Transdermal Optical Communications

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Active medical implants (AMIs) are "electronic medicators and monitors" that inject controlled currents to the heart, spine, brain, or other organs or control electromechanical medical devices such as medication dispensers. Imagine an AMI with molecular *in vivo* sensors for biological assay that uses these data to monitor a patient's condition and its own performance as well as diagnose, indicate status to health care providers, and automatically adjust its operation. In this scenario the AMI provides rapid, bidirectional through-skin (transdermal) data/information transfer and programming, relying on high-capacity memory storage. Future AMI communications will require a significantly increased data rate to/from an external reader-programmer in addition to improved operational aspects. This article presents early efforts to develop a high-data-rate (>1 Mbps) optical link to achieve these future requirements.

INTRODUCTION

Active medical implants (AMIs) are battery-powered electronic devices that facilitate the medical diagnosis and treatment of humans and animals with chronic diseases or conditions. These diagnostic/therapeutic devices require stable performance, biocompatibility, and high reliability while exposed to environmental conditions inside a human body. AMIs are implanted for periods ranging from months to decades, depending on the progress of treatment, specifics of the disease or condition, and the patient; they can control electromechanical systems (e.g., medication dispensers), perform neural and sensory assist (e.g., sexual stimulators and cochlear implants), restore functionality (e.g., to the heart or eye), maintain operation (e.g., cardiac rhythm), and perform other functions. Today, AMIs are widely accepted and prescribed as cardiac pacemakers, defibrillators, nerve stimulators, medicinal dispensers, pain neuromodulators, and cochlear hearing aids. New and exciting future applications include, for example, treatment of Parkinson's disease, memory loss, depression, and epileptic seizure.[1] Still other emerging AMI application areas include fertility, seizures, gastro-intestinal tract problems, physiological status monitoring, sight problems, and prostheses.[2] With the rapid pace of technological development permitting the microminiaturization of electronic circuitry, an expanding list of applications is likely for AMIs that will greatly improve the quality of life of many afflicted people.

AMIs deliver voltage and current to electromechanical mechanisms such as medicinal dispensers or directly inject current into human tissue to alter the biophysical state for therapeutic consequence, as in the case of cardiac pacemakers or pain management. The expansion of electronic treatment promises to be rapid, but observation of curative effects under experimental conditions has not been concurrent with, or quickly followed by, fundamental understanding and modelling of the mechanisms involved. A lack of "first principles" understanding of cause and effect risks unknown medical outcomes, and this situation enforces caution in offering new electronic medication to the general population. Nevertheless, electronic medicine implemented by AMIs is rapidly evolving and will be sought by an aware, demanding public.

The trend in electronic therapy is toward increased complexity in support of the real-time measurement of physiological indicators, data acquisition and processing, internal diagnosis and decision making, event prediction, response, alarm, and automatic remote patient data collection and monitoring. Together, these characteristics require rapid and accurate communication to command functions, to program performance, and to acquire/transfer data.

Today's commercial cardiac implants use a transdermal radio-frequency inductive (magnetic) link operating at typical data transfer equipment (DTE) rates of up to 120 Kbps (for example, the Medtronic CareLink Programmer). Although these DTE rates satisfy current designs, demand is growing for significantly increased AMI data rates, with a near-term challenge of 1 Mbps. And while electromagnetic coupling continues to evolve to meet future requirements, there will likely be fundamental performance limitations to this approach such as electromagnetic interference issues[3,4] and challenges related to alignment, localization, and exposure to electromagnetic fields.

For optimum results, therapeutic treatment must be modified according to patient need, response, and condition, so AMI operation needs to be adjusted accordingly. Operation can be automatically reprogrammed by an internal controller or by a physician (local or remote) based on information provided by a patient's implant. In this regard, AMIs are designed to capture and store key patient data and process the data internally if necessary, and are externally commanded to deliver raw data/information to the patient's physician. As AMIs evolve, this capability will demand ever-increasing data storage capacity to collect patient and device performance data, continuous or sampled, over relatively long periods of time.

