THE ORTHOPAEDIC TRAUMA SOCIETY CLASSIFICATION OF OPEN FRACTURES

AIMS To describe a new objective classification for open fractures of the lower limb and to correlate the classification with patient-centred outcomes.

METHODS The proposed classification was investigated within a cohort of adults with open fractures of the lower limb who were recruited as part of two large clinical trials within the UK Major Trauma Network. The classification was correlated with patient-reported Disability Rating Index (DRI) and health-related quality of life (EQ-5D) in the year after injury, and with deep infection at 30 days according to the Center for Disease Control and Prevention definition of a deep surgical site infection.

RESULTS 748 participants were included in the analysis, 288 (38.5%) had a simple open fracture, and 460 (61.5%) had a complex fracture as defined by the new classification system. At 12 months the mean disability (DRI) in the simple fracture group was 32.5 (SD=26.8) versus 43.9 (SD=26.1) in the complex fracture group (OR 8.19, 95% CI 3.69, 12.69). At 12 months the mean health-related quality of life (EQ-5D utility) in the simple fracture group was 0.59 (SD=0.29) versus 0.56 (SD=0.32) in the complex fracture group (OR -0.03, 95%CI -0.09, 0.02). The differences in the rate of deep infection at 30 days was not statistically significant.

CONCLUSION The OTS open fracture classification is based upon objective descriptors of the injury and correlates with patient-centred outcomes in a large cohort of open fractures of the lower limb

Key Words: Open Fracture, Outcome, Classification

Open fractures of the lower limb are a significant cause of morbidity for patients and are associated with large healthcare costs.[1,2,3] Recently, there have been major changes in the way that healthcare systems manage patients with open fractures.[4,5] However, the systems which we use to classify open fractures and to predict outcomes have not changed.[6,7,8] There are two major problems with current classification systems.

Firstly, they rely on subjective descriptors of the extent of the injury, for example ‘extensive degloving’, ‘stripping’ of periosteum and ‘massive’ contamination. This leads to problems of mis-classification.[9,10,11]

Secondly, they were constructed in order to predict the incidence of complications such as infection,[6] or amputation.[8] Recent studies investigating the patient experience of open fractures identify the importance that patients place upon the emotional as well as physical effects of these injuries.[12,13] While avoiding complications following open fractures is clearly important, patients consider a broader perspective of their recovery.

The aim of this study was to propose a new classification for open fractures of the lower limb and to correlate the classification with patient-centred outcomes.

Patients and Methods

New classification system. The proposed new classification is based upon the objective assessment of the open fracture wound at the end of the first wound excision (debridement). Injuries are classified as 'simple' or 'complex'. A simple open fracture is one in which primary closure of the open fracture wound is achieved following wound excision. A complex open fracture is one in which closure of the wound requires a reconstructive procedure; complex fractures are sub-classified into three objective groups to reflect the extent of the reconstructive intervention.

1. 'Simple' open fractures where primary wound closure is achieved without the need for a reconstructive procedure
2. 'Complex' open fractures require a reconstructive procedure, further subdivided into:
    a. Wound closed primarily, but required bone deformation or acute bone shortening to facilitate closure
    b. Soft-tissue reconstructive procedure required to cover the wound
    c. Repair/reconstruction of vascular injury required in association with the open fracture

Correlation of the new classification with outcomes. We used two large datasets of patients with open fractures of the lower limb whose outcomes were collected as part of the WHIST and WOLLF trials.[14,15,16,17] Full details of the patients included in both trials are reported elsewhere and in *Table 1* but, in summary, the WHIST trial recorded outcomes in adult patients with open fractures closed primarily after the first surgical wound excision whereas the WOLLF trial reported outcomes in those open fractures which could not be closed primarily.

Outcome measures. Patient-reported outcomes were assessed pre-injury (participant recall at baseline) and at 3, 6 and 12 months after the injury.

The **Disability Rating Index** (DRI) is a self-administered, 12-item Visual Analogue Scale questionnaire assessing the patients' own rating of their disability[18]. Total scores range from 0 to 100 with higher scores indicating more disability. This measure was chosen as it addresses "gross body movements" rather than specific joints or body segments. Therefore, it facilitates the assessment of patients with different fractures and injuries of the lower limbs.

