epilepsytoday

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Unlocking the brain

Matt Ng speaks to Professor Mark Richardson, head of neuroscience at King's College London. Mark discusses a new type of device that could revolutionise seizure prediction

The technology to predict seizures in people with epilepsy is still in its infancy. Previous efforts have involved electrodes placed invasively in direct contact with the brain. However, there is a new approach that could lead the way in effective seizure prediction for many.

Q:What technology has been used in the past to predict seizures in an individual person?

A:The most important and convincing study was carried out in Australia on 15 people with epilepsy, using a system called NeuroVista. This system consisted of electrodes placed directly on or in the brain, connected to an electronic unit under the skin of the chest. This unit communicated wirelessly with a handheld device. Their brainwaves were then analysed, and the person was

provided with real-time feedback about their current level of seizure risk, using the device's coloured lights.

The study found the method was safe and provided a reliable indication of seizure risk for some of the people, so the concept was effective. However, the need for electrodes inside the skull was found too invasive and unfortunately, the NeuroVista system is no longer available.

Q: What are the benefits and drawbacks of older technology?

A:The NeuroVista study obtained extremely high-quality data as it was recorded directly from the brain. However, this also turned out to be the drawback, as the study was never continued due to how invasive the system was. Unfortunately, no other

technologies have shown to have the same performance in predicting seizures. That is why we are very motivated to promote the investigation of new devices that are less invasive.

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Q: What new technology is being developed to do this now?

A:With the NeuroVista we looked at putting electrodes inside the skull. This solution involves placing electrodes outside the skull but underneath the skin. It received CE-certification last spring, so has EU approval as a medical device. With this, we can record brainwaves 24/7 for weeks or even months in a very unobtrusive way.

This technology therefore has the potential to give us an accurate measure of the brain-state at any time over the long-term.

Q: In what way does it improve on the older technology?

A:With the electrodes outside the skull, the implantation procedure is much less invasive and therefore carries a lower risk of infection and device-related complications. The location still provides good quality data, as the electrodes are shielded from many sources of noise by the skin.

Q: How does the new type of technology work?

A:The implant consists of a 10cm wire with three electrodes to record the brainwaves, and a £1 coin-sized ceramic housing which contains the electronics. The wire and the housing are implanted under the skin with a brief local anaesthetic procedure.

The device uses technology based on long-established inner ear implants used as a treatment for deafness. Therefore, after implantation under the skin it can be used for a very long period of time. There is no battery inside the housing – the device is powered using a well-known approach called induction.

Inside the housing is a coil, and another coil is attached to the skin next to the housing with a medical-grade adhesive patch. These two coils lying close together allow the device to be powered wirelessly and allow brainwave data to be retrieved wirelessly from the device.

The coil stuck to the skin is attached by a thin wire to a small box. This box is around the size of a credit card, which contains a battery and stores the brainwave data. The external coil and the box are attached by a thin cable which is the only visible part of the device.

Q:Would it be difficult or painful to put in or impractical to have in for people?

A: Studies from Denmark have shown that it is easy and safe to place underneath the skin. In 34 volunteers no device-related serious events were recorded. The procedure is carried out in 20-30 minutes under local anaesthesia.

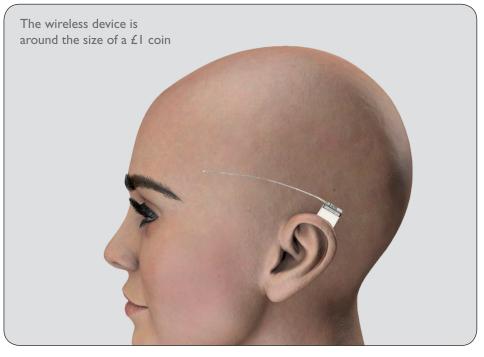
Some patients experience slight headaches for the first few days after surgery, but this tends to disappear and then the implant is no longer noticed. The only thing patients should be aware of is that if they need to have an MRI scan, the device needs to be removed.

Q: In what ways is it different to seizure detection devices that are being sold now?

A: Seizure detection devices sold today are made for convulsive seizures and there is little evidence they work for

non-convulsive seizures. Many people with epilepsy have non-convulsive seizures. Also, seizure detection devices generally detect movement, muscle activity, heart rate and skin sweating — which are indirect evidence of a seizure.

Only brainwave data is able to provide direct evidence of a seizure as well as direct evidence of the current state of the brain.





epilepsy **feature**



Q:What types of seizures would it be able to detect?

