High Capacity Implantable Data Recorders: System Design and Experience in Canines and Denning Black Bears

Introduction

The use of implantable recording equipment has been essential for understanding the physiology and behavior in a spectrum of animal species. In many cases, data collected by such devices can be telemetered to high capacity storage devices, but in other situations this approach is not feasible. Furthermore, biomedical devices for human application are now incorporating features for monitoring, requiring increased data management and storage capabilities. Typically, for the needs of large capacity laboratory studies or home monitoring of specified data, tethered or telemetry systems (e.g., Holter monitors) have been commonly employed. Yet, advances in technology have allowed such devices to become smaller and to have substantially increased data storage capabilities. Nevertheless, certain applications still necessitate free-standing and or remote systems with capabilities beyond those available in current commercial systems. Here we describe the design process of such prototype devices.

Although significant advances have occurred in sensor technology and the need for physiological monitoring of ambulatory patients has grown, there are only a limited number of FDA approved implantable monitoring systems available today. Examples include the Chronicle Implantable Hemodynamic MonitorTM [1] and the Reveal Insertable Loop RecorderTM [2] (both from Medtronic, Inc., Minneapolis, MN). In contrast, numerous systems exist for wildlife monitoring via telemetry from companies such as Advanced Telemetry Systems, Telonics, and Transon Medical. We envision continued growth in devices for both application areas. Specifically, such advances will be enabled as battery and memory technologies evolve and as improvements occur in the biostability and size of implantable sensors through the application of microelectromechanical systems and/or application of nanotechnology.

The objectives of the present report were to describe our development of novel implantable data recorders and to provide the readers with information as to the advantages and limitations of their applications in two unique studies. Our specific aim was to generate a design for an implantable data recording system that could be used for both: (1) chronic monitoring of canines with implanted cardiac leads and (2) chronic monitoring of free-ranging American black bears with subcutaneous lead implants during hibernation in their natural habitat. As such, our study protocols dictated that the implantable recorder systems elicit minimal influence on the natural behaviors of the animals; e.g., in the case of the bears, we needed to allow them full motility in the event that they chose to move to a secondary denning site during the overwintering period. An additional goal was to achieve data collection rates that allowed for the subsequent characterization of...
broadband electrical data relative to cardiovascular electrical activities, respiratory frequencies, and/or skeletal muscle activations. Therefore, we leveraged existing technology from the implantable pacing and defibrillation industry to create a new generation of implantable devices. These studies were designed to not only collect physiologic data, but also to determine features for future design iterations.

Materials and Methods

Detailed Description of the System Hardware. The implantable data recorder (IDR) system consisted of market-released defibrillation leads, the implantable device, a programmer, and a programming cable, as shown in Fig. 1. The system was designed to be flexible, lightweight (to allow procedures in remote areas), and easy to use. The development of the system took less than 12 months and utilized components from existing implantable devices.

Implantable pacing and defibrillation systems, with the associated intracardiac and subcutaneous leads, have been successfully used for decades. The materials required for chronic biocompatibility and biostability in these applications are well known. These devices are typically placed subcutaneously or submuscularly in a surgically created pocket. Pocket complications typically include: hematoma, wound dehiscence, migration, erosion, pain, and infection. Reported infection rates range from 0% to 19%, but device rejection due to foreign body response does not normally occur unless the patient has a rare allergic reaction to one of the materials employed. To leverage past success and experience, these devices were used as a platform for the development of the implantable data recording systems. The systems were designed for chronic implantability, while allowing preoperative programming and postexplant data recovery.

Implantable Device. The IDR was designed to record physiologic data over an extended period of time (up to 6 months) without the need for intermittent data retrieval. The implantable canister was the heart of the system, containing all electronics necessary to record and store wave form data (see Fig. 2). In order for the system to continue to function in the highly corrosive environment of a living organism, the electronics and power source needed to be contained in a hermetically sealed enclosure. Specifically, two titanium shield halves, which were seam welded, formed this enclosure. These devices also required glass feedthroughs, which permitted an electrical connection through the enclosure without compromising the hermeticity. A polyurethane connector block was mechanically attached to each enclosure and the interface was sealed using silicone medical adhesive. A laser-etching of the “University of Wyoming” designator and a contact phone number onto the titanium housing, in case of loss (e.g., due to hunting or shed radio-collar) was added to the devices for the bear research.

