Do radiolucent lines and stress shielding of the humeral shaft really matter in shoulder arthroplasty?

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The purpose of this study is to evaluate at a mid-term follow up, the radiological survival of an uncemented humeral stem in shoulder arthroplasty. One hundred and twenty-six replacements including hemi (HA), total (TSA) and reverse (RSA) implanted from 1999 to 2008 were reviewed at a mean follow up of 7.2 years (48-144 months). The same uncemented triconical stem (SMR, Lima Corporate) was implanted. There were: 23 HSA, 43 TSA, 60 RSA. An independent observer evaluated all the patients with Constant Score. A radiologic analysis by an expert radiologist and an orthopaedic surgeon was performed: humeral component-bone interface was divided in seven zones. They judged a mobilisation if a migration or tilt of the humeral implant or if≥ 2 mm radiolucent line in at least three zones was present. Chi-squared test, Fisher test and analysis of variance were performed and a $p<0.05$ was considered statistically significant. No major radiological signs of loosening and no tilt or migration of the humeral component were found. Only 23 (18.2%) patients had no RL around the humeral implant. In the remaining 103 (81.7%) implants: 96 (76.1%) presented RL less than 2 mm, particularly 75 (59.5%) in less than 3 zones and 21 (16.6%) in more than 3 zones. Of the remaining 7 (5.5%) implants the presence of RL of 2 mm or greater in only one zone was seen. Apart from sepsis no revision was performed for humeral component loosening. Although a high rate of RL, uncemented humeral stem has an excellent survivorship at a mid-term follow up. Relationship between presence, position and depth of RL and internal stress shielding is commonly observed but does not appear to compromise quality of fixation or clinical outcomes in shoulder arthroplasty.

The history of modern shoulder replacement started with the uncemented press-fit monoblock hemi-prosthesis implanted by Neer in 1951 to treat proximal humerus fractures (1). This implant was first modified by the same author to make it suitable for the use of a polyethylene glenoid component (2) and subsequently the implant was redesigned for fixation with cement (3).

Although early results were good, many failures were observed over time because of different reasons according to the type of the implants.

Glenoid pain, due to bone erosion, was seen in patients with hemi-arthroplasty (4). Whereas in patients with total shoulder replacement, glenoid loosening was the main reason for failure (5). Today we are still debating over cementless metal back glenoid or cemented PE component (6, 7) and furthermore over a keeled or a pegged one (8). Ultimately, in both type of implants many failures were seen because of rotator cuff insufficiency (9).

In 1985 reverse implant was introduced by Grammont (10). Again, we had failure and revision

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because of instability of glenoid and scapular notching (11). The development of shoulder implants is ongoing with new design and new materials. We are probably far from the definitive type of shoulder replacement.

Many papers analysed complications and survivorship of shoulder arthroplasty. Humeral component complications are essentially grouped in periprosthetic fractures (intraoperative and postoperative), in malposition and in stem loosening (9). Different types of stem-less implants were recently introduced advocating less complications (12). However, a careful operative technique is probably the best prevention for intraoperative fractures and for malposition of the humeral component. Whereas it is quite difficult to prevent postoperative fracture.

Regarding humeral loosening, many papers in the literature discuss the long-term results of the humeral component in shoulder arthroplasty. Only a few papers analysed the radiological results of a shoulder humeral stem specifically designed for uncemented use in a large population at a mid-term follow-up (13-19). The purpose of this study was to evaluate at a mid-term follow up, the radiological survival of an uncemented humeral component in shoulder arthroplasty.

MATERIALS AND METHODS

We reviewed 126 shoulder replacements including hemi (HA), total (TSA) and reverse (RSA), at a mean follow up of 7.2 years (48-144 months), implanted from 1999 to 2008. In all cases, the same uncemented triconical stem (SMR system Lima Corporate, Villanova di San Daniele del Friuli, Italy) was implanted.

All stems are made of Ti6Al4V alloy. They are characterized by an outline with a triple conicity to guarantee the proximal fixation and the correct fit, reducing, in this way, the stress shielding phenomenon, independently of canal morphology. The first conicity fits well into cylindrical canals, while the second one suits the fluted geometry. The last one acts as guide avoiding the distal press-fit in canals with narrow cross section.

They are characterized by a finned design, to allow stable primary fixation of the component in the proximal part of the humerus during surgery. In addition, the proximal part of the stem is sand blasted to enhance surface roughness and therefore improve osteointegration and secondary fixation. The distal part is polished. Ten different diameters are available for uncemented conical stems (from 14mm to 24mm, increasing by 1mm for each size) with a length of 80mm for all sizes.

All the patients were clinically evaluated by an independent observer pre- and post-operatively with Constant Score (20). The radiological analysis was done with three plain film projections: 1. axillary view, 2. 40° posterior oblique radiograph with the arm in internal rotation and 3. external rotation executed preoperatively, immediate postoperatively and at the last follow up.

