Early management of complex proximal humeral fractures using the Aequalis fracture prosthesis

A TWO-TO FIVE-YEAR FOLLOW-UP REPORT

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We reviewed the outcome of 28 patients who had been treated using the Aequalis fracture prosthesis for an acute fracture of the proximal humerus at a mean follow-up of 39.3 months (24 to 63). The mean age of the patients at the time of the fracture was 66.3 years (38 to 80). The mean Constant score was 68.2 (37 to 84) for the operated shoulder, which represented 89.5% of the mean score for the uninjured side (p < 0.001). The quality of the reconstruction as shown on the immediate post-operative radiographs was categorised into three types, anatomical, acceptable, and unacceptable, depending on the position of the tuberosities relative to the prosthetic head and the humeral shaft. Anatomical reconstruction was associated with a higher mean Constant score as well as higher mean values of anterior forward elevation, abduction and external rotation than the other types, but the differences were not statistically significant (p > 0.231).

A total of 18 patients had active anterior elevation ≥ 150°. Their mean active abduction and external rotation were 163.6° and 31.3°, respectively. In seven of the 28 patients, the mean active anterior elevation, abduction and external rotation were 130.7°, 129.2° and 22.8°, respectively. In all, 12 patients were very satisfied with the results, 12 were satisfied, two were dissatisfied and two were disappointed; 26 reported no or only mild pain while only two had moderate pain. In five patients proximal migration of the humeral head was shown on the anteroposterior radiographs of the shoulder. No evidence of loosening was found in any prosthesis.

Several surgical options are available for the management of displaced fractures of the proximal humerus. Closed reduction and percutaneous pinning with or without isolated screws, open reduction and internal fixation with sutures either alone or combined with hardware, or plating are among the most commonly used methods. Fixed-angle plates have been introduced to provide a durable reduction especially when there is concern over the quality of the bone. The common aim of any operative intervention is the preservation of the vascularity of the humeral head and avoidance of avascular necrosis (AVN). Although not all cases of AVN will progress to collapse of the humeral head it does lead to a significantly worse outcome.

Shoulder hemiarthroplasty for fractures is indicated in cases of displaced and comminuted fractures in which the development of AVN of the humeral head seems to be inevitable. In younger individuals with similar patterns of fracture, if osteosynthesis cannot provide an anatomically reduced and stable proximal humerus, replacement with a prosthetic head may be the alternative.

Since the introduction of the first shoulder prosthesis for the management of fractures by Neer, several designs have been produced. Initially, the prostheses were monoblock. These were followed by a second generation of modular shoulder implants, which allowed better soft-tissue balancing. Contemporary third-generation prostheses additionally aim to recreate the bony geometry of the proximal humerus. However, the efficacy of shoulder hemiarthroplasty in terms of restoring normal kinematics and function remains a matter of controversy. The enthusiastic results published by Neer have not been repeated by all surgeons and debate continues between advocates and opponents of shoulder hemiarthroplasty for the treatment of fractures. The Aequalis fracture prosthesis (Tornier, Saint-Ismier, France) was developed to manage the
distorted anatomy as well as to provide the special functional requirements following fracture. It has a low-profile design with a metaphyseal window for bone graft and provides extensive space for bony ingrowth in order to maximise consolidation of the tuberosities. The metaphyseal portion of the prosthesis has a roughened surface with a thin coating of hydroxyapatite (HA) for bonding with bone, but its neck is polished to prevent abrasion of the sutures. Eccentric humeral heads of several sizes can be placed in several rotations to provide optimum cover of the reduced tuberosities (Fig. 1). The configuration of its upper, metaphyseal, part preserves more space for bone than in other designs, and necessitates a particular technique of osteosynthesis for the tuberosities.

We have evaluated the intermediate term results in a series of patients with a fracture of the proximal humerus in whom the Aequalis fracture prosthesis had been implanted at a single centre by a single surgeon (GMK).

