 CapSureFix 5076 leads, were analyzed. The baseline lead characteristics are shown in Table 1. The mean age at implant was 68 ± 15 years, 4337 leads (56.5%) were implanted in male patients, 4728 (61.5%) leads were implanted in the atrium, and 1886 (24.6%) were connected to a defibrillator system. Mismatch between lead brand and generator brand was seen in 791 (10.3%) leads. The numbers of leads connected to Abbott Medical generators, Medtronic generators, and other generators were 2323 (30.3%), 4790 (62.4%), and 560 (7.3%), respectively. The mean follow-up period for all leads was 4.1 ± 3.6 years. Non-Optim Tendril leads were more frequently implanted in male patients. Optim-insulated Tendril leads were more likely to be implanted in the atrium and more likely to be connected to a defibrillator system. Approximately 90% of all leads were connected to a same-manufacturer generator, though Tendril leads were slightly less likely to be connected to a mismatched generator. Non-Optim Tendril leads had longer follow-up.

In univariate analysis, HFAs were more common in both Optim-insulated and non-Optim Tendril leads than in CapSureFix 5076 leads (Table 2 and Figure 1A). Leads displaying HFA were more frequently connected to Abbott Medical pulse generators than those without (odds ratio [OR] 10.230, $P < .001$, Table 2). In addition, the mean age at implant was significantly lower, atrial lead position more common, and connection to a defibrillator more likely in leads with HFA compared to those without.

In the multivariate analysis, only age at implant and connection to Abbott Medical generators were independent predictors of HFA (OR 0.988 per year, 95% confidence interval [CI] 0.979–0.997, $P < .001$, and OR 7.686, 95% CI 4.096–14.420, $P < .001$). Optim insulation, atrial lead position, and connection to a defibrillator system showed a nonsignificant trend toward higher incidence of HFAs. While virtually all leads connected to a defibrillator were implanted in the atrium, atrial lead position and connection to a defibrillator system were both included in the multivariate model, as the collinearity between the 2 groups was acceptably low (variance inflation factor = 1.219).
In order to assess for a difference between Tendril leads, the univariate and multivariate analysis was repeated with Optim-insulated leads set as the comparator (adjusting for generator type, which would likely be different across different lead vintages). In this analysis, non-Optim Tendril leads had significantly less HFA detected than Optim-insulated Tendril leads (OR 0.493, 95% CI 0.338–0.720, \( P < .001 \), Supplementary Table 1). Similarly, in an analysis of only leads connected to Abbott generators, the incidence of HFA was greater in Optim-insulated than in non-Optim Tendril leads. However, there was no significant difference in the HFA rate between Optim-insulated Tendril leads and Medtronic CapSureFix 5076 leads (Table 3 and Figure 1B).

Of 2323 leads connected to Abbott Medical generators, HFAs were detected in 172 leads (7.4%). In contrast, HFAs were detected in 40 of 5350 leads connected to non-Abbott generators (0.7%). While HFAs alone and HFAs with pacing/sensing failure and normal impedance were more frequently observed in leads paired with Abbott Medical generators, artifact in association with abnormal impedance was seen at similar rates in both groups (Supplementary Table 2). No CapSureFix leads were found to have low impedance in association with HFAs (Supplementary Table 3). Of 212 leads with HFA, lead inactivation (including extraction or abandonment), reprogramming, and observation were undertaken in 72, 44, and 75 leads, respectively. Management of HFA was similar for leads connected to Abbott and non-Abbott generators (Supplementary Table 4).

Of extracted leads with HFA, returned product analyses were available in 50 leads (Table 4). No abnormalities or only periprocedural damage was found in 32% of leads, including the only 2 CapSureFix leads connected to Abbott Medical generators for which analysis was available. Clavicular crush seemed to be more common in non-Optim Tendril leads, though Medtronic does not seem to report this abnormality specifically, and many CapSureFix lead fractures seemed to likely fit this description. Lead-to-device abrasion was not reported with CapSureFix leads. HFAs were reproduced in real time with isometric exercises in the clinic in 19.0%, 14.6%, and 24.4% of Optim-insulated Tendril, non-Optim Tendril, and CapSureFix 5076 leads.

