■ SHOULDER AND ELBOW

Long-term outcomes of cemented *versus* cementless humeral components in arthroplasty of the shoulder

A PROPENSITY SCORE-MATCHED ANALYSIS

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Aims

In the initial development of total shoulder arthroplasty (TSA), the humeral component was usually fixed with cement. Cementless components were subsequently introduced. The aim of this study was to compare the long-term outcome of cemented and cementless humeral components in arthroplasty of the shoulder.

Patients and Methods

All patients who underwent primary arthroplasty of the shoulder at our institution between 1970 and 2012 were included in the study. There were 4636 patients with 1167 cemented humeral components and 3469 cementless components. Patients with the two types of fixation were matched for nine different covariates using a propensity score analysis. A total of 551 well-balanced pairs of patients with cemented and cementless components were available after matching for comparison of the outcomes. The clinical outcomes which were analysed included loosening of the humeral component determined at revision surgery, periprosthetic fractures, post-operative infection and operating time.

Results

The overall five-, ten-, 15- and 20-year rates of survival were 98.9%, 97.2%, 95.5%, and 94.4%, respectively. Survival without loosening at 20 years was 98% for cemented components and 92.4% for cementless components. After propensity score matching including fixation as determined by the design of the component, humeral loosening was also found to be significantly higher in the cementless group. Survival without humeral loosening at 20 years was 98.7% for cemented components and 91.0% for cementless components. There was no significant difference in the risk of intra- or post-operative fracture. The rate of survival without deep infection and the mean operating time were significantly higher in the cemented group.

Conclusion

Both types of fixation give rates of long-term survival of > 90%. Cemented components have better rates of survival without loosening but this should be weighed against increased operating time and the risk of bony destruction of the proximal humerus at the time of revision of a cemented humeral component.

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Fixation of the humeral component during arthroplasty of the shoulder with methyl methacrylate was introduced by Neer et al.[1] However, there are various complications, specifically in revision cases when removal of the cement can be difficult. Cofield[2] reported that in certain revision cases, it may be impossible to remove a cemented humeral component without destroying the proximal humerus. Cementless fixation has therefore became popular during the last few decades.[3] Cement has continued to be used in patients with a proximal humeral fracture,[4] and in some with osteoporosis or an inflammatory arthritis.[5]

A few studies comparing cemented and cementless fixation of the humeral component in different types of arthroplasty of the shoulder have been published, but they have mainly dealt with the radiographic findings,[6-8] have had a short follow-up with few cases,[3] and have not considered factors related to the patient, the design of the component or the surgical technique.

Our aim, in this study, was to compare the long-term outcomes of a large cohort of cemented and cementless humeral components for loosening observed at revision, and other aspects of fixation including operating time,

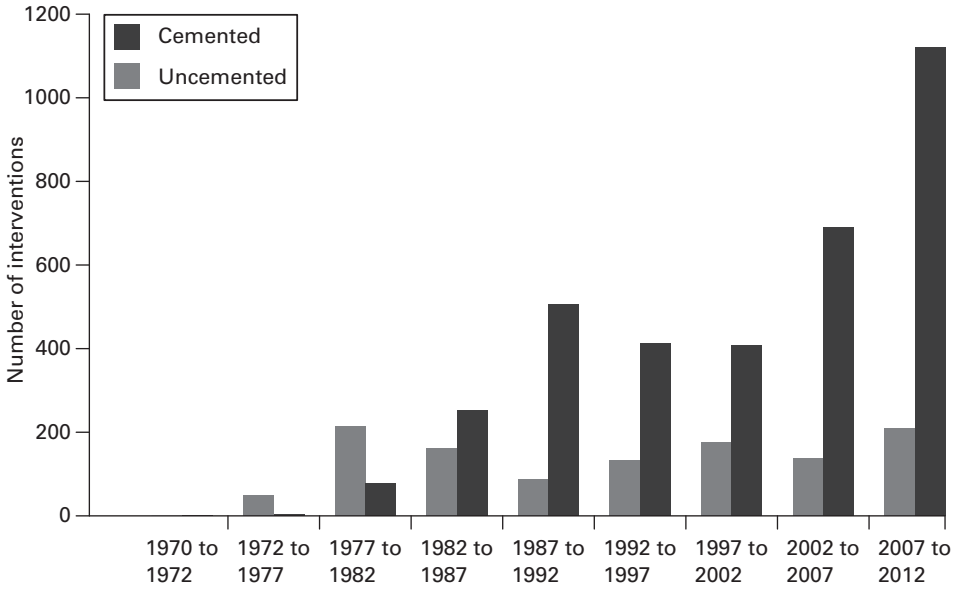

Fig. 1

Chart showing the distribution of cemented and cementless fixation of the humeral component over time.

