

RESEARCH PAPER

Embedded research in rehabilitation engineering

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ABSTRACT

We examine concepts of new knowledge creation and embedded research in a case study on the i-limb, the world's first commercial prosthetic hand with five independently powered digits. Although the case demonstrates many elements of the mode 2 concept, that does not adequately describe the influence of context. In addition to the forces of contextualization, we argue there was also a strong influence on the R&D process and product from the embedding of scientific research and technology development in a location of use, specifically a prosthetic clinic in a hospital. We use the literature on embedded research to supplement our examination of this case of new knowledge creation. We contribute to the literature on mode 2 knowledge production and contexts of application by applying the literature on embedded research to explain the creation of new knowledge in locations of use.

Introduction

In this paper we examine concepts of mode 2 knowledge production and embedded scientific research and technology development. In the first section of the paper we review the concepts of mode 2 knowledge production, contexts of application and embedded research. In the second we describe our research questions and methods. On the basis of the literature review, we formulate two research questions: first, whether the mode 2 concept describes our case and second, what role the context of application or embedded research has in the case. The third section contains the case narrative, which begins at the bio-engineering unit at the University of Edinburgh and then migrates to the Princess Margaret Rose Hospital. The reduction to practice of an organization of clinical R&D is the first of two fundamental innovations in our case. The second is the development of the i-limb, the world's first commercial prosthetic hand with five independently powered digits. Following the case presentation, we discuss our research questions, our conclusions and our suggestions for further research.

New knowledge in contexts of application

This idea that contexts of application can be of critical importance in the orientation of scientific research and development is hardly novel. Historians and sociologists of science and technology have been emphasizing the importance of situating their histories and case studies within social contexts for at least a couple of generations. Most recently, theorists of knowledge creation have developed frameworks for understanding how contexts of applications and users influence research and development. Well-known concepts include mode 2 knowledge production (Gibbons *et al.*, 1994; Nowotny, Scott and Gibbons, 2001; Nowotny, Scott, and Gibbons, 2003; Hessels and van Lente, 2008), the triple helix of university-industry-government relations (Etzkowitz and

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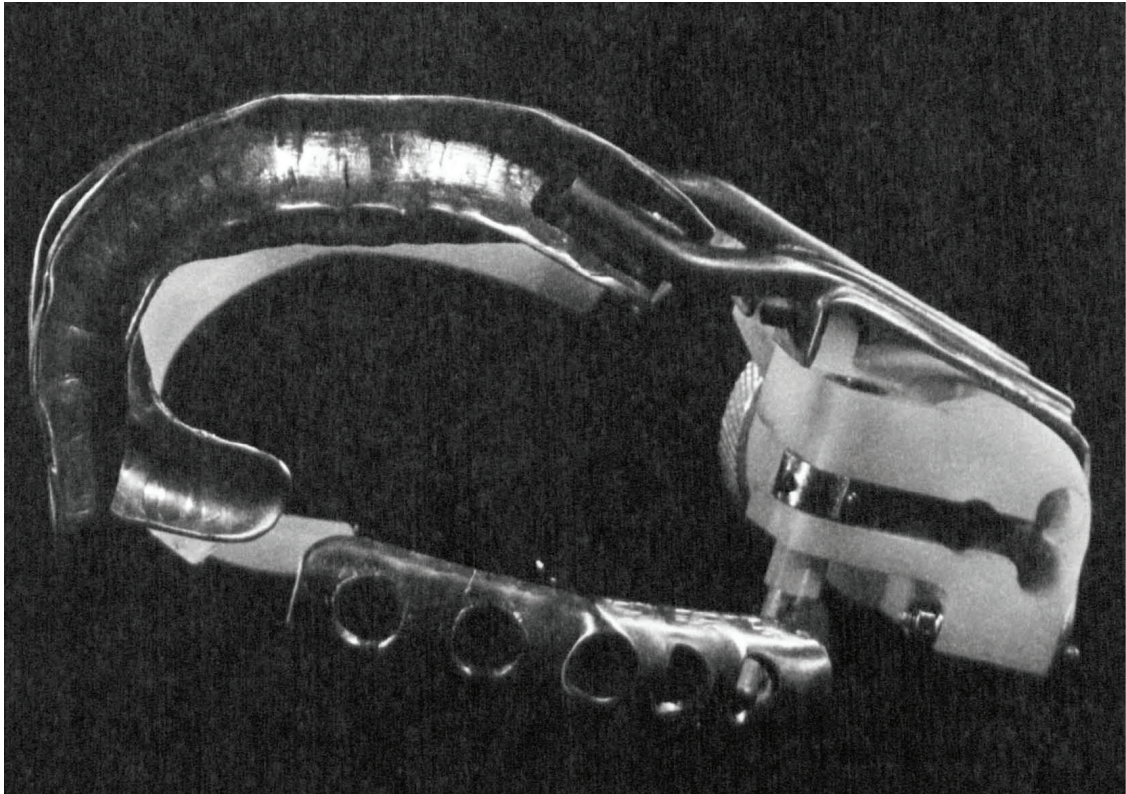


Figure 1. Hand mechanism (image by A. M. Devlin from Kenworthy, 1974)

