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ORIGINAL PAPER

Use of a locking stem for reverse shoulder arthroplasty is a rare but reliable option

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Abstract

Introduction RSA is widely used in the treatment of complex trauma or degenerative changes of the shoulder. Strong primary fixation of the stem is necessary to prevent any loosening of the stem and subsequent revision. Presently, cement fixation or press-fit fixation are two options for humeral fixation, though each has its own limitations and risks. The aim of the current study is to evaluate the effectiveness of an alternative option involving a distal screw interlocking system for fixation of the humeral stem from initial implantation.

Methods We performed a retrospective multicenter study of patients implanted with the Humelock Reversed® stem RSA that can be locked with distal humeral screws in cases of operative poor press fit or to modulate the lengthening of the arm via prosthetic humeral height. Seventy-two patients with a minimum two year follow-up were included, 13 for acute trauma, 42 for degenerative changes, and 17 for revision surgery.

Results No difference was seen in radiological or clinical results for patients with or without interlocking screw primary stabilization. For non-trauma patients, the mean raw Constant score improved significantly from 31 (± 12) to 71 (± 12). For trauma patients, the mean raw Constant score for trauma (63.4) was significantly lower than for non-trauma cases (72.1) ($p < 0.001$). Analysis of the filling ratio demonstrated that interlocking screws were not used for lower filling ratios and that midterm fixation of the stem is not negatively impacted by distal interlocking screw fixation.

Discussion Even if use of a distal interlocking screw fixation system is rare, it can be useful for patients with poor quality fixation of stemmed RSA.

Conclusion Use of an interlocking screw system to stabilize the stem in RSA provides good immediate and midterm stability of the implant allowing for clinical and radiological outcomes comparable to those obtained with press-fit fixation alone.

Keywords RSA · Interlocking system · Stability · Stem

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Introduction

Reverse shoulder arthroplasty (RSA) is commonly used for treatment of cuff tear arthropathies, failed rotator cuff repair, and osteoarthritis in elderly patients or young patients with complex glenoid deformity [1–3]. They are also widely used for treatment of complex proximal humerus fractures [4, 5]. For all indications, clinical results are good, with better patient outcomes for indications unrelated to trauma [1]. If stemless or short stem are more and more popular in TSA, there are still several concern regarding RSA. In elderly patients, particularly for traumatic indications or for patients with poor proximal humerus bone quality, primary fixation of the stem is often challenging. In the case of revision surgery, a bone defect at the metaphysis can also be a challenge for primary fixation. In all these type of cases, cement fixation of the stem may be required [6]. However, the literature also reports several problems and complications with cement fixation of humeral stems including infection, nerve injury, thromboembolism, and a higher rate of acromial fractures [7, 8]. Use of a locked humeral stem in TSA or RSA has been proposed by several in the orthopaedic community for over 5 years, but there are limited reports of clinical use. The aim of the current study is to evaluate the benefit of a distal screw interlocking system in primary fixation of RSA. In order to evaluate this alternative method of fixation, we analyzed the results of a cohort of patients who underwent Humelock® Reversed Arthroplasty (FX Solutions®, Viriat, France) with and without a locking screw fixation of the humeral stem (Fig. 1).

Material and method

IRB approval was obtained from the Cos Ramsay Santé: IRB00010835. We collected the data from six European centres located in France and Monaco. Informed consent was obtained from all individual participants included in the study. Patients were included if they had RSA with the studied stem and had available clinical and radiological data with a minimum of two year follow-up. All indications for shoulder arthroplasty were collected, and reasons for use of the interlocking screws were documented. Complications were also recorded. Clinical evaluation was based on the pre- and post-operative Constant score. Because the pre-operative Constant score was not available for patients operated for trauma, the results and comparison of pre-operative to post-operative Constant scores