periprosthetic fractures and infection using a propensity score (PS)-matched analysis.[9] PS analyses are statistical techniques for dealing with confounding bias in observational studies. This analysis can approximate that of a randomised controlled trial by directly comparing outcomes between two groups, one receiving the treatment of interest (treated subjects) and the other not (untreated subjects), by matching them with subjects with identical or close scores. The characteristics of the patient, context, and provider are used to calculate a PS for each patient (i.e., the probability that he or she will receive the intervention). This analysis can produce estimates that are less biased, more robust, and more precise than when using multivariable analysis. The PS method is very reliable when used in epidemiological studies,[10] and is particularly useful in surgical studies when randomisation is difficult.[11]

Patients and Methods

This is a retrospective analysis of prospectively gathered data from the total joint registry of the Mayo Clinic, which contains the records of all patients who underwent different types of arthroplasty of the shoulder since 1969.[12] There is pre-, intra- and post-operative data for all patients. Patients are routinely reviewed clinically and radiographically one, two and five years post-operatively and every five years thereafter. Those who are unable to attend are sent a standardised, validated questionnaire[13] in order to assess function and satisfaction. Patients are also requested to obtain appropriate clinical and radiographic data from a local orthopaedic surgeon. Complications including loosening, fracture, infection and further surgery are recorded. A detailed review of the clinical notes, including the operation notes and any notes relating to infection and those who suffered a complication, was undertaken by one of the authors (JDW).

All patients who were aged >18 years, who underwent surgery between 1970 and 2012 and had a cemented or cementless arthroplasty of the shoulder (total, hemi or reverse), with a minimum follow-up of two years were included in the study. Patients whose arthroplasty was performed for resection of a tumour were excluded.

Surgical technique. The operations were performed under general anaesthesia with the patient in the beach chair position, by 45 surgeons. Once cementless components were designed and approved by the Food and Drug Administration, the decision to use cement was made at the discretion of the surgeon (Fig. 1). If the component seated firmly, with or without the addition of some metaphyseal allograft from the humeral head, a press-fit was used. If the fit was not firm, or there was osteopenia, cement was used.

Two techniques of introducing cement have mainly been used. First and initially, the technique was as Charnley suggested[14] for the femur using irrigation, suction, drying with swabs, and then introducing the cement with a doughy texture from proximal to distal. Secondly, beginning in the mid-eighties,[15] with a distal plug, meticulous preparation of the canal with pulsed lavage, drying with swabs and introducing the cement in a liquid state from distal to proximal using a long tipped syringe. Before introducing the component, the cement was pressurised with a thumb using the first method and with a rubber-like washer on the syringe using the second method.

Between 1970 and 1985, the Neer I (3M, Saint Paul, Minnesota) and II (Zimmer Biomet Inc., Warsaw, Indiana) components were usually used. These were designed to be cemented and were lightly textured and cylindrical with a slight proximal conical expansion. Between 1985 and 1995, the Cofield-1 component (Smith & Nephew, London, United Kingdom) was usually used. This could be used with or without cement, was cylindrical with a slight proximal conical expansion and, like the Neer, was monoblock. Between 1995 and 2008, the Cofield-2 component (Smith & Nephew) was usually used. This was designed to be used with or without cement and was cylindrical with a slight proximal conical expansion. It was also modular and had more sizes and a stem holder. Several different designs of humeral component have been used since 2008 including: the Neer I and II components (3M, Saint Paul, and Zimmer Biomet Inc., respectively), the Cofield 1 and 2 components (Smith & Nephew), the Comprehensive component (Biomet, Zimmer Biomet Inc.), the Aequalis component (Tornier, Bloomington, Minnesota), the DePuy Global component (DePuy, Warsaw, Indiana), the Delta component (DePuy), the Encore RSP component (DJO Global, Vista, Californa) and the Stryker Reunion component (Stryker Corp., Kalamazoo, Michigan). With these cylindrical components which have a slight proximal conical expansion, it was possible to achieve a firm press-fit in the humeral canal and the metaphysis.