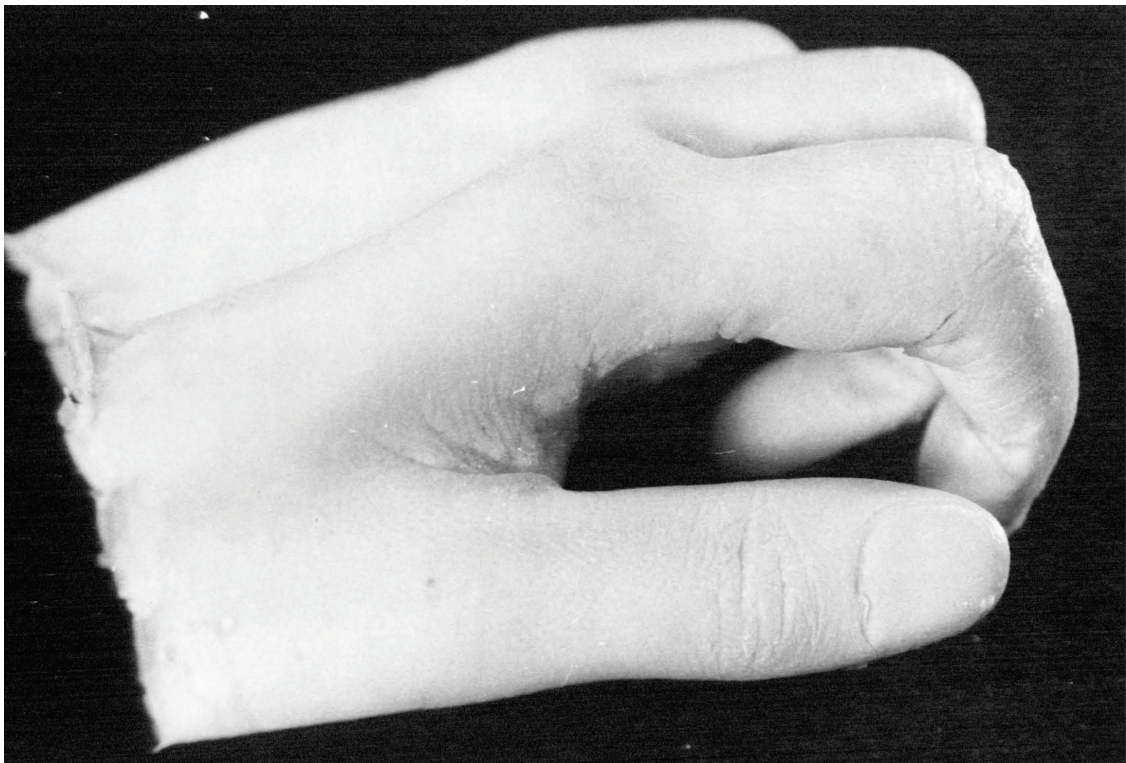


Figure 2. Glove from the master mould (image by A. M. Devlin from Kenworthy, 1974)

Leydesdorff, 1998, 2000), and knowledge translation (Greenhalgh and Wieringa, 2011) among many others. In the language of mode 2, the transition consists of a change from the old paradigm of scientific discovery (mode 1) to a new one of knowledge production (mode 2). The old approach consists of experimental science, internally driven by autonomous, university and discipline-based researchers. Its ideal is Newtonian empirical and mathematical physics. In contrast, the new knowledge – according to mode 2 theory – is carried out in the context of application, produced through socially distributed, application-oriented, transdisciplinary projects, subject to multiple accountabilities and intended to be useful. Examples of mode 2 science include chemical engineering, aeronautical engineering and computer science. It is different, according to its authors, from applied science in that it does not transfer discipline-based science and subsequently apply it in a context of application, but rather creates and shares new knowledge all within a context of application.

The mode 2 authors distinguish between weak contextualization, such as situating research within national research and development programmes, and ‘middle range’ or ‘strong contextualization’ (Nowotny, Scott and Gibbons, 2003). The middle range, according to the mode 2 authors, contains the majority of mode 2 science in which transaction spaces help local contingencies shape new knowledge. An example is collaborative R&D among three sub-cultures of nuclear physicists: theorists, experimentalists and engineers developing particle detectors used as synchrotron light sources for the study of condensed matter physics, among other applications. Another example of a middle-range contextualization is the human genome mapping project and its complex process of negotiation among diverse public and private sector parties.

The third mode 2 context of application is strong contextualization in which powerful social movements influence science and society (Nowotny, Scott and Gibbons, 2001). Feminism and environmentalism, for instance, have influenced the development of gender studies and environmental sciences. The Boston big dig mega-project (which rerouted interstate 93 highway underneath Boston) was cited by the mode 2 authors as an example of strong contextualization, given its messy complexity and negotiations among environmentalists, businesses, professionals, residents and others. The mode 2 authors also referenced investments by the patient-based association for the treatment of muscular dystrophy (AFM) in molecular biology research to advance technology development for the interest of members, and then subsequent funding of genetic studies using molecular biological techniques. In an essay on the new deal between research and society, Bruno Latour (1998) emphasizes the strong influence and the depth of connections between the AFM and its funded researchers.

The concept of ‘new knowledge production’ has been strongly criticized as more political ideology than descriptive theory (Godin, 1998; Shinn, 2002), overstating the role of universities in innovation (Mowery and Sampat, 2004), wrongly representing the transition as something new (Fuller, 1999) and failing to identify a distinct and separate knowledge production process (Boon and Knuuttila, 2011; Boon, 2011) ‘even in engineering-oriented research undertaken in the context of application’ (Knuuttila, 2013, p.4).¹ Nevertheless, the mode 2 concept has also been the subject

