



## Stemmed hemiarthroplasty with a suture collar and a common platform system for acute proximal humeral fractures

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**Background:** Hemiarthroplasty for acute proximal humeral fractures gives disappointing results, often due to rotator cuff insufficiency. Better tuberosity fixation might improve results. Therefore, the aim of this study was to: 1) report the outcome of a stemmed hemiarthroplasty with a common platform system and a modular suture collar; 2) compare the outcome with that of a standard stemmed hemiarthroplasty; 3) report the feasibility of revision arthroplasty with retention of the stem; and 4) to evaluate the association between tuberosity healing and functional outcome.

**Methods:** Forty-four fractures that were deemed not suitable for nonsurgical treatment or open reduction and internal fixation were treated with the Global Unite fracture system between January 2017 and July 2019. The functional and radiographic results at 2 years were compared with the results of 44 Global Fx arthroplasties. The results of patients who had adequate healing of the greater tuberosity were compared with the results of patients who had severe malunion or nonunion (resorption).

**Results:** Mean Oxford Shoulder Score, Constant-Murley Score, and Western Ontario Osteoarthritis of the Shoulder index was 33 (range: 10 to 48), 40 (range: 10 to 98), and 68 (range: 18 to 98) at 2 years. There were no differences in functional outcome scores or in the risk of inadequate healing of the greater tuberosity between the Global Unite and the Global Fx systems. Five (11%) patients underwent revision surgery with retention of the stem. Inadequate tuberosity healing was associated with an inferior Constant-Murley Score (mean difference: 6; 95% confidence interval: 1 to 10,  $P = .01$ ) and an inferior Oxford Shoulder Score (mean difference: 9; 95% confidence interval: 1 to 16,  $P = .03$ ).

**Conclusion:** The use of stemmed hemiarthroplasty with a suture collar did not improve the healing of the greater tuberosity or the functional outcome. Five arthroplasties were revised with retention of the stem. This possibility could be arguments for using the Global Unite system when a stemmed hemiarthroplasty is used for acute proximal humeral fractures.

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The stemmed hemiarthroplasty was introduced by Neer in the 1950s for head-split fractures and fracture dislocation of the proximal humerus.<sup>21</sup> The indication later expanded to include displaced 3- and 4-part fractures unsuitable for open reduction and internal fixation. The outcome of stemmed hemiarthroplasty for

acute fractures are, however, unpredictable and often disappointing.<sup>1,7,11,17,22,25</sup> Randomized clinical trials have reported similar poor functional outcome of hemiarthroplasty and nonoperative treatment for displaced 4-part fractures.<sup>6,23</sup>

Several factors may affect the outcome of stemmed hemiarthroplasty, including the healing of the tuberosities and rotator cuff integrity. Severe malunion and nonunion of the tuberosities occur in up to 44% of patients with an acute fracture treated with hemiarthroplasty.<sup>4,12–15,18</sup> The use of a stemmed hemiarthroplasty with a modular suture collar may, in theory, improve the functional outcome by reducing the risk of tuberosity and rotator cuff complications.

In contrast to the poor functional outcome, the rate of revision of stemmed hemiarthroplasty for acute fractures remains low.

Permission to handle and store data was obtained from the Danish Data Protection Agency (j.no.: 2012-58-0004), and the study was evaluated by the Regional Research Ethic Committee (j. no.: H-17003344).

This trial was registered at ClinicalTrials.gov (NCT identifier number: NCT03097406).

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Surgeons may be reluctant to revise because of the risk of perioperative fractures when the cement and stem are removed. The use of a stemmed hemiarthroplasty with a common platform system allows the retention of the stem if revision surgery is needed. Thus, revision arthroplasty with the retention of the stem is associated with lower operative time and fewer complications compared with revision arthroplasty with stem removal.<sup>16</sup>

The aim of this study was to: 1) report the outcome of a stemmed hemiarthroplasty with a common platform system and a modular suture collar; 2) compare the outcome with that of a standard stemmed hemiarthroplasty; 3) report the feasibility of revision arthroplasty with retention of the stem; and 4) evaluate the association between tuberosity healing and the functional outcome.

