Institution: Ulster University

Unit of Assessment: Computer Science and Informatics (11)

Title of case study: ICS1 NeuroCONCISE: consciousness assessment in disorders of consciousness, enablement in spinal injury and growing the UK neurotechnology sector

Period when the underpinning research was undertaken: 2005 - 2015

Details of staff conducting the underpinning research from the submitting unit:

<table>
<thead>
<tr>
<th>Name(s)</th>
<th>Role(s) (e.g. job title)</th>
<th>Period(s) employed by submitting HEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof Damien Coyle</td>
<td>Prof of Neurotechnology</td>
<td>2005 - present</td>
</tr>
<tr>
<td>Prof Girijesh Prasad</td>
<td>Prof of Intelligent Systems</td>
<td>1999 – current</td>
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</tbody>
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Period when the claimed impact occurred: 2014 - 2020

Is this case study continued from a case study submitted in 2014? N

1. Summary of the impact

Ulster has significantly improved patient outcomes, stimulated the UK neurotechnology sector and promoted knowledge exchange arising from the University’s AI for brain-computer interface (BCI) research. Impacts include:

I1 – establishing non-subjective evidence of consciousness in brain-injured patients with prolonged disorders of consciousness with specific beneficial, life-changing outcomes and leading to a national neurotechnology trial with 17 hospitals

I2 – influencing two medico-legal High Court cases resulting in substantial compensation for brain-injured victims

I3 – enabling a spinal-injured person to compete against other teams from around the world as a Cybathlete at Cybathlon 2016, 2019 (BCI series) and 2020

I4 – creation of a spinout company, NeuroCONCISE Ltd (Nov 2016), employing 5 people, to commercialise Ulster BCI research

I5 – informing national reports that influenced the establishment of the KTN Neurotechnology Innovation Network and the UK roadmap for neurotechnology

2. Underpinning research

Since 2003 neurotechnology and brain-computer interface (BCI) R&D at Ulster has led to the development of advanced award-winning algorithms, software and hardware for translating brain activity recorded non-invasively (electroencephalography (EEG)) into control signals to enable people to communicate and interact with technology without moving and to assess awareness/consciousness following brain injury, as evidenced in [C1-C9]. Significant research advances that underpin the impacts are clustered in three main topics and mapped to references [R1-R6] and the specific impacts [I1-I5]:

R1 - R3 - Design of award-winning AI and algorithms to translate brain activity into control signals [I1-I5]: Advanced EEG-based signal processing framework called Neural-Time-Series-Prediction-Preprocessing (NTSPP) involving multiple neural networks and/or self-organising fuzzy neural networks (SOFNN) which enhance the separability of signals recorded while a BCI user performs motor imagery (imagined movement). NTSPP is combined with other machine learning approaches to maximise classification accuracy in low signal to noise situations. The NTSPP framework produces a surrogate data space which is more...
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separable through neural network based specialization in time-series prediction of individual EEG channels/sensors and for different mental tasks (e.g., imagined left vs right hand movement). NTSSPP has been extended to include multiple time-series, multiple classes and integrated with a range of other signal processing techniques. It has also been shown that subject-specific time-embedding of the time-series increases network specialization to improve BCI performance as spatially disparate EEG channels have different optimal time embedding parameters which change and evolve depending on the brain signal being processed. With self-organising fuzzy neural networks the NTSSP can be trained easily and deployed to decode and translate brain signals into control signals in real time.

R4 - Design of advanced neurofeedback technologies for disabled users [11-15]:
Motor imagery to modulate sensorimotor rhythms (SMR) that are classified in BCI technologies is a skill that can be learned but very much depends on the type of neurofeedback the user receives. Auditory [R4] and visual (games) [R5] can be used. Novel visual feedback modalities have been presented and analysed on able-bodied and spinal-injured research participants in [R5] (co-authored with clinical collaborators and now in NeuroCONCISE Products). A novel auditory feedback paradigm, presented in [R6] with patients (co-authored with clinical collaborators and now in NeuroCONCISE Products) was proposed and trialled on able-bodied users in [R4].

