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Routine fixation of humeral shaft fractures is cost-effective

COST-UTILITY ANALYSIS OF 215 PATIENTS AT A MEAN OF FIVE YEARS FOLLOWING NONOPERATIVE MANAGEMENT

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Aims
The primary aim was to estimate the cost-effectiveness of routine operative fixation for all patients with humeral shaft fractures. The secondary aim was to estimate the health economic implications of using a Radiographic Union Score for HUmeral fractures (RUSHU) of < 8 to facilitate selective fixation for patients at risk of nonunion.

Methods
From 2008 to 2017, 215 patients (mean age 57 yrs (17 to 18), 61% female (n = 130/215)) with a nonoperatively managed humeral diaphyseal fracture were retrospectively identified. Union was achieved in 77% (n = 165/215) after initial nonoperative management, with 23% (n = 50/215) uniting after surgery for nonunion. The EuroQol five-dimension three-level health index (EQ-5D-3L) was obtained via postal survey. Multiple regression was used to determine the independent influence of patient, injury, and management factors upon the EQ-5D-3L. An incremental cost-effectiveness ratio (ICER) of < £20,000 per quality-adjusted life-year (QALY) gained was considered cost-effective.

Results
At a mean of 5.4 yrs (1.2 to 11.0), the mean EQ-5D-3L was 0.736 (95% confidence interval (CI) 0.697 to 0.775). Adjusted analysis demonstrated the EQ-5D-3L was inferior among patients who united after nonunion surgery (β = 0.103; p = 0.032). Offering routine fixation to all patients to reduce the rate of nonunion would be associated with increased treatment costs of £1,542/patient, but would confer a potential EQ-5D-3L benefit of 0.120/patient over the study period. The ICER of routine fixation was £12,850/QALY gained. Selective fixation based on a RUSHU < 8 at six weeks post-injury would be associated with reduced treatment costs (£415/patient), and would confer a potential EQ-5D-3L benefit of 0.335 per 'at-risk patient'.

Conclusion
Routine fixation for patients with humeral shaft fractures to reduce the rate of nonunion observed after nonoperative management appears to be a cost-effective intervention at five years post-injury. Selective fixation for patients at risk of nonunion based on their RUSHU may confer even greater cost-effectiveness, given the potential savings and improvement in health-related quality of life.

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Introduction
Humeral diaphyseal fractures are relatively common injuries, with an annual incidence of 12 per 100,000 adults.[1] Nonoperative management using a humeral brace remains the default approach for many patients with isolated, closed humeral shaft fractures,[2] partly because the functional benefits

associated with operative fixation appear to be transitory with no significant advantage over bracing at one year post-injury.[3,4]

One of the principal differences between these two management strategies is the rate of nonunion, which is reported to be less than 3% after open reduction and compression plating,[5] and 15% to 17% after nonoperative management.[6,7] Given the potential impact of humeral shaft nonunion upon longer-term patient-reported outcomes,[8,9] one of the most compelling arguments for offering fixation to more patients may lie in mitigating the detrimental effects of this complication upon patient function and health-related quality of life (HRQoL). Health economic analyses have been recommended as essential in rationalizing humeral shaft fracture management.[10] The authors are aware of only one simple cost analysis comparing operative and nonoperative management of these injuries, but this did not account for the morbidity associated with nonunion that occurred in 25% of patients in that study.[11] The authors are not aware of any published cost-effectiveness or cost-utility analyses comparing these treatment methods and accounting for the effect of nonunion upon patients' HRQoL.

The primary aim of this study was to estimate the cost-effectiveness of routine operative fixation for all patients with humeral shaft fractures, in order to reduce the nonunion rate associated with nonoperative management. The secondary aim was to estimate the health economic implications of using a Radiographic Union Score for HUmeral fractures (RUSHU) of < 8 to facilitate selective fixation for patients at risk of nonunion.

Methods

Study cohort. The cohort was retrospectively identified from an established database of adults (aged ≥ 16 years) with a humeral shaft fracture managed at the study centre.[1] Inclusion criteria were patients with a fracture of the humeral diaphysis, sustained between January 2008 and December 2017, and undergoing initial nonoperative management (for at least 12 weeks post-injury). Exclusion criteria were patients with re-fractures, pathological fractures, periprosthetic fractures, patients undergoing initial operative fixation (within 12 weeks of injury), non-residents, and those with inadequate radiological follow-up. Patients who were unable to indicate their HRQoL (due to death, cognitive impairment, or having invalid contact details) were also excluded.

