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GETTING INTO THE GROOVE: A SOFT AUDITORY BRAINSTEM IMPLANT

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Cochlear implants can restore or improve hearing for many deaf people – but they do not work for everyone. Patients with missing or damaged auditory nerves can regain some hearing from auditory brainstem implants (ABIs). These implants capture sound via a microphone worn on the ear, translate it into electrical signals and interface directly with the cochlear nucleus, feeding electrical impulses directly into the nervous system and bypassing the faulty auditory nerve.

ABIs have been around since the 1970s, however the success rate varies and most ABI users don't regain enough hearing to understand speech[1]. The device can also cause unpleasant side effects such as dizziness or pain. This disappointing performance is thought to be partly due to the stiff electrode array does not match up well with the soft curvy inner ear, leading to faulty connection and signal transmission, and off-target electrical stimulation where the implant connects with the tissue. To complicate matters further, the cochlear nucleus isn't just curvy - it's in constant motion due to breathing, head and neck movements and the flow of blood and cerebrospinal fluid in the brain. So the ideal implant has to be able to adapt to a curvy surface, and accommodate the micro-movements of the tissue it's interfacing with. A Swiss-US collaboration believes that a more flexible electrode array would better hug the curvaceous interior of the cochlear nucleus, making sure that every electrode is in contact with the target tissue. This could improve the hearing gain and reduce unwanted side effects.

The team from Stéphanie Lacour's Laboratory for Soft BioElectronic Interface (LSBI) at EPFL, Switzerland[2]

Infirmary at Harvard Medical School (Boston, USA)[3] to test proof of concept in agar brains, human cadavers and mice.

A conformable ABI

Their first task was to design a flexible multichannel ABI that interfaces with the tissue of the cochlear nucleus compared to the traditional rigid "paddle" electrodes. The electrodes were made of a platinum-silicone composite, a material commonly used in other medical devices[4], and linked by 2.2 μm thick interconnects made of layered polyimide, platinum and polyimide (PI/Pt/PI). The problem was that, apart from the silicon casing surrounding the device, these materials are not very flexible or stretchable. "Metals which conduct electricity cannot intrinsically stretch," says Nicolas Vachicouras, a postdoctoral researcher in the team and lead author on the paper describing the device[4].

To make the implant flexible, the team borrowed a concept from the Japanese art of kirigami, which cuts intricate patterns into paper. The team etched a series of Y-shapes in hexagonal arrays on the metallic surface. This renders non-stretchable materials "stretchable by design," says Vachicouras, "we do not need huge strength. We just want to be able to avoid breakage during surgery and, with the natural movement of the head and brain of the patient, once it is implanted." Mechanical testing showed that the implant stood the test of repeated bending and stretching up to 10% elongation for one million cycles – a good indication that the implant will withstand its planned lifetime.

Ease of implantation

Next they tested how easy it was to implant the ABI into an agar model of the human brain, and then into human cadaver brains. Ironically, the flexibility of the implant has a drawback. "Soft implants are nice once they're in the body," says Vachicouras. But they are surgically difficult to implant. "It's a general problem with all flexible electrodes, they are too floppy to be inserted." To overcome this, the team tweaked the design of the implant, adding a temporary guide to the non-electrode side of the array that stiffens the implant for around half and hour, giving the surgeon enough time to nudge the implant into place. Electrical impedance measurements also gave an early indication that electrical signals were being transferred from the implant to the brain tissue with better efficacy than the traditional rigid ABI.

Functional testing

Next, the team miniaturised the device and implanted it into mice for a month, primarily to test if it could withstand regular pulses of electrical stimulation. The implant appeared durable, but the low number of pulses over the 4-week test period is far below the billions of daily pulses that would occur in normal use. Some creativity was required to test functionality, explains Vachicouras "it's very hard to know if a mouse is hearing or not. So we recorded brain activity from a brain region activated after the brainstem in the auditory pathway. When we provided sound, we saw activation of this region." The team used probes to measure the neural and auditory responses when the soft electrode array was stimulated directly with an electrical pulse, or when a click was played into the ear using an earphone.

The soft ABI is a multi-disciplinary, international collaboration. “The idea was to bring the expertise from the engineering and technical side of EPFL to solve clinical issues using the clinical expertise of Harvard Medical School,” says Vachicouras, an engineer by training. He performed the technical work of developing the soft ABI in Geneva and then made several visits to the Lee & Brown lab in Harvard[4] to participate in the cadaver and mouse experiments, led by the two lead co-authors of the study and ENT residents Osama Tarabichi and Vivek Kanumuri. Collaboration with clinicians is critical, but Vachicouras says that engineers need to get closer to the action. “It's very important for the engineer to go and see the surgeries, how they are performed in humans, says Vachicouras, “ because sometimes you might just talk to the doctor who will maybe not tell you something, some small detail which is actually critical for you.”

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Next steps

This proof of concept paper showed that soft materials and flexible electronics can be used to manufacture an electrode array that hugs the curved cochlear nucleus, maximising the tissue-electrode interface. This yielded better electrical connectivity than a traditional rigid array that connects less with the curved tissue. The better, more targeted, connectivity of the soft electrode array should allow more electrical signals to be delivered. This could improve the hearing gain, without the risk of scattered off-target stimulation of surrounding tissue and the resulting side effects. Vachicouras notes that the soft implant also shows up better under CT and MRI scans; surgeons will find this a big help when positioning the electrodes in the cochlear nucleus.

The next step is to test the implant in monkeys, which are more anatomically similar to humans. Another big job before the device will be ready to enter human clinical trials is to streamline the manufacturing. “You have to show that the device is biocompatible, that it can be sterilised,” says Vachicouras, “we're also transferring all the materials used, which are still research grade, to medical grade materials.” There's a lot of regulatory work to do before moving into clinical trials, but as Vachicouras notes, “building a completely new technology from the ground up takes a lot of time and effort.” In the meantime, the demand for better ABIs is there. “Surgeons are always asking questions, when can we take your device and put it in humans and see if it works?” says Vachicouras.

REFERENCES

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