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ORIGINAL ARTICLE • SHOULDER - FRACTURES

Cementless and locked prosthesis for the treatment of 3-part and 4-part proximal humerus fractures: prospective clinical evaluation of hemi- and reverse arthroplasty

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Abstract
Introduction Cemented stem remains the gold standard for prosthesis in trauma. The purpose of this study was to evaluate the functional and radiological outcomes of a cementless, trauma-specific locked stem (hemi and reverse) for 3- and 4-part proximal humeral fractures.
Materials and methods One hundred and thirty-four 3- and 4-part fractures have been treated by locked stem, 69 with hemiarthroplasty [mean age 68 years (50–90)] and 65 with reversed [mean age 78 years (66–91)]. The length of the stem was 15 cm with a proximal coating of HA automatic locking system (two screws) and four different diameters. Preliminary cadaver study allowed us to validate the system (22 shoulders, no injuries of nerves, locking system efficient).
Results In the group of hemi, Constant score with ponderation reached 72 (11–120) and QDash 31.2 (4.5–77.27) with a mean FU of 25 months (6–96). In the group of reversed, Constant score with ponderation reached 77.6 (28.8–119) and QDash 36.2 (2–84) with a mean FU of 15 months (6–41). Specific complications due to locking system reached 3% but without reoperation. Other complications were capsulitis and infection.
Discussion In this population of elderly patient, new fall with periprosthetic fracture or infection led the surgeon to remove the stem. At shoulder level, the removal of a cemented stem remains a highly demanding procedure with sometimes bad functional results and elevated level of complications. This series is the first one of locked stem without significant complications. Locked stem remains a new but logical tool in trauma.

Keywords Proximal humerus fracture · Locked stem · Hemiarthroplasty · Reverse prosthesis

Introduction

Four-part fractures of the proximal humerus in patients between 60 and 70 years of age should theoretically be treated by hemiarthroplasty (HA) [1]. In this age group, use of reverse shoulder arthroplasty (RSA) implants is contraindicated and fracture fixation is not always feasible, either because of compromised humeral head vascularity (varus, extensive comminution, very osteoporotic bone) [2] or because of a complex fracture pattern (varus, associated dislocation, low head volume). However, because the functional outcomes of HA for these fractures are correlated to implant height and anatomical reduction in the tuberosities [3–5], less and less surgeons are using this technique. For the same type of fracture, the results are more predictable with an RSA implant; this has contributed to a marked increase in the number of RSA procedures performed on patients between 60 and 70 years of age. We

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report the first series of locked stem of implant in trauma (hemi and reverse).

Materials and methods

The first part of the study consisted of an assessment of a fracture-specific stem with diaphyseal locking (Humelock™, FX Solutions, Viriat, France) on 11 cadavers (22 shoulders) (Fig. 1). The goals of the cadaver study were to determine whether the diaphyseal locking mechanism was mechanically reliable, determine whether the implant was safe for the vascular and nerve structures and verify the data generated by Murachowsky et al. [6] and Torrens et al. [7] regarding the distance between the upper margin of the pectoralis major tendon and the top of the humeral head.

To set the stem height, we decided to directly lock the chosen stem; this allowed us to focus our time on the aspect we felt was most important: the fixation of the tuberosities. After locating the upper margin of the clavicular part of the pectoralis major, the stem was locked in a trial position that placed the head 5.5 cm from the pectoral landmark. A K-wire was used to lock the distal end of the stem temporarily; this enabled carrying out primary tuberosity reduction using trial heads and checked the configuration on fluoroscopy with the arm in neutral position, internal rotation and external rotation (Figs. 2, 3).

Patients were recruited for the prospective clinical study conducted between 2009 and 2011. Patients of each centre were reviewed prospectively by an independent assessor. One hundred and thirty-four patients have been treated by locked stem, 69 with hemiarthroplasty and 65 with reversed. The clinical review consisted of measuring the shoulder range of motion and calculating the Constant [8] score and QuickDASH [9]. The radiological review consisted of an analysis of the position and consolidation of the tuberosities around the implant; these elements were analysed according to looped suture use.

This study also allowed us to assess tuberosity reattachment using specially designed suture loops (Smartloop®, FX Solutions), aiming to generate a reliable and reproducible construct, independent of fracture type. We also evaluated the mechanical advantage of adding a cage (Offset Modular System®, OMS, FX Solutions) below the head. This optional cage was developed to make it easier to position and fix the tuberosities as a function of the remaining tuberosity volume and to provide a recess where cancellous autograft taken from the patient's humeral head can be added against the prosthesis. The shoulder was immobilized in an internal rotation cast or sling for 4 weeks with no passive or active mobilization during this time period.

