A Fully-Implantable MEMS-Based Autonomous Cochlear Implant

Reporting

Project Information

FLAMENCO

Grant agreement ID: 682756

Project website

Status
Ongoing project

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€ 1 993 750

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Periodic Reporting for period 2 - FLAMENCO (A Fully-Implantable MEMS-Based Autonomous Cochlear Implant)

Reporting period: 2018-01-01 to 2019-06-30

Summary of the context and overall objectives of the project

Today, congenital or acquired hearing loss affects around 5% (360 million people, of which 32 million are children, WHO, 2015) of the world population and presents significant impact on people's social, emotional, and economic wellbeing. Deafness is a partial or total inability to hear, and classified as conductive, sensorineural, and mixed deafness. Sensorineural impairment, which represents the majority of the profound deafness, can be restored using cochlear implants (CIs), which electrically stimulate the auditory nerve to repair hearing in people with severe-to-profound hearing loss (>90 dB sound pressure level in both ears). CIs are used for more than 40 years and today implanted in around 220.000 individuals worldwide. However, conventional CIs have major drawbacks such as replacing the entire natural hearing mechanism with electronic hearing, even though most parts of the hearing

system (such as the eardrum and ossicles) are operational. Moreover, daily battery recharge/replacement requirement, damage risk of external components especially if exposed to water (shower, rain, swimming, etc.), and aesthetic concerns particularly for children and young adults are other critical drawbacks. Therefore, researchers in this area try to eliminate these problems via fully implantable, self-powered, and stand-alone cochlear implants.
FLAMENCO has a ground-breaking nature as it revolutionizes the operation principle of the conventional CIs. The overall objective of FLAMENCO is to develop a fully implantable, low-power, energy harvesting (self-powered), next generation CI mimicking the natural hearing mechanism of the ear. Fully implantable CI has the potential to eliminate the aforementioned concerns, but a reliable internal power source and an implantable acoustic sensor that are fit into a small volume are the main bottlenecks. In FLAMENCO project, we are working towards overcoming these challenges to improve the lives of people with sensorineural impairment. The goal is to give the patients their freedom to hear and be exposed to water, and social confidence.

Work performed from the beginning of the project to the end of the period covered by the report and main results achieved so far

FLAMENCO project is composed of five main subjects: sound detection, energy harvesting, interface electronics, integration of devices, validation by animal tests. Progress in these subjects from the start of the project to the end of this period are given below:

Sound Detection and Energy Harvesting: All the tasks related to development of sound detection and energy harvesting transducers have been executed in line with proposed timeline except vacuum packaging of energy harvester.

Two fabrication batches, which were comprised of 2 silicon wafers per batch, containing ~35 sound detection chips per wafer were fabricated. A novel design with multiple cantilevers on a single layer has been developed to minimize the mass. Feasibility of the method was shown with 1-frequency transducers, and 8-frequency prototypes have been fabricated and tested with the highest voltage output among other acoustic sensors in the literature.

Five fabrication batches, which were comprised of 2-3 silicon wafers in each batch, containing ~40 harvester per wafer were fabricated. We improved micro-fabrication process for piezoelectric energy harvesters (PEHs), and the fabrication yield increased from 5% to 90%. However, harvesting performances are lower than expected but we still achieve the highest power density among acoustic energy harvesters in the literature. Alternative piezoelectric materials are also being considered for increased power output.

Packaging and integration:
We fabricated and tested the first prototype of the flexible carrier for the integration of individual components (i.e. transducers, harvester chips, interface electronics etc.). Currently, we are developing a more advanced foldable design. To achieve robust packaging, we developed a customized Through Silicon Via process, instead of utilizing fragile wire bonds suggested in the proposal.

