Towards a wireless system that can monitor the encapsulation of mm-sized active implants *in vivo* for bioelectronic medicine

Gonçalo Rodrigues[1], Mariana Neca[1], João Silva[1], Diogo Brito[1], Taimur Rabuske[1], Jorge Fernandes[1],
Rainer Mohrlok[2], Christoph Jeschke[2], Jannis Meents[2], Kambiz Nanbakhsh[3], and Vasiliki Giagka[3,4]

***Abstract*— Active neural interfaces for bioelectronic medicine are envisioned to be mm-sized. Such miniaturization is at the moment hampered by the available wireless power techniques as well as the large volume the conventional hermetic packaging adds to the implant. Alternatively, conformal coatings are being explored for the protection of the implant electronics. Such approach has the potential to allow for the use of RF (radio-frequency) energy for powering, and miniaturization to the extreme of having a single IC (integrated circuit) as the whole implant (single chip implants). The longevity of conformal encapsulation can be assessed using accelerated soak tests in a dedicated apparatus** *in vitro*, **but these are usually not sufficient, as they fail to reveal additional failure modes that manifest themselves** *in vivo*. **Therefore, to investigate the performance of conformal coatings** *in vivo* **a compact, mm-sized wireless monitoring system is required. The development of such a system exhibits several challenges, mostly concerned with how to receive enough energy in such a small implant to power the monitoring sensor and transmit information regarding the integrity of the coating.**

In this paper we propose a system architecture for such a mm-sized wireless system, suitable for medium-to-long term monitoring of implants, by designing the whole system as a single monolithic IC. It is shown, by experiments, simulation or analytically that the identified challenges are possible to overcome, allowing to proceed towards the practical prototype.

I. INTRODUCTION

Most active implants are protected by a hermetic titanium housing that protects and isolates the human tissue from both electronic devices and batteries, offering decades of implant lifetime. The main limitations of such solutions are that they are generally bulky and rigid, while also isolating the interior electronics from radio or ultrasound waves limiting the external powering of the implant circuits. While titanium housing has been successfully used in older generations of implantable devices, such as pacemakers, the new era of bioelectronic medicine, where implants are envisioned to be mm-sized and wirelessly energized, calls for a new approach [1].

Conformal encapsulation based on polymers or thin film ceramics, has the potential to achieve equally long lifetimes with a much smaller footprint, while allowing for efficient wireless power transfer. In contrast to hermetic approaches, where the integrity of the package is evaluated by helium leakage assessments, the longevity of conformal encapsulation depends on good adhesion among all interfaces. It can be assessed using accelerated soak tests in a dedicated apparatus *in vitro*, using impedance spectrometry on interdigitated comb structures [2], [3] or even changes in the resistance of the chip's interlayer dielectric using on-chip integrated sensors [4]. All of these assessments are useful however, they are usually not sufficient, as they fail to reveal additional failure modes that manifest themselves *in vivo* [5]. Therefore, to investigate the performance of conformal coatings *in vivo* a compact, mm-sized wireless monitoring system is required.

Such a system should obey the following boundary conditions: (1) be implanted in a mouse (small), (2) be fully implantable, (3) allow for long term operation (self-powered), (4) operate below Specific Absorption Rate (SAR) threshold (low-power, conservatively <10μW), (5) avoid any external components and allow for the sole evaluation of the IC – no bonds, no pads (no passivation openings), no external components.

We therefore envision such a monitoring system implemented in a single monolithic IC without any external components, evaluating solely the degradation of the IC passivation over time under conformal encapsulation materials. The IC will be fully passivated, comprising energy harvesting, an encapsulation integrity sensor and communication capabilities.

In this work, we investigate the feasibility of such an approach, propose a system level architecture, and discuss the crucial implementation details for the most important blocks. Particularly the two main challenges to be discussed in this paper are (1) how much energy can we harvest in an IC without external components or MEMS (Microelectromechanical systems), using small coils (few hundred μm in size)? (2) Is this energy enough to power a sensor and a communication link? Through the next sections it is argued that it is possible and a system topology is proposed.

