Preliminary Clinical Results of a New Bipolar, Active Fixation, Single-Pass ICD Lead

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Summary
Active fixation implantable cardioverter-defibrillator (ICD) leads are becoming increasingly popular due to their easier detachment, placement flexibility, and minimal dislodgement characteristics. The Kainox RV-S is a new active fixation, single-coil, single-pass lead that, when attached to an active housing ICD, provides true bipolar sensing and defibrillation shock delivery. For those patients with refractory arrhythmias, an additional shock vector may be integrated into the system by adding a new accessory superior vena cava (SVC) coil (Kainox VCS) in conjunction with the single-pass lead. Preliminary results from an ongoing U.S. clinical study have shown that the operational characteristics of this new lead system are comparable to other lead systems on the market. Twenty-four patients were enrolled in the study and implanted with 26 Kainox RV-S leads, with nine patients also receiving Kainox VCS leads. Ninety-seven out of the 98 sensing evaluations demonstrated appropriate sensing without any instances of lead noise resulting in inappropriate detection or therapy. Ninety-five out of the 98 pacing evaluations demonstrated appropriate pacing. One hundred percent of a total of 158 ventricular tachyarrhythmia episodes (17 spontaneous and 141 induced) were successfully detected and treated with the lead system. Three patients experienced lead-related complications, including two dislodgements and one sensing failure. The Kainox RV-S lead compares favorably to other manufacturers' active fixation leads. The data from this clinical study to date indicate that the Kainox RV-S and VCS leads are safe and effective for use in ICD therapy.

Key Words
Implantable cardioverter-defibrillator (ICD) therapy, single-pass ICD lead, active fixation lead, bipolar lead

Introduction
Active fixation ICD leads are becoming increasingly popular due to their easier detachment [1], placement flexibility, and minimal dislodgement characteristics [2]. One example of the advantage of active fixation is for patients with persistent left SVC. This congenital abnormality has been determined by autopsy to exist in 0.3% of the general population [3]. Active fixation leads have been shown to perform reliably in these patients [3,4]. Attachment directly to the His bundle or outflow tract for permanent pacing has been described using an active fixation lead [5]. Preventing lead dislodgement due to "sagging heart syndrome" with an active fixation lead has also been reported [6]. Active fixation leads have been recommended for use in pediatric patients [1]. This article discusses preliminary clinical results with the new active fixation Kainox RV-S ICD lead (Biotronik, Germany).

Materials and Methods
Kainox RV-S Lead Description
The Kainox RV-S is an active fixation, single-pass lead that provides true bipolar sensing and defibrillation shock delivery in connection with an active housing ICD (Figure 1). The isodiametric lead, with a distal surface area of 5.3 mm², has two electrodes for sensing
and pacing and one defibrillation electrode (10.5 F), all of which are contained in a single-pass, 7.8 F lead body. The tip and ring electrodes form the most distal portion of the lead and provide dedicated bipolar sensing and pacing. The short distance of 14 mm separating the ring from the tip minimizes the potential for oversensing. Additionally, the distance of only 21 mm from shock coil to tip (pullback) enables coil placement near the apex of the heart, which may help lower defibrillation thresholds [7].

The Kainox RV-S active fixation lead is positioned with the help of a conventional stylet. Its flexible shock coil simplifies lead introduction and placement. The lead features an electrically inactive extendable/retractable fixation helix for use in lead placement. The helix is extended and retracted by means of a screwdriver stylet. The screw can be completely extended with two to three rotations. A radiopaque marker is visible on the X-ray when the helix is extended. The risk of perforating the ventricle is significantly reduced due to the small extension size of the 1.8 mm screw.

The tip, ring, and shock coil electrodes are composed of platinum/iridium with an iridium fractal surface structure. The fractal surface of the lead electrodes provides a larger effective tissue interface, which may contribute to the lead's sensing characteristics [8]. The iridium coating has also been shown to facilitate early reduction of polarization effects on the shock coil, which in turn allows early post-shock sensing [9-11].

The lead body has silicone insulation for proven reliability. The Kainox RV-S lead has one standard IS-1 bipolar sensing and pacing connector and one standard DF-1 defibrillation lead connector.

The Kainox RV-S lead is designed for use with an ICD that provides a defibrillation shock pathway that includes the housing of the ICD (active housing). The Kainox RV-S can also be used in conjunction with the accessory unipolar Kainox VCS lead placed in the SVC to create a dual-coil system. By adding the second lead to the system, the shock pathway is modified, potentially lowering the defibrillation threshold for patients with refractory arrhythmias [7]. The Kainox VCS lead is composed of a single platinum/iridium shock coil (7.9 F) at the distal end of the silicone lead body. It has a single DF-1 connector.