Interface Electronics:

We designed, fabricated and tested 4 different sound processing ICs ending up with outstandingly low power consumption (<500µW) crucial for the project objective. Other main achievements are as follows:
• Novel circuit design and stimulation waveforms
• Novel logarithmic compression
• Digital patient fitting for stimulation adjustment
• High sensitivity for sound sensor output
• Special measures for preventing tissue damage and enabling continuous operation
We designed, fabricated and tested 4 different power conditioning ICs ending up with ultra efficient energy harvesting IC. Other main achievements are as follows:
• Fully autonomous operation
• Load independent architecture with power improvement compared to conventional structures
• Capability to operate with minimized inductor size (critical for implant size)
• Up to 90% maximum power conversion efficiency (best in the literature)

RF transmission was anticipated only for patient fitting. After realizing risk of having insufficient power supply from energy harvester, wireless power transmission is decided to be included as a back-up source for recharging the battery. As an improvement to proposal, a wireless power unit for transferring power and data will be integrated. Currently, the design is in progress.

Testing:
After the fabrication of the harvester and transducers, vibration tests were carried out. For acoustic tests a special structure mimicking the ear canal was manufactured and used with harvester chips. Later, we developed an artificial tympanic membrane (TM) reproducing basic vibrational characteristics of a human TM. Performance tests of transducers have been conducted on artificial TM.

After the implementation of first generation sub-units of FICI, tests at electronics laboratories were performed with success. Animal tests have been started earlier than expected in the proposal, and the feasibility of the overall system has been verified via initial tests. In these tests, we validated neural stimulation performance on a deafened guinea pig. Briefly, a sound wave is supp

Progress beyond the state of the art and expected potential impact (including the socio-economic impact and the wider societal implications of the project so far)

FLAMENCO has a ground-breaking nature as it revolutionizes the operation principle of cochlear implants (CI) by overcoming the major drawbacks such as; electronic hearing, power hungry units, damage risk of external components and aesthetic concerns. Progress up to date has demonstrated that the novel concept proposed by FLAMENCO; fully implantable, autonomous, and low-power CI is feasible. Progress beyond the state of the art can be summarized as follows:

Sound Transducer
We developed a sound transducer based on mechanical sensors on a single layer for 8 different frequencies covering the human hearing band. This single layer acoustic transducer based on thin film

PLD PZT material having outstandingly small footprint (6.4mm × 6.4mm) with weight limit is a novel combination resulting in an outstanding sensitivity.

Energy Harvester

The main novelties in energy harvesting is the efficient harvesting in a very small footprint (6.4mm × 6.4mm) with weight limit, and an improved fabrication process. As there are no conventional design and fabrication methodologies for implantable micro energy harvesters, piezoelectric energy harvester's development is unique to FLAMENCO.

Sound Processing IC

The developed sound processing IC with the lowest power consumption in literature is one of the major novelties. This achievement is based on novel power-efficient current-mode circuits that process the acoustic sensor signals and stimulate the auditory neurons through energy-optimized current waveforms. This system is the first FICI interface with 60 dB input dynamic range and patient fitting compatibility that operates with a total power dissipation of ~470 μW. Another novelty of the circuit is active charge balancing technique enabling stable operation by protecting auditory neurons from excess charge damage.

Energy Harvesting IC

A novel multistage energy extraction technique has been implemented to simultaneously achieve low cost and high power conversion efficiency. A novel nonlinear switching technique and a new energy extraction technique called Synchronized Switch Harvesting on Capacitor-Inductor is introduced to the literature.

Packaging

A customized TSV technique and an original parylene-based packaging have been developed for 3D integration of energy harvesting and sound detector chips to form a compact transducer stack. This package is required to be biocompatible with a weight <25mg and should have long enough life time as it will be implanted to a location hard to be accessed.