Our hypotheses were that: 1) the use of a stemmed hemiarthroplasty with a modular suture collar would improve the functional outcome; 2) the stemmed hemiarthroplasty with a modular suture collar would reduce the risk of tuberosity and rotator cuff complications; 3) the use of a stemmed hemiarthroplasty with a common platform system would allow for revision with retention of the stem and subsequently an improved outcome of the revision procedure; and 4) severe malunion or nonunion of the greater tuberosity is associated with a poor functional outcome.

## Patients and methods

### *The Global Unite system*

Patients with proximal humeral fractures that were deemed not suitable for non-surgical treatment or open-reduction and internal fixation were treated with the Global Unite fracture system (DePuy Synthes, Warsaw, IN, USA). Sixty patients were admitted to Herlev and Gentofte University Hospital or Zealand University Hospital between January 2017 and July 2019. All patients underwent preoperative radiographs and computed tomography scans.

The indication for hemiarthroplasty treatment was determined by specialized shoulder surgeons. The inclusion criteria were fracture dislocations, selected displaced 4-part fractures, selected displaced 3-part fractures, or head-split fractures. We excluded patients who were younger than 50 years ( $n = 2$ ) or older than 89 years ( $n = 0$ ), patients who were not living in Denmark ( $n = 0$ ), patients without a Danish civil registration number ( $n = 0$ ), patients who were treated with a reverse shoulder arthroplasty because of severe degeneration of the rotator cuff ( $n = 1$ ), patients with linguistic or cognitive impairment ( $n = 2$ ), patients who refused to participate in the follow-up examination ( $n = 4$ ), and patients who died before the 2-year follow-up examination ( $n = 6$ ). Furthermore, we excluded one patient whose surgical procedure was abandoned because of severe anesthetic complications. Forty-four patients attended the 2-year follow-up examination, and their results were included in the analysis.

Surgery was performed by senior consultants at Herlev University Hospital or Zealand University Hospital. All patients received a Global Unite hemiarthroplasty with a suture collar and a common platform system. The procedures were performed according to the surgical technique guide provided by the manufacturer.<sup>10</sup> Patients were placed in the beach chair position and operated under general anesthesia and interscalene block. All patients were operated by deltopectoral approach.

The affected arm was placed in a sling for 6 weeks postoperatively. Passive and unloaded exercises were initiated after 48 hours. Exercises with loads were initiated 6 weeks postoperatively.

The preoperative computed tomography scans were assessed by the authors and classified according to the Neer classification<sup>20</sup> based on a consensus agreement. Data related to the injury, the patient, and the operations were recorded.

### *The comparator, the Global Fx system*

We identified a historical consecutive cohort of 94 patients who were treated with the Global Fx system (DePuy Synthes) for acute proximal humeral fractures at our departments before the Global Unite system was introduced. The patients were treated between July 2013 and January 2017 by the same surgeons who later used the Global Unite system. The procedures were performed according to the surgical technique guide provided by the manufacturer. Patients were placed in the beach chair position and operated under general anesthesia and interscalene block. All patients were operated by deltopectoral approach. The rehabilitation was the same as for the Global Unite system.

Six out of the 94 (6%) arthroplasties were revised. Five of these patients died before the follow-up examination, and the sixth patient, who had a revision arthroplasty refused to participate. Of the remaining 88 patients, 18 died before the follow-up examination, 3 were younger than 50 years, 4 were older than 89 years, and 19 refused to participate. Thus, 44 patients were available with a minimum follow-up of 2 years.

The inclusion of 44 patients with a Global Unite system and 44 patients with a Global Fx system was based on an equality sample size calculation with the Constant-Murley Score (CMS) at 2 years as the primary outcome, a power of 80%, a difference of 12, and a standard deviation of 20. The difference of 12 was based on the minimal clinically important difference of the CMS for patients with a proximal humeral fracture.<sup>26</sup>

### *Functional outcome measures*

Patients were clinically evaluated at 3, 6, 12, and 24 months postoperatively using the Oxford Shoulder Score (OSS), the CMS, the Western Ontario Osteoarthritis of the Shoulder index (WOOS), and the subscale score of pain from the CMS. Patients were contacted by phone or mail and were invited to a new visit if they missed a follow-up examination. The functional outcome at 2 years was used as the primary outcome and was compared with the 2-year results of the Global Fx.

