

## Long-Term Evaluation of a VDD Lead for Dual-Chamber ICD Systems in an Animal Study

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### Summary

*Delivery of inadequate shocks during supraventricular tachycardia represents the main problem of single-chamber defibrillator therapy. Furthermore, high complication rates related to atrial electrodes in dual-chamber defibrillation systems have been reported. Therefore, we developed and evaluated a single-lead VDD shock electrode. The aim of our study was to evaluate the long-term stability of this new electrode and its chronic sensing capabilities during atrial and ventricular arrhythmias in animals. Eleven female sheep (1 – 2 years, 79 ± 8.4 kg) anesthetized with Propofol-Isosfluran/N<sub>2</sub>O were implanted with a size-adapted, tined, single-lead defibrillation electrode with two fractal coated sensing rings in the right atrium and an additional bipolar screw-in electrode located in the right atrium. For intraoperative measurements, the single-lead electrode was connected to a digital recording system and atrial and ventricular signals were recorded. Subsequently, a Phylax AV implantable cardioverter/defibrillator was connected to the VDD lead and implanted subcutaneously at the right lateral part of the animal's throat. Follow-ups were performed monthly. After 6 months, the intraoperative measurements were repeated, followed by induction and termination of ventricular fibrillation. After the animals were euthanized, their hearts were explanted for histopathological examination. No dislocation or defect of the VDD electrode was observed. Even during activity, no oversensing or undersensing of atrial and ventricular signals during sinus rhythm was found. The pathological examination showed the "correct" position of the VDD electrode with sensing rings in contact with the lateral wall of the right atrium in 80% of the animals. In two animals, the distal atrial ring was located in the annulus of the tricuspid valve. In conclusion, the new VDD-defibrillation electrode provides stable detection of atrial and ventricular signals without undersensing or oversensing even during activity in a long-term animal model.*

### Key Words

Implantable cardioverter/defibrillator (ICD), single-chamber defibrillator therapy, single-lead VDD shock electrode, supraventricular tachycardias

### Introduction

Inappropriate therapies of implantable cardioverter defibrillators (ICDs) due to supraventricular arrhythmias are very common because single-chamber ICD systems use only the ventricular rate criterion in deciding when to deliver therapy. While these devices provide high sensitivity, a lack of specificity has been demonstrated in the detection of supraventricular and

ventricular tachycardias using only the rate criterion in combination with the stability or sudden onset criterion. This leads to an inappropriate electrical therapy by the device [1]. Inappropriate shocks for fast ventricular rates during atrial fibrillation (AF) occur in up to 12% to 25% of ICD patients who have a history of AF [2,3]. Additional discrimination algorithms such as morphol-

ogy detection [4,5] have been developed, but they have shown a limited sensitivity and specificity resulting in the potential under-detection of ventricular arrhythmias. Schuger et al. [6] have shown an improved discrimination between atrial and ventricular tachyarrhythmias by incorporating atrial signals in the sensing algorithms of dual-chamber ICDs. This ability to operate using dual-chamber detection to classify both atrial and ventricular signals allows the device to better identify the rhythm and deliver appropriate ventricular therapy [7]. Despite a higher specificity in dual-chamber detection systems, a higher complication rate has been found, most often due to dislocations of the atrial lead [8].

In order to combine the information from an atrial channel (for better differentiation of arrhythmias) with the lower complication rate of a single electrode, a single-lead electrode for use with dual-chamber ICDs was designed. After promising results in acute tests [9,10], the current study was performed to determine the long-term mechanical stability and the chronic sensing capabilities of atrial and ventricular signals.

## Materials and Methods

This study was approved by the Animal Study Committee of the district government and of the local ethics committee.

### *VDD Defibrillation Lead*

The new VDD lead (research product, Biotronik, Germany) has a tip with four tines for passive fixation, one shock coil, and two fractal coated bipolar atrial sensing rings (Figure 1). It is situated in a five-polar silicon tube with a maximum diameter of 10.5 F. The distance between the atrial sensing rings and the lead tip was adapted to the size of the animals' hearts. This has been estimated in measurements on sheep during gross pathological examination. The distance between the two sensing rings was 10 mm. For implantation of this lead, an 11 F introducer sheath can be used.