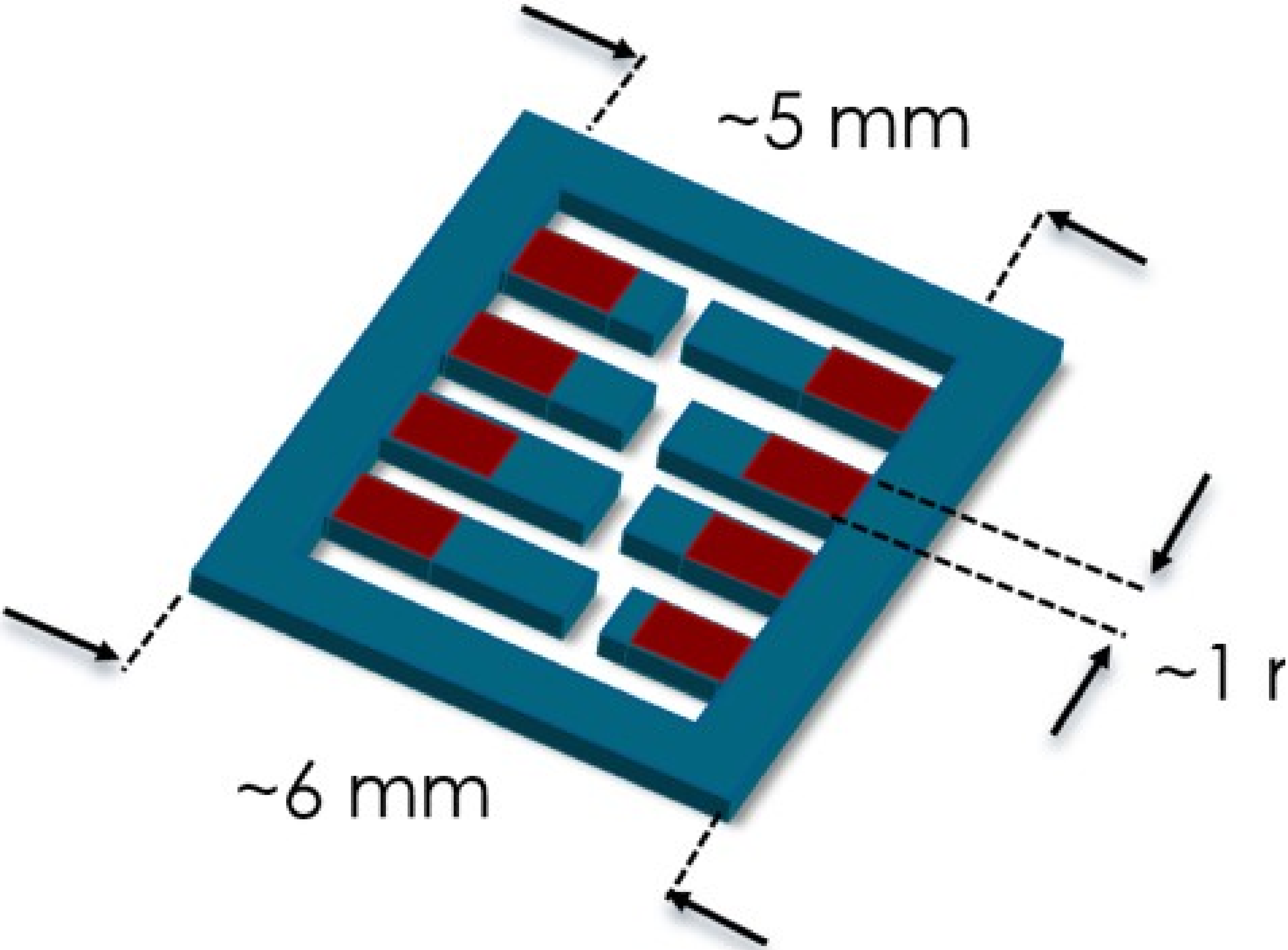
Tympanic Membrane Modelling

An artificial tympanic membrane (TM) reproducing the basic vibrational characteristics of a human TM is developed for testing the transducers. This has been one of the first successful efforts in the literature (to the best of our knowledge) ending up with an easily accessible test platform for minimizing the need for cadaveric and/or animal's tympanic membrane.

