CLINICAL AND RADIOGRAPHIC MID-TERM OUTCOMES AFTER TOTAL SHOULDER REPLACEMENT: A RETROSPECTIVE STUDY PROTOCOL INCLUDING 400 ANATOMICAL AND REVERSE PROSTHETIC IMPLANTS

Giovanni Merolla¹,², Antonio Tartarone¹, Giuseppe Porcellini¹

¹Unit of Shoulder and Elbow Surgery, D. Cervesi Hospital, Cattolica, AUSL della Romagna Ambito Territoriale di Rimini - Italy
²Biomechanics Laboratory “Marco Simoncelli” D. Cervesi Hospital, Cattolica AUSL della Romagna Ambito Territoriale di Rimini - Italy

Corresponding author: Giovanni Merolla, MD
Unit of Shoulder and Elbow Surgery, “D. Cervesi” Hospital
AUSL della Romagna Ambito Territoriale di Rimini
L.V. Beethowen 5, code:47841 Cattolica - Italy
phone: +39 0541 966382 - fax: +39 0541 966312
email:giovannimerolla@hotmail.com; giovanni.merolla@auslrn.net

Principal investigator and promoter: Giovanni Merolla
Co-investigators: Antonio Tartarone, Giuseppe Porcellini

Investigation performed at the Unit of Shoulder and Elbow Surgery, D. Cervesi Hospital, Cattolica, AUSL della Romagna Ambito territoriale di Rimini – Italy


Approved by AV/IRST Ethical Committee (Comitato Etico Area Vasta Romagna) and authorized by AUSL della Romagna (Prot. 2198/2013/I.5/45) (“Deliberazione AUSL della Romagna “Analisi clinica e radiografica a medio termine della protesi totale anatomica e inversa di spalla”).

Abstract

Objectives: To obtain outcomes data on anatomical and reverse total shoulder arthroplasty by analysis of clinical scores and standard radiographs.

Subject selection and enrollment: 400 consecutive series of patients replaced with anatomical and reverse total shoulder arthroplasty (minimum 3 years follow-up).

Study Design: retrospective monocenter.

Preoperative assessment: Demographics, clinical scores (Constant-Murley) as available, shoulder X-ray (AP, outlet and axillary views).

Last follow-up: Postoperative radiographs and clinical scores. Adverse events and complications to be reported as occurred since implantation.

Statistical analysis: Data collected will be summarized and analyzed for statistical significance.

I. INTRODUCTION

Shoulder arthroplasty is an effective device to treat osteoarthritis and other degenerative conditions of the glenohumeral joint. Modern prosthetic implants allow a total replacement of the shoulder joint to gain a pain free range of motion, and as result this leads to a significant improvement in patient’s quality of life [1-8]. For over 30 years, orthopedic surgeons used anatomical and reverse prosthetic implants that ensured safety and reliability.

Indications for one or the other type of prosthesis depends on the quality of the rotator cuff (RC) tendons, reserving reverse arthroplasty for those with severe insufficiency of the RC [7]. In our Shoulder Unit both type of prostheses have been implanted to treat shoulder osteoarthritis and proximal humeral fractures, but the results previous published refer to small sample size and short-term follow-up.

II. PURPOSE

Aim of the current study will be to assess clinical and radiological outcomes of anatomical and reverse shoulder arthroplasty within a minimum 3 years follow-up (mean 8 years).

II. PATIENT AND METHODS

Study Design

The current research project refers to a retrospective observational study on a consecutive series of patients underwent to anatomical and reverse shoulder replacement with the prosthetic devices available at the Unit of Shoulder and Elbow Surgery of D. Cervesi Hospital in Cattolica (Italy) where the same patients were enrolled for preoperative clinical and radiographic exams.

Study population and enrollment

We foresee to enroll 400 subjects with anatomical and reverse total shoulder replacement (Zimmer, Tornier, Lima, Biomet) implanted between march 2005 and december 2013, to collect preoperative demographic and clinical data, technical data of intraoperative phase and postoperative clinical and radiographic outcomes at last follow-up.

Prosthetic design

Anatomical

Anatomical total shoulder arthroplasty assessed in this study includes: i) unconstrained monoblock or modular humeral components, ii) unstemmed hydroxyapatite
coated “corolla” impacted without cement in the humeral metaphysis (TESS®), iii). short stem prostheses with a prevalent metaphysal grip. Head prostheses available in several size, standard or with eccentric offset. Glenoid prostheses including: i) polyethylene components with keel or pegs, fixed in the cancellous bone with cement; the pegged gelenoid are also available with a flanged uncemented central peg to promote osseointegration, ii) standard metal-backed gelenoid fixed with screw and covered with a polyethylene liner, iii) trabecular tantalium-backed gelenoid (TMT®) fixed in the bone under pressure.

Reverse

Reverse prostheses assessed in this study is a semiconstrained totally modular device. The gelenoid component consist of a baseplate (metaglene), provided with a large central peg and secured to the native gelenoid by cortical screws (2 or 4), which may be straight or angled, on which is fit the gelenosphere (a rounded metal ball approximately two third of sphere) that is attached to the baseplate with a screw. The gelenosphere can be completely medialized or slightly lateralized, to prevent scapular neck erosion. The humeral component consists of a proximal cup-shaped portion and a metal stem to be press-fitted or cemented in the medullary canal. A radiolucent polyethylene insert sits in this cup portion and articulates with the gelenosphere. As for the anatomical implantants, also for reverse prostheses are available short stem having a predominantly metaphyseal grip.

