

## Researchers convert brain speech signals into written text

Patients with paralysis-related speech loss could benefit from a new technology developed by University of California San Francisco (UCSF) researchers that turns brain signals for speech into written sentences.

Operating in real time, this technology is the first to extract intention to say specific words from brain activity rapidly enough to keep pace with natural conversation.

The software is currently able to recognise only a series of sentences it has been trained to detect, but the research team believes this breakthrough could act as a stepping stone towards a more powerful speech prosthetic system in the future.

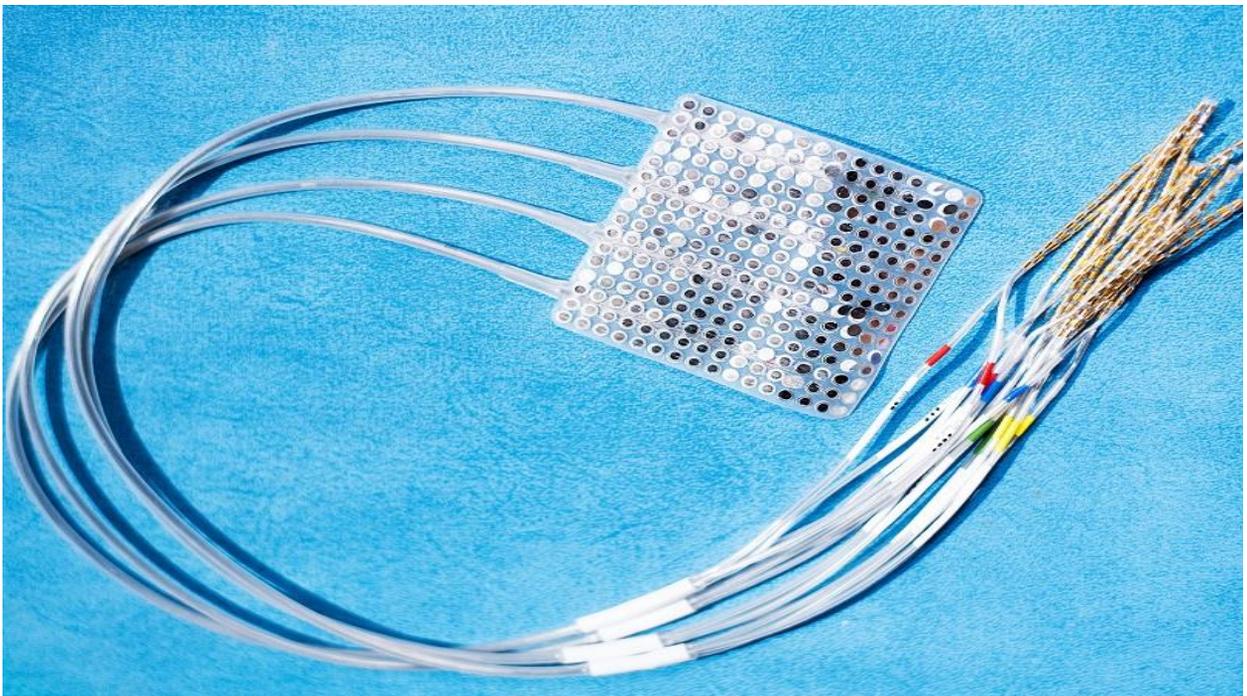
UCSF neurosurgery professor Eddie Chang, who led the study, said: “Currently, patients with speech loss due to paralysis are limited to spelling words out very slowly using residual eye movements or muscle twitches to control a computer interface. But in many cases, information needed to produce fluent speech is still there in their brains. We just need the technology to allow them to express it.”

The patients, all of whom have regular capacity for speech, had a small patch of recording electrodes placed on the surface of their brains ahead of their surgeries to track the origins of their seizures. Known as electrocorticography (ECoG), this technique provides much richer and more detailed data about brain activity than non-invasive technologies like electroencephalogram or functional magnetic resonance imaging scans.

The patients’ brain activity and speech were recorded while they were asked a set of nine questions, to which they responded from a list of 24 pre-determined responses. The research team then fed the data from the electrodes and audio recordings into a machine learning algorithm capable of pairing specific speech sounds with the corresponding brain activity.

The algorithm was able to identify the questions patients heard with 76% accuracy, and the responses they gave with 61% accuracy.

The researchers are now seeking to improve the software so it is able to translate more varied speech signals. They are also looking for a way to make the technology accessible to patients with non-paralysis-related speech loss whose brains do not send speech signals to their vocal system.



## ECGs to become part of everyday healthcare

Electrocardiograms (ECGs or EKGs) are diagnostic tests carried out to detect abnormalities of the heart by measuring its electrical activity. Typically, ECGs require 12 to 15 sensors attached to the body in different locations for five to ten minutes, which measure the heart's electrical activity.