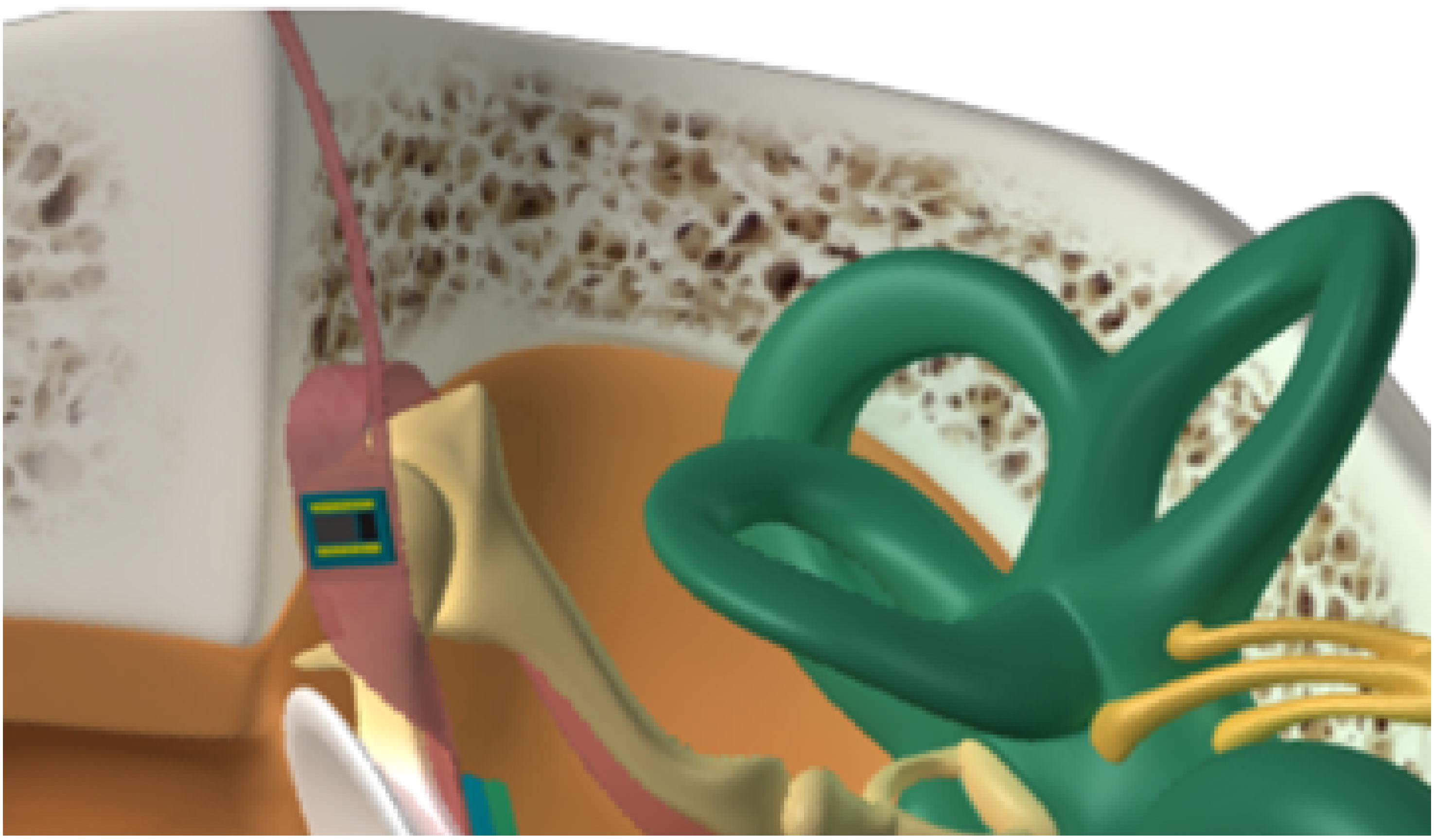
Expected results until the end of project are as follows:

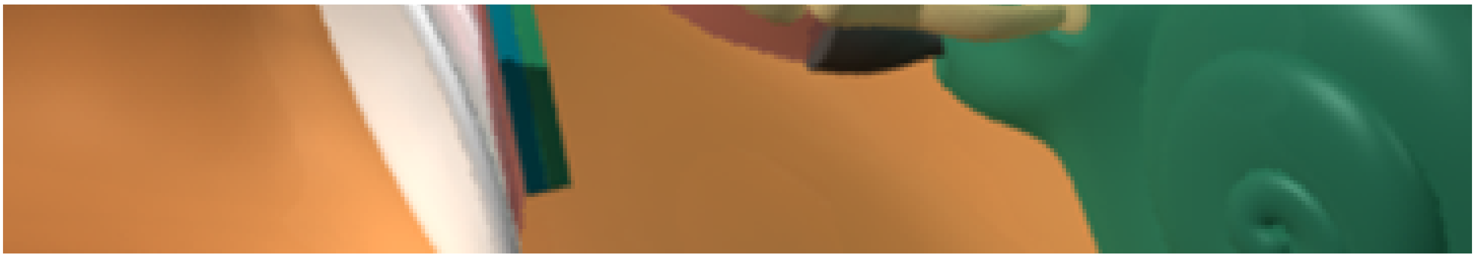
- Interface circuits which are developed as prototypes will be finalized for implantation
- Energy harvester and sound detector transducers will be improved and packaged to be biocompatible
- Laboratory tests will be performed on the final assembly of the fully implantable cochlear implant to validate functionality of the devices both individually and as whole package.
- After validation at the laboratory, FICI will be implanted to a deafened animal to demonstrate that the device can stimulate the auditory neurons by processing the sound waves

device can stimulate the auditory neurons by processing the sound waves.