Fig. 1 New generation of hemi- and reverse arthroplasty with a locked and uncemented stem but which can be cemented. The stem is reversible allowing to use the platform as hemi- or reversed prostheses

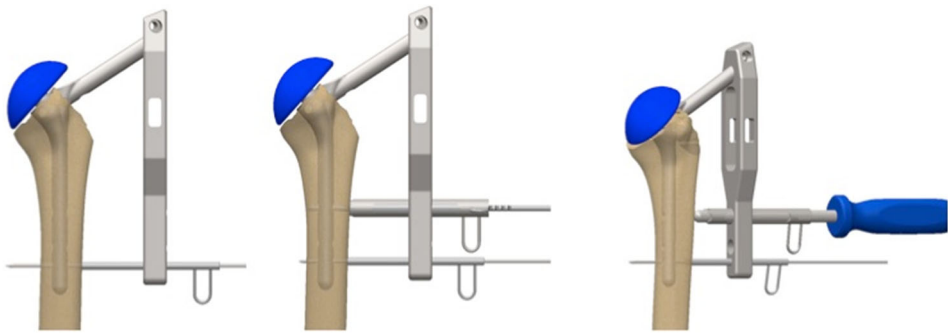
Results

In the cadaver study, the distance between the top of the humeral head and the pectoralis major was 5.8 cm ± 5 mm, which is consistent with published data [1]. This finding validated the height adjustment gauge developed for this implant. All stems could be solidly locked using the distal dual-locking instrumentation. The mechanical advantage of using the OMS to help positioning the tuberosities was evident in the cadaver study. The cage walls were further refined based on our findings to improve the biological exchanges around the implant.

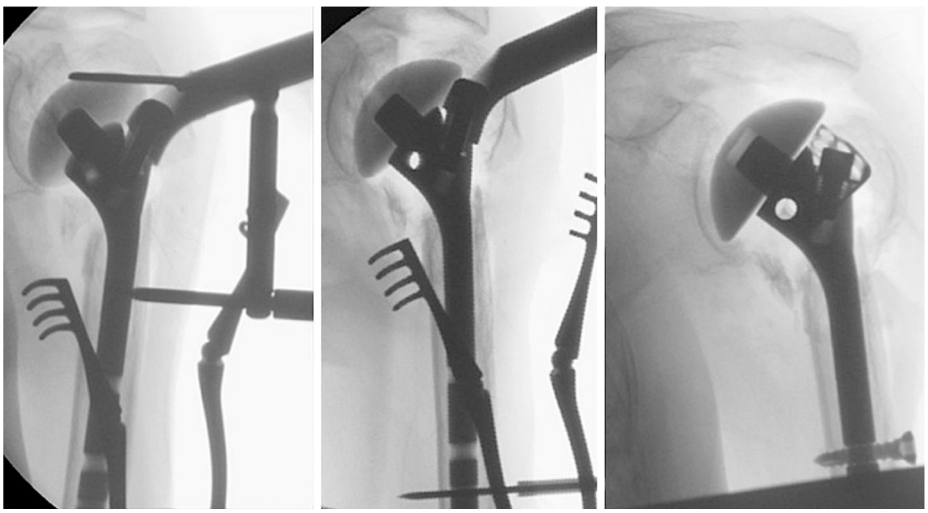
The clinical study enrolled 134 3- and 4-part patients with 134 fractures, which have been treated by locked stem, 69 with hemiarthroplasty [mean age 68 years (50–90)] and 65 with reversed [mean age 78 (66–91)]. Twenty senior surgeons at sixteen different hospitals performed the surgical procedures. The patients were operated at a mean of 7.1 days (1–17) after the fracture event by deltopectoral approach in 88% of cases (12% in superolateral approach). Immobilization in internal rotation for 1 month was proposed in case of hemiarthroplasty and a sling for 3 weeks in case of reverse prosthesis.

In the group of hemiarthroplasties, active flexion reached 99.5° (25°–160°), active abduction 90.3° (35°–160°) and active external rotation 28.3° (0°–55°). Constant score with ponderation reached 72 (11–120) and QDash 31.2 (4.5–77.27) with a mean FU of 25 months (6–96) (Fig. 4).

In the group of reversed prosthesis, active flexion reached 108.7° (30°–160°), active abduction 99.4° (10°–150°) and active external rotation 20.9° (−10° to 80°).



