Institution: Imperial College London

Unit of Assessment: 01 Clinical Medicine

Title of case study: Acrobot: Active Constraint Robots Improve Outcome in Arthritis Surgery

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

Collaboration between Imperial College Departments of Mechanical Engineering and Surgery led to the development of active constraint robot solutions which augment surgeon skills so that joint replacement components are implanted accurately and successfully. This led to the founding of Acrobot to develop innovative surgical technologies. Acrobot was acquired by Stanmore Implants Worldwide in 2010. An orthopaedic stereotaxic instrument, based on Imperial research, obtained US Food and Drug Administration (FDA) clearance in 2013. This has led to Mako-Surgical purchasing Stanmore Implants Acrobot technology in April 2013.

2. Underpinning research (indicative maximum 500 words)

Key Imperial College London researchers:
Professor Justin Cobb, Professor & Chair of Orthopaedics (2005 - present)
Professor Brian Davies, Professor of Medical Robotics (2000-2005, currently Emeritus)
Dr Simon Harris, Postdoctoral researcher (1989-2003, 2008-present)
Dr Ferdinando Rodriguez y Baena, Reader (2000-2004; 2006-present)
Dr Matjaz Jakopec, Research Associate (1995-2002)

Since the mid-1990s, Imperial researchers have been working across disciplines to design and trial an orthopaedic robot engineering solution which has resulted in real translational clinical benefit. With Imperial software and hardware engineers and surgeons working as a cohesive group, an entire robotic system for surgical assistance was built. This system comprised four fundamental technical advances: two software advances; in robot 3D planning and registration and minimally invasive intra-operative registration and two hardware developments in robot Active Constraint boundary control and back-drivable surgical robots. All the work was carried out in the Mechatronics in Medicine Laboratory under the technical and academic supervision of Professor Davies and the clinical supervision of Professor Cobb. In 1999, a spin out company 'Acrobot' was formed. The system was first trialled successfully on humans in 2002 (1). The study demonstrated that the Acrobot system was successfully used to accurately register and cut the knee bones in total knee replacement surgery and the significant potential of a "hands-on" robot for improving accuracy and increasing safety in surgery.

The first key software achievement seems simple now: to be able to make a 3D model of the bones that comprise the knee joint and to perform virtual surgery on them, allowing the surgeon to plan and rehearse an operation accurately (2). The second achievement was the development of an algorithm by which allowed a low cost computer to co-register the bone model with the cloud of points derived from touching the bone surfaces (3). This recent paper discloses a method and algorithm which were shown to improve by an order of magnitude the intra-operative localisation of the femur, when performed through a single small incision in the knee. The method is patented (WO2006048651). This paper forms part of a body of work on robotic assisted orthopaedic surgery, with a "world-first" in robotic-assisted unicompartmental knee arthroplasty and further two licensed patents by the team (WO03043515, WO2007045810).

The key hardware development of a fully back-driveable robotic arm allowed both enabling and resisting of a surgeons pressure on the hand-piece, depending on whether the bone in that zone was planned for removal or not. In addition to feeling this "active constraint" the surgeon could also see onscreen the position of the tool in relation to the plan (4).

In 2006, Professor Cobb and colleagues led randomised clinical trial. A total of 27 patients had a unicompartmental knee arthroplasty operation performed conventionally or with the assistance of

the Acrobot. The primary outcome measurement was the angle of tibio-femoral alignment in the coronal plane, measured by CT. The entire Acrobot group had tibio-femoral alignment in the coronal plane within 2° of the planned position, while only 40% of the conventional group achieved this level of accuracy (5). This proved that using robot assisted technology it was possible for patients to have minimally invasive procedures with 100% of cases within the 2mm/2° window that was considered desirable. In contrast the control arm cases had examples of errors of translation and angulation that were over three times those encountered in the robotic arm (6). The clinical application of a robot for unicompartmental knee arthroplasty represents a "world-first" in robotic assisted surgery.

