Institution: University of Strathclyde

Unit of Assessment: 3

Title of case study: Commercialisation of non-invasive wound monitoring system leads to quality of life benefits to patients.

1. Summary of the impact (indicative maximum 100 words)

As a result of research on moisture sensing, Professor Patricia Connolly developed and successfully clinically trialled a disposable, sterile, moisture sensor which enabled real-time measurement of the moisture level in a wound without disturbing the dressing. Ohmedics Ltd was spun out in 2009 to market the disposable sensor and associated hand-held meter. The system, known as WoundSense™, gained the CE mark in 2010. The device is available commercially and is in use in hospitals in Saudi Arabia and Qatar, is starting to penetrate international markets, and had first sales to the NHS in the UK in 2012. The system is being piloted for use with remote monitoring 'telehealth' technology. The British military currently (July 2013) have the system in clinical trial for monitoring of complex trauma wounds. The creation of Ohmedics has given specialist employment to 6 people in the company and helps support another 4 skilled jobs at UK contract manufacturers.

2. Underpinning research (indicative maximum 500 words)

Context

The cost of treating chronic wounds is estimated to be £2.6Bn in the UK alone, with 200 000 patients at any one time having a chronic wound [2]. The nursing time involved in dressing changes takes up a considerable amount of this cost. Hydration levels in a wound can alert a clinician to sub-optimal healing conditions; wounds that are too dry do not heal well and those that are too wet cause further tissue breakdown. This is important for both acute and chronic wounds and so covers many patients. Real-time measurement of moisture level in a wound was not previously possible until we developed a disposable, sterile, moisture sensor for wound monitoring. Having a sensor to monitor dressings without their removal saves time, costs and patient trauma and, by not disturbing the wound bed, promotes better healing and less opportunity for infection.

Key Research Findings

The work on wound moisture sensing initiated from a novel model wound bed and sensors built and tested in our laboratory [1]. This work critically showed that moisture could be mapped under a wound dressing by impedance sensing. The principle of the measurement relies on the high conductivity of wound exudate (largely driven by the physiological level of sodium chloride, 133 mM. Wet wounds have a low impedance and dry wounds a high impedance. The wound interface with the dressing has an impedance versus time "dry out" characteristic, from wet to dry in various stages, which we have been able to measure using sterile printed electrodes in a sensor placed within the dressing. We have been able to create a 'five drop' moisture scale to guide clinicians on dressing status and changes, without disturbing the dressing [2,3]. This research at Strathclyde has demonstrated that moistness in wound dressings can be measured in a reagent-less way by a sensor that can be left in any dressing for up to 7 days. We reached this point by carefully developing and characterising an advanced artificial wound bed, followed by developing a prototype sensor for a dressing, and then researching the sensor under an ethical clinical trial in the NHS [4]. This was the first time that moisture had been tracked within a wound dressing in real time and the results paved the way for the clinical trials and provided the pump-priming results for further studies. Work on wound sensors directed by Professor Connolly and Professor Iain Hunter in the period from 2007-2011 focussed on bacterial sensing by impedance linked to the moisture sensor. The work built on an invention filed as a patent by Connolly and Shedden for impedance signatures of cells and bacteria. A patent has been granted in the EU and a first paper has been published on this work [5]. Ohmedics is developing a bacteria sensor based on this IP. In Qatar in 2012, we established a $1M research project between Connolly and Hamad Medical Corporation funded by QNRF for Advanced Wound Diagnostics.

Key researchers at Strathclyde

Patricia Connolly - Professor of Bioengineering 2007 – present conducted all research on

moisture sensing in wounds, cell and bacteria impedance sensing. **Iain Hunter** – Professor in the Strathclyde Institute of Pharmacy and Biomedical Sciences from 2007 – present, conducted research on cell and bacteria impedance sensing

