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The Everyday Cyborg: Mapping Legal, Ethical, & Conceptual Challenges

The integration of biological persons with non-biological parts and devices raises a number of legal, ethical, and conceptual challenges which have hitherto been underexplored. Haddow and colleagues use the term 'everyday cyborg' to describe such integration between the organic person and inorganic parts and devices. They conceptualise the everyday cyborg as one where "modifications are required that quite literally become part of a person and that are automated and beyond individual autonomy" (Haddow et. al 2015). We draw on, and, extend this concept. Thus, for us, everyday cyborgs are persons with replacements and augmentations ranging from the simple to the complex. Some examples of these include artificial joint replacements and aesthetic limbs, internal cardioverter defibrillators and implantable pacemakers, externally worn insulin pumps, and retinal prostheses and myoelectric prosthetic limbs.

The increasing complexity and sophistication of these devices present additional challenges for the law. For instance, some modern prosthetics and implants are now equipped with computing functions such as integrated software, and internet and wireless connection. This is necessary to facilitate a 'software-based control' of therapies. It also enables medical data and device data to be sent to servers so that a patient's health status and device can be monitored remotely by healthcare professionals. However, software and wireless capabilities can allow third parties access to such devices, potentially allowing their remote programming or even deactivation.

Everyday Cyborgs represent integration between persons and technologies, this leads to conceptual and normative complexity

Everyday cyborgs raise a number of questions for the law. For instance, is damage to a prosthesis (or an implant) personal injury or damage to property? Who ought to own/control the data generated and collected by these devices? Who ought to own/control the intellectual property rights in these devices once they become attached to the person? What legal framework applies or ought to apply where there has been unauthorised access and hacking of the device software or interference with the wireless communication from the device?

This workshop brought together experts from law, philosophy, science and technology studies, the social sciences, and the biomedical sciences to identify the state of the art of implantable medical devices and complex prosthetics, and to begin to map the challenges posed by these technologies. Ten papers were presented, and responses to these were provided. Short summaries of these discussions are presented here.

Session 1 – Becoming an Everyday Cyborg

What are the state of the art of implantable medical devices & complex prosthetics?

Speakers: Dr. Andrew Jackson, Dr. Kianoush Nazarpour, Prof. Tom Joyce, Dr. Gill Haddow

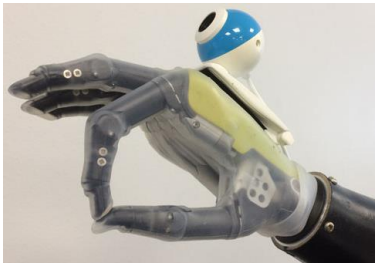
Andrew Jackson

Neural interfaces: from science fiction to clinical reality

The possibility of connecting the human brain directly to electronic devices (neural interfaces) has been extensively explored in science fiction. However, this idea is no longer confined to the medium of science. It is now becoming a clinical reality because neural interfaces are now being used in clinical practice to restore brain functions that have been lost as a result of neurological injury or disease. For instance, some implanted devices send electrical signals into the nervous system, and can be used to restore lost sensation. Other devices that detect brain activity can be used to provide communication and control of artificial limbs to those that have been paralysed. At present, wireless neurostimulators are being used for treating Motor disorders such as Parkinson's disease, and are being tested in clinical trial as a potential treatment option for depression. There has been a rapid progression in the development of this technology into clinical models, and application to people. Currently, a 7 year Wellcome Trust Project (CANDO) is exploring the possibility of controlling abnormal network dynamics with Optogenetics. This technique incorporates brain stimulation with genetic engineering, and involves the insertion of modified genes into brain cells through engineered viruses. Scientists can then trigger and control specific patterns of neural activity with flashes of light. At present, it is widely used in experimental neuroscience and is more precise than electrical stimulation, its application in the first in human trial is being explored as part of the CANDO project. The project seeks to develop a brain implant and gene therapy for 'closed-loop control of network dynamics' that will enable detection of 'electrical potentials' in the brain, and deliver 'spatially and temporally precise' optogenetic stimulation. It is hoped that this technique will help to modify and provide control over abnormal activity in the brain, a characteristic of many neurological disorders such as focal epilepsy, migraine, tremor, schizophrenia and Parkinson's disease.