¹Boon (2011) and, separately, Boon and Knuuttila (2011) have examined the distinction between concepts of basic science focused on theoretical understanding and depiction of nature truthfully and, on the other hand, interventional science that seeks to manipulate and shape the world within contexts of application. They argue that the distinction between representational science and interventional science collapses when examined closely. Modelling in the engineering sciences, they suggest, is no different from modelling in the pure sciences. In both, the common goal of modellers is not to generate realistic representations, but instead to learn from models by interacting, trying out different arrangements, seeking to match the model to anticipated results or providing an interesting starting point for theoretical concepts and experimental programmes. Given the practical problem-orientation of engineering science, models function as:

epistemic tools to find out how to produce, control, intervene—or to prevent some properties of materials or behavior of processes and devices. . . . [and for the] imagining and reasoning about how to improve the performance of the devices, processes, or materials of interest. (Boon and Knuuttila, 2011, p.71)

of numerous fine-grained cases, including studies of carbon capture and storage, type 2 diabetes (Hardeman *et al.*, 2015), coastal dikes (Seijger *et al.*, 2013), construction management (Voordijk, 2011), professional doctoral programmes (Armsby, 2012), public health (Jansen, 2015), and catalysis, environmental chemistry and biochemistry (Hessels and van Lente, 2008).² Findings have indicated that mode 2 knowledge creation projects in academic research are the exception, not the rule (Albert, Laberge and McGuire, 2012).³ Even in highly applied fields, such as land-use planning, the practice of transdisciplinary research has been slow to be adopted (Zscheischler and Rogga, 2015).⁴ One noted exception within academia is engineering design projects, which find that

The argument can be extended to the mode 1 and mode 2 distinction. Boon and Knuuttila (2011, p.68), however, distinguish between engineering sciences ‘which primarily aim at scientific modeling, and engineering, which is more directly concerned with creating, producing, improving, controlling, or designing various devices and materials.’

Does this mean that in our case the distinction between mode 1 and mode 2 is, contrary to Knuuttila (2013), a meaningful one between scientific discovery and the new knowledge production? As with Knuuttila’s case of the Finnish language-technology research group, we can distinguish between those problems that are more basic or fundamental, such as whether extended physiological proprioception (EPP) has the same characteristics as proprioception with natural limbs, and those that are more applied and less scientifically rewarding, such as whether a gas-powered arm could be designed to achieve certain key performance indicators based on proportional, timely and specific EPP. Also consistent with Knuuttila’s philosophical analysis, Simpson’s scientific research is not clearly distinguishable as mode 1 and mode 2. There are mode 1 elements, such as theoretical modelling, experimental science and doctoral scientific research combined with mode 2 characteristics, such as a concern with application, which is subject to multiple accountabilities. However, given that mode 2 knowledge production is not just the result of science but the broader category of research, we claim that the engineering design and R&D projects directed by Gow (Gow *et al.*, 2001) were, in at least one fundamental way, distinct from the earlier scientific research projects of Simpson in that they were not directed to theoretical questions. We could see clearly in these design projects led by Gow the conditions of mode 2 new knowledge created in a location of application.² The study on type 2 diabetes by Sjoerd Hardeman *et al.* (2015, p.543) declares that ‘the fact that we do not find strong evidence for mode 2 knowledge production in this field casts considerable doubt on the prevalence of mode 2 knowledge production as an organizing principle of contemporary innovation systems in general’. Likewise, Alexander Nicolai and his co-authors find that the demands of academic and practitioner reviewers are hardly compatible because of different worldviews of academics and practitioners, and their contrasting understandings of practical relevance. Hessels and van Lente (2008), in their study of three fields of Dutch academic chemistry, find that practical applications in chemistry are a source of credibility for catalysis, a mixture of positive and negative credibility for environmental chemists, and of little benefit to biochemists. To the positive view of mode 2, Chris Seijger’s (2013) case study of interactive knowledge development in a coastal dike project concludes that the development of a ‘sandy seaward solution’ in contrast to traditional engineering solutions arose in part from context of application research, such as modelling of sediment transport, calculation of wave conditions, and exploration of the feasibility of the design with respect to the nature protection act.

³ Albert, Laberge and McGuire (2012) undertook a qualitative study of Canadian university biomedical scientists, clinical scientists, and social scientists to determine whether novel forms of quality control, associated with mode 2, supplement the traditional peer-review process, associated with mode 1. The authors conclude:

Results showed that the vast majority of participants were aligned with the ‘traditional’ mode 1 peer-reviewed procedures for assessing research and defining scientific excellence . . . In contrast, participants ascribed a low value to non-academics’ judgment of their work. (Albert *et al.*, 2012, p.661)

⁴ Zscheischler and Rogga (2015, p.28) conclude:

Our results demonstrate that, in spite of an increasing conceptual consistency in the theoretical discussion of [transdisciplinary research] TDR, the implementation of TDR remains a substantial challenge, in part because of the gap between theory and practice. In addition, research on TDR is science and process centred. The benefits of TDR in addressing real-world problems within the field of land use remain unproven.

‘the practice of engineering design in academia and industry have tended to converge towards a mode 2 approach’ (Williams and Figueiredo, 2010, p.24). Our view of mode 2 is similar to that of the authors of an empirical study of Danish sociology (Kropp and Blok, 2011, p.223) who found the mode 2 concept flawed, but not so flawed as to be rejected:

Rather than an outright rejection of the mode-2 concept, as some have argued, what we need is a more historically grounded, empirically sensitive, and conceptually refined approach to studying these changing science–society relations.

We have sought to achieve this in our case study and in further developing the concept of ‘contexts of application’.

