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Abstract

Aims

This study aims to assess the reliability and validity of the <u>Unified Classification System</u> (UCS) for postoperative periprosthetic femoral fractures (PFFs) around cemented polished taper-slip (PTS) stems.

Methods

PFF radiographs of 71 patients admitted consecutively at two centres from 25/12/2012 to 19/05/2020 were collated by an independent investigator. Six observers (three hip consultants, three trainees) were familiarised with the UCS. Each case was classified on two separate occasions with a mean time between assessments of 22.7 (range, 16-29) days. Interobserver reliability for more than two observers was assessed using percentage agreement and Fleiss' kappa statistic. Intraobserver reliability between two observers was calculated with Cohen kappa statistic. Validity was tested on surgically managed type B cases where stem stability was documented in operation notes (n=50). Validity was assessed using percentage agreement and Cohen kappa statistic between radiographic assessment and intraoperative findings. Kappa statistics were interpreted using Landis and Koch criteria. All six observers were blinded to operation notes and postoperative radiographs.

Results

Interobserver reliability percentage agreement was 58.5% and the overall kappa value was 0.442 (moderate agreement). Lowest kappa values were seen for type B fractures (range, 0.095 to 0.360). The mean intraobserver reliability kappa value was 0.672 (range, 0.447 to 0.867) indicating substantial agreement. Validity percentage agreement was 65.7% and the mean kappa value was 0.300 (range, 0.160 to 0.4400) indicating only fair agreement.

Conclusion/Discussion

This study confirms that the <u>UCS</u> is inadequate for radiographic classification of PFFs around PTS stems and that it has considerably lower reliability and validity than previously described for other stem types. Radiographic PTS stem loosening in the presence of PFF is poorly defined and formal intraoperative testing of stem stability is recommended. These complex cases must be managed by surgeons who are capable of performing appropriate revision surgery.

Introduction

Total hip arthroplasty (THA) with cemented femoral stems is cost-effective and has excellent clinical outcomes.¹⁻⁴ Traditional composite beam (CB) stems have been overtaken by modern polished taper slip (PTS) stems which demonstrate very low rates of aseptic loosening.^{5,6} Concerns have arisen due to the increased risk of postoperative periprosthetic femoral fracture (PFF) with PTS stems compared to CB stems.⁷⁻¹³ Reported rates of PFF vary from 1-3.5% following primary THA but this incidence is expected to rise as increasingly more THAs are being performed in elderly patients.¹⁴⁻¹⁶ PFFs usually require surgical treatment which is associated with high complication rates and healthcare costs.^{17,18}

Surgical management of PFFs is guided by the well-established Vancouver Classification System developed by Duncan and Masri in 1995.¹⁹ <u>This classification has more recently been</u> <u>superseded by the Unified Classification System (UCS) but the underlying principles of PFF</u> <u>location, stem stability, bone loss and treatment strategies remain identical.</u>²⁰ An effective classification system should be both valid and reliable. Validity refers to the extent that the classification system accurately describes what it was intended to describe whereas reliability refers to the degree that it yields the same outcomes between different observers (interobserver reliability) and by the same observer at different time points (intraobserver reliability).

Previous studies have found moderate to substantial reliability and validity using this classification system to define PFFs in mixed series of cemented and cementless stems.²¹⁻²⁴ However, it has never been validated in a large single series of PTS stems. This may be important as it depends critically on the radiographic assessment of stem stability. Loose cemented stems have different radiographic appearances depending on their fixation philosophy. CB stems allow a mechanical interlock of cement to their roughened surface and hence radiolucency at the stem-cement interface is indicative of loosening. In contrast, PTS stems allow controlled subsidence within the cement mantle and therefore radiolucency at the stem-cement interface of loosening. This predicament may lead to a misclassification of PFFs around PTS stems with consequences for surgical treatment as the treatment algorithm suggests that PFFs around well-fixed stems can be treated with internal fixation whilst loose stems require more complex revision surgery. The aim of this study is to assess the reliability and validity of the <u>UCS</u> for PFFs around PTS stems.