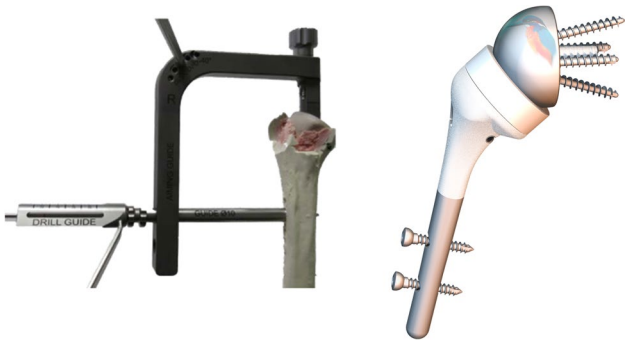

Fig. 1 Specific Trauma Aiming Guide is available with Humelock Reversed stem to perform. A locking of the stem with one or two 4.5-mm screws

were analyzed separately for trauma and non-trauma patients. Radiological assessment was completed immediately post-operatively and at a minimum of two years post-operative with anteroposterior (AP) and lateral shoulder X-rays reviewed.

On immediate post-operative X-rays, the main radiological parameter evaluated was the filling ratio, as determined with the method described by Schnetzke [9]. On AP views, the humeral shaft axis (HSA) was identified, and two perpendicular lines to the HAS were drawn. The proximal line intersected the prosthesis on the medial edge of the humeral baseplate. The distal line intersected the prosthesis at the junction between the second and the distal third of the humeral stem. At the two intersection points, the width of the prosthesis was measured and normalized to the endocortical bone width to obtain a metaphyseal (FRm) and a diaphyseal (AP-FRd) filling ratio. The measurement process was repeated on lateral views to assess the diaphyseal (L-FRd) filling ratio. Finally on immediate X-rays, the contact between the prosthesis and the humeral cortex on AP or lateral views was recorded. Radiological analysis correlated the indication for interlocking for stability and the relative size of the proximal and distal part of the stem to the global volume of the humerus. The underlying rationale of this analysis was that the interlocking procedure is not necessarily induced by poor distal press-fit fixation (Fig. 2).

On the latest X-rays, glenoid notching was investigated and rated according to the Sirveaux classification [10, 11].

Migration, stress shielding, or cortical bone resorption around the stem were identified and located according to Inoue's criteria [12]. If the stem was interlocked, mobility of the screws was particularly evaluated.

