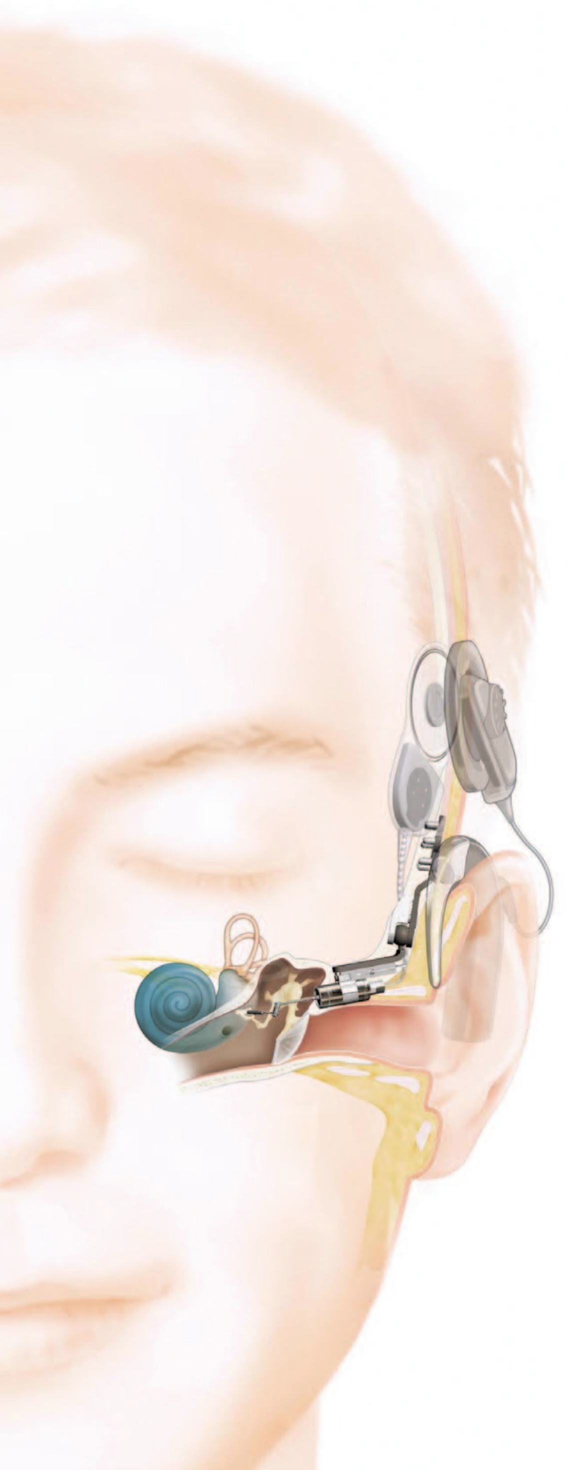

Simulation-Based Design of New Implantable Hearing Device

A new hearing solution holds the promise of being able to treat a hearing defect for which currently no good solution exists. Cochlear Ltd. has used COMSOL Multiphysics to develop a unique acoustic cochlear implant from the ground up.

BY PAUL SCHREIER

Hearing loss is not uncommon, and in fact, approximately 17% (36 million) of American adults report some degree of it. Moderate to severe hearing loss can be treated with a hearing aid. Beyond a certain level of hearing loss, a conventional hearing aid no longer provides a solution. For these cases, a hearing implant such as a bone conduction implant or a cochlear implant may be a solution. Cochlear Ltd., headquartered in Australia, has annual sales exceeding AUD 800 million and claims more than three-quarters of the market for such implants.

Over the years, Cochlear Ltd. has helped more than 250,000 people in over 100 countries connect to a world of hearing, and the company is very involved in coming up with even better solutions. In 2011, it invested 13% of its revenues in R&D. "A recent development," reports Dr. Patrik Kennes, CAE Engineer at the Cochlear Technology Center Belgium (CTCB), "is a completely new type of implantable hearing implant, a Direct Acoustic Cochlear Implant (DACI) called Codacs™. It provides mechanical (acoustic) stimulations directly to the cochlea — and it's a product our company developed from the ground up using COMSOL Multiphysics. While providing a new solution to people who suffer from severe to profound mixed hearing loss, this device fills the gap where a conventional hearing aid isn't powerful enough. The unit is now in clinical trials, and the outcomes from this feasibility study are encouraging and confirm the design direction and viability of a commercial product."

