Institution: Newcastle University

Unit of Assessment: 12

Title of case study: VAIOS® shoulder joint replacement device

Period when the underpinning research was undertaken: 2000 - 2010

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Professor Garth Johnson	Reader in Biomedical Engineering	1981-1995
	Professor, Rehabilitation Engineering	1995-2008
Dr Andreas Kontaxis	PhD student	2001-2004
Dr Milad Masjedi	Research Associate	2004-2011
	PhD student	2005-2009
Dr Ian Flatters	KTP Associate	2007-2009

Period when the claimed impact occurred: 2013 to 2020

Is this case study continued from a case study submitted in 2014? N

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

A new reverse shoulder prosthesis has been developed on the basis of scientific research carried out at Newcastle University. Subsequent clinical research in collaboration with a clinical research partner (Nottingham University Hospitals NHS Trust) has led to the novel prosthesis being commercialised by JRI Orthopaedics, in collaboration with Newcastle University and Nottingham University Hospitals NHS Trust, with the first products implanted in April 2010.

Between 2014 and 2020 over 17,000 prostheses have been sold worldwide, and prostheses have been implanted into patients in 7 countries to the benefit of the collaborating partners and the patients.

2. Underpinning research (indicative maximum 500 words)

The research pathway for the impact described in this case study was:

(i) Research on the development of a biomechanical model of shoulder function (the Newcastle Shoulder Model, NSM), supported by grants G1 & G2. The model was completed in 2006 and led to publications P1, P2 and P3.

(ii) The use of the NSM to design a new shoulder prosthesis began in 2006, supported by grants G3-G5, and leading to publications P4 & P5.

Initial research by Johnson developed mathematical models which allowed calculation of lines of action, moment arms and force production within the shoulder, based on anatomical data. This technique was used by Johnson to study the kinematics and kinetics of the shoulder during a set of upper limb tasks, leading to a database of inputs for a biomechanical model [P1 & P2]. A model of the shoulder complex, the Newcastle Shoulder Model (NSM), was then developed [G1 & G2], and improved through the use of muscle wrapping algorithms [P3]. The NSM was adapted by Kontaxis and Johnson [P4] to investigate a reverse anatomy prosthesis, in which the ball and socket in the prosthesis are reversed from that seen in human anatomy [G1]. This allowed

quantification of the increased moment arm of the deltoid muscle after an implant had been inserted, and highlighted the problem of impingement, where part of the prosthesis contacts and erodes the scapular neck.

The NSM allowed detailed modelling of the shoulder and prosthesis, allowing development of design features that could decrease impingement without compromising stability. Surgical research carried out by Prof Wallace at Nottingham University Hospitals NHS Trust (NUH) allowed the prosthesis to be designed to suit surgeons' requirements, such as versatility and ease of insertion. A prototype was manufactured, and in 2006 Newcastle University filed for a patent jointly with NUH, and this was granted in 2008. Further work by Kontaxis, Masjedi and Johnson, supported by grants G4 & G5, led to designs for new reverse and anatomical prostheses. Experiments led to quantification of prosthesis function and a new database of limb kinematics and kinetics was established [P5]. Collaboration between Newcastle University, NUH and JRI Ltd (now JRI Orthopaedics Ltd) for product development was supported by a Knowledge Transfer Partnership (KTP) Award [G4, with KTP Associate Flatters], with the patent licensed to JRI. This project resulted in the VAIOS® shoulder system being developed, with the first operation for insertion occurring in April 2010.

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

P1. Murray & Johnson. A study of the external forces and moments at the shoulder and elbow while performing everyday tasks. Clin Biomech 19 (2004): 586-594. DOI: 10.1016/j.clinbiomech.2004.03.004.
Key publication: established shoulder load patterns and loading data sets in a systematic way for the first time.

P2. Charlton & Johnson. A model for the prediction of the forces at the glenohumeral joint. J Eng Med. Pt H Proc I Mech E. 220 (2006): 801-812. DOI: 10.1243/09544119JEIM147.

P3. Marsden et al. Algorithms for exact multi-object wrapping and application to the deltoid muscle wrapping around the humerus. J Eng Med. Pt H Proc I Mech E. 222 (2008): 1081-1095. DOI: 10.1243/09544119JEIM378.

P4. Kontaxis & Johnson. The biomechanics of reverse anatomy shoulder replacement - a modelling study. Clin Biomech 24 (2009): 254-260. DOI: 10.1016/j.clinbiomech.2008.12.004.
Key publication: first examination of the biomechanics of reverse anatomy shoulder prostheses.

P5. Masjedi & Johnson. Glenohumeral contact forces in reversed anatomy shoulder replacement. J Biomech 43 (2010): 13, 2493-2500. DOI: 10.1016/j.jbiomech.2010.05.024.
Key publication: demonstration that reversed anatomy prostheses would work well under all anticipated loading conditions.

Grants

G1. Johnson. Development of new designs of reverse anatomy shoulder prostheses. £50,000, Wright Medical Ltd, 2004-2005.

G2. Bull & Johnson. Preclinical testing and patient-specific implantation/design of shoulder prosthesis. £135,000, Furlong Res Foundation, 2005 (in collaboration with Imperial College).

