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 mm^2, has two electrodes for sensing

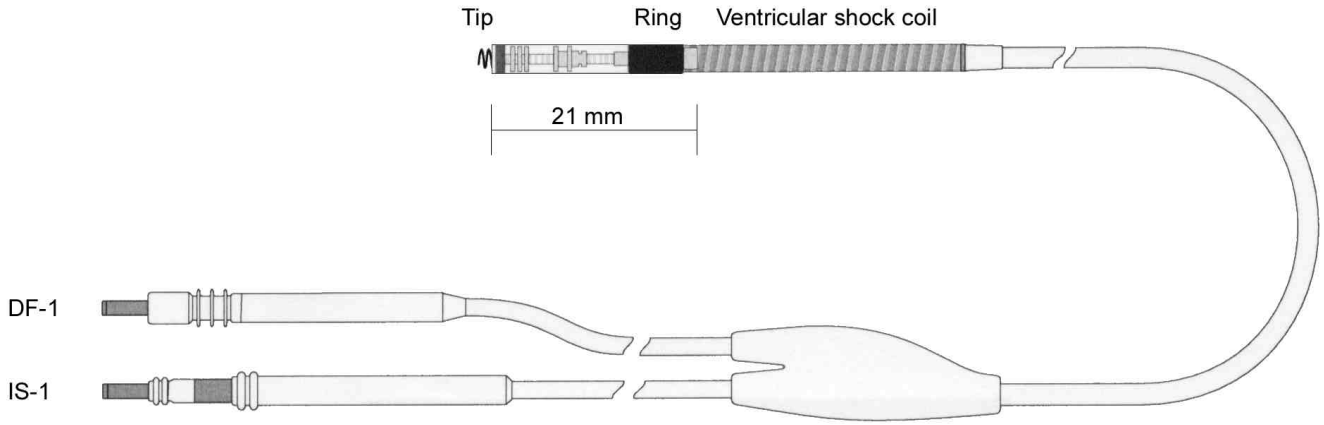

Figure 1. Kainox RV-S active fixation, single-pass, single-coil, bipolar ICD lead (Biotronik, Germany).

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.

	Patient characteristics	
Age at implantation (years)	Mean ± SE	69.0 ± 2.1
	Range	40 – 84
Gender	Male	21 (87.5%)
	Female	3 (12.5%)
Primary tachyarrhythmias	VF/PVT	15 (62.5%)
	MVT	12 (50.0%)
Bradyarrhythmias	Sinus bradycardia	4 (16.7%)
	AV block	4 (16.7%)
	Other bradycardias	2 (8.3%)
	None	15 (62.5%)
Antiarrhythmic drug therapy	Amiodarone	3 (12.5%)
	Sotolol	2 (8.3%)
	None of the above	19 (79.2%)

Table 1. Patient characteristics. Note that the sum of the percentages may be more than 100% because some categories allow more than one response. SE = standard error of the mean, VF = ventricular fibrillation, PVT = polymorphic ventricular tachycardia, MT = monomorphic ventricular tachycardia.

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

		Two successes at 20 J or less	Step-down DFT testing
Defibrillation threshold	No. of tests	12	7
	Mean ± SE (J)	16.3 ± 1.0	6.9 ± 0.8
	Range (J)	10 – 20	4 – 10

Table 2. Safety margin evaluation for Kainox RV-S alone. The number of measurements at a given procedure may be less than or greater than the number of patients enrolled in the study. In some cases, measurements were not completed or additional measurements were performed due to individual circumstances. SE = standard error of the mean, DFT = defibrillation threshold.

		Two successes at 20 J or less	Step-down DFT testing
Defibrillation threshold	No. of tests	10	0
	Mean ± SE (J)	14.6 ± 1.9	Not available
	Range (J)	5 – 26	Not available

Table 3. Safety margin evaluation for Kainox RV-S and VCS together. The number of measurements at a given procedure may be less than or greater than the number of patients enrolled in the study. In some cases, measurements were not completed or additional measurements were performed due to individual circumstances. SE = standard error of the mean, DFT = defibrillation threshold.