HFAs were seen more commonly on the atrial channel than on the ventricular channel in Abbott generators (9.0% vs 4.6%, \( P < .001 \)), but not in non-Abbott generators (0.8% vs 0.7%, \( P = .629 \)). HFAs on right ventricular leads resulted in syncope in 5 patients owing to loss of ventricular pacing and inappropriate shocks in 1 patient who had a Tendril lead connected to a defibrillator as the pace-sense component. All of these leads underwent lead revision. In leads with HFA, the artifact disappeared after generator change in 4 of 14 leads that underwent a generator change or upgrade, 1 of which was changed from an Abbott

### Table 1 Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>All leads (n = 7673)</th>
<th>Tendril with Optim (n = 1628)</th>
<th>Tendril without Optim (n = 825)</th>
<th>CapSureFix (n = 5220)</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at implant (y)</td>
<td>68 ± 15</td>
<td>67 ± 14</td>
<td>68 ± 15</td>
<td>68 ± 15</td>
<td>.112</td>
</tr>
<tr>
<td>Sex (male)</td>
<td>4337 (56.5)</td>
<td>887 (54.5)</td>
<td>498 (60.4)</td>
<td>2952 (56.6)</td>
<td>.021</td>
</tr>
<tr>
<td>Atrial lead</td>
<td>4728 (61.6)</td>
<td>1084 (66.6)</td>
<td>515 (62.4)</td>
<td>3129 (59.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Defibrillator system (ICD and CRT-D)</td>
<td>1886 (24.6)</td>
<td>489 (30.3)</td>
<td>227 (27.5)</td>
<td>1170 (22.4)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mismatched generator*</td>
<td>791 (10.3)</td>
<td>137 (8.4)</td>
<td>81 (9.8)</td>
<td>573 (11.0)</td>
<td>.011</td>
</tr>
<tr>
<td>Abbott generator</td>
<td>2323 (30.3)</td>
<td>1491 (91.6)</td>
<td>744 (90.2)</td>
<td>88 (1.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Medtronic generator</td>
<td>4790 (62.4)</td>
<td>72 (4.4)</td>
<td>71 (8.6)</td>
<td>4647 (89.0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Other generator</td>
<td>560 (7.3)</td>
<td>65 (3.9)</td>
<td>10 (1.2)</td>
<td>485 (9.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Follow-up period (y)</td>
<td>4.1 ± 3.6</td>
<td>3.9 ± 2.8</td>
<td>4.7 ± 3.9</td>
<td>4.0 ± 3.7</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*Mismatched generator indicates different manufacturer for generator and lead.

Data are presented as mean ± standard deviation or frequency (percentage).

CRT-D = cardiac resynchronization therapy-defibrillator; ICD = implantable cardioverter defibrillator.

### Table 2 Factors associated with high-frequency artifact

<table>
<thead>
<tr>
<th></th>
<th>Univariate analysis</th>
<th>Multivariable analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds ratio</td>
<td>95% CI</td>
</tr>
<tr>
<td>Age at implant (per year)</td>
<td>0.989</td>
<td>0.981–0.997</td>
</tr>
<tr>
<td>Sex (male)</td>
<td>1.118</td>
<td>0.850–1.470</td>
</tr>
<tr>
<td>Lead type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CapSureFix</td>
<td>1.000</td>
<td>-</td>
</tr>
<tr>
<td>Tendril without Optim (1688)</td>
<td>4.739</td>
<td>3.094–7.258</td>
</tr>
<tr>
<td>Tendril with Optim (1888/2088)</td>
<td>10.440</td>
<td>7.341–14.850</td>
</tr>
<tr>
<td>Atrial lead</td>
<td>1.729</td>
<td>1.267–2.360</td>
</tr>
<tr>
<td>Defibrillator system</td>
<td>1.787</td>
<td>1.357–2.354</td>
</tr>
<tr>
<td>Mismatched generator*</td>
<td>0.629</td>
<td>0.372–1.063</td>
</tr>
</tbody>
</table>

\( CI = \) confidence interval; CRT-D = cardiac resynchronization therapy-defibrillator; ICD = implantable cardioverter defibrillator.
implantable cardioverter-defibrillator (ICD) to Boston Scientific cardiac resynchronization defibrillator. The other leads were changed to the same manufacturer generators. Rates of HFAs were significantly higher in Abbott ICDs as compared to pacemakers (11.4% vs 5.8%, \( P < .001 \)). In Abbott pacemakers, the Accent series had a higher HFA rate than the Assurity/Endurity/Allure series (8.9% vs 3.0%, \( P < .001 \), Supplementary Figure 1).

HFAs detected with Abbott generators were most often 1–4 seconds in length with an amplitude similar to or lower than that of the P wave or R wave. The frequency was typically very high, with deflections occurring at \(<100\)-ms intervals, though not all deflections were detected (Supplementary Figure 2). HFAs detected with non-Abbott generators were often higher amplitude and were typically longer in duration.