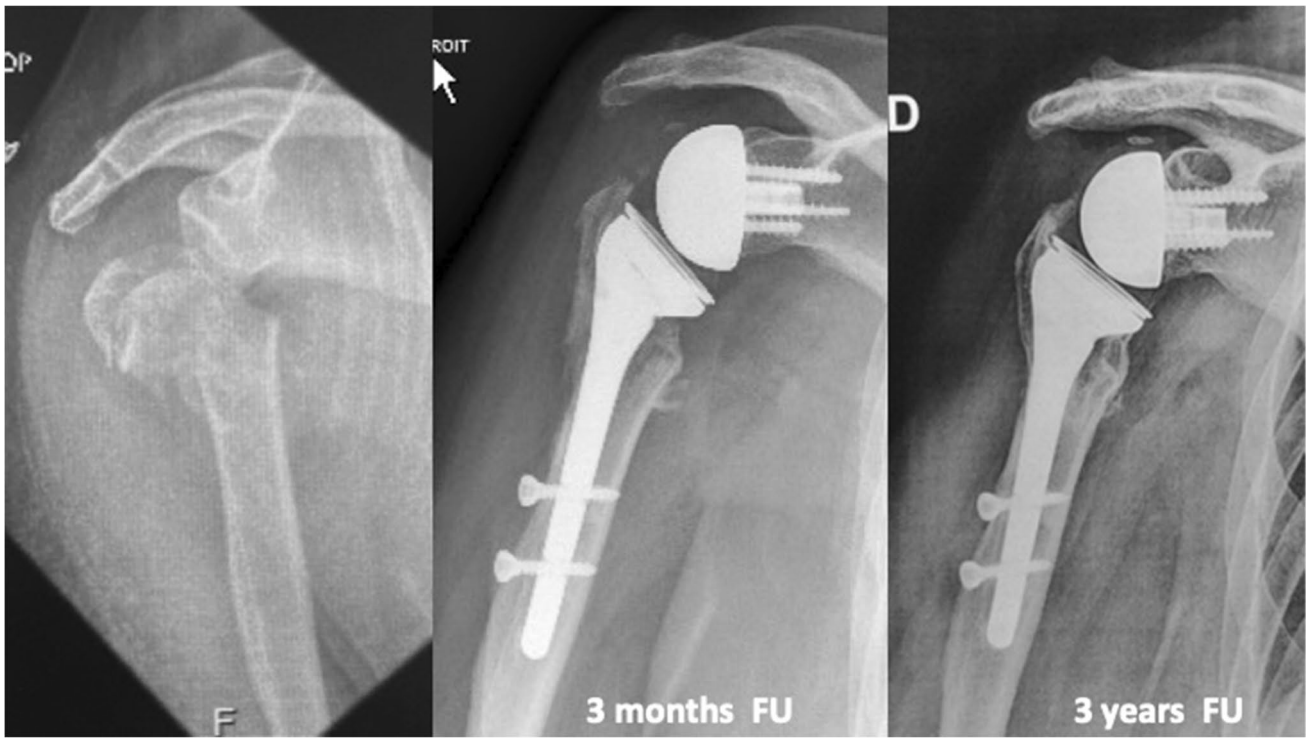

Fig. 2 Measurements of the filling ratio on AP (proximal and distal) and lateral (distal) X-rays. The blue line materializes the shaft axis (SA) of the humerus. At the level of the humeral baseplate and at the level of the junction between the 2nd and the distal third of the stem, two lines are drawn perpendicular to the SA. The green lines illustrate the measurements of the stem width, and the red lines illustrate the measurements of the endocortical width. The filling ratio is calculated by dividing at each level the stem width by the endocortical width

Statistical analysis

Continuous quantitative variables were described by mean and standard deviation (SD). Dichotomous variables were described by their number of events and their percentage. Fisher's exact test and Wilcoxon rank sum test were used for categorical and continuous variables. The threshold of significance retained was 5% for a power of 80% and a risk of the first species at 5%. All tests were two sided. The R software (version 3.5.0) was used to perform the statistical analyses.

Results

Seventy patients with 72 shoulders were included in the present study with 22 men (31.4%) and 48 women (68.6%). Mean age at surgery was 63 years old (range 49 to 78).

Surgical procedure

All patients had the same glenoid replacement with 69 patients receiving a centered glenosphere in sizes 36 mm (83%) or 40 mm (16%) and one patient receiving an eccentric 36 mm glenosphere. All glenospheres were impacted and screwed onto a 24 mm diameter base plate. This hydroxyapatite coated baseplate was secured to the glenoid by a central peg coated with hydroxyapatite (HA) and fixed by one to four locking or compression screws.

This Humelock Reversed® implant is 145° inlay implant. The polyethylene humeral cup used was + 3 in 90% of cases, + 6 in 6% of cases, and + 9 in only one case (Fig. 1).

All stems in this study were press fit, and no cement was used during surgery. For eight cases, press fit was not enough to allow stability, and the interlocking screw system was also used.

Eight stems needed interlocking screwing. There were two primary reasons for choosing to interlock the stem:

– The first indication ($n = 6$) for interlocking was when the surgeon considered that the primary fixation was not rotationally or otherwise stable. Primary stability was systematically assessed by providing a rotation of the trial stem inside the humerus. Any mobility at this time was considered to be a risk of fixation failure, which then led to locking the stem. This can occur during revision

surgery after the removal of a previous implant or in a complex proximal trauma.

– The second indication ($n = 2$) for interlocking was to restore the length of the humerus in traumatic complex fracture patterns. For this specific indication, surgery was performed under C-arm control, and lengthening of the deltoid was assessed on pre-operative X-rays. The interlocking system provides the ability to put a temporary wire through the stem to check the arm lengthen, the proximal humerus reconstruction, and the implant stability before interlocking the screws (Figs. 1, 3, and 4).

