Institution: Staffordshire University

Unit of Assessment: 15 – General Engineering

Title of case study: Tibial Fracture Management Research – STORM® / IOS® and Intelligent Orthopaedics Ltd

1. Summary of the impact

Globally, around 400 people in every million head of population will present with a fracture of the tibia that requires surgical intervention. This case study describes the exploitation of research that commenced with a DTI/EPSRC grant. The results have a direct impact on the 400/million population, their family, employers, and associated healthcare providers.

During the period 2008-today:

over 200 surgeons in 10 countries have been retrained in the new methodology;
between 2000-3000 patients have benefited from improved outcomes;
47 hospitals benefited from reduced operating times and reduced costs;
and surgeons benefit from a marked reduction in per-operative x-ray exposure (reducing the risk of cancer).

The initial project was to identify the optimum movement of the fracture fragments to promote healing; this was to lead to devices with the potential for significant impact. A spin out company was formed which has attracted over £1.4 million investment.

2. Underpinning research

The underpinning research started in 1993 under GR/J55984/01 (£155k). Professor Ogrodnik and Professor Thomas led the project. Together, with Dr CI Moorcroft, they have built a recognised centre for the investigation of human fracture healing. The project's members have grown to include Staffordshire University, the University Hospital of North Staffordshire and Keele University. Global partners have been recruited including teaching hospitals and universities in the UK, Germany and the USA.

The project's aim was to investigate the effect of inter-fragmentary movement of a fractured tibia on the formation of callus. The hypothesis was that identifying the optimum movement pattern and then designing a device that would allow this movement to occur would result in shorter healing times. Several innovative experimental devices were developed. The first was a unique theatre based, operative tool. Its aim was to ensure that all patients in the trial had their fractures reduced to near anatomical alignment [1]. It is, now, being sold as a stand-alone piece of operating theatre equipment (**STORM**) and is used to help align the fractured bone and to retain its position during fixation. It is the subject of a number of granted world patents (for example EP0984729 and US8080016). A unique disruptive technology was also developed: the first autonomous data logging system to monitor patient activity and fracture healing progression [2]. This device led to granted patents – for example EP0740927. The third device was a unique system to monitor fracture fragment movement in a hospital clinic [3]. This device led to further research (funded by the NHS under the LORS system) to investigate the polar non-linear properties of healing callus [4]. Interestingly this research was the first to demonstrate the effect of smoking on fracture healing: a statistically significant delay of 4 weeks. This discovery led to further research [5]; enabling them to use the by-products of this team's research to investigate the effects of nicotine at the cellular level.

The team identified the optimum design criteria for the fixation of mid-shaft tibial fractures. This led to a new generation of external fixation (**IOS**); it being the subject of granted patents (for example

GB2427141). This fixator also incorporates a passive fracture healing detection system (influenced directly from the research results); it has been clinically verified. The research has led to a better understanding of fracture healing progression and, more importantly fracture healing issues. Current research is concerned with addressing the issues of atrophic and hypertrophic non-union, and mathematical modelling of the callus mass is also leading to significant results [6]. Other centres are starting to use the devices for their own research. For example German teaching hospitals have undertaken an independent study to examine the clinical benefits of STORM.

STORM and the research team were finalists in the 2006 Royal Academy of Engineering MacRobert Award and won the Lord Stafford Award for Innovation in 2005. STORM and IO were selected by HRH Prince Phillip as an example of the impact of engineering on society in his article *Promoting Engineering* within INGENIA.

3. References to the research

(1) Moorcroft CI, Thomas PBM, Ogrodnik PJ, and Verborg S, (2000), A device for improved reduction of tibial fractures treated with external fixation. *Proceedings IMechE Part H: Journal of Engineering in Medicine*, 214 (5), 449-457.

(2) Moorcroft CI, Ogrodnik PJ, Thomas PBM, and Verborg S. (1997). A data-logging system to monitor bone fracture movement continuously. *Journal of Medical Engineering and Physics*. 19(3). 286-290.

(3) Ogrodnik PJ, Moorcroft CI, and Thomas PBM (2001). A fracture movement monitoring system to aid in the assessment of fracture healing in humans. *Proceedings IMechE Part H: Journal of Engineering in Medicine*, 215(4), 405-414.

(4) Ogrodnik PJ, Moorcroft CI, and Thomas PBM (2007). Measuring multi-dimensional, time-dependent mechanical properties of a human tibial fracture using an automated system. *Proceedings IMechE Part H: Journal of Engineering in Medicine*, 221(6), 641-652.

(5) Walker LM, Preston MR, Magnay JL, Thomas PBM and El-Haj AJ (2001) Nicotinic regulation of c-fos osteopontin expression in human-derived osteoblast-like cells and human trabecular bone organ culture. *Bone*. 28(6), 603-608.

(6) OGRODNIK, Peter, THOMAS, Peter, MOORCROFT, Christopher and MOHAMMED, Khaja (2013) A multi-directional fracture stiffness model to determine the principal stiffness properties of a healing human tibia. Journal Of Engineering In Medicine - Part H. ISSN 09544119

4. Details of the impact

Economic Impacts

- STORM is the commercial name for the reduction device described earlier; IOS is the external fixator [1],
    - Both have CE mark and FDA clearance to market and,
    - are being commercialised within the spin out company Intelligent Orthopaedics Ltd (£1.4 million investment).
    - generated £123k in sales in 2012 [1].
- 4 patents have been filed; a new patent granted will minimise the effort of drilling 'blind' holes. [1,2]
- It supports (indirectly) employment in 5 companies in Derby, Leeds, Littlehampton, Portsmouth and Sheffield [1,3].
- The experience has created a unique centre for medical devices design; we have

supported other industries and institutions [1,4].

