High Rates of Occult Infection After Shoulder Fracture Fixation: Considerations for Conversion Shoulder Arthroplasty

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Abstract *Background:* Existing hardware may contribute to increased risk of bacterial contamination and subsequent periprosthetic joint infection (PJI) in conversion shoulder arthroplasty performed for failed fracture fixation. *Questions/Purposes:* This study examined the incidence of positive pre-operative aspiration and inflammatory marker data, along with correlation of pre-operative positive aspiration or inflammatory markers and subsequent infection following conversion shoulder arthroplasty for failed open reduction and internal fixation (ORIF) and the need for re-operation at 4.6-year follow-up. *Methods:* Twenty-eight patients who underwent conversion to shoulder arthroplasty for any reason after fracture fixation were retrospectively reviewed in a single center. A pre-operative aspiration was

done in 17 patients; all patients had intra-operative tissue sampling. All procedures were single-stage removal of hardware and performance of the arthroplasty. In cases of pre-operative positive bacterial growth, a single-stage procedure was performed according to the septic ENDO-Klinik protocol. *Results:* In 4 of 17 pre-operative joint aspirations, bacterial growth was detected; one pre-operative negative aspiration demonstrated bacterial growth in intra-operative sampling. In three of them, the infection has been validated through intra-operatively results. Pre-operative aspiration showed a sensitivity of 75% and specificity of 92% ($p < 0.005$) for infection. No post-operative PJIs were observed. Six revisions were performed, most commonly for aseptic loosening (two cases) and conversion of hemiarthroplasty to a reverse design (two cases). *Conclusions:* In conclusion, the risk of low-grade shoulder infection after fracture osteosynthesis may be higher than in hip and knee joints, based on limited study data. Adequate pre-operative testing is recommended to rule out occult shoulder infection in this setting.

Level of Evidence: Therapeutic study Level IV

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Introduction

The rising number of humeral fractures undergoing operative treatment is related to a growing elderly population and an increase in the number of patients with osteoporosis [7, 16, 18]. Alternatively, these fractures can be treated by intramedullary nailing or with open reduction and internal fixation with plates and screws. Despite efforts to reduce the number of post-operative infections after fracture fixation, including routine perioperative antibiotic therapy and improved surgical technique, there still exists an important

number of infections of the shoulder after implantation of fixation devices. The reported rates of infection range from 0 to 8% after open reduction and internal fixation (ORIF) or closed reduction and extramedullary or intra-medullary fixation (CRIF) [10, 1]. On the other hand, the reported rate of infection ranges from 0 to 3.9% after primary total shoulder arthroplasty (TSR), increasing up to 18.8% after a reversed implant technique [2, 4, 8, 9, 22].

When a TSR or hemiarthroplasty (HA) is performed in the setting of previously failed primary fracture fixation (e.g., for humeral head necrosis, non-union, or malunion), special consideration must be given to occult shoulder infection at the time of arthroplasty. Bacterial contamination may cause low-grade infection associated with the previously implanted fixation device. Consequently, some authors have suggested performing a two-staged procedure, which involves removing the plate fixation first, and, second, implanting a joint prosthesis. In contrast, in the knee and hip literature, it has been demonstrated that there is only a minor risk for periprosthetic infection in patients with pre-existing fixation devices [13, 15]. There is only limited information regarding the risk for periprosthetic infection of conversion SR in the context of salvage arthroplasty after failed ORIF or CRIF.

The aim of this retrospective study was to evaluate the incidence of possible bacterial contamination or low-grade infection of pre-existing fracture fixation metal hardware in the shoulder, especially when no overt clinical signs of infection are observed prior to the arthroplasty. The aims of this study were (1) to determine the incidence of positive pre-operative aspiration and inflammatory markers in these cases of failed osteosynthesis, (2) to document the outcomes of the conversion shoulder arthroplasties in this series, and finally, (3) to calculate the correlation between pre-operative positive aspiration or inflammatory markers with pre-operative infection of the conversion arthroplasties as well as other complications requiring additional surgery in this series out to 4-year follow-up.