The evolution of low-power memory storage devices is evident in chip-scale memory storage cards used for modern digital cameras, personal digital assistants, and cell phones. For example, assume 512 Mb of static random access memory (SRAM) data operating at 1.7 V in a packaged FBGA (fine ball grid array) with $10 \times 10 \times 1$ mm^3 volume. This storage capacity can record almost 18 h of continuous patient data at an 8-bit resolution and 1-kHz sampling rate. It is reasonable to expect that several times this capacity and recording time is practical to consider if not prevented by power consumption issues.

Note: SDRAM is synchronous dynamic RAM, which needs continuing refresh. DRAM draws too much current for embedded systems. SRAM is not available in as high a density as SDRAM; however, this is changing as future memory capacity increases and power consumption decreases. Looking ahead,

> Toshiba America Electronic Components, Inc. today announced that its parent Toshiba Corporation (Toshiba) has developed a Multi-Chip Package (MCP) of 1.4 mm thickness that can stack 9 layers (6 memory chips with 3 spacers) . . . .The miniature MCP consists of a combination of memory chips, such as SRAM, SDRAM, NOR Flash memory, and NAND Flash memory, and has a total capacity of 776 Mb in one sample application.[5]

Also, data compression can be utilized to lower power and increase processing speed.

At 100 Kbps it takes 90 min to "dump" 512 Mb of data. Herein is the nature of the advance needed as data storage capacity grows. For a patient to dedicate 1.5 h to dump his or her data is neither convenient nor practical, even with wearable relay schemes. However, a communications link operating at 10(100) MHz can accomplish this task in 90(9) s, a much more reasonable request of a patient. A noninvasive, noninterfering, effective, and robust high-data-rate bidirectional transdermal communications link will be increasingly important to advance AMI technology.

The work presented here suggests that optical communications is a promising approach to meet the high-data-rate transfer requirements of future AMIs and complements efforts of other investigators experimenting with optical means to deliver power to implants and extract physiological signals in real time.[6]

OPTICAL TRANSMISSION

Properties of Skin

Skin is a complex, multilayer, biological structure composed of the surface epidermis, separated from the underlying dermis by a basement membrane, and the supporting subepidermal tissue. This structure has many different constituents; it is highly anisotropic and includes cells, corpuscles, blood vessels, nerve endings, channels, glands, muscles, and hair follicles. Human skin is ethnically different, diverse in topology, penetrated by hair and sweat ducts, and approximately 0.5 mm (eyelid) to 4 mm (palm) thick. Therefore, characterizing the optical properties of skin is challenging and definable only in the context of average values for very specific sample conditions (topology, region), optical sources (wavelength, beamwidth, intensity), and subjects (race, gender, age). Numerous models and experimental methods are applied to characterize tissue (skin) from foundational principles.[7,8] While fundamental studies are valuable for characterization of skin conditions and diagnosis of tissue, they are less relevant to transdermal optical communication (TOC). A pragmatic approach to TOC is to experimentally determine the ability to send and receive data via an optical link of specific wavelength and intensity, through actual or model skin.

Light incident on skin is reflected, scattered, and absorbed by all of its structural components. The resulting transmission and reflection is the spatial and temporal integration of light arriving from the many influences in the path from source to observation point.[9] Because our aim is to demonstrate a TOC link that shows promise for future AMIs, determining the optical properties of skin was not a focus of this effort. It suffices to use human skin's 600- to 1300-nm (wavelength) optical window to maximize optical penetration depth for a given beam intensity. In this window we evaluated link properties related to beam transmission intensity, spreading (diffusion), and shape. Operation in this spectral window is readily satisfied using a commercial 860-nm light emitting diode (LED), which is available with different beam and intensity specifications. Optical link measurements were made for this source to determine the ability to achieve low-error-rate data transfer through skin thickness corresponding to human implant locations and the effect of off-axis positioning between sending and receiving units.

