Road to Market for Fully Implantable Cochlear Implant: Phase 1

Reporting

Project Information

OPERA

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Periodic Reporting for period 1 - OPERA (Road to Market for Fully Implantable Cochlear Implant: Phase 1)

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Summary of the context and overall objectives of the project

Today, congenital or acquired hearing loss affects around 6% of the world population (over 460 M people, of 7% are children, Source: WHO) and presents significant impacts on people's social, emotional, and economic wellbeing. In certain cases, hearing function can be restored using cochlear implants (CIs). CIs are composed of an external unit to collect the sound, process, and transmit to a receiver under the skin which has the output connected to the electrode inserted into the cochlea.

These implants are used for more than 40 years and today implanted in around 800.000 individuals worldwide. However, conventional CIs have major drawbacks of which the significant ones are: concerns due to external unit (risk of damage and aesthetics concerns leading to psychological impacts), daily recharge/replacement of batteries (high power consumption), electronic hearing (due to electronic processing of sound), prevention from medical diagnosis and treatments involving magnetic field (due to the magnet under the skin).

To eliminate the aforementioned concerns, a radically different concept from the conventional approach was introduced by the BIOMEMS research group at the Middle East Technical University of Turkey: a fully implantable, low-power, next generation CI concept. We introduced the 1st generation fully implantable cochlear implant (FICI) concept in the FLAMENCO project (ERC CoG Horizon 2020), which started in July 2016. For full implantation, the FLAMENCO concept was based on locating all the components into the middle ear (ME). Afterwards, the outstanding concept of FLAMENCO was evolved to integrating the sound transducer preferably clamped between the umbo and ossicular chain to sense the vibrations of the incoming sound utilizing its mechanical frequency selective structure. This novel sound sensing and transmission device based on piezoelectric cantilevers eliminates the external unit. This revolutionary CI concept has the additional potential of improving the quality of hearing, as its sound sensors mimic the physiological auditory process in principle, instead of the digital (electronic) sound processing of the state-of-the-art CIs. To amplify and process generated signals over a transducer, an ultra-low power interface electronics was developed, by which the signals are processed and transferred to the cochlear electrode for stimulating auditory nerves.

Being fully implanted, it will not suffer from mechanical damage risks or contact with water (even underwater), and raise no aesthetic concerns by users. The system does not use magnets, eliminating the MRI scanning limitations for patients. Moreover, an RF coil placed next to the battery under the skin is coupled with an external RF coil aligned to the implanted one to charge the battery, and also for data transfer for diagnosis and fitting operation. Contrarily to conventional CIs, which require continuous RF power transmission to operate, FICI needs only short transmission duration for battery charging, on-demand only. Briefly, this innovation will not only enable the restoration of the sense of sound in people affected by profound hearing loss in a radically improved way, but also provide this without any clear deviation from the comfort of a healthy individual.

After the feasibility of sound sensing and processing has been confirmed by animal tests within FLAMENCO project, we started OPERA project funded by ERC Proof of Concept (PoC) grant in September 2020 to explore the commercial path for our FICI technology.

In the scope of OPERA; we performed tests for comparing OPERA and a conventional CI in terms of the stimulation outputs. This provided feedback about key characteristics compared to the market standard. The other focus of OPERA was testing one of the most outstanding technologies of FICI; MEMS acoustic transducer, which senses vibrations of middle ear elements, mimicking the operation of a healthy ear. For the connection between the sensor and ossicles, an attachment system is designed considering biocompatibility, lightweight, strength, and resonance characteristics. We observed that MEMS transducers can effectively transform vibrations in the middle ear into proper electrical signals. Briefly, we had valuable feedback for both transducer design and surgical procedures to allow us develop a working prototype in the medium term. We also performed a comparison study amongst the CI models available in the market in terms of clinical parameters; number of channels, input dynamic range, frequency allocation, stimulation rate, pulse width, signal

coding strategy, and we have identified the specifications that can help us improve the FICI; stimulation mode, electrical compound action potentials measurements, fitting interfaces, packaging materials etc.
Alongside the technical activities, the team carried out a series of activities aimed at identifying the best route to exploitation. The objective was mainly to decide on the future path, finding possible applications, partners, defining the opportunity to create a start-up and identifying sources of funding. By doing so, the OPERA team has acquired the sense of potential stakeholders relevant to the project scope: oto surgeons, audiologists, and patients. During the project, several interviews were conducted highlighting the needs and preferences of each of these stakeholders. Moreover, a survey among the CI users were conducted to retrieve a direct feedback and indications as to the preferred attributes of the future OPERA product. Among oto surgeons, the stakeholders from Italy and Turkey were interviewed. Similarly, the audiologists from Switzerland, Germany, Poland, and Turkey were also included in the survey.
Additionally, a preliminary HTA was conducted with the aim to identify all the parameters that should be benchmarked to take the product to the market. This includes both performance related and economic criteria.
Regarding the IP strategy, new patent applications to protect the technology, with the support of the technology transfer office (TTO) at the METU will be filed in near future. With reference to the prior art analysis, it must be highlighted that our preliminary analysis conducted with the support of the TTO office has shown no infringements of IP by our patents and future patent applications. Regarding the business model, the activity related to the validation of the initial assumptions as to the Business Model to be adopted will allow choosing among a variety of possible exploitation routes has conducted to the conclusion that the only viable route is to partner with an established producer through licensing-out or a co-development agreement of the technology or part of it.
The next step following FLAMENCO and OPERA is to complete the technical development and perform the tests including preclinical tests needed towards the clinical validation.

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