Figs. 2 and 3 Stem is permanently fitted at the correct height, and then, the prosthesis is secured to the bone using a pin, by means of the ancillary; it allows the first images the operator; can apply tuberosities and assess the anatomical reduction; and finally locking is completed



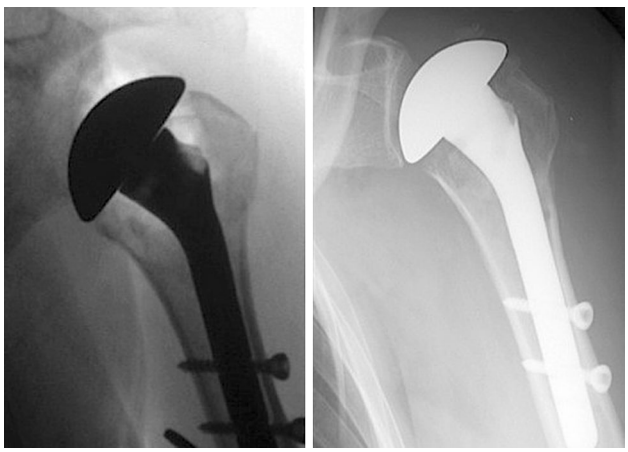


Fig. 4 Osteosuture of tuberosities and peroperative X-ray control are mandatory in order to achieve bone union at the right place

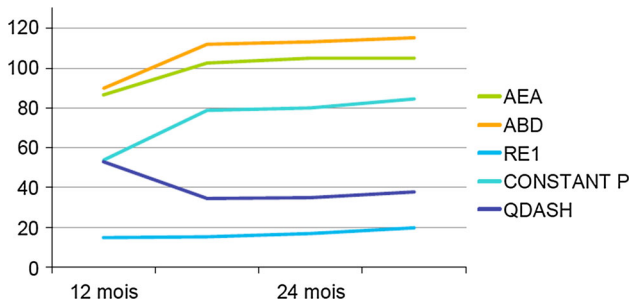


Fig. 5 Evolution from 1 year of active flexion, abduction, external rotation and Constant score with ponderation and QuickDASH score in the group of reverse shoulder arthroplasty

Constant score with ponderation reached 77.6 (28.8–119) and QDash 36.2 (2–84) with a mean FU of 16 months (6–41) (Fig. 5). No complications related to stem locking were observed. Thirty-seven complications occurred, 14 in the "hemi group" and 23 in the "reverse group". Complications are described in Table 1.

Two of these rotator cuff cases required RSA conversion, which was easy to perform because no cement had been used initially. In the reverse group and at this follow-up, only 1 case of notch (grade 1) was pointed (Fig. 6).

Discussion

Hemiarthroplasty

Consolidation of the lesser tuberosity and retroversion of the humeral stem are difficult to evaluate reliably. CT scanning would have provided a more accurate assessment,

Table 1 Complications in subgroups

Complications	Hemiarthroplasty	Reverse prosthesis
Capsulitis	5	3
Phlebitis of upper limb	–	2
Axillary palsy	1	1
Diaphyseal fracture of the humerus	1	2
Infection	–	1
Lysis of great tuberosity	1	4
Notches	–	3 (grade 1) 2 (grade 3)
Problem with locking	2 (screw removal)	5 (screw removal)
Secondary cuff rupture	3	–
Lymphoedema	1	–