Demonstrating a TOC link using actual human skin proved impractical because of technical, regulatory, and other challenges. Although animal skin has different properties and yields different results than human skin, porcine skin does provide a similar optical transmission window and has characteristics that represent a reasonable alternate. Our measurements, therefore, used freshly prepared porcine ear, stomach, and back skin samples. An infrared (IR) communications link was used for this experiment. It was an RS-232 system with rates up to 115,200 Kbps (photonic detectors: LED PDI-E804, 880-nm peak intensity, 80° beamwidth, and optical power output of 200 mW/A; Panasonic PIN PNZ330CL, 850-nm peak sensitivity, 140° beamwidth, and sensitivity of 10 μA/1000 lux [2856 K tungsten]; IrDA MAXIM MAX3131, 115,200 Kbps).

A test fixture was made to hold the porcine skin samples between, and normal to the axis of, the optical transmitter/receiver pair (Fig. 1). Transmit LED intensity was adjusted by setting the resistor value R in series with the LED. Minimum LED current for acceptable data transfer was determined by sending data at 115,200 Kbps while incrementally increasing R (decreasing intensity) until errors appeared in the received data; error detection and correction were not used. Measurements are summarized in Table 1, where T is an average porcine skin sample thickness, R is the resistor value to set the LED current I at the minimum value for data transfer at ≈115 Kbps, and J is I normalized to unit skin thickness (1 mm). Measurements for samples 4 and 9 were taken with the transmitter and receiver diodes axially opposed and touching the skin; the other samples' data were taken with the transmitter and receiver diodes axially opposed at a 24-mm separation.

The transmitter and receiver diodes have an 80° and 140° beamwidth, respectively. As expected, their off-axis lateral relative displacement caused an increased error rate, that is, required higher LED drive current for error-free data transfer (narrower transmission beamwidth reduces lateral scattering for improved communications and reduction of power requirements). The intensity and sensitivity of currently available commercial IR transmitters and receivers suggest that transdermal data rates of 100 MHz should be realizable. However, for AMI applications, power consumption (proportional to data rate) is a critical issue for nonrechargeable power sources; in this regard, transcutaneous optical links have been used to power implants.[10]

In addition to determining thresholds for data transfer through porcine skin, it is important to determine

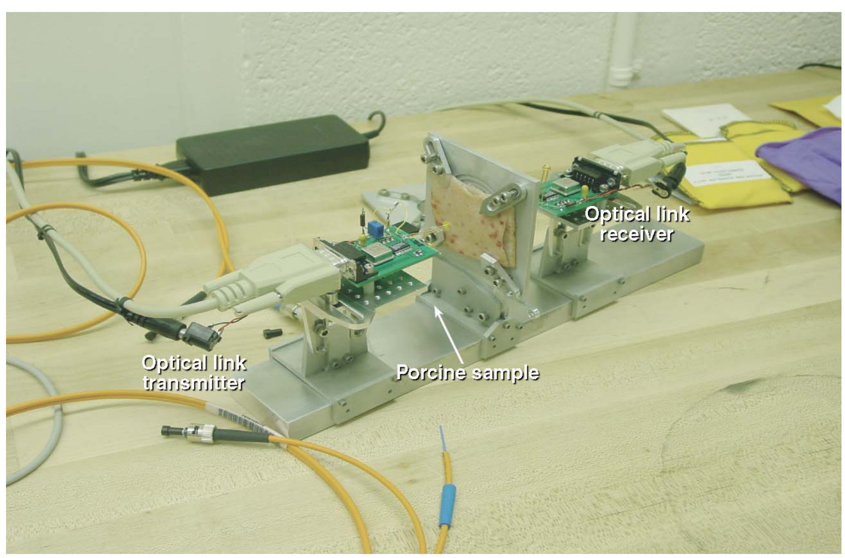

Figure 1. Data transfer through porcine skin.

Table 1. Optical transmission measurements obtained from porcine skin samples.

