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Proposal for the classification of peri-implant femoral fractures: Retrospective cohort study

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ABSTRACT

Background Peri-implant fractures occur in association with an implant used to treat a previous injury and that is still attached to the bone. Peri-implant fractures are considered to be relatively "new" fractures and they lack any classification system that is accepted in practice. Generally, the fracture classification systems currently used in our clinical practice were not developed or validated using rigorous scientific evaluation methods.

Aim To provide data for a proposed classification of peri-implant femoral fractures.

Methods This is an international and multicentre study (12 centres) based on a cohort of consecutive peri-implant fractures with the criterion being: a fracture in any segment of the femur in association with previously-used osteosynthesis material, whether a nail, plate or screws. A proposed system for the classification was tested, based on a topographical classification using alphanumeric coding, following a similar nomenclature to that explained in the "Vancouver-Classification-for-Total-Hip-Arthroplasty-Periprosthetic-Fractures", and classified according to whether the implant is a nail, a screw or a plate, and the location of the fracture in relation to the original implant and the affected femoral segment.

The study coordinator performed the first classification exercise, which was discussed subsequently for the study coordinator group to reach a consensus. A descriptive analysis of the fractures was produced. The proportion of peri-implant femoral fractures was estimated, and 95% confidence interval (95%CI) was calculated.

Results Between January 2013 and December 2016, data on a total of 143 peri-implant femoral fractures were collected.

Only 5 (3.5%) fractures had to be discussed to reach a consensus. The most common peri-implant femoral fractures were located at the diaphyseal segment (#32) and associated with nails or plates: 51%, 73/143, 95%CI:43-59%; at the proximal segment (#31): 39%, 56/143, 95%CI:32-47%; and at the distal femoral segment (#33): 10%, 14/143, 95%CI:6-16%. The highest proportion of peri-implant femoral fractures corresponded to #31-AN (trochanteric and neck area) and #32-CNP (diaphysis fractures distant from the implant, often distal and spiral).

Conclusion The proposed classification for peri-implant femoral fractures appears to be useful and easy to accomplish. Future studies will be necessary to validate it and demonstrate the effectiveness of its application in clinical practice.

Introduction

Peri-implant fracture occurs related to an implant, used to treat an initial injury, and that is still present in the bone. The presence of such implants (nails, plates or screws) causes changes in bone elasticity and creates stress riser areas, which in turn increases the risk of a subsequent femoral fracture [1–3]. The implant may be located in another segment of the bone, but the presence of the

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original implant material can influence the definitive treatment of the new fracture. We would like to differentiate between periprosthetic fractures, which are those that occur in association with the stem of a hip prosthesis or with a total knee prosthesis, and peri-implant femoral fractures which are those that occur in a femur containing implants used for a fracture fixation or an osteotomy. Peri-implant fractures are considered as relatively "new" fractures, and currently lack any classification system that is accepted in practice.

Classification systems have multiple purposes. The term "classification" has several meanings. We consider the most important to be the use of measures to individualize or bring together in a group, i.e. methodically grouping classes, subclasses and categories under logical and definite criteria [4–6]. Generally, the fracture classification systems currently used in clinical practice were not developed or validated by rigorous scientific evaluation methods [7,8]. Classification categories should allow us to make diagnoses with sufficient confidence to limit misclassification and associated treatment errors, and, in addition, should be a useful tool for communication between health professionals [5].

Within the different classifications described for periprosthetic femoral fracture associated with both hip and knee replacement [9–13], there appears to be some consensus on using the Vancouver Classification for fractures around the hip prosthesis [14] and the Rorabeck classification for those related to the knee replacement [15]. The common feature of both is that the diagnostic coding relates the level of the femoral fracture with the location of the implants. In 2013, a global classification was published called the Unified Classification System (UCS), with an extrapolated coding system for all locations in long bones, and valid not just for periprosthetic injuries, but also for peri-implant fractures [16]. Perhaps it is because we are still at the beginning of the peri-implant fractures epidemic, but there is no classification for femoral fractures associated with the material used for internal fixation implanted in the femur, as mentioned above. Therefore, the aim of this study is to provide preliminary data for a proposed peri-implant femoral fractures classification.

