Flexible Communication and Control Protocol for Injectable Neuromuscular Interfaces

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Invited Paper

Abstract—BION2 is a system based on injectable neuromuscular implants whose main goal is to restore the functional movement of paralyzed limbs. To achieve this objective, the functional requirements of the implanted interfaces include not only stimulation but also integrated sensors in order to detect patient intention, to provide servocontrol of muscle activation and to sense posture to inform more global motor planning and coordination. The technical constraints for managing the system include the efficient use of forward and reverse telemetry channels with limited capacity, minimization of adverse consequences from errors in data transmission or intermittent loss of power to the implants, and ability to adjust stimulation rates and phases to achieve efficient fine control of muscle force while minimizing fatigue. This paper describes a communication and control architecture with several novel features that address these requirements.

Index Terms—Communications protocol, implantable microstimulators, implantable sensors, RF battery-less implants, sensor control protocol.

I. INTRODUCTION

ELECTRICAL stimulation is a rehabilitation therapy that has been widely used to exercise weak and paralyzed muscles in order to prevent or reverse disuse atrophy. The BION (BIOnic Neuron) system includes individually addressable, wireless microstimulators that can be injected into one or more muscles to control their activation, thus avoiding the discomfort of transcutaneous stimulation and the invasiveness of surgically implanted multichannel stimulators [1]. An externally worn coil transmits power and command signals inductively to a coil in each implant (see Fig. 1). The BION1 system has been used successfully for rehabilitation of patients with various consequences of disuse atrophy [2], [3].

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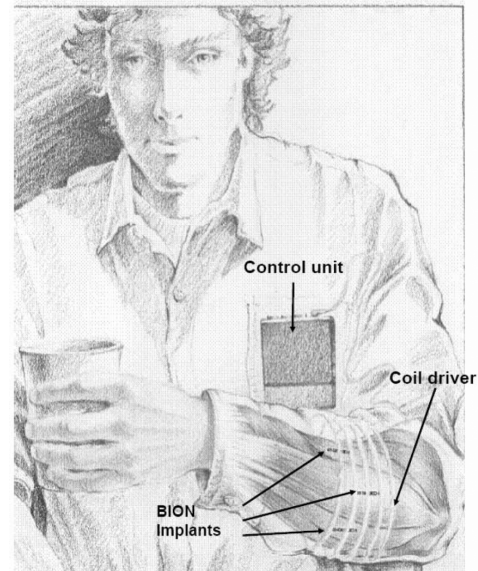
Fig. 1. BION System Overview.

Use of neuromuscular electrical stimulation to recover the functional movement of a limb [functional electrical stimulation (FES)] requires the generation of sequences of muscle contractions that are not predictable and are likely to need real-time control. The BION2 implants now under development include several types of electrical, magnetic and mechanical sensors of limb posture and trajectory (described in detail elsewhere, [4]–[6]). Information obtained from residual voluntary limb movement can be used to derive commands signaling the intentions of the operator [7]. Information about the posture and trajectory of the limb produced by the FES can be used to adjust the muscle stimulation parameters, much as the central nervous system normally uses reflexes to adjust motor neuron activity. Some systems provide stimulation and sensing in different devices [8]. However, by collocating stimulation and sensing functions in the same BION2 implants, the number of different devices that must be designed and supported can be minimized, as can the number of implants required in a given patient. This mandates a system design in which general purpose implants can be configured flexibly to meet the requirements of a wide range of clinical applications and then controlled dynamically during the performance of motor tasks.

This paper presents the architecture and communication protocol of the BION2 system in the context of the physiological properties of the neuromusculoskeletal system to be con-

trolled (Section II), the clinical requirements (Section III), and the hardware capabilities of the BION2 implants (Section IV). Section V presents the essential features of the protocol and some innovative features designed to meet all system requirements. Section VI provides the output of a complete digital simulation that is a key step in the development and testing of an application-specific custom IC (ASIC) in the implants and a field-programmable gate array (FPGA) in the external controller.

II. Physiological Considerations

The function of the BION system is constrained by the properties of the neuromusculoskeletal system with which it must interact. As the brain learns to control the limbs in infancy, it is effectively performing system identification and developing strategies for dealing with the system that it discovers. In order to build upon those natural strategies, biomimetic design principles have been chosen to be applied where possible, considering how the prosthetic hardware can replace missing functions and enable the reuse of control strategies that have been studied in intact subjects.

A. Control of Muscle Activation

Muscles are composed of hundreds of thousands of individual fibers that are organized into a few hundred motor units, each controlled by a separate motor neuron. Muscle force depends on the number of motor units that have been recruited and their frequencies of firing, as well as nonlinear effects of the length and velocity of motion (shortening or stretching) of the muscle fibers (see [9] for general physiology).

BIONs are usually implanted near the entry zone of the nerve containing the motor axons, where increasing the intensity of pulsatile stimuli can recruit an increasing percentage of the motor units. Stimulus efficacy is generally proportional to the charge delivered with each pulse, the product of pulse current and pulse duration. All recruited motor units fire synchronously at the stimulus pulse repetition rate, rather than the asynchronous, smooth modulation typical of physiological recruitment (typically 10–40 Hz). If the stimulus rate is set too high, the recruited muscle fibers will fatigue quickly. If it is set too low, the force produced by the muscle may have a substantial ripple at the stimulus rate and it will be difficult to ramp up force quickly or to achieve brief maximal effort such as for responding to perturbations.