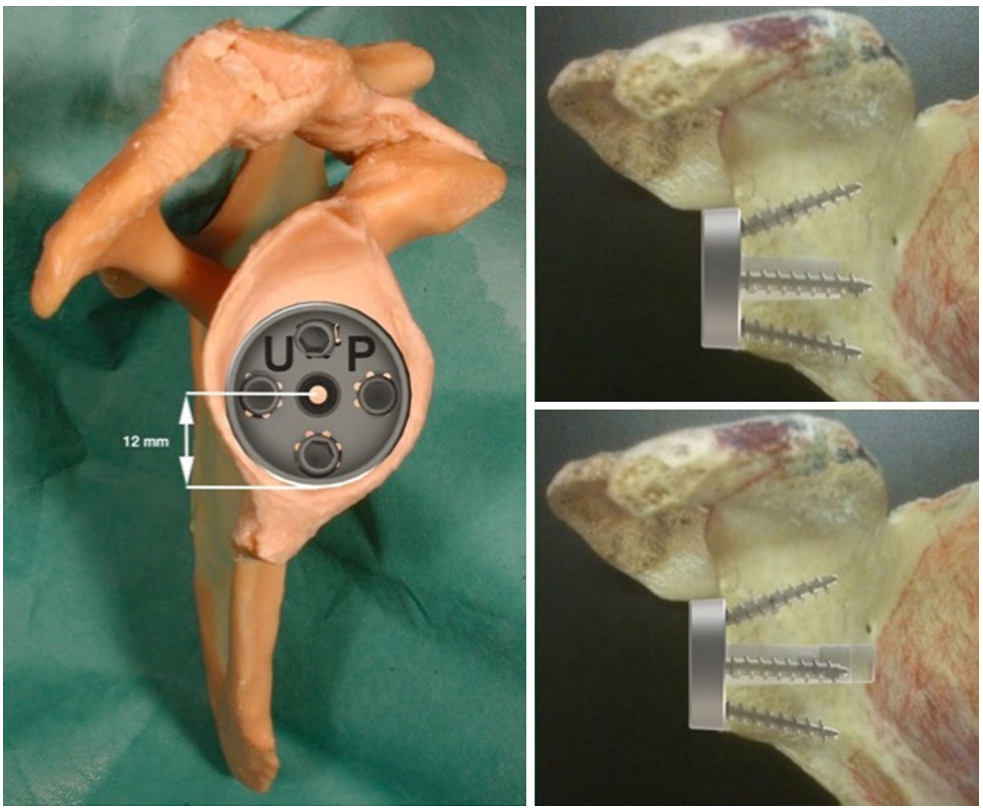


Fig. 6 With the smallest base plate of the market and a low implantation on the glenoid bone, the FX reverse prosthesis allows to diminish the notch

but also would have exposed the patient to more radiation. It was not possible to determine whether humeral length had been restored because X-rays of the entire humerus were not taken.

The number of patients in this study, as well as their ages and genders, was comparable to other published studies. The effect of age on tuberosity consolidation, and in parallel, the functional outcomes, has been demonstrated by several authors. Reuther [3] found that the tuberosity union rate was 61.5% in patients under 60 years of age, but only 26.5% in those over 80 years of age. Grönhagen et al. [4] showed that the Constant–Murley score was significantly better in patients under 60 years of age. Boileau et al. [5] found that tuberosity migration was significantly correlated to being over 75. In the current study, no differences were observed between patients over and under 60 years of age. Comorbidities also impact the functional outcomes. Kabir et al. [10] found that the Constant–Murley score decreased from 41 to 27 when patients have three or more comorbidities.

Many studies have shown that women have worse functional outcomes and joint range of motion [5, 10, 11]. This can be explained by poor bone quality and increased risk of tuberosity non-union. However, we found no differences in the outcomes between genders in the current study.

We did not find the time before surgery to have any impact on clinical outcomes. Mighell et al. [12] reported that functional outcomes were significantly better when patients were operated within 2 weeks of the fracture event; this concept was not supported by Fallatah's study [13]. The deltopectoral approach used in this study is the same approach used in most published studies. A significant correlation between stem height and consolidation of the tuberosities in their anatomical position has been found [5]. A reliable reference for appropriate stem height is the distance between the apex of the humeral head and the superior margin of the pectoralis major tendon [6]. This distance can be measured only when using the deltopectoral approach. Better clinical outcomes have been found when the height is set using the distance between the apex of the humeral head and the superior margin of the pectoralis major tendon [14, 15]. In our opinion, bone grafting is essential because it increases the primary stability of the tuberosities and adds a biological element to the healing process. We believe that the HA results are more predictable when the tuberosities are stabilized by transosseous sutures placed around the implant's metaphysis, which is filled with autograft.

Some authors have shown that tuberosity consolidation is not significantly affected by the use of bone graft [3, 16]. However, several teams have shown that tuberosity consolidation is critical to achieving good functional outcomes [3, 5, 16–19]. Complications related to tuberosity consolidation are the main cause of functional catastrophe.

The non-union rate in the current study (20, 2%) falls within the range (0–17%) reported in other studies [5, 11]. Transosseous tuberosity suturing must be performed meticulously. Anatomical reduction in the tuberosities is an essential prerequisite for good functional outcomes. The malunion rate in the current study (24, 6%) falls within the range (0–39%) reported in other studies [5, 11].