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

(1) Jakopec, M., Harris, S.J., Rodriguez y Baena, F., Gomes, P., Cobb, J., Davies, B.L. (2001).The first clinical application of a "hands-on" robotic knee surgery system. *Comput Aided Surg*., 6 (6), 329-339. DOI. Times cited: 132 (as at 11th November 2013). Journal Impact Factor: 0.78

(2) Harris, S.J., Jakopec, M., Cobb, J., Davies, B.L. (1999). Intra-operative application of a robotic knee surgery system. *Lect Notes Comput Sc.*, 1679, 1116-1124. DOI. Times cited: 6 (as at 11th November 2013 on ISI Web of Science).

(3) Rodriguez y Baena, F., Hawke, T., Jakopec, M. (2013). A bounded iterative closest point method for minimally invasive registration of the femur. *Proceedings of the Institution of Mechanical Engineers, Part H: J. Engineering in Medicine*, 227: 1135-1144. DOI. Times cited: 0 (as at 11th November 2013 on ISI Web of Science). Journal Impact Factor: 1.48

(4) Davies, B.L., Harris, S.J., Lin, W.J., Hibberd, R.D., Middleton, R., Cobb, J. (1997). Active compliance in robotic surgery--the use of force control as a dynamic constraint. *Proceedings of the Institution of Mechanical Engineers, Part H: J. Engineering in Medicine*, 211(4), 285-292. DOI. Times cited: 32 (as at 11th November 2013 on ISI Web of Science). Journal Impact Factor: 1.41

(5) Cobb, J., Henckel, J., Gomes, P., Harris, S., Jakopec, M., Rodriguez, F., Barrett, A., Davies, B.L. (2006). Hands-on robotic unicompartmental knee replacement: a prospective, randomised controlled study of the acrobot system. *J Bone Joint Surg Br*., 88 (2), 188-197. DOI. Times cited: 46 (as at 11th November 2013 on ISI Web of Science). Journal Impact Factor: 2.73

(6) Cobb, J.P., Kannan, V., Brust, K., Thevendran, G. (2007). Navigation reduces the learning curve in resurfacing total hip arthroplasty. *Clin Orthop Relat Res.*, 463, 90-97. DOI. Times cited: 38 (as at 11th November 2013 on ISI Web of Science). Journal Impact Factor: 2.78

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

Impacts include: commercial, health and welfare, society
Main beneficiaries: industry, patients and the public

Knee replacement is now the largest surgical industry in the developed world, with over 80,000 replacements performed last year in England and Wales, and more than a million performed worldwide with continued growth predicted for many years. However, it remains more expensive and less successful than hip replacement. Surgical-error remains a significant cause of poor outcomes across the field of conventional joint replacement. The long 'learning curve' associated with a less invasive technique such as partial replacement is a powerful force delaying the adoption of newer, cheaper yet more effective techniques, hence the drive for technological assistance.

From the first 27 cases published in 2006 by Imperial surgeons, over 23,000 robot assisted CT-based partial knee replacements have now been undertaken worldwide [1]. Despite the procedure having a lower reimbursement than Total Knee Replacement, surgeons are now noticing that

patients want a more conservative approach, and armed with the technology that enables reliable delivery of a high standard of care, they feel safe to offer it. The prospects are good for this leading to a substantial reduction in the cost of delivering appropriate care to patients with osteoarthritis of the knee. It is estimated that about 50% of all patients with osteoarthritis of the knee are suitable for this approach [2].

Our technology innovations have had considerable commercial impact. The Imperial spin-out 'Acrobot' was acquired by Stanmore Implants Worldwide in 2010 [3]. The method to improve by an order of magnitude the intra-operative localisation of the femur, when performed through a single small incision in the knee (patent: WO2006048651) is incorporated into the Stanmore Sculptor Robotic Guidance Arm (RGA)[4]. The Stanmore Sculptor RGA device obtained FDA clearance to be sold into the USA in January 2013 [5]. Following USA 510K acceptance [5], Acrobot technology and patents were recently purchased by Mako Surgical [6]. Since their first clinical case in 2006, shortly after our clinical trial was published, almost 25% of partial joint replacements performed in the USA are now performed with this approach. The value of the business is in the public domain as indicated by the purchase of Mako by Stryker for $1.65 billion [7; 2013].