This procedure is traditionally carried out in a hospital, a physician's office, or in a laboratory setting. However, companies such as Apple, AliveCor, Qardio and Withings are making strides to push cardiac monitoring into the hands of the patient, rather than the clinic, through use of personal, portable ECG monitors.

In 2012, AliveCor received FDA 510(k) clearance for its mobile health monitor, a small, portable medical device and associated smartphone app with the ability to record, display, store, transfer, and evaluate single-channel ECG readings. Since then, AliveCor has progressively updated its device, securing further FDA clearances along the way to add more and more diagnostic functionality. Today, AliveCor's Kardia device is FDA-approved to detect atrial fibrillation (Afib), brachycardia and tachycardia. The device is being sold across North America and Europe.

### Smart watches lead the way

More recently, Apple has entered the portable, personal ECG market with its Apple Watch Series 4. ECG functionality for the watch received FDA 510(k) clearance in 2018. The advantage of Apple's device is its integration with other built-in health features of the smartwatch, such as the activity tracker, fall detector, menstrual tracker, and more.

However, since it is newer to market, the Apple Watch ECG function is currently only commercially available in the US and some countries in Europe, with further global releases planned in the future.

Wearable devices, in general, are gaining huge traction as healthcare devices, and smartwatches are among the biggest players in this market. GlobalData estimates that 13.8% of the US population aged 12–100 owned a wrist-worn wearable in 2018, which is predicted to grow at a staggering Compound Annual Growth Rate (CAGR) of 12% between 2018 and 2024.

### Room for improvements

Factors driving this market include America's ageing population, who are invested in preventative healthcare, an increased focus on patient-centred care and improving the technology. Barriers to this market include the inaccuracy of data and analysis, concerns over data privacy and slow regulation timelines. Apple dominates this market, while smaller companies that specialize in personal medical devices (such as AliveCor, Withings and Qardio) are also major players.

Given the strong entry of multiple personal ECG devices into the market in recent years, GlobalData expects a shift in cardiac monitoring guidelines to occur in the forecast period. Within the near future, personal ECGs will likely be recommended for general cardiac monitoring and maintenance. However, personal ECGs will probably not completely replace regular doctor visits (especially for important diagnoses) until technology improves and clinical trials provide more evidence for data accuracy.



## Medical device sales skills: why so shabby?

In 2018, Huthwaite International released a white paper on the medical device sector's sales skills shortage, based on a Europe-wide study of more than 300 senior medical device sales leaders.

Unpicking the pressures, challenges, and strategic imperatives facing the industry led Huthwaite to four separate conclusions: existing selling techniques are not as effective as they once were; sales leaders are embracing new commercial models in order to make a profit; many manufacturers believe future growth will come from new product development; and the industry exhibits a clear correlation between profit, and having a systematic approach to selling and negotiating.

One year on, we caught up with Huthwaite regional director Marco Weijers to unpick what exactly is behind the skills shortage, and how the industry can improve.

Chloe Kent: Why are sales skills in the medical device sector so lacking?

Marco Weijers: In the medical sector things have been changing quite a lot in the last few years. Sellers need to adapt to that – and some do and some struggle. But it also has to do with the background of a typical salesperson in medical technology, or medical devices.

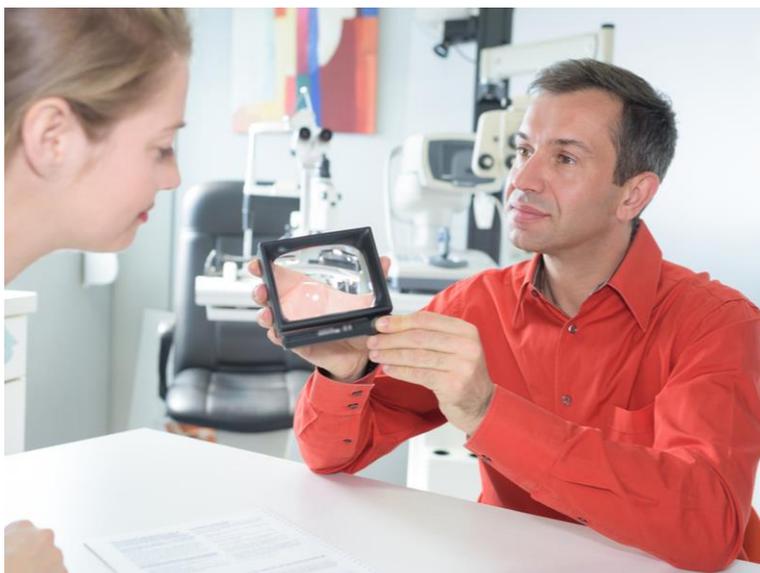
Perhaps 20 or 30 years ago, many of the sales people in medical devices had a medical background, former nurses or people that work in an operating theatre. They had a deep knowledge of the product, device, disposable, whatever they were selling, but not necessarily of the impact it has on the top line for a hospital or consumer.