This study formed part of a larger audit of 291 humeral shaft fractures managed in the study centre.[9] Of this larger study, as well as patients initially managed operatively (n = 64), patients who developed a recalcitrant nonunion following nonunion surgery (n = 4) and patients who declined operative management of their nonunion (n = 6) were excluded. Those with a delayed union following nonoperative management, defined as nonunion at six months with spontaneous union thereafter, without further surgical intervention (n = 2), were also excluded. The present study cohort therefore comprised 215 patients who met the above criteria. The larger study was assessed by the NHS Research Ethics Service (NR/161AB6) and registered with the local musculoskeletal quality improvement committee.

Patient and injury characteristics. Demographic and injury details were retrospectively obtained from medical records and radiographs. Fractures were classified using a picture archiving and communication system (Carestream Vue PACS; Carestream Health, USA), on the basis of fracture location and the AO-OTA classification.[12]

The majority of patients (70.7%, n = 152/215) had documented medical comorbidities. Most injuries were sustained during a fall from standing height (78.1%, n = 168/215). Half of fractures involved the middle-third of the diaphysis (53%, n = 114/215), with the remainder involving the proximal (34%, n = 73/215) or distal thirds (13%, n = 28/215). Two-thirds were AO-OTA type-A injuries (67%, n = 144/215), with the remainder type-B (31.6%, n = 68/215) or type-C (1.4%, n = 3/215). Two percent (n = 5/215) involved a concomitant radial nerve palsy at presentation, all of which were managed expectantly in a wrist splint and resolved without further intervention.

Management and union outcome. All patients underwent nonoperative management of their fracture, with initial plaster of Paris cast immobilization in the emergency department (ED) and subsequent application of a functional brace within the first two weeks of injury. Patients were generally advised to begin pendular shoulder exercises and range of motion exercises at the elbow, wrist, and hand following brace application. Complete details regarding humeral shaft fracture management in our centre have been published previously.[9]

Union outcome was determined through review of medical records and radiographs. Union was determined using established criteria, and was defined clinically as reduced/absent pain at the fracture site, and radiologically as bridging callus across all fracture cortices prior to clinic discharge.[13,14] Nonunion was defined as a failure of the fracture to unite after 12 weeks of nonoperative management, with the requirement for subsequent nonunion surgery.[4,15]

Treatment cost estimation. The total cost of treatment was estimated on the basis of follow-up and union outcome (Table I). Costs were measured in pounds sterling (GBP) and based upon the English NHS Tariff 2020 to 2021,[16] or departmental procurement costs where appropriate.

All patients underwent initial ED management, including clinical assessment, radiographs, and plaster of Paris immobilization (total cost £230, NHS Tariff). This cost was assumed for all patients, and was therefore omitted from subsequent cost comparisons. Definitive

Table I. Estimated minimum treatment costs by management and outcome.

Nonoperative management, union		**Nonoperative management, nonunion surgery**		**Initial operative management**	
Treatment	**Cost, £**	**Treatment**	**Cost, £**	**Treatment**	**Cost, £**
Initial management		**Initial management**		**Initial management**	
Humeral brace*	50	Humeral brace*	50	Major shoulder procedure for trauma without complication	2,771
Outpatient F/U (3 appts)	302	Outpatient F/U (3 appts)	302	Outpatient F/U (3 appts)	302
Physiotherapy (3 sessions)*	255	Physiotherapy (3 sessions)*	255	Physiotherapy (3 sessions)*	255
		Nonunion management			
		Major shoulder procedure for trauma with complication	4,152		
		Additional outpatient F/U (6 appts)	408		
		Additional physiotherapy (6 sessions)*	510		
Total cost	607	Total cost	5,677	Total cost	3,328

Unless otherwise specified, costs were based on the 'Payment by Results in the NHS: Tariff for 2020 to 2021'. The cost of initial emergency department management (including radiographs and immobilization; £230, NHS Tariff) was based on radiographs being a 'high-cost investigation' (HRG code V04).
*Local procurement costs (from finance department).
F/U, follow-up.