Sample	*T* (mm)	*R* (Ω)	*I* (mA)	*J* (mA/mm)
1 (ear)	2.87	892	3.80	1.32
2 (ear)	2.11	1072	3.17	1.50
3 (ear)	3.15	793	4.29	1.36
4 (contact)	3.15	6670	0.51	0.16
5 (stomach)	2.18	670	5.07	2.33
6 (stomach)	2.52	427	7.96	3.16
7 (back)	2.79	714	4.76	1.71
8 (back)	6.90	445	7.64	1.11
9 (contact)	6.90	4051	0.84	0.12

off-axis spreading of the beam intensity caused by diffuse transmission. This information applies to error rate, depth of communication, and operational alignment conditions. A difficult set of porcine skin requirements was satisfied for off-axis diffusion characterization using large samples (>10-cm dia.) with uniform thickness, smooth surface, and dimensional stability.

Another approach for diffuse transmission characterization was also taken, based on a simulation of the skin's light diffusion using whole milk (for example, agarose gel doped with milk to match the scattering coefficient of human skin; private communication, S. A. Boppart, Beckman Inst., University of Illinois). Symmetry about the normal axis is assumed for two representations of diffuse light transmission. The first were digital photographs (Sony MVC-CD300) of the transmitted intensity pattern recorded using an LED narrow-beamwidth source (Photonics PDI-E805, 880 nm, 3° 1/2 PBW) passing through 0.5-cm-, 1-m-, and 1.5-cm-thick layers of simulated skin. The other was obtained from subsequent intensity plots of digital images using image-processing software (Adobe PhotoShop and NIH Image). The experimental setup and a diffused light photo are shown in Fig. 2.

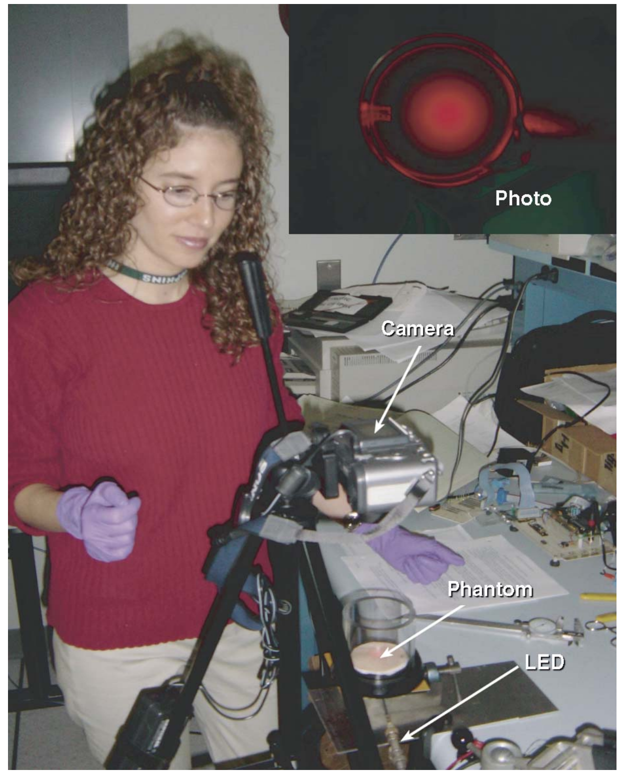

Figure 2. Photographing a 1.5-cm-thick "milk" simulation.

Relative transmitted light intensity (μW/mm^2) profiles of whole milk and porcine samples were measured and showed similar qualitative results. The experimental setup is shown in Fig. 3; results for the porcine samples (3.9, 8.3, and 16.5 mm thick) are shown in Fig. 4.

These optical measurements obtained intensity and orientation data in order to specify design requirements and select components for a prototype transdermal optical link. Key to the success of this design is low power consumption for the implanted transceiver in keeping with low-error-rate data transmission.