3. References to the research (indicative maximum of six references)

1. David McColl, Brian Cartlidge, Patricia Connolly, Real-time monitoring of moisture levels in wound dressings *in vitro*: An experimental study , International Journal of Surgery Volume 5, Issue 5, pp. 316-322, October 2007,
2. David McColl, Margaret MacDougall, Lynne Watret, Patricia Connolly, Monitoring moisture without disturbing the wound dressing, Wounds UK Journal, 2009, Vol 5, No 3, pp 94-99. Note: **Included in REF 2 Submission for UoA 3**
3. P. Connolly, L Watret, D. McColl, M, MacDougall, Wound Moisture Can Be Measured Without Disturbing the Dressing, Electronic Supplement to European Wound Management Journal, Vol 10, 2, May 2010. http://ewma.org/fileadmin/user_upload/EWMA/pdf/conference_abstracts/2010/Poster/EWMA2010_P%2038.pdf
4. Burke J, Khanbhai M, Connolly P, Temple E, McCollum C . Profiling of moisture status in venous leg ulcers, EWMA, Copenhagen. EWMA Journal Supplement Volume 13 Number 1, pp. 82, April 2013. http://ewma2013.org/fileadmin/user_upload/EWMA/galleryimages/Conferences/EWMA_2013/EWMA2013_AbstractBook_WEB.pdf
5. Farrow, M., Hunter, I. S. & Connolly, P. Developing a real time sensing system to monitor bacteria in wound dressings. Biosensors, Vol 2, pp 171-188, May 2012. Note: **Included in REF 2 Submission for UoA 3**

Information on quality of research

The research has been published in peer reviewed journal papers in the field. In addition the work gained prizes at the largest international wound care meeting SAWC in Florida in 2004 and from Wounds UK. In 2010, the project was shortlisted by the Times Higher as one of four projects considered for Research Project of the year. The following patents are granted or pending:
P. Connolly, D. McColl, "Wound dressing hydration and performance monitoring of wound dressings", WO 2005/099644, 2005. Granted EU and Japan, pending USA.
Shedden, L., Connolly, P. A system and method for cell characterisation. PCT Patent filing: WO 2009/ 136157 A2 Granted EU, Pending USA, Japan, and China.
Connolly P, Wound Dressing with Impedance Sensor PCT Patent Filing WO2011004165. 2009. Pending EU, USA, China, India, and Japan.

4. Details of the impact (indicative maximum 750 words)

Process from Research to Impact

Scottish Enterprise funding was obtained for the period 2006-2008 to develop a device that could be clinically trialled for moisture sensing in patients' dressings. A collaborative programme of work for the trial was developed with tissue nurses within NHS Greater Glasgow & Clyde. The device details and trial protocol were cleared for trial pre-CE mark by the Medicines and Health Regulatory Authority in the UK, a substantial process. The trial commenced in 2007 for 12 months. Sixteen patients attending a leg ulcer clinic in Clydebank Health Centre were recruited to the trial. It was shown that the sensor accurately reported moisture levels and showed that moist wounds were healing best [Reference2].

New clinical protocols and findings were developed using the system in conjunction with a new home monitoring texting app developed by NHS Stoke and known as NHS Florence. The work was done in conjunction with a telehealth expert team from NHS South of Tyne and Wear (SOTW) and this team has been given permission to offer the protocols to other NHS Boards commercially working with Ohmedics Ltd.

Types of Impact

Creation of spin-out company:

The spin-out company, Ohmedics Ltd (Source A), was formed on the basis of the University of Strathclyde research in June 2009. [Text removed for publication.] Ohmedics needed to establish itself as a medical device company by obtaining ISO 13485 certification. This was awarded by Intertek in January 2010. Intertek also awarded WoundSense™ the CE Certificate (Mark) for a Class IIa medical device in January 2010. This allowed the device to be placed on the market in the EU and other non-EU countries that accept the CE mark (such as Saudi Arabia). This is the first ever device for diagnostics within a wound dressing that has been certified in the EU, USA or elsewhere. Ohmedics obtained the Nexxus award for Innovation in 2009 and the University's Innovation Spin Out award in the same year. The company also started activities in the Middle East working through UKTI and Scottish Enterprise. To date Ohmedics has appointed distributors in Qatar (Gentech) and the Kingdom of Saudi Arabia (Husnksa - Source B).