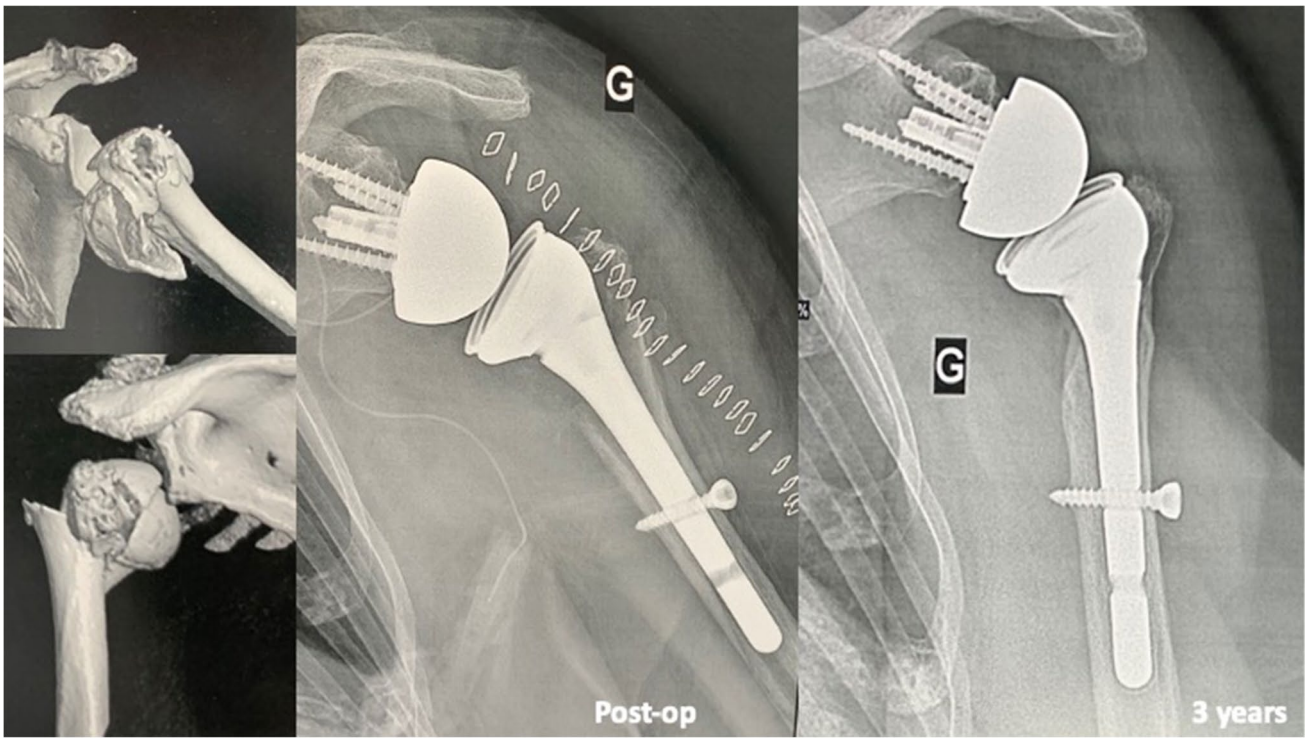

Fig. 3 Trauma case: 4 parts fracture with humeral head split treated with locked Humelock Reversed. X-rays at 3 months and 3-year follow-up: healing of the tuberosity is seen at the proximal stem, and no stress shielding is seen around the distal screws fixation