Methods

Study design

This was a retrospective, international and multicentre study (centres with active AOTrauma members) based on a series of consecutive peri-implant femoral fractures. This study was conducted in accordance with the principles of the Declaration of Helsinki while a high level of confidentiality, in terms of the protection of personal data as required by Spanish Law (LOPD 15/1999), was also ensured.

Study population

All consecutive peri-implant femoral fractures with the criterion of being a fracture in any of the segments of the femur and related to previously used osteosynthesis material, whether nails, plates or screws from Orthopaedic and Trauma Surgery Departments were identified and their related medical files were examined and included. The following data were gathered: date of birth, gender, date of peri-implant femoral fracture, and pre-operative Rx study.

Proposed system for the classification of peri-implant femoral fractures

Our proposed classification of peri-implant femoral fractures is based on the location of the fracture's centre in relation to the initial implant and the affected segment of the femur, following an alphanumeric coding nomenclature (2 digits) similar to that used in the AO/OTA Fracture Classification [17]. The type of fracture follows the rules set out in the "Vancouver Classification for Total Hip Arthroplasty Periprosthetic Fractures" [14]: Type A, fractures at the proximal end of the femur; Type B, fractures located at the tip of the implant; Type C, fractures distant from the implant; Type D relates to a specific pattern of subtrochanteric fracture secondary to the screws used for subcapital femoral fractures, and Type E, fractures through an implant with good anchorage where the healing process of the previous fracture was almost or completely concluded. Likewise, they are classified according to whether the implant involved is a nail, a screw or a plate, based on the location of the fracture site in relation to the original implant and the affected femoral segment. We defined the femur with number 3 (in line with the AO-OTA classification) [17] and location in the proximal segment with number 1, in the shaft with number 2 and in the distal segment with number 3 (Fig. 1). The definitive diagnosis is obtained by combining the fracture's location in the femur with the location of the fracture's centre with regard to the previous implant. We also code the implant type using N-> nail or P-> plate. Finally, we code P for proximal or D for distal, depending on whether the nail or plate were used antegrade (proximal) or retrograde (distal) in the initial fracture.

We have not considered the degree of comminution because the majority are simple fractures, and also taking into account the principles of alignment of the axis in the treatment of shaft fractures and the principles of relative stability, which we should use to approach the treatment of fractures in osteoporotic bone. We have considered therefore that comminution is not relevant for the selection of the final treatment.

The third digit is used to define 5 types of fractures from A to E according to the relationship of the fracture with the original implant.

Type A fractures are those sited at the proximal end of the femur, either subcapital, transcervical or pertrochanteric/intertrochanteric. We also include in this fracture type femoral head fractures associated with the tip of a cephalic screw or blade. This enables the coding of cut-out and cut-in injuries.

To define the subtypes (fourth digit) that relate the peri-implant fracture to the primary implant, we use the letters N for nails and P for plates. As a last digit we can add the letter P, which will indicate if the implant is proximal, or the letter D if insertion of the implant, whether a plate or a nail, was distal or retrograde.

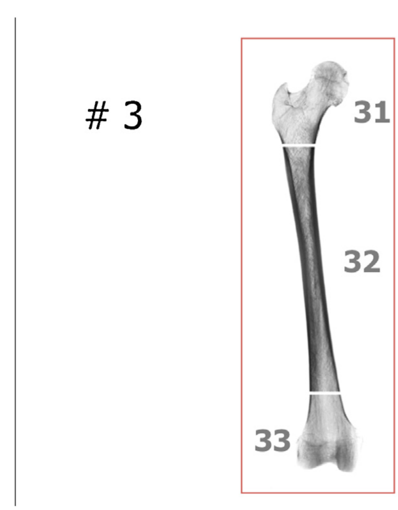

Fig. 1. Segments of the femur and alphanumeric coding for the diagnosis.