Patients and Methods
Between April 2003 and December 2006, 33 patients with an acute fracture of the proximal humerus were treated using a cemented Aequalis fracture hemiarthroplasty. The indications for replacement of the humeral head were displaced three- and four-part fractures or fracture-dislocations, according to the criteria of Neer, in elderly patients with good general health. Inability to obtain a stable and anatomical osteosynthesis because of the severity of the fracture displacement and/or comminution, was the indication for prosthetic replacement in younger patients. This was an intraoperative decision, made in five patients who were aged less than 60 years. We excluded patients who posed a high peri-operative risk because of medical comorbidities such as coronary artery disease, recent myocardial infarction or respiratory disorders, those with pathological fractures or impaired mental status, and those who refused surgical treatment. All the shoulder injuries were isolated fractures.

Of the 33 patients who underwent treatment with this prosthesis, five were lost to follow-up, one of whom had died and four could not be traced. The remaining 28 patients (23 women and 5 men) were recalled for assessment. Their mean age at the time of fracture was 66.4 years (38 to 80) and the mean follow-up was 39.3 months (24 to 63). The indication for surgery was a four-part fracture in 18 patients, a four-part fracture with posterior dislocation in two, a four-part fracture with anterior dislocation in two, a three-part fracture with anterior dislocation in three, a three-part fracture in two and a three-part fracture with posterior dislocation in one (Table I). Surgery was undertaken at a mean of 5.14 days (0 to 15) after injury.

Operative technique. The deltopectoral approach was used with fixation of the tuberosities around the prosthesis performed according to the technique recommended by Boileau, Walch and Krishnan. This requires the fixation of the tuberosities around the prosthesis using four strong non-absorbable sutures, which are passed around the neck of the prosthesis for horizontal fixation of the greater tuberosity followed by the lesser tuberosity, and two vertical sutures to secure the tuberosities to the humeral shaft. We increased the number of horizontal sutures to six to eight No. 5 sutures (Ethibond, Ethicon Inc, Somerville, New Jersey) or the horizontal fixation. In all patients the prostheses were implanted in 20° of retroversion by externally rotating the arm in relation to the body. The tendon of long head of biceps was divided at its insertion and tenodesed by strong non-absorbable sutures into the insertion of pectoralis major. The latter was the reference point for the determination of the height of the stem when comminution of the calcar was present.

Post-operative rehabilitation. After the operation, the arm was supported in a sling. Pendulum exercises and passive anterior elevation of the shoulder in neutral rotation were begun on the first post-operative day. None of the patients was discharged before gaining at least 140° of supervised passive anterior elevation, usually at least one week after operation. Thereafter, passive anterior elevation in neutral rotation and pendular exercises were continued during the first six weeks and until radiological evidence of consolidation of the tuberosities was present. At this stage active shoulder movements were encouraged.

A detailed and supervised post-operative rehabilitation programme was not possible because of socio-economic factors in the organisation of the health system in our geographical region.
Clinical and radiological evaluation was performed by two of the authors (TIT, ZC) working together. **Radiological evaluation.** The immediate post-operative radiographs of the shoulder were used to categorise the reconstruction into one of three types depending on the position of the tuberosities relative to the prosthetic head and the humeral shaft. In type A the proximal humerus had been restored anatomically with respect to the prosthesis. In type B

<table>
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<th>Follow-up (mths)</th>
<th>Quality of tuberosity repair</th>
<th>Anterior elevation (°)</th>
<th>Abduction (°)</th>
<th>External rotation (°)</th>
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the tuberosities had been placed up to 1 cm inferior to the prosthetic head with the proximal humerus lacking the normal anatomical appearance. In type C the tuberosities had been fixed in a position more proximally than the prosthetic head or more than 1 cm distal to it (Fig. 2).

The most recent radiological examination of the shoulder comprising a true anteroposterior (AP) and a scapulolateral or axillary view, was evaluated for the position of the tuberosities around the prosthesis, the position of the prosthetic head relative to the acromion (the acromiohumeral distance), and the cement mantle for the development of radiolucencies in comparison with the immediate post-operative radiographs.

Clinical evaluation. Shoulder function was assessed using the scale of Constant and Murley²² and compared with the opposite uninjured shoulder. The score was rated from 0 to 100 and had two subjective components (pain up to 15 points and activities of daily living up to 20 points), and two objective components (range of movement up to 40 points and strength up to 25 points). We graded pain as none, mild, moderate or severe being in accordance with most published articles, which have used this scale of pain, instead of the recently recommended visual analogue scale for the Constant score evaluation.²² The range of movement was measured with a goniometer, and the muscle strength was estimated using a spring-resisted scale. In addition, the patients were asked about their satisfaction with the intervention.