The mode 2 scholarship is one of many that emphasize the importance of contexts of application. In the knowledge translation literature, the change towards an emphasis on application in contexts can be seen in the emergence of the concept of integrated knowledge translation (or iKT). iKT emphasizes the ‘exchange of knowledge between relevant stakeholders that results in action’ (Graham *et al.*, 2006, p.22). In this model, the first research step consists of identification and cultivation of relationships with users based on a common understanding of iKT. Knowledge users are said to collaborate with researchers to determine the research questions, methodology, data collected, as well as interpret findings and help disseminate research results. Others have noted the similarity of knowledge translation with mode 1 research, and iKT with mode 2, and in particular the situating of research within the context of application from the outset of the project (Greenhalgh and Wieringa, 2011; Estabrooks *et al.*, 2008; Kitson, 2009; Gagnon, 2011; Morgan, 2011). But there are also differences as iKT contains elements that express the values of the linear model of innovation, involving the

- (a) incorporation of basic science innovations into the design of new tests and treatments, and
- (b) uptake of validated tests and treatments into clinical practice. (Greenhalgh and Wieringa, 2011, p.502)

Another linear model-like description suggests:

Knowledge translation is about turning knowledge into action and encompasses the process of both knowledge creation and knowledge application. (Graham *et al.*, 2006, p.22)

Research in this field of organizational design has also examined the importance of context in new knowledge creation. The research agenda seeks to bring physical locations back into organization theory and to conceptualize space as jointly physical and social (Fayard and Weeks, 2007). Research on the links between physical space and collaboration in knowledge work has identified the central conflict of collaboration as being to balance the need to interact and the need to work effectively by oneself (Heerwagen *et al.*, 2004). This research has been applied in studies of multi-professional teams in hospitals and emphasizes the importance of informal face-to-face social networks for healthcare delivery (Waring and Bishop, 2010). It has examined the role of locations in supporting face-to-face communication for reaching higher productivity in science-based businesses (Boutellier *et al.*, 2008). Building on this, researchers have begun to explore the relationships between physical spaces and the consequences for knowledge creation (von Krogh and Geilinger, 2014). We are seeking to extend this line of research by investigating the role locations of use had in the research and development of prosthetic hands, and in this paper the role in development of the i-limb.

Another concept that emphasizes the role of location in research is ‘embedded research’. Within anthropology it has been used to refer to researchers physically being there in the field of study to learn elements of social and cultural life. The concept has been broadly applied outside anthropology, including to the performance of field-based studies by cybersecurity researchers in operational environments (Goldrich *et al.*, 2015), education researchers in schools (McGinity and

Salokangas, 2014), criminologists in police departments (Braga and Davis, 2014), healthcare investigators in hospitals (Walley *et al.*, 2007; Thompson and Steiner, 2014), science and technology scholars in nanotechnology laboratories (Jenkins, Maxwell and Fisher, 2012) and engineering designers with users (Segalowitz and Brereton, 2009). Common elements of embedded research in these studies include the expectation that researchers participate as a team member within the group they are studying and, second, have research independence, often with a view to improving practice or increasing research impact (Lewis and Russell, 2011). In conservation, science policy embedded research has included the building of relationships with policy makers to bridge gaps between research and conservation policy (Jenkins *et al.*, 2012; Ghaffar *et al.*, 2017). In social care research, it has included the development of relationships with managers and practitioners, and collaboration in the development of research-based guidance, protocols and tools (Nutley, Jung and Walter, 2008). In the healthcare field, it has been characterized as featuring four key elements (Vindrola-Padros *et al.*, 2017):

1. The researcher is usually affiliated to both an academic and a non-academic host organization.
2. The researcher develops relationships with staff and is seen as part of a team.
3. The researcher generates knowledge (in conjunction with local teams) which corresponds to the needs of the host organization.
4. The researcher builds research capacity in the host organization.

In this paper, we use the definition of embedded research from Vindrola-Padros *et al.* (2017)

This definition of embedded research shares with the concept of mode 2 knowledge production an emphasis on social process of co-production of knowledge and an emphasis on utility, although embedded research is particularly concerned with host organizations outside academia. In common with weak contextualization, there may be influence from national research and development programmes, but with embedded research the influence will be mediated by local organizational mandates. As with middle-range contexts of application, embedded research appears to have similarities with the concept of ‘transaction spaces’ and its focus on local contingencies that shape new knowledge, but for embedded research the local is restricted to a specific location or a specific organization. Although the focus of location and organization in embedded research is in direct contrast to social movements that make up strong contextualization, we argue that both share a capacity for powerful influences on the bionic hands developed in this case study. This may be because of the specific channel they provide for social movements, or alternatively, unique, contingent forces.

Research questions and methods

On the basis of the literature review, we formulated two research questions. Is this a case of mode 2 science in which new knowledge was created in a context of application, produced through socially distributed, application-oriented, transdisciplinary projects, subject to multiple accountabilities and intended to be useful? Or is this a case of embedded research and of R&D in a location of use?

The study of the development of the i-limb is part of a broader study of research and development of powered hands and arms from the 1940s to the present. For this paper, we have used case study methods. The case was identified from the literature and interviews with researchers and company representatives about advances in the field of bionic hands and arms, and products that cross the line from clinical testing into commercialization. We prepared a questionnaire for use with interview subjects in the light of the research project goals and knowledge of the cases derived from the literature. The interview subjects included engineers, occupational therapists, prosthetists and users. We also prepared a form for making observations about locations of use. In advance of the interviews, we wrote an outline of the case to present to the interview subjects a simple account of the case and

have them validate or correct the narratives and fill in the details. Face-to-face semi-structured interviews were held with subjects in Edinburgh and archival material was collected from the University of Edinburgh archives. After conducting the initial interviews with research subjects, there were follow-up questions posed in written correspondence and interviews.

From the University of Edinburgh to the Princess Margaret Rose Hospital

The founder of the powered prosthetic unit at the Princess Margaret Rose Hospital was David Simpson, a University of Edinburgh-educated physicist. Born in 1920, he graduated with a bachelor's degree in science in 1945 and obtained a PhD in medical physics in 1952 (Simpson, 1952). He stayed on at the University of Edinburgh's department of surgery after receiving his PhD in a dual role as lecturer in medical physics and designer of medical instruments. During this tenure, he designed monitoring equipment for use in transplant surgery and a foetal heart monitor. In May 1963, he was hired to put together the powered prosthetic unit.