Patients and Methods

A retrospective study design was chosen. Via the clinical database between December 2002 and April 2012, a total of 32 patients had been found, who were treated with conversion to shoulder arthroplasty with pre-existing fixation devices. Patients with previous known shoulder infection or clear clinical signs of infection, in case of the presence of a fistula, prior to the arthroplasty were excluded. There is a lack of a guideline for infected fixation device like for periprosthetic infection as published by the Musculoskeletal Infection Society (MSIS) [20]. For this reason, the guideline was modified, so that a fixation device was rated infected when two different microbiological samples showed bacterial growth or if a histo-pathological sample showed infected tissue in combination with bacterial growth in one probe. Six men, with an average age of 67 years (range, 56 to 89 years), and 22 women, with an average age of 69 years (range, 47 to

84 years), comprised the study group. The average follow-up was 4.6 years (range, 1 to 11 years).

In this series, there were 23 proximal humeral fracture, 4 glenoid fracture, and 1 humeral shaft fracture treated by plate fixation in 19 cases, 6 by intra-medullary nail fixation, and 3 by screw fixation only (Table 1).

From primary osteosynthesis to implantation of the arthroplasty, the mean time was 1.6 years (range, 1 month to 13 years). In three patients, surgical revision of the osteosynthesis was performed prior to the conversion arthroplasty. A re-fracture necessitated revision osteosynthesis in one patient. In the other two patients, a partial removal of the fixation device was performed due to incorrect implantation due to a failure of surgical technique. All of these revision fixation surgeries were performed at outside institutions.

In 17 (61%) of the patients, a joint aspiration was performed before the arthroplasty was performed. The decision to perform a aspiration was based on the specific surgeon experience. If antibiotics had been given (e.g., because of urinary tract infection), they were stopped 2 weeks before aspiration. Synovial fluid samples were cultured for 2 weeks. In all patients, pre-operative laboratory testing of serum C-reactive protein (CRP) and white blood cell (WBC) count were performed.

The standard delto-pectoral approach was used in all arthroplasty implantations. All fixation devices were removed completely, and a minimum of three microbiological culture tissue samples were taken around the fixation device and joint. All samples were cultured for 2 weeks. The antibiotic prophylaxis consisted of a cephalosporin administered after microbiological samples were obtained.

Except for one, all arthroplasty prostheses were cemented. In 20 patients, a reverse prosthesis was necessary due to concomitant rotator cuff insufficiency (8 Delta, DePuy, Sulzbach, Germany; 12 anatomical inverse, Zimmer, Freiburg, Germany). Two patients were treated

Table 1 Descriptive data for the patient cohort

Indication for primary fracture fixation	Number
Humeral head fracture	12
Subcapital humerus fracture	11
Fracture of the glenoid	4
Fracture of the humerus	1
Fixation-device utilized	Number
Fixation plate	19
Intra-medullary nail	6
Screws	3
Diagnosis prompting shoulder replacement	Number
Pseudoarthrosis	15
Arthritis	7
Humeral head necrosis	4
Malunion	2
Risk factors for infection	Number
Diabetes mellitus	4
Steroid therapy	3
Cancer	2

with a hemi-arthroplasty (anatomical shoulder, Zimmer, Freiburg, Germany), and one with a total joint arthroplasty (anatomical shoulder, Zimmer, Freiburg, Germany). A hemiprosthesis with a bipolar head was used in another four patients (anatomical shoulder, Zimmer). In one patient, a cementless stem-less shoulder prosthesis (Eclipse, Arthrex Inc, Naples, USA) was used.

Also, all patients in which a pre-operative bacterial organism was detected underwent a one-stage procedure, with removal of the infected fixation device and implantation of a cemented prosthesis in accordance with our strict institutional protocols (akin to our published hip and knee protocols) [14, 12]. This protocol for one-stage exchange of infected prosthesis requires the knowledge of the specific resistance profile of the affecting organism prior to implantation of a prosthesis and is critical for the success of the septic protocol. After an extensive surgical debridement of all infected tissue and all foreign materials, the joint will be cleaned with polyhexanide (Lavasept, Fresenius-Kabi Ag, Bad Homburg, Germany). The new prosthesis will be fixated with bone cement with the specific admixed antibiotic (concentration of antibiotic up to a maximum of 10%). The choice of antibiotic is always made in consultation with our microbiologist. At the same time, a specific course of systemic antibiotic treatment starts for around 14 days. The definitive length of antibiotic treatment is influenced by the clinical picture, wound healing, and improvements in the laboratory infection parameters.