Limb motion is the result of coordinated activity in many muscles with different combinations of actions at joints with varying degrees of freedom. Most muscles cross more than one joint, act on more than one axis of motion, and have moment arms that depend complexly on joint angles. Because muscles can pull but not push, control of joint motion depends on the relative recruitment of antagonistically arranged muscle groups. Active muscles have spring-like (length-dependent) and dashpot-like (velocity-dependent) contractile properties, so cocontraction of antagonistic muscles can be used to alter the impedance of joints independently from their net torque on the joint.

B. Feedback Signals

Biological muscles are endowed with a variety of sense organs, most prominently including Golgi tendon organs, which sense muscle force, and muscle spindles, which sense combinations of length and velocity that can be adjusted dynamically by the fusimotor gain control system. These signals are combined with those from cutaneous sensors and with the descending command signals from the brain in a sophisticated set of excitatory and inhibitory interneurons in the spinal cord that provide much of the input to the motor neurons. This somatosensory information also projects up to the brain, where it is combined with other sensory modalities such as the acceleration and orientation of the head with respect to gravity.

The response time of the biological system to perturbations is limited by physiological constraints. Both sensory and motor nerve fibers conduct at approximately 50 m/s in humans, so the transit delay to and from the spinal cord is on the order of 20–30 ms. Muscle fibers respond sluggishly to changes in their neural activation with time constants of about 50 ms (rising phase) and 100 ms (falling phase) to step changes in that activation. There are also various central delays (1–100 ms) while the interneuronal system computes the desired responses at various levels of the spinal cord and brain with varying degrees of integration with other signals (e.g., considerations of interlimb coordination, postural balance, visual feedback, etc.). These delays pose serious challenges for the use of closed-loop control in both biological and prosthetic systems but they provide useful hints about specifications of a biomimetic communication and control scheme (see Section III). They must be considered in the context of the natural mechanical resonances of the limb, which are restricted by the substantial inertial mass of the limb segments.

III. Clinical Requirements

The functionality of each BION2 implant can be summarized as:
1) to sense patient intention;
2) to activate the muscle by causing contraction and measuring the contraction effectiveness;
3) to sense posture and movement in various coordinate frames;
4) to communicate all sensed data to the controller and receive new stimulation commands.

As discussed below, the clinical requirements for BION2 system are related to the wide variety of applications, the number of muscles involved in the applications and the safety of operation required.

A. Range of Applications

BIONs are an unusual type of implantable electronic device because they are not intended for a single anatomical site or clinical application. Rather, they are general-purpose modules intended to be injected where and when they are needed and combined in virtually unlimited ways to support functions that may not have been considered when the system was designed. In fact, we are already considering use of BION2 implants to detect myoelectric command signals for prosthetic limbs and to generate electrotactile sensations to restore a sense of touch from prosthetic hands. This means that there are no definite requirements from which to extract specifications for system design. Instead,

the designer must consider the way in which a compromise in any individual specification might interact with other specifications to limit the possible range of applications for which the system might work adequately.

B. Number of Channels

The number of different muscles that must be controlled prosthetically to perform a given task is highly dependent on the nature of the task and the number of muscles still under voluntary control of the operator. The total number of muscles that operate the arm and hand is on the order of 30–50, depending on how much of the scapular and shoulder motion is included and whether the intrinsic muscles of the hand are included. Some clinical applications of FES may require only a few channels, such as to open or close the whole hand around a large object (so-called palmar grasp). The upper limit seems more likely to be set by considerations of cost-benefit, because each BION2 implant will have a cost for the device itself, its implantation, and the fitting time required to integrate it into control algorithms. For the purposes of system design, the assumption is that applications will be limited to 20 simultaneously active implants.

C. Fault Tolerance

The biological sensorimotor control system is actually quite noisy, with many stochastic processes involved in the transmission and integration of all-or-none action potentials over a small dynamic range of possible frequencies [typically 5–300 pulses per second (pps)]. The natural redundancy of biological sensors and actuators, the low-pass properties of muscle and the inertial properties of the limb all tend to smooth out this noise. Furthermore, humans are adept at learning behavioral tactics that minimize its consequences for the performance of individual tasks. This suggested that the requirement for fault tolerance could be expressed more usefully in terms of functional consequences for the task at hand rather than bit-error rates and detection and correction levels.

IV. System Design

In this section, the main features of the designed system that fulfills the functional requirements for recovering functional movement are presented.

A. Patient Intention

The electromyogram (EMG) is a stochastic pattern of electrical potentials (typically on the order of 100–1000 μV @ 100–3000 Hz when recorded from within a muscle) that arises from the temporospatial overlap of asynchronously firing motor units [1]. If the patient has a paralyzed limb but there is some residual voluntary control of some muscles, the modulation envelope of their EMG signals can be used to infer the patient's intentions and control the electrical stimulation of the paralyzed muscles. The stimulating electrodes already present on the BION can be used to pick up the EMG potentials provided they are disconnected from the stimulus generation circuitry and the first stage amplifier blocks any polarization potentials on the electrodes. The EMG signal has a modest signal-to-noise ratio $(< 40$ dB$)$ but wide dynamic range. Because of its stochastic nature, any assessment of its amplitude requires integration over as many samples as possible. The EMG sensing scheme included in BION2 is based on digitizing the difference in amplitude between successive samples at a rate appropriate for the bandwidth (6 kS/s) and integrating the absolute value of those differences for a period of 10–50 ms that can be determined dynamically by the external controller (see frame architecture description in Section V-B). A 10-bit analog-to-digital converter (ADC) and a 16-bit accumulator have been chosen to meet these demands.