Kianoush Nazarpour

Prosthetics hands - fiction or reality?



Neural interfaces & myoelectric prosthetic arms

The main aim of research involving artificial limbs is to restore some lost function and dexterity that has been lost due to accident or disease through prosthetic limbs. Artificial limbs have been around for a while. William Selpho, for instance, received a US patent for one in 1857. While the design of artificial limbs have been improved and the material used in making them are lighter in weight and are much more durable, they have changed little since then because they still work in the same way. The current state of the art of artificial limbs consists of 'myoelectric' hand prostheses, which are controlled using electrical signals recorded from muscles in the user's residual limb. Commercially available myoelectric hands on the market include the Michelangelo, BeBionic 3, and iLimb Ultra Rev. However, research has shown that many people that get these high-tech limbs do not use them because they are slow and clumsy compared to a natural hand and can be difficult to control. There is also no feedback from the device to the user (user's brain), therefore if the user cannot see the hand, they would not know what the hand is doing and there is no sense of touch.

A new generation of artificial limbs has been developed by a team of biomedical engineers at Newcastle University as part of a project funded by the Engineering and Physical Sciences Research Council. Unlike the myoelectric hands that are currently on the market, the prosthetic hands that have been developed from this project (the 'hand that sees/artificial vision for

Artificial joints & implantable cardiac defibrillators

artificial hands') are fitted with a small camera to solve the problem of object recognition. The camera which is attached to the hand takes a picture of the object in front of it, makes an assessment as to its shape and size, and activates movement in the hand. This avoids one of the main limitations of current myoelectric prosthetic hands, which rely on visual feedback from the user. With these prosthetic hands, the user is required to 'see the object, physically stimulate the muscles in the arm and trigger a movement in the prosthetic limb' (Newcastle University Press Office 2017). The new device is able to perform these functions within a matter of milliseconds and ten times faster than any other limb that is currently being sold on the market (Newcastle University Press Office 2017). The research is part of a larger project that seeks to develop a prosthetic limb that is equipped to sense pressure and temperature, and transfer the information back to the brain (Newcastle University Press Office 2017).

Tom Joyce, Newcastle University

Everyday Cyborgs – A view from the orthopaedic front

Total hip replacement was hailed as 'the operation of the century' back in 2007 (Lancet, 2007), with over 1 million artificial hips implanted every year. However, by 2011, this procedure had come to be viewed as 'a public health nightmare' (New England Journal of Medicine, 2011) due to problems with some metal on metal hip implants. The metal-on-metal hips scandal which resulted from defective DePuy Articular Surface Replacement metal-on-metal hips, has been described as a 'tragedy for many patients' (New England Journal of Medicine, 2011), and 'one of the biggest disasters in orthopaedic history' (BMJ, 2011). Data collected from individuals with failed hips and their families as part of Newcastle University's 'When Technology Fails Patients' project, indicate that many patients felt that the UK government's response to the problem was worse than the problem itself. Patients felt abandoned, and wondered who was responsible for evaluating and responding to evidence of failures. At present in the UK, medical devices are regulated by the Medical Devices Regulations 2002 which implement three European Union directives. New EU medical devices Regulations came into force on 26 May 2017. These regulations have been published to replace the directives, partly in response to the failures in a number of implants which include metal-on-metal hips, breast implants and mesh implants.

Gill Haddow

Life with an Implantable Cardiac Defibrillator: The Process of Becoming an Everyday Cyborg

The race is on to replace the heart with alternative sources from non-human animal and mechanical sources. Whilst different types of mechanical devices can be used to supplement or replace the functioning of the heart, for example, total artificial hearts, pacemakers, and left ventricular assist devices, this project focuses on the use of the implantable cardiac defibrillator (ICD). It explores the experiences of those who wear these devices (the 'everyday ICD cyborg'). The ICD monitors a patient's heart rhythm, determines whether or not a shock is required, delivers the appropriate shock, monitors the response, identifies whether more therapy is required, and then records and stores the data about these clinical events for transfer back to the healthcare facility. One of the central questions of this project is focused on exploring whether changes to the inside of the body, specifically the implantation of an ICD within the body, affect personal identity.