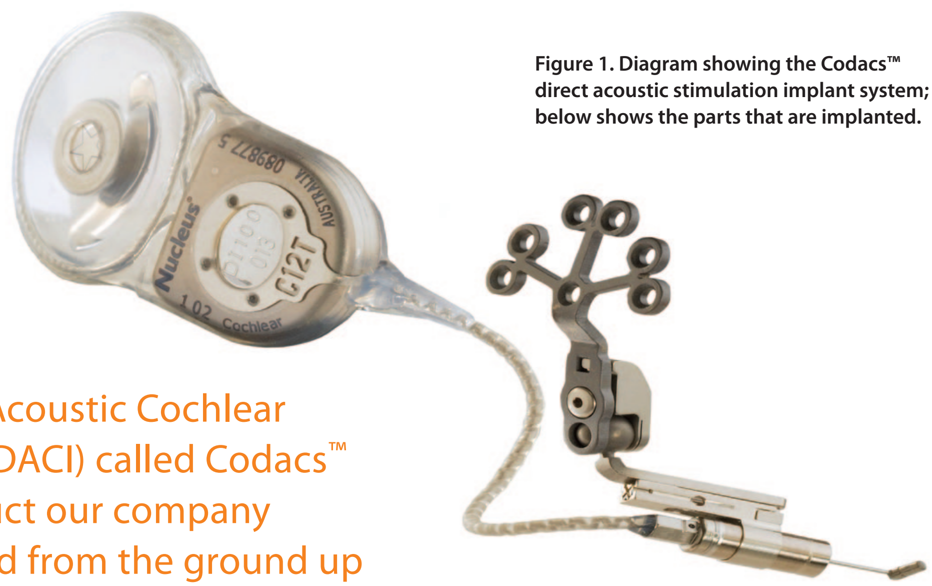

Figure 1. Diagram showing the Codacs™ direct acoustic stimulation implant system; below shows the parts that are implanted.

"A Direct Acoustic Cochlear Implant (DACI) called Codacs™ is a product our company developed from the ground up using COMSOL Multiphysics."

Wireless Implantable Actuator Mimics the Natural Hearing Pathway

"The Codacs system," explains Dr. Kennes, "starts with a BTE (Behind The Ear) unit that has a similar functionality as the outer ear: picking up the sound (Figure 1). It contains batteries, two microphones for directional hearing, along with some digital signal-processing circuitry. The signal is sent over a wireless link to the actuator (Figure 2), which is implanted in the ear cavity right behind the external auditory canal. That link eliminates the need to feed a cable through the skin and also provides the power for the implanted unit, which requires no batteries."

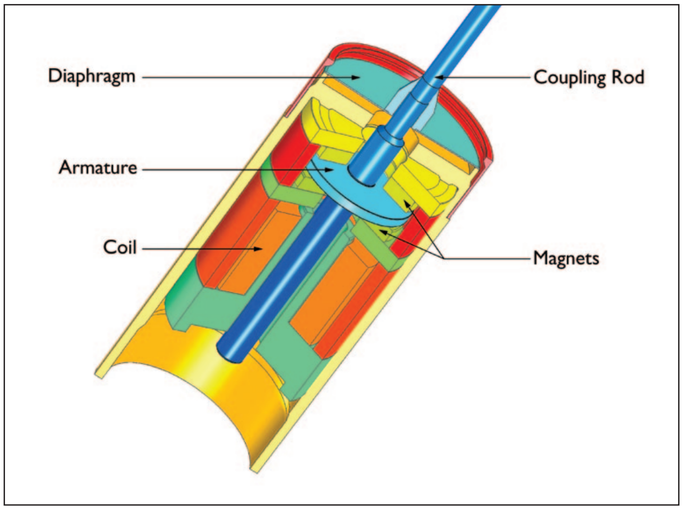

Figure 2. The actuator that is embedded in the ear cavity.