		Kainox RV-S	Kainox RV-S and VCS
Lead impedance	No. of tests	19	10
	Mean ± SE (Ω)	69 ± 3	41 ± 2
	Range (Ω)	42 – 90	32 – 50

Table 4. Shock lead impedance. The number of measurements at a given procedure may be less than or greater than the number of patients enrolled in the study. In some cases, measurements were not completed or additional measurements were performed due to individual circumstances. SE = standard error of the mean, VCS = additional Kainox VCS lead placed in the superior vena cava to create a dual-coil system.

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-

		Implantation	Pre-discharge follow-up	1-month follow-up	3-month follow-up	Other follow-ups
R-wave amplitude	No. of tests	27	25	20	12	12
	Mean ± SE (mV)	12.1 ± 0.7	10.8 ± 0.8	10.5 ± 0.7	12.8 ± 0.7	13.3 ± 1.0
	Range (mV)	4.3 – 16.0	3.2 – 16.0	3.6 – 16.0	8.5 – 16.0	7.0 – 16.0

Table 5. R-wave amplitude. 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.

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

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.

		Implantation	Pre-discharge follow-up	1-month follow-up	3-month follow-up	Other follow-ups
Ventricular pacing impedance	No. of tests	25	25	19	11	13
	Mean ± SE (Ω)	539 ± 17	488 ± 15	508 ± 23	525 ± 28	523 ± 28
	Range (Ω)	410 – 773	370 – 680	400 – 809	420 – 720	361 – 720

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.

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.

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.

Follow-up	No. of tests	Appropriate tests
Implantation	28	28 (100%)
Pre-discharge	25	25 (100%)
1-month	20	20 (100%)
3-month	12	12 (100%)
Other	13	12 (92.3%)
All procedures	98	97 (99.0%)

Table 8. Ventricular sensing.

Follow-up	No. of tests	Appropriate tests
Implantation	28	28 (100%)
Pre-discharge	24	24 (100%)
1-month	20	19 (95.0%)
3-month	12	12 (100%)
Other	14	12 (85.7%)
All procedures	98	95 (96.9%)

Table 9. Ventricular pacing.

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.

Type of episodes	No. of patients	Rhythm	No. of episodes	Successful device conversions
Induced	9	VF/PVT	46	46 (100%)
	0	MVT	0	Not available
Spontaneous	2	VF/PVT	5	5 (100%)
	0	MVT	0	Not available
Total	11	VF/PVT/MVT	51	51 (100%)

Table 10. Tachyarrhythmia conversion rates for Kainox RV-S and VCS. VF = ventricular fibrillation, PVT = polymorphic ventricular tachycardia, MT = monomorphic ventricular tachycardia.

Type of episodes	No. of patients	Rhythm	No. of episodes	Successful device conversions
Induced	16	VF/PVT	93	93 (100%)
	1	MVT	2	2 (100%)
Spontaneous	3	VF/PVT	12	12 (100%)
	0	MVT	0	Not available
Total	20	VF/PVT/MVT	107	107 (100%)

Table 11. Tachyarrhythmia conversion rates for Kainox RV-S alone. VF = ventricular fibrillation, PVT = polymorphic ventricular tachycardia, MT = monomorphic ventricular tachycardia.

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.

		Implantation	Pre-discharge follow-up	1-month follow-up	3-month follow-up	Other follow-ups
Kainox RV-S	No. of tests	27	25	20	12	12
	Mean ± SD (mV)	12.1 ± 3.6	10.8 ± 4.0	10.5 ± 3.1	12.8 ± 2.4	13.3 ± 3.5
SWEET TIP	No. of tests	61	60	54	52	-
	Mean ± SD (mV)	10.4 ± 5.0	7.9 ± 3.0	7.9 ± 2.7	8.1 ± 2.5	Not available

Table 12. Comparison of R-wave amplitude values. SD = standard deviation.