In cases with negative or without pre-operative aspiration, the fixation device and any scarf tissue was removed careful. The used prosthesis was always fixed with revision bone cement (gentamicin 0.5/40 g). An exception was the patient with the eclipse prosthesis who had also a negative pre-operative aspiration. Before cementing starts, the bone bed was cleaned via pulsatile jet lavage. A cement restrictor was used for the stem and the cement was vacuum-mixed.

A telephone interview was conducted with all 28 remaining patients to query whether they had developed any post-operative complications and/or if they required further operative procedures at other institutions.

Four of the 32 patients (13%) were excluded: one due to unrelated death and the others due to loss to follow-up.

Institutional Review Board (IRB) approval is given.

Differences between subgroups were proofed with the Wilcoxon signed-rank test. Comparisons of categorical data were done by chi-square and Fisher's exact test for analyzing sensitivity, specificity, and odds ratio. A p value less than 0.05 was considered statistically significant. Statistical analysis was carried out by means of a statistical software package (GraphPad Prism Version 5.02, GraphPad Software Inc., La Jolla, CA, USA).

Results

Intra-operatively obtained cultures confirmed pre-operatively bacterial growth (*Staphylococcus capitis*) in one patient. It must be noted that the other three patients pre-operatively had been administered antibiotics prior to

implantation for a time period of more than 10 days. The surgical histopathology revealed infected tissue, so the patients were treated as infected following the Musculoskeletal Infection Society guidelines [15]. In both patients, no signs of persistent infection were seen at the time of latest follow-up. In one patient, a single intra-operative sample showed growth of *Staphylococcus epidermidis*, while the other two cultures were negative; for this patient, the intra-operative samples were considered contaminated. In the same patient, 2.5 years later, the stem of the prosthesis showed loosening and revision of the stem was necessary. Aspiration prior to this revision procedure, as well as the five intra-operative microbiological cultures, did not show any bacterial growth. One patient revealed intra-operatively tissues highly suspicious for infection, despite a negative pre-operative aspiration. The surgeon decided in this case to perform a two-stage procedure. The culture samples of this patient showed growth of *Propionibacterium acnes*. At the latest follow-up, there was no re-infection observed. In aid of the Wilcoxon signed-rank test, differences between the subgroups regarding occurrence of infection were tested. There were no significant differences found between the used fixation devices plate, intra-medullary nail, and screws, as well the diagnosis for requiring shoulder replacement and potential risk factors for infection.

Of the 17 patients, in which a joint aspiration of the affected shoulder was performed pre-operatively, bacterial growth was detected in 4 cases: one case of *Propionibacterium acnes*, one case of *S. capitis*, one case of *Anaerococcus prevotii*, and one case of *Paenibacillus pabuli*. The indication for the conversion surgery in three patients was a pseudarthrosis followed by humeral head necrosis and malunion. In two of the four patients with bacterial growth pre- or intra-operatively, a histopathological analysis was done that was found to be consistent of infection in one patient but negative in the second. The inflammatory marker CRP was elevated pre-operatively in 9 (32%) patients, with a mean of 15.2 mg/L (range, 5.5 to 55.6 mg/L; normal <5.0 mg/L) Table 2.

The pre-operative aspiration resulted in a sensitivity of 75% (95% confidence interval 0.19 to 0.99), whereas the specificity was 92% (95% confidence interval 0.64 to 1.0), with a $p < 0.005$. This results in a positive predictive value of 0.75 and a negative predictive value of 0.92. The odds ratio was 36 for an infection in case of a positive aspiration. The sensitivity of an elevated CRP for existing infection was 75% (95% confidence interval 0.19 to 0.99), whereas the specificity was 74% (95% confidence interval 0.52 to 0.9), $p = 0.093$. The positive predictive value was 0.33, and the negative predictive value was 0.94. The odds ratio was 8.5 for an infection in case of elevated CRP. The WBC count was within the normal range in 27 out of 28 patients, with a mean of 6.2 cells/nL (range, 4.2 to 10.4 cells/nL). There was only one patient with elevated WBC count, which had no overt signs of infection.