The powered prosthetic unit was initially funded by the Scottish home and health department (subsequently restructured as the NHS Scotland) in response to the thalidomide tragedy. The organization of the powered prosthetic unit and its research programme was strongly influenced by Simpson's visit to the University of Heidelberg's orthopaedic clinic in 1963. The Heidelberg clinic, originally established in the 1890s, had emerged as one of the world's foremost orthopaedic clinics. It had also been confronted by greater numbers of children affected by thalidomide than anywhere else. While there, Simpson met Ernst Marquardt, who had developed carbon dioxide gas powered prostheses in the 1950s and was now applying the technique to children whose mothers had taken thalidomide and developed upper limb anomalies. Although the application of the technology was still at an early stage of development, Simpson was sufficiently impressed to accept the offer from Marquardt to take some of the prostheses back to Edinburgh for Scottish patients.

The other significant idea brought back from Heidelberg was the location of an engineering science department and powered prostheses clinic at a hospital. It was conventional for Marquardt to work in a hospital. He was a medical doctor as well as a researcher. For a medical physicist, however, the more typical career path was employment in industry or academia. Indeed, this was the path Simpson was on at the University of Edinburgh. The idea Simpson adapted in Edinburgh was the location of a physicist and an engineering department not in a university electrical engineering department or medical school, but off campus in a hospital, close to patients, occupational therapists, prosthetists and users.

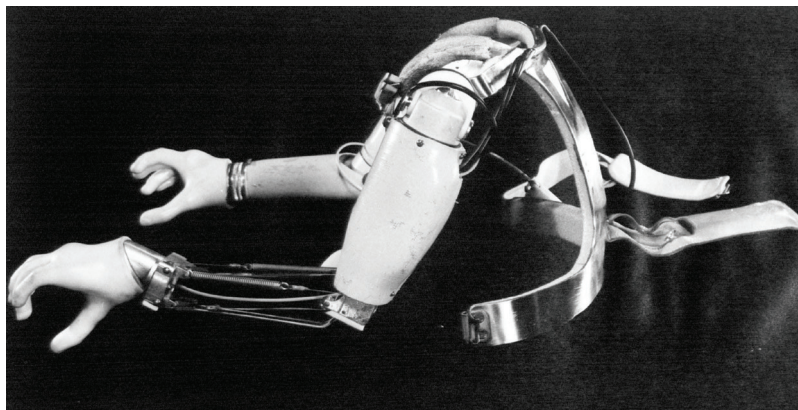


Figure 3. Upper arm prosthesis (image by A. M. Devlin from Kenworthy, 1974)

The idea was not crystallized in Heidelberg and applied in Edinburgh, but incrementally developed with changing practices at the University of Edinburgh and then the Princess Margaret Rose Hospital, especially as patient relationships become more and more central to the work of powered prosthetic unit staff. The University of Edinburgh had its own traditions in research and design to draw upon. These included the employment of a medical physics unit in the University's college of medicine. Simpson was involved with this group in projects to design and implement instruments for the NHS at the Royal Infirmary of Edinburgh. The location of the first home of the powered prosthetic unit in 1963 on the campus of the University of Edinburgh, in close proximity to the Royal Infirmary of Edinburgh, was consistent with these practices. But the arrangement turned out to be far from practical. Located in the basement of a (now demolished) house near George Square, it was about five kilometres from the Princess Margaret Rose Hospital. Although the campus facility had a workshop and a mandate to design upper limb prostheses for children, it lacked the proximity and relationships that Simpson had profited from while at the University's college of medicine and the Royal Infirmary of Edinburgh.

In 1965, Simpson and four technicians of the powered prosthetic unit moved into a 'hut' at the Princess Margaret Rose Hospital. The hut was the home of three workshops: mechanical, plastics and electronics. In 1966, the hospital opened three residential accommodation units for children with limb anomalies and their mothers. This was to last four years, from 1965 to 1969, when there was another move, a name change from powered prosthetics unit to the orthopaedic bioengineering unit, and an expanded mandate to include the design of beds, wheelchairs and other biomedical devices. Funding from the medical research council and the Scottish home and health department was provided to build and equip new facilities in the Princess Margaret Rose Hospital to accommodate the 25 people in the orthopaedic bioengineering unit. There was also a change in relationships with patients. The powered prosthetics unit had provided services to other hospital departments, but increasingly, the orthopaedic bioengineering unit provided services directly to patients. This meant that physicists, engineers, and technicians in the orthopaedic bioengineering unit were forced to deal with patients, the users of their devices, on a daily basis.

Simpson's work remained directed to powered upper limbs. One of the theoretical ideas that emerged from his work during this period came from the realization that control of the arm prosthesis is, like control of natural limbs, unconsciously informed by physical information from movement of the limb. Called 'proprioception', it is the sense that allows us to know the location of our limbs without looking at them (Boyd and Roberts, 1954; Matthews, 1933; Cleghorn and Darcus, 1952; Boyd, 1954). The application of the concept to prosthetics came to be known as 'extended physiological proprioception' (EPP) (Simpson and Kenworthy, 1973; Kenworthy, 1974). Guiding a multi-joint prosthetic arm, Simpson realized, was much harder without additional feedback. EPP sought to get round the problem with prosthetic arms and hands by feeding back the position of the limb to the operator. Simpson's work largely confirmed the theory during the period (Simpson, 1974; Simpson and Smith, 1977). He and his research and design team achieved this by designing and building gas-powered upper limbs with EPP control, and testing them with subjects from the clinic (Simpson and Sutherland, 1964; Lamb *et al.*, 1965; Simpson and Lamb, 1965; Simpson and Sutherland, 1965; Simpson, 1971; Simpson, 1973). This established a research and development methodology and organizational design that would influence two generations of the hospital's prosthetics group and the start-up company that would commercialize its electronic hand projects in the 1990s.