R5-R6 - Technology trials with patients [11-15].
In [R6] to date Ulster has conducted BCI research with 25 patients who have suffered a traumatic brain injury (TBI) resulting in prolonged disorders of consciousness (PDoC). The initial study in [R6] describes work with four patients and had three main aims: 1) showing, for the first time, results of motor imagery feedback to a patient with minimally conscious state (MCS) and reporting on how this could influence a detection of awareness/consciousness protocol involving BCI, allowing the participant (PDoC patient) to experience control of something external from the body as opposed to BCI protocol that involved no feedback. All EEG-based awareness detection studies prior to our research did not provide real-time feedback to the patient during the assessment; 2) As many PDoC patients have limited eye gaze control visual feedback modalities for motor imagery are often not suitable. Our research involved auditory feedback [R4] of sensorimotor activity allowing the user to hear the target and listen to the feedback even when eye gaze control was not possible; and 3) we used musical auditory feedback in the form of a palette of different musical genres to improve the experience for the user. Using music feedback allowed us to engage with the patients and their care teams/families to enliven the experimental conditions for this challenging patient group. No other research study had trialled or demonstrated the impact of this approach.

3. References to the research Outputs can be provided by Ulster University on request.


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Indicators of research quality  
[R1-R4, R6] have been peer reviewed by internationally-based editorial boards of the relevant journals. [R5] is peer reviewed handbook publication which contains novel results with spinal injured patients, co-authored with clinical collaborators and describes novel feedback technologies now in NeuroCONCISE products. Research and impacts are associated with several international awards between 2008 and 2018 [C6]. Research in [R5] and [R6] was approved by multiple ethics committees and deployed and trialled with end-users – people with physical disabilities – and now in a national trial (NCT03827187). Prestigious grants have supported or followed from the research e.g.,

- Damien Coyle, Intelligent Pre and Post Processing Algorithms for a Brain Computer Interface, EPSRC EP/H012958/1, 2009-2011, GBP101,096, to develop and trial BCI technology with physically impaired patients
- Girijesh Prasad, Damien Coyle, Martin McGinnity, Innovations in Intelligent Assistive Robotics, UK-India Education and Research Initiative, 2008-2011, GBP144,557, to develop BCI for assistive robotics
- Martin McGinnity, Damien Coyle, Liam Maguire, Girijesh Prasad, Computational Neuroscience Research Team, Department of Education and Learning Northern Ireland, 2008-2011, GBP1,535,807, to establish a Computational Neuroscience Research Team
- Damien Coyle and Liam Maguire: Assessing and Optimising Human-Machine Symbiosis through Neural signals for Big Data Analytics, Defence Science Technology Laboratory, GBP215,535, 2014-2018, for cognition based neurotechnology R&D
- Damien Coyle, NeuroCONCISE - Developing Brainwave Controlled Technologies, Invest Northern Ireland Proof of Concept Funding, 2013-2015, GBP106,000
- Damien Coyle, Cognitive Based Computer Aided Engineering Design (CAED), EPSRC EP/M01214X/1, 2015-2019, approximately GBP1,300,000 with Strathclyde University (GBP147,142 to Ulster)

3 prestigious fellowships awarded to Prof Coyle

- Assessing the Neural Correlates of Motor Learning and Control: Towards Adaptive BCIs, Royal Academy of Engineering/The Leverhulme Trust Senior Research Fellowship, 2013-2014, GBP43,453
- NeuroCONCISE project, Royal Academy of Engineering Enterprise Fellowship, 2015-2016, GBP60,000
- UKRI Turing AI Acceleration Fellowship, AI for Intelligent Neurotechnology, EPSRC, (EP/V025724/1), 2021-2025, GBP1,807,387 (case for support underpinned by research and impacts described in this ICS).

