Available online at www.sciencedirect.com

ScienceDirect

www.elsevier.com/locate/jajs

Original Article

Implant survivorship and clinical outcomes of the Bigliani-Flatow shoulder prosthesis at a mean of five years: A post-marketing surveillance study from three centres☆

A.J. Weusten [a,*], S.K. Khan [a], M.J. Lawson-Smith [a], J. McBirnie [b], W. Siebert [c], A. Rangan [a]

[a] The James Cook University Hospital, Middlesbrough TS4 3BW, United Kingdom
[b] New Royal Infirmary of Edinburgh, Edinburgh EH16 4SA, United Kingdom
[c] Vitos Orthopaedische Klinik, Wilhelmshöher Allee 345, 34131 Kassel, Germany

ARTICLE INFO

Article history:
Received 9 November 2014
Accepted 26 November 2014
Available online 21 January 2015

Keywords:
Bigliani-Flatow
Shoulder hemiarthroplasty
Total shoulder arthroplasty

ABSTRACT

Background: This is the first study to report survivorship and clinical outcomes of a third generation shoulder prosthesis [Bigliani-Flatow (BF)], comparing BF total shoulder arthroplasty (TSA) versus hemiarthroplasty (HA); and cemented versus uncemented implantation.

Methods: Prospectively collected data including Constant-Murley (CM) and Oxford Shoulder Scores (OSS) were analysed for clinical outcome and survivorship of 164 arthroplasties (164 patients) performed in three established shoulder arthroplasty centres. The mean follow-up was 65 months (range 46–111; SD 13.3).

Results: One hundred and five of 164 patients followed up at a mean of 5 years demonstrated implant survivorship of 96.6% (95% CI: 93.4%–99.9%). There was no significant difference between cemented and uncemented stems in implant survivorship [97.9% (CI: 93.9%–100%) v/s 95% (CI: 91.3%–100%)], or in final CM and OSS. Intra-operative blood loss was significantly less in uncemented stems ($p = 0.016$), and also in HA compared to TSA ($p = 0.004$). There were no significant differences between TSA and HA in functional outcomes and implant survivorship.

Discussion: The first outcome study of the BF prosthesis shows satisfactory survivorship and comparable functional outcomes at five years. Loss to follow up of surviving patients despite active, structured post-marketing surveillance underscores the need for mandatory joint registries.

☆ Presented as a free paper at the 13th 37 EFORT Congress at Berlin, May 2012 and 38 The British Elbow and Shoulder Society, Newcastle upon Tyne, UK, June 2011.

* *Corresponding author*. 13 Victory House, Oxford Street, Tynemouth NE30 4PR, UK. Tel.: +44 7906827825; fax: +44 1642 854375.
E-mail address: aweusten@yahoo.com (A.J. Weusten).

http://dx.doi.org/10.1016/j.jajs.2014.11.001

1. Introduction

The first shoulder arthroplasty was performed on a patient with glenohumeral joint destruction due to tuberculosis. However, almost 60 years passed before an implant with reproducible long-term function and pain relief was developed for widespread use.[1] Charles Neer devised an unconstrained shoulder implant for the treatment of proximal humeral fractures in 1951, starting a new era of shoulder arthroplasty.[2] Encouraged by the advances in hip arthroplasty, Neer redesigned his humeral component and added a polyethylene glenoid component.[3] A multitude of shoulder implants have been introduced since, and analysis of failure modes has led to further improvements in implant technology.[3–5] Understanding of potential factors that influence survivorship, long-term function and associated complications has led to changes in patient selection, implant geometry and cementing technique.[2,6,7] Monitoring of newly introduced implants is essential to aid this process and ensure safe clinical use.

The Bigliani-Flatow (BF) shoulder implant was introduced in 1999; it may be inserted as a hemiarthroplasty (HA) or as a total shoulder arthroplasty (TSA), with stem implantation being either cemented or uncemented. Results of the BF arthroplasty have not been previously published in literature. Our aim was to analyse the medium-term survivorship of the BF shoulder prosthesis from prospective post-marketing surveillance data. We also compared clinical outcomes of cemented versus uncemented humeral stems in a consecutive series of TSA and HA performed at three established shoulder arthroplasty centres.