B. Stimulus Control

As noted above, it is desirable to have fine control of the percentage of the muscle that is recruited. The threshold and slope of electrical recruitment can vary widely depending on placement of the implanted stimulator. The strength of a stimulus pulse depends on its charge, the product of pulse current and pulse duration. We have chosen to control pulse current over a wide but coarse range consisting of powers of two (0.5, 1, 2, 4, 8, 16, and 32 mA). Pulse duration in each of these ranges will be controlled finely over the range 2–8000 μs by counting the internal clock extracted from the incoming 480-kHz RF carrier frequency for power and data.

As noted above, the usual firing rates for motor units are relatively low (typically 20–30 pps to achieve reasonably smooth and minimally fatiguing contractions), but it is desirable occasionally to provide bursts at much higher frequencies in order to achieve rapid and/or strong contractions or to produce electrotactile sensory percepts. This is accommodated by the frame architecture described in Section V-B, which provides a mechanism to generate duplicate or triplicate stimulus pulses with identical parameters within a given frame. It is desirable also to reduce force ripple at low stimulation rates by staggering the stimulus pulses from synergistic sites at different times within each frame.

C. Muscle Response

It is often useful to be able to measure the relative recruitment of the muscle in response to each stimulus pulse. This can be used during implantation to help direct a new implant into a site with a low threshold, to map a range of stimulus intensities to a percentage activation of the muscle, and to adjust stimulation parameters online to cope with shifts of this recruitment curve due to mechanical deformation of the contracting muscle. The same EMG recording and integration subsystem described in Section IV-A can be used for this task but the sampling time must be controlled and synchronized with the stimulation pulse. It is important to avoid sampling the initial stimulus artifact and to sample only the so-called M-wave reflecting the immediate response of the activated muscle fibers (typically 1–5-ms window after the stimulus pulse).

D. Posture Sensing

In order to plan and coordinate movements and compensate for perturbations, the controller needs information about the starting posture and ongoing trajectory of these movements. We have developed three separate sensing modalities related to this information but with complementary strengths and weaknesses.

1) The inductive coil inside each BION implant can be used as an antenna to detect reference magnetic fields created outside the body such as by orthogonal coils mounted in a wheelchair. We have developed mathematical techniques

to extract absolute position and orientation of a limb segment from such measurements obtained by two or more implants in that segment [5]. This might require up to eight 10-bit samples per implant per frame.

2) Orientation with respect to gravity and translational acceleration can be determined by a MEMS accelerometer which has 2 axes of piezoresistive bridge elements [4]. This would require two 10-bit samples per implant per frame.

3) The posture of distal joints of the hand and fingers can be determined without implanting devices in these sites, where they would be difficult to power. Instead, it can be inferred from changes in the relative position of implants in the muscles that operate those joints, much as the biological system infers those joint angles from the spindle stretch sensors in these muscles in the forearm [6] (hence the name BIONic Spindle.). Brief electrical pulses ($< 10~\mu s$) generated by the stimulus pulse circuitry create potential gradients that spread by volume conduction throughout the limb (so-called stimulus artifact) but are ineffective at stimulating motor units. The EMG recording function of other implants must be synchronized with these brief stimulus pulses so that they measure the differences between the voltage at the height of the artifact and the baseline potentials on either side. Each implant can function as an emitter while some or all of the other implants act as detectors, producing a rich set of coupling values from which to infer complex hand postures. We anticipate using up to eight implants as emitters each frame, resulting in up to eight 10-bit samples per implant per frame.

The communication scheme presented here is intended to support all of these sensing functions and the substantial numbers of samples that each might need to collect, hold and transmit each frame. The first version BION2 will incorporate only the BIONic Spindle, so the description here provides details only for this posture sensing method and the EMG sensing functions described above.

V. COMMUNICATION PROTOCOL

There are several systems designed for neuromuscular stimulation that include wireless RF powered microstimulators. In [10] and [11], unidirectional communication provides stimulation parameters but there is no bidirectional communication to receive a feedback to control the movement. Other systems, like the ones included in [12], [13], or [14], are designed for a single implant application as cochlear implants or retinal prostheses so they do not present multiple control or implant synchronization issues. Some of them do not have demanding bandwidth requirements, for example, [12] uses the same frequency for forward and reverse telemetry from a single implant and [13] uses system reinitialization with every stimulus as the security mechanism to avoid errors in stimulation parameters.

The communication protocol for the BION system has been developed to control up to 20 implants in real time. Bandwidth management is a critical issue along with communication error control so network security should be provided without consuming bandwidth or interfering with time available for sensing functions. BIONs provide a platform for multiple applications and the protocol should provide reconfiguration of similar implants to perform very different tasks with different sensori-

motor control requirements. The RF powering scheme poses additional requirements to respond gracefully and rapidly to loss of configurational data stored in volatile registers if and when individual implants move to a position where their received power drops below a critical level. Those features are the key points that drive the BION protocol implementation and will be detailed in the Sections V-A–D. Most of these aspects either mandate or reflect the selection of a communication protocol based on a sequence of frames, each of which consists of the same number and length of messages and the same order of actions.