Methods

Following local institutional approval, this study was performed in two stages consisting of an inter- and intraobserver reliability assessment followed by a validity assessment. Using pre-existing local databases, the records of all patients with PFF following hip arthroplasty admitted consecutively at two centres between 25th February 2012 and 19th May 2020 were reviewed. All cases were compiled for review by the lead investigator (XX) who did not participate in any of the assessments.

Inclusion criteria for reliability assessment included patients with PFF around a cemented primary PTS stem and cases where preoperative radiographs showing the full extent of the stem and fracture were available (n=71). These included 66 cases of PFF around previous THA and five cases of PFF around previous hip hemiarthroplasty with a PTS stem. The series included 37 CPT (Zimmer Biomet, Warsaw, Indiana) stems, 22 Exeter (Stryker, Kalamazoo, Michigan) stems, five Exeter Trauma Stems (Stryker, Kalamazoo, Michigan), four classic Cstems (Depuy Synthes, Warsaw, Indiana) stems and three AMT C-stems (Depuy Synthes, Warsaw, Indiana). Demographic details are presented in Table 1. Each radiograph was anonymised and collated into a study series. Interobserver reliability was tested on each case through independent assessment by six different observers (three consultants specialising in hip replacement surgery and three orthopaedic trainees) all of whom were familiarised with the UCS (Table 2).^{19,21} Intraobserver reliability was tested on each case through independent assessment by the same six observers on two separate occasions with a minimum gap of two weeks between assessments. In order to avoid influencing the assessments, no postoperative radiographs were reviewed. Validity was tested on surgically managed type B cases where stem stability findings (fixed versus loose) were documented in operation notes (n=50). All six observers were blinded to the operation notes and their initial assessment was compared to the operative findings.

Statistical analysis

Data were analysed using percentage agreement and weighted kappa statistics to measure the level of agreement between assessments. Interobserver reliability for more than two observers was assessed using percentage agreement and the Fleiss' kappa statistic. Intraobserver reliability between two observers was calculated with the Cohen kappa statistic. Validity was

assessed using percentage agreement and the Cohen kappa statistic between radiographic assessment and intraoperative findings for each observer. All statistical analyses were performed using IBM SPSS Statistics Program (Version 26). Kappa statistic values were interpreted using the Landis and Koch criteria with values of 0.00 to 0.20 indicating slight agreement, 0.21 to 0.40 indicating fair agreement, 0.41 to 0.60 indicating moderate agreement, 0.61 to 0.80 indicating substantial agreement and values of more than 0.80 indicating almost perfect agreement.²⁵

Results

Interobserver reliability was calculated from the first assessment (**Table 3**). Percentage agreement for interobserver reliability was 58.5% between all six observers, 52.6% between consultants and 59.6% between trainees. Fleiss' kappa value for interobserver reliability was 0.442 (moderate agreement) between all six observers, 0.381 between consultants (fair agreement) and 0.444 (moderate agreement) between trainees. Fleiss' kappa value for interobserver reliability by fracture type ranged from 0.095 (slight agreement) for type B3 fractures to 0.784 (substantial agreement) for type A_G fractures. This was lowest for type B fractures, ranging from 0.095 (B3 fractures, slight agreement) to 0.360 (B2 fractures, fair agreement). The standard error was 0.17 and 0.031 for reliability by observers and fracture type, respectively.

Intraobserver reliability was calculated from both assessments with a mean time between assessments of 22.7 (range, 16-29) days (**Table 4**). Cohen kappa values for intraobserver reliability amongst consultants ranged from 0.629 (substantial agreement) to 0.867 (almost perfect agreement) and were higher than trainees' values which ranged from 0.447 (moderate agreement) to 0.674 (substantial agreement). The mean value for all assessments was 0.672 (substantial agreement) and a standard error ranging from 0.048 to 0.085.