Methods developed by Imperial researchers have also generated a knowledge-based economy. More than one company has used a method reported by our group as reliable ways of orienting the tibia [8]. Informally, they call it the 'Cobb' method. Commercial competitors have used this method for defining the accuracy of their own systems: in 2012 (and prior to the acquisition of Stanmore Implants Worldwide), Mako surgeons reported their accuracy, using our method, and then compared their clinical and radiological outcome to the 'gold standard' of robotic accuracy - the method described by us in 2006 [9]. On the back of this proven clinical demand for accuracy, planned accurate surgery is now performed in other ways too: CT-based are now enabling more complex procedures such as the world's first robot assisted combined replacement and ligament reconstruction [10]

The programme to use robotic technologies to reconstruct injured soldiers has now gained the support of the Military, and the DMRC, Headley Court are discussing with the MSK lab the number of soldiers to be referred [10]. This marriage of high tech planning, prosthesis manufacture and robotic reconstruction (BBC1 2013) was another world first [10].

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

[1] Swank, M.L., Alkire, M., Conditt, M., Lonner, J.H. (2009). Technology and cost-effectiveness in knee arthroplasty: computer navigation and robotics. *Am J Orthop.*, 38 (2), 32-36.

[2] Citak, M., Suero, E.M., Dunbar, N.J., Branch, S.H., Conditt, M.A., Banks, S.A., et al. (2012). Unicompartmental knee arthroplasty: Is robotic technology more accurate than conventional technique? *The Knee*. DOI.

[3] Stanmore sale http://www.sciencebusiness.net/news/74387/Imperial-spin-out-Acrobot-acquired-for-computerised-surgery-system. Archived on 11th November 2013.

[4] Contact the Sr. Director of Clinical Research of Mako Surgical to corroborate the claim

[5] FDA US. 510(k) Premarket Notification of Stanmore Sculptor Robotic Guidance Arm (2013). http://bir-llc.com/wp-content/uploads/Stanmore-Sculptor-RGA-510k-Clearance.pdf. Archived on 11th November 2013.

[6] Mako-Surgical purchase Stanmore Implants Acrobot technology, April 2013 http://ir.makosurgical.com/releasedetail.cfm?ReleaseID=756741 (archived on 11th November 2013)

[7] Stryker buy Mako Surgical Sept. 2013 http://www.bloomberg.com/news/2013-09-25/stryker-to-buy-mako-for-1-65-billion-for-robotic-

surgery-1-.html (archived on 11th November 2013)

[8] Signature knee, Biomet 2010. www.**biomet**.co.uk/patient/**signature** (archived on 11th November 2013)

[9] Mako Surgical Operating Results for 2012/2013 http://ir.makosurgical.com/releasedetail.cfm?ReleaseID=731773. Archived on 11th November 2013

[10] New complex surgeries:

- My 'Savile Row' knee op: This yoga teacher suffered years of agony until doctors fitted her with a bespoke new joint. 25 February 2012 http://www.dailymail.co.uk/health/article-2106429/My-Savile-Row-knee-op-This-yoga-teacher-suffered-years-agony-doctors-fitted-bespoke-new-joint.html#ixzz2KRfFqNZY (archived on 11th November 2013)

- Contact: Officer Commanding Medical Division, DMRC Headley Court, Royal Air Force

- "Robotic surgery gives soldier a new spring in his step" http://www.telegraph.co.uk/health/healthnews/9730086/Robotic-surgery-gives-soldier-a-new-spring-in-his-step.html (archived on 11th November 2013)