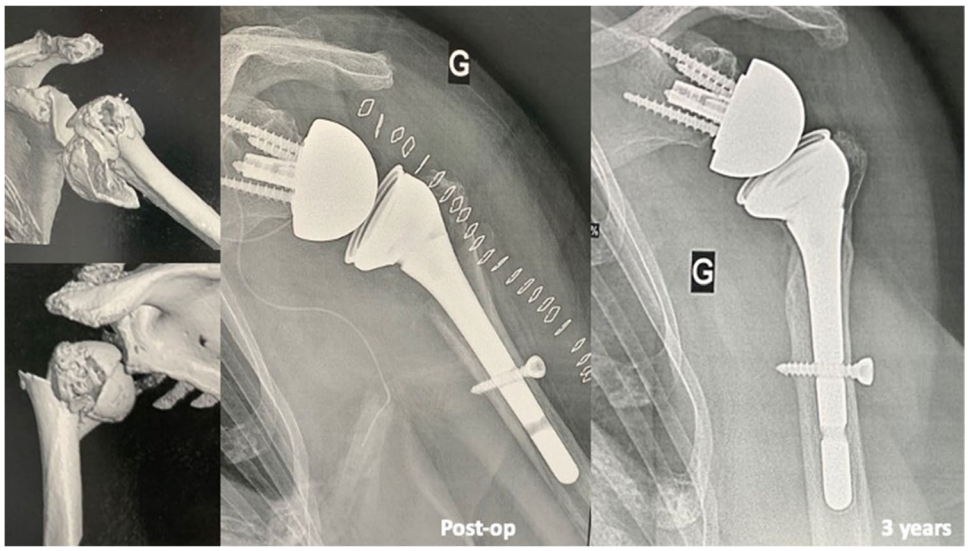

Fig. 4 Trauma case: 4 parts fracture with humeral head split treated with locked Humelock Reversed. X-rays at post-operative and 3-year follow-up: healing of the tuberosity is seen at the proximal stem, and no stress shielding is seen around the distal screw fixation

Technical procedure of the locking system

The surgical procedure was performed based upon the surgeon's standard approach like for any other RSA. Selection of the final humeral implant included both the unlocked and locked stem. For the locked humeral stem, one or two 4.5-mm cortical screws are available as an option for locking the humeral stem. To lock the stem, it is first impacted using the Trauma Aiming Guide (Fig. 1). Then one or two incision points are prepared for the Drill Guide Sleeve, with blunt dissection of the soft tissue to expose the bone using forceps. After having carefully dissected the soft tissue, the 10-mm guide is inserted into the proximal hole of the aimer until contact is made with the cortex using the soft tissue holder. The 4.5-mm guide is inserted into the 10-mm guide, and the drill guide is placed into the desired hole for screw fixation. The Drill Guide Sleeve should contact bone to provide an accurate screw length than can be measured directly on the drill guide.

Clinical results

Clinical indications

Pre-operative indications included 31 (46%) cases for cuff tear arthropathy, 13 (19%) cases for fractures, 11 (16%) cases for osteoarthritis, eight (12%) cases for irreparable rotator cuff tear, and three (4%) cases for revisions after ORIF. In two (3%) cases, the Humelock Reversed® stem was implanted in revision surgery after removing the primary stem. Based on bony deformity for degenerative cases and on previous conditions (revision) on other cases, surgeons reported that 48 cases (68.6%) were "complex" arthroplasties (Table 1).

Functional results

The minimum follow-up was 24 months, with mean follow-up of 38 (SD ± 13) months. At the longest follow-up, the global post-operative raw Constant score was 70 (SD ± 13); and the age-adjusted Constant score was 96.4 (SD ± 26). As previously mentioned in the method above, the pre-operative Constant score was not available for patients operated for trauma. Constant score for trauma and non-trauma patient is analyzed separately. For non-trauma patients, the mean raw Constant score improved significantly from 31 (SD ± 12) pre-operative to 71 (SD ± 12) at final post-operative follow-up. The final post-operative mean raw Constant score for trauma patients was 63.4 and significantly differed from the mean Constant score from non-trauma cases with a mean of 72.1 points. The final mean raw Constant score for trauma was 63.4 and significantly differed from the mean Constant score from non-trauma cases with a mean of 72.1 points. At last follow-up, the mean Constant score in revision procedures (69.65 (SD ± 3.37)) was not statistically different from primary procedures (71.74 (SD ± 12.11)) (Tables 2 and 3).

Radiological evaluation

Analysis of the filling ratio at the proximal and distal part of the stem demonstrated no difference between interlocked and pure press-fit stems. Those elements demonstrate that the humeral shaft and metaphysis was not larger compared to the stem size when using locking system (Table 4). Ten (10%) of the patients are presented with loosening around the stem at the final follow-up. But this loosening appeared only in cases of hardware or stem removal during surgery or in trauma cases. Locking the stem did not increase the risk of loosening. We identified no mobility chamber,

Table 2 Global clinical and radiological results at minimum 2-year follow-up using Humelock Reversed stem (Fx Solutions) results

Parameters	Values	*N*	Statistics*
		72	
last_follow_up_.months		67	38 (13.08)
Postop_complication_Y / N	No	51	79.69%
	Yes	13	20.31%
raw_constant_last_follow_up		65	70.27 (12.76)
adjusted_constant_last_follow_up		66	96.4 (26.04)
LATE_RX_glenoid_notch_Y / N	No	50	94.34%
	Yes	3	5.66%
LATE_RX_humeral_osteolysis_Y / N	No	40	80%
	Yes	10	20%