Flesh and Bone

How deep within the body is it possible to optically communicate? The answer depends on wavelength, beam intensity, noise, dispersion, scattering, and location within the body, among other considerations. Transmission through 2-mm-thick human skin in the near IR is 10 to 20%.[11] Differences between human and animal skins significantly affect optical transmission properties. To gain insight regarding "deep-body" optical communications, transmission measurements were taken on a porcine rib section, through bone, and between adjacent bones (Fig. 5). The sample was approximately 2.5 cm thick. Since tissue and bone optical transmission was of interest, the skin was removed from the rib

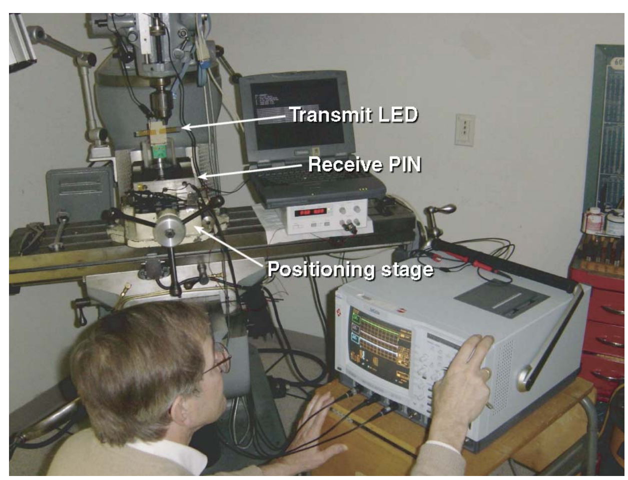

Figure 3. Measurement of diffused light profile for porcine samples.

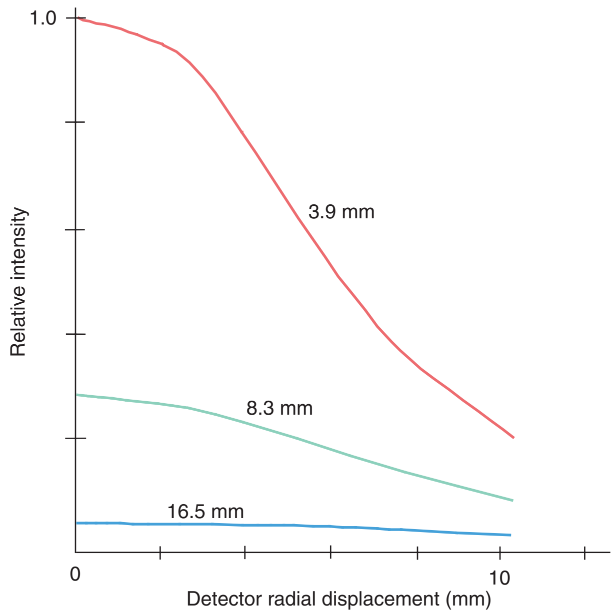

Figure 4. Relative radial intensity profiles of porcine skin.

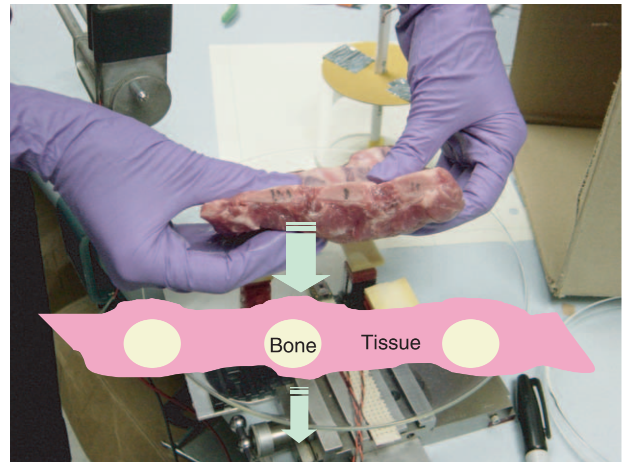

Figure 5. Porcine transmission test sample.

section and placed on a glass plate under which an OPT101 sensor (0.6 V/μW at 860 nm) could be moved parallel to the glass plate using an *x*-*y* positioning stage. A PDI-E804 LED (880 nm, 80°) was placed opposite the OPT101 in contact with a sample, and measurements were taken through tissue and bone. The findings indicate that, even with transmission intensity through bone ≈75% less than the tissue in between, there is more than sufficient signal to obtain threshold conditions for accurate 115-Kbps optical communication with the transceiver pair used (90 nW/mm^2).