### *Animals*

Measurements were performed in 11 healthy female sheep 1 – 2 years old, weighing  $79 \pm 8.4$  kg. The animals were anesthetized using Propofol-Isfluran/N<sub>2</sub>O, and were then intubated and ventilated. Vascular access was obtained through double puncture of the right jugular vein, and 10 and 11 F sheaths were inserted.

### *Implantation Procedure*

Using the 10 F sheath, a common bipolar screw-in electrode was implanted in the right atrial appendage followed by the implantation of a size-adapted single-lead defibrillation electrode using an 11 F sheath. To determine atrial and ventricular sensed signals, pacing threshold, and pacing impedance during sinus rhythm (SR) a digital recording system was used. Atrial flutter (AFI) and AF were induced several times using a burst generator (Biofib, Biotronik) connected to the screw-in atrial electrode. Simultaneously, the continuous signals from the VDD's atrial channel and common atrial electrode were recorded. Afterwards a standard dual-chamber ICD (Phylax AV, Biotronik) was connected to the VDD lead and implanted into a subcutaneous pouch at the right side of the animal's neck. At least, the atrial screw-in lead was connected to a standard pacemaker implanted at the same site. The implantation was considered successful if X-rays documented close contact of the atrial rings to the mid-lateral wall of the right atrium, and if electrical parameters were acceptable (stable detection of atrial and ventricular signals and a ventricular pacing threshold of  $< 2$  V for 0.5 ms pulse width).

### *Follow-ups*

Detection of tachyarrhythmia by the implanted devices was deactivated between the monthly-performed follow-up examinations. During each follow-up procedure, sensing capabilities of the atrial and ventricular channels were studied by continuously recording atrial and ventricular intracardiac electrograms and markers over 60 s intervals during rest and exercise (Figure 2). A special long telemetry cable for the programmer TMS 1000 (Biotronik) was used. Thereafter, the animals were heavily sedated with Propofol to obtain a fluoroscopic picture.

### *Final Follow-up*

After 6 months, intraoperative measurements were repeated while the animals were under general anesthesia. Atrial and ventricular sensed signals, atrial and ventricular pacing thresholds, and pacing impedances were recorded. Afterwards, AFI and AF were induced using the atrial screw-in electrode. This was followed by induction of ventricular fibrillation (VF) with a 50 Hz burst and termination of VF by a standard biphasic shock. After the animals were euthanized, their hearts were explanted for macro- and micropathological examination.