Table 1 Possible indications for locking the stem RSA

Indication of locked stem	Improve primary stem fixation	Adjustable Lengthening of arm
Complexes proximal fractures (fracture dislocation/mal-union)	Proximal bone loss challenging stability	Good deltoid lengthening
Poor metaphyseal quality bone/bony defect/ONA	Rotation instability inside the bone	
Revision surgery of arthroplasty/ORIF	Poor proximal primary fixation	
Sequelae of trauma	Hazardous proximal fixation	Good deltoid lengthening

no sign of stress shielding, and no loosening around the distal part of the stem or the screw (Table 5). For fracture cases, the healing of the tuberosities was equivalent in both groups.

Glenoid notching was observed in three (6%) cases. According to Sirveaux classification [11], glenoid notching were observed in zone 1 in one case and in zone 2 in two cases.

Complications and revision

Six (6) complications were reported: one acromial fracture after a fall trauma treated non-operatively, one infection, one malunion of tuberosities after trauma, one complex regional syndrome (with negative aspiration), one haematoma with phlebitis, and one intra-prosthetic dislocation. One (1) single surgical revision was for a patient with an intra-prosthetic dislocation at eight months post-operatively. Only the glenoid components were replaced. Eleven months after the revision, radiological assessment identified radiolucencies around the dome of the glenoid. This patient had a history of alcoholism and died two years post-operatively due to hepatic impairment.

Discussion

The current study demonstrates good clinical outcomes of the Humelock Reversed® stem for various indications, by press-fit or interlocking screw fixation of the humeral stem [1–3]. The rate of complications (8.6%) and revision (1.4%) appears lower than those reported in literature by Barco et al. [13]; however, in comparison, these results are for shorter follow-up. RSA is commonly used in degenerative and trauma conditions in elderly patients because they provide rapid and good clinical outcomes. Humelock Reversed® stem can be used without cement, with a neck shaft angle of 145°, inlay implant, with the potential to interlock with one

Table 3 Results for primary or revision procedure

Parameters	Values	*N*	Statistics*	*N*	Statistics*	*p* value
		46	Revision procedures	21	Primary procedure	
raw_constant_last_follow_up		44	69.65 (13.37)	19	71.74 (12.11)	0.38

Table 4 Radiological results: filling ratio—radiological analysis demonstrates that there is no direct correlation between the filling ratio at the metaphyseal and distal part of the stem and the locking indication

Parameters	Values	*N*	Statistics*	*N*	Statistics*	*p* value
		64	Pure press-fit fixation	8	Locked stem	
RX_J0_FRm		30	0.6787(0.1399)	1	0.68(NA)	1.00
RX_J0_AP_FRd		30	0.803(0.115)	1	0.67(NA)	0.24
RX_J0_L_FRd		22	0.7855(0.08064)	1	0.61(NA)	0.15

Table 5 Proximal osteolysis: the current table demonstrates that proximal integration of the stem is not impacted by a primary distal fixation performed by a screw nor by the presence of a cortical contact of the distal stem

Parameters	Values	*N*	Statistics*	*N*	Statistics*	*p*-value
		40	No proximal resorption	10	Proximal resorption	
RX_J0_FRm_taux	< 0.7	13	59.09%	2	50%	1.00
	> 0.7	9	40.91%	2	50%	
RX_J0_AP_FRd_taux	< 0.7	3	13.64%	2	50%	0.15
	> 0.7	19	86.36%	2	50%	
RX_J0_L_FRd_taux	< 0.7	3	21.43%	0	0%	1.00
	> 0.7	11	78.57%	3	100%	
Humeral_stem_screw_Y / N	*n*	38	95%	9	90%	0.50
	y	2	5%	1	10%	
RX_J0_Humerus_contact_cortical_distal	0	15	38.46%	2	25%	0.69
	1	24	61.54%	6	75%	

or two screws if required for intra-operative stability. This interlocking system can be used when the primary fixation of the stem seems to be jeopardized by the bone quality or anatomy or when the proximal humerus reconstruction needs to be performed on a stem that does not have a good primary press-fit stability in the shaft. The interlocking system is performed using a specific guide allowing for a simple and reproducible inter-locking procedure, similar to a short nail for hip fractures. The use of a 145° angulation was based on the experience of design surgeons who used the original Grammont prosthesis for fracture cases [5, 11]. The glenosphere is a 10° inferiorly inclined glenosphere that is fixed to a 24-mm baseplate. This combination has been confirmed to be one of the most efficient combinations to restore range of motion by Ladermann et al. [14].