II. BACKGROUND OVERVIEW AND REASONING APPROACH

The architecture for an autonomous wireless sensor node generally comprises an energy collector to avoid the use of batteries, followed by an energy harvester/receiver circuit to

---

* This work has been supported by the EU projects funded by the ECSEL JU: POSITION-II under grant number Ecsel-783132-Position-II-IA, Moore4Medical under grant number H2020-ECSEL-2019-IA-876190 and by FCT, Fundação para a Ciência e a Tecnologia (Portugal), under projects UIDB/50021/2020, UNSEEN PTDC/EEI-EEE/31416/2017 and scholarship SFRH/BPD/116007/2016;

[1] are with INESC-ID, Instituto Superior Técnico, Universidade de Lisboa (corresponding author: phone: +351-3100-327; e-mail: jorge.fernandes@inesc-id.pt).

[2] are with Multichannel Systems MCS GmbH, Germany.

[3] are with the Department of Microelectronics, Faculty of Electrical Engineering, Mathematics and Computer Science, Delft University of Technology, Delft, The Netherlands. (V.Giagka@tudelft.nl).

[4] is with the Department of System Integration and Interconnection Technologies, Fraunhofer Institute for Reliability and Microintegration IZM, Berlin, Germany.

generate the DC power source for the sensor biasing, reading, and processing. Finally, a communication circuit is required to send the sensor information back to the exterior.

A. *Wirelessly Powering the Implantable Node*

The main sources for energy harvesting or wireless power transfer are (1) Solar, (2) Thermal -both DC energy sources-, (3) Vibrational, and (4) Inductive/RF – both AC sources- [e.g. 6-12]. Due to the full implantability requirement of our application, solar and thermal options have not been considered further. Vibrational harvesters often require MEMS which are non-conventional IC elements, require post-IC fabrication processing and compromise a full passivated IC.

Inductive coupling is commonly chosen for short range wireless power links and RF for longer distance communication. RF requires non-integrated antennas at the frequencies of interest. Even NFC (Near Field Communication) uses antennas that are in the tens of mm range. Inductive coupling usually uses a transformer with high coupling coefficient, but examples exist with implants that make use of low coupling coefficients on large coils for transferring energy [9]. Reasoning that inductive coupling is the best solution, it still has to be evaluated if it can provide the necessary power on a small planar integrated inductor.

B. *Sensors and Processing*

Hermetically protected implants have cavities and can rely on a sensitive humidity sensor for leakage detection. For conformally coated implants, a different sensing approach is necessary. A soaked IC will allow for a gradual absorption of humidity. On-chip resistance and capacitance values will change in the presence of moisture, and even the bulk of the single IC can serve as a suitable sensor [13]. Sensor readings can be quantified using ADCs, however, in this implementation, due to power consumption limitations we propose to use an oscillator with a frequency dependent on an RC constant, that will reflect the changes of the RC time constant in moist environments.

C. *Communication Link*

To adhere to the extremely low power budget for the communication link backscattering is proposed. With this approach, when the load impedance on the implant side changes, it affects the carrier wave which in turn, can be detected outside the implant. The feasibility for the target specification needs to be evaluated as an extremely weak coupling coefficient is envisaged.

III. REASONING APPROACH VALIDATION

Due to the complexity of modelling and simulation of such a complex inductive coupling system, an experimental assessment was first conducted, to have an idea of the order of magnitude that the harvester system can obtain with an integrated inductor. The following experiment has been conducted: a custom IC (Figure 1(a)) comprising an RF power harvester IC designed and implemented to be connected to a 50Ω antenna [14] is connected to allow for the matching coils to be used as resonant secondary coil of an inductive coupling system and expedite the feasibility evaluation. It is important to note that four coils are used as the RF harvester has a differential topology and is implemented with a T-match network.