PROTOTYPE AMI LINK

Each type of AMI is unique in function and operation and therefore requires unique data processing circuits. It is therefore advantageous to have a broadly applicable "universal" link to communicate through the skin from a standard external interface to a standard internal interface. If this type of transdermal optical link is incorporated, then meeting the custom requirements "on the back side" of these standard interfaces can accommodate most AMIs. We envision an implant transceiver that is embedded in an AMI behind an optically transparent window acting as the gateway for bidirectional data flow (Fig. 6).

An AMI performs its function according to internally generated or externally commanded rules, which are either fixed as in early implant technology, variable according to internal data processing, or externally reprogrammed based on data/information extracted from the AMI. If the implant microprocessor does not participate in data transfer, data stored by the implant must be available to both the unit's primary operating circuitry and the data link, that is, held in a "dual-port" memory. At low data rates, an implant's microprocessor may be able to handle control of data transfer in addition to its primary tasks. For high data rates, a separate communications controller is necessary; thus, time- and date-stamped patient data are structured so they can be separated, routed, and organized properly.

The IR emitter of the communications transmitter consists of an IR LED (≈860 nm), a current-limited high-speed driver for the LED, and a >2-V power source. The IR responder of the communications receiver consists of an IR sensor (PIN diode), a diode current-to-voltage converter, and a narrowband filter and comparator to set frequency and signal thresholds and reject ambient optical noise.

The communications receiver passes data to, and the communications transmitter receives data from, a communications controller in bit-parallel format. A

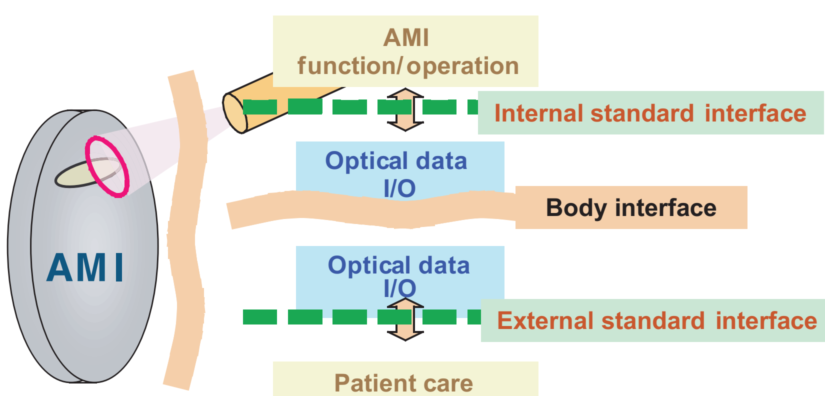

Figure 6. Standard optical data interface.

communications controller typically receives data in parallel format and sends the data in serial format to the transmitter, in reverse for the receiver. The serial encoding varies from one standard to another. However, data are usually streamed (passed via the link) in bit-serial form. Thus, serial-to-parallel data conversion is necessary. This conversion can select from a number of formats.

Several options were considered for serial-to-parallel conversion. Asynchronous (at any time) communication sends data in small fixed-size packets of bits using a self-clocking encoding format that can transmit large variable-size packets of bits. This format is supported in a universal asynchronous receiver/transmitter (UART) embedded in most microcontroller chips. A modern UART operates at bit rates approaching 1 Mbps, although the input/output line drivers are often limited to ≈115 Kbps.

Another format, an infrared data association (IrDA) standard, uses a fixed pulse width for better signal/noise amplification of weak signals, as might be the case for (optical) signals undergoing significant attenuation in traversing the path from transmitter to receiver. This format is conveniently derived from the asynchronous format and is advantageous for power conservation and data discrimination. A simple integrated circuit makes this format usable with any UART.