The Codacs actuator is not intended to amplify the sound (as a traditional hearing aid does), but it directly amplifies the pressure waves inside the cochlea. For a person with normal hearing, those pressure waves are generated by vibrations of the stapes footplate. The hair cells inside the cochlea bend as a result of the pressure fluctuations, and generate tiny electrical pulses that are transmitted to the brain by the hearing nerve.

With the Codacs system, a tiny actuator generates amplified pressure waves in the cochlear fluid, thus mechanically intensifying the sound energy to compensate for the hearing loss. In order to do this, the artificial incus at the actuator end is connected to a stapes prosthesis that protrudes into the cochlea. Vibrations of the piston-like stapes prosthesis cause pressure variations in the cochlear fluid, in a very similar way as movements of the ossicles are doing.

Actuator Design Challenges

The Codacs actuator is an electromagnetic transducer based on the balanced armature principle (Figure 2). When the armature is at the mid position between both permanent magnets, it is equally attracted towards both of them and thus no net magnetic force is executed (i.e. balanced position). As soon as the armature moves out of its mid- position, the distance towards both magnets and thus the force exerted by them is no longer equal: the armature is attracted more by the nearest magnet than by the other magnet. This is also referred to as "negative spring stiffness" because it is the opposite of what happens with a normal structural spring: if you deform the spring, it tends to return back to its original position. For the Codacs actuator, the diaphragm acts as a restoring spring and prevents the armature from sticking to the magnets. A precise balancing of the diaphragm force and magnet force is indispensable for a correct working of the actuator: when the diaphragm stiffness is too low, for example, the air gap collapses and the armature will stick to one of the magnets. Powering the coil modulates the magnetic field, provoking a movement of the armature towards one or both magnets.

According to Dr. Kennes, "We first came up with this concept roughly five years ago and have used COMSOL extensively