Clinical and radiographic evaluation

Preoperative and postoperative clinical outcomes will be evaluated with the Constant-Murley score (CS) [9]. The CS includes a subjective questionnaire for pain, the ability to perform daily living activity (DLA), an objective evaluation of active range of motion (ROM) and strength. Pain will be scored on a 15 points scale (0 severe pain, 15 no pain), while DLA will be scored on a 20 points scale, with lower scores associated with greater impairment on DLA. ROM will be measured using a standard goniometer between the upper arm and the upper part of the thorax. Shoulder strength will be assessed using the Lafayette handheld dynamometer (Lafayette Instruments, Lafayette, Ind, USA), that has a microprocessor with a resolution of 0.4 lb (0.2 kg) in the range 0-50 pounds (0-22.6 kg), 0.03% accuracy with two calibration points: 0.25 and 50 lbs (0.11 and 22.6 kg). Data will be recorded and analyzed using SPSS v.10 software (SPSS Inc, Chicago, IL, USA). We will assign 1 point for each 0.5 kg of strength registered. Radiographic assessment included standard AP, outlet and axillary views. These radiograms were prescribed when the patient was discharged from Cervesi Hospital to be shown at the first follow-up visit (mean 2 months) and then advised at 6 months, and every years to assess implants features. Clinical and radiographic data of last follow-up will be compared with those performed annually to detect any pathological features of the implants. In anatomical prostheses the following parameters will be evaluated [10] orientation of the humeral component, translation of the humeral component, offset of the humeral head, size and height of the humeral head, acromio-humeral distance, distribution and fixation of the cement, stress shielding and cortical resorption, radiolucent lines, subsidence and tilt of gelenoid and humeral component, gelenoid loosening.

Axillary radiograph is the gold standard to assess subluxation of the prosthetic head in sagittal plane that can be classified based on direction and severity as:

Absent: the humeral head is centred in the gelenoid cavity
Slight: < 25% translation of the centre of the head component with respect to the gelenoid centre
Moderate: 25% to 50% translation of the centre of the prosthetic head with respect to the gelenoid centre
Severe: > 50% translation of the centre of the head component with respect to the gelenoid centre.

In patient with reverse arthroplasty the following radiographic features will be analyzed: Scapular notching classified according to Nerot et al [11], lucent lines around humerus, baseplate and screws, pillar spur, instability, component disassembly, baseplate mobilization or migration.

Inclusion criteria

Age: 18 years minimum.
Gender: male and female.
Informed Consent - patient or patient's legal representative has signed a “Patient Informed Consent form”.
TC or MRI to identify concentric osteoarthritis (Samilson grade III and IV) or eccentric osteoarthritis with irreparable rotator cuff tear

Exclusion criteria

Cognitive limitations that precluded a valid consent to be included in the study
Unwilling to be enrolled
Lack of appropriate patient information
Lost to the last follow-up

Statistical analysis

Data collected will be summarized descriptively. Summaries will routinely describe categorical data as counts and percentages, and ninety-five percent confidence limits will be generally used to assess differences between different implant configurations. Summaries describing continuous data will be in the form of means, medians, standard deviations, minima, and maxima, and ninety-five percent confidence intervals will be used to contrast differences. Routine summaries of implant survival, return to function, etc. (e.g. time to event) will generally be described via the Kaplan-Meier method and these will generally be accompanied with the corresponding crude rates (expressed as percentages). Routine summaries of complication data will be in the form of frequencies and percentages. Summaries may be further generated for strata within the study population.
A “serious adverse event” is synonymous with complication or medical event. This definition does not imply that there is a relationship between the untoward medical occurrence in a subject. This definition includes any event that is a result of a user error. An “adverse device effect” is defined as “an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event or that might have led to any of these consequences if suitable action had not been taken or intervention had not been made or if circumstances had been less opportune”. NOTE: The term “severe” refers to the intensity of the event and can be used with any event, without regard to whether or not it meets the criteria for being classified as “serious” or “unanticipated”. For example, a subject can have a severe headache, but it is not a serious event.

Reporting of Adverse Events and Adverse Device Effects

All adverse events which occur during the study will be reported and will identify the following:
- Description of symptoms
- Date of onset
- Severity of symptoms: mild, moderate, severe
- Relation to device: not related, uncertain, probably, definitely
- Treatment
- Outcome of treatment: resolved, tolerated, pending, study withdrawal, device removed/re-operation, death
- Additional comments

Ethical considerations

Patient Information and Informed Consent

The investigator must explain to each patient the nature of this retrospective study, including any risks and benefits, its purpose and procedures and expected duration of involvement in the study. Patients have full rights to withdraw from the study at any time, irrespective of their initial consent.

Subject Confidentiality

Confidentiality of patient data will be maintained at all times. Patient anonymity will be guaranteed and all documentation relating to a subject will be kept in a secure location.

Declaration of Helsinki

This study will be conducted in accordance with the relevant articles of the Declaration of Helsinki as adopted by the 18th World Medical Assembly in 1964 and as revised in Tokyo (1975), Venice (1983), Hong Kong (1989), South Africa (1996) and Edinburgh (2000).

References


Università degli Studi di Salerno