CMS is a shoulder-specific observer-administrated instrument containing two subjective aspects: pain and activities of daily living, and two objective aspects: range of motion and strength. The total score ranges from 0 to 100, with 100 being the best. For the strength test, a dynamometer (IsoForceControl; MDS Medical Device Solutions AG, Oberburg, Switzerland) was used with the patient's arm in 90 degrees abduction, elbow fully extended, and hand in pronation.<sup>8</sup>

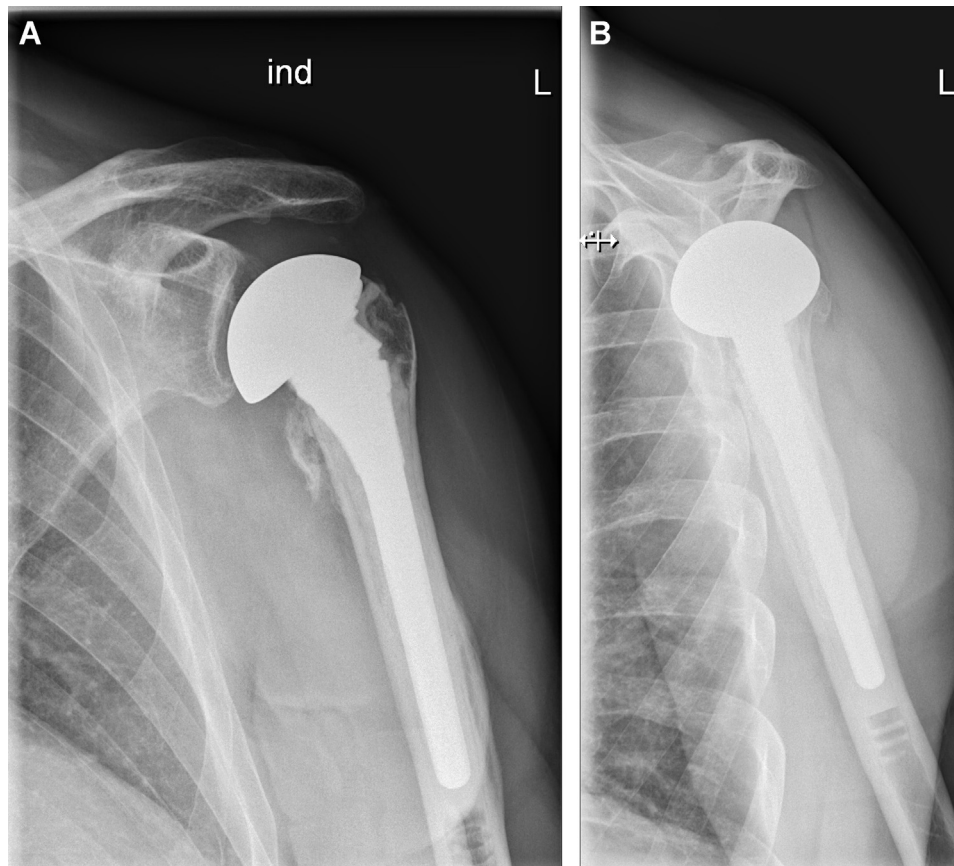
We used the subscale score of pain from CMS as an outcome. The patients report the most severe pain felt during normal activities over a 24-hour period using a visual analog scale ranging from 0 to 15, with 15 as a pain-free should.<sup>8</sup>

OSS is a shoulder-specific, patient-administered questionnaire containing 12 items with a categorical score from 0–4 for each item. Thus, the total score ranges from 0 to 48, with 48 being the best.<sup>9</sup>

WOOS is a patient-administered questionnaire with 19 questions. Each question is answered using a visual analog scale ranging from 0 to 100, with 100 being the worst. The total score ranges from 0 to 1900, with 1900 being the worst. We converted the total score to a percentage of the maximum score, with 100 being the best.<sup>19</sup>

### *Revisions*

The reason for revision, whether the revision procedure was done with retention of the stem, and date of revision were registered. Patients who underwent revision surgery were followed with visits as planned according to the primary surgery. Revision



**Figure 1** Anterior/posterior (A) and lateral view (B) showing adequate healing of the greater tuberosity.

was defined as exchange, or removal of any component or the addition of a glenoid component.