4. Details of the impact

Following international award-winning research completed between 2003 and 2009 [R1 - R3, C6 - C6] trials with physically impaired patients (spinal cord injury, stroke and PDoC patients) began at the National Rehabilitation Hospital (NRH) of Ireland. PDoC patients are often incapable of reliable behavioural responses and thus behavioural based consciousness scales are insufficient to confirm awareness. We have collected substantial evidence (25 patients) that a subset of PDoC patients can modulate their brain activity to confirm consciousness and potentially enable interaction/communication without movement, thus impacting the patient, patient’s families and clinical teams. Associated impacts include:

**I1: Establishing non-subjective evidence of awareness/consciousness in PDoC patients.** For example, we used a BCI to assess awareness in a patient who had not communicated for 12 years, since suffering a brain injury as a teenager, and was considered to be in a minimally conscious state (MCS). We provided non-subjective evidence of awareness and showed that the patient could modulate brain activity to interact with a
computer in over twenty follow-up sessions between 2014 and 2018. The family reported immediate and long-lasting impact stating “[this] was a life-changing experience for our son… far better diagnosis of his condition… greater understanding of E’s capabilities… encouraged those working with E to redouble their efforts … reducing the amount of his medications [C4]”. The research was top-10 nominated for the Annual BCI award 2015 [R6, C6]. Ethical approval for a national clinical trial with 17 hospitals across UK & Ireland has been granted (NCT03827187). Trials have been undertaken with twenty-five PDoc patients to date with additional reported immediate impacts as stated by clinical collaborators “…since 2014 the impact of the research has been deep and widespread, impacting patients, families, care teams, clinical interdisciplinary teams, awareness of spinal and brain injury, legal cases, international competitions and economically… from a clinical perspective the translational component of this research has been outstanding, enhancing and adding to real-time interdisciplinary team (IDT) therapeutic input, enhancing the clinical team-patient-family experience and incorporation of components of the BCI research in real-time patient care and augmenting IDT interventions.” [C7].

II2: Influencing the outcome of two medico-legal High Court cases. Research results with patient E and S have been presented in the High Court of Ireland (2015, 2020): “the evidence that [Prof Coyle] gave to the High Court, in Dublin Ireland, in E’s case, against the Health Service Executive, Ireland, was instrumental in ensuring a successful outcome to the case which afforded E the financial ability to purchase the care regime [needed]…” (family, patient E) [R6, C4]; The High Court Judge’s report for patient E, [2015] IEHC 752, states the evidence by Damien Coyle “…was acknowledged … as substantially reflecting interaction with the plaintiff that was alternative to what was conducted [by others]” and “persuaded that some allowance should be made …in respect of Brain Computer Interface … annual sum of EUR3,750 (11-2015) [and] EUR25,520 (11-2015) for provision of a Brain Computer Interface system…” [C4]. The family in the case of patient S stated “Our legal team produced the report from Prof. Coyle and argued that this report clearly showed that S’s brain function was coherent and stimulated when asked questions and that indeed she was aware of her surroundings and could make her preferred choices when given the option…this report had been a major contribution to getting the outcome we hoped to get...” [R6, C5]. Solicitors in the case of patient S highlighting lasting impact in such cases stated that “…we have no doubt that [Prof Coyle’s] services will be [the] cornerstone of the presentation of evidence in catastrophic injury cases…and … services will be required, used and approved by the Courts…” and the research report “…made a substantial financial difference to the level of damages we were in a position to claim and ultimately achieve for the client…” [C5]