G3. Johnson. Design of NGRi shoulder prosthesis. £62,000, Wright Medical Ltd, 2006.

G4. Joyce & Johnson. KTP programme with JRI Ltd to develop novel shoulder prostheses. £98,845, KTP, 2007-2009.

G5. Taylor et al. Improving reverse-anatomy shoulder implant outcomes using models validated with measured in vivo forces. Part 1: measurement of forces and model validation. £100,000, Arthritis Res Campaign, 2007 (in collaboration with UCL).

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

The impact addresses two groups: the partnership which commercialised the prosthesis, and the patients who received prostheses. The impact was made possible by two linked areas of research: (i) development of the Newcastle Shoulder Model (NSM), and (ii) the use of the model in developing the VAIOS® implant.

The eventual outcome, the VAIOS® shoulder prosthesis, was developed using the NSM to model loaded and unloaded areas, therefore predicting where material should be removed to minimise impingement. NUH provided clinical experience in terms of the required ease and speed of insertion of the implant, inserted the implant into patients and reported on the clinical outcomes of surgery. JRI have licensed the patent [E1] from Newcastle University and NUH and manufacture the VAIOS® implant, and the implant has now also been patented in New Zealand and Australia, with further patent applications being pursued in Europe, the USA and Canada. Over 17,300 prostheses have been sold (~300 in the period 2010 to 2013, and over 17,000 in the period from 2014 to 2020, [E2]) and the prostheses have been implanted in the UK, Germany, Norway, Brazil, Italy, Poland and Australia.

The first set of beneficiaries are the collaborative group that produced the implant. The VAIOS® accounted for £4.3million of sales as of September 2020 [E2]. The implant has been awarded two high profile industry prizes [E3 & E4] and has gained high profile media coverage [E5].

The second group of beneficiaries are the patients whose shoulder pain can be relieved by the implant. Shoulder pain is a frequent occurrence (with some conditions having a prevalence of 54% in the over 60s [E6]), has a high recurrence and shows poor response to treatment. Patients who received the VAIOS® report an overall decrease in pain, greater mobility and independence. A study of 100 patients who received a reverse prosthesis over a ten-year period investigated two factors; acromio-humeral distance (AHD, associated with deltoid muscle weakness) and notching. The VAIOS® (fitted in 26 patients) showed less scapular notching than more established prostheses and AHD was not significantly different [E7]. A second study focused on 102 patients who received the VAIOS® over a 15-month period [E8]. Patients were assessed in terms of Oxford and Constant Scores, two questionnaires based on activities of daily living including work, sleep patterns and functional assessment including range of motion and strength measures. Both scores were significantly higher after the implant was fitted, indicating that patients' quality of life was greatly improved by the implant. These positive outcomes are now benefitting the recipients of the 17,000 prostheses implanted from 2014-2020 [E2].

The VAIOS® implant continues to be implanted and has demonstrated excellent performance in service, gaining a rating of 5A from the UK Orthopaedic Data Evaluation Panel (ODEP) in recognition of its clinical performance [E9, E10].

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

E1. Patent: WO2008087415 Reverse Shoulder Prosthesis. https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2008087415

E2. Information from JRI Orthopaedics confirmed in letter from Mr Dennis Chung, member of the Board of Directors.

E3. Best New (Mechanical) Product at the British Engineering Excellence Awards in October 2010 (http://www.beeas.co.uk/2010/winners-2010.html).

E4. Design Futures Innovation Award at the Medilink Healthcare Business Awards in November 2011 (http://www.designfuturesgroup.com/design-futures-sponsors-medilink-innovation-award).

E5. Derbyshire man receives pioneering shoulder surgery. BBC News Article. http://www.bbc.co.uk/news/uk-england-derbyshire-14446866

E6. Sher et. al., Abnormal findings on magnetic resonance images of asymptomatic shoulders. J Bone Joint Surg, 77A (1995), pp. 10–15.

The following two publications occurred prior to the current impact period but are included to attest to the improvements experienced by patients receiving the VAIOs implant. These outcomes are, in part, the reason for the 17,000 global VAIOs implants to date and evidence of the benefits those 17,000 patients are experiencing over other implant models.

E7. Wallace et al., A Radiographic Analysis of 100 Uncemented Reverse Shoulder Arthroplasties from 2000 to 2011. Paper presented at the European Federation of National Associations of Orthopaedics and Traumatology (EFORT, www.efort.org/berlin2012) in May 2012, Ref. EFORT12-5117.

E8. Wallace et al. Early Outcome from a Versatile Shoulder Arthroplasty Designed for both Anatomical & Reverse Use. Paper presented at the European Federation of National Associations of Orthopaedics and Traumatology (EFORT, www.efort.org/berlin2012) in May 2012, Ref. EFORT12-5647.

E9. ODEP Rating for VAIOS® Reverse Uncemented Shoulder Replacement. https://www.odep.org.uk/product.aspx?pid=9617.

E10. Orthopaedic Product News online article, posted on the 23rd October, 2019. 15778http://www.opnews.com/2019/10/jri-orthopaedics-celebrates-gold-standard-rating-for-shoulder-replacement-system/.