nonoperative management was undertaken using one of two functional brace designs, the ProCare over-the-shoulder humeral fracture brace (DJO Global, USA) or the Clasby humeral brace (Beagle Orthopaedic, UK). The choice of brace was at the discretion of the treating surgeon, taking into account fracture location and configuration. Both braces had an approximate local procurement cost of £50. Nonunion surgery was considered as a day-case major shoulder procedure for a trauma complication (£4,152, NHS Tariff). Similarly, initial operative management was considered as a day-case major shoulder procedure for trauma without a complication (£2,771, NHS Tariff). Both tariffs included the cost of implants required for fixation.

Orthopaedic outpatient follow-up costs were estimated at £166 for the first attendance and £68 for each subsequent attendance (NHS Tariff). The cost of physiotherapy input was estimated at £85 per clinic attendance (local procurement cost). All patients were assumed to have received three outpatient follow-up appointments as per our standard departmental protocol (at two weeks, six weeks, and three months), and to have undergone three physiotherapy sessions following their initial management. Patients who united uneventfully were assumed to have been discharged from the outpatient clinic thereafter. Patients who developed nonunion were assumed to have received six additional outpatient appointments, both before and after their nonunion surgery. This group was also assumed to have undergone six additional physiotherapy sessions.[17] All patients who underwent nonunion surgery were assumed to have undergone plate and screw fixation without the requirement for supplementary bone graft or biological adjuncts,[18] and all subsequently united without further intervention.

Health-related quality of life. The EuroQol five-dimension three-level health index (EQ-5D-3L), obtained via postal survey, was used to measure patients' HRQoL.[19] The outcome assessed five domains (mobility, self-care, ability to perform usual activities, pain/discomfort, and anxiety/depression) with patients asked to indicate their level of difficulty in each domain (no problems, some problems, extreme problems). A single health index was derived from patient responses, between -0.54 (worst possible health) and 1 (best possible health).

Cost-utility analysis. Comparison of union after nonoperative management and union after nonunion surgery (for failed initial nonoperative management) was based upon the incremental cost-effectiveness ratio (ICER). This was calculated by dividing the difference in estimated total cost between groups by the difference in the resultant mean health index (i.e. EQ-5D-3L). The National Institute for Health and Care Excellence (NICE) considers an intervention to be cost-effective if it results in a cost of less than £20,000 per QALY gained.[20,21] The principal assumptions of the cost-utility analysis were: nonunion surgery involving simple plate and screw fixation (without bone grafting or biological adjuncts) would generate union after failed nonoperative management (i.e. recalcitrant nonunion rate negligible); initial operative management involving plate and screw fixation would generate fracture union (i.e. nonunion rate after initial fixation negligible); longer-term HRQoL (according to the EQ-5D-3L) would be equivalent after initial nonoperative and initial operative management, provided union had been achieved;[3,4,8,9] and any difference in longer-term HRQoL (according to the EQ-5D-3L) resulting from nonunion after nonoperative management would be present throughout the preceding five years.

The Radiographic Union Score for HUmeral fractures. The RUSHU is a tool used to identify patients at risk of nonunion following a non-operatively managed humeral shaft fracture, based on the presence of callus on

Table II. Overview of Radiographic Union Score for HUmeral fractures.

Score per cortex	Callus
1	Absent
2	Present, non-bridging
3	Present, bridging

anteroposterior and lateral radiographs at six weeks post-injury (Table II).[22] Data from the original study suggested a RUSHU < 8 identified patients at risk of nonunion with a sensitivity of 75% and a positive predictive value (PPV) of 65%.[22] A subsequent external validation study suggested both the sensitivity and PPV may be as high as 78%.[23]

We considered a hypothetical scenario involving three patients, all managed non-operatively and subsequently identified as being at risk of nonunion (based upon a RUSHU < 8). Based on a PPV of 65% we estimated that, if these three at-risk patients all underwent fixation at six weeks post-injury, two would avoid a nonunion and one (who may have progressed to union following non-operative management) would have undergone an 'unnecessary' fixation procedure. Based on a sensitivity of 75% we estimated that, for every four patients who ultimately developed nonunion, three would have been identified as potentially at risk (i.e. RUSHU < 8). We performed a separate cost-utility analysis to assess the potential health economic implications of using the RUSHU to identify at-risk patients.