These different components were grouped into categories based on their design and on whether or not their surface allowed the ingrowth or ongrowth of bone. Therefore "appropriate" implants were either implants not designed for fixation to bone which had not been cemented, or implants designed for fixation to bone which had been cemented.

Outcomes. The primary outcome was aseptic loosening of the humeral component. Secondary outcomes included: intra- or post-operative humeral fracture, infection and operating time.

Loosening was determined at the time of revision surgery. The indications for revision depended on the clinical and radiographic findings. Some components were grossly loose and could be easily removed from the humerus. Others were tested. If the component was monoblock, it was rotated, and displaced anteroposteriorly and mediolaterally. If there was any movement, it was removed with an impactor. If there was no movement, it was considered to be tight. For the modular components, the humeral head was removed and force was applied in rotation using the stem holder in the anteroposterior and mediolateral directions. If there was movement, it was considered to be loose and if there was no movement, it was considered to be tight. The date of diagnosis of loosening was considered to be from the first date of further symptoms in the records. Patients with radiological evidence of loosening, who did not undergo further surgery were considered to have a well-fixed component.

Intra- and post-operative humeral fractures were classified according to the Mayo classification.[16] Infection was defined by the presence of a positive culture of synovial fluid, positive culture of synovium or bone, intra-operative findings or positive blood culture associated with a presentation suggestive of infection. Superficial infections due to an infected suture or stitch abscesses were not analysed.

Statistical analysis. Continuous variables are summarised as mean (standard deviation (SD)) or as median (interquartile range (IQR)). Categorical variables are summarised by frequencies and percentages. Multivariate imputations by chain equation to impute missing values were used. Multiple imputation is the method of choice for missing data problems;[17] we used five multiple imputations. The PSs were analysed as described by Mitra and Reiter.[18]

In order to reduce the influence of selection bias for the surgical choice between cemented and cementless arthroplasty, we used a PS-matched analysis. Analysis is performed in three steps (PS calculation, construction of pairs, assessment of imbalance). In the first step, we calculated the PS from a logistic regression for each patient. The selection of variables included in the model was guided by clinical expertise and review of the literature. Selected variables included: age, gender, side, body mass index, diagnosis, history of previous surgery, type of implant (total shoulder arthroplasty (TSA), hemiarthroplasty (HA) or reverse, shoulder arthroplasty (RSA)), decade of surgery, surgeon, and "appropriateness" of the humeral component. In the second step, we matched one patient who was treated using a cemented component with one who was treated using a cementless component with an identical or close PS. The matching procedure was realised without replacement and with a greedy algorithm (where a treated subject is first selected at random). The nearest neighbour technique, with a predefined caliper of 0.2 of the SD of the logit of the PS, was used. In the third step, we assessed the comparability of the two groups. A successful matching procedure is inferred if residual imbalance as measured by standardised difference (d) is small for all baseline characteristics.[9] A value of $d < 0.1$ has been empirically considered as acceptable.

The overall survival of the component was calculated from the whole sample. All comparisons between cemented and cementless components were done on the matched samples. Survival curves for the two groups were plotted using the Kaplan–Meier method and compared with the log-rank test. A p-value of < 0.05 was considered statistically significant. Similar survival analyses were undertaken for fracture and infection. The mean operating time and rates of intra-operative fracture were compared using parametric tests (Student's *t*-test and chi-squared respectively). The analyses were undertaken using R (version 13.0, R Development Core Team, Vienna, Austria).