Phadnis et al. [8] compared the results of cemented vs. uncemented RSA in a systematic review. The authors reported that the functional outcome and range of motion were equivalent in the two groups. Uncemented stems had a significantly higher incidence of early humeral stem migration and nonprogressive radiolucent lines but a significantly lower incidence of post-operative fractures of the acromion compared with cemented stems. Even if there was no difference in the risk of stem loosening or revision between the groups, the cemented stems had a greater relative risk of infection, nerve injury, and thromboembolism. Those risks may be related to the fact that cement is often used in more complex conditions when distal fixation is uncertain.

More recently, Rossi et al. [7] focused specifically on uncemented vs. cemented RSA in trauma conditions. They found in a retrospective study no significant differences in the final range of motion and functional scores between the cemented and uncemented groups of a study of 67 patients. The rate of tuberosities healing did not vary significantly in relation to whether the stem was cemented or not. "Lo et al. [15] reported good clinical outcomes in acute and chronic proximal humeral fractures with a rate of complications of 21%.

The study outlines the benefit of the current interlocking stem design even in complex cases with poor primary proximal fixation. Our rate of complications was reasonably low compared with standard stem reverse prosthesis (13)."

The rate of complications and revision in the current study appears to be lower than those reported in the review from Barco et al. [13]. It is important to note that the follow up in the current study is only three years.

Analysis of the filling ratio at the proximal and distal part of the stem demonstrates no difference between interlocked and non-locking stems. It suggests that the stability of this uncemented stem is not only based on the distal press fit of the stem or the cortical contact of the distal part of the stem. In the same way, this data tends to demonstrate that rotation stability is not only based on the quality of the proximal bone but also to the diaphysis, independently of any cortical contact. We hypothesized that smaller stems in the diaphysis and metaphysis (lower filling ratio) would be more at risk of interlocking, but this was not found in the current study. Thus, the diameter of the humerus and size of the proximal geometry, and then the filling ratio provided by the stem, are not predictive of primary stability.

Limitations

This is a retrospective study in which patients who refused to participate or were lost to follow-up at minimum two years were not included in the analysis. The number of patients that underwent a locking of the stem is limited, probably because of the design of the stem that naturally provides good quality of primary stability. The number of acute trauma cases is also low.

Conclusion

This study confirms good results of the Humelock Reversed® stem design in degenerative or traumatic conditions with and without interlocking the humeral stem. When the primary fixation of the stem is jeopardized by the quality of the bone or the difficulty to reconstruct the proximal epiphysis, the interlocking system of the stem is a good alternative to the cement fixation. We do not report any complication related to the locking process, and midterm follow-up confirms that the fixation of the stem in the bone is not negatively impacted by the interlocking fixation.

Author contribution GN, principal investigator, edition, data collection radiology analysis, and writing; SC, data collection, radiology analysis, and writing; US, edition; AS, KB, SP, OL, and TL, data collection; PAB, statistical analysis.

Data availability Data are available in an excel file.

Declarations

Ethics approval This research study was conducted retrospectively from data obtained for clinical purposes. We consulted extensively with the IRB of XYZ who determined that our study did not need ethical approval ("comité d'éthique d'établissement de la Clinique Maussins-Nollet" on November 2019 number 2019–11/03).

Consent to participate Consent to participate was obtained from all patients by sending a non-opposition letter during review.

Consent for publication Not applicable.

Conflict of interest Authors GN, US, AS, KB, SP, OL, and TL are consultant for Fx Solutions and have had received speaker and consultant honoraria from FX Solutions Company. Authors SC and PAB have no financial interest with the current study.

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