Type AP fractures are associated with plates and Type AN with nails. We should use ANP for proximal nails AND for retrograde intramedullary nails.

Any fracture in the trochanteric region or femoral neck area, even if distant from a short retrograde nail or a distal short plate, will be considered and coded as a 31-A, either 31-AND or 31-APD.

Type B fractures are those with a transversal or short oblique path, which usually occur at the tip of a nail or at the end of a plate, due to a sudden change in elasticity modulus between the implant and the bone.

Type BP fractures are fractures associated with plates: BPP for proximal plates and BPD for distal plates. Type BN fractures are associated with a nail. BNP should be used for proximal nails and BND for retrograde intramedullary nails.

Type C fractures are those that are distant from the initial implant site. These are the most frequent in our series, and are usually located in the distal third of the femur, with a spiral path. We can also find supracondylar fractures, distant from the implant with a transverse path.

Type CP fractures are those associated with plates: CPP for proximal plates and CPD for distal plates; and Type CN are associated with a nail. CNP should be used for proximal nails and CND for retrograde intramedullary nails.

Type D fractures are subtrochanteric fractures that occur after internal fixation of subcapital fractures using screws. These fractures probably occur due to the weakening of the lateral cortex of the trochanteric region, either through deterioration caused by the heads of the screws or by multiple and failed drilling.

Other weakening factors include screws placed below the level of the lesser trochanter.

Special attention is paid to these "type D" fractures. We must bear in mind that they have specific morphological and technical implications, not least related to the entry point and location of the screws, which must be proximal to the lesser trochanter. It is also well known that this could be a starting point for the technical failure of fractures related to weakness of the lateral femoral cortex during drilling and insertion of the screws [18].

Type E fractures are those that occur through an implant that has not lost its initial anchorage and where the healing process of the previous fracture is nearly or completely concluded. Type EP fractures are those associated with plates: EPP for proximal plates and EPD for distal plates; and Type EN are associated with nails: ENP for proximal nails and END for retrograde intramedullary nails.

Fig. 2 shows examples of our proposed classification for peri-implant femoral fractures.

Procedure for classification of peri-implant femoral fractures

In a first phase, between 1 January 2013 and 31 December 2016, data on all consecutive peri-implant fractures from the 12 tertiary collaborating hospitals (Table 1) were collected and a database was created. Once the database was closed (31 December 2016), the study coordinator (MV-C) proceeded to perform a morphological and descriptive diagnosis according to the proposed system for the classification of peri-implant femoral fractures discussed above. Subsequently, the classification was discussed case by case with the study coordinator group (JMS-P, RS-N and ER-P) in order to reach a consensus. In this first phase of classification, we have focused solely on a morphological and descriptive diagnosis. We did not consider the definitive treatment for the peri-implant femoral fracture.

Statistical analysis

No formal sample size was established, insofar as the sample size was defined as all peri-implant fractures with the criterion being a fracture in any of the segments of the femur and associated with a previously used internal fixation implant, whether nail, plate or screws, during the inclusion period.

Baseline characteristics were summarized using standard descriptive statistics, and a descriptive analysis was carried out. Continuous variables were described as mean (standard deviation) or median (range) and categorical data were summarised as absolute frequency and percentages. A descriptive analysis (morphological and descriptive diagnosis) of the fractures was produced. The proportion of peri-implant femoral fractures was estimated, and a 95% confidence interval (95%CI) was calculated. Data analysis was carried out using R Core Team (2015). R: A Language and Environment for Statistical Computing.

Results

A total of 143 peri-implant femoral fractures provided by 12 hospitals, all with active AOTrauma members in their respective Trauma Units, were collected during the inclusion period. The demographic characteristics for these patients are shown in Table 2. The previous implant was made of steel in 84 out of 143 (59%) patients and of titanium alloy in the remaining of patients, 59 out of 143 (41%). The intramedullary nails, including the trochanteric nails, were made of titanium in all participants hospitals except in one, where these were of steel. As for internal fixation with plates for proximal femoral fractures, these were steel plates, mostly DHS, some with a trochanteric support plate, but also DCS and angled plates of 90° and 130°.