In 1976, Simpson resigned as director of the orthopaedic bioengineering unit to become assistant dean of the University of Edinburgh's faculty of medicine. With the departure of Simpson there was a decline in the pneumatically powered prostheses work he had championed. The orthopaedic bioengineering unit's mandate expanded into areas of service for surgeons, clinicians, and patients. One of the results of this increasing focus on patient services was another organizational

change. In 1987, the orthopaedic bioengineering unit became rehabilitation engineering services, formalizing the centre's patient service activities. It was another step for the research group in the direction of clinical practice.

From the Edinburgh arm to the i-limb hand

It was into the orthopaedic bioengineering unit that David Gow was hired in 1984. Born in 1957, Gow studied mechanical engineering at the University of Edinburgh, graduating with an honours degree in engineering science in 1979. Like Simpson, shortly after obtaining his degree (undergraduate, not doctorate in the case of Simpson) he was hired by the University of Edinburgh to study control systems for artificial limbs. He began his doctorate shortly thereafter, on pneumatic upper limb prosthetics, but did not complete his degree programme, nor did he acquire a professional teaching and research mentor. He worked at the university from 1981 to 1984, when he left to join the orthopaedic bioengineering unit.

Even though Gow and Simpson did not work together at the hospital, Gow was influenced by the way Simpson had structured the orthopaedic bioengineering unit. According to Gow, Simpson wanted the orthopaedic bioengineering unit to be an engineering unit, not a clinical department.⁵ Simpson developed the orthopaedic bioengineering unit on this model, despite being immersed in the hospital's clinical environment. Simpson, in Gow's view, struggled against the forces that pulled the orthopaedic bioengineering unit into the mainstream of the hospital clinical culture. Simpson's development of a low-pressure bed for prevention of bed sores fits into that engineering/production development model, as did commercial development, production and sales by a third-party licensee. Gow saw himself as a system developer working in an engineering research and development department, not a clinical unit. In 1986, Gow became responsible for the service and research areas of the orthopaedic bioengineering unit. His initial assignment in this new role was to design more cosmetic prostheses. Gow's view was that improving the aesthetics of the prosthetic hand involved not just cosmetics, but overall design. The aim was to go well beyond 'pliers on wires' to create something that looked and functioned like a human arm and hand. This project would extend over the next 20 years, and eventually result in development of the Edinburgh arm and prodigits, the basis for the i-limb. Prodigits are the self-contained, individually powered fingers for partial-hand patients. The i-limb hand is effectively a chassis for five prodigits.

The conceptualization of the technology that was the basis for prodigits and the i-limb occurred during what Gow calls the 'two years of indolence', from 1993 to 1995, a period when research grant funding had dried up and ironically, 'he had time to think'.⁶ The focus of the



Figure 4. Prodigits (image *circa* 2008 from Touch Bionics)

⁵ David Gow, author interview, November 2010.

⁶ David Gow, author interview, November 2010.



Figure 5. The i-limb has five independently powered digits, controlled by a traditional myoelectric system (image source: David Foord, 2008)

engineering group oriented Gow towards gaps in contemporary device offerings. In the early 1990s, there were no powered solutions for partial hands. A person with the loss of only part of the hand (say, all the fingers distal of the knuckles) would not be able to wear a conventional prosthesis without making the arm significantly longer to accommodate a full hand. What was required was a shorter hand, or powered fingers. The design work initially focused on a partial hand for children as young as 9.

The powered digit was the basic module, and it was then adapted for the specific finger or thumb. The design used round worm and wheel gears, but Gow reversed the conventional roles so that the motor turned the worm which drove the wheel at a reduced speed. The initial prototype design, construction and tests of the individual digits occurred over a period of two years, from 1996 to 1998. Orthopaedic bioengineering unit staff did most of the work as part of the 20% of their time permitted for other projects. Gow managed the project. The overall costs from initial design to filing of the first patent were modest, about £50,000 for materials and supplies to produce a prototype. Once the finger was produced, it occurred to Gow that five digits could be placed together to make a complete hand, with space in the palm for the electronics and perhaps the wrist flexor. This was the inventive concept behind the i-limb.

A patent application for the prototype prosthetic finger was filed in 1996. The patent was granted in 1999, and assigned to an NHS trust by the sole inventor, David Gow (1999). Its novelty was a motor and gear-box inside the prosthetic finger, and the ability of the finger joint to move up and down at the knuckle. The two additional joints of the finger and the one in the thumb did not move. In 2000, another NHS patent application naming Gow (2002) as sole inventor was filed, this one for an upper limb prosthesis, consisting of a mechanical pivoting wrist, elbow and shoulder joint. The patent was granted in 2002 and assigned to another local NHS trust. Patents, along with press releases and news stories, were the major sources of information about the new arm and hand products. Those familiar with modern practices in patenting will not be surprised that a commercial product was still far in the future, and would require substantial redesign and user testing.

In 1998, newspaper stories announced a fitting of the Edinburgh arm to a local hotelier, Campbell Aird, whose right arm had been amputated after he was diagnosed with muscle cancer. Aird turned out to be a major force in the development of both the Edinburgh arm and i-limb technologies because of his persistence in seeking improved prostheses from the NHS and his skills in generating press coverage for what he wanted. Aird had been fitted with the electric version of the