A. Efficient Use of Forward and Reverse Data Rate

BIONs are intended to be used for a wide range of clinical applications in which different numbers of implants will be used with widely varying requirements for sensing, stimulation and reaction speed. The main objective of the communication protocol was to allow the limited bit rate in each direction to be configured as needed for such applications. This configuration occurs during an initialization transmission to each implant, which sets the number of bits and the data that they represent for both forward and reverse telemetry during a given operational session.

1) Duplex Communication: The physical layer is designed to allow full duplex communication with different codification schema and higher data rate for reverse telemetry because of the larger amount of sensory data expected for most applications. Forward telemetry in BION1 is via a frequency-shift keyed (FSK) signal over a 480-kHz carrier frequency that provides the clock and power for all implants. The data are Manchester-encoded with 2 carrier cycles per state and 2 Manchester-encoded states per bit, resulting in 120 kb/s transmission. The reverse telemetry capability is added in BION2 via an on–off keyed (OOK) bursts of a crystal-stabilized 400-MHz carrier whose bandwidth is limited by the boundaries of a single channel in Medical Implant Communications Service (MICS) band [15], [16]. Each bit occupies one cycle of the 480-kHz master clock, with the presence and absence of carrier signifying ones and zeros, respectively. Each reverse telemetry transmission arises in turn from a separate implant, which must preface the actual data with a short, fixed header of ones and zeros to allow the external receiver to determine the appropriate detection threshold.

2) Prefixed Time Slots: The time slots to define the forward and reverse transmissions for each implant are fixed by the external controller when the system is turned on and the implants are initialized (see Fig. 2). The use of these predefined channels has a few advantages: first, collisions between transmissions from several BION implants sending data to the controller simultaneously are avoided. In addition, the controller can identify data from each BION without including extensive headers in back telemetry and each BION can identify the presence of incoming data from the controller also without headers in forward telemetry. All devices and actions are synchronized by counting clock cycles based on the inward telemetry and power carrier transmitted by the external controller.

B. Predictable Frame Intervals for Reflex Adjustment

Frame in this context means a programmed sequence of events performed by all implants that repeats at a rate consistent with the default stimulation frequency for each muscle (typically 20–30 pps) or an integer multiple thereof. The minimal delay for responding to any sensory feedback or command
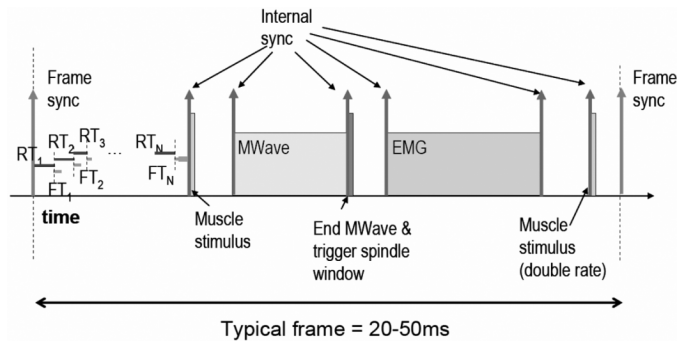
Fig. 2. Control signals in a BION frame. RTi: Reverse telemetry channel of BION i. FTi: Forward telemetry channel of BION i.

Fig. 3. Control signals in a BION frame for two different sets of BION to obtain a smooth joint torque.

signal is two frames. Sensory transduction occurs in one frame to assemble the data sent by reverse telemetry in the next frame; the controller then computes the desired response and transmits it at the beginning of the third frame for execution during the remainder of that frame. The duration of a frame and the exact timing of events within the frame are controlled by two types of sync signals that are encoded by special inward telemetry transmissions as violations of Manchester coding that cannot arise from the data sequences themselves.

A frame sync is a signal that triggers a new sequence of actions. In this protocol a frame is defined as the period between two frame syncs and the frame time is set by the external controller in real time.

Internal syncs are signals that can be received at any time inside the frame. These signals are responsible for triggering each action in the frame (e.g., stimulation, starting and ending points of sensing modalities and reinitialization if necessary) in an order that is programmed as part of the initialization transmission.

Frame sync and internal sync concepts are illustrated in Fig. 2 by the sequence of events included in a frame and their respective timing. The first event after a frame sync is the communication stage: reverse and forward telemetry from and to each implant, respectively, according to bit counts and time slots that are programmed as part of the initialization of each implant. After the communication stage, the BIONs wait for the internal syncs that are used to trigger various events during the frame.

The BION example included in Fig. 2 stimulates the muscle, measures the muscle response by integrating the M-wave for a variable period, then detects the joint position by measuring spindle pulses from other implants, and finally integrates the background EMG activity over a variable period to provide voluntary command data. All sensor data gathered during these functions are held in a last-in–first-out (LIFO) register until the next frame, when its reverse telemetry slot arrives and it sends the data back to the controller.