CK: What is the impact of this skills shortage on the sales floor?

MW: Let's say you have a new idea or a new device, and you try to sell it in a way that you've been selling it in the past, going to surgeons and explaining how wonderful your device is. It may be that the people who decide whether or not they're going to buy it aren't just the people that you're talking to. You may be missing out on stakeholders in the decision making unit.

What has changed in the last few years is that procurement has a much bigger say in decisions around what is, or is not, going to be used in a hospital. If I try to persuade somebody in procurement to buy a device with exactly the same reasons that I use for persuading a surgeon, this might not resonate with them at all.

The effect of that is, although your device might be brilliant, you're not talking to the right people about the right issues. In the end, they don't buy it because they don't see any value in it. You've failed to create value for different stakeholders who weren't there ten years ago when you only had to sell to surgeons.



## Medical device sales skills: why so shabby? Contd...

CK: What can medical device salespeople do to improve?

MW: What you're looking for is people and organisations that are able to demonstrate clinical and economic outcomes to the various stakeholders. It goes beyond a product specialist who can very enthusiastically explain why device B is better than device A. What does it mean at an economical level for the hospital? What does it mean in terms of saving time for the operating theatre? Does that have an impact on the image of the hospital? Does it have an impact on the amount of days that people have to spend in hospital after surgery, and is that a good thing or a bad thing?

It also depends on who you're talking to. You have to be able to deliver effective clinical and economic information to the right stakeholders at the right time.

The next question then is how do I do that? What are the behavioural skills that help me to do that? It starts with understanding needs at all those stakeholder levels, and this is where sales technique comes into play.

CK: What practical changes are Huthwaite helping the industry make?

MW: We have two international clients, one we're working with already and one we're talking to, who have innovative, high-value solutions which could make a real difference in fields like cancer therapy and robotic surgery. If you talk to these people, everybody is convinced that they have a solution for the problems that are out there, but if you look at how they are trying to persuade stakeholders in hospitals to actually buy their product you can see that there's an immense desire to become better at that.

Say I have invented something wonderful for the world – if I talk to anyone about it, they say, 'well, you work for company XYZ, tell me what's new in your company?' If I'm just giving them information about my product, how useful is that? How persuasive is that?

Before I start sending anything about my product, I should establish what the potential value for this particular stakeholder could be. That is where the majority of sales people can still improve. We're not re-inventing the wheel, but we teach our clients to practice what in today's world is a timeless principle – finding out what it is people actually want before you offer them a solution.



## Low battery: finding alternative ways to power medical devices

The vast majority of medical devices currently rely on some form of battery to run. As devices become more functional and complex, and therefore consume more power, creating batteries capable of powering them has become one of the major barriers to continued development and innovation.

There is also an issue regarding reducing the size of batteries without sacrificing their power, a situation that has been hindered further by limited financial incentives for device manufacturers to research and develop new ways to power devices.

The challenge of battery-powered pacemakers

One device where new, innovative alternatives to battery power are urgently needed are pacemakers.

An editorial in the British Medical Journal (BMJ) written by Royal Devon and Exeter Hospital consultant cardiologist John Dean and Eastbourne Hospital consultant cardiologist Neil Sulke noted that surgically replacing pacemakers, which usually has to be done every five to ten years because the battery has no more power, causes a serious risk of complications, including life threatening infections.

More than half of patients with pacemakers require a replacement procedure and between 11% and 16% need multiple replacements.

Researchers from Dartmouth College, in collaboration with clinicians at the University of Texas in San Antonio, have created “devices [which] will be self-charged by the energy harvested directly from the human body,” as explained by study lead and Dartmouth professor of engineering John Zhang.

This approach “could significantly extend the lifetime of implantable medical devices” in the words of Dartmouth research association and first author of the study Lin Dong.

As well as “remove the requirement for surgeries just to replace the battery,” which both “creates medical complications...and additional healthcare expenses”, according to Zhang.

Zhang continues: “We developed a new design for energy harvesting that can be miniaturised and integrated within existing pacemakers. It uses dual-cantilever structured thin films made of piezoelectric materials for effective conversion of kinetic energy into electrical energy.”

Modified from the pacemaker, the device creates electrical energy by harnessing kinetic energy from the heart through the lead wire attached to it and converts it into electricity to charge the batteries.

The device is biocompatible with patients because the device also contains a thin polymer piezoelectric film (PVDF).

Dong notes: “The excellent biocompatibility of PVDF has already been confirmed and verified through in vivo tests in earlier work.”

The Dartmouth team are using their funding from a five-year transformative research award from the National Institute of Health to demonstrate the efficacy and safety of the devices in large animal models. Zhang says: “We have completed the first round of animal studies recently with great results which will be published soon.

“The next stage will be long-term animal studies, which Zhang expects will be “the outcome of the two remaining years of NIH funding,” followed by clinical studies in humans.