Validity of stem stability assessment was based on intraoperative findings (**Table 5**). The overall percentage agreement between all six observers was 65.7% (range, 58% to 74%) and was similar between trainees and consultants (67.3% versus 64.0%). Cohen kappa values for the consultants ranged from 0.160 (slight agreement) to 0.400 (moderate agreement) whilst for the trainees, values ranged from 0.240 (fair agreement) to 0.440 (moderate agreement).

The mean value for all assessments was 0.300 (fair agreement) with a standard error ranging from 0.116 to 0.139. Our results compared to previous studies are shown in **Table 6**.

Discussion

This study confirms that the UCS is inadequate for radiographic classification of PFFs around PTS stems and that it has considerably lower reliability and validity than previously described for other stem types.²¹⁻²⁴ The Vancouver group demonstrated substantial agreement during reliability and validity assessment in their original series of 40 PFFs around a mixture of cementless and cemented CB stems.²¹ An independent European validation study into 28 PFFs around a comparable group of stems reported similar results.²² A larger study involving 45 PPFs again reported substantial agreement for reliability and validity but each of these studies are limited by their sample size and incomplete description of femoral stems in their series. More recently, an investigation into 53 PPFs around cementless stems found only moderate interobserver agreement indicating a lower diagnostic reliability than earlier studies.²⁴

An effective classification system should be valid, reliable and easy to use. It should be comprehensive and its subcategories must be mutually exclusive with no potential for overlap.²⁶ It should have the ability to guide clinical decision making and reduce variation in practice for the benefit of patients. Ideally, it should be stable over time or, at the very least, be subject to repeat assessment and improvement as knowledge is gained and newer technologies are developed.²⁶ To date, the UCS and its predecessor have never been tested in a single large series of PFFs occurring around modern cemented PTS stems nor have they been appropriately updated given the widespread use of cemented PTS stems. The present study reports only moderate interobserver agreement indicating significant variation in opinion, even between experienced hip surgeons. Substantial intraobserver agreement was seen suggesting that although the UCS may have been applied differently by each observer to the study series, the observers maintained their own interpretation of it over time. Validity assessment produced the most striking results with lower percentage agreement than reported in previous studies²¹⁻²⁴ and only fair agreement between assessors. This confirms that the UCS has low diagnostic value for PPFs around PTS stems, particularly in distinguishing between type B subcategories. This may have important consequences as treatment is guided by each type B subcategory with internal fixation generally advocated for type B1 fractures

around stable stems and revision surgery suggested for type B2 and B3 fractures around loose stems. We also evaluated the effect of experience in using the UCS as classification systems should not ideally be prone to significant variation resulting from differences in user familiarity or experience. Compared to the consultants, trainees achieved better interobserver reliability scores, worse intraobserver reliability scores and similar validity scores. These inconsistent findings suggest that the UCS is subject to observer bias based on their level of experience with this outcome having been reported in previous studies.^{22,23}

This study highlights the limitations of radiographic classification of PFFs around PTS stems, most notably in the context of type B fractures where stem stability assessment guides treatment. Previous reports suggest that even computed tomography (CT) scans offer little additional benefit in determining implant stability in PFF.²⁷ Our observations are likely due to the fact that PTS stem loosening in the context of PFF is poorly defined. PTS stems normally subside within their cement mantle and radiolucencies at the stem-cement interface may not necessarily indicate pathological stem loosening as ongoing subsidence is expected during the first decade after implantation.²⁸ It is therefore important to perform serial radiographic review as any marked change in stem position may indicate stem loosening. Conversely, cemented CB stems and cementless stems are intended to achieve either a mechanical interlock to their cement mantle or a biological fixation to host femoral bone, respectively. With these stems, radiolucencies at either the stem-cement or stem-bone interfaces are more likely to represent a failure of stem fixation.