One of the initialization registers is called "sync mask" because it determines which BION action (i.e., stimulation or various sensing modes) is triggered by each successive internal sync signal. The combination of frame syncs, internal syncs, and sync masks is one of the key points that make the control inside a frame very flexible while permitting tight synchronization of events between implants (e.g., having one implant sense the response to stimuli generated by another implant).
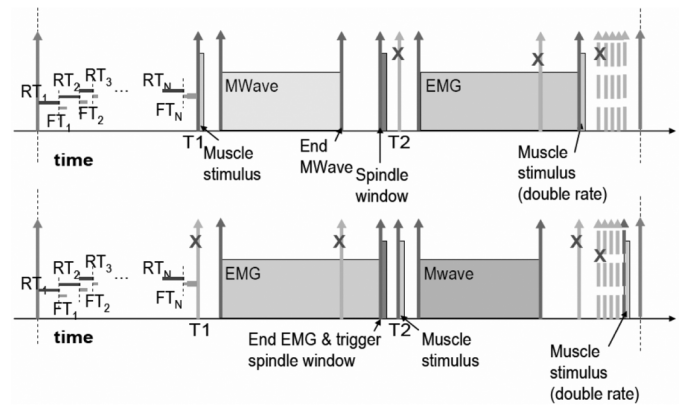
- *Improving sensing modality accuracy and dynamic range*: The integration time of two sensing modalities (EMG and M-wave) is controlled from the outside with internal syncs to start and stop the measuring period. M-wave measures the muscle response to a stimulus pulse from the same or a different implant; it varies in latency and duration from muscle to muscle. EMG records the residual voluntary control of the muscle; accuracy is improved by integrating for as long as possible. By starting and stopping these digital integrators according to the internal syncs, the external controller can adjust them dynamically without requiring transmission and storage of these timing parameters.

- *Increasing the strength of muscle contraction*: One powerful and rapid way to increase the effectiveness of muscle stimulation is to stimulate twice within a normal frame, making use of the "catch property" that arises from the calcium kinetics in the muscle fibers. This can be done using internal syncs to trigger this "extra stimulus pulse" in some selected BION implants. According to Fig. 2, the last internal sync is sent by the controller only when an additional stimulation pulse is required. Thus, this provides a simple way to change between single and double stimulation that can be controlled frame by frame.

- *Smoothing limb movements*: In order to produce smooth joint torques, the physiological activity of motor units tends to be asynchronous. To emulate this effect it is desirable to stimulate synergistic muscles at different times in each frame. This is another feature that can be achieved by strategically phasing sync mask values for stimulation, as shown in Fig. 3.

In Fig. 3, the internal sync signals that are not used for the corresponding BION are marked with an X and the optional ones are represented as broken lines. In this particular case, some of the BION implants in the system are stimulating the muscles at time T1 and some of them at T2. After stimulation, each implant records the M-wave response. In the case shown, to obtain double rate stimulation additional internal syncs can be sent, and the double stimulation rate is achieved with the eighth internal sync for the first BION and with the 13th for the second one.

C. Error Tolerance by Limiting Consequences

In this system, communication errors can be classified into critical errors and bearable errors depending on the potential
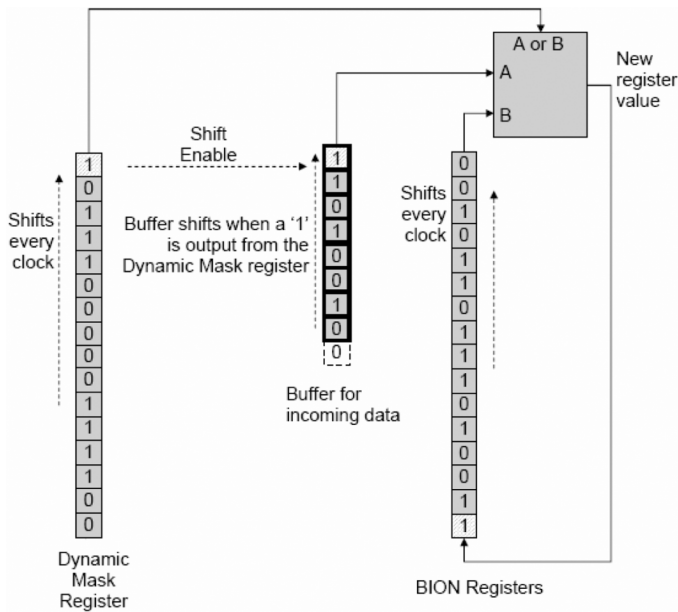
Fig. 4. Dynamic mask operation.

Fig. 5. BION state diagram.

consequences. Bearable errors in this system are errors in dynamic data transmission whose possible range is limited to "safe values" with the "dynamic mask" mechanism presented in this section. Critical errors in BION communication that must be avoided are those whose consequences are indeterminate, such as sending commands to the wrong implant.

- To avoid errors in BION identification, initialization commands are preceded with the unique 32-bit ID code that is hard-wired into each implant ASIC as read-only memory, similar to the ROM used in radio frequency identification (RFID) transponders. This includes the critical timing information for the forward and reverse telemetry slots during the communication phase of each frame. To avoid critical errors in BION initialization, each BION echoes the whole initialization sequence of parameters, bit by bit, back to the controller.
- To ensure that the maximal stimulation error caused by communication errors in the dynamic parameters are bearable and will never be dangerous for the patient, the "dynamic mask" mechanism is used. The dynamic mask is a register included in each BION whose bits correspond to each bit stored in the parameter registers for stimulation and sensing modalities. If a bit in the parameter registers is to be affected by dynamic data on a frame-by-frame basis, its corresponding bit in the dynamic mask register is set to a "1;" if that value is to remain unchanged, its corresponding bit in the dynamic mask register is set to a "0," essentially protecting that bit to stay at the value initially set in the parameter registers.

