Boston Scientific

CLINICAL SUMMARY

CONTAK RENEWAL

CAUTION: Federal law restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.

Boston Scientific Corporation acquired Guidant Corporation in April 2006. During our transition period, you may see both the Boston Scientific and Guidant names on product and patient materials. As we work through the transition, we will continue to offer doctors and their patients technologically advanced and high quality medical devices and therapies.

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CLINICAL STUDY - CONTAK RENEWAL

SUMMARY

Guidant conducted the CONTAK RENEWAL Study, which demonstrated the device's ability to appropriately detect ventricular tachyarrhythmias with an independent sensing configuration. In addition, the CONTAK RENEWAL Holter Study was conducted to provide confirmation of the device's ability to provide continuous biventricular pacing on both a daily basis and during exercise.

The CONTAK RENEWAL Study was a prospective, multi-center, non-randomized evaluation conducted in Europe and enrolled a total of 45 patients. The purpose of the study was to verify that the CONTAK RENEWAL device performs according to specification.

STUDY DESIGN

Inclusion/Exclusion Criteria

Patients who were enrolled in the study were required to meet the following inclusion criteria:

- Symptomatic heart failure
- Left ventricular dysfunction
- Wide QRS
- At risk for sudden cardiac death
- 18 years or of legal age in order to give informed consent according to national laws
- Able to understand the nature of the procedure
- Available for follow-up on a regular basis at an approved investigational center

Patients were excluded from the investigation if they met any of the following criteria:

- Life expectancy of less than six months due to other medical conditions
- For women: Pregnancy or absence of medically accepted birth control
- Inability or refusal to sign the Patient Informed Consent
- Inability or refusal to comply with the follow up schedule or protocol requirements

- Mechanical tricuspid prosthesis
- Currently enrolled in another investigational study, including drug investigations
- Hypertrophic Obstructive Cardiomyopathy
- Are unable to undergo device implant, including general anesthesia if required
- Have pre-existing leads other than those specified in the investigational plan (unless the investigator intended to replace them with the permitted leads)

STUDY RESULTS

Demographic Data

The patient characteristics at study entry are summarized in Table 1.

Table 1. Preimplant Characteristics of Study Patients

Characteristics[a]	Patient Data
N patients implanted	44
Gender	Male (91%), Female (9%)
Age (years)	65 ±9
NYHA	II (14%), III (77%), IV (9%)
LVEF (%)	22 ±6
BBB	LBBB/NSIVCD (86%),RBBB (14%)
Etiology	Ischemic (56%), Non-ischemic (44%)
QRS Width	172 ± 24 ms
PR Interval	211 ± 49 ms
Resting HR	70 ± 12 bpm

a. Continuous measures are reported as means ± standard deviations.

Ventricular Tachyarrhythmia Detection Time

The CONTAK RENEWAL device has independent Left Ventricular and Right Ventricular Sensing. Ventricular tachyarrhythmia detection time was analyzed to determine if the sensing configuration had any effect on sensing VT/VF. Based on previous clinical studies of the VENTAK AV family, upon which the ICD function of CONTAK CD and CONTAK RENEWAL are built, Guidant's ICDs typically have a VF detection time of approximately two seconds. The VF detection time of 2.4 ± 0.5 seconds in the RENEWAL study was statistically lower than 6 seconds[1] ($p < 0.01$), demonstrat-

1. Detection time at implant with legally marketed Guidant ICD devices is typically two seconds, and investigators have stated than an additional delay of 3 to 5 seconds would be a clinically significant event. The expected detection time is 2 seconds (95% CI: [0, 6 sec]).

ing that there was no statistically significant prolongation of induced VF detection times with the independent sensing configuration. There were no adverse events reported in which a CONTAK RENEWAL device failed to detect a spontaneous ventricular tachyarrhythmia.

CONTAK RENEWAL HOLTER STUDY

Summary

The CONTAK RENEWAL Holter Study was a prospective, multi-center, non-randomized evaluation conducted in Europe, in which 46 patients completed testing. The purpose of the study was to demonstrate continuous appropriate biventricular (BiV) pacing over a 24 hour period and during exercise using Holter monitor recordings. All patients had been implanted with a CONTAK RENEWAL for a minimum of one month at the time of the study initiation.