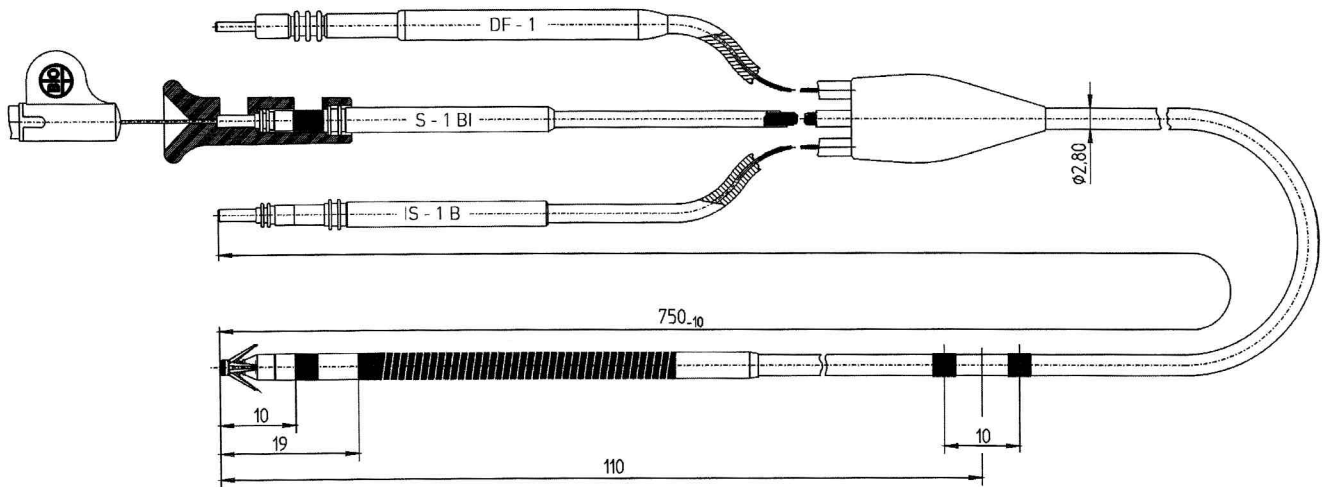


Figure 1. Technical drawing of the VDD lead (sizes in mm).

*Data Analysis*

Measurements of the atrial and ventricular signals were carried out as a peak-to-peak analysis using the TMS 1000. Detection feasibility was evaluated by counting the atrial and ventricular marker signals in the marker channel of the TMS 1000. The data are pre-

sented as the mean value ± standard deviation. Differences between the mean values were evaluated using the paired two-tailed t-test; p-values < 0.05 were considered significant.

**Results**

*Implantation Procedure*

In all animals implantation of the VDD electrode was successfully completed. In 10 animals implantation was conducted without any problems. In one case following the surgery, a dislocated lead was observed in the final X-ray picture. The position of the lead was revised and no further problems were experienced. Mean implantation time of the VDD lead was 19.6 ± 7.5 min; mean fluoroscopy time was 2.9 ± 2.2 min for both electrodes.

*Clinical Observations During Follow-up*

Two animals were euthanized at the 1-month follow-up because they developed wound dehiscence from severely rubbing themselves on the right side of their neck. One animal died from fulminant pneumonia after 4 months.

*Electrical Parameters at Implantation*

During SR, mean sensing amplitude in the atrial channel of the VDD lead was 2.1 ± 1.7 mV, mean stimulation impedance was 218 ± 19 Ω, and mean pacing



Figure 2. Extensive exercise test with a special telemetry wand fixed at the lateral throat.

threshold of the atrial rings was  $2.4 \pm 1.5$  V at 0.5 ms. Mean ventricular sensing amplitude was  $3.7 \pm 1.3$  mV, and mean ventricular pacing threshold was  $1.1 \pm 1.3$  V at 0.5 ms.

#### Comparison of Detection Feasibility at Implantation and Explantation

Comparison of sensing capabilities during implantation versus explantation of the individual atrial VDD channel are presented in Figure 3. There is no statistically significant difference due to the small sample size, but, in most cases a decrease of the amplitude 6 months post implantation was observed. Figure 4 shows the atrial amplitudes during implantation and explantation for SR, AFI and AF. The amplitudes were lower after 6 months in all cases, but only during AF the reduction was statistically significant. The feasibility of detection by the ICD acutely was 99.7% for SR, 93% for AFI, and 91% for AF (Figure 5). This latter reduction reached the limit of significance ( $p$ -value = 0.03).

#### Trends of Pacing Thresholds

Figure 6 shows the behavior of the atrial and ventricular pacing thresholds during follow-up. A significant increase in the atrial pacing threshold was observed at 1 month after implantation; this stabilized at the second follow-up after 2 months. The ventricular pacing threshold was found to be stable below 2 V at 0.5 ms during follow-up.

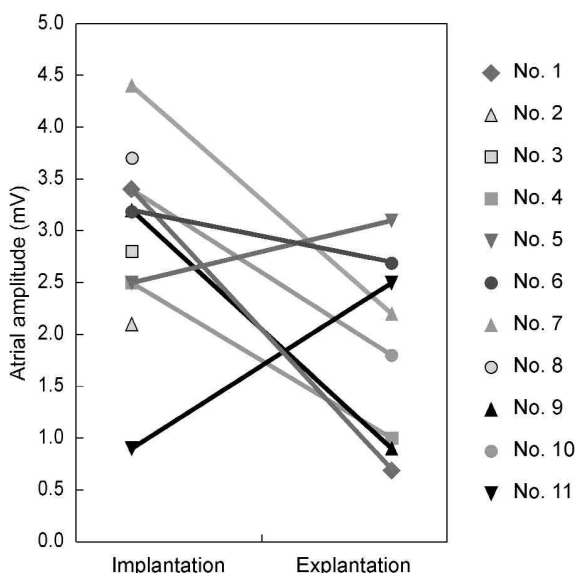


Figure 3. Comparison of individual atrial amplitudes during sinus rhythm.