To answer this question, material and data collected from interviews with individuals who wear an ICD, as well as their families and friends, were examined. While ICDs undoubtedly save lives, for the ICD recipients that took part in the study, becoming a cyborg and living as an everyday ICD cyborg can be challenging because of the location of the device within the body and its functioning. Data from the study indicates that these devices introduce issues, which include

Changes inside the body such as the implantation of a mechanical device within the body can give rise to changes to identity

disruptions to embodiment and loss of control, thereby supporting the notion that living as an everyday ICD cyborg 'involves a process of acclimatisation to changes in the muddled body, personal identity and social life'. In line with the literature on body image and personal identity, it is also suggested here that changes inside the body such as the implantation of a mechanical device within the body can give rise to changes to identity when the embodiment of the body and person is disrupted (although this was not prevalent in the study).

Discussion

Question: How do implants interact with external substances, for example, someone who is under the influence of drugs, alcohol?

This has not yet been tested in research. It is a question that will need to be explored because it might have implications with regard to liability where a person takes external substances that interact with the functioning of an implant, resulting in its malfunction, and the person subsequently causes an accident, or even commits a crime.

Question: What is the potential impact of Brexit on the uptake of the new Medical devices regulation in the UK?

The regulations will be cut off as a source of law post Brexit, and will not have legal force in the UK unless an Act of Parliament is passed to incorporate and implement its provisions. Therefore, in the UK, we might be left with directives which are already part of national law.

Question: The received wisdom in practice is that the implant belongs to the patient and this position has not been disputed in spite of the multibillion dollar legal cases across the globe. What are the possible reasons for maintaining this position?

The reason why device companies involved in the legal cases might have chosen not to dispute ownership is potentially to avoid shifting and assuming liability in relation to the devices.

Question: Did those patients who were involved in the interviews raise concerns about the potential hacking of their devices?

Patients were more worried about the device being in the body and everyday concerns rather than hacking.

Session 2 – Identifying Everyday Cyborg Challenges I

Speakers: Prof. Muireann Quigley, Dr. Shawn Harmon, Dr. Imogen Goold

Muireann Quigley, Newcastle University

Everyday Cyborgs & the Law: Transgressing Boundaries & Challenging Dichotomies?

What are the ethical, legal, and conceptual challenges posed by the everyday cyborg?

The idea of the everyday cyborg is not simply an evocative metaphor. The linking of the organic, biological person with synthetic, inorganic parts and devices, which the everyday cyborg represents, poses questions which the law is ill-equipped to deal with. These questions have hitherto been underexplored. Everyday cyborgs prompt a re-analysis of the conceptual and ethical terrain underpinning the law, as well as the law itself. With implanted devices such as internal cardiac defibrillators or pacemakers, and complex prostheses such as retinal prostheses and myoelectric prosthetic arms, external objects become intimately integrated into the bodies (and lives) of persons. There are at least four ways in which implanted devices and complex prosthetics become incorporated into (the lives of) persons: (1) physical internalisation, (2) functional integration, (3) psychological constitution, and (4) phenomenological assimilation (or

Everyday cyborgs transgress a range of accepted conceptual lines and dichotomies, including that between the subject and object

dissimilation). These devices become part of persons and arguably transgress the boundary between persons and things, and between subject and object.

This has implications for the law of property because the established legal position is that only those things which are separate from a person can be considered to be property. The property status of these devices prior to being implanted within the body is not in doubt. They are objects of property which are transferred, bought and sold, and protected both by the law of personal property that applies to tangible chattels, and through the allocation and enforcement of intellectual property rights. However, once these devices are attached onto or into the body, a question arises as to the conceptual, moral and legal status of these devices. When implanted in the body, does a device retain its property status? I suggest that it does. If this position is accepted for the purpose of this analysis, then what does this mean for the received legal wisdom that only those things which are separate from persons can be classified as objects of property?

Shawn Harmon, University of Edinburgh

Body Extensions: Concepts and Legal Issues

Both prosthetics and avatars can be perceived as forms of bodily extensions (mechanical and digital). While the use of both forms of extensions is becoming more common place, their impact upon user's lived experiences is under explored. This presentation discusses some initial observations from an ongoing Wellcome Trust funded project called 'Identity and Governance of Bodily Extensions: The Case of Prosthetics and Avatars.' As part of this project, a preliminary examination was conducted to identify how different bodily extensions (physical and digital) are understood and experienced by individuals, and the potential legal issues that arise from this practice.