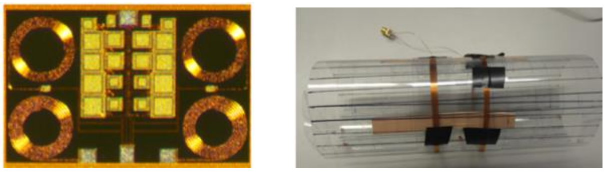

(a) (b)

Figure 1. (a) RF power harvester IC die photo (1100×700µm2), (b) Emitter coil on tube and AM modulation with backscattering approach.

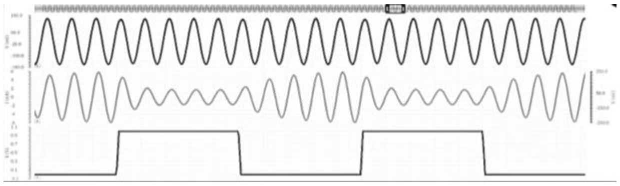


Figure 2. Backscattering Simulation on Cadence Spectre: (top) Carrier, (middle) AM backscattered modulation, (bottom) Load modulation.

Several inductors were designed as emitters for powering the circuit, from solenoids and planar inductors in XYZ axis test setups, to pancake coils in cylinders mimicking a tube in a mouse cage (Figure 1(b)). Measurements showed that a voltage ~1V in a 1MΩ load (~1µA of current) is obtainable without further optimization. It also showed that even at a few mm distance (measured from the center of the coil towards the IC) a voltage of around 100mV is still obtainable. However, it is expected that the presence of tissue will increase the energy absorption and thus reduce the link efficiency.

To evaluate the feasibility of the backscattering technique a switch is used to change the secondary load and observe if a change occurs at the primary. It is observed that it leads to amplitude modulation (AM) and a simulation on Cadence Spectre with a high-level model is shown in Figure 2.

The described experiment acts as a proof of feasibility (on a custom RF harvesting circuit) that can now be explored, further developed, and optimized towards an *in vivo* encapsulation monitoring system on a monolithic IC (several other analytical models, electromagnetic simulations, Cadence Spectre simulations, etc, were used to evaluate individual blocks behaviour, but are not shown due to space limitations). The conducted experiments show that power in the order of µW is obtainable and that communication with the exterior is possible without a power greedy transmitter.

IV. PROPOSED SYSTEM

The complete *in vivo* reliability monitoring system is composed by four major parts: 1. wireless power transfer; 2. Power receiver and rectifier; 3. Resistive humidity sensor and oscillator; 4. Backscattering modulation for data transmission (Figure 3).

The wireless power transfer is composed by an energy source connected to an external coil and inside the chip (grey area in Figure 3) an integrated receiving inductor forms the inductive link. The power harvester/receiver is responsible for converting an AC signal into DC. For the sensor part, an RC time constant is used inside the chip that is related to the sensed

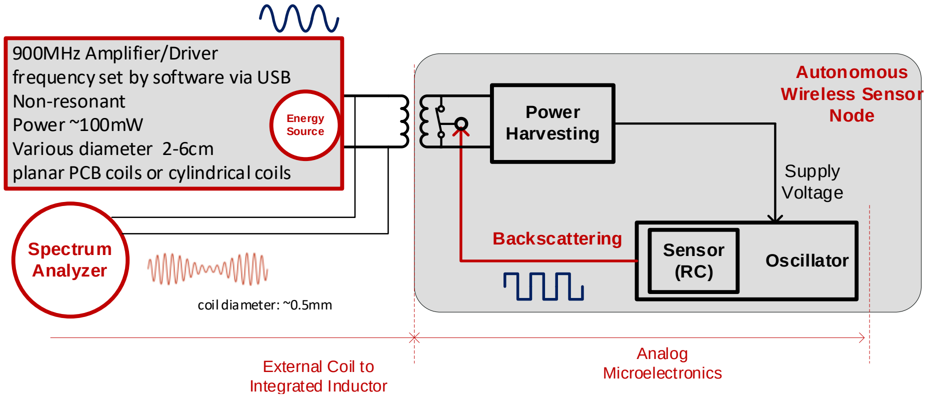


Figure 3. Complete system architecture.