A third format (biphase) uses a transition every bit, even for long runs of ones and zeros. This allows the data-sampling clock to be generated from the signal and eliminates clock drift between the receiver and transmitter for long multibyte messages. However, this approach requires a unique synchronization word, is inefficient, and requires stream space for a computed checksum word. (To validate transmission, a checksum should be included independent of serial protocol.)

After considering the pros and cons of the several formats, we chose, for the prototype selected here, a simple off-the-shelf hardware solution—IrDA encoding and conversion/translation to interface with a PC serial COM port (RS-232). The first prototype's data rate was limited to 115 Kbps by the PC desktop computer's serial COM port data transfer rate. The subsequent version of this prototype operates at a rate of ≈1 Mbps, interfacing with the much faster COM interface converter using the Universal Serial Bus (USB) interface.

For a medical implant, power consumption is critical. Its energy source (battery) should have a high volumetric energy density (ampere-h/cm^3), long self-discharge time (>10 years), and >2.7 V for single-cell operation of low-voltage logic and optical components. One such readily available battery (Li/MnO_2) is the 3.3-V, 200-mA-h, CR2032 (20-mm dia. × 3.2-mm disk), which can provide short-pulse current up to 15 mA. Using this cell, a 10-year "still life" TOC implant prototype design is limited to a current draw of 2 μA in standby mode. Thus, an always-on idle-mode low-power-consumption circuit, consisting of a separate PIN diode with a large value load resistor, is used to receive an external optical command to "wake up" (activate) the implant transceiver. Once activated, the implant transceiver prototype draws <5 mA when not transmitting and up to 100 mA peak LED current when transmitting. The implant optical transceiver presents challenges for power, packaging, and interfacing. The external transceiver does not have the same stringent requirements, but it must address user and commercial product factors. The first prototype setup and components are shown in Fig. 7.

To interface directly to the serial COM port of a PC, the first prototype TOC system was designed, fabricated, and tested for operation at 115 Kbps. The next iteration took advantage of the COM interface converter to use the USB interface on newer PCs for operation up to 1 Mbps. A UART asynchronous format of data transmission was chosen for its simplicity. Other serial communications protocols such as USB, IrDA, or Ethernet are possible, but are more complicated and consume more power. The 1-Mbps design is made possible by a tiny, fast microcomputer (Cygnal C8051F301). Although this microprocessor UART controller is limited to 115.2 Kbps, its high speed allows a software approach to

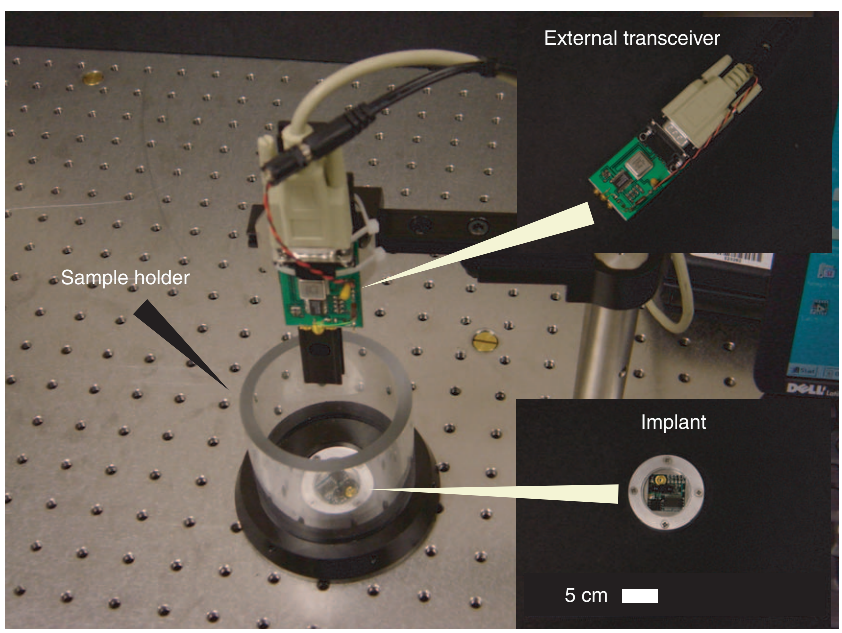

Figure 7. Prototype optical data communicator transceivers.