Table I. Patient and treatment characteristics

	All patients (n = 4636)		
Variable	**Cemented, n = 1167 (%)**	**Cementless, n = 3469 (%)**	**Standard mean difference**
Age (yrs)	65.5 SD 13.8	66.5 SD 11.9	0.07
Gender (female)	401 *(34)*	1668 *(48)*	**0.28**
Left side	503 *(43)*	1469 *(42)*	0.01
Body mass index	28.9 SD 6.4	29.7 SD 6.3	0.09
Diagnosis			
OA	215 *(18)*	1844 *(53)*	**0.77**
RA	194 *(17)*	380 *(11)*	**0.16**
CTA	249 *(21)*	654 *(19)*	0.06
Acute fracture	200 *(17)*	36 *(1)*	**0.58**
Post-traumatic	222 *(19)*	393 *(11)*	**0.21**
Other	87 *(8)*	162 *(5)*	**0.11**
Prior shoulder surgery	256 *(22)*	616 *(18)*	**0.1**
Type of implant			
TSA	372 *(32)*	2539 *(73)*	**0.9**
HA	565 *(48)*	693 *(20)*	**0.6**
RSA	230 *(20)*	237 *(7)*	**0.4**
Appropriate stem	877 *(75)*	3044 *(88)*	**0.32**
Decade of surgery			
1970s	164 *(14)*	7 *(0.2)*	**0.55**
1980s	315 *(27)*	627 *(18)*	**0.21**
1990s	256 *(22)*	871 *(25)*	0.07
2000s	344 *(29.5)*	1449 *(41.8)*	**0.25**
2010s	88 *(7.5)*	515 *(15)*	**0.23**

Bolding represents values not statistically acceptable (standard mean difference > 0.1)
OA, osteoarthritis; RA, rheumatoid arthritis and other inflammatory diseases; CTA, cuff tear arthropathy;TSA, total shoulder arthroplasty; HA, hemiarthroplasty; RSA, reverse shoulder arthroplasty

Results

Between 1969 and 2012, 4636 patients underwent arthroplasty of the shoulder; 1167 humeral components were cemented, 272 with antibiotic-loaded cement, and 3469 were cementless (Table I). A total of 152 patients who had an arthroplasty performed for a tumour were excluded. The overall mean follow-up was 7.3 years (2 to 35). After PS matching, the outcome could be compared for 551 well-balanced pairs of patients (cemented and cementless humeral components). The clinical and pathological characteristics of the patients are shown in Table II.

The rates of survival at five, ten, 15 and 20 years for all patients were 98.9% (95% confidence interval (CI) 98.6 to 99.3), 97.2% (95% CI 96.5 to 97.9), 95.5% (95% CI 94.4 to 96.6) and 94.4% (95% CI 92.9 to 95.9), respectively. The rate of survival without humeral loosening at 20 years was 98% (95% CI 97.0 to 99.1) for cemented components and 92.4% (95% CI 90.1 to 94.8) for cementless components (Fig. 2). After PS matching including appropriate component fixation, according to the design of the component, humeral loosening was found to be significantly higher in the cementless group. Survival without humeral loosening was 98.7% (95% CI 97.5 to 100) for cemented components and 91.0% (95% CI 86.3 to 95.9) for cementless components at 20 years ($p < 0.01$) (Fig. 3).

After PS matching, intra-operative fractures were found in 11 patients (2%) who were treated with a cemented component and nine (1.63%) who were treated with a cementless component ($p = 0.08$). The rate of survival without post-operative fracture was not statistically significant (Fig. 4) ($p = 0.42$). The rate of survival without deep infection (Fig. 5) was significantly higher in the cemented group ($p = 0.044$). The mean operating time was 171 minutes (SD 81) for the cementless group and 222 minutes (SD 86) for the cemented group (Fig. 6; $p < 0.001$).