humidity and an integrated oscillator will, in turn, produce a frequency related to the RC constant. Finally, the oscillator will actuate a switch in parallel with the integrated inductor to send the AM-modulated information to the outside of the implant through backscattering. Externally to the implant, a transmitter coil with an amplifier with a controllable frequency and amplitude is used (Figure 4) to transfer energy for the IC. To receive the backscattered signal, a spectrum analyzer is used to measure the frequency of the AM-modulated wave.

A. *System Specifications*

Table I presents the power budget specifications for the different parts of the systems. On the external side the frequency and amplitude of the signals that will be transmitted and received are specified. Inside the IC, the oscillator and the sensor must be designed for ultra-low power consumption (approximately 1 µW). For a conservative margin, a power greater than 2 µW must be available to the load. Simulation results show that rectifiers working with small amplitude signals present low efficiencies, so once again, a conservative received power of 50 µW is specified.

Previous works also show that link efficiencies are typically around 1% - 10%, the external source is designated to emit enough power for the worst case. Regarding the backscattering, the amplitude modulation of the signal inside the IC must present at least 200 mV of variance, at a frequency in a range of 3 to 13 MHz (directly dependent on the humidity inside the chip). Outside the IC it is expected to detect a modulation of 1.5 mV with a spectrum analyzer.

In the next sections we will present each component of the system and size it to achieve the specifications of Table I.

B. *Inductive Link Efficiency*

Two models were used to predict the efficiency of the link, one theoretical with literature experiments, and the other with a specific Matlab toolbox for inductive links (Cucco). Typically the most important factor to estimate the efficiency of the link is the coupling coefficient K. The results obtained by the two methods for a 10 mm diameter emitter coil (Tx) and a 300 µm diameter receiver coil (Rx) for a distance range from 0 to 2.5 cm are shown in Figure 5. The two methods show similar behaviour with different absolute values however, a K inferior to 0.1 is expected at any distance (which translates to less than 10% of efficiency).

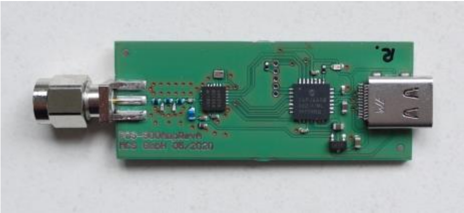
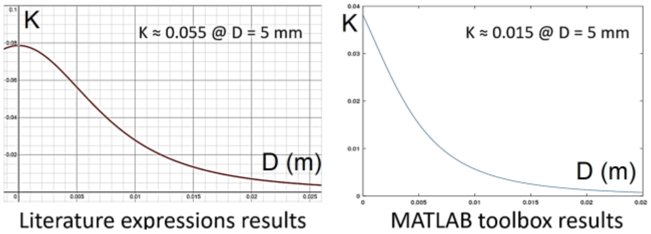


Figure 4. External emitter energy source.

TABLE I. SYSTEM LEVEL SPECIFICATIONS

Power Budget			
External Circuit		**Integrated Circuit**	
Emitted Power (Tx)	>50mW at 900MHz	Received Power (Rx)	>50µW
		Power Available to Load	>2µW
		Oscillator Power	<1µW
		Sensor Power	<30nW
Backscattering			
AM Modulation (Rx)	>1.5mV	AM modulation (Tx)	>200mV
		Frequency Range	3-13MHz



Literature expressions results

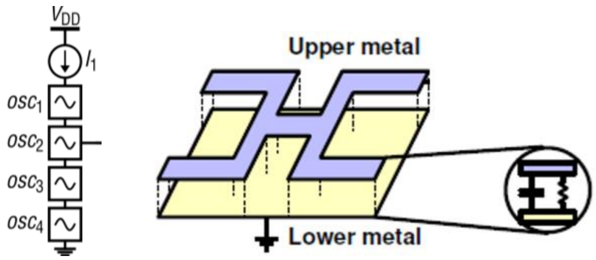
MATLAB toolbox results

Figure 5. Coupling coefficient for the two methods.