Classification of peri-implant femoral fractures

The study coordinator performed the first classification of all peri-implant femoral fractures according to the proposal as the first step. As the second step, some days later, the study coordinator group reached a consensus regarding the classification. In the consensus discussion, only in 5 (3.5%, 95%CI:1.5–7.9%) of all the fractures evaluated was there any disagreement and with only one member of the study coordinator group. After discussion, the consensus was reached.

The most common peri-implant femoral fractures were located in the diaphyseal segment, 51% (73 out of 143) to be exact. Of these, 40% (29 out of 73) were type C fractures, associated with either nails or plates. Fig. 3 shows the distribution of peri-implant femoral fractures. The proportion of #31 peri-implant femoral fractures was 39% (56 out of 143, 95%CI: 32–47%), of #32 51% (73 out of 143, 95%CI: 43–59%), and #33 10% (14 out of 143, 95%CI: 6–16%). Table 3 depicts the proportion (and 95%CI) of all types of peri-implant femoral fractures. The greatest proportion of peri-implant femoral fractures correspond to #31-AN, #31-AP, #32-BP, #32-CNP and #32-CP. Forty-three out of 143 (30%) of the cases behaved as a first fracture event, subsequently establishing a cascade of fractures in the same femur.

Discussion

To our knowledge, this is the first time that data for a systematic classification for peri-implant femoral fractures using a global and common language have been tested. Proper classification of a fracture has to be considered not only based on the fracture lines visible in the X-ray study, but a correct diagnosis must also assess the severity and complexity of the fracture, possible complications, prognosis and the risk inherent to the fracture. The UCS is most likely a good comprehensive method [16], but the specificity that a topographical classification gives, as with our proposal for a femoral peri-implant classification system, which is restricted only to femoral fractures associated with a non-prosthetic implant, is an added plus for this classification proposal in terms of specificity.