- Indirectly this project has supported the exploitation of medical devices from the 13 West Midlands region's universities through Medical Interchange; exhibiting their devices at MEDTEC 2008, 2009 and 2010 and at MEDICA 2010 [4].
- The company employs postgraduate students from Staffordshire for work experience and provides internships as a part of their 2nd year studies in Engineering [1].
- 30 publications including one research led book.
- The research has been cited in over 300 other publications.

Impacts on Public Policy and Services

- STORM is used in Teaching Hospitals and there is evidence that registrars are being influenced by this new reduction technique [1,5,6,7].
- STORM has been, and is being used in key hospitals across the world: 7 centres in the USA; 12 in Germany; 22 in the UK (including teaching hospitals at Cambridge, Manchester, Liverpool and Southampton); and 12 in the rest of the World (Eire, Turkey, Saudi Arabia, Greece, Italy and Bulgaria) [1].

Impacts on Society, Culture and Creativity

- Exemplified by peers for innovation and engineering [1,8].
- Papers have been presented at key conferences and meetings and the research group are invited to present their methods at surgical continuing professional development events [1,4].
- The main researchers have presented over 14 invited papers or keynotes.[1]

Health Impacts

- To date 2000-3000 patients have been treated with **STORM** and about 250 with IOS [1].
- Shorter operating times reduces exposure to General Anaesthesia: improving operative mortality [1,5,6,7,9].
- Use of STORM has been shown to produce near perfect reduction [1,5,6,7,9];
  - for the patient this means their leg is as close to normal as possible [1,5,6,7,9];
  - and producing a causal link (that we are investigating) to improved healing and a reduction in non-unions[1,5,6,7].
- As improved reduction can be shown to improve prognosis; inherently reducing the total cost of the procedure [1,6,7].
- The most common reason for litigation (USA) for post-operative issues related to tibial fractures is rotation of the foot. The near anatomical reduction produced by STORM eliminates this issue and, hence, reduces potential litigation costs [1,6,7].

- Use of **IOS** has shown to reduce healing times; the shortest being circa 9 weeks. This is 7-8 weeks below the accepted average [1,7];
- Allows patients to be mobile the day after their operation [1,7];
- Allows patients to wear normal clothing, hence promoting return to normal activities.[1,7];
- Patients prefer IOS to other methods they have been treated with, even plaster [1,7].
- IOS has no moving parts potential failure modes have been eliminated;
  - regular x-rays have become redundant, minimising direct costs [1,7];
  - mechanical failure is no longer a root cause of malunion, saving circa £9000 per patient [1].

Impacts on Practitioners and Professional Services

- 200+ Surgeon's have received training in new methods of fracture reduction [1]
- The research has challenged the use of radiographs in fracture assessment [1,5,7].

- Using **STORM** has been shown to shorten operating times by 25-30%. This signifies an overall saving about 1250-2500 operating room hours: or at least one operating theatre for

one year. This reduces costs significantly [1,5,9].

- An independent German study [1,5] has shown that using STORM reduces x-ray exposure by 50%.
    - It reduces overall cost to the hospital.
    - More importantly, it reduces overall lifetime exposure for the surgeon.
- The study also demonstrated that using STORM reduces the number of surgical assistants required [1,5];
    - reducing the overall cost of the operation.
- STORM has been proposed as a preferred method for the super-patella method of IM nailing beneficial for the treatment of calcaneal fractures [1,5].

- **IOS**, when compared with a direct comparator (Orthofix), saves a hospital over 50% of purchase price [1,10].
- The in-built fracture healing detection system has been shown to be effective (a 100+ patient study is to be published) [1,7];
    - reduction of post-operative complications and pin-site issues means fracture clinics are shorter [1,7];
    - reducing total cost to the hospital [1].

5. Sources to corroborate the impact

[1] Chair, Intelligent Orthopaedics Ltd. (Contact Identifier 3)

[2] OGRODNIK, Peter Jan, and Peter Brian MacFarlane THOMAS. "SURGICAL TARGETING GUIDE." WIPO Patent No. 2013017833. 8 Feb. 2013.

[3] Managing Director, Kirkstall Precision Ltd. (Contact Identifier 4)

[4] Medical Interchange
http://eprints.staffs.ac.uk/cgi/search/archive/simple?screen=Search&dataset=archive&order=&q_merge=ALL&q=ogrodnik+davis&_action_search=Search

[5] Leitender Oberarzt der Klinik fur Unfallchirurgie
Universitatsklinikum Schleswig-Holstein. (Contact Identifier 1)

http://www.intelligent-orthopaedics.com/news/717/tibial-fractures-storm-shown-to-reduce-radiation-exposure-during-surgery

[6] Consultant Orthopaedic and Trauma Surgeon,
University Hospital Southampton. (Contact Identifier 2)

[7] Consultant Orthopaedic and Trauma Surgeon,
Robert Jones and Agnes Hunt Hospital. (Contact Identifier 5)

[8] HRH Prince Phillip, (2009). Promoting Engineering, *Ingenia,* 41, 13-16.

[9] Hull P, Whalley H, and Docker C, (2008). STORM – A revolutionary aid for fracture reduction. Orthopaedic Product News, April. (A)

[10] NHS supplychain website
https://my.supplychain.nhs.uk/catalogue/product/fqw007