Discussion

This is the first large study to compare loosening of the humeral component following arthroplasty of the shoulder between cemented and cementless components using a PS, to minimise the effect of unbalanced covariates and taking the presence of competing risks into account. Our main findings were that both methods of fixation lead to good long-term outcomes with > 90% survival at 20 years. Failure of the humeral component is a rare indication for revision[19,20] and good results with both types of fixation have also been reported previously.[2,21,22] PS analysis from 4636 patients suggests that the long-term outcome depends on the method of fixation of the humeral component. The rate of loosening of the component was significantly higher in cementless components. This could be related to the fact that cementation may delay or prevent the passage of polyethylene wear particles into the humeral canal[23,24] and thus decrease the rate of loosening. In addition, cementing the humeral component decreases rotational micromotion.[24] Our findings

Table II. Patient and treatment characteristics with propensity score-matched patients

	All patients (n = 1102)		
Variable	**Cemented n = 551 (%)**	**Cementless n = 551 (%)**	**Standard mean difference**
Age (yrs)	65.3 SD 14	64 SD 14	0.09
Gender (female)	206 *(37)*	201 *(36)*	0.02
Left side	239 *(44)*	233 *(42)*	0.02
Body mass index	28.5 SD 6.2	28.6 SD 6.6	0.09
Diagnosis			
OA	157 *(28.5)*	150 *(27)*	0.03
RA	110 *(20)*	123 *(22)*	0.06
CTA	91 *(16.5)*	94 *(17)*	0.01
Acute fracture	51 *(9)*	30 *(5.5)*	**0.14**
Post-traumatic	99 *(18)*	116 *(21)*	0.09
Other	43 *(8)*	38 *(7)*	0.07
Prior shoulder surgery	101 *(18)*	118 *(21.5)*	0.07
Type of implant			
TSA	244 *(44)*	237 *(43)*	0.02
HA	262 *(48)*	251 *(45)*	0.04
RSA	45 *(8)*	63 *(12)*	**0.11**
Appropriate stem	366 *(66)*	361 *(65)*	0.02
Decade of surgery			
1970s	10 *(1)*	6 *(1)*	0.06
1980s	216 *(39)*	228 *(32)*	0.04
1990s	146 *(28)*	133 *(30)*	0.05
2000s	160 *(29)*	152 *(31)*	0.03
2010s	19 *(3)*	32 *(6)*	**0.11**

Bolding represents values not statistically acceptable (standard mean difference > 0.1)
SD, standard deviation; OA, osteoarthritis; RA, rheumatoid arthritis and other inflammatory diseases; CTA, cuff tear arthropathy; TSA, total shoulder arthroplasty; HA, hemiarthroplasty; RSA, reverse shoulder arthroplasty

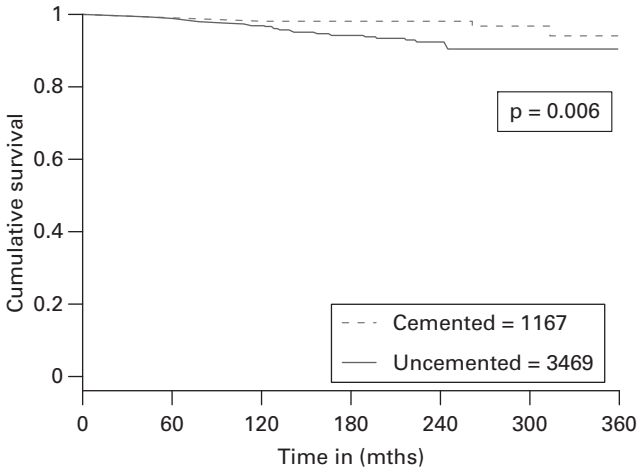

Fig. 2

Graph showing the overall survival without aseptic loosening for cemented and cementless humeral components (including 95% confidence intervals).

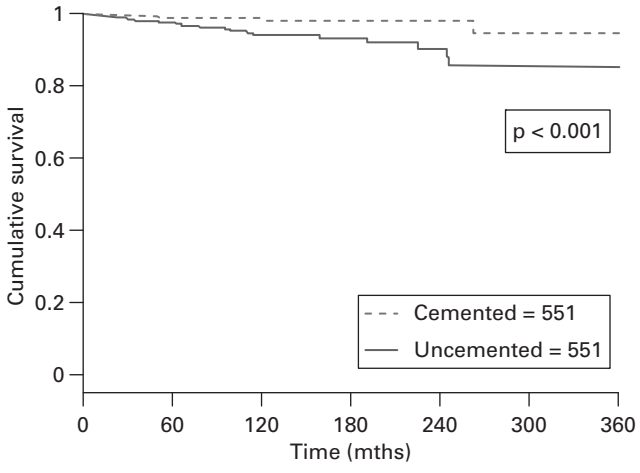

Fig. 3

Graph showing the survival without aseptic loosening for cemented and cementless humeral components after propensity score-matching (including 95% confidence intervals).

are consistent with those of other studies which have shown higher rates of humeral radiolucent lines and migration with cementless components.[25-27] However, recent authors have not found a difference in the rates of loosening between cemented and cementless components following RSA.[27,28] This could be due to insufficient follow-up as the mean follow-up in these studies was about 40 months.