In order to confirm the validity of the communications protocol designed, a software simulator has been developed. The simulator consists of two modules, a module to simulate the external controller function and a BION module, that are combined to generate a system with one controller and up to 20 implants. The dynamic mask is thus used to specify which bits of any parameter of any stimulus or sensing modality are to be changeable and "dynamic" during normal operation (see Fig. 4).
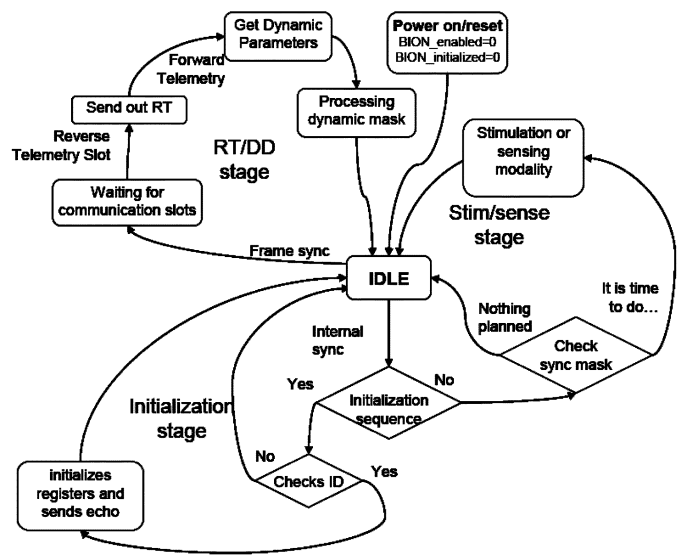
It has two purposes: to avoid dangerous errors and to allow frequently changing parameters to be adjusted while minimizing the number of bits sent in each frame. One example of how this might be used is to set the dynamic range of possible stimulation values to cover only the values from threshold to saturation for each muscle. The coarse control of stimulus current (n steps of 2^n) could be set at one value (e.g., 4 mA) and the central five bits of stimulus duration (12-bit counter with 2-μs clock) would be enabled by the dynamic mask so that the only possible stimulus durations would be 16–496 μs in 16-μs steps. Bearable errors in dynamic parameters are detected with a single parity bit (50% probability) in order to report the occurrence of received errors to the controller during the reverse telemetry phase of the next frame. Because the possible errors have been limited to a safe range by the dynamic mask, it is better for the BION to act with the wrong parameters than to skip stimulation and allow the muscle to relax.

D. Dynamic Reinitialization of Individual Implants

All of the programmable parameters of an implant (including the critical communication timing and mask registers described above) are held in volatile registers that depend on power received by inductive coupling from the external coil-driver. The very movement created by the muscle stimulation can cause shifts in the relative alignment between the coil-driver and one or more implants. If the received voltage in a given implant drops under a critical level, that implant goes through a reset operation, clearing all internal registers. Upon the return of sufficient power, this implant no longer participates in the normal communication phase of any ongoing frames unless and until it is completely reinitialized. The absence of any detectable reverse telemetry carrier during the preassigned time slot for this implant informs the external controller which implant needs reinitialization. The possibility of such occasional, isolated drop-outs makes it important to enable dynamic reinitialization of individual implants without affecting the ongoing performance of the other implants.
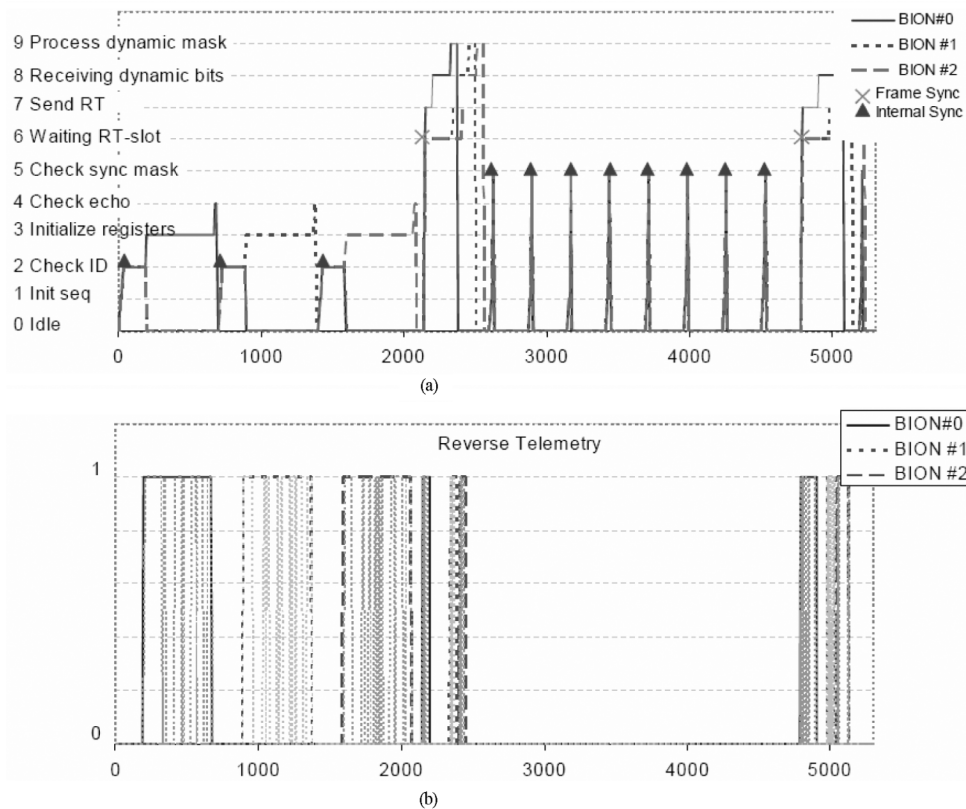
Fig. 6. Simulation of a BION system composed by three implants. (a) Sequence of events to initialize the system and first frame. (b) Reverse telemetry: echo during initialization stage and data after the first frame.