Electronics. Briefly, the electronics consisted of a microcontroller circuit board, compact-flash memory card, magnetic switch, and batteries. Signals from the lead and programming cable were routed through the header block and glass feedthroughs to the circuit board (Figs. 2 and 3).

The primary function of these implantable devices was to collect and record sensor signals in a pre-programmed, easy-to-select manner. The devices were capable of recording two sensor signals—broadband electrical potentials (EPs) from the submuscular lead, and activity from a single-axis accelerometer mounted on the circuit board. Standard operating parameters are listed in Table 1.

As shown in the block diagram of Fig. 4, the generalized circuitry consisted of four major subcomponents:

- **Microcontroller** (PIC16F877, Microchip Technology Inc., Chandler, AZ): provides overall management and control of the implantable device, including programming, scheduling, wave form conversion, and wave form storage.
- **Amplifiers**: amplification and filtering for broadband electrical potentials (EPs) from the submuscular lead and activity from a single-axis accelerometer mounted on the circuit board.
- **Memory card** (96 Mbyte CompactFlash™, SanDisk Corporation, Sunnyvale, CA): nonvolatile memory for storage of wave form signals and parameters.
- **Power Management**: two lithium batteries (TL-5903, 2.4 AH, nominal 3.6 V, Port Washington, NY), magnetic switch and circuitry to manage low power modes.

![Fig. 1](image1.png) The system and implant configuration used in the bear studies. The implantable data recorders were programmed and the data quality was assessed in each animal at the den sites prior to final system implantation.

![Fig. 2](image2.png) Exploded view of the implantable data recorder detailing the internal componentry. Within the outer titanium-alloy canister halves the following main components were contained: (1) compact-flash memory card (SanDisk® 96 Mbyte CompactFlash™), (2) microcontroller circuit board with a microcontroller (PIC16F877, Microchip Technology Inc., Chandler, AZ) and an accelerometer, (3) batteries (nominal 3.6 V, two AA tadiran lithium TL-5903, 2.4 AH), (4) a magnetic switch, and (5) a polyurethane connector block.
Accelerometer

Accelerometer

LabVIEW™ software. Setup and programming of the implantable device was performed on a commercially available notebook computer running Windows® 98 and positioning a magnet over the magnetic switch. Once programming of the implantable device was completed, the circuitry entered into low-power mode, to conserve power. This mode was maintained until this pre-programmed wake-up time was reached for initiation of data recording. Following each data recording session, the devices returned to the lower power mode to maximize device longevity.

Programmer. The programmer system consisted of a commercially available notebook computer running Windows® 98 and LabVIEW™ software. Setup and programming of the implantable device parameters were completed just prior to implantation to sets parameters within the microcontroller firmware. The programming cable was inserted into the header block on the implantable device and the set screws were tightened. The other end of the programming cable was connected to the standard RS232 port on the notebook computer. The portability and light weight of the notebook computer permitted easy programming in the field (Fig. 1).

Custom applications were developed for the programmer using LabVIEW™. As shown in Fig. 5, the graphical user interface was used to verify communication with the implantable device, setup data recording parameters, test waveform quality, and program the devices. For example, parameters were programmed as follows:

- **Start delay:** time after implant for the implantable device to wake up and begin recording. User selectable from 0 days and 0 h, to 60 days and 24 h.
- **Mode:** sets the schedule for data recording. The modes were programmable, allowing the user to define the duration of data collection and the sampling interval (e.g., recording 30 s of data every 5 min).
- **Animal ID:** unique identification numbers for each animal logged into the study. This was stored in the implantable device.

During the setup phase, all communications with the implantable device were echoed back and displayed on the programmer screen to verify correct programming. Upon successful completion of setting parameters, the user had the option of performing a wave form test to check sensor performance. When initiated, the implantable device sent real-time wave form data to the programmer for 10 s; this step could be repeated as many times as necessary. All parameter information and real-time wave forms were stored to the programmer hard drive. The final programming step was to prepare the implantable device for implant, which initiated the low-power mode. If successful, the programming cable was then disconnected and the implant was considered completed.

**Lead and Programming Cable.** The sensing of broadband electrical data with a high signal-to-noise ratio was accomplished using commercially available intracardiac defibrillation leads. These were positioned either in an intracardiac (dog), submuscular (bear), or intraperitoneal (bear) location. A pair of electrodes at the distal end of the leads was used to record a differential voltage.