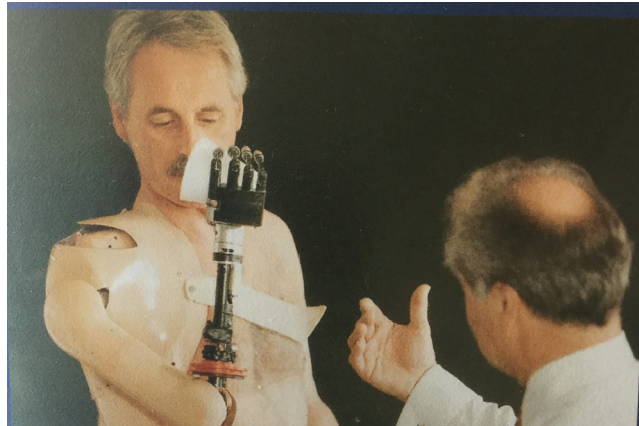


Figure 6. Robert Campbell Aird and the Edinburgh arm circa 1998 (courtesy of Lothian Health Services Archive, Edinburgh University Library)

earlier gas arms, so when Gow wanted to try out the Edinburgh arm, he turned to Aird. Aird was vocal in his feedback and went as far as to announce dates for his arm and hand system fittings – before even consulting with Gow. Gow elected to go along with his plans and was able to meet the deadlines. Aird was relaxed and a willing demonstrator and presenter. He was happy to show off the arm’s capabilities and collaborated with Gow in the demonstrations. When the arm did not possess a passive swing for walking, and thus moved rigidly when he walked, Aird practiced driving it in synch with his stride to match the swing of his other arm. In response, Gow altered the design to allow a little free swing at the shoulder. And even when technical issues arose in demonstrations, Aird would find ways to demonstrate the system. As it turned out, the resulting international press from an Aird demonstration in 1998 marked the turning point for Gow, as it was then that investors became interested in the technology.

To secure the investment meant forming a company and licensing technology from the NHS. In June 2002 the company, Touch EMAS, was incorporated. It was the first such company to be spun out of the Scottish NHS. Scottish Health Innovations Ltd., an NHS subsidiary, became a significant shareholder because of its license of patents, technology and other intellectual property to the company. Investments came from a variety of sources. A grant of £60,000 came from Scottish Enterprise, matched by a \$US15,000 award from the NHS. The funding was used to develop a version of the i-limb with fingers that bent at both the knuckle and the two finger joints. An angel funding organization, Archangel Informal Investments, and a local regional development body, Scottish co-investment fund, both invested directly in Touch EMAS. The funding was used to develop shoulders, elbows, wrists and hands of the modular system, and to fund the two-year secondment (two days per week) of David Gow into Touch EMAS to serve as its first president. In this role, Gow oversaw work by an external engineering design firm and subcontractors that took his clinical systems and developed prototype products for clinical trials. He also oversaw the development of a business plan calling for recruitment of a CEO with commercial experience.

In July 2005, Stuart Mead, the new CEO, was recruited. Mead was a career manager. He said that when he first arrived there was no company, just an idea, a patent and a few prototypes. His view was that the company (now called Touch Bionics) was ‘set up as a philanthropic exercise’.⁷ Mead wanted to develop the business in the US, given the market for upper limbs among

⁷Stuart Mead, author interview.

amputee veterans of the American wars in Iraq. One of the challenges of this market was making the hand robust. Mead and colleagues took an early version of the i-limb to the US Walter Reed Army Medical Center and fitted it on a veteran. The first thing the veteran did was take the artificial hand to the firing range and use it to fire a Colt 45 handgun and an AK15 rifle. The hand ‘just fell to pieces’, according to Mead. This led to yet another redesign of the hand, this time using a new plastic that Du Pont had developed.

As this was the first powered hand in the marketplace with articulated fingers, Touch Bionics discovered that prosthetists, occupational therapists and the users did not know how to use it, nor how Touch Bionics would train occupational therapists and users. The company also discovered that there was more revenue in the servicing than in the sale of the hands. As a result, Touch Bionics spent a number of years learning how to develop and deliver these services. They employed occupational therapists to develop the service programmes and to train patients and professionals. To support the service, R&D and production business, the company moved to a new facility in Livingston, a 15-minute drive from the Edinburgh suburbs. The new facility replicated the organization and spaces of the engineering unit at the hospital.

By April 2009, the company reported sales of more than 500 i-limb hands and had entered the Chinese market. Growth from 2007 to 2009 exceeded planning. The number of employees grew from about 20 in 2007 to over 200 by 2009. Initially, all of the staff at the Livingston location could fit into one of the modular buildings in the industrial park. By 2009, there were three buildings, one for the clinic, corporate and administrative offices, a second for R&D, and a third for production. Also in 2009, Gow left the company after two years as director of technology. He considered that, by then, his services were no longer required.⁸ Replacing Gow was another engineer who came to the position with years of experience in product development for large multinational firms. He started after production had begun and after the third-party design had occurred, but nevertheless saw a need for another redesign of the products to address input from customers and to fit better with the production process. Initially the hand was designed with components from a third-party competitor. The new version used components designed solely by Touch Bionics. By 2015, the number of Touch Bionics employees had decreased to about 120, but had operations in Scotland, the United States and Germany, and had increased annual revenue to about \$US21 million. The year after, Touch Bionics announced that it had been purchased by Reykjavík-based orthopaedics firm Össur for about \$USD39 million.

Discussion

Did the knowledge creation from the design engineering meet the conditions for mode 2 knowledge creation? Was there generation of problems and methodologies? Was there dissemination of results to hospitals and clinics? Did the design process involve not just engineers, but also occupational therapists, prosthetists, users, company managers and others using their own theories, methods and experience to solve problems? Did people fitted with artificial limbs talk to engineers? Did definitions of quality emerge that were judged not just by disciplinary peers, but also by prosthetists, companies, occupational therapists, users and others? To all of these questions we answer in the affirmative. Even over the course of David Simpson’s career there was a move from the University of Edinburgh’s laboratory-based research to dissemination of results to the Princess Margaret Rose Hospital, then to the Eastern General and Edinburgh Astley Ainslie hospitals, and finally to the clinic housed by Touch Bionics. This was where products were conceptualized, developed, designed, built and demonstrated. The change in context made it easier to involve occupational therapists, users and others in the development process. This was also where Campbell Aird provided Gow with the features of, and delivery dates for, the new prosthetic hand. The definitions of quality that

⁸ David Gow, author interview, November 2010.

emerged from the development of prodigits and the i-limb arose not just from Gow, but also from patients and colleagues at Touch Bionics and third-party testers.