II3: Enabling a spinal-cord injured (SCI) person to compete in Cybathlon. Between 2010 and 2011 EPSRC funded (EP/H012958/1) technology trials involving 11 people with spinal injury (3 reported in [R5]). Since 2016 one of the study participants competed with the Ulster team using our technology [R1 - R3] at the 1st Cybathlon (Zurich: ranking 6th), and subsequently in 2019 (Graz: ranking 3rd) and in 2020 (Global Format: ranking 6th). Enabling this person, who has had severe disability from SCI for over 20 years, to compete at an international level has impacted on the quality of life “…[the research] has had a major impact on my life and well-being…” [C8]. Cybathlon events have been attended by approximately 10,000 spectators, from “…over 100 countries…” and the organisers “…acknowledge the impact [Ulster] research and efforts have had on the establishment of the CYBATHLON initiative and raising awareness of disability globally…” [C9]

II4: Creating a start-up company that employed 5 people, selling software, hardware and services in Rwanda, UK, Bangladesh. In 2013 an Invest Northern Ireland Proof of Concept project produced a prototype neurotechnology product, wearable electronics and suite of software applications. This led to two prestigious Royal Academy of Engineering fellowships for Professor Coyle (including an Enterprise Fellowship). In 2016, NeuroCONCISE Ltd was founded and seed-funded by Innovation Ulster and TechStart venture capital funds, to commercialise AI-enabled, wearable technology. NeuroCONCISE provides a suite of products (hardware and software) and services and has sold products
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(Valued at GBP49,500) in 3 countries, has raised approximately GBP350,000 grant income (Innovate UK Project Nos. 103607, 104959), GBP210,000 equity investment, employed 5 FTE (83 person months) and has engaged multiple subcontractors across the UK [C10.1-3], won multiple awards including the IET Innovation Awards Best Start-up category 2018 and the inaugural IET & E&T Innovation of the Year Award 2018 where the new top award was chosen by the E&T editorial team, who said: "The judges felt that this project was part of something bigger, something genuinely important. It pulls on many interesting disciplines such as AI, electronics, software and big data, and interweaves them in a solution that promises real developments in the field. In terms of 'engineering a better world' this ticks all the boxes." [C6], [R1 - R6].

I5: Contributing to national reports that led to the formation of UK KTN Neurotechnology Innovation Network and UK Neurotechnology roadmap. On the basis of EPSRC (EP/H012958/1) funded research [R1 - R3] Prof Coyle was invited to contribute to a parliamentary report on assistive technologies [C1] and provide expert advice to Nuffield Council on Bioethics who reported on Novel Neurotechnologies in 2013 [C2]. Both reports have been cited in a proposal by KTN that led to the successful establishment of the Knowledge Transfer Network Neurotechnology Innovation network (March 2019) (where Professor Coyle is now an advisory board member) as acknowledged by KTN. “Your research, the neurotechnology research at the Intelligent Systems Research Centre and recently established Spatial Computing and Neurotechnology Innovation Hub along with your spinout company, NeuroCONCISE Ltd, has substantially impacted on [...] neurotechnology awareness in the UK, providing underpinning evidence that UK has a burgeoning and growing neurotechnology sector and driving the [KTN Neurotech] initiative… The impactful research you presented at a number of our workshops… [3 events] … has helped inform a much wider audience about the potential impact of neurotechnology, not only for the health sector, but also non-medical applications … Prof Damien Coyle helped design …a survey …with … response from across the neurotechnology community and has helped shape …a transformative roadmap for UK neurotechnology… and… also fed into the Regulatory Horizons Council’s recent study on regulatory reform around medical devices” [C3].

5. Sources to corroborate the impact

C1: Parliamentary report on Research and Development Work Relating to Assistive Technology 2011 to 2012 (cited in testimony C3).
C3: Testimony from the KTN Knowledge Transfer Manager Emerging Technologies who led the establishment of the KTN Neurotechnology Innovation.
C4: Testimony from family of patient E: High Court Report [2015] IEHC 752 for patient E.
C5: Testimony from family of patient S; testimony from legal team of patient S following successful High Court case.
C7: Testimony from clinical partners at the National Rehabilitation Hospital.
C10: NeuroCONCISE company; NeuroCONCISE investment profile; NeuroCONCISE Overview and Product brochure; NeuroCONCISE Management accounts to 31 Dec 2020.