For conservative purposes, it is assumed that a reasonable value for the coupling coefficient is in the 0.01 to 0.05 range. With this value, we can estimate the order of magnitude of the link efficiency (1% - 5%) and design the whole system for the desirable available power.

C. *RC Oscillator*

An inverter-based ring oscillator is the most reasonable choice since CMOS inverters have no static consumption. For this system it is proposed to stack multiple ring oscillators (4



(a) (b)

Figure 6. a) Stacked Oscillator (4 ring Oscillators). (b) Resistance sensitive to humidity in chip.

TABLE II. OSCILLATOR SPECIFICATIONS

Bias current (I_1)	Frequency	Power
2.5 nA	3 MHz	65 nW
7.5 nA	5 MHz	128 nW
15 nA	7.5 MHz	209 nW
40 nA	10 MHz	328 nW

in our case) as it divides the available supply voltage V_{DD} in 4 equal fractions (Figure 6(a)). This increases delay t_d, and thus results in a lower frequency. Moreover, as there is current reuse in a stack, it lowers the current consumption and can operate with very low voltage headroom. With these techniques, an extremely low power oscillator (less than 500 nW) can be obtained with a frequency in the low MHz range, that changes with the bias current I_1 as shown in Table II. Next, a sensor is required to generate a current proportional to the humidity inside the chip to complete the monitoring system.

D. Humidity Sensor

In [4] it is shown that inter-layer dielectric resistance changes with humidity for circuits soaked during a long time. In other words, when we have two metal plates (Figure 6(b)) on different metallization levels, as M4 and M5, the resistance between them is extremely high, in the 200 to 500 TΩ range. When water penetrates the chip, the resistance lowers by 1-2 orders of magnitude. The sensor combined with the circuitry to amplify the current to the nA range consume less than 30 nW. Combining the sensor with the low power current controlled oscillator, it is possible to generate a frequency proportional to humidity inside the chip while still keeping the power consumption lower than the proposed in Table I.

V. CONCLUSION

This paper presents the proposed architecture for an in-vivo encapsulation reliability monitoring system. While developing the system architecture, all the decisions were based in reasoned studies and/or experiments, however the solution proposed is ambitious and risky due to the fact that it consists of a single fully passivated IC. On the other hand, the gain, being successfully is enormous since it is minimally intrusive, and suitable for medium-to-long term monitoring of implants, totally isolating a single circuit from any external connection that can be itself a source of failure.

ACKNOWLEDGMENT

The authors acknowledge the contributions due to all Position-II project participants during brainstorm sessions.

REFERENCES

[1] V. Giagka, and W. Serdijn, “Realizing flexible bioelectronic medicines for accessing the peripheral nerves – technology considerations,” *Bioelectronic Medicine*, vol. 4, no. 8, Jun. 2018. doi: 10.1186/s42234-018-0010-y

[2] K. Nanbakhsh *et al.*, “Effect of signals on the encapsulation performance of parylene coated platinum tracks for active medical implants,” in *Proc. 41st Annu. Int. Conf. IEEE Eng. Med. Biol. Soc. (EMBC)*, 2019, pp. 3840–3844. doi: 10.1109/EMBC.2019.8857702.