In the light of these features of the mode 2 concept, we argue that the location of application was of critical importance. The location of Simpson's research and design activities in the Princess Margaret Rose Hospital, and the existence of a combined research and limb fitting service, meant the other elements of mode 2 knowledge production were difficult to avoid. The occupational therapists, prosthetists and users were seen daily. The generation of problems and methodologies, and dissemination of results, occurred in the hospital because that was where Simpson and Gow spent most of their time. Users spoke to engineers because this was part of both the research process and the limb fitting process. A 1974 doctoral dissertation project performed at the Princess Margaret Rose Hospital had this to say about the context of application:

it is necessary to describe in some detail the themes and environment underlying the whole project. The effects of the environment will be seen to be particularly important, since all new work has necessarily required [sic] to be compatible with the complete powered prostheses and limb fitting programme already in existence at the time of commencing the development of a hand prosthesis' (Kenworthy, 1974, p.2).

For David Gow, whose office and laboratory were located in a clinic and who was immersed in the daily demands of a clinical practice, the challenge was not to seek out occupational therapists and patients, but rather to avoid being consumed by the clinical practice. Indeed, Gow claimed that time away from the clinic was useful in the development of the concept behind the i-limb. The drawings of what became the prodigits were made at his residence. Consistent with the research findings of Heerwagen *et al.* (2004), a balance had to be struck between the need to interact and the need to work alone.

We further argue that the case points to the need for new ideas that go beyond contexts of application and locations of use. While the case may seem to possess strong contextualization, the influence is difficult to see in the mode 2 understanding of the phrase in which powerful social movements influence science and society. While there was arguably a powerful social movement in the 1960s to provide new artificial limbs for children with phocomelic limbs, by the 1980s that movement was on the wane in the NHS. Funding programmes established in response to the thalidomide crisis in the 1960s had been closed by the time Gow had begun developing his design ideas for a new powered hand. Rather, the 1960s focus on development of new artificial limbs for children was behind Simpson moving his R&D activities from the University of Edinburgh campus to the Princess Margaret Rose Hospital. Gow, in turn, was influenced by the location of the R&D unit in a hospital and, subsequently, by users and others in the hospital in the design of the powered upper limbs.

Does this meet the characteristics of embedded research as outlined by Vindrola-Padros *et al.* (2017)? We argue it does. Whereas Simpson was affiliated with the University of Edinburgh as well as the Princess Margaret Rose Hospital, Gow had no affiliation with an academic institution. However, both worked in a clinic with a mandate for new knowledge creation. Both Simpson and Gow developed relationships with hospital and clinical staff and were seen as part of the team. They generated new knowledge in conjunction with teams in response to the needs of the hospital and its patients, and sought to build research capacity in the host institution through public and private sources of funding. However, building the clinical R&D programme was unsuccessful over the longer term as it was unable to resist the forces that pulled research back into academia, submerged engineering design activities under the pressures of clinical operations and extracted clinic staff and intellectual property in successful hand designs into Touch Bionics. As well, during the period of embedded research from 1965 to the mid-2000s, the knowledge creation methodologies changed from scientific research in 1960s to a largely design engineering approach by the 1980s. Moving the primary design activities for the i-limb out of the hospital and into the commercializing company as the i-limb venture attracted significant third-party investment.

Conclusion

The mode 2 knowledge production concept provides a robust framework to understand our case, although the idea of context of application has weak explanatory power for the development of bionic hands. The context of application was, however, instrumental in the first major innovation in the case, the movement of the R&D group from the university to the hospital. To explain the influence of context, we have used the concept of embedded research. This does not just add to the mode 2 vocabulary of contexts of application, but is also integral to understanding the transition from mode 1 to mode 2. The relocation, reorganization and reduction to practice of Simpson's research from the University of Edinburgh to the Princess Margaret Rose Hospital began the transition which eventually culminated in the innovative activities of Gow, Baird and others in designing and launching the i-limb. The creation of an embedded research location was foundational for the other elements of the knowledge creation process as well as the eventual development of the i-limb.

Further research

Case studies on mode 2 knowledge creation have not emphasized locations of use or embedded research. Are there other existing cases in which the location of use has had a fundamental influence on R&D-based new knowledge? Were weak, middle-range or strong contexts of applications present? In these cases, did the embedding of R&D in a location of use provide an unstable research environment because of the pressures of operational environments for production, or have groups found novel organizational designs to accommodate this R&D? If so, what are the organizational designs and management approaches that have supported the building of research capacity in locations of use in the long term? The mode 2 concept is premised on the growth of R&D outside academia and the development of new relations among research fields and sectors. How have these interdisciplinary relationships been developed and maintained in research in locations of use? Are they determined by the nature of work in the location? For instance, in our case, the social influence on the i-limb appeared to arise largely from people who worked in, or were served at, the hospital. Will other case studies reveal more complex and hybrid social influences, with some influences that are location based and others that are not?

This account of development of the i-limb and the role of locations of use is part of a larger study on bionic upper limb research and product development from the 1940s to the present. Initial findings indicate that the development of powered upper limbs in the second half of the twentieth century consistently featured R&D in clinics and hospitals involving prosthetists, occupational therapists, technicians, users and others. These include the Boston arm, Utah arm, VASI hands and Otto Bock hands and arm products, all of which feature fundamental designs reduced to initial experimental practice and improved in clinical environments (Foord, 2013; Foord and Kyberd, 2015). Additional research will examine whether these cases and the development of the industry in general conform to concepts of mode 2 knowledge production with a context of application including embedded research.

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