Theoretically, the risk of intra-operative fracture should be higher with cementless components as more vigorous impaction is required. This impression, however, was not confirmed in our study. Singh et al[29] recently reported no correlation between the type of fixation of the humeral component and periprosthetic fractures both intra- and post-operatively. This, however, is in contradistinction to a recent meta-analysis including 1783 RSAs, which showed a

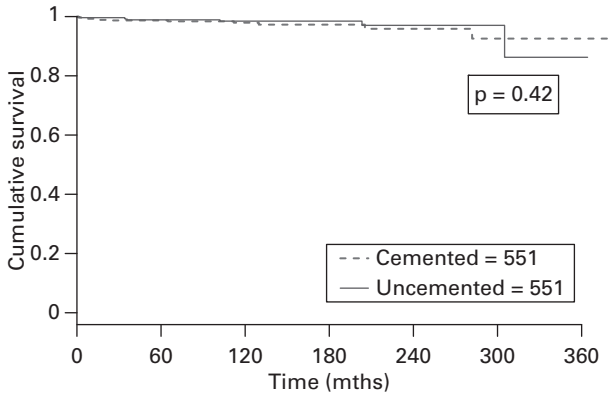

Fig. 4

Graph showing survival without post-operative humeral fracture for cemented and cementless components after propensity score-matching.

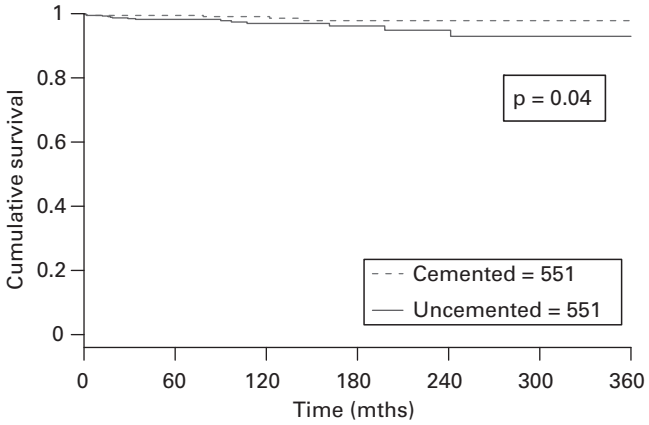

Fig. 5

Graph showing survival without infection for cemented and cementless components after propensity score-matching.

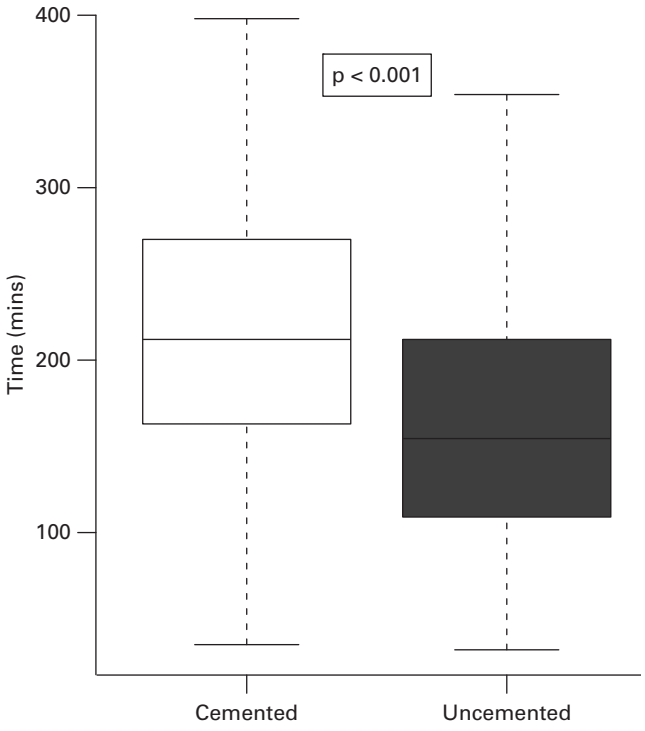

Fig. 6

Box plot showing comparison of mean operating times after propensity score-matching.