Discussion

In this retrospective observational study, we reviewed 7691 Abbott and Medtronic pacing leads and found that Abbott Medical pacemaker and defibrillator pulse generators, but not Abbott pacing leads, are associated with an increased incidence of recorded HFAs in a multivariate analysis (Table 2, OR 7.686, \( P < .001 \)). Upon direct comparison of Tendril leads, Optim insulation predicted significantly higher rates of HFA when compared to silicone-insulated model 1688 leads (Supplementary Table 1). This effect was unchanged when the analysis was restricted to Abbott generators alone (Figure 1 and Table 3). The increased incidence of HFAs on Abbott generators seems most likely due to episodes of true electrical noise, which other devices may not report owing to their brevity or low amplitude.

Mechanism of HFAs

HFAs can have many causes, including lead fracture with make-break connections; external electromagnetic interference; a lead-header interface issue such as a loose set screw; far-field oversensing of T waves, R waves, or P waves; and diaphragmatic or pectoral myopotentials.4–6 A previous study reported that the overall incidence of ventricular oversensing in ICDs was 7.3%, and 38% of oversensing was caused by lead failure or myopotentials.7

The important work by El-Chami and colleagues2 initially identified an increased incidence of lead malfunction (predominantly noise with normal impedance) in the Tendril lead family. They concluded that a vulnerability of Optim insulation (a proprietary copolymer of silicone and polyurethane) in some Tendril leads (models 1888 and 2088) may partially explain the high rate of malfunction. A greater incidence of HFAs in Tendril leads with Optim insulation than in those without was confirmed in our study as well (5-year HFA rate 8.8% vs 4.7%, \( P < .001 \)), and this association remained after adjusting for the generator model (Supplementary Table 1). There are 2 primary differences in outer insulation, which could potentially explain this difference. In addition to being composed of a different material, Optim outer insulation on the 6Fr 1888 and 2088

Table 3 Pairwise comparison of 5- and 10-year high-frequency artifact rates among leads connected to Abbott Medical pulse generators

<table>
<thead>
<tr>
<th>Lead</th>
<th>5-year HFA rate (%)</th>
<th>95% CI</th>
<th>10-year HFA rate (%)</th>
<th>95% CI</th>
<th>( P )</th>
<th>1688</th>
<th>CapSureFix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tendril with Optim (1888 and 2088)</td>
<td>8.8</td>
<td>7.1-11.0</td>
<td>27.7</td>
<td>22.2-34.1</td>
<td>&lt;.001</td>
<td>.387</td>
<td></td>
</tr>
<tr>
<td>Tendril without Optim (1688)</td>
<td>4.7</td>
<td>3.0-7.2</td>
<td>13.4</td>
<td>9.5-18.7</td>
<td>.344</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CapSureFix (n = 88)</td>
<td>9.6</td>
<td>4.4-20.5</td>
<td>17.0</td>
<td>8.0-44.1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\( CI = \) confidence interval; HFA = high-frequency artifact.
models is thinner than the silicone outer insulation used on the 1688 lead (0.005 inches vs 0.012 inches). While the difference in HFA could be due to a greater incidence of breach in Optim-insulated leads, it also seems feasible that any given insulation breach may be more likely to lead to detectable artifact with a thinner insulation “spacing” between the conductor and tissue.

Although the study by El-Chami and colleagues noted that mismatched lead-generator combinations did not predict lead malfunction, they did not comment on the association between each generator manufacturer and lead “malfunction” despite having a large population of mismatched devices. In that study, it seems that Optim-insulated leads showed a 7.8% rate of malfunction when paired with Abbott generators (n = 4707) compared to 5.0% when paired with a non-Abbott generator (n = 3290).

Given the very large number of leads in both groups, this association is likely statistically significant, though we do not have the primary data available for analysis.

Atrial detections
After establishing that Abbott generators record more HFA, the next logical question is, are Abbott generators seeing things that are not there or reporting things that are common but usually go unnoticed? To answer this question, one must understand the criteria that must be met for a given device to record and display electrograms. An in-depth description of differences in atrial detection algorithms is included in a Supplementary Appendix. In brief, Abbott generators record electrograms continuously and document atrial mode switch or noise episodes typically within 1–2 seconds (Figure 2A, Supplementary Figure 2).

In contrast, Medtronic generators do not nominally store electrograms continuously and must reach atrial tachycardia / atrial fibrillation detection criteria and then sustain an atrial rate above atrial tachycardia / atrial fibrillation detection for 32 ventricular cycles before any event will be stored (Figure 2B, Supplementary Figure 3).