Commercialisation of the technology:
Full production of the system comprising a meter and disposable sensors, commenced in 2011 [text removed for publication] (Source D). The company have already established first sales in Saudi Arabia and Qatar. Manufacture of product (meters and sensors) is done in the UK via subcontracts.
A major US company is investigating the use of the system in their dressings. Ohmedics Ltd have signed a confidentiality agreement with a major Chinese medical company with a view to forming a partnership covering China, Malaysia and Thailand. Although the initial markets targeted are UK and Middle East based, global markets are opening up.

Benefits to patients:
A team at Wythenshawe Hospital have collaborated with the research team to show that moisture is correlated with leg ulcer healing in compression treatment, the first time this has been proved in patients [Reference 4]. The researchers have worked in King Abdullaziz Hospital Jeddah on vascular surgery patients being treated with medicinal honey and with the British Army at Queen Elizabeth Hospital, Birmingham for trauma and burns patients. The British Army work in collaboration with Lt Col Professor Stephen Jeffery required military ethics approval (MODREC) which was obtained at the end of 2011.The WoundSense monitor was used in Negative Pressure Wound Therapy in 2012-13 at The Queen Elizabeth Hospital and Lt Col Jeffrey has stated "*NPWT involves the application of suction, via a dressing, to the wound area using a pump. This draws out exudate - wound fluid - and stimulates the healing process. However, before WoundSense came to the market, it was not possible to monitor moisture in a patient's dressing in real time."* (Source C).

Results of clinical trials show that the WoundSense system reduces dressing changes and allows the clinician to monitor the crucial moisture levels inside the wound dressing. This allows clinical guidelines on moisture levels to be actively applied, including the European Wound Management Association's TIME Guidelines for wound bed preparation. Patients suffering from diabetic ulcers, venous leg ulcers, diabetic foot, pressure sores and post-surgical wounds, e.g. Caesarean, are affected positively by our wound monitoring technology. Patients find dressing changes less painful as those wounds which have dried will be changed before the tissue can begin to bind to the dressing. As there are fewer dressing changes there is also less chance for infection. Improved wound exudate control, in general, also leads to faster, more effective healing [Refs 2, 4].

Economic Benefits:
Use of WoundSense has resulted in significant savings in nursing staff time as fewer dressing changes are required. This increased efficiency has an economic benefit as the nursing time involved in dressing changes has a considerable cost. Ohmedics Ltd. was invited in January 2013 to present a confidential Costs Benefits Analysis for the system to NHS Scotland and to the Department of Health. The analysis showed projected savings for use of the device of around £28,000 per annum and a saving in community wound care of £9800 per annum in the nursing of chronic wounds (Source E). Conservatively, for every chronic wound care patient being treated at home over a 6 week period, WoundSense saves 12 community nurse hours and £1100 per patient. Following the presentation, Ohmedics was invited by Department of Health officials to participate in the NHS Innovations Expo 2013 in London linked to achieving the Government's aims of rapidly expanding telehealth through its 3 Million Lives programme. The researchers have

now started 2 telehealth pilot projects in NHS England (Source F).

Wider adoption: The link to telehealth through the partnership with NHS South of Tyne and Wear led to an invitation to meet the Danish Government's telehealth team who have a particular interest in wound care and in the WoundSense NHS telehealth pilots. An invited presentation to the Danish telehealth groups took place on September 10th 2013 at the British Embassy in Copenhagen. Medecin sans Frontieres in Cameroon also requested training materials and a presentation from Ohmedics and Prof Connolly with a view to assessing the WoundSense system in Buruli Ulcer treatment. This presentation took place in June 2013.

5. Sources to corroborate the impact (indicative maximum of 10 references)

A. www.ohmedics.com Formation of a University of Strathclyde spin out, Ohmedics Ltd, in June 2009

B. http://www.husnksa.com/en/CatagoryProducts/ProductDetail.aspx?ID=54 evidence for marketing of product in Saudi Arabia

C. http://www.lifesciencesscotland.com/connections/news/news-content/wound-care-device-to-be-trialled-in-birmingham.aspx evidence for trials of Woundsense in Birmingham.

D. Confidential memo from Operations Director February 2013 – evidence of sales to NHS January 2013

E. Confidential Document: Ohmedics Costs Benefits Analysis for Ward or Community Use. Report prepared and submitted to the Department of Health, January 2013.

F. http://www.ohmedics.com/11.html WoundSense monitoring applied to remote 'telehealth' applications