Neuroscience research indicates that under some conditions, the brain can treat a tool as part of the body. Gaming and Performance research also demonstrates that individuals do extend their presence and identity into virtual worlds through embodiment of their avatars. Thus, body representation which is crucial to the formation of identity is plastic and can incorporate salient and external objects, tools, and assistive devices. Additionally, the purpose of the device along with factors such as its appearance, capabilities, and means of control could influence how the device is perceived within the bodily schema. Related to this is the increasing understanding of the person as an 'assemblage', 'a variably integrated collection of physical/physiological, material/mechanical, and virtual/digital elements in fluid relation to one another'.

The law as it applies to everyday cyborgs is limited, disjointed and indirect

The law relies on relatively static categories to assign rights and privileges which include: Human/nature, Human/machine, Individual/group, and Man/woman. We argue that some of these categories are now outdated legal conceptions and that the law needs to draw from other disciplines in relation to different understandings of being if it is to adequately respond to the possibilities created by technology. Some of the broad themes and concepts identified from our research include identity (assemblage), techno-moral change ('technological provocations to moral values'), and power/control ('role and relative authority of actors'). Broadly, we note that the law as it applies to everyday cyborgs is limited, disjointed and indirect. Particularly, we note that the meaning of identity or how it is informed has not been clearly articulated, the law usually requires a problem or conflict relevant to its particular aim before it can be triggered, and the law often focuses on narrow situations and conflicts. On techno-moral change, we found that this is a concept that is not well recognised or managed, that the law is usually devised to maintain particular statuses, and the law is uneasy with value discussions. With regard to power and control, this is not evenly distributed between funders, intellectual property rights holders,

In order to fully compensate for harm done to the everyday cyborg when a prosthesis has been damaged, should the law expand its notions of harms to persons to include damage to prosthetics?

and manufacturers. Furthermore, the law is largely implemented to maintain established structures in that it favours some authorities, relationships, moral perspectives, ideologies and parties, and excludes other positions.

Imogen Goold

Damage to Prostheses and Compensation for Harm

The legal rules that apply to damage to the person and damage to property differ considerably. This paper identifies and examines the challenges posed to this established distinction by the blurring of the line between the human body and non-biological additions to the body. I suggest that this dichotomous approach could become problematic as prosthetic enhancements become more ubiquitous and more deeply integrated into the human body because it might preclude some individuals who have suffered harm from accessing appropriate legal protections and compensation for the new forms of harm that they may suffer. Research indicates that over the years, people who wear prosthetics come to think of their device as being part of them, in other words, as part of the 'living self'. This view has a bearing on how such individuals might perceive harm to the device. Presently, it is not clear whether damage to prosthetics will be considered by the courts as damage to the person or damage to property. However, if it is conceived in law as property damage, the penalties and redress available under such a classification might not fully reflect the extent of the wrongdoing or compensate for the harm suffered by their users if compared to a view that classifies it as a form of harm to the person. This is because the law provides strong protections for invasions of bodily integrity in comparison to interference with property. For instance, the penalties under the criminal law for harm to the person are more significant than for damage to property, and for civil claims, individuals can claim a wider range of harms for personal injury than for property damage. While civil claims for property damage might not include compensation for psychiatric damage, a personal injury claim can involve compensation for psychiatric damage. In the context of prostheses attached to the body, this could bolster the redress available to their users because for some of these people, the integration between the device and the person might be psychological and they might therefore suffer psychological harm if damage is done to it. In view of the blurring of the bodily boundary in this context, it seems plausible to argue that the law should expand its notions of personal injury/harms to the person to include damage to prosthetics because they both impact upon bodily integrity, and have the sort of psychological impact that require a response from the law.

Discussion

Comment: The law on waste and its implications for explanted devices

There is a problem when dealing with waste because property law does not give an answer. The law relating to waste and abandonment is generally incoherent both under English law and under the EU Framework. The courts have in the past made a determination of value, but in very few cases. This could have potential implications for explanted devices.