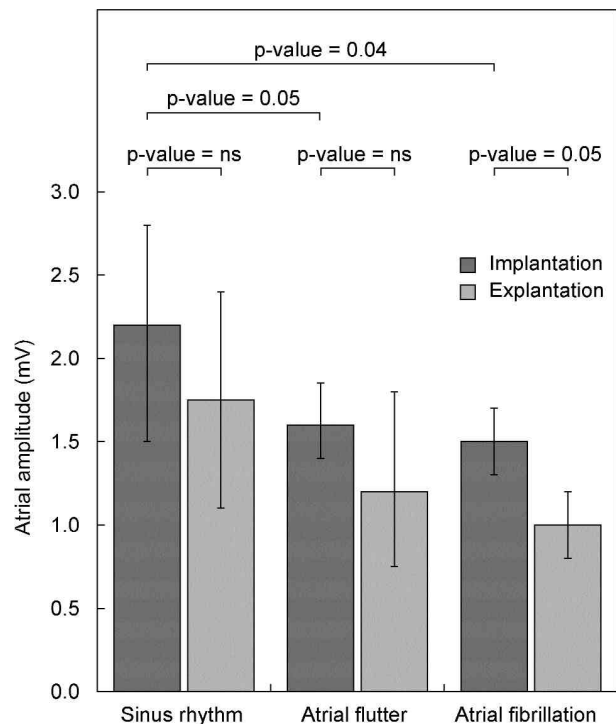


Figure 4. Atrial VDD signals during different atrial rhythms; ns = not significant; mean values  $\pm$  standard deviations.

#### Intracardiac Electrogram (EGM)

EGM recordings during rest and activity did not show significant changes in atrial sensing. Furthermore, no significant oversensing in the atrial channel was found.

#### Radiological Documentation

During implantation the tip of the VDD lead was fixed in the apex of the right ventricle. In this manner, the atrial rings were closely positioned to the mid-lateral wall of the right atrium. On X-ray examination, this position did not change in eight animals (typical fluoroscopic pictures are presented in Figure 7). At the first follow-up, in nine of 11 animals a loop was observed in the lead between the atrial sensing rings and the shock coil. In two sheep this loop was still present 1 month later. During subsequent follow-ups, no more changes in the location of the VDD lead were found.

#### Pathological Examination

After the animals were euthanized the hearts of the eight remaining sheep were explanted and opened dorsally from the right atrium to the right ventricle. In seven cases the correct position of the atrial rings (mid-

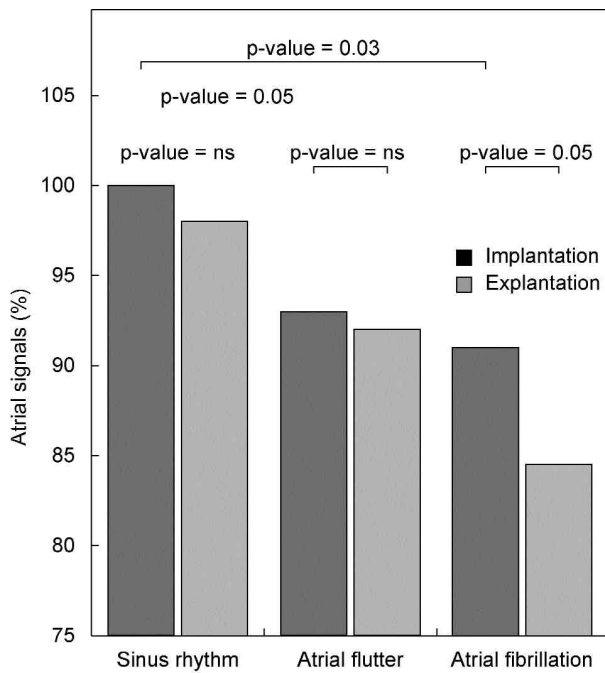


Figure 5. Feasibility of detection of atrial VDD signals during different atrial rhythms.