		Implantation	Pre-discharge follow-up	1-month follow-up	3-month follow-up	Other follow-ups
Kainox RV-S	No. of tests	27	25	19	12	13
	Mean ± SD (V)	0.47 ± 0.16	0.59 ± 0.30	1.57 ± 0.78	1.29 ± 0.59	1.37 ± 0.72
SWEET TIP	No. of tests	67	54	61	54	-
	Mean ± SD (V)	0.76 ± 0.44	0.59 ± 0.24	1.68 ± 0.74	1.52 ± 0.52	Not available
Accufix II DEC	No. of tests	20	20	20	20	39
	Mean ± SD (V)	0.51 ± 0.09	0.51± 0.20	0.70 ± 0.45	0.67 ± 0.42	0.67 ± 0.47
SWEET TIP Rx	No. of tests	38	-	38	-	38
	Mean ± SD (V)	0.71 ± 0.29	Not available	0.95 ± 0.27	Not available	0.98 ± 0.24

Table 13. Comparison of ventricular pacing thresholds. SD = standard deviation.

		Implant	Pre-discharge follow-up	1-month follow-up	3-month follow-up	Other follow-ups
Kainox RV-S	No. of tests	25	25	19	11	13
	Mean ± SD (Ω)	539 ± 86	488 ± 76	508 ± 98	525 ± 93	523 ± 100
SWEET TIP	No. of tests	67	66	61	54	-
	Mean ± SD (Ω)	664 ± 104	837 ± 148	841 ± 143	839 ± 135	Not available
Accufix II DEC	No. of tests	20	20	20	20	39
	Mean ± SD (Ω)	557 ± 92	558 ± 83	614 ± 124	605 ± 105	586 ± 98
SWEET TIP Rx	No. of tests	38	-	38	-	38
	Mean ± SD (Ω)	647 ± 161	Not available	628 ± 92	Not available	668 ± 110

Table 14. Comparison of ventricular pacing impedance values. SD = standard deviation.

Gelder [13] reported in 2000 that four out of 20 Endotak active fixation leads picked up noise that resulted in inappropriate detections in three patients. This clinical investigation specifically looked for the possibility of lead noise phenomenon by reviewing real-time and stored electrograms. Based on the clinical results applicable to the second endpoint (evaluation of sensing with the Kainox RV-S lead), there were no reported events or instances of oversensing due to lead noise. In addition, based on a review of the events stored in the ICD, there were no cases where inappropriate therapy was delivered to a patient as a result of lead noise.

Complications from the Kainox RV-S lead have been few in number and minor in significance. Several reports of perforation by active fixation leads have been made over the past two years [14-17]. However there were no reports of perforation in patients participating in this study. Two of the 26 implanted leads became dislodged, one spontaneously 2 days post-implantation, and the other 6 weeks post-implantation, ostensibly due to extreme physical interaction (wrestling). This 7.7% dislodgement rate is higher than the 2.9% reported by Glikson [18], or the 3.7% reported by Krein [19]. However, if the lead that became dislodged due to wrestling is excluded, this brings the figure down to 3.8% (1 out of 26), which is in the same range as the other reports. One lead stopped sensing, requiring insertion of a new sensing/pacing lead. This failure will be monitored closely as the clinical study continues.

In 2000, Giudici [20] provided R-wave amplitude, pacing threshold, and impedance data for an active fixation lead, the SWEET TIP (Guidant CRM, USA). Also in 2000, Ceviz [21] reported pediatric pacing threshold and impedance data for an active fixation, steroid-eluting lead, the Accufix II DEC (Telectronics Pacing Systems, USA). Threshold and impedance data from another Guidant active fixation lead, this one with a steroid-eluting tip (SWEET TIP Rx) was reported in 2000 by Hidden-Lucet [22]. Table 12 shows that over the course of follow-up, the Kainox RV-S lead and the Guidant SWEET TIP lead have comparable R-wave amplitude measurements.

Table 13 shows that the Kainox RV-S lead and the Guidant SWEET TIP lead have comparable pacing threshold measurements. The table also shows the steroid-eluting effect that provides lower pacing thresholds for the Accufix II and the SWEET TIP Rx leads as compared to the non-steroid-eluting leads, while still remaining within normal range.

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 sensing evaluations (99.0%) demonstrated appropriate sensing without any instances of lead noise resulting in inappropriate detection or therapy. Ninety-five 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.

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