Comment: Legal recognition of the psychological impact of prostheses and implants

There is a lack of understanding of how different people experience implants. Maybe, we should be exploring the psychological impact of these prostheses rather than the different categories of prostheses, e.g. artificial, made from tissue, etc.

Session 3 - Identifying Everyday Cyborg Challenges II

Speakers: Dr. Sean Thomas, Prof. Burkhard Schafer, Mr. Shane Patrick McNamee

Sean Thomas, University of Durham

Title: An everyday ownership regime for everyday cyborgs?

Intellectual property rights held by third parties restricts the everyday cyborg's use of the device attached to his or her body

This presentation explores the way in which the law needs to adapt to deal with transactions involving cybernetic goods. It examines the (non-existent) interaction between intellectual property law and tangible property law. Additionally, it considers the obligations on transfers of ownership in sales, and the issues arising from the potential for secured financing of cybernetic enhancements, which incorporate developing technologies and integrations between goods, intellectual property, and persons. The increasing possibility of everyday cyborgs who represent an integration between goods, intellectual property (IP) and persons raises significant challenges for our current understanding of personal property law. Currently, the legal rules that apply to the sales of goods regulate the transfer of property rights in the tangible object and intellectual property law controls property rights attaching to the intangible aspects of an object. All types of goods will have intellectual property protecting their constitutive parts. For instance, some goods might contain components that are protected by patent, trademark, and/or copyright.

The lack of integration between the legal regimes that apply to the sales of goods and intellectual property creates complications in transactions involving cybernetic goods and potential issues for everybody cyborgs in whose bodies these goods might be attached or implanted. One such complication is in relation to the downstream control that an IP rights holder can exert over a product after it has been sold. For instance, some products containing software might be the subject of a licence which stipulates what the user can or cannot do with the software in the product, and in so doing, restricts the user's enjoyment of the product. Another issue is the possibility that intellectual property rights held by third parties can result in breach of section 12 of the Sales of Goods Act 1979. This section of the Act, in broad terms, introduces an implied term in contracts for sale of goods that the seller has a right to sell the goods and the 'buyer will enjoy quiet possession of the goods'. The potential problem raised in this context is illustrated in the case of *Niblett v Confectioners' Material* [1921] 3 KB 387. In this case the defendant had sold goods to the claimant that were in breach of a third party's trademark, and which the court found that the seller did not have the right to sell. Another such example is that of *Microbeads SA v Vinhurst Road Markings* [1975] 1 WLR, where the claimant had purchased a product from the defendant. A third party was subsequently granted a patent in the product, the result of which was that the claimant could not use the product unless granted a licence to do so by the patent holder. For the current law to be equipped to deal with the challenges posed by cybernetic goods which can contain components that might be subject to a series of intellectual property rights, and everyday cyborgs, it will need to be reformed so as to be fit for an integrative digital future.

Burkhard Schafer, University of Edinburgh

Self-made Man? IP Ownership, Self-ownership, and Intelligent Prostheses

Who owns or control the data that trained an implant or prosthesis?

The increasing sophistication and smartness of modern prosthetic devices and implants means that some of these 'intelligent' devices can now learn and improve their performance while attached to the body of the patient. The information technology revolution has also made it possible for these devices to be equipped with networking functions that enable them to communicate with other similar devices which may or may not be implants. Some of the data collected from this process is held on the device, while some is transmitted to remote server

While UK law generally struggles with intangibles, the conceptual framework of Roman law (admixture) might offer some utility in bringing together data and tangibles

databases. This data is valuable because it can be used to improve the functioning of the device and it also facilitates 'sensor based monitoring' of the patient, as well his or her interaction with the device, which aids the rehabilitation process. However, the collection of this data raises questions for both data protection and data ownership law. For example, assuming that the data is not all personal identifiable data and that it could be of value to device manufacturers, a question arises as to who owns or control the data that trained an implant or prosthesis? Additionally, 'is there a civic duty to share this data if it can lead to improved products?' Furthermore, 'is there a difference between data that improves the functioning of the device and data that is used to assist the rehabilitation process?' Ascertaining who has ownership of data, such as the data that trained an implant or prosthesis is important for a number of reasons. For example, to determine rights to access for commercial exploitation, or to discharge the burden of proof where a civil action has been initiated following a malfunction of a device. The law (Data Protection and Intellectual Property) generally struggles with intangibles. For instance, Intellectual Property (IP) law traditionally requires human input but in this context, we have computer generated works where valuable data is being produced by machines. Additionally, database rights are not traditionally protected by IP rights. That being said, the conceptual framework of Roman law could help. One solution might be to adopt concepts from Roman law such as admixture to bring together data and tangibles.