#### Radiographic outcome

Standardized radiographs with anterior/posterior and lateral projection were obtained at the follow-up visits. At 2 years, the status of the greater tuberosity was classified as nonunion (resorption), severe malunion (visible greater tuberosity on the lateral view but not on the anterior-posterior view), or bone healing with adequate position based on a consensus agreement, **Figs. 1–3**.

#### Statistical analyses

Descriptive statistics were used to report demographics. Continuous data were reported as mean or median depending on the distribution of data. A linear mixed effects model was used to report the prospectively collected outcome scores of the Global Unite system. The outcome scores were used as dependent variables, and the time of visits were used as fixed factors. An unstructured covariance matrix was used. The results of the revision arthroplasties were reported as case level data. The results of the Global Unite system and the Global Fx system were compared using a multiple linear regression model. Gender and age group (70 years or younger and older than 70 years) were included in the model. The logistic regression model was used to compare the healing of the greater tuberosity for the Global Unite and Global Fx systems. Gender and age group (70 years or younger and older than 70 years) were included in the model. The results for patients with non-union or severe malunion were compared with the results for

patients with adequate bone healing using a multiple linear regression model. Arthroplasty system, gender, and age group (70 years or younger and older than 70 years) were included in the model. Differences were reported with a 95% confidence interval (CI). *P* value less than .05 was considered statistically significant. SPSS version 25 (IBM Corp., Armonk, NY, USA) was used to perform the analyses.