A: Basically, any type of seizure that will show brainwave changes on conventional EEG recordings would be detectable. However, there might be some types of seizures where it is impractical to implant the electrodes over the area where the seizure originates. Or the seizures might be masked by electrical noise from the muscles so you cannot see the brainwaves clearly.

Q:What are the potential benefits to people with epilepsy of this new technology today?

A:Today, the beneath-the-skin EEG-device is mainly made to accurately measure the occurrence of seizures. Many people with epilepsy may not be able to report in their seizure diary all of their seizures. They may not be aware of all of them or may forget seizures.

There's also evidence that seizure diaries are sometimes very inaccurate despite every effort to keep them up-to-date. Which means it can be very difficult for a clinician treating someone with epilepsy to be certain whether changes in treatment have been effective. Long-

term beneath-the-skin EEG provides a remarkable opportunity to record EEG continuously, and therefore have a fully objective and accurate record of seizures.

Q:What are the potential future benefits for people with this technology?

A: Our trial is part of the My Seizure Gauge initiative and funded by the Epilepsy Foundation of America. We'll be looking at the feasibility of using the EEG recordings to forecast seizures. If this is possible, it could mean a huge improvement in quality of life for some people.

Many people with epilepsy describe the unpredictability of seizures as the most stressful and disabling aspect of having epilepsy. Providing a warning signal would tell a person with epilepsy when the risk of having a seizure is high. Not only that, but they would also know when there would be a low risk of seizure. People participating in the NeuroVista study especially appreciated knowing when they were at low risk.

The beneath-the-skin EEG device is also able to pick up sleep patterns very well. We know there is a high correlation

between sleep and seizures. Therefore it's possible that understanding sleep quality might prove useful in empowering people with epilepsy and enabling them to have some control over their condition.

Q: How can this technology currently improve on research?

A: I see many areas where an objective count of seizures can help research. For example, in studies of new drug treatments for epilepsy, we rely on seizure diaries. However, we already know that seizure diaries can be unreliable. Then it gets difficult to be certain whether a new drug is effective or not. A second area of research might be in improving diagnosis for possible seizure events that happen rarely. In such a situation, it can sometimes be very difficult to reach a diagnosis.

By recording beneath-the-skin EEG over a very long period of time, we might see the changes in brainwaves occurring during an event. Therefore, we could potentially make a definitive diagnosis more quickly.

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Another area of intense research interest at the moment is understanding the patterns of seizure occurrence over time. It seems that in many people, seizures occur in complex cycles that may be predictable. I believe that using very long periods of beneath-the-skin EEG recording will enable us to understand epilepsy much better than we do now.

Q:What studies have been carried out already on this? How effective has it been shown to be?

A:Three studies have been carried out so far; on healthy volunteers, people with diabetes and people with temporal lobe epilepsy. What we've learned is that the device is safe, people find it comfortable, and we can record brainwaves and seizures very well in everyday life.

Q: What is the My Seizure Gauge project?

A:The My Seizure Gauge project is an effort initiated by the Epilepsy Foundation of America. The aim is to create an individualised seizure risk 'gauge'. It will hopefully allow someone with epilepsy to monitor the likelihood of having a seizure on a continuous basis.

The project is a consortium of researchers from the Mayo Clinic in the US, The University of Melbourne, Seer Medical in Australia and King's College London here in the UK. The researchers are investigating what is necessary to be recorded to achieve good performance in seizure prediction. At King's College London we are focusing on beneath-the-

skin EEG and wearable devices, while the other sites focus on other areas.

Within three years, I hope we can provide a device to at least 50% of people with epilepsy with seizures

Q: How far away are we from a potential device that could predict seizures (of different types) in people and offer a treatment or a warning, in your view?

A: Within three years, I hope we can

people with epilepsy who are still having

provide a device to at least 50% of

seizures. We will be recording data for the next year and a half, and after that we need to analyse the results.

Finally, our findings need to be fully developed and implemented in the portfolio of the company manufacturing the device. However, we have an excellent clinical team obtaining the data, and our collaboration with the company is impeccable so hopefully this timeline is reachable.

Q: In what way can people get involved with the project?

A:The project is running in a small number of epilepsy clinics in London at the moment. If you attend one of these clinics, you may be offered the opportunity to participate. Currently, you can't unfortunately refer yourself to the study. However, we anticipate in the future there will be more trials recruiting people with epilepsy more widely.

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