lateral wall of the atrium) was documented (Figure 8). In two hearts, the distal atrial ring was found to be in the annulus of the tricuspid valve. In one heart the proximal atrial ring was found to be in the superior cava vein. We did not find any thrombotic formations around the VDD lead. In three of the animals we saw an endothelialization of the shock coil with fixation in the right ventricle (Figure 8).

**Discussion**

The main purpose of a single-pass VDD defibrillation lead is to improve the discrimination between atrial and ventricular tachyarrhythmias. Reliable detection capabilities of a VDD defibrillation lead have recently been observed in an acute study [11,12]. Nevertheless, reliable performance of this system needs stable detection of atrial signals over a long time period, which was analyzed in our long-term follow-up study. The modified VDD defibrillation lead used in our study was easy to implant; the mean implantation time was inbetween the time of a single-chamber and a dual-chamber ICD system. The mechanical stability of the new lead was reliable; no critical dislocation of the leads was found.

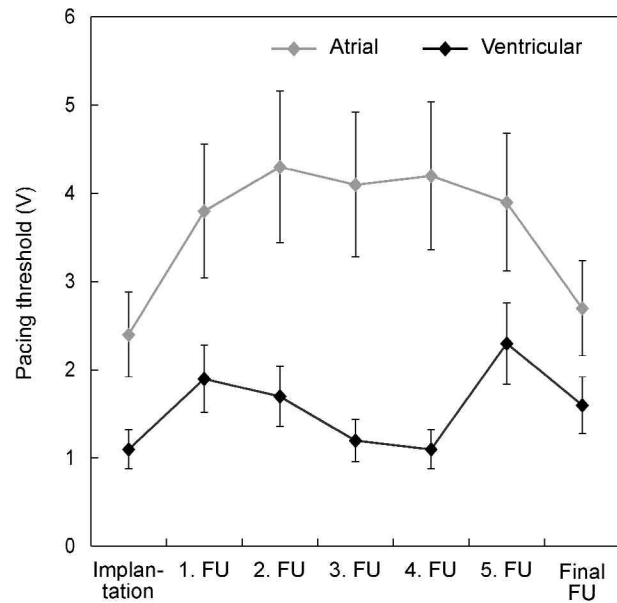


Figure 6. Pacing thresholds at 0.5 ms of all follow-ups (FU). Final FU = explantation; mean values ± standard deviations.

The detection feasibility of atrial signals in the atrial VDD channel was comparable to those in antibradycardia VDD systems [13,14]. During SR, 99.7% of the P-waves were detected by the Phylax AV. The mean sensing amplitudes during SR are comparable to those observed in VDD pacemaker trials [15-17]. During AFI a decrease in the atrial signals was found. This observation is in accordance with a study of Neuzner et al. [18], who described a decrease of 26% between SR and AFI in antibradycardia systems. About 85% of the fibrillation waves could be detected by the ICD without any modification of the amplifier. These findings are similar to a study that evaluated the detection feasibility of acute atrial arrhythmias [19]. Nevertheless, AF remains – in accordance with other VDD studies – a problem when using this form of therapy. Therefore, patients with chronic AF should be excluded from therapy with VDD systems according to international guidelines.

In VDD pacemaker systems there is convincing evidence of a decrease of initially large atrial signals during the first months after implantation. We could demonstrate this as well, but even measurements after more than half a year revealed sufficient sensing of atrial signals.