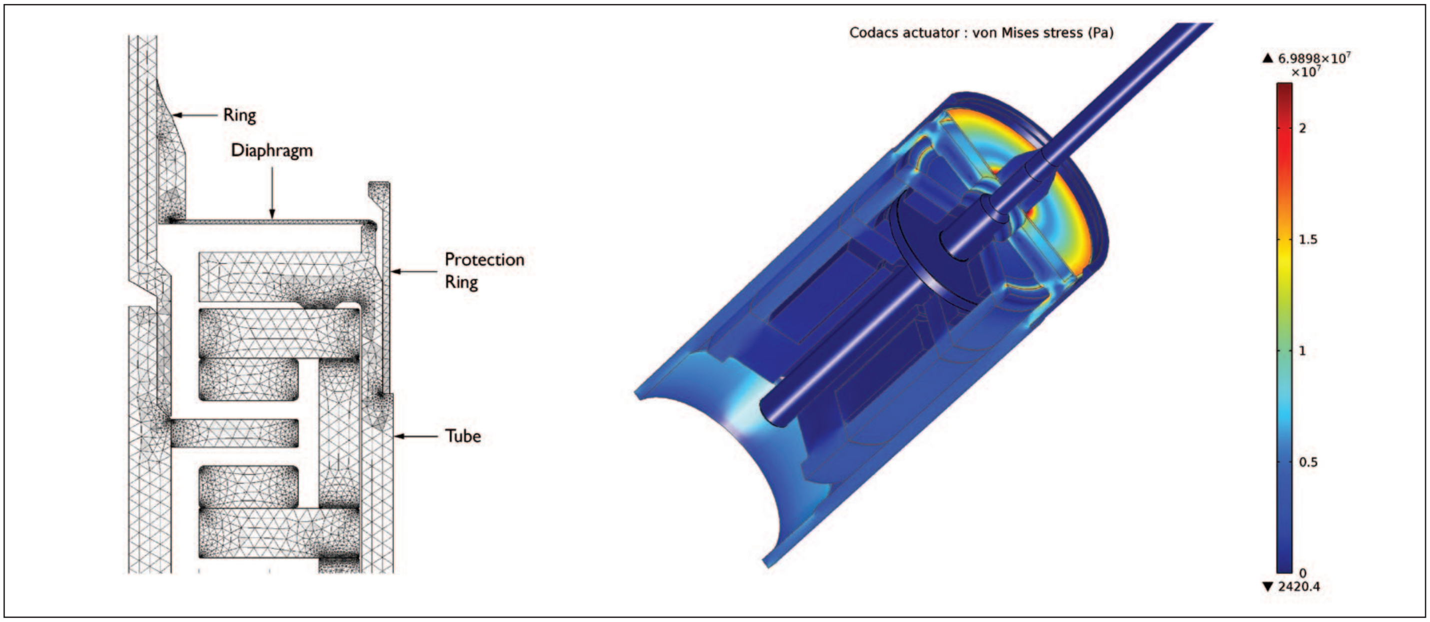

Figure 3. A structural model analyzing von Mises stress helps find the optimum diaphragm thickness.

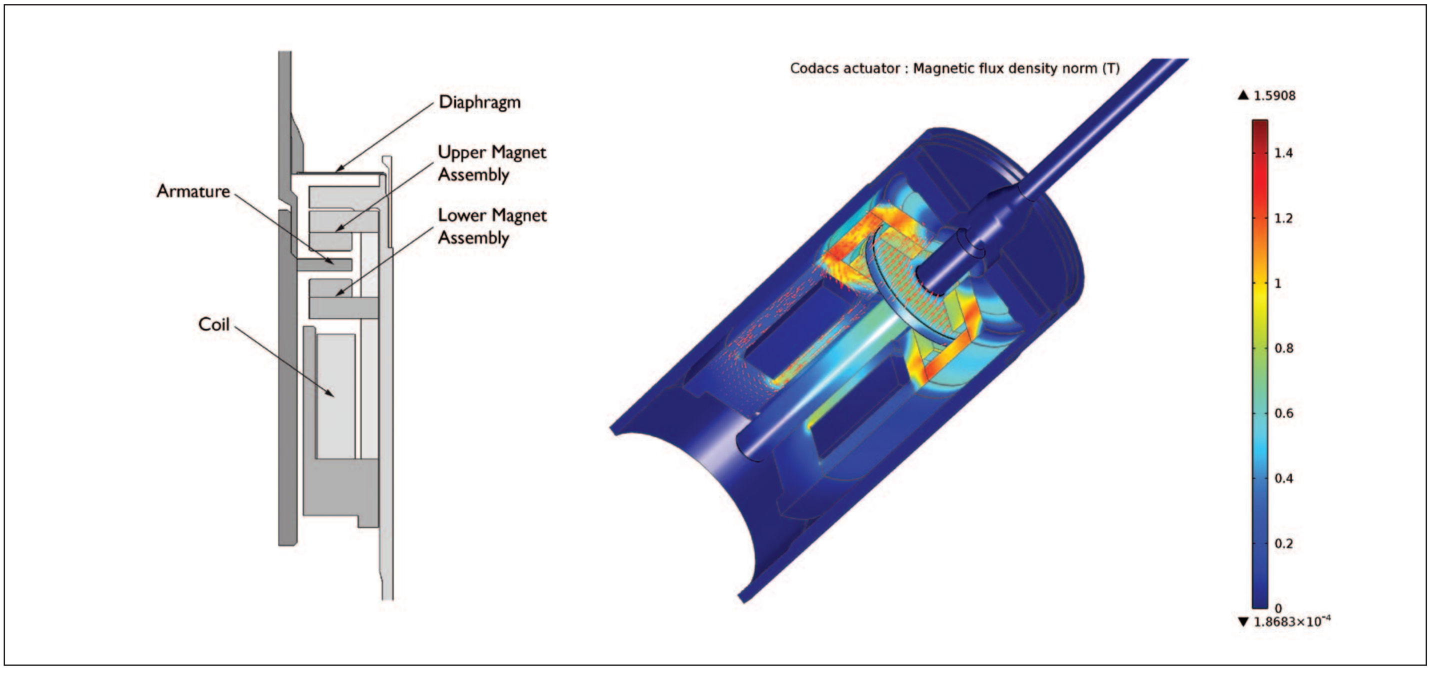

Figure 4. 3D model to study the electromagnetic fields within the balanced armature.

in every stage of the design process. The initial idea was to create a small actuator producing vibrations, but we had no idea of the dimension of the components. A first COMSOL model was thus simply a feasibility study to help us compare various concepts."