At the latest follow-up, after an average of 4.6 years, none of the patients evidenced signs of periprosthetic infection. Surgical revision of the prosthesis was necessary in six patients (21%). Two patients needed a conversion of their

Table 2 Relevant information for the five patients with pre- or intra-operative bacterial growth

Patient	Diagnosis	Fixation device	Risk factor	Pre-operative aspiration	Intra-operative organism isolated <2 probes	Final Histo-pathological Result	WBC <10 cells/nL	CRP <5.0 mg/L	Infection fixation device
1	Pseudoarthrosis	Nail	Diabetes	<i>Propionibacterium acnes</i>	None	Positive	5.5	13	Yes
2	Pseudoarthrosis	Plate	None	<i>Anaerococcus prevotii</i>	None	N/A	8.1	10.4	No
3	Pseudoarthrosis	Plate	Cancer	<i>Staphylococcus capitis</i>	<i>Staphylococcus capitis</i>	N/A	6.7	55.6	Yes
4	Humeral head necrosis	Plate	Diabetes	<i>Paenibacillus pabuli</i>	None	Positive	8.2	8.2	Yes
5	Malunion	Plate	None	None	<i>Propionibacterium acnes</i>	Negative	6.3	3	Yes

Patients with two or more positive probes or with one positive probe and an infection positive histo-pathological finding were rated as infected
 WBC white blood cell count, CRP C-reactive protein

total shoulder prosthesis to a reverse design due to development of rotator cuff insufficiency after 1 and 1.5 years, respectively. In one patient, already described above, there was aseptic loosening of the cemented stem after 2.5 years. A revision due to loosening of the glenoid was done after 2 years in another patient. Because of unsatisfactory range of movement in one patient, a lysis of adhesions with exchange of the inlay was performed. In another patient, after almost 1 year, a revision of the glenoid was done due to malpositioning of the glenoid, unsatisfactory movement, and pain.

All revisions were done in the current institution. In none of the revised shoulder prostheses was a positive bacterial culture obtained at the time of revision surgery.

Discussion

With regard to shoulder arthroplasty, there is only limited information on possible bacterial contamination of fixation devices and the potential risk for periprosthetic infection in the setting of salvage arthroplasty. The aim of this retrospective study was to determine the incidence of positive pre-op aspiration and inflammatory markers in cases of failed osteosynthesis and to document the outcome of the arthroplasty in this series correlating pre-operative positive aspiration or inflammatory markers with post-operative infection. We also wished to document the mid-term clinical success of the arthroplasties in this series referring to the need for re-operation out to 4-year follow-up.

The limitations of this study include the retrospective study design, the relatively small number of patients, and the rate of loss to follow-up. The low rate of pre-operative aspirations is another limitation of this study. This limits the ability to conclusively prove that there is no persistent low-grade infection in all cases. However, the patients stated good results of prosthesis surgery, and laboratory parameters and radiological follow-up were acceptable. A further limitation and possible bias are the arbitrary decision and small number of performed pre-operative joint aspirations. Another bias might be the widespread distribution and therefore small number of different diagnoses prompting salvage shoulder arthroplasty.

Reviewing the existing literature shows a high prevalence of periprosthetic infection in patients requiring secondary arthroplasty for failed fracture fixation [3, 23, 11, 17]. Boileau et al. and Wall et al. showed in study groups of 5 and 33 patients, respectively, that patients with post-traumatic arthritis had a higher infection rate compared to patients with primary rotator cuff arthropathy when undergoing the same operative procedure [3, 23].

The pre-operative joint aspiration of 17 patients revealed in 4 a bacterial growth, and the intra-operative tissue samples showed in 1 patient a pre-operatively undetected bacterial growth. At the end of follow-up, no periprosthetic infection was observed.

Kilic et al. described the rate of complications and functional outcome of patients undergoing secondary anatomic or reverse shoulder arthroplasty due to sequelae of fractures of the humeral head. They found a high infection rate of

11.4%, where 2 of the 55 patients had a history of shoulder infection [11]. Martinez et al. reported, in 18 patients treated with a reverse prosthesis for proximal humeral non-unions, an infection rate of around 11% [17]. Therefore, our results show a demonstrable rate of low-grade infections, based on positive cultures in 4 of 28 (11%) patients with pre-existing fracture fixation devices.