the UART function and permits formatting of its output as required for optical transmission. The IR transceiver used for both components is an IrDA standard transceiver found in portable PCs.

With the selected approach and components, the feasibility of 1-Mbps optical communication was demonstrated at a wavelength within the window for transdermal data transfer. The communications implant electronics developed here would have to be miniaturized, packaged, and integrated with the functional electronics of the implant in order to create a balanced and minimum-size product.

The main objective of this effort was to demonstrate high data rate, consistent with the feasibility for transdermal communications and operating characteristics suited for medical implants. Because transmitting and receiving a small number of bytes at high speed to validate high-data-rate capability achieves this goal, an 8K memory storage capacity of the implant transceiver prototype is adequate.

A FORTH program written for this demonstration has the implant respond to five single-character commands as follows:

A [Are-You-There]: responds with an integer value of accesses
S [Send Configuration File]: sends 16 stored bytes from data memory
W [Write Configuration File]: writes 16 bytes into data memory
D [Data File Send]: sends 512 bytes of printable ASCII data
P [Pattern File Send]: sends 128 bytes of binary data for plotting

A PC issues these commands and displays the commands and responses. For the S and W commands, the PC receives a 16-byte ASCII printable string, displays it, rotates it one character to the left, and retransmits it back into memory for retrieval at the next S command, that is, the data displayed change every time the S-W-S instruction sequence is executed. This sequence was successfully demonstrated, validating that in each cycle the data are being written and sent.

SUMMARY

Medical implants play an increasingly important role for medication, prostheses, regulation, pain, sensory stimulation, and yet-to-be-discovered therapeutic and diagnostic applications. Future AMI applications will include monitoring patients and collecting large amounts of data to automatically adjust performance parameters and transfer data to remote telecare centers. Current commercial AMIs employ a near-field inductive (magnetic) link to program and extract data from implants at ≈100-Kbps rates. Although an inductive (or perhaps radio wave) approach will make strides to achieve higher data rates, it may not be feasible for transferring the capacity of future memory storage in an acceptable time, or for real-time reprogramming with necessary high data streaming rates. High-frequency rates for electromagnetic devices will be challenged by increased noise, electromagnetic interference, radiation, and other considerations. An optical communications approach shows promise for these considerations and may be better suited for remote monitoring and control as a patient goes about normal living.

An optical approach for transdermal high-data-rate communications has been explored. The scheme implemented demonstrates the possibility for standard internal and external optical communications interfaces to serve a spectrum of different AMI applications. Successful laboratory demonstration of the feasibility of such an optical link is reported here, having achieved data rates of ≈1 Mbps. Porcine skin served this initial work, but human skin must ultimately be tested. Much study and development remain to realize even an embryonic commercial TOC system. However, the findings and results described in this article are encouraging.

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Joseph L. Abita managed the Guidant-APL R&D Program for the development of biomedical technology and applications, and in this capacity he defined and oversaw this program's projects. He contributed to the system concept, design, and test procedures for the transdermal optical communication prototype system presented here. Dr. Abita is an APL Principal Professional Staff physicist in the National Security Technology Department and an instructor in the JHU Whiting School of Engineering. **Wolfger Schneider** is an APL Principal Professional Staff electrical engineer in the Technical Service Department with broad expertise in digital and analog electronic design and microcomputer applications. He was responsible for this project's electronics and software design, system integration, and performance characterization. The team can be contacted through Dr. Abita. His e-mail address is Joseph.Abita@jhuapl.edu.

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