Study Design

Inclusion/Exclusion Criteria

Patients who were enrolled in the study were required to meet the following inclusion criteria:

- Availability for 24 hours follow-up at an approved study center
- Willingness and ability to participate in all testing associated with this study
- Age 18 or above, or of legal age to give informed consent as specified by national law
- Implanted with the CONTAK RENEWAL system for at least 1 month
- Stable when programmed according to labeled recommendations for continuous BV pacing
- Sinus rhythm at follow-up
- Active atrial lead implanted

Patients were excluded from the investigation if they met any of the following criteria:

- Life expectancy of less than six months due to other medical conditions
- Concurrent participation in any other clinical study, including drug study
- In atrial fibrillation at follow-up
- Inability or refusal to sign the Patient Informed Consent
- Inability or refusal to comply with the follow-up schedule
- Known pregnancy

Programming Parameters

Refer to product literature for information about programming to maintain CRT. Programming recommendations in this study were consistent with product recommendations.

Endpoints

The study had two primary endpoints: 1) continuous appropriate BiV pacing during activities of daily living and 2) continuous appropriate BiV pacing during exercise. The mean percentage of sinus beats appropriately BiV paced was measured by a Holter monitor over a 24 hour period and during exercise. Exercise intensity was measured using the Borg rating of perceived exertion (RPE) 6-20 scale. Patients were asked to exercise to a Borg level of 15 (difficult). The exercise protocol used was left to the discretion of the physician based on the patients' functional status. The type of exercise performed, duration and intensity of exercise testing is listed in Table 2 and Table 3.

Table 2. Type of Exercise Testing Performed

Exercise Performed	Number of Patients
Bicycle Ergometry	24 (52.2%)
Hall Walk	8 (17.4%)
Stair Climbing	14 (30.4%)
Total	46

Table 3. Duration and Intensity of Exercise Testing

		Results (N=46)
Borg RPE Rating Obtained	Mean ± SD	15 ± 1
	Median	15
	Range	7 – 18
Duration of Exercise (minutes)	Mean ± SD	6.6 ± 3.3
	Median	6.0
	Range	1 – 17
Maximum HR Obtained (bpm)	Mean ± SD	103 ± 20
	Median	105
	Range	60 – 156

Study Results

Demographic Data

The patient characteristics at study entry are summarized in Table 4.

Table 4. Preimplant Characteristics of Study Patients

Characteristics		Patient Data
N patients		46
Gender		Male: 40 (87%), Female: 6 (13%)
Age (years)		60.9 ± 9.0
NYHA at implant [N (%)]	I	0 (0%)
	II	5 (10.9%)
	III	34 (73.9%)
	IV	7 (15.2)%
NYHA current [N (%)]	I	9 (19.6%)
	II	25 (54.3%)
	III	11 (23.9%)
	IV	1 (2.2%)
Duration implanted (months)	Mean ± SD	8.3 ± 4.1
	Range	1.5 –- 15.0
	Median	9.0

Pacing during activities of daily living

The mean percentage of appropriately continuously paced beats during daily living was calculated as 99.6 ± 1.3% with a median of 100% and is summarized in Table 5. Continuous appropriate BiV pacing is defined as pacing provided between the lower rate limit and the MTR, excluding PVCs.

Table 5. Activities of Daily Living: Continuous Appropriate BiV Pacing

	Statistic	P-value[a]
Mean ± SD	99.6 ± 1.3	--
Range	91.4 – 100	--
Median[b]	100	<0.01

a. The p-value is based on the sign-rank test.

b. Due to the non-normality of the data a non-parametric test of the median was performed comparing the median to 90%.

Pacing During Exercise

The mean percentage of appropriately continuously paced beats during exercise was calculated as 98.3 ± 5.6% with a median of 100% and is summarized in Table 6. Continuous appropriate BiV pacing is defined as pacing provided between the lower rate limit and the MTR, excluding PVCs.

Table 6. Exercise: Continuous Appropriate BiV Pacing

	Statistic	P-value[a]
Mean ± SD	98.3 ± 5.6	--
Range	68.1 – 100	--
Median[b]	100	<0.01

a. The p-value is based on the sign-rank test.
b. Due to the non-normality of the data a non-parametric test of the median was performed comparing the median to 90%.

Device Counters

Finally, during the study CONTAK RENEWAL device counters were found to correlate highly to the data collected on the independent Holter monitors.

Table 7. Correlation Between Holter and Device

	Mean ± SD	Correlation (P-value)
Holter	97,536 ± 13,307	0.97 (<0.01)
Device	100,143 ± 13,373	--

Boston Scientific

Manufacturer

Boston Scientific
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

www.bostonscientific.com

1.800.CARDIAC (227.3422)
+1.866.484.3268

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