The importance of discriminating B subtypes is critical to surgical management. The treatment algorithm proposed by the classification system under investigation states that B1 PFFs around well-fixed stems can be treated with internal fixation whilst B2 and B3 PFFs around loose stems should be treated with revision surgery.^{19,20} Recent evidence suggests that locking plates confer no additional benefit over conventional plates and that cemented and cementless revision stems perform comparably in terms of reoperation risk.²⁹ There is little debate that in appropriate patients, revision surgery with stem exchange is likely to give more successful outcomes than internal fixation for the majority of B2 and B3 PFFs.^{30,31} This study shows that UCS interobserver reliability is lowest for the B subtypes and this is likely due to variation in interpretation of the definition of a loose stem and/or poor bone in the context of PTS stems. The UCS does not provide enough detail regarding the definition of radiographic loosening and/or poor bone with respect to PTS stems nor is there an accepted standard by

which this decision can be made. A loose PTS stem can only truly be identified intraoperatively in which case revision surgery is often the most accepted treatment strategy. Cement-in-cement stem revision techniques can be successfully utilised providing that the cement-bone interface remains intact.^{32,33} Interestingly, internal fixation is also shown to be a successful treatment option providing stable anatomic reconstruction of the fracture and cement mantle can be achieved (**Figure 1**).^{34,35} These reports highlight the variation in practice in both diagnosing and treating type B fractures around PTS stems. Although equally successful results can be seen with both fixation and revision, large comparative studies do not yet exist.

Due consideration must also be given to the effect of the fracture personality on treatment algorithms. Unstable fracture patterns, such as short oblique or transverse fractures, around PTS stems that are not loose are biomechanically inappropriate for internal fixation with a single plate and are better treated with an additional plate, a supplementary cortical strut graft or even revision to a long cementless modular fluted stem with distal fixation.³⁶⁻³⁸ Similarly, the fracture may not be reducible intraoperatively due to comminution of bone or cement and in this case stable internal fixation may not be possible. These are important intraoperative decisions and rely on the operating surgeon being able to evaluate stem stability, assess adequacy of reduction and perform revision surgery (**Figure 2**) with stem and/or acetabular component exchange with the goal of allowing the patient to weight-bear postoperatively.

This study is strengthened by its sample size making it the largest published validation study into this classification system. By focusing on an exclusive series of PTS stems, definitive conclusions can be drawn about the inappropriate use of the UCS for this stem type which has fundamental biomechanical differences to cementless and cemented CB stems. A heterogenous group of observers were involved including orthopaedic surgeons of different experience levels and an independent investigator ensured that each assessor was blinded to any information which may have introduced bias. This study has some limitations related to operative documentation as some cases had to be excluded for validity assessment due to the lack of intraoperative reporting of stem stability. It is also possible that the effect of assessment fatigue may lead to error when classifying a large group of fractures and this may lead to experimental bias. In conclusion, this study confirms that the UCS has inadequate reliability and validity for PFFs around PTS stems and therefore it should not be used on its own to guide their treatment. These fractures must be classified intraoperatively rather than based on radiographic classification. Formal intraoperative testing of stem stability and fracture reduction must be performed, and these cases must be managed by surgeons with the expertise of performing complex revision surgery as appropriately indicated. There is an express need for a standardised intraoperative classification system for PFFs around PTS stems to reduce variation in practice and improve clinical outcomes. This must include an assessment of fracture personality, stem stability, cement loosening at the cement-bone interface and the ability to achieve a stable anatomic reduction of the fracture and cement mantle. This study also supports the growing realisation that these challenging cases should be managed in specialist centres with the appropriate surgical skill set, experience and revision implant inventory.