EuroQol EQ-5D-5L; The EuroQol EQ-5D is a validated measure of health-related quality of life, consisting of a five dimension health status classification system.[19] Responses to the health status classification system were converted into multi-attribute utility (MAU) scores using tariffs currently under development for England.[20] Scores range from -0.594 to 1, with higher scores indicating a better quality of life and a score of 0 equating to death.

We also recorded the rate of infection related to the open fracture wound using the Center for Disease Control and Prevention definition of a “deep surgical site infection” up to 30 days, that is a wound infection involving the tissues deep to the skin.[21]

Analysis. Descriptive baseline characteristics of participants in each of the two primary categories (simple and complex) and three subcategories of the complex group were summarised and compared using numbers and percentages for categorical variables and means and standard deviations (SDs) or medians and inter-quartile ranges (IQRs) for continuous variables as appropriate. Trends over time in patient-reported outcome measures were summarised graphically.

Multivariate linear regression models were used to investigate whether fracture classification predicts either DRI or EQ-5D utility at 3, 6 or 12 months. The models were adjusted for participant age at baseline, participant gender, randomised treatment and for baseline (pre-injury) values of DRI and EQ-5D. An analogous multivariate logistic regression model was used to investigate whether fracture classification predicts the presence of deep infection at 30 days.

Results

In total there were 748 participants from WOLLF and WHIST who were eligible for inclusion in the analysis. 288 (38.5%) had a simple open fracture, and 460 (61.5%) had a complex fracture as defined by our new classification system. Within the complex group, 79 (10.6%) had a complex fracture of type A, 336 (44.9%) a complex fracture of type B, and 45 (6.0%) a complex fracture of type C. The baseline characteristics of the four groups are presented in Table 1. Some variability in the populations can be seen. Notably those with more severe fractures were more likely to suffer injuries due to road traffic accidents, more likely to have a wound on the tibia/fibula, and more likely to have had initial temporary external fixation.

Table 1: Comparison of study population groups according to the new classification system at baseline

Baseline (pre-injury) values of the disability rating index (DRI) and EQ-5D utility and VAS are presented. These pre-injury values were similar in all groups. EQ-5D measures immediately post-injury were also recorded and are also summarized. Again, these were similar across all groups.

Trends over time (baseline to 12 months post-randomisation) on both the DRI and EQ-5D are provided in Figures 1 and 2. Improvements are seen in all four groups. In general scores are best in the simple fracture group and worst in the complex C group (most severe fractures). For the EQ-5D, all 3 complex fracture groups show more improvement between 3 and 12 months than the simple group for whom little change is seen over this time frame.

Figure 1: DRI scores over time by fracture classification group

Note: DRI scores range from 0 to 100 with higher scores indicating worse disability

Figure 2: EQ-5D utility scores over time by fracture classification group

Note: EQ-5D utility scores range from -0.594 to 1 with higher scores indicating better quality of life

DRI scores, EQ-5D utility scores and rates of deep SSI are summarised separately for simple and complex fractures (Table 3). Comparisons of simple versus complex fracture classification are also provided; outcomes are presented as odds ratios or adjusted differences and associated 95% confidence intervals as appropriate. There were significant differences between simple and complex fractures in terms of both DRI scores (at 3, 6 and 12 months) and EQ-5D utility scores (at 3 and 6 months). At 12 months the mean disability (DRI) in the simple fracture group was 32.5 (SD=26.8) versus 43.9 (SD=26.1) in the complex fracture group (OR 8.19, 95% CI 3.69, 12.69). At 12 months the mean health-related quality of life (EQ-5D utility) in the simple fracture group was 0.59 (SD=0.29) versus 0.56 (SD=0.32) in the complex fracture group (OR -0.03, 95%CI -0.09, 0.02). The differences in deep SSI rates at 30 days was not statistically significant at the 5% level.

Table 2: Comparison of outcomes complex vs. simple. Odds ratios (and associated 95% CIs) are presented for deep SSI and adjusted differences (with 95% CIs) for the DRI and EQ-5D utility

The outcome measures (deep SSI, DRI and EQ-5D utility) are summarised by fracture sub-classification group in Table 4. For DRI and EQ-5D utility, these summaries are presented separately for each of the time points (3, 6 and 12 months). The mean DRI at 12 months was higher (worse) through each sub-classification: simple group 32.5 (SD=26.8), Complex A 40.7

(SD=26.6), Complex B 44.1 (SD=26.1) and Complex C 47.7 (SD=25.6). Similarly, the mean EQ-5D quality of life scores were lower (worse) through each sub-classification.