Humeral component-bone interface was divided in 7 zones (Fig. 1) as validated in the literature (17). Any change of position of the implant and the presence of radiolucent lines (RL) between the humeral component and the cortical bone interface, were analysed by an expert radiologist and an orthopaedic surgeon.

We specifically looked for radiological signs of loosening as follows: the component was judged at risk if at least one of the observers noticed a migration or tilt of the humeral implant or if both observers found ≥ 2 mm radiolucent line in at least three zones (21). In case

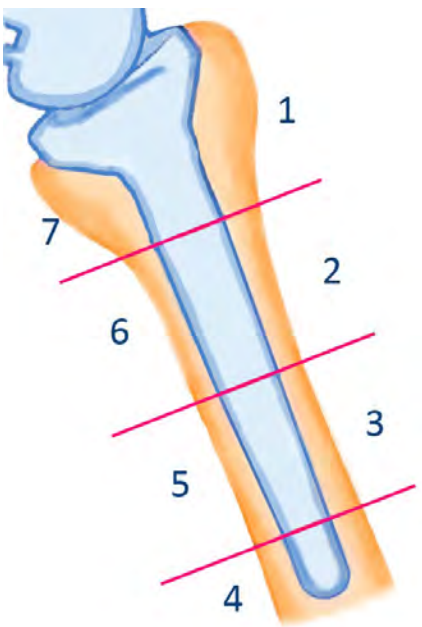

Fig. 1. *Humeral zones for radiographic analysis. The humeral stem is divided into 7 zones. Zones 1 and 7 are proximal to the junction of the metaphyseal component.*

of persistent pain or loss of motion or function with no radiological sign of loosening, a bone scan was performed.

Statistical analysis

A statistical analysis of the data was undertaken to evaluate the results with chi-squared test, Fisher test and analysis of variance for the comparison. We also performed the Wilcoxon's rank sum test, two sample t-tests and paired t-tests.A $p<0.05$ was considered statistically significant.

RESULTS

HSA was implanted in 23 cases; TSA was used in 43 cases and RSA in 60 cases. The indications for surgery were varied. These included proximal humeral fractures, osteoarthritis, rheumatoid arthritis and cuff tear arthropathy. The mean age at the time of surgery was 69.8 years (42-82 years) and there were 47 men and 79 women.

All patients were treated *via* a deltopectoral approach, subscapularis tenotomy (and then reattached at the end of the procedure with non-resorbable transosseous sutures). Osteotomy of the humeral head was done with the aid of an intramedullary guide. The humeral canal was prepared with increasing trial stems and stable fixation was assessed with traction manoeuvres. Then the remaining part of the procedure was completed according to the choice of the implant (HSR, TSR or RSR).

No patients had major radiological signs of loosening and there was no tilt or migration of the humeral component. However only 23 (18.2%) patients had no RL around the humeral implant.

In the remaining 103 (81.7%) implants, RL were seen as follows: in 96 (76.1%) implants, there was the presence of RL less than 2 mm, particularly 75 (59.5%) in less than 3 zones and 21, (16.6%) in more than 3 zones. Of the remaining 7 (5.5%) implants the presence of RL of 2 mm or greater in only one zone was seen.

There was no relationship between the presence of RL with type of implants (HA, TSA, or RSA) (Fisher's exact=0.829) or with sex (Fischer's exact=0.205). However, we did find a correlation between the presence of RL and increasing patient age at time of surgery (two-sample Wilcoxon rank-sum/Mann-Whitney test).

At the final follow up, Constant Score increased from a mean preoperative value of 27 points (range 7-38) to 58 points (range 24-78) ($p<0.0001$). Importantly, there was no relationship between the clinical results (Constant Score) and presence of RL (two-sample Wilcoxon rank-sum /Mann-Whitney test).

Apart from sepsis no revision was performed for complications associated with the humeral component. Revision surgery was performed in 21 (16.6%) cases: 14 implants (11.1%) were converted from HA or TSA to reverse prosthesis, due to rotator cuff failure or recurrent instability, 7 implants (5.5%) were retrieved due to sepsis and treated with a spacer and then revised with a two stage procedure to a RSA in 5 cases (3.9%) and to a HA with a special Cuff Tear Arthropathy Head in 2 patients (1.5%).

Seven (5.5%) patients reported persisting pain not related to any evident reason. They were all in the group with RL less than 2 mm and particularly 5 had RL in three zones and 2 in two zones. These patients were further investigated with three-phase bone scintigraphy using technetium (22) to better investigate the cause of pain. We found 4 (3.1%) patients with a positive bone scintigraphy for aseptic loosening of the humeral implant, but the patients declined a revision surgery.

DISCUSSION

Boileau, analysing the complications in a multicentric series of 1842 anatomical shoulder prosthesis with a cemented humeral component, had 1.5% of humeral loosening and a 0.3% revision rate due to stem loosening (22). Complications and survivorship of shoulder arthroplasty are treated in many papers published in literature (9, 23). Bohsali in a large review of the literature regarding complications in TSA found a prevalence of 1% humeral component complications in 2540 total shoulder arthroplasties, which represents 7% of all complications (3).