Statistical analysis. One-way analysis of variance (ANOVA) was used to compare the means related to the function and the range of movement in relation to the quality of the upper humeral reconstruction in both the operated and uninjured shoulders.

A p-value ≤ 0.05 was considered to be statistically significant.

Results
The clinical details and information related to the operation and the outcome are shown in Table I. A total of 18 of the 28 patients had active anterior elevation of 150° or greater (mean 166.9°, 150° to 180°). In these 18 patients the mean active abduction and external rotation were 163.6° (120° to 180°) and 31.3° (10° to 40°), respectively. In seven of the 28 patients (6, 7, 9, 11, 24, 26, 28), the mean active anterior elevation, abduction and external rotation were 130.7° (125° to 140°), 129.2° (110° to 140°) and 22.8° (20° to 30°), respectively. The inferior results in the remaining three patients were attributed to the extensive soft-tissue damage associated with marked posterior dislocation of the humeral head and the development of severe heterotopic ossification (HO) which obstructed movement (case 13), to technical errors, such as higher placement of the prosthetic stem of about 1 cm (case 5) and placement of an oversized head (case 12). In two patients (5 and 12) overtensioning of the shoulder led to superior migration.

The mean modified Constant score was 68.2 points (SD 12.3) for the shoulders with a hemiarthroplasty and 76.2 points (SD 8.3) for the uninjured shoulders (p = 0.006). A total of 12 patients were very satisfied with the results, 12 were satisfied, two considered the result to be unsatisfactory and two were disappointed. Of the series, 19 patients reported no pain, seven mild and two moderate.

Table II gives the findings according to the quality of the reconstruction. The radiological assessment classified 13 patients as having an anatomical type A reconstruction, 14 as having an acceptable but not anatomical type B reconstruction and one patient had a type C unacceptable reconstruction (Fig. 2). Type A reconstruction was associated with a higher mean modified Constant score (p = 0.231) as well as higher mean values of anterior forward elevation (p = 0.261), abduction (p = 0.222) and

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Fig. 2a
Post-operative anteroposterior radiographs showing the categorisation of reconstruction of the tuberosities as a) anatomical, b) non-anatomical but acceptable and c) unacceptable.

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Fig. 2b

Fig. 2c

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external rotation (p = 0.275) than the other types, but the differences were not statistically significant (p > 0.2).

In five patients superior migration of the humeral head was noticed on the most recent AP radiographs and the acromiohumeral distance was less than 7 mm. In three of the five resorption of the greater tuberosity was also present. Assessment of the radiological appearance of the cement mantle found no differences between the initial and final radiographs and no evidence of prosthetic loosening in any of the 28 patients.

There were no intraoperative complications and no cases of neurological injury, infection, instability or nonunion of the tuberosities. One patient developed severe HO and no patient required revision of their prosthesis.

**Discussion**

We are not aware of any reports to date concerning the outcome of treatment of proximal humeral fractures using the new Aequalis fracture prosthesis. The major aims after hemiarthroplasty for the treatment of a fracture are relief from pain, adequate shoulder function and patient satisfaction. In our series only four patients were not satisfied with the outcome.

Boileau et al. reported the results of the use of the classical Aequalis shoulder prosthesis in a series of 66 patients with a mean age 66 years (31 to 85) and a mean follow-up of 27 months (18 to 59). The mean absolute Constant score was 56 (20 to 95) points and the mean postoperative active elevation was 101°. Initial malposition of the tuberosity was observed in 27% and detachment and migration of tuberosities in 23%, including patients who had an initial anatomical reconstruction. From this the authors emphasised the need for modification of the prosthetic design as well as the technique of osteosynthesis of the tuberosities. This view has been supported in a study by Sosna et al. which recommended a new technique for proximal humeral reconstruction after three- and four-part fractures. They developed an implant which allowed fixation of the tuberosities to the prosthetic stem and the humeral diaphysis using screws, washers and a special toothed plate. This gave Constant scores which were higher than those of patients in whom the tuberosities had been fixed using the classical suthuring technique.