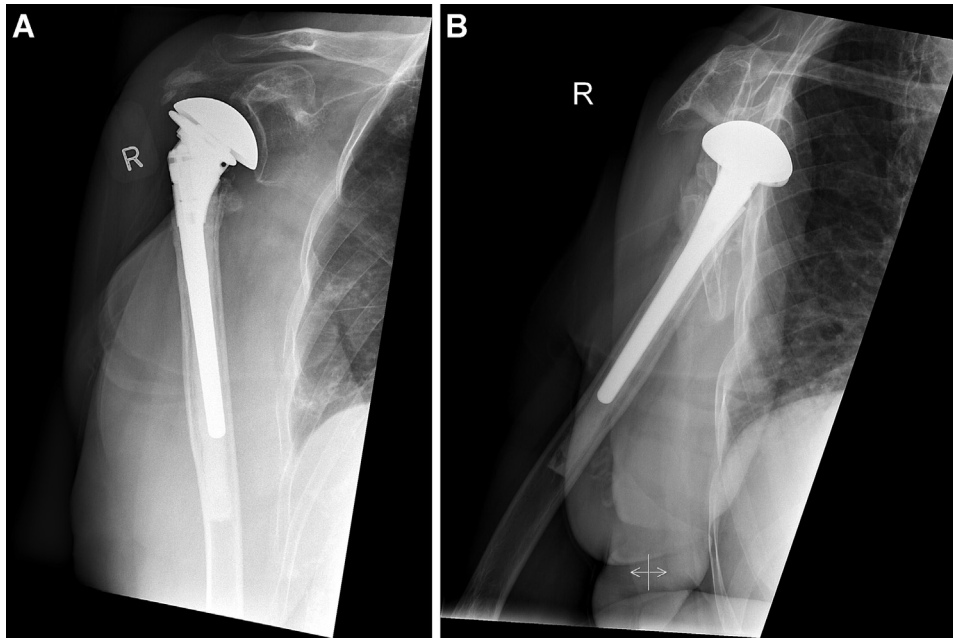
#### Results

##### *The Global Unite system—baseline characteristics*

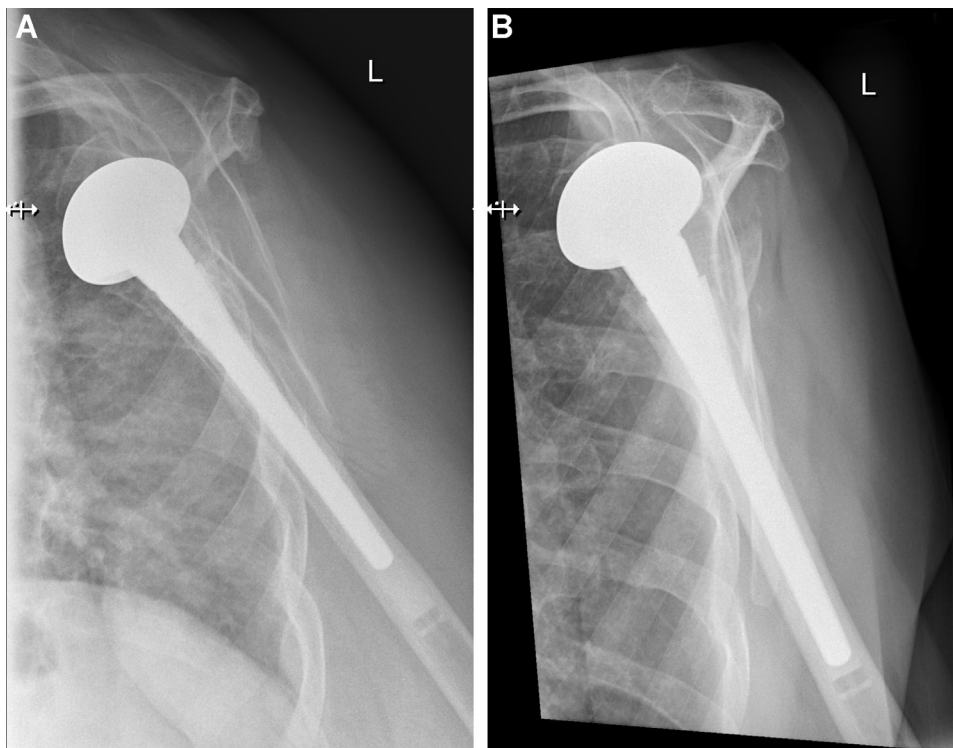
The mean age was 69.8 years (range: 51.0 to 88.0), and 18 (41%) patients were 70 years or younger. Thirty-five (79.5%) patients were women. The median time from injury to surgery was 8 days (range: 1 to 68). Four patients were treated for more than 30 days after the injury. Two patients because of an open wound/excoriation on the humerus (41 and 49 days), and two patients because of surgeon delay (34 and 68 days). The procedures were done at Herlev Hospital (*n* = 23) and Zealand Hospital (*n* = 21). Fractures were classified as Neer type 8 (*n* = 9), type 9 (*n* = 4), type 10 (*n* = 4), type 12 (*n* = 9), type 13 (*n* = 6), and type 15 (*n* = 12). Cemented fixation was used in 32 (72.7%) patients. Mean surgery time was 111 minutes (range: 69 to 165 minutes).

##### *The Global Unite system—functional outcome and revision*

The mean OSS, CMS, WOOS, and pain score was 33 (range: 10 to 48), 40 (range: 10 to 98), 68 (range: 18 to 98), and 12 (range: 2 to 15) at 2 years. The differences between the four time-points were



**Figure 2** Anterior/posterior (A) and lateral view (B) showing severe malunion of the greater tuberosity (defined as visible greater tuberosity on the lateral view but not on the anterior-posterior view).