Pairwise comparisons of the subgroups are provided in Table 4. In terms of disability (DRI), the simple fracture group were significantly better than either the complex B or complex C group at all time points and also better than the complex A group at 3 and 6 months. At 12 months, the complex A group outperform the complex C group on the DRI. For quality of life (EQ-5D utility), the simple fracture group are better than any of the other groups at 3 and 6 months post-randomisation; however, there are no significant differences between the groups at 12 months. There were no significant differences between any of the groups in terms of deep SSI rates.

Table 3: Outcomes by fracture classification group

Table 4: Comparison of outcomes between wound classification groups. Odds ratios (and associated 95% CIs) are presented for deep SSI and adjusted differences (with 95% CIs) for the DRI and EQ-5D Utility.

Discussion

In this study we propose a new classification of open fractures based upon an objective assessment of the associated wound after the first surgical excision (debridement). Using data from two large, high-quality clinical datasets we demonstrate that the new classification is correlated to patient-reported disability and patient-reported quality of life in the first 12 months after the injury.

The new classification is not correlated with deep surgical site infection. In contrast to previous studies, the analysis of the new classification uses data from patients treated in contemporary management pathways. In the UK Major Trauma Network, patients with serious traumatic injuries, including those with open fractures of the lower limb, bypass the nearest hospital to be taken to a designated Major Trauma Centre. The Major Trauma Centre specification included the co-location of orthopaedic trauma surgeons and plastic surgeons, creating 'orthoplastic' centres[5,22]. These centres facilitate joint care between the two surgical specialties and greatly increased the volume of patients with open fractures seen in each centre and hence the experience of the surgical and support teams. This greater experience and model of shared decision-making has led to more confidence in early wound excision even in association with severe contamination and definitive wound closure where appropriate, and has been associated with lower rates of deep surgical site infection than in earlier studies.[14,16,23]

The first widely adopted and still most commonly used classification of open fractures is the Gustilo and Anderson.[6] This classification was the first to be correlated with patient outcome, albeit only with the incidence of infection. However, even in the revised classification,[24] the use of subjective descriptors has led to well-reported issued of misclassification.[10,11] In 2010, the OTA published their classification system for open fractures based upon the anatomy, tissue involvement and degree of contamination.[7,25,26] This classification was found to be superior to Gustilo and Anderson in terms of predicting outcome but complexity and subjectivity in the use of descriptors has led to ongoing concerns of mis-classification, with particular regard to the assessment of muscle injury.[27,28] The Ganga classification incorporates aspects of patient co-morbidity as well as a description of the injury with improved inter-observer reliability and correlation with clinical outcomes.[8,29] However, it was designed to predict the success or otherwise of limb salvage and was not based upon the patient experience of open fractures of the lower limb or their priorities in terms of recovery.

The new classification system presented here was designed to address the issues of objectivity and patient-centred outcome described above. However, there are several limitations to this study. Firstly, the cohort of open fractures used in the correlation analysis were from the lower limb only. While open lower limb fractures are associated with an increased need for reconstructive surgery and worse outcomes than those in the upper limb, caution is indicated in extrapolating this classification to other areas of the body. Similarly, all of the patient data used in the analysis were from adults and further research would be required to repeat these analyses in children. With regard to the data pertaining to deep surgical site infection, we used the Center for Disease Control and Prevention definition of a "deep surgical site infection". At the time of data collection this definition was for infections 'up to 30 days'. The definition has subsequently been revised to 90 days and it is possible that more deep infections would have been noted at this later time-point. Finally, the data used in this study reflects the contemporary management of open fractures in a national Major Trauma Network with treatment in specialist orthoplastic centres. The outcomes described reflect modern standards of care,[4,5] but may not be representative of management pathways in other healthcare systems.

In summary, the proposed OTS open fracture classification is based upon objective descriptors of the open fracture and correlates with patient-centred outcomes in a large cohort of open fractures of the lower limb. This is just the beginning of the process of validation of the new classification system. Further research is required to test intra- and inter-observer reliability and to correlate the new classification with outcomes in different cohorts of patients and in different healthcare systems.

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