Statistical analysis. Analysis was performed using SPSS v. 27.0 (IBM, USA). Odds ratios (ORs) were calculated for contingency tables. The statistical relationship between two groups of continuous non-parametric data was assessed using the Mann-Whitney U test. Significance was set at $p < 0.05$; 95% confidence intervals (CIs) and two-tailed p-values were reported. Multiple linear regression was used to assess the independent influence of patient, injury, and management factors upon the EQ-5D-3L.

Results

Cohort summary. The cohort comprised 215 patients, of whom 60.5% were female (n = 130/215) and 39.5% male (n = 85/215). The mean age at injury was 57 years (17 to 85). Overall, 76.7% (n = 165/215) of patients united following initial management. The remaining 23.3% (n = 50/215) developed a nonunion, but subsequently underwent successful nonunion surgery at a mean of seven months (3 to 19).

Health-related quality of life. The mean survey follow-up was 5.4 years (1.2 to 11.0). The mean EQ-5D-3L for the study cohort was 0.736 (95% CI 0.697 to 0.775; range -0.536 to 1). The EQ-5D-3L was lower among patients who required surgery for nonunion (mean EQ-5D-3L 0.633 (95% CI 0.536 to 0.731; range -0.181 to 1)) compared with those who united after initial

Table III. Multiple regression model showing factors independently associated with long-term Euro-Qol five-dimension three-level health index (EQ-5D-3L) following a humeral diaphyseal fracture ($R^2 = 0.295$, adjusted $R^2 = 0.183$; $p < 0.001$). All variables were entered into the model; data for variables significantly associated with EQ-5D-3L are presented.

Predictors in the model	β (95% CI)	p-value
Age at injury, yrs	0.004 (0.001 to 0.008)	0.025
Medical comorbidities		
No	Ref	
Yes	-0.128 (-0.232 to -0.025)	0.016
Union outcome		
After initial management	Ref	
After nonunion surgery	-0.103 (-0.198 to -0.009)	0.032
Employment status		
Employed	Ref	
Unemployed/retired	-0.116 (-0.217 to -0.016)	0.024
Sports participation		
Plays sport	Ref	
Does not play sport	-0.107 (-0.198 to -0.016)	0.022

The following variables were entered into the model: patient sex; age at injury (yrs); medical comorbidities; BMI classification; Scottish Index of Multiple Deprivation quintile; injury energy; injury side (dominant/non-dominant); fracture location; AO-OTA classification; radial nerve palsy; associated injuries; union outcome; length of follow-up (yrs); smoking status; alcohol intake; employment status; and sports participation.
B, regression coefficient; CI, confidence interval.

nonoperative management (mean EQ-5D-3L 0.767 (95% CI 0.726 to 0.808; range -0.536 to 1); p = 0.008, Mann-Whitney U test). Adjusted analysis indicated that union after nonunion surgery was independently associated with an inferior EQ-5D-3L (β 0.103 (95% CI 0.009 to 0.198); p = 0.032) (Table III).

Routine fixation to reduce nonunion rate. Offering routine fixation to all patients, in order to reduce the rate of nonunion associated with nonoperative management, would be associated with an increased overall treatment cost of £1,542 per patient (Table IV). However, based on the superior EQ-5D-3L among patients who initially united compared with those who required nonunion surgery (0.103 utility), the aggregated EQ-5D-3L utility benefit accrued over the five-year period of study follow-up was estimated to be 0.515. By preventing nonunion among 23.3% of the study cohort (n = 50/215), this approach would confer an estimated EQ-5D-3L utility benefit of 0.120 per patient over the five-year period of study follow-up (0.515 × 0.233). At five years post-injury, the ICER of routine humeral shaft fracture fixation was therefore estimated at £12,850 per QALY gained.