**Figure 3** Anterior/posterior (A) and lateral view (B) showing nonunion (resorption) of the greater tuberosity.

statistically significant for OSS ( $P = .011$ ), CMS ( $P = .049$ ) and WOOS ( $P = .007$ ) but not for the CMS subscale score of pain ( $P = .941$ ), [Table I](#). Five (11%) arthroplasties were revised. The reason for revision was rotator cuff insufficiency in all cases. In all 5 cases, the hemiarthroplasty was converted to a reverse shoulder arthroplasty with retention of the stem. Three patients who had a revision arthroplasty had outcome scores comparable to the entire cohort, whereas two patients had poor outcomes ([Table II](#)).

#### Comparison of the Global Unite system and the Global Fx system

For patients who were treated with the Global Fx system the mean age was 71 years (range: 50 to 83 years), and 21 (48%) patients were 70 years or younger. 37 (84%) patients were women. The mean OSS, CMS, WOOS and pain score was 35 (range: 6 to 48), 40 (range: 13 to 94), 70 (range: 7 to 100), and 12 (0 to 15). The difference between the Global Unite system and the Global Fx

**Table 1**  
Pairwise comparison of the outcome score at 6, 12, and 24 months with the outcome score at three months as reference.

Follow-up time	Difference	95% CI	P value
CMS			.049
3 mo	reference	reference	reference
6 mo	3.7	−0.5 to 7.8	.079
12 mo	5.4	1.3 to 9.6	.011
24 mo	7.3	1.8 to 12.9	.011
OSS			.011
3 mo	reference	reference	reference
6 mo	3.6	1.1 to 6.2	.007
12 mo	3.9	1.2 to 6.5	.005
24 mo	4.4	4.4 to 7.2	.003
WOOS			.007
3 mo	reference	reference	reference
6 mo	3.9	−3.3 to 11.2	.277
12 mo	9.3	2.8 to 15.8	.007
24 mo	11.6	3.7 to 19.4	.005
Pain score			.941
3 mo	reference	reference	reference
6 mo	0.5	−1.2 to 2.3	.556
12 mo	0.3	−1.6 to 2.1	.782
24 mo	0.3	−1.4 to 2.1	.724

CMS, Constant-Murley Score; OSS, Oxford Shoulder Score; WOOS, Western Ontario Osteoarthritis of the Shoulder index; CI, confidence interval. Pain score (subscale score of pain from the Constant-Murley Score).

system was 0 (95% CI: −4 to 5,  $P = .89$ ) for OSS, 3 (95% CI: −5 to 10,  $P = .45$ ) for CMS, 4 (95% CI: −6 to 11,  $P = .40$ ) for WOOS, and 1 (95% CI: −1 to 2,  $P = .46$ ) for the CMS subscale score of pain in the multiple linear regression model.

### Healing of the greater tuberosity

Twenty-three (52%) patients who were treated with the Global Unite system and 18 (41%) patients treated with the Global Fx system had severe malunion or nonunion (resorption) of the greater tuberosity at 2 years. The risk of severe malunion or nonunion (resorption) for the Global Unite system was 1.6 (95% CI 0.7 to 3.9,  $P = .289$ ) with the Global Fx as reference. The mean OSS, CMS, WOOS, and pain score was 37 (range: 12 to 48), 41 (range: 10 to 98), 78 (range: 11 to 100) and 12 (0 to 15) for patients who had healing of the greater tuberosity, and 31 (range: 6 to 48), 37 (range: 10 to 75), 68 (range: 7 to 93) and 13 (0 to 15) for patients who had severe malunion or nonunion (resorption) of the greater tuberosity. The difference between patients who had healing of the greater tuberosity and patients who had severe malunion or nonunion (resorption) of the greater tuberosity was 6 (95% CI: 1 to 10,  $P = .01$ ) for OSS, 9 (95% CI: 1 to 16,  $P = .03$ ) for CMS, 10 (95% CI: −1 to 21,  $P = .06$ ) for WOOS, and 1 (95% CI: −1 to 2,  $P = .52$ ) for the subscale score of pain in the multiple linear regression model.

