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In vitro wear testing of a contemporary design of reverse shoulder prosthesis

S.L. Smith [a], B.L. Li [b], A. Buniya [c], S. Ho Lin [a], S.C. Scholes [a], G. Johnson [a], T.J. Joyce [a,*]

[a] School of Mechanical and Systems Engineering, Newcastle University, Claremont Road, Newcastle upon Tyne, NE1 7RU England, UK
[b] School of Engineering, Technology and Maritime Operations, Liverpool John Moores University, James Parsons Building, Byrom Street, England, UK
[c] Biomedical Engineering Department, Al-khwarizmi Engineering College, Baghdad University, Iraq

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ABSTRACT

Reverse shoulder arthroplasty is an increasingly common surgical intervention. However there are concerns and known limitations in relation to such joint replacement, while novel designs of reverse shoulder prostheses continue to appear on the market. Many claim to offer improvements over older designs but such assertions are difficult to validate when there is no consensus as to how such implants should be tested *in vitro* or even if such testing is necessary. In order to permit appropriate *in vitro* testing of reverse shoulder prostheses a unique, multi-station test rig was designed which was capable of applying motion in three axes to test prostheses. The shoulder simulator can apply up to 110° of motion in the flexion–extension and abduction–adduction axes and up to 90° in the internal–external rotation axis. Dynamic loading of up to 1500 N can be provided. The simulator is computer controlled so that the motions and loading associated with particular activities of daily living can be applied. A 4.5 million cycle wear test of commercially available reverse shoulder prostheses was undertaken using a 'mug to mouth' activity of daily living. Gravimetric analysis was used to characterise wear. After 4.5 million cycles of 'mug to mouth', the average wear rate of the test components was 14.3 mm^3/million cycles. Polyethylene test components showed a reduction in roughness and the median wear particle diameter was 167 nm. A three axis shoulder simulator has been designed and used to successfully test multiple samples of a commercially available reverse shoulder prosthesis.

1. Introduction

After hip and knee joint replacement, replacement of the glenohumeral joint is the third most common orthopaedic procedure. The latest National Joint Registry (NJR) for England, Wales and Northern Ireland reports that there were 3894 primary shoulder joint replacements in the year 2013 in these countries (Annual Report of the National Joint Registry for England, 2014). Most frequently performed was reverse shoulder replacement with 1363 (35%) procedures, followed by the standard total joint replacement with 1110 (29%) procedures. Of the 425 revisions of shoulder implants listed by the NJR for the same period 195 (46%) were revisions of reverse shoulders.

Reverse shoulder arthroplasty is a relatively new procedure in shoulder surgery which aims to salvage shoulders with rotator cuff-deficiency, arthritis, or those which are unstable and weak, and hence improve function and reduce pain. It has been noted that there are more than 20 companies marketing reverse shoulder implants and other manufacturers are developing new designs (Scarlat, 2013). Differences exist in terms of bearing materials. Whereas the conventional arrangement is for a cobalt chromium (CoCr) glenosphere articulating against an ultra high molecular weight polyethylene (UHMWPE) humeral component, some manufacturers have interchanged these materials (Kohut et al., 2012) and others have introduced a ceramic counterface.

It is recognised that the long term survival of artificial joints employing UHMWPE is limited by the wear of UHMWPE, and the body's reaction to its wear debris (Illgen et al., 2009). As recently as 2012, it was stated that 'To date, there are no wear studies in the literature comparing the different reverse total shoulder prosthesis designs currently available' (Vaupel et al., 2012).

Wear in reverse shoulder prostheses is a concern. In one study, 14 retrieved humeral polyethylene components were examined and it was stated that despite 'the short mean length of implantation (0.46 ± 0.5 years), scratching and abrasion were seen in 14 and 13 components, respectively, followed by third-body debris and pitting' (Nam et al., 2010). It is important to note that

* Corresponding author. Tel.: +0191 208 6214; fax: +0191 222 8600.
E-mail address: Thomas.joyce@ncl.ac.uk (T.J. Joyce).

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Table 1
Comparison of shoulder simulator studies.

Reference		Loading	Motion	Wear result	Notes
Muller et al. (2001)	Single-station. Ringers. 1 Hz	Constant 200 N	A swinging phase of 90° and axial rotation of ±30°	200,000 cycles. POM-C 10.02 ± 2.14 mm^3 and PEEK 1.64 ± 5.94 mm^3 respectively [50 and 8.2 mm^3/million cycles]	44 mm hemi-prostheses of POM-C and PEEK, both against bovine cartilage. Lubricant uptake of both polymers said to be important
Pijl et al., (2004)	Single-station. Newborn calf serum. 1 Hz	Between 150 and 660 N	Abduction–adduction 0–90–0°	2 million cycles. 45 mg/million cycles [47.6 mm^3/million cycles]	44 mm diameter CoCr head. Reciprocating motion. Weight loss to ASTM F1714-96
Geary et al. (2010)	Single station. 30% serum. 0.8 Hz	Biaxial loading. To 750 N lateral, 150 N superior	Biaxial motion. Abduction–adduction 50–120° and rotation 25–60°	Two tests to 1 and 2 million cycles. Average penetration rate of 0.16–0.39 mm/million cycles (mounted in Sawbone so gravimetric measurements inappropriate)	44 mm CoCr heads v 48 mm UHMWPE components. ADL of “hanging wet clothes on a washing line”
Swieszkowski et al. (2011)	Single station. 25% newborn calf serum. 1 Hz	From 150 to 650 N	Abduction–adduction movements to 90°.	3 million cycles. 38–54 mg. [13.4 mm^3 to 19.0 mm^3/million cycles]	44 mm diameter CoCr head. Reciprocating motion. Weight loss to ASTM F1714-96
Wirth et al. (2009)	Multi-station knee simulator. Bovine serum 62 g/l. 37 °C. 1 Hz	Constant 756 N	Abduction–adduction ±8° sliding translation ±2 mm; and elevation 0–8°	5 million cycles. 46.7 ± 2.6 mg/million cycles and 7.0 ± 0.4 mg/million cycles for UHMWPE and XLPE. [49.4 and 7.4 mm^3/million cycles]	Size 48 CoCr humeral with 6mm mismatch. Load soak controls employed
Vaupel et al. (2012)	Multi-station hip simulator. Bovine serum 21g/l	Alternated 20 to 618 N abduction, 20 to 927 N flexion	Abduction from 44° to 90°. Flexion arc 0–46°	5 million cycles. 126 mm^3/million cycles	36 mm diameter CoCr femoral heads as gleno-spheres, UHMWPE as humeral components
Kohut et al. (2012)	Multi-station hip simulator. Bovine serum 30 g/l. 1 Hz	250–1000 N	Flexion–extension 25° to −18° Abduction–adduction 7° to −4° internal external rotation 2° to −11°	500,000 cycles. 18.6 mg/million cycles for UHMWPE Glenosphere/CoCr and 13.2 mg/million cycles for CoCr Glenosphere/UHMWPE. [19.7 and 14.0 mm^3/million cycles]	36 mm diameter reverse prostheses. UHMWPE tested as glenoid and as glenosphere

Note: Where required, shown in […], wear rates have been converted to mm^3/million cycles to allow comparison between simulators.