These infections were all rated as unexpected low-grade infections due to no prior history of infection of the shoulder and no overt clinical signs of infection, such as fever, weight loss, or presence of a fistula. C-reactive protein elevation was found in four of these infected patients; therefore, this could not be used as a reliable pre-operative marker in our cohort. In two patients, the pre-operative administration of antibiotics may have led to the negative intra-operative culture results. The appearance of false negative intra-operative microbiological probes is an already well-described multifactorial phenomenon in the field of periprosthetic shoulder infections, and it is therefore not surprising that it also occurs in cases of previously implanted fixation devices [12, 5, 6]. Furthermore, our results show a sensitivity of only 75% for the joint aspiration and pre-operative serum CRP for the detection of an ongoing infection associated with the fixation device. This makes the aspiration a relatively restricted diagnostic tool. Our recommendation is that shoulder aspiration should not be considered the sole pre-operative diagnostic tool. In support of this, we consider the patient in our series with a negative pre-operative aspirate but intra-operatively detected *Propionibacterium acnes*; all other pre-operative markers, including CRP and WBC, were within normal limits. Consequently, it is of great importance to take into account all other findings like elevated serum CRP and/or WBC, histopathology results of the tissue, and synovial fluid cell count in the diagnose an infection of the fixation-device [20, 19].

Raiss et al. treated 32 patients with a reverse shoulder arthroplasty for a non-union of the surgical neck of the proximal humerus [21]. Of these patients, 22 had been treated previously for a humeral head fracture with a plate or intra-medullary nail; the others received non-surgical treatment. In three of these patients, an infection of the osteosynthesis was known pre-operatively. After a mean follow-up of 4 years, they reported 13 complications (41%) with a need for surgical revision in 9 cases (28%). Most often of the complication was dislocation (11 cases). Periprosthetic infections were observed in four patients (12%): two early, one after 2 years, and another after 7 years. All these patients had a history of open reduction and internal fixation, but not an infection before arthroplasty. It is unclear whether the authors performed pre- or intra-operatively any microbiological testing. Also, it is not clear if any antibiotics were admixed to the bone cement like in our institution. Martinez et al. described a similar remarkable high periprosthetic infection rate of 11% [17]. They treated 18 patients with a reverse shoulder arthroplasty for non-union of surgical neck fractures. Complications requiring surgical revision were recurrent dislocation in 11%. As with the study of Raiss et al., it is again unclear from the study of Martinez et al. whether there was any pre-operative microbiological testing. Even if we, so far, had no post-operative periprosthetic infection observed in our study

cohort after a mean of 4.5 years of follow-up, we find the rate in concordance with our pre- and intra-operatively identified four different bacterial growths. In contrast with the studies of Raiss et al. and Martinez et al., we observed in two patients (11%) an aseptic loosening of the components after 2 and 2.5 years, during which the pre- and intra-operatively microbiological samples excluded persistent infection. A clear explanation for the elevated early aseptic loosening rate in comparison to the other studies cannot be given by the authors. A possible higher loosening rate due to the use of revision bone cement with admixed antibiotic seems unlikely. In the case of the stem loosening, the bad bone stock due the hypotrophic pseudarthrosis of the proximal humeral shaft fracture may be the most likely reason for failure.

The literature shows that shoulder arthroplasty, in the setting of failed fracture fixation, is a challenging procedure. Moreover, it is linked with a high complication rate, even in high-volume centers. The high rates of periprosthetic infections are a serious complication. We have been able to show that the pre-existing fixation devices of the shoulder seem to have a much higher risk for an occult bacterial infection. Therefore, with respect to results of this study, it has to be recommended that a pre-operative aspiration and serum laboratory infection markers should be obtained prior to implantation of a shoulder prosthesis in the setting of prior fixation hardware. If both results are not suspicious for infection, the general risk of a low-grade infection seems to be relatively low.

Nevertheless, if there is doubt due to suspicious intra-operative tissue, the authors recommend the removal of the fixation device and sampling of three to five cultures. A second-stage surgery for implantation of the prosthesis may then be performed under planned septic-precaution conditions.

Disclosures

Conflict of Interest: Till O. Klatte, MD, Reza Sabihi, Daniel Guenther, MD, Atul F. Kamath, MD, Johannes M. Rueger, MD, PhD, Thorsten Gehrke, MD, PhD, and Daniel Kendoff, MD, PhD, have declared that they have no conflict of interest.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5).

Informed Consent: Informed consent was waived from all patients for being included in the study.

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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