Any implant that is in an uninitialized state is effectively idling and will respond only to a special initialization code consisting of an internal sync followed by a bit value indicating that the subsequent data constitute an initialization sequence (Fig. 5).

The first part of an initialization sequence must be the complete 32-bit ID code of the implant in question. If this ID code matches the ID code in the ASIC ROM, the subsequent data are used to initialize all programmable registers and are echoed via reverse telemetry to external controller for complete verification. The implant is now initialized but not yet enabled, which occurs only in the next frame, when the external controller detects its reverse telemetry signal in the correct timeslot and transmits the first set of dynamic command data in its forward telemetry slot. Thus, the state diagram in Fig. 5 can be divided into three stages: initialization, communication, and stimulation/sensing. The controller can reinitialize any device at any time that the device is in the "idle" state, i.e., not transmitting or receiving data. This can be useful to allow changes in parameters that are outside the previous dynamic range (e.g., the stimulus current in the example above could be shifted from 4 to 8 mA).

VI. SIMULATION AND PERFORMANCE

The input of the controller module is a high level sequence of parameters used to initialize the BIONs and control the system through several subsequent frames, and the output is the sequence of bits that will be sent to each BION along with the times these sequences are to be sent. Each simulated BION

node is represented by the BION module, and receives the sequence of bits, responds according to the protocol and generates an output file that includes the sequence of states of the implant. Each output file records the contents of each register in the BION, the reverse telemetry data output and the states of the signals to activate the different sensing modalities. Figs. 6 and 7 show the graphical representation of the simulator output for a complete system and for individual implants respectively. Fig. 6(a) shows the sequence of events for each one of three BION implants in the system. Each BION starts in the idle state and checks the initialization sequence and the ID sent, but only the implant whose ID matches with the ID sent by the controller initializes its registers and sends the echoed data to the controller (with this, the controller can ensure that the sequence sent was properly received by the BION). After initializing all the implants, the external controller sends a frame sync and the three implants wait for their designated RT slot, send the reverse telemetry data, receive new dynamic bits and then process the dynamic data. The simulation demonstrates that there is no overlap between RT transmissions from different implants and that each one of the implants receives its new parameters and updates its registers correctly. Once all implants have their dynamic data processed, the external controller sends a series of internal syncs. With each internal sync, all implants simultaneously check their sync masks to identify the action that each should perform. The data sent back from the implants are illustrated in Fig. 6(b). During initialization, initialization data are echoed back to the external controller as they are received, and during each frame, sensory data are sent during "send RT" state.
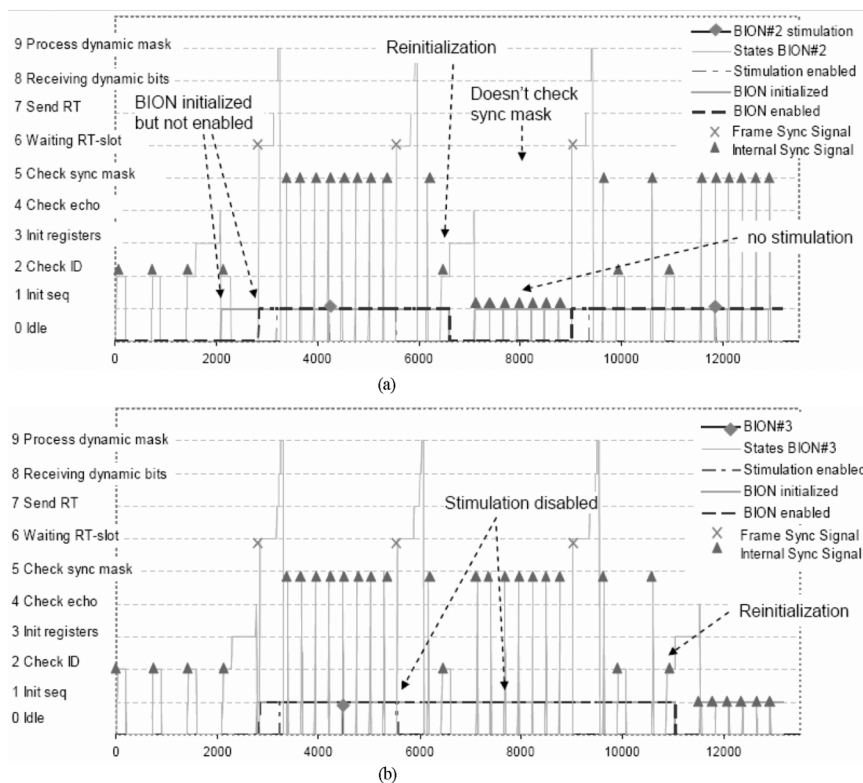
Fig. 7. Simulation of a BION system composed by four implants. BION #2 performance. (a) Reinitialization of a single implant in second internal sync signal. (b) Reinitialization of other implants does not affect performance of this BION.