## Discussion

### The functional outcome of the Global Unite system

The mean CMS in our cohort was lower than the CMS reported in previous studies. A systematic review reported a mean CMS of 57 for eight studies involving 560 patients treated with hemiarthroplasty for a proximal humeral fracture.<sup>17</sup> The mean CMS in our study was, however, comparable with the results of stemmed hemiarthroplasty reported in previous randomized controlled trials.<sup>5,24</sup>

The reason for the inconsistent reporting is speculative. It might be related to differences in fracture morphology (eg, the severity of the fractures), follow-up time, age, comorbidity, functional

demands, and the surgical skills of the surgeons. We also emphasize that the use of CMS as an outcome measure may influence the comparison. Thus, the use of the CMS depends on the observers and their interpretation of the guidelines for using the CMS. According to the modified CMS guidelines, a patient needs to have 90 degrees abduction in the scapular plane to perform the strength test.<sup>27</sup> If patients cannot do this, they do not get any of the 25 points for the strength subscale score. The modified guidelines for the CMS were published in 2008, the same year as the systematic review.<sup>17</sup>

An outcome score should measure what the authors believe is important to the patients. Elderly and fragile fracture patients often have low functional demands but are very concerned about pain and, especially, their ability to remain independent of others. Sixty-five percent of the CMS is related to shoulder function (eg, range of motion and strength), whereas only 15% is related to pain. In this perspective, the CMS does not, in our opinion, measure what is important to the patients. An important finding of this study is the discrepancy between a low mean CMS score and a good mean pain score, good suggesting that the majority of patients experienced little or no pain at 2 years.

The discrepancy between the CMS and the impairment in the patient’s everyday life can also be reflected in differences between the CMS and the patient-reported outcomes (eg, the WOOS and the OSS). Thus, the OSS and WOOS scores in our cohort were relatively higher than the CMS when the total score was compared with the maximum score. A similar discrepancy was found in another study reporting functional outcome scores and social implications of hemiarthroplasty treatment of proximal humeral fractures in the elderly.<sup>11</sup> The patients had a median age of 80 years and suffered from mainly 3- and 4-part fractures. The authors found that 41 out of 48 elderly patients managed their daily lives and lived in their own homes for four years after their hemiarthroplasty, despite a mean CMS of 41. It is also worth noticing that the mean OSS in that study was 30 or 63% of the maximum score, which is comparable with our mean OSS of 33 or 69% of the maximum score.

### The functional outcome of the Global Unite and the Global Fx system

To our knowledge, this is the first study to compare the functional outcome of a stemmed hemiarthroplasty with a modular suture collar with the functional outcome of a standard stemmed hemiarthroplasty. We found similar outcomes for the Global Unite and the Global Fx system which were neither statistically significant nor clinically relevant. Thus, the Global Unite system does not seem to improve the modest functional outcome of stemmed hemiarthroplasty for acute proximal humeral fractures. We included the functional outcome scores of revised patients in the analysis at 2 years, providing an estimate for all patients who were treated with the Global Unite system during the study period. The inclusion of the revised patients’ scores might negatively affect the overall scores of the Global Unite system. This is important to keep in mind, especially since none of the six patients who had their Global Fx arthroplasty revised to a reverse arthroplasty during the study period were available for follow-up examination.

### Revision arthroplasty

All 5 revision procedures were performed with retention of the stem, and no intraoperative complications occurred. The outcome of the revision arthroplasty was promising. Information about the results of revision arthroplasty for failed hemiarthroplasty with retention of the stem is sparse. A systematic review concluded that the revision procedures with humeral stem retention are associated with lower operative time, blood loss, overall complications, and reoperations compared with revision procedures with stem

**Table II**  
Demographics, surgical data, and outcome scores for the five patients who had revision surgery.

Individual data	#1	#2	#3	#4	#5
Age (y)	75	65	63	70	71
Gender	female	male	female	female	female
Neer type	13	8	8	9	8
Healing	Yes	nonunion	nonunion	nonunion	nonunion
Time to revision (mo)	6	9	18	11	17
Reason for revision	Cuff problem	Cuff problem	Cuff problem	Cuff problem	Cuff problem
Stem retention	Yes	Yes	yes	yes	yes
Follow-up (mo)	12	15	14	13	7
CMS	38	14	38	55	15
OSS	33	14	40	32	10
WOOS	66	29	77	76	24
Pain score	10	5	13	13	3

CMS, Constant-Murley Score; OSS, Oxford Shoulder Score; WOOS, Western Ontario Osteoarthritis of the Shoulder index.

exchange.<sup>16</sup> However, the results should be interpreted with caution as it included all indications for primary shoulder arthroplasty and only included 1 level III study and 6 level IV studies.