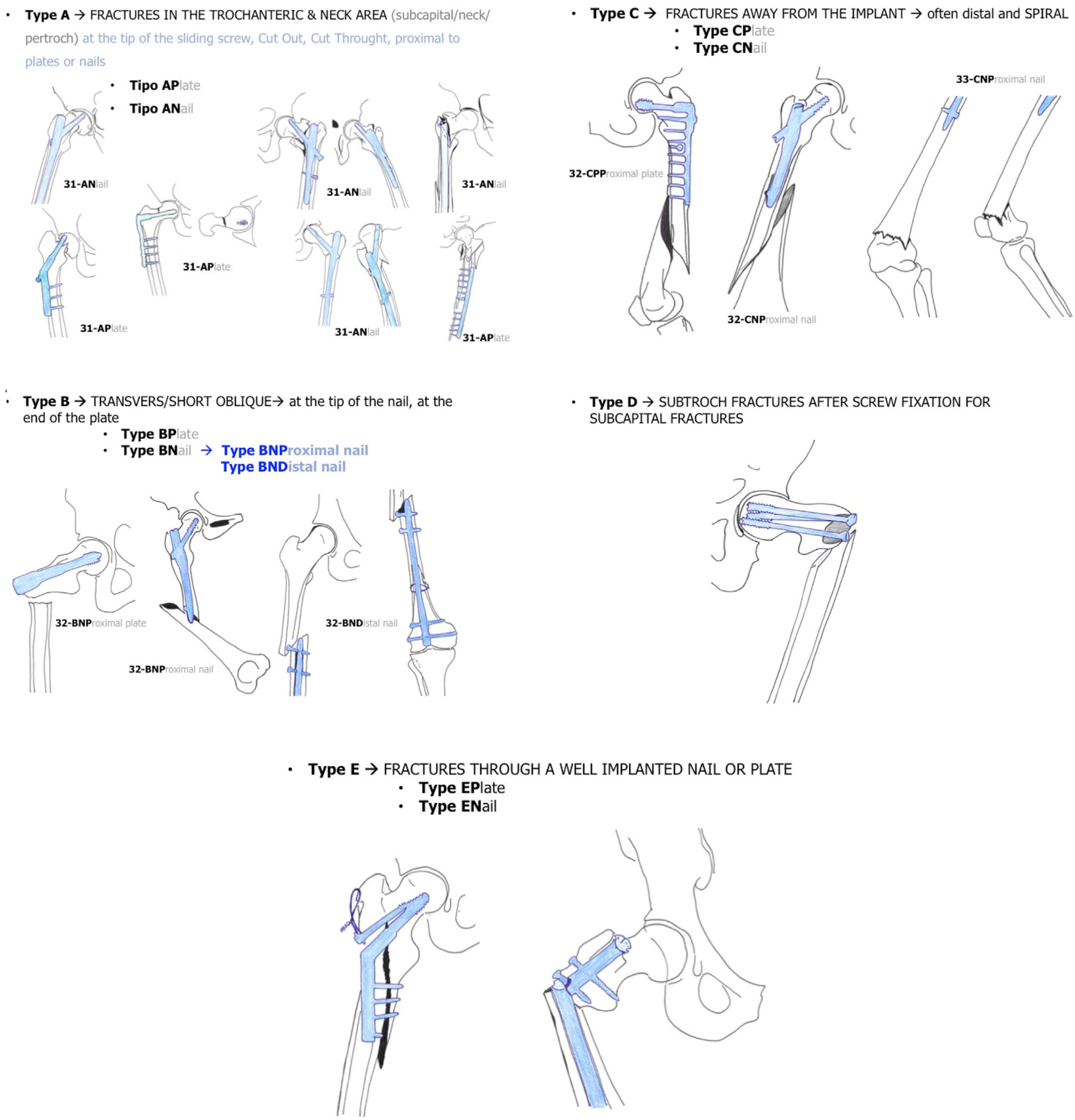

Fig. 2. Examples of our proposed classification for peri-implant femoral fractures.

Table 1
List of collaborating hospitals (multicentre collaboration).

Country	Hospital's name	City
Spain	H. Sant Joan Despí – Moises Broggi	Sant Joan Despí
	H. Clinic of Barcelona	Barcelona
	H. del Mar	Barcelona
	SCIAS – H. de Barcelona	Barcelona
	H. General Universitario de Elche	Elche
	H. Jove Gijón	Gijón
	H. de Girona	Girona
	H. Doce de Octubre	Madrid
	H. La Vega Baja	Orihuela
	H. Segovia	Segovia
	H. Valladolid	Valladolid
Israel	Herzliya Medical Center	Tel Aviv

It is worth noting that during the 20th and 21st century, life expectancy has increased considerably in developed countries. According to Spain's National Institute of Statistics ('Instituto Nacional de Estadística'), over the past 20 years life expectancy in Spain has increased from 76 to 82 years of age (http://www.ine.es/). It is also true to say that someone who reaches the age of 65 will

Table 2
Patient characteristics.

		Peri-implant femoral fractures n = 143
Age (yr)	mean (SD)	84.0 (10.2)
	median (min–max)	86 (54–100)
Male / Female	n (%) / n (%)	39 (27%) / 104 (73%)