In a recently published systematic review of 16 studies dealing with 810 hemiarthroplasties for fractures of the proximal humerus, the mean active anterior elevation was 105.7° and the mean abduction was 92.4°. The mean Constant score was 56.6 and the most common complication was related to the fixation and healing of the tuberosities (11.15%). Subjective evaluation of the results by 291 patients showed unsatisfactory results in 41.6%. Most patients had no or only mild pain, but the pre-injury level of function was almost never regained. It was concluded that scientific evidence to support the effectiveness of early hemiarthroplasty in the treatment of shoulder fractures was not strong. In our series the mean modified Constant score in the operated shoulders was 68.2 points a value corresponding to 89.5% of the score in the opposite shoulder. We chose the Constant score for patient evaluation since it is the most commonly used scoring system in Europe and it has been validated.

Relief from pain remains the most consistent benefit of this operation. In three of the largest published series no or only mild pain was reported in 79%, 87.5%, and 64% of patients, respectively. In our study 26 of 28 patients had no or only mild pain. Since disruption of the biceps tendon may be a source of post-operative pain after shoulder hemiarthroplasty because of the distortion of the anatomy of the bicipital groove, we performed tenotomy and tenodesis of the long head of the biceps tendon in all our patients.

It has been shown that meticulous surgical technique correlates directly with the outcome of hemiarthroplasty. The procedure is demanding with the need for careful osteosynthesis because of the complexity of the reconstruction of the tuberosities, and the need to ensure implantation of the prosthesis at the proper height and retroversion. We restored the prosthetic height either by using the calcare as a reference point or the insertion of pectoralis major when the medial metaphysis was severely comminuted, but did not use jigs or other devices to calculate the retroversion of the stem.

Malposition of the tuberosities and their migration have been identified as the most important determinants of unsatisfactory results after hemiarthroplasty. Placement of the prosthesis in a higher position than normal may lead to malposition, nonunion and secondary migration. In addition, the rotator cuff may be trapped under the acromion leading to a tear of the cuff and superior migration of the upper humerus. By contrast, implantation of the prosthesis in a position lower than normal may also result in a poor outcome, particularly if more than...
2 cm of humeral height has been lost, because of loss of deltoid power. Early migration of the tuberosities has been described as one of the principal reasons for reoperation and healing of the tuberosities at the anatomical site has been deemed the most important determinant of outcome. For this reason we have used the technique of Boileau et al with a modification concerning the number of sutures for the horizontal fixation. This proved to be reliable with no migration and/or nonunion of the tuberosities in our patients.

Rehabilitation after prosthetic replacement for proximal humeral fractures remains contentious. Neer initially advocated early passive movements as the optimal post-operative protocol. Naranja and Iannotti suggested an aggressive rehabilitation protocol whilst Boileau et al recommended a more conservative protocol to prevent failure of the fixation of tuberosities. Agorastides et al, in a randomised, controlled trial, concluded that late mobilisation of the shoulder after hemiarthroplasty for proximal humeral fracture was equally as safe as early mobilisation. The outpatient rehabilitation regime in our series was influenced by the socio-economic status of the patients. This required a member of the patient’s family to be educated in assisting the patient to perform the exercises. If a more structured rehabilitation programme had been available for our patients the results may have been even better.

The outcome of certain operations is considered to be related to the number of the surgical procedures performed proficiently by a single surgeon. In a recent review it was shown that in shoulder hemiarthroplasty for fracture, less than three surgical procedures were performed by individual surgeons per year. In our study all the operations were performed by the same surgeon which may account for the high percentage of anatomically reconstructed prostheses as well as the low rate of complications.

We recognise that our study lacks a control group and relates to a single design of implant. Therefore the results should be extrapolated to other designs with caution. In addition, the reconstruction has been evaluated in a qualitative manner rather than using quantitative measurements of the restoration of the proximal humeral anatomy in which factors such as the humeral length, the retroversion of the implant and the size of the prosthetic humeral head could be determined.

We found the Aequalis fracture prosthesis to be a safe and efficient option for the treatment of proximal humeral fractures with a high probability of reattachment of the tuberosities.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References