Shane Patrick McNamee, Irish Civil Service

Do Cyborgs Dream of Electric Lawsuits? - Legal Implications of the Augmented Human

Techno-progressive and transhumanist trends such as biohacking and the biopunk movement are becoming increasingly prominent with a growing number of people augmenting their bodies through a number of DIY methods. One example of biohacking is Neil Harbisson, an artist and cyborg activist, who has an antenna implanted in his skull that allows him to 'hear' colour. Another example is Rob Spence, a one eyed filmmaker who wears an 'Eyeborg', a prosthetic eye device with an embedded wireless video camera. Added to these are the advances in the sophistication of traditional prosthetics, and the increasing use of wearable technology. Given this increasing integration between man and technology, it does not seem too far-fetched to suggest that we may be entering an age of the everyday cyborg where the line between the 'natural' and 'unnatural' is becoming increasingly blurred, as well as that between what is 'therapeutic' and 'non-therapeutic', and 'correction' or 'enhancement'. Whilst there has been a considerable amount of academic discussion about the ethics of human augmentation and enhancement, everyday cyborgs raise implications for the law of tort and administrative law which range from official recognition, permission to 'wear' such augmentations, or issues of medical negligence or manufacturer's liability which will need to be addressed by existing legal systems. Additional questions raised in the context of biohacking include how much regulation (if any) should be implemented to govern these activities? Should this activity be confined to the realm of doctors, or piercing parlours and body modifiers? How should the law address security weaknesses, proprietarily or through open source? Other broader questions include what happens when these devices can be hacked? If a manufacturer has been warned of the possibility of hacking and they have not done anything, are they liable? For the law to accommodate the various legal challenges posed by the everyday cyborg, it may need to adapt, through analogy or creation of new law, to the changing definition of the human body, and the legal implications arising.

For the law to accommodate the diverse range of challenges posed by everyday cyborgs, it may need to adapt, through analogy or creation of new law, to the changing definition of the human body, and the legal implications arising

Report written by Dr. Semande Ayihongbe Newcastle University

Roundtable Discussion

Comment: Biohacking and the involvement of medical professionals

As biohacking becomes more sophisticated and those that are part of this movement modify devices that are more complex, it might not be sustainable for public safety reasons to continue with the status quo where such activities can be conducted without the involvement of medical professionals.

Question: Are users of medical devices required to sign end-user licence agreements?

No, individuals who have devices implanted within their bodies do not have to sign end user agreements before or upon implantation of the device within the body (Does the NHS have to?).

Comment: The transnational aspects of the everyday cyborg

In addition to the legal issues that have already been discussed, everyday cyborgs also raise cross border issues, both between member states of the European Union (EU) and between jurisdictions outside the EU. For instance, in relation to the cross border movement of people to maintain enhancement, transnational travel can facilitate everyday cyborgs to coming into being. Therefore, if a prosthesis or implant is not available within the UK and a UK citizen travels to a different country to get it inserted, who pays if the device malfunctions? Related to this are potential issues with cybernetic enhancements operated by software. For instance, where software is operated out of one country via another and cannot be located in a single jurisdiction (e.g. the cloud). The Digital world makes information hypermobile, therefore in many cases, software is copied and multiplied not transferred. There could be issues arising from different licenses and permits in different jurisdictions.

Comment: User access to data collected by medical devices

Some ICD patients in the US have been requesting and been denied access to data collected by their devices. In the UK and Europe, patients might be more successful in accessing data collected by their devices because the law as contained under the Data Protection Act 1998 which implements the 1995 EU Data Protection Directive, allows them to access their personal data. Data collected by these devices might fall within the definition of personal data. However, there is a potential issue with patients not being skilled enough to interpret the data.