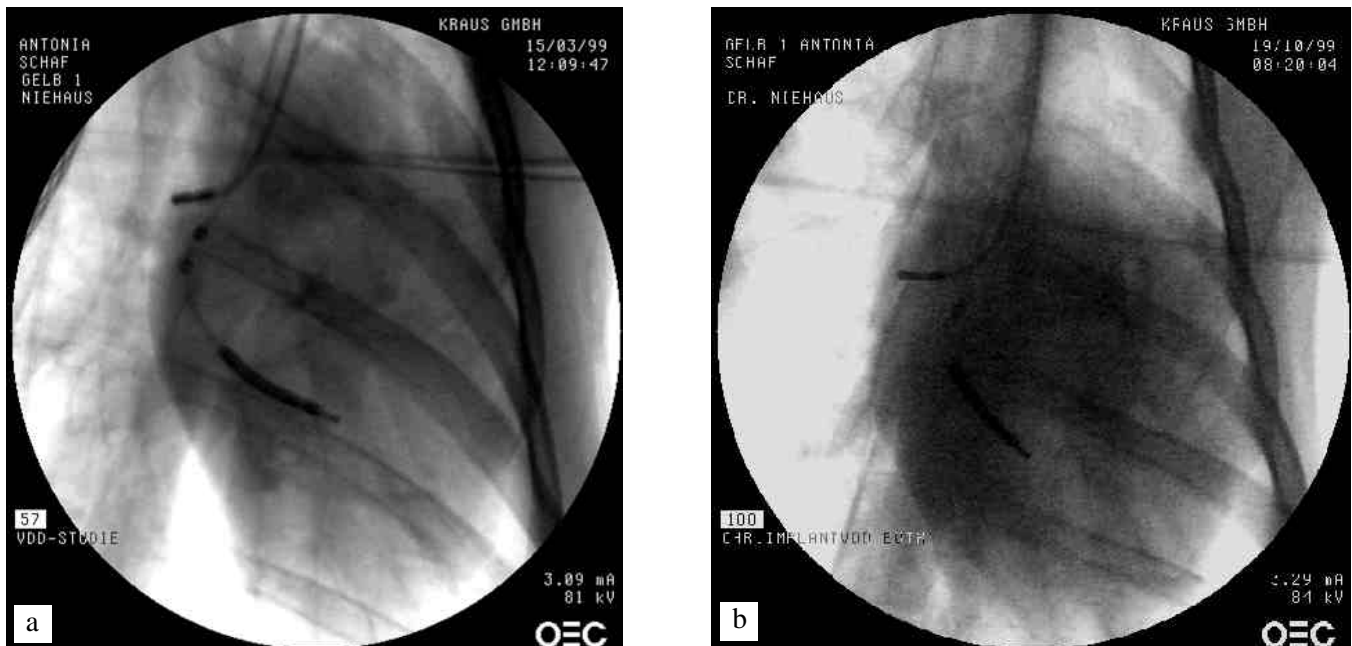


Figure 7. Fluoroscopy picture (anterior-posterior-view) of the leads in place during implantation (panel a) and after 6 months (panel b).

Oversensing in the atrial VDD channel due to rapid movements with strong innervation of the pectoral muscles has been described as a particular problem in VDD leads. During this study we performed online

recordings of EGMs and markers during extensive activity of the animals (Figure 2) and did not find any oversensing. This might be caused by the space of 10 mm between the atrial sensing rings, which seems to be protective against oversensing pectoral myopotentials.

During follow-up we found increased loop development of the VDD lead. This is related to the different position of thoracic organs in sheep, as compared to humans.

### Conclusion

The newly designed VDD dual-chamber lead for ICDs provides stable detection of atrial and ventricular signals during SR and AFI in this investigation. Reliable detection of atrial signals by a Phylax AV is possible without modifications to its amplifier even in the ongoing follow-up. However, amplitudes of AFI and AF were significantly lower compared to SR. Using a 10 – 15 mm spacing between the two atrial sensing rings, the VDD system seems to be protected against oversensing myopotentials.

In dual-chamber ICDs, the newly designed VDD lead provides additional information for discrimination algorithms by increasing the specificity of the algorithms to detect supraventricular tachycardias [20].



Figure 8. Gross examination: VDD lead in situ with atrial sensing rings in the right atrium and the endothelialized shock coil in the right ventricle.

Nevertheless, AF remains a problem that may be solved by introducing more sensitive discrimination algorithms.

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