More recent studies found a tuberosity non-union or malpositioning rate of 40–66% [20–22]. The transosseous sutures are as important as the implant's design and height for ensuring that the tuberosities heal in the correct position. Krishnan et al. [23] and Boileau et al. [24] have recently reported tuberosity non-union rates of 21 and 13%, respectively, when a fracture-specific stem was used. This reinforced our research on implant that effectively treats humeral fractures involving the head and tuberosities.

The intraoperative complication rate in this study was low. The published rate is under 2%. Boileau et al. [25] reported one case of axillary artery damage (1.6% complication rate). Brandao reported one periprosthetic humeral fracture (1.5% rate).

All the patients in this study underwent post-operative immobilization for 1 month using a shoulder immobilizer with the arm internally rotated. This position is controversial. Some authors recommend immobilization in neutral position or external rotation to reduce tension on the lesser trochanter, as this is a source of migration [5, 26]. However, this position is difficult to maintain during sleep.

Although Robinson et al. [27] have shown that the Constant score levels out starting at the sixth post-operative month, very few studies have more than 2-year follow-up. An analysis of published results shows a wide variation in the resulting shoulder range of motion (ROM). The mean forward flexion ranges from a low of 53.5° [26] to a high of 149° [18]. The Constant–Murley score ranges from a low of 42 points [4] to a high of 73.6 points [19]. The overall Constant–Murley score of 45.9 in this study falls within this range.

The condition of the rotator cuff directly affects the functional results of HA for fracture. Impaired functional outcomes due to reduced subacromial space have been demonstrated in many studies [4, 11, 12] and can reach 52% [4].

At the latest review, the functional outcomes were significantly altered when the subacromial space was less than 7 mm. In this study, it can be attributed to secondary rotator cuff damage in all cases. No damage to the rotator cuff was identified intraoperatively. One cause of post-operative rotator cuff damage is excessive humeral length. According to Boileau et al. [5], length of more than 10 mm had two effects:

- Rotator cuff damage (less subacromial space) due to excessive tension on the supraspinatus muscle.
- Tuberosity migration due to lack of union with the humeral shaft.

Humerus length could not be determined in the current study because X-rays of the entire humerus were not taken.

Mighell et al. [12] found a smaller subacromial space in 20.8% of patients. This radiological finding is systematically associated with impaired functional outcomes. Shah et al. [28] counter these results and find no significant difference between patients who have reduced subacromial space and those who have not.

No infections were identified in this study but with short follow-up. The published rate of deep infection after HA for fracture is 1.6% [25]. For all aetiologies combined, the prevalence of infection of anatomical shoulder implants is 2% according to Pelegri [29]. *Staphylococci* and *Propionibacterium acnes* are the most commonly found microorganisms (23–40%). The infectious prognosis is relatively

good: the infection is resolved in 71% cases when all treatments are considered altogether.

Ectopic bone formation identified on X-rays is generally not considered as a complication. Grönhagen et al. have reported ectopic bone formation in 54% of cases [4]. The impact of this abnormal radiological finding on functional outcomes is controversial. Grönhagen et al. [4] and Goldman et al. [11] found no changes in the functional outcomes in patients with ectopic ossification. Kjaergaard-Andersen et al. [30] described three stages of ectopic ossification in a series of 26 out of 58 arthroplasty cases. In stage III, the bone bridges the humerus and acromion. The functional outcome is negatively affected only after ossification reaches stage III.

Reversed prosthesis

The epidemiological variables are comparable to the published series. The mean age was 77 years (range 72–86 years). The proportion of female patients varied from 70% for Klein et al. [31] to 100% for Hubert et al. [32]. The mean follow-up reported in the literature is 33 months (range 10–86 months).

The superolateral and deltopectoral approaches can be used in reversed arthroplasty with fracture. In previous studies, the superolateral approach remains the most widely used. Bufquin et al. [33] found no differences in the results for these two approaches. For Sirveaux et al. [34], the superolateral approach is preferable because it results in fewer dislocations. However, this approach presents the disadvantage of weakening the deltoid muscle, the main motor of the prosthesis, whereas in a fracture situation the subscapularis tendon does not need to be resected. Osteosuture of the tuberosities should be attempted whenever possible. Bufquin et al. [33] and Gallinet et al. [29] showed that this reinsertion was possible and effective in restoring rotation. The literature does not report criteria for defining anatomical union of the tuberosities in reversed prostheses. In another study, Gallinet et al. [35] showed significant improvement of the Constant score and throughout range of movement when anatomical union of the tuberosities was observed. Cuff et al. [36] nuanced these observations, considering that reinsertion of the tuberosities and their union significantly influence external rotation but not the functional scores.