Selective fixation based on the RUSHU. For patients with a RUSHU < 8, the nonunion rate was assumed to be 65% (based on data from the original study).[22] Therefore, offering selective fixation to our three hypothetical patients would result in an overall cost saving of £659 per patient (Table V). Moreover, as two of the three patients in this scenario would avoid nonunion surgery (instead

Table IV. Estimated minimum treatment costs comparing fixation of established nonunion only cf. initial operative management in all patients.

Scenario	Cost, £
Routine nonoperative management (surgery for established nonunion only)	
Nonoperative management cost (n = 165)	
165 × 607	100,155
Nonunion surgery cost (n = 50)	
50 × 5,677	283,850
Total cost	
Overall	384,005
Per patient	1,786
Routine operative fixation (surgery for all patients)	
Initial operative management (n = 215)	
215 × 3,328	715,520
Total cost	
Overall	715,520
Per patient	3,328
Additional cost of routine operative fixation	
Total cost	
Overall	331,515
Per patient	1,542

Table V. Cost analysis of selective fixation based on Radiographic Union Score for HUmeral fractures < 8.

Scenario	Cost, £
3 patients with RUSHU < 8 (n = 3)	
No selective fixation (based on PPV 65%)	
2 nonoperative management, nonunion surgery = 2 × 5,677	11,354
1 nonoperative management, union = 1 × 607	607
Total cost	11,961
Selective fixation	
3 operative fixation, union = 3 × 3,328	9,984
Total cost	9,984
Cost saving	
Overall	1,977
Per patient	659
Nonoperative management, nonunion group (n = 50)	
No selective fixation	
50 nonoperative management, nonunion surgery = 50 × 5,677	283,850
Total cost	283,850
Selective fixation (based on sensitivity 75%)	
38 operative management, union = 38 × 3,328	126,464
12 nonoperative management, nonunion surgery = 12 × 5,677	68,124
Total cost	194,588
Cost saving	
Overall	89,262
Per patient	1,785
Nonoperative management group (n = 215)	
No selective fixation	
165 nonoperative management, union = 165 × 607	100,155
50 nonoperative management, nonunion surgery = 50 × 5,677	283,850
Total cost	384,005
Selective fixation (based on sensitivity 75%)	
165 nonoperative management, union = 165 × 607	100,155
38 operative management, union = 38 × 3,328	126,464
12 nonoperative management, nonunion surgery = 12 × 5,677	68,124
Total cost	294,743
Cost saving	
Overall	89,262
Per patient	415

PPV, positive predictive value; RUSHU, Radiographic Union Score for HUmeral fractures.

achieving union after initial operative management), selective fixation would also confer an annual EQ-5D-3L utility benefit of 0.067 per patient (0.103 × 0.65). Over the five-year study period, it was therefore estimated this strategy would confer an EQ-5D-3L utility benefit of 0.335 per patient (0.067 × 5).

When applied to patients who ultimately went on to develop a nonunion in the study cohort (n = 50), we estimated that the RUSHU would have identified 38 patients at risk (based on a sensitivity of 75%).[22] Selective fixation would result in an estimated cost saving of £1,785 per patient (Table V) and would confer an annual EQ-5D-3L utility benefit of 0.077 per patient ((0.103 × 0.75), equivalent to 0.386 per patient over the study period. Applied to the entire cohort (n = 215), selective fixation based on a RUSHU < 8 at six weeks following injury would result in a cost saving of £415 per patient (Table V) and would confer an annual EQ-5D-3L utility benefit of 0.018 per patient (0.103 × 0.233 × 0.75), equivalent to 0.090 per patient over the study period.

Discussion

This study includes a representative cohort of patients with a nonoperatively managed humeral shaft fracture, and has demonstrated that offering routine fixation to all patients would be a cost-effective intervention in terms of HRQoL at five years post-injury. Although routine fixation would be associated with additional treatment costs of £1,542 per patient, this approach would be cost-effective by potentially mitigating the longer-term impact of nonunion on HRQoL. Moreover, selective fixation for patients at risk of nonunion based upon their RUSHU at six weeks post-injury may represent a pragmatic option, by conferring overall cost savings compared with routine nonoperative management and a net improvement in HRQoL.