**Patient Selection**

Patients were selected using standard inclusion/exclusion criteria for ICD therapy. Candidates with severe tricuspid valve disease or who had a mechanical tricuspid valve were not included in the study. Patients already enrolled in another cardiovascular clinical study or who required a separate bradycardia pacemaker were also excluded. Informed consent was obtained from all study participants.

**Protocol**

All patients were implanted with a commercially available Biotronik ICD and an investigational Kainox RV-S lead. At the discretion of the investigator, some patients also received the investigational Kainox VCS lead. Patients could also receive other commercially available pacing/sensing leads to augment the system as necessary (e.g., atrial pacing/sensing lead for a dual-chamber ICD).
Lead performance data was collected to establish the safety and efficacy of the new lead system. Data was collected on the following occasions:

- Implantation
- Pre-discharge follow-up
- One-month follow-up
- Three-month follow-up
- Subsequent routine follow-ups (every 6 months after implantation)

The following electrophysiologic lead measurements were taken with the Biotronik TMS-1000 Programmer:

- Safety margin testing at implantation
- Shock impedance at implantation
- R-wave amplitude
- Ventricular pacing threshold at 0.5 ms pulse width
- Ventricular pacing impedance

Performance Metrics
Four primary endpoints were selected to evaluate the safety and efficacy of the investigational lead system:

- Complication-free rate (safety)
- Lead performance – sensing (effectiveness)
- Lead performance – pacing (effectiveness)
- VT/VF conversion efficacy of the Kainox VCS augmented lead system

Results
Following the U.S. Food and Drug Administration's approval of the clinical investigation, the first implantation was performed on May 10, 2001. Through February 26, 2002, a total of 24 patients received the investigational lead system. The cumulative implant duration was 112.2 months (9.4 patient years) with a mean implant duration of 4.7 months. The patient follow-up compliance rate was 96.9%. Table 1 provides a summary of the patient demographics for the enrolled patients.

During the study, a total of 26 Kainox RV-S leads were implanted in 24 patients, with 24 leads positioned in the right ventricular apex and an additional two leads positioned in the right ventricular outflow tract. The accessory Kainox VCS lead was implanted in nine of the 24 patients. One of those leads was indicated because of high defibrillation threshold values recorded with the Kainox RV-S lead. The rationale for implanting the other eight Kainox VCS leads was empirically driven by various other indications that called for a dual-coil system.

A clinician survey asked the physicians to rate the lead handling characteristics of the investigational leads on a scale of 1 (poor) to 5 (excellent), with 3 being average. In the three areas:

- positioning,
- helix manipulation, and
- visualization of the radiopaque marker,

the Kainox RV-S lead received mean scores of 3.8, 3.8, and 3.6, respectively. The Kainox VCS lead received an overall lead handling score of 3.9. The results of the electrophysiologic lead measurements are summarized below.

Safety Margin Testing at Implantation
The protocol allowed for safety margin testing by either two-shock safety margin testing, defined as two successes at 20 J or less, or defibrillation threshold (DFT) step-down testing. Tables 2 and 3 provide a summary of the testing results for patients implanted...
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with only the Kainox RV-S lead and patients implanted with both the Kainox RV-S and VCS leads, respectively. The mean defibrillation threshold for the single-coil lead configuration (Kainox RV-S lead only) was slightly higher than the mean defibrillation threshold for the dual-coil lead configuration (Kainox RV-S plus Kainox VCS). The mean defibrillation threshold for each group, 16.3 J and 14.6 J, respectively were within the required safety margin of 20 J.

Shock Impedance at Implantation

During safety margin evaluation, investigators were asked to report the shock lead impedance in any lead configuration tested. The average shock impedance in the two-lead configuration (Kainox RV-S plus VCS) was expected to be lower than the shock lead impedance with only one lead (Kainox RV-S only). However, impedance values in both cases were expected to be within the normal range of shock impedance values. Table 4 summarizes the reported shock lead impedance values in each lead configuration.

As expected, the mean shock impedance with the Kainox RV-S/Kainox VCS lead system was lower than with the Kainox RV-S lead alone. Both groups demonstrated mean shock impedance values that were within the normal range of shock impedance values.

R-Wave Amplitude

Table 5 provides a summary of measured R-wave amplitude values for the Kainox RV-S lead. Since the implanted device can only measure a maximum intrinsic ventricular amplitude of 16 mV, this was the maximum value reported in each category. All of the R-wave amplitude values were within normal limits for each follow-up recorded.