In these studies, both the lead and programming cables utilized standard pacing and defibrillation lead connectors for optimized compatibility with the connector block. The programming cable was bifurcated, carrying the three signal lines necessary for RS232 communication (two signals go into one port of the header block and the third signal goes into a second port). The connectors on the lead and the programming cable plugged directly into the header block and were secured with set screws. Silicone sealing rings on the lead connectors prevented fluid ingress and short-circuiting. Once programming was complete, the programming cable was removed, the leads were attached, and the unused ports on the connector block were plugged to prevent fluid ingress from shorting these connections.

**Experimental Method**

**Canine Testing.** Twelve canines (1–2 year old mongrel hounds, 23–35 kg) were implanted with a commercially available endocardial implantable cardioverter defibrillator (ICD) leads and ICD systems. The surgical sites were shaved, cleaned with an antiseptic, and a sterile surgical drape was placed over each animal. The leads (models 6944, 6947, and 6949; Medtronic, Inc., Minneapolis, MN) were surgically implanted using aseptic technique with the lead bodies passed through the venous system, via a left jugular venotomy, for the ultimate implantation of the distal electrodes within the chambers of the heart. Model 6944 is a

**Fig. 3** Photos of the internal components of the data recorders. The circuit board and memory card are shown in (A) and in (B). The posterior surface of the board is shown with the microprocessor in place (B). The system was packaged within a titanium-alloy housing and hermetically sealed using laser welding. The componentry is shown prior to welding in (C) and (D).

Because of canister size constraints, which in turn limited battery capacity, custom low-power circuitries were designed to provide the necessary functionalities. Prior to programming at implant, the implantable devices were held in sleep mode by positioning a magnet over the magnetic switch. Once programming of the implantable device was completed, the circuitry entered into low-power mode, to conserve power. This mode was maintained until this pre-programmed wake-up time was reached for initiation of data recording. Following each data recording session, the devices returned to the lower power mode to maximize device longevity.

**Table 1 Recording parameters for electrical potentials (EPs) and accelerations**

<table>
<thead>
<tr>
<th></th>
<th>Bear</th>
<th>Canine</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>EPs</td>
<td>EPs</td>
</tr>
<tr>
<td>Frequency</td>
<td>1–100 Hz</td>
<td>2–100 Hz</td>
</tr>
<tr>
<td>Gain</td>
<td>72 dB</td>
<td>54 dB</td>
</tr>
<tr>
<td>Sample rate</td>
<td>256 Hz</td>
<td>256 Hz</td>
</tr>
<tr>
<td>Data resolution</td>
<td>8 bits</td>
<td>8 bits</td>
</tr>
<tr>
<td>Storage capacity</td>
<td>96 MB or 60 h</td>
<td>96 MB or 60 h</td>
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</table>
passive fixation lead that uses a hemispherical electrode in passive contact with the endocardium and models 6947 and 6949 are active fixation leads that use a helical electrode screwed into the myocardium for fixation. The IDRs (n=12) were positioned subcutaneously in the left superiolateral thoracic regions, with the leads tunneled superficially from the left jugular vein. The pocket for the IDR was inferior to the incision site (see Fig. 6). The IDRs were programmed to record both electrocardiographic signals and acceleration signals for 30 s every 90 min for the 6 month study period. These parameters were chosen to maximize the utilization of the battery capacity and flash memory for data collection.

**Black Bear Testing.** In two different seasons, the IDRs and sensing leads (model 6942; Medtronic, Inc., Minneapolis, MN) were surgically implanted using aseptic techniques in the field.

The surgical sites were shaved, cleaned with an antiseptic, and a sterile surgical drape was placed over each animal. In the first year, devices were positioned in a subcutaneous pocket in either the region of the pectoralis muscle or deltoid muscle (to avoid potential disruption by cubs) with the leads tunneled towards the heart (Fig. 1). The pocket for the IDR was inferior to the incision site. The site was closed using a series of single knot stitches spaced at 6–8 mm using absorbable sutures (Ethicon Vicryl 2-0, Johnson & Johnson, Piscataway, NJ). Stitches were placed in both subdermal and dermal tissues. The sensing electrodes were secured with a single suture in a subcutaneous location so to lie over the left pectoralis muscle near the sternum.