greater relative risk ratio of intra-operative humeral fracture with cementless components.[30]

The risk factors for periprosthetic infection after arthroplasty of the shoulder have been examined in several studies. The main factors that were found were gender,[31-33] age,[31,32,34] the design of component used to treat a fracture[32] and RSA.[32] Singh et al[31] did not find that the use of cement had any significant effect on the incidence of post-operative infection. However, in this study, a component was considered to be cemented if either the humeral and/or the glenoid component had been cemented.

The cement used in our series was often impregnated with vancomycin or gentamycin, which could explain the difference in the infection-free rate of survival between the two groups. Recent studies have suggested that antibiotic-loaded cement decreases the rate of infection after primary arthroplasty of the hip, knee and shoulder arthroplasty.[35-37]

Litchfield et al[3] found, in a prospective randomised study, that cement could also have an impact on the functional outcome. They reported that patients with a cemented humeral component had a better quality of life, strength and range of movement, than those with a cementless component. They mentioned, however, that the component used in their study (Biglani/Flatow Total Shoulder Solution; Zimmer Inc.) was not specifically designed to be used without cement although it is commonly used in this fashion.

The beneficial effects of cement on the risk of aseptic loosening and on the quality of life must, however, be counterbalanced by the advantages of cementless fixation.

The operating time was significantly shorter when cementless components were used. Although this did not correlate with a decreased risk of infection, shorter operating time reduces the cost.

Finally, and importantly, revision of a proximally coated cementless component may lead to less destruction of bone. Attempts to remove a well-fixed cemented component may require a cortical window or split to remove the cement, in addition to the use of allograft to reconstruct the proximal humerus.[38] We have previously reported the clinical results of revision of the humeral component for aseptic loosening.[39] Surgery was complex due to bone deficiencies with the need for bone grafting with longer or custom-made components being required in many patients, and complications were common for revision of both cemented and cementless components including intra-operative fractures and the extrusion of cement.

This study has three main limitations. First, it was from a single institution, which questions the applicability of the results generally. However, the large number of surgeons involved (45) may enhance the applicability of the findings. Secondly, the study included the design of components between 1970 and 2012, with many changes in technique including two different generations of cementing. However, cementless components evolved during this time and PS analysis matched the decade of surgery, limiting this potential bias. Thirdly, the matching procedure did not perfectly balance the baseline characteristics. Three characteristics were still not considered to be "statistically acceptable" after matching. However, we decided not to re-do the matching procedure because it had been specified in the protocol and the standard mean difference was just above 0.1.

The strengths of the study are the large size of the cohort, the length of prospective follow-up and the matched analysis of all patients included in our institutional registry.

In conclusion, both cemented and cementless fixation show excellent results, with rates of long-term survival of > 90%. Cemented components have better rates of survival without loosening, but this should be weighed against longer operating time and the risk of bony destruction of the proximal humerus at the time of revision of a cemented humeral component. Better rates of survival can also be expected with newer designs of cementless components which allow ingrowth and have sizes with increments of 1 mm.

Take home message:

- Both cemented and cementless stem fixation give rates of long-term survival of > 90%.

- Cemented components have better rates of survival without loosening but this should be weighed against the risk of bony destruction at the time of revision.

Author contributions:
J-D. Werthel: Wrote the manuscript, Collected data.
G. Lonjon: Statistical analysis.
S. Jo: Data collection.
R. Cofield: Scientific advisor, Helped edit the manuscript.
B. T. Elhassan: Scientific advisor, Helped edit the manuscript.
J. W. Sperling : Scientific advisor, Helped edit the manuscript.

Each author certifies that his or her institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

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