In the only previous cost analysis of humeral shaft fracture management of which we are aware, Singhal et al[11] analyzed 20 patients who underwent functional bracing, of whom 15 united and five (25%) developed a nonunion. The authors estimated the total cost of treatment for their cohort (15 successful nonoperative management + five failed nonoperative management requiring nonunion surgery) was £36,025 (£1,801 per patient), and that the total cost of routine fixation for all patients would have been £45,860 (£2,293 per patient). They concluded that functional bracing was efficacious and cost-effective. However, that study did not incorporate a patient-reported health index and was therefore unable to assess the potential utility of avoiding nonunion from the patients' perspective.

One possible reason that functional bracing remains the default strategy for many patients with humeral shaft fractures is that the early advantages of initial fixation—in improving rates of union, reducing rates of malunion, and facilitating earlier functional recovery—have not been clearly demonstrated in existing randomized studies comparing operative and nonoperative management.[3,4] Similarly, operative management does not appear to improve return to work or sporting activity after a humeral shaft fracture.[24] In the absence of any clear benefit, it has been difficult to justify the operative risks and increased costs associated with routine fixation for patients with these injuries. However, considering the differential nonunion rate between nonoperative and operative management,[6,7] and the increasing body of evidence that humeral shaft nonunion leads to inferior patient-reported upper limb function and health-related quality of life even after successful nonunion surgery,[8,9] there may be longer-term advantages to operative fixation that have been previously underappreciated. This study attempts to quantify the longer-term utility of reducing the risk of humeral shaft nonunion, by offering early surgery to all patients. At five years post-injury, the estimated cost-effectiveness of routine humeral shaft fracture fixation fell below the NICE threshold of £20,000 per QALY gained. Our results therefore offer an alternative perspective to the position that most humeral shaft fractures are best managed nonoperatively in the first instance.

Though few surgeons would advocate a strategy of routine fixation for all patients with an isolated, closed humeral shaft fracture, a pragmatic option may lie in a strategy of selective fixation for patients at risk of nonunion at an early stage in their nonoperative management. Accurately identifying these at-risk patients may present a challenge to surgeons treating them, but baseline clinical risk factors[25,26] and fracture mobility at six weeks post-injury[27] have been suggested as valid options. The present study sought to evaluate the cost-effectiveness of a published radiological scoring system,[22] and found that selective fixation based on the RUSHU may actually result in lower overall treatment costs, as well as conferring a benefit in terms of QALYs gained. Selective fixation based on the RUSHU may represent a compromise that facilitates a rational increase in the rate of operative fixation performed for patients with humeral shaft fractures.

This large study reports generalizable data regarding treatment costs and longer-term HRQoL in a typical humeral shaft fracture population. Of note, this analysis is based on the 'best-case scenario' regarding nonunion surgery; had it been possible to factor in the potentially increased rate of complications following nonunion surgery (compared with initial fixation) and the indirect societal costs of nonunion (e.g. loss of productivity), the benefits of routine fixation may have been even more pronounced. Moreover, a move away from the default nonoperative approach may have a synergistic effect, as a more general resort to initial operative fixation could feasibly reduce the costs of surgical treatment and improve operative outcomes as caseload increases.

The principal limitation of this study was the retrospective design. Costs reflected those in the English NHS, but we recognize that the NHS Tariff is not equivalent to the total healthcare cost and that treatment costs may vary considerably across different health systems. We also acknowledge the assumptions upon which the cost-utility analysis was based, and that published nonunion rates following nonunion surgery and initial operative fixation are invariably slightly higher than 0%. Likewise, other complications such as radial nerve palsy and infection were not accounted for in the analysis, although many comparative studies have found these to be broadly equivalent between nonoperative and operative management.[6,7] Prospective randomized studies of humeral shaft fracture management, incorporating detailed health economic analyses that account for both direct and indirect costs associated with these injuries, will hopefully provide robust evidence relating to cost-effectiveness.[28,29]

Take home message

- Routine fixation for patients with humeral shaft fractures, in order to reduce the rate of nonunion observed after nonoperative management, appears to be a cost-effective intervention at five years post-injury with an incremental cost-effectiveness ratio of £12,850 per quality-adjusted life year gained.
- Selective fixation of patients at risk of nonunion (based upon a Radiographic Union Score for HUmeral fractures < 8 at six weeks post-injury) may confer even greater cost-effectiveness, given the potential savings and improvement in health-related quality of life.

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