Table 1. Baseline clinical and demographic characteristics

	n (%)		
Patients (PFFs)	71 (71)		
Age (mean, range)	79.45 (56-99) years		
Female patients	39 (54.9%)		
Previous hip arthroplasty			
Total hip arthroplasty	66 (92.9%)		
Hemiarthroplasty	5 (7.1%)		
Left sided	41 (57.8%)		
Stem brand			
СРТ	37 (52.1%)		
Exeter	22 (30.9%)		
Exeter Trauma Stem	5 (7.0%)		
C-stem classic	4 (5.6%)		
C-stem AMT	3 (4.2%)		

NB: PFF is postoperative periprosthetic femoral fracture; THA is total hip arthroplasty

Table 2. Unified Classification System²⁰

UCS type	Description
Type A	Apophyseal or extraarticular/periarticular
A_G	Greater trochanter
A_L	Lesser trochanter
Type B	Bed of the implant or around the implant
B1	Stem stable, good bone
B2	Loose stem, good bone
B3	Loose stem, poor bone, defect
Type C	Clear of or distal to the implant
Type D	Dividing the bone between two implants or interprosthetic or intercalary
Type E	Each of two bones supporting one arthroplasty or polyprosthetic
Type F	Facing and articulating with a hemiarthroplasty

Percentage agreement by assessor grade (%)	
All	58.5
Consultants	52.6
Trainees	59.6
Reliability by assessor grade (Fleiss kappa)	
All	0.442
Consultants	0.381
Trainees	0.444
Reliability by fracture type (Fleiss kappa)	
A_{G}	0.784
A _L	0.522
B1	0.284
B2	0.360
B3	0.095
С	0.739

Table 4. Intraobserver reliability of Unified Classification System in PTS stems

Reliability by assessor grade (Cohen kappa)					
All consultants					
Consultant 1	0.791				
Consultant 2	0.866				
Consultant 3	0.629				
Mean	0.762				
All trainees					
Trainee 1	0.447				
Trainee 2	0.624				
Trainee 3	0.674				
Mean	0.582				
Mean (all)	0.672				

Percentage agreement by assessor grade (%)			
All	65.7		
All consultants	64.0		
Consultant 1	74.0		
Consultant 2	60.0		
Consultant 3	58.0		
All trainees	67.3		
Trainee 1	62.0		
Trainee 2	68.0		
Trainee 3	72.0		
Validity by assessor grade (Cohen kappa)			
All consultants			
Consultant 1	0.400		
Consultant 2	0.200		
Consultant 3	0.160		
Mean	0.253		
All trainees			
Trainee 1	0.240		
Trainee 2	0.360		
Trainee 3	0.440		
Mean	0.347		
Mean (all)	0.300		

Table 6. Results of other studies

Study	Number	Stem type	Interobserver	Intraobserver	Validity	Validity
	of PFFs		reliability	reliability	(%	(kappa value)
			(mean, kappa	(mean, kappa	agreement)	
			value)	value)		
Brady et	40	Cementless	0.625	0.770	80.0%	0.690
al^{21}		and cemented	(range, 0.560 to	(range, 0.730 to		
(2000)		СВ	0.650)	0.830)		
Rayan et	28	Mixed	0.677	0.625	77.0%	0.670
al ²²			(range, 0.610 to	(range, 0.590 to		
(2008)			0.740)	0.670)		
Naqvi et	45	Mixed	0.650	0.805	81.0%	0.680
al ²³			(range, 0.560 to	(range, 0.740 to		
(2012)			0.720)	0.900)		
Lee at	53	Cementless	0.445	0.710	79.0%	NR
al ²⁴			(range, 0.300 to	(range, 0.570 to		
(2019)			0.590)	0.830)		
Present	71	Cemented	0.442	0.672	65.7%	0.300
study		PTS only	(range, 0.381 to	(range, 0.447 to		
(2021)			0.444)	0.866)		

NB. PFF is periprosthetic femoral fracture, CB is composite beam, PTS is polished taper slip, NR is not reported

Figure legends

Figure 1. Periprosthetic femoral fracture around polished taper-slip stem (a) treated with internal fixation with locking plate (b and c)

Figure 2. Periprosthetic femoral fracture around polished taper-slip stem (a) treated with stem revision (b)

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