Implications of HFAs
In order to determine whether intermittent short-duration noise uncovered by Abbott algorithms is clinically important, we need to understand the proportion of leads that ultimately failed in some other way than intermittent noise. This could be defined in many ways, including lead replacement/extraction, loss of pacing, or loss of sensing. However, given the retrospective nature of our study, the limited data available, and the many variables that go into the decision to extract or replace a lead, we decided to assess the proportion of leads with HFAs that also displayed an out-of-range impedance, which would seem to be an objective though incomplete measure of true lead failure or impending failure in this dataset. While HFAs were more frequently observed in leads connected to an Abbott generator compared to non-Abbott generator, the rate of abnormal impedance was similar (0.37% vs 0.47%,
Notably, low impedance was a phenomenon primarily seen on Optim-insulated Tendril leads, potentially suggesting a higher rate of outer-insulation breach in this group. Only 6.4% of leads displaying HFA on an Abbott generator developed an abnormal impedance, as opposed to 35.7% of those connected to other generators. This suggests that Abbott generators detect HFA on many leads without an overt fracture or breach.

**Treatment for HFAs**

Beyond abnormal impedance, another primary reason to be concerned with lead noise is loss of pacing and loss of atrioventricular synchrony. Infrequent loss of atrioventricular synchrony is typically a minor concern. However, loss of ventricular pacing in a pacing-dependent patient can certainly be dangerous. A high density of HFA on ventricular leads resulted in syncope in 5 and inappropriate shocks in 1 patient in this study. It is not clear from our data whether Abbott devices are more or less likely to successfully respond to lead HFA (ie, mode switching, noise reversion pacing), but our data strongly suggest that the Abbott algorithms are more likely to result in the storage and presentation of short-duration or low-amplitude HFAs. It is notable that in our study, approximately one third of leads with HFAs were revised or deactivated (Supplementary Table 3). This is approximately double the rate of revision/deactivation in the study by El-Chami and colleagues, likely owing to local practice patterns. In light of our findings, optimal management for most pace-sense leads with short-duration noise seen on Abbott generators would seem to be reprogramming or monitoring initially.

**Age as a risk factor**

Younger age is a known risk factor for lead fracture, thought to be due to increased shoulder mobility and overall activity level. This association was seen in our cohort as well, though given that the majority of our patients had HFA without evidence of true fracture, it could also be the case that higher-amplitude intermittent myopotentials are more likely to be sensed in a younger population.

All of this together suggests that Abbott generators are likely reporting true electrical noise that other devices also “see” but may not report owing to its brevity or amplitude. The most likely explanation for this seems to be detection of pectoral myopotentials on bipolar leads owing to breakdown of outer insulation. If these defects are small (allowing fluid but not tissue to directly contact the outer conductor), it is certainly plausible that episodes could be short duration, low amplitude, and intermittent. Second, diaphragmatic myopotentials could be detected on ventricular leads, though ventricular leads constitute a minority of the HFAs detected. Lastly, it is possible, but seems less likely, that more pathologic lead breakdown or lead-header issues (ie, loose set screw) could be present but only cause very short episodes of oversensing and subsequently are more likely to be detected on Abbott CIEDs, though normal impedance and generally low amplitude of the detected signals argues against this. In fact, many of the leads (32%) sent for returned product analysis had no evident abnormalities (Table 4). It is not clear what the mechanism for HFAs is likely to be in this scenario, though it seems plausible that preexisting outer insulation defects could have been present that were indistinguishable from perioperative trauma or were so small as to evade detection at the time of returned product analysis. It seems unlikely that HFAs were caused by muscle artifact transiting across an intact outer insulation, given that the incidence of HFAs starts out very low and
increases linearly over time (as would be expected with progressive breakdown).

Limitations
Our study has several limitations. We identified leads with HFAs via a cardiac device electronic monitoring system using search terms. If there were any leads with HFAs that were not described using the search terms, they would likely have been excluded. However, all leads were screened with the same protocol. Because our study was retrospective, it cannot definitively adjust for the effect of unmeasured confounders. It is also not known what the natural history of the revised/deactivated leads would have been. Our follow-up is limited, and it is unclear whether longer follow-up would have demonstrated other features of frank lead failure. Lastly, the analysis of only leads connected to Abbott generators is limited by the relatively small numbers of Medtronic leads.

Conclusion
Abbott pacemaker and defibrillator generators are significantly and strongly associated with increased detection of HFAs, likely owing to the detection of brief or low-amplitude noise that may not be recorded by other manufacturers. Optim-insulated Tendril leads have a greater incidence of HFAs compared to non-Optim Tendril leads.

Acknowledgments
We would like to thank William Caudill and Matthew Desmond with Abbott Medical, James T. Reedy Jr and Rachel Tidwell with Medtronic, and Clinton Langston and Elizabeth Weigand with Boston Scientific for their assistance with the technical and manufacturer-specific aspects of the current study. We would like to thank M. Benjamin Shoemaker, MD, MSCI for statistical assistance.

References

Appendix
Supplementary data
Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2019.05.020.