Once the concept was selected, the researchers moved into the prototype definition phase where they worked on the exact size and shape of the parts. The designers had to keep a number of factors in mind; in particular, the maximum allowable size due to the limited space in the mastoid cavity — the diameter had to be < 4 mm with a length < 15 mm. The actuator must provide a similar frequency characteristic similar to the human ear (resonance frequency near 1 kHz). They also had to keep power consumption in mind, and all the actuator parts in contact with human tissue must be biocompatible or hermetically encapsulated.

"Through COMSOL, we were able to avoid a time-consuming and costly trial-and-error design approach whereby we would have to build many prototypes to determine the appropriate part dimensions."

A Critical Component: The Diaphragm

One critical component is the titanium diaphragm that combines multiple functionalities. It serves as a radial bearing for the coupling rod and as a restoring spring for the armature movement. But at the same time, it also must hermetically seal the device and must be biocompatible. Its thickness is a critical tuning parameter because it helps establish the actuator's spring stiffness. That thickness (actually less than only 50 microns) should not be too thin, making the actuator unacceptably vulnerable for losing hermeticity. On the other hand, the diaphragm cannot be so thick that it increases actuator stiffness too much. The tradeoff between robustness and stiffness is made by means of a structural mechanics analysis for various thickness values. At this design phase, the material stress within the actuator components was verified. A plot of the von Mises stress (right hand image in Figure 3) shows how the diaphragm is stressed when the rod moves axially (i.e. when the actuator is operating); stress elsewhere is due to the preload on the parts that is applied during the actuator assembly process. For example, the colored ring area in the upper magnet assembly indicates the contact area where the magnet assembly seats against the tube (modeled in COMSOL as contact pair).

Once the diaphragm thickness is fixed, the corresponding mechanical stiffness of the actuator is known. In order to lower the actuator's overall axial stiffness, the magnetic stiffness of the electromagnetic assembly must be tuned to the correct value. Key parameters here are the magnet strength and air gap size. To optimize the layout of the magnetic circuit, Kennes used COMSOL's AC/DC Module to calculate the magnetic flux density within the parts (Figure 4). In the plot of the magnetic flux lines, the major flux is due to the permanent magnets (short loop formed by the upper and lower magnet assembly). When the coil is powered, an additional flux is generated (flux in the shaft and the coil assembly). The latter changes the magnetic force on the armature, causing the actuator to move. It was very convenient to set up a parametric study that defines the armature position and coil current, and calculates the corresponding force on the armature. Resulting data are automatically gathered in a force map that can easily be exported.

An All-in-One Package

What impressed the team greatly was that COMSOL allowed them to do a number of studies — structural, acoustics, electromagnetic, piezoelectric — in one, unified package. “Once we had one model, we didn’t have to start from scratch to set up another that used different physics. We simply added or removed components as needed, changed the physics, and in just a few steps, we had a new case study.

“Through COMSOL,” summarizes Dr. Kennes, “we were able to avoid a time-consuming and costly trial-and-error design approach whereby we would have to build many prototypes to determine the appropriate part dimensions. Even with the approximations made in the model, we were able to tune the device successfully in software. Tolerances in this device are extremely tight, and to get parts for prototypes, they deal with specialist suppliers who have lead times of several weeks. Without COMSOL, it would take us half a year to run through just five prototypes, thus considerably slowing down the development process.” ■

Research Paper

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About the Researcher

Patrik Kennes joined the Cochlear Technology Centre Belgium as a CAE engineer in January 2007, where he gained initial experience with COMSOL Multiphysics, mainly for structural calculations. Now he also uses that software for electromagnetic, acoustic, piezo and thermal calculations. He previously worked as a research engineer at Tenneco Automotive in the field of continuously controlled electronic suspension systems. He earned a Master of Science and a PhD in Bioscience Engineering at Katholieke Universiteit, Leuven.