In our study, rotator cuff failure was the indication for revision for all 5 patients. The Australian Orthopedic Association National Joint Replacement Registry flagged the Global Unite hemiarthroplasty in 2017 due to a higher than expected revision rate compared to other stemmed hemiarthroplasties.<sup>2</sup> They reported a 3-year cumulative revision rate of 19% for the Global Unite hemiarthroplasty when used for fractures.<sup>3</sup> The high rate of revision can, of course, be related to the arthroplasty design, but it is also possible that the indication for revising the Global Unite system with a common platform system is different from other well-fixed and nonconvertible stemmed hemiarthroplasty designs. Thus, some surgeons may see the Global Unite stemmed hemiarthroplasty with the common platform system as a first-in-line arthroplasty that can be converted to a reverse shoulder arthroplasty in case of rotator cuff failure.

The aim of this study was not to compare the results of the revision procedure of failed Global Unite and failed Global Fx. For this purpose, we would need a much higher number of patients. Even if the 6 patients with a revised Global Fx had been available for the follow-up examination, we would not have been able to make any safe conclusion.

*Healing of the greater tuberosity*

Previous studies have reported tuberosity resorption rates of up to 44% between 1 and 7 years postoperatively.<sup>12,15,18,22,24,25</sup> We found that 23 (52%) patients who were treated with the Global Unite system and 18 (41%) patients treated with the Global Fx system had severe malunion or nonunion (resorption) of the greater tuberosity at 2 years. It is important to keep in mind that 4 out of 5 Global Unite arthroplasties had nonunion of the greater tuberosity prior to the revision procedure and that these revised arthroplasties were included in the analyses. This can explain the higher rate of tuberosity resorption when the Global Unite group is compared with not only the Global Fx group but also with the results reported in the literature. In theory, the modular system with a suture collar allows the surgeon to anatomically reduce and fixate the tuberosities. However, we were unable to prove the concept.

The outcome of hemiarthroplasty depends on the rotator cuff and the healing of the tuberosities.<sup>4,5,12-14,18</sup> Studies have found lower CMS among patients with displacement or resorption of the greater tuberosity<sup>6,23</sup> and that tuberosity complications are associated with poor outcomes of every subscale scores of the CMS.<sup>25</sup> We found a difference between patients who had healing of the

greater tuberosity and patients who had severe malunion or nonunion (resorption) of the greater tuberosity of 6 for the OSS and 9 for the CMS. The differences were statistically significant but may not be clinically relevant.

*Methodological considerations*

This study has limitations known to observational studies. The risk of selection bias is important to keep in mind. Any systematic difference in fracture morphology, preoperative status of the rotator cuff, factors that could influence bone healing (eg, age, comorbidity, smoking status, etc.) might have influenced the results.

To our knowledge, there are no optimal outcome measures for elderly patients treated with shoulder arthroplasty for acute proximal humeral fractures. We emphasize that neither the CMS nor the patient-reported outcomes used in this study measure what is important to the patients. Furthermore, there is no defined value for a clinically relevant difference for fracture patients treated with shoulder arthroplasty for any of the outcome measures. This will inevitably impair the interpretation of the comparison of the Global Unite and the Global Fx systems.

**Conclusion**

The use of a stemmed hemiarthroplasty with a suture collar neither improves adequate healing of the greater tuberosity nor the functional outcome. Adequate healing of the greater tuberosity had a statistically significant impact on the functional outcome. Five arthroplasties were revised with retention of the stem. This possibility could be arguments for using the Global Unite system when a stemmed hemiarthroplasty is used for acute proximal humeral fractures.

**Disclaimers:**

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