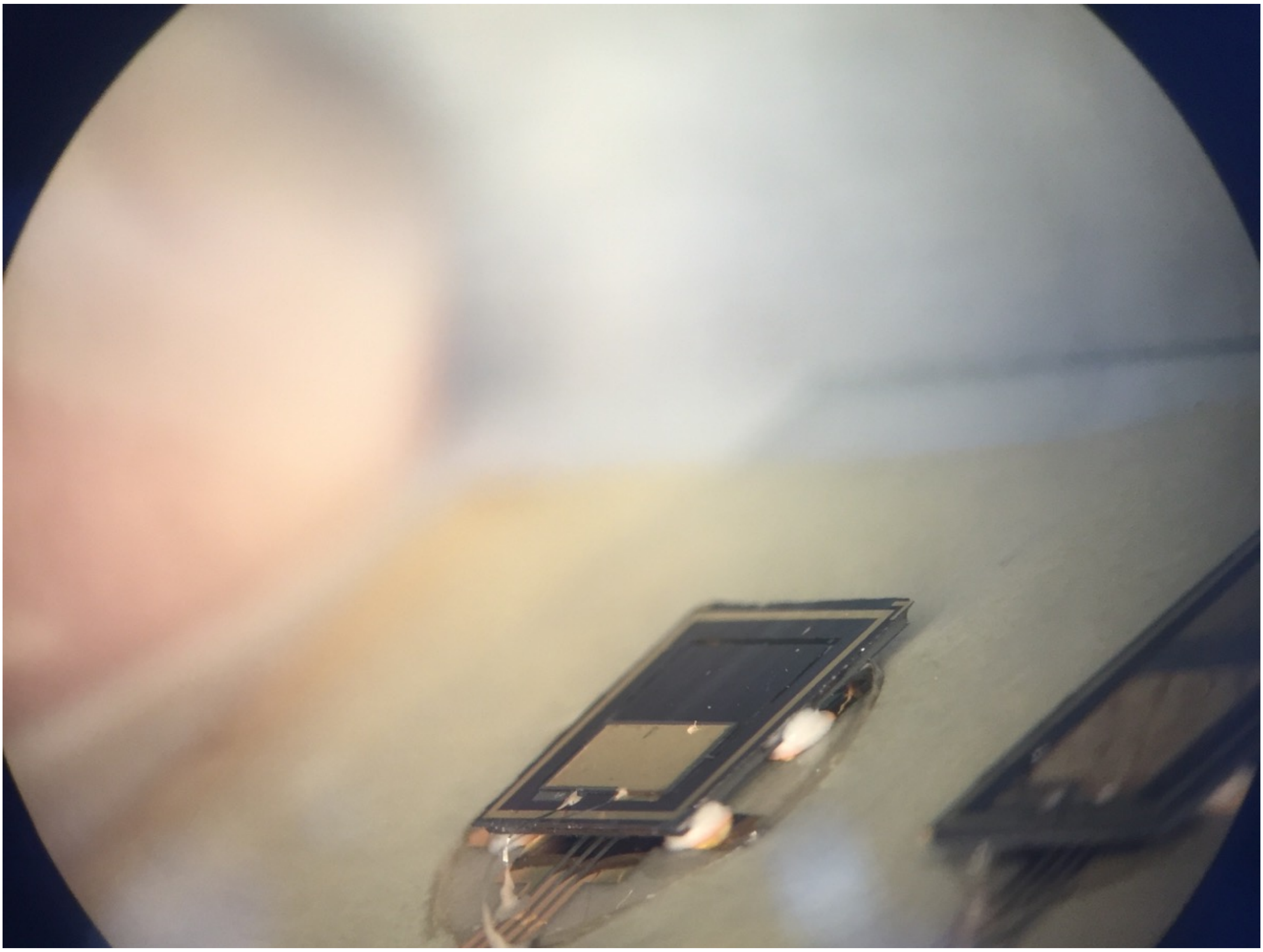


Schematic of sound detection transducer

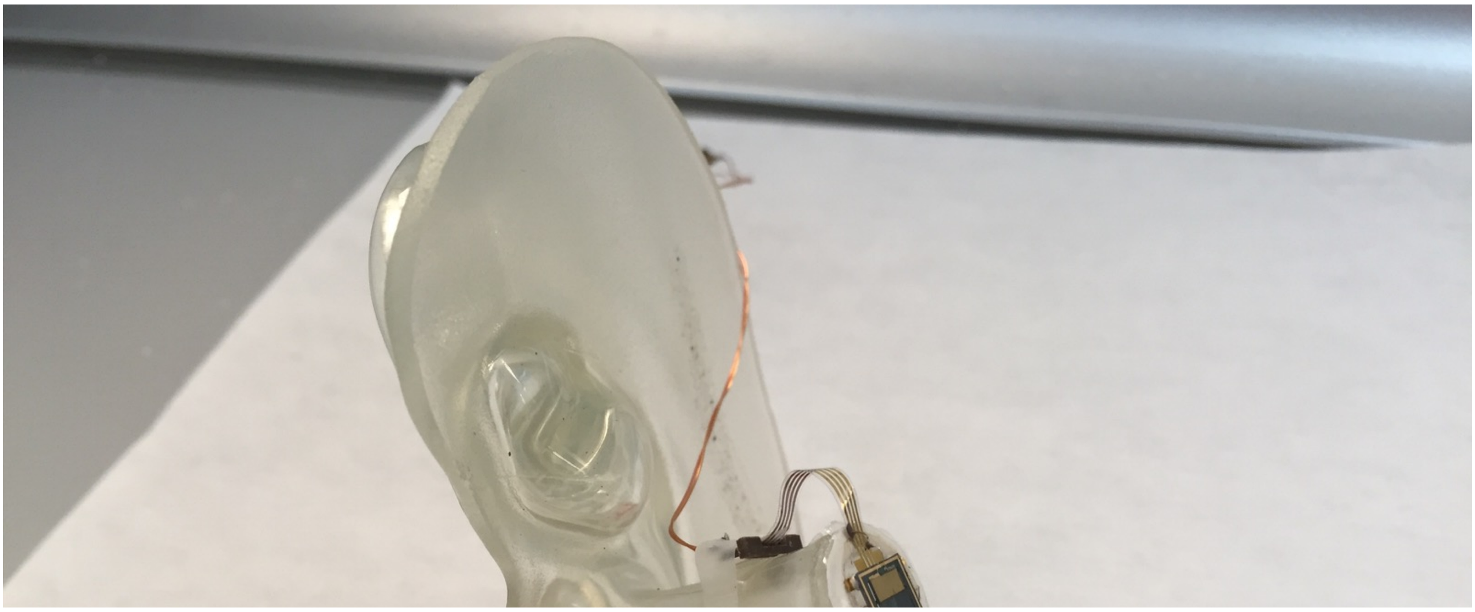




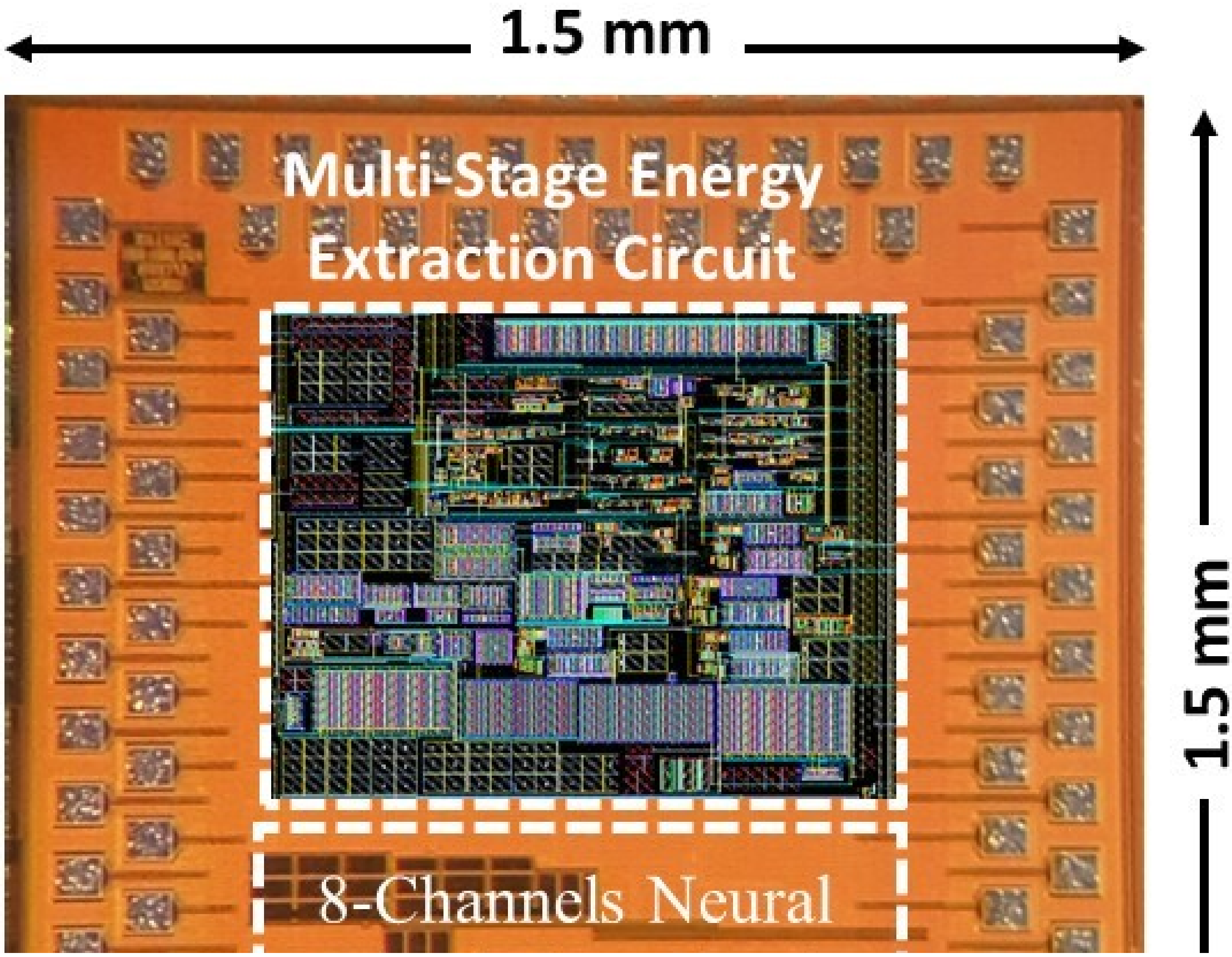
Schematic view of the overall system



Close view of energy harvester



Implant integrated on the ear model



Micrograph and layout view of the Interface Circuits

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