Ventricular Pacing Threshold and Impedance

Table 6 summarizes the ventricular pacing threshold values and Table 7 gives a summary of ventricular pac-
ing impedance values. The threshold and impedance values were within normal limits throughout the follow-up period.

Primary Endpoints
In addition to the lead characteristic measurements, four primary endpoints were defined as performance metrics. These performance metrics are summarized as follows.

Complication-Free Rate (Safety)
The complication-free rate was designed to evaluate the safety of the implanted lead systems. This metric included all lead-related complications, which were defined as adverse events requiring additional invasive intervention to resolve. Three of the 24 patients had lead-related complications. Of the 26 Kainox RV-S implants, two lead dislodgements were observed. One occurred 2 days post-implantation, and the second occurred nearly 6 weeks post-implantation, after the patient had reportedly wrestled with family members. One Kainox RV-S lead failed ventricular capture at the 1-month follow-up. An additional ventricular pacing/sensing lead was implanted and the Kainox RV-S lead was configured to deliver only defibrillation shocks. With 9.4 patient years (112.2 months) on record, these three lead complications translate to 0.32 complications per patient year. One patient death was reported, which the investigator determined was not related to the investigational lead system.

Table 6. Ventricular pacing threshold. The sum of the measurements at a given procedure may be more than the number of patients in the study. Some patients may have required additional testing due to modification of the lead system. SE = standard error of the mean.

<table>
<thead>
<tr>
<th>Threshold at 0.5 ms</th>
<th>Implantation</th>
<th>Pre-discharge follow-up</th>
<th>1-month follow-up</th>
<th>3-month follow-up</th>
<th>Other follow-ups</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of tests</td>
<td>27</td>
<td>25</td>
<td>19</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>Mean ± SE (V)</td>
<td>0.47 ± 0.03</td>
<td>0.59 ± 0.06</td>
<td>1.57 ± 0.18</td>
<td>1.29 ± 0.17</td>
<td>1.37 ± 0.20</td>
</tr>
<tr>
<td>Range (V)</td>
<td>0.2 – 0.9</td>
<td>0.3 – 1.2</td>
<td>0.7 – 3.5</td>
<td>0.7 – 2.8</td>
<td>0.6 – 3.4</td>
</tr>
</tbody>
</table>

Table 7. Ventricular pacing impedance. The sum of the measurements at a given procedure may be more than the number of patients in the study. Some patients may have required additional testing due to modification of the lead system. SE = standard error of the mean.

<table>
<thead>
<tr>
<th>Ventricular pacing impedance</th>
<th>Implantation</th>
<th>Pre-discharge follow-up</th>
<th>1-month follow-up</th>
<th>3-month follow-up</th>
<th>Other follow-ups</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of tests</td>
<td>25</td>
<td>25</td>
<td>19</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Mean ± SE (Ω)</td>
<td>539 ± 17</td>
<td>468 ± 15</td>
<td>508 ± 23</td>
<td>525 ± 28</td>
<td>523 ± 28</td>
</tr>
<tr>
<td>Range (Ω)</td>
<td>410 – 773</td>
<td>370 – 680</td>
<td>400 – 809</td>
<td>420 – 720</td>
<td>361 – 720</td>
</tr>
</tbody>
</table>

Lead Performance – Sensing (Effectiveness)
The lead sensing performance metric was designed to evaluate the ability of the Kainox RV-S to appropriately sense the intrinsic cardiac signal. The lead's sensing ability was scored based on an assessment of measured R-wave amplitudes (Table 5) and on the clinician's evaluation of sensing using real-time electrograms (Table 8). Testing for appropriate (as determined by the investigator) ventricular sensing was required at implantation, pre-discharge, 1 month, 3 months, and 6 months post-implantation, and during subsequent routine follow-ups. Out of a total of 98 evaluations, 97 displayed appropriate sensing behavior. Therefore, the overall rate of appropriate ventricular sensing was 99.0%. Table 8 summarizes the ventricular sensing evaluations at each follow-up.

Table 8. Ventricular sensing.