Of the 12 series reported in the literature, the functional range of motion reached 118.6° (range 97°–139°) for anterior elevation, 107.4° (range 80°–128°) for abduction and 16° (range 8°–27°) for external rotation with the elbow against the body. The mean crude Constant score varied from 44 points for Bufquin et al. [33] to 67.9 points for Klein et al. [37].

Intraoperative fractures are exceptional, but they aggravate the prognosis. Bufquin et al. [33] reported fractures of the glenoid (2.3% of the complications). In these symposium series, we found no acromion or spine of scapula fractures. Dislocation is one of the most stressful complications for the patient. The risk of recurrence is even higher when the first episode occurs early. Its rate has been reported to be 16.6% in recent injuries [38]. The factors of instability described in the literature are the approach and most particularly the deltopectoral approach, which may be related to an increased risk of dislocation compared to the superolateral approach [37], because of the anteroinferior capsular release (more frequently used in scheduled surgery); a humeral length defect and therefore deltoid tension [39]; fat degeneration of the subscapularis muscle [40]; and finally, use of a small-diameter glenoid sphere (36 mm) [41].

Neurological lesions are not rare. The distinction between post-traumatic and iatrogenic neurological impairment remains subject to a preoperative examination that is often difficult. In the literature, the axillary nerve is the most frequently injured. The neurological lesion rate was 12.5% for Bufquin et al. [33].

The infection rate in series of reversed prostheses with fractures was 10% for Klein et al. [37]. The series of the 2006 SOFCOT symposium found 5.1% infections in scheduled surgery [41]. Pelegri et al. [42] found 3% infections all indications combined, with an 80% healing rate.

The rate of a notch on the lower side of the neck of scapula varies from 0% for Cuff and Pipello [36] and Valenti et al. [43] to 96% for Werner et al. [44]. This is a specific radiological anomaly of the reversed prosthesis, but the analysis of this phenomenon can be delicate because it depends on the quality of the X-ray. Most frequently, the notch is partially hidden by the glenoid sphere when the patient is positioned too frontal. The use of a horizontal or slightly ascending ray coupled with radioscopy makes it possible to assess the presence of a notch. This scapular notch generally appears in the first year after surgery. In the 2006 SOFCOT series [41], the notch rate was 48% at 1 year of follow-up. These changes remain difficult to assess because it varies from case to case. Lévigne et al. [45] found a tendency towards progression of the notch over time. This notion of aggravation over time was also observed by Cazeneuve and Cristofari [46] and may stem from two related phenomena: mechanical impingement between the medial edge of the humeral cup and the lower edge of the neck of scapula and an osteolytic reaction to the polyethylene particles released in the joint capsule. The notch's clinical and radiological consequences continue to be debated in the literature. According to Lévigne et al. [45], the presence of a notch has no

significant incidence on the Constant–Murley score or joint range of movement. On the other hand, it is associated with a significant decrease in strength. The 2006 SOFCOT symposium series [41] showed that the presence of a notch was significantly correlated with lower anterior elevation and less strength. For Sirveaux et al. [47], the presence of a stage 3 or 4 notch is significantly associated with a lower Constant–Murley score. Even in cases of fracture, prevention of the notch seems logical to improve the longevity of reversed prostheses. The means to reduce its incidence are well known: low implantation of the glenoid insert flush with the lower edge of the glenoid [44], positioning the glenoid insert with at least 10% downward inclination, polyethylene cup depth as low as possible to preserve satisfactory stability, lateralization of the glenoid implant pulling away the humerus from the neck of scapula [48], and reduction (verticalization) of the neck-shaft angle of the humeral implant [49].

Conclusion

This is a relatively short-term study, but optimization of a fracture-specific implant leads to more predictable results if the tuberosities are reduced, they will heal. In case of hemiarthroplasty, the predictable results with this implant can be explained by the ease of setting the stem height, the ability to lock the stem in place without cement, the use of suture loops for transosseous fixation and the stabilization of the horseshoe-shaped graft in the metaphyseal area. In the hands of an experienced surgeon who makes use of fluoroscopy, the results of HA can be improved without having to perform RSA on every fracture cases. At shoulder level, the removal of a cemented stem remains a highly demanding procedure with sometimes bad functional results and high level of complications. This series is the first one of locked stem without significant complications. Locked stem remains a new but logical tool in trauma.

Compliance with ethical standards

Conflict of interest L. Obert is consultancies for FX solution, Zimmer, Medartis, Wright, Argo and Lilly. T. Lascar is consultancies for FX solution.

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