It appears that humeral loosening is not a frequent occurrence in evaluating shoulder replacements results. Very few papers specifically analysed the survivorship of the humeral component in shoulder

replacement (3, 13-19, 24).

Maynou reported the presence of RL in 50% of 40 humeral implants in TSA and the evidence of radiological loosening in two implants (5%) even if none required revision (25). This study included different types of implants with different types of fixation (29 cemented and 11 uncemented). It is quite difficult to make a comparison with other papers, but it was the first study to focus on humeral component results. Mayo Clinic group, produced many studies on humeral stem assessment in shoulder replacement.

In 2000, Sperling analysing 62 ingrowth Cofield TSA (Smith & Nephew, Memphis, TN, USA) found the presence of RL in 17.7% of the implants while six stems (9.7 %) were judged to be at risk of loosening (21). These results may be affected using a metal back glenoid which has been associated with a high risk of loosening (17).

Sanchez-Sotelo in 2001 analysed 72 Neer II (3M St Paul, MN, USA) implanted without cement and he found the presence of RL in 50% of the implants and 55.6% were judged to be at risk of loosening (18). It is important to underline that Neer II prosthesis was designed to be used with cement and that this group of patients were treated with HA or TSA. Therefore again, glenoid loosening could be an influencing factor in the high rate of humeral component judged to be at risk (17). Sanchez-Sotelo found a relationship between the presence of a glenoid component and presence and thickness of humeral RL (3). In fact, polyethylene particles resultant from wear of the glenoid component could be responsible for the presence of humeral RL.

Matsen using a tapered metaphyseal stem, (Global, Depuy Orthopaedics, Warsaw, IN, USA) implanted 127 shoulder replacements (HA and TSA) without cement and found 61% radiolucency lines around the implant, but only 8.3% of the RL were greater than 1 mm and no differences were seen between HA or TSA. Furthermore, they found no subsidence or shielding of the component and none of the implants were judged to be at risk of loosening according to the criteria by Sanchez-Sotelo (16, 18). Rahme analysing the radiological results in rheumatoid people using both cemented and press fit humeral components in a published randomized study, found no radiological loosening at 2 years follow up (15).

Verborgt reviewed 37 uncemented humeral stems (Neer II -3M St Paul, MN, USA) and he found 59% presence of RL with 41% greater than 2 mm. 19% were judged to be at risk (14). There was no association between age, sex, diagnosis and type of prosthesis, and there was no difference in term of Constant Score between implants at risk or not (14). Throckmorton reviewed 76 TSA with a press fitted stem with proximal porous coating and a cemented glenoid, 6.5% had RL and no implants was judged to be at risk (19).

Our study reveals a higher rate of RL, 81.7%, compared with literature, but no implant was judged at risk, according to criteria of Sanchez-Sotelo (18). It must be underlined that the presence of RL appears to be not related to type of implant (HA, TSA and RSA) or to sex and the only influencing factor was increasing patient age. We found 4 cases (3.1%) with a positive bone scintigraphy for aseptic loosening even in absence of radiological signs of humeral loosening. Therefore, the importance of RL in correlation with radiological failure should be reconsidered.

Analysing the literature, it seems that humeral loosening is not a major issue particularly with uncemented stems specifically designed to be used without cement. Examining 1584 humeral implants (HA and TSA, Neer II, Cofield I and II, cemented and uncemented), Cil found an 82.8% survivorship at 20 years, with the end point being revision or the removal of the humeral component (13). However, the main reason for revision of the stem in HA appears to be progressive arthritis of the glenoid and rotator cuff insufficiency. TSA glenoid loosening or PE wear were related to aseptic loosening of the humeral component, with only 2.2% of revision (13, 24). Internal stress shielding is commonly observed but does not appear to compromise quality of fixation or clinical outcomes (26). In a recent paper by Cole, stress shielding was found common at midterm follow-up in press-fit TSA but did not appear to affect functional outcomes (27).

In case of arthroplasty revision, it is obviously better to have a stable stem, able to host a reverse implant rather than to change the whole humeral component resulting in longer operative time,

increased duration of open wound (with a higher risk of sepsis), higher operating room costs, more difficult procedures, with need for bone osteotomy and a higher risk of periprosthetic fracture (28).

This study has some limitations. Although the data were prospectively collected, the consequent limitations of a retrospective review are present. When evaluating for radiolucent lines on radiographs, we did not perform our reliability analysis. Strengths of this study include a large sample size, blinding of reviewers to radiographic changes and clinical outcomes and a quite long follow-up.

Our results prove that although a high rate of RL, uncemented humeral stem has an excellent survivorship at a mid-term follow up. Relationship between presence, position and depth of RL and internal stress shielding is commonly observed but does not appear to compromise the quality of fixation or clinical outcomes in shoulder arthroplasty.

Compliance with ethical standards

All procedures performed for this study were in accordance with the Ethical Standards of the Institutional and National Research Committee and with the Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by the Institutional Review Board of our Institute. Written informed consent was obtained from all people included in the study.

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