Fig. 7 shows a 4 implant system from the perspective of an individual implant. Fig. 7(a) includes the internal register values for BION#2. In the sequence of events it is seen that this BION is initialized with the third initialization sequence, which is when this particular implant recognizes its own ID. Upon its initialization, the implant activates its "BION initialized" flag. Then the first frame starts, in which the implant receives a frame sync signal and immediately the "BION enabled" flag is activated. The BION then waits for its designated RT slot, when it sends RT, receives the new dynamic bits, processes those dynamic bits and activates the "stimulation enabled" flag. When the stimulation has been activated, BION#2 stimulates upon the proper internal sync, depending on its "stimulation sync mask" register. In the example illustrated in Fig. 7(a), stimulation will correspond to the fourth internal sync signal. When the next frame sync is received the "Stimulation enabled" flag is deactivated until the new dynamic parameters have been processed. But in this example, in the second frame the external controller will reinitialize this BION. Thus, at the second internal sync the external controller includes an initialization sequence followed by BION#2 ID and the complete set of initialization parameters. This BION is deactivated in this frame with respect to stimulation and sensing and will be enabled again in the next frame. Fig. 7(b) includes the same system but from the point of view of BION#3, which is not affected by the BION#2 reinitialization sequence and which, in this case, has its stimulation disabled in the second frame through the dynamic data sent to it by the external controller in that frame.

In addition to confirming the correct and robust operation of the communication protocol under a range of command sequences and conditions, the software simulation serves two ad-
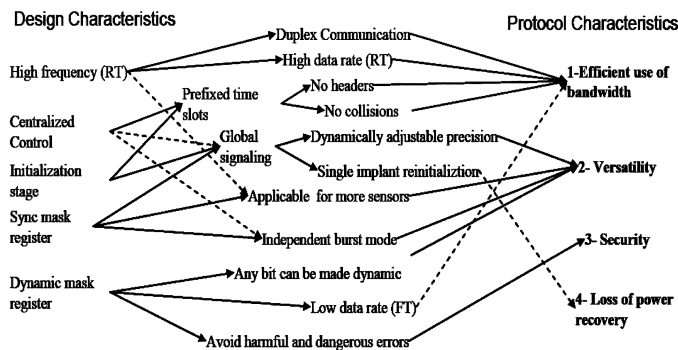

Fig. 8. Summary of protocol characteristics.

ditional purposes. First, the simulation programs can be used to generate and validate the digital logic blocks for the actual hardware, which will be ultimately compiled into silicon for the implant ASIC and programmed into an FPGA for the external controller. Second, it generates valid input and corresponding output files to be compared with the performance of actual hardware during the testing phase.

The current design for a BION2 implant requires 32 bits of ID code plus 137 bits of initialization data for fixed parameters, dynamic mask, and control bits. One such BION is initialized in 1.14 ms, and a system with 20 BIONs can be initialized in 22.8 ms. The maximal duration of the reverse telemetry depends on the length of the LIFO register, presently set to 113 bits but likely to be extended as new sensory modalities become available in future models. The longest duration of the reverse telemetry from 20 such implants would be about 5 ms (with all or most of the forward command data to one implant occurring

during the reverse-telemetry period of the next implant). If the frame duration is set at 20 ms, most of the frame time will be available for stimulating and sensing, with only about 25% required for communication purposes and processing overhead. Such a frame rate would enable continuous adjustment of stimulus parameters at 50 Hz, which is about twice the usual firing rate for human muscle fibers. Even higher stimulus rates could be achieved using the repetitive stimulus train capabilities enabled by the sync mask.

VII. CONCLUSION

The communication protocol described in this paper incorporates several strategies useful in systems in which multiple devices with a range of possible functions must be configured dynamically to work with command and data channels that have limited bit rates and nonzero bit error rates. A summary of the system characteristics used in BION 2 implementation is presented in Fig. 8 to illustrate how this system implementation makes possible the fulfillment of the clinical requirements. The global signals frame sync and internal sync and the run-time assignment of bit slots for inward and outward full-duplex telemetry for each device greatly reduces time normally allocated to headers and device addresses in reconfigurable systems. In addition, the dynamic mask described in this paper allows the controller to select specific parts of sensing and stimulating parameters for dynamic adjustment, while protecting the system from gross error. This enables aggressive use of the available carrier bandwidth to achieve high data rates without requiring complex and time-consuming error correction. As of this writing, the digital logic has been validated in simulations and is being integrated into the mixed-signal ASIC of the BION2 implants and an external controller based on a Xilinx FPGA and ARM-9 microprocessor running the Windows CE real-time operating system.

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