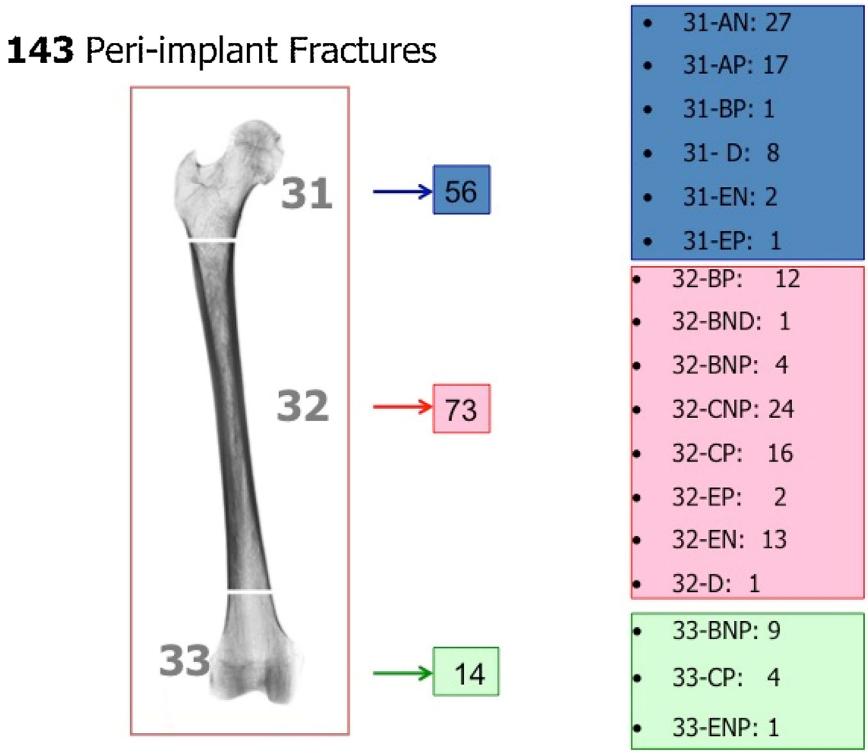

Fig. 3. Distribution of peri-implant femoral fractures according to the proposed classification.

Table 3
Proportion (and 95%CI) of all described types (n = 143) of peri-implant femoral fractures.

Peri-implant femoral fractures classification		N	%	95%CI
#31	31-AN	27	19	13–26
	31-AP	17	12	8–18
	31-BP	1	0.7	0.1–4
	31-D	8	6	3–11
	31-EN	2	1	0.4–5
	31-EP	1	0.7	0.1–4
#32	32-BP	12	8	5 – 14
	32-BND	1	0.7	0.1–4
	32-BNP	4	3	1 – 7
	32-CNP	24	17	12–24
	32-CP	16	11	7–17
	32-EP	2	1	0.4–5
	32-EN	13	9	5–15
	32-D	1	0.7	0.1–4
#33	33-BNP	9	6	3–11
	33-CP	4	3	1–7
	33-ENP	1	0.7	0.1–4

live, on average, for another 20 years. This increased life expectancy brings with it a major biological impact, meaning that the final part of the journey through life is a period of frailty. Furthermore, it leads to the appearance of fragility fractures, which are more common during this physiological process of deterioration [2,19,20]. As a result of this increase, and given the persistent physical activity levels among some elder patients, such peri-implant fractures are being seen more often and becoming more common. These days, surgeons frequently have to deal with patients who suffered a femoral fracture – whether proximal, distal or diaphyseal – during the last decade or two. These are patients initially treated with internal fixation implants or prosthetic devices, who could suffer a new fracture around this material or directly related to it. Treatment for these peri-implant injuries is associated with increased morbidity [21]. The mortality rate following a periprosthetic, peri-implant femoral fracture is alarmingly high, at around 11% to 31% during the first year following surgical treatment [2,19,21]. Hence, for all these reasons, it is expected that peri-implant femoral fractures are set to become a health problem that must be taken into account.

The chosen code for classification must be simple and easy to memorize and reproduce. It is essential to categorize and evaluate different treatment options [7,22–24]. The fact that our proposed classification system is based on alphanumeric characters facilitates its use in a database. It breaks down any language barriers, putting forward a common language, an alphanumeric Esperanto. The simplicity in informatics terms of these alphanumeric codes benefits our criteria, as well as the processes of collecting information and documentation. Focusing on one single bone or segment, using the location method also used in the AO-OTA classification of fractures, and following the “Vancouver Classification” method [14] when encoding the different types of fractures