2. Materials and methods

Between January 2001 and December 2005, 164 patients (164 shoulders) underwent shoulder arthroplasty with the Bigliani-Flatow prosthesis (Bigliani/Flatow Total Shoulder Solution; Zimmer, Warsaw, IN, USA) at three different centres in Europe (Fig. 1). Research regulatory approvals were obtained at all three centres for prospective data collection for this structured post-marketing surveillance study. Individual surgical preferences dictated the use of HA or TSA and the choice of cemented or uncemented stem. All included patients provided written informed consent for participation in the study. Data collected included patient demographics, body mass index (BMI), indications for surgery, type of operation (TSA or HA), method of fixation of humeral stem (cemented or uncemented), duration of surgery and intra-operative blood loss.

Two validated functional scores were selected for pre- and post-operative functional assessment.[8] Patients were asked to fill in the 12-item Oxford Shoulder Score (pre-revision) questionnaire when listed for surgery. Physiotherapists recorded the Constant-Murley score pre-operatively and at follow up, independent of the treating surgeons.[9,10] The range of motion was entered as a mean of two values recorded by two physiotherapists. Strength measurement was standardised using a calibrated load cell myometer. All post-operative Oxford Shoulder Scores were recorded when patients attended physiotherapy clinics.

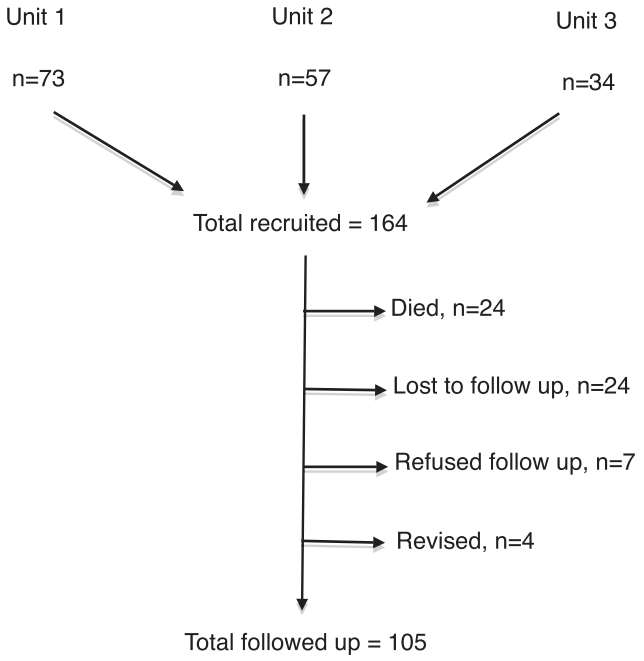

Fig. 1 – Recruitment and loss to follow up.

Differences between treatment groups (cemented versus uncemented; TSA versus HA) were assessed using the Mann–Whitney U-test for continuous variables. Nominal data were compared using either the Pearson's Chi square test (for variables with three or more expressions) or the Chi square test (for variables with two expressions). All tests were performed two-sided. Cumulative survival estimates of the BF prosthesis were assessed using the Kaplan–Meier method with 95% confidence intervals; the endpoint was defined as a revision or removal of any component. Differences of survival distribution between groups were assessed using the log rank test (Mantel–Cox). Results were stratified for cemented/uncemented and TSA/HA. Statistical analysis was performed with SPSS (version 19, SPSS Inc, Chicago, IL).

3. Results

The original cohort consisted of 51 men and 113 women, with mean age at the time of surgery being 67.3 years (range 28–92). Table 1 compares cemented and uncemented procedures, and TSA and HA in terms of distribution of gender, age, BMI and indications for surgery. The indications for surgery included osteoarthritis (OA; 45.1%), rheumatoid arthritis (RA; 21.9%), post-traumatic arthritis (12.2%), acute fracture (10.4%), avascular necrosis (6.1%) and psoriatic arthritis (1.8%). Sixty (36.6%) prostheses were implanted with cement. Thirty-one (18.9%) patients received a total shoulder arthroplasty. There were no significant differences between the three units in the primary indications for surgery, gender distribution, and in the proportions of cemented/uncemented and TSA/HA. Patients receiving cemented stems tended to be older overall ($p = 0.042$), but there were no significant differences in gender distribution or mean BMI between the treatment groups.