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>No. of tests</th>
<th>Appropriate tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implantation</td>
<td>28</td>
<td>28 (100%)</td>
</tr>
<tr>
<td>Pre-discharge</td>
<td>25</td>
<td>25 (100%)</td>
</tr>
<tr>
<td>1-month</td>
<td>20</td>
<td>20 (100%)</td>
</tr>
<tr>
<td>3-month</td>
<td>12</td>
<td>12 (100%)</td>
</tr>
<tr>
<td>Other</td>
<td>13</td>
<td>12 (92.3%)</td>
</tr>
<tr>
<td>All procedures</td>
<td>98</td>
<td>97 (99.0%)</td>
</tr>
</tbody>
</table>
Lead Performance – Pacing (Effectiveness)

This performance measure evaluated the ability of the Kainox RV-S lead to appropriately capture the cardiac tissue. Evaluation was based on the measured pacing thresholds (Table 6) being within normal ranges and on the appropriate capture of the cardiac tissue (Table 9). Testing for appropriate (as determined by the investigator) ventricular pacing was required at implantation, pre-discharge, 1 month, 3 months, and 6 months post-implantation, and during subsequent routine follow-ups. Out of a total of 98 evaluations, 95 displayed appropriate pacing behavior. Therefore, the overall rate of appropriate ventricular pacing was 96.9%. Table 9 summarizes the ventricular pacing evaluations.

VT/VF Conversion Efficacy of the Kainox VCS Augmented Lead System

This performance measure was designed to evaluate the ability of the Kainox VCS to appropriately augment the shock pathway of the Kainox RV-S single-coil ICD lead. The patients fell into two categories: those who the physicians determined were in need of a second shock coil, and those who were not. Patients in the first group were given ICD systems with Kainox RV-S/Kainox VCS lead combinations; those in the second group were implanted with only the single-coil lead (Kainox RV-S). Performance evaluation was based on the arrhythmia conversion rate of Group 1 versus Group 2. Since the implantation protocol required two inductions and conversions of ventricular fibrillation for the two-shock safety margin test, data recorded during the implantation procedure was the basis for the comparison. There were a total of 158 ventricular tachyarrhythmia episodes (17 spontaneous and 141 induced). Tables 10 and 11 provide a summary of all ventricular tachyarrhythmia conversion rates for Groups 1 and 2, respectively. Both groups experienced 100% successful ventricular arrhythmia conversion. Since, according to the physicians, Group 1 needed the dual-coil system, it can be said that the Kainox VCS lead appropriately augmented the Kainox RV-S lead, providing equivalent conversion rates for these refractory patients, as the Kainox RV-S lead alone provided for the others.

Discussion

Active fixation leads are an important addition to the ICD lead family because of their ability to be fixated at the most appropriate location in the myocardium, their greater resistance to dislodgement, and the ease with which they can be detached for repositioning or revision. Biotronik has introduced a new isodiametric, active fixation lead (Kainox RV-S) that combines the advanced features of the commercially available Kainox RV single-coil, passive fixation lead with the easy-to-use extendable/retractable fixation helix of the
commercially available Retrox lead. When the new Kainox RV-S is combined with the Kainox VCS unipolar SVC lead, the system is electrically identical to the commercially available Kainox SL dual-coil, passive fixation lead. This new lead system provides the physician more flexibility in tailoring a system appropriate for the patient.

This clinical study was designed to demonstrate that this new lead system performs within normal ranges for safety margin, shock impedance, R-wave amplitude, pacing threshold, and pacing impedance. Additionally, four primary endpoints were designed to assess the safety and efficacy of the investigational lead system. The system showed a low complication rate and high performance in sensing and pacing effectiveness. Finally, both the Kainox RV-S and the Kainox VCS augmented lead system showed 100% VT/VF conversion efficacy.

In a 2001 report, Doshni [12] noted the presence of non-physiologic sensing with an active fixation (CPI) lead. That report postulated that protrusion of the fixation screw made the lead more vulnerable to sensing myopotentials, and that movement of the screw in an integrated bipolar lead could result in inappropriate sensing.

![Table 12. Comparison of R-wave amplitude values. SD = standard deviation.](image)

![Table 13. Comparison of ventricular pacing thresholds. SD = standard deviation.](image)

![Table 14. Comparison of ventricular pacing impedance values. SD = standard deviation.](image)
Table 14 shows that the Kainox RV-S lead pacing impedance measurements are in the same range as the Guidant leads and the Telectronics lead.

Conclusion

Of the 24 patients enrolled and implanted with 26 Kainox RV-S leads and 9 Kainox VCS leads, three (12.5%) experienced lead-related complications. Ninety-seven out of the 98 pacing evaluations (96.9%) demonstrated appropriate pacing. One hundred percent of a total of 158 ventricular tachyarrhythmia episodes (17 spontaneous and 141 induced) were successfully converted with the appropriate lead system. The Kainox RV-S lead compares favorably to other manufacturers’ active fixation leads. The data collected to date from this clinical study indicate that the Kainox RV-S and VCS leads are safe and effective for use in ICD therapy.

References


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