In the second season, the devices were surgically placed in the intraperitoneal cavity with the electrodes positioned on the linea alba in the proximity of the diaphragm using a single suture near the distal end of the lead. Next, the implanted leads were connected to the IDRs, and the signals received were viewed using the software interface to verify that adequate broadband electrical data could be obtained: e.g., we positioned the leads so to obtain electrocardiogram (ECG) signals and variations in the QRS amplitude of these signals that correlated with a respiratory cycle (as
Week 1 - Low Activity

Week 1 - High Activity

Week 26 - Low Activity

Week 26 - High Activity

Fig. 7 Shown here are sample electrograms from the canine testing. The signals were collected from leads placed in the right ventricular apex. An electrogram from week 1 (left) is shown during a period of low activity (above) and high activity (below). Note that the morphology of the T-wave is similar in both cases. Additional electrograms are shown for week 26 (right) for periods of low activity (above) and high activity (below). In this case, the T-wave is both inverted (reversed polarity) and has a substantial increase in amplitude. The x axis is time (seconds).

detected by QRS amplitude changes associated with alterations in thoracic impedances during respiration). When an acceptable signal was achieved, the desired data collection mode was programmed. The titanium canisters were then fixed to the linea alba with a single suture site through the connector block, thus allowing the canister bodies to freely move within the peritoneal contents.

The IDR's for these animals were implanted between November 28 and January 13 and were programmed to initiate data collection for a minimum of 21 days postimplant in an attempt to minimize the influences associated with the surgical procedure and the tranquilization/handling of the animals. The data-sampling rates for all devices were programmed to collect a minimum of 30 s of data in each 15 min interval. Follow-up visits were made to the dens during March to retrieve the devices.

Results

Canine Testing. Implantations of the IDR systems were achieved without complication. Of the 12 initial implants, the data from three of the devices were lost due to file corruption. In the remaining devices, chronic wideband T-wave recordings were achieved from the right ventricular apex over a period of at least 106 days in all animals (177±33 days). The initial analyses of this data consisted of: T-wave amplitude comparisons (1) over time and (2) during periods of rest and activity as defined by the acceleration signal. During the first month postimplantation, no consistent differences were found when comparisons were made between lead type and activity level. In contrast, significant changes in T-wave morphology were observed in the period post-one month implantation. All animals experienced a ≥80% increase in the T-wave amplitude due to activity >1 month after implant, and passive fixation leads produced a T-wave amplitude that was ≥60% larger than the active fixation leads >1 month after implant [6]. The changes noted with passive fixation leads were more pronounced during periods of maximal acceleration and activity (Fig. 7). The statistical analysis of this data is ongoing.

Black Bear Testing. Although an adequate data set was achieved in support of the goals of this study, an unexpected foreign body response occurred. In contrast to the canine IDR implantations where the devices remained stably implanted, the devices were unexpectedly externalized in five out of six bears at various times during the data collection interval. A seventh bear left the den prior to the March visit. This female bore cubs during the overwintering period. Two cubs were seen while tracking the female using her radio-collar, but the IDR was never recovered. The externalized devices were found inside the dens during the follow-up visits in March, including three of four subcutaneous implants and two of two intraperitoneal implants. The bears damaged three of these devices, with one resulting in total loss of data (Fig. 8). The six implants are summarized in Table 2.

From the retrieved bear implants, the broadband electrical data were used to identify ECGs, respiratory rates, electromyogram activity, gross body movement, and/or shiver. Figure 9 shows an example of the wideband EKG; from recorded data, QRS complexes and T-waves are easily visualized and postprocessing to
Fig. 8 Photos of recovered data recorders from two different implants: bear B03 shown in panel (A), and bear B01 shown in panel (B). In both cases these bears bit onto these titanium canisters with such force as to leave tooth impression on both the anterior (left) and posterior surfaces (right).

minimize electromyographic influences was also employed. The respiratory circle was identified by both the transient changes in heart rates (respiratory sinus arrhythmia) and the modulation of the QRS amplitudes, as a result of the variations in intrabody impedances associated with chest expansions and lung inflations [7,8]. An expanded view of one such prominent ECG signal is shown in Fig. 10 and an example of an associated acceleration signal collected is shown in Fig. 11. The heart rates recorded were remarkably low, with one bear averaging 27.0±7.2 beats/min over a 68 day period (minimum recorded rate=4.6 beats/min).

Discussion

Here we describe two diverse applications of a novel high-capacity implantable data recorder system. For the specialized applications described here, commercially available technologies were not deemed adequate or practical. Although the IDRs allowed for successful completion of both studies, numerous opportunities for improvements in the system design exist.

In the configuration of the systems we describe here, the data storage capabilities were ultimately limited by the longevity of the lithium batteries. Memory cards with substantially greater storage

<table>
<thead>
<tr>
<th>Bear ID</th>
<th>Implant date</th>
<th>Start of data collection</th>
<th>Implant location</th>
<th>Externalized? (implant duration)</th>
<th>Data collected</th>
<th>Comments</th>
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<tbody>
<tr>
<td>B01</td>
<td>19-Dec-99</td>
<td>1-Feb-00</td>
<td>SubQ pectoralis</td>
<td>Yes (&gt;53 days)</td>
<td>9 days</td>
<td>Cardiac signal not visible</td>
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<tr>
<td>B02</td>
<td>8-Jan-00</td>
<td>31-Jan-00</td>
<td>SubQ pectoralis</td>
<td>No</td>
<td>16 days</td>
<td>Good signal quality</td>
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<tr>
<td>B03</td>
<td>13-Jan-00</td>
<td>4-Feb-00</td>
<td>SubQ pectoralis</td>
<td>Yes (&gt;44 days)</td>
<td>22 days</td>
<td>Good signal quality</td>
</tr>
<tr>
<td>B04</td>
<td>1-Dec-00</td>
<td>31-Dec-00</td>
<td>SubQ deltoide</td>
<td>Yes (Unknown)</td>
<td>Memory card not readable</td>
<td></td>
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<tr>
<td>B05</td>
<td>28-Nov-00</td>
<td>27-Jan-01</td>
<td>IP</td>
<td>Yes (&gt;97 days)</td>
<td>67 days</td>
<td>Good signal quality</td>
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<tr>
<td>B06</td>
<td>28-Nov-00</td>
<td>27-Jan-01</td>
<td>IP</td>
<td>Yes (&gt;83 days)</td>
<td>23 days</td>
<td>Good signal quality</td>
</tr>
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Fig. 10 Shown here is a single cardiac cycle recorded from a subcutaneous site while an American black bear (Ursus americanus) was overwintering in a den. The wideband signal is shown in the upper panel and a filtered signal in the lower panel (third order Butterworth bandpass filter with cutoff frequency of 5–50 Hz). One second of data is shown. Following an isopotential period, a QRS cardiac wave form can be seen (cardiac depolarization) followed by a T-wave (cardiac repolarization).

Fig. 11 Shown here is an example of the recorded broadband electrical activity and the corresponding acceleration from a system implanted in the peritoneal cavity of an American black bear.
for other large mammals. It should be noted that subsequent to our field studies, it was recently reported that a similar foreign body response was observed for subcutaneous implants placed in black bear cubs by Echols [10]. It is intriguing that this rejection response and subsequent healing occurred during hibernation in these adult bears, a time of reduced metabolic activity and hypothermia. [11] Although we observed a high rejection of the IDRs, these bears also had small intraperitoneal temperature loggers (StowAway® TidbiT™ temperature loggers, Onset, Bourne, MA) which were, in most cases, not rejected. This could be due to the method of implantation (freely floating in the peritoneal cavity with a tether for retrieval) or due to the tissue contacting material (the devices were dipped in ethyl vinyl acetate). Although the temperature loggers were successfully used in the peritoneal cavity, we recommend either avoiding subcutaneous implantation of devices in these animals or further work in screening materials for biocompatibility, possibly through allergic screening. Work is ongoing by our group to better understand and characterize this unique behavior, with the hope that it may have application to patients in which healing is impaired.

The utilization of these specially constructed implantable data recorders provided valuable information in the two situations described. Chronic variations in canine T-wave morphologies following the implantations of endocardial defibrillation leads were recorded and analyzed. Normal physiological variations in the cardiac repolarization pattern (T-wave) were recorded, providing new data in support of the design of future arrhythmia discrimination algorithms. Although complicated by unanticipated foreign body responses, new information was also gained about the physiology of the hibernating black bear by utilizing such devices. The recorded signals indicated the elicitation of dramatic respiratory sinus arrhythmias and dramatically low heart and respiratory rates during the overwintering period.

In summary, the data recording systems described here have proven utility for the collection of chronic physiological data, even in remote and extreme environments. This testing in animal populations served to identify issues relating to the design that should be addressed prior to human clinical use. Additionally, we have described substantial differences in the response of two species to a common device. Potential variations in the foreign body responses of different mammals must be considered when choosing tissue-contacting materials in the application of biomedical technology to physiologic research.

Acknowledgments

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References