[3] K. Nanbakhsh, R. Ritasalo, W. A. Serdijn, and V. Giagka, “Long-term encapsulation of platinum metallization using a HfO2 ALD – PDMS bilayer for non-hermetic active implants,” in *Proc. IEEE Electron. Comp. Tech. Conf. (ECTC)*, Orlando, FL, USA, May 2020. doi: 10.1109/ECTC32862.2020.00081

[4] O. C. Akgun, K. Nanbakhsh, V. Giagka, and W. A. Serdijn, “A chip integrity monitor for evaluating moisture/ion ingress in mm-sized single-chip implants,” *IEEE Trans. Biomed. Circuits Syst.*, vol. 14, no. 4, pp. 658-670, Aug. 2020. doi: 10.1109/TBCAS.2020.3007484.

[5] R. Caldwell, M. G. Street, R. Sharma, P. Takmakov, B. Baker, and L. Rieth, “Characterization of Parylene-C degradation mechanisms: In vitro reactive accelerated aging model compared to multiyear in vivo implantation,” *Biomaterials*, 119731, 2019.

[6] G. L. Barbruni, P. M. Ros, D. Demarchi, S. Carrara and D. Ghezzi, "Miniaturised Wireless Power Transfer Systems for Neurostimulation: A Review," in *IEEE Transactions on Biomedical Circuits and Systems*, vol. 14, no. 6, pp. 1160-1178, Dec. 2020, doi: 10.1109/TBCAS.2020.3038599.

[7] Y. K. Ramadass and A. P. Chandrakasan, "An Efficient Piezoelectric Energy Harvesting Interface Circuit Using a Bias-Flip Rectifier and Shared Inductor," in IEEE Journal of Solid-State Circuits, vol. 45, no. 1, pp. 189-204, Jan. 2010, doi: 10.1109/JSSC.2009.2034442.

[8] P. D. Mitcheson and T. C. Green, "Maximum Effectiveness of Electrostatic Energy Harvesters When Coupled to Interface Circuits," in IEEE Transactions on Circuits and Systems I: Regular Papers, vol. 59, no. 12, pp. 3098-3111, Dec. 2012, doi: 10.1109/TCSI.2012.2206432.

[9] D. Maurath, P. F. Becker, D. Spreemann and Y. Manoli, "Efficient Energy Harvesting With Electromagnetic Energy Transducers Using Active Low-Voltage Rectification and Maximum Power Point Tracking," in IEEE Journal of Solid-State Circuits, vol. 47, no. 6, pp. 1369-1380, June 2012, doi: 10.1109/JSSC.2012.2188562.

[10] M. Piedade, J. Gerald, L. A. Sousa, G. Tavares and P. Tomas, "Visual neuroprosthesis: a non invasive system for stimulating the cortex," in IEEE Transactions on Circuits and Systems I: Regular Papers, vol. 52, no. 12, pp. 2648-2662, Dec. 2005, doi: 10.1109/TCSI.2005.857923

[11] H. Bhamra et al., "A 24μW, Batteryless, Crystal-free, Multinode Synchronized SoC “Bionode” for Wireless Prosthesis Control," in IEEE Journal of Solid-State Circuits, vol. 50, no. 11, pp. 2714-2727, Nov. 2015, doi: 10.1109/JSSC.2015.2480854.

[12] S. Yang, J. Yin, H. Yi, W. Yu, P. Mak and R. P. Martins, "A 0.2-V Energy-Harvesting BLE Transmitter With a Micropower Manager Achieving 25% System Efficiency at 0-dBm Output and 5.2-nW Sleep Power in 28-nm CMOS," in IEEE Journal of Solid-State Circuits, vol. 54, no. 5, pp. 1351-1362, May 2019, doi:10.1109/JSSC.2018.2888874

[13] K. Nanbakhsh, R. Ritasalo, W. A. Serdijn and V. Giagka, "Towards CMOS Bulk Sensing for In-Situ Evaluation of ALD Coatings for Millimeter Sized Implants," 2020 42nd Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC), Montreal, QC, Canada, 2020, pp. 3436-3439, doi: 10.1109/EMBC44109.2020.9176103.

[14] Hugo Gonçalves, ““Radio-Frequency Energy Harvesting Circuits”, PhD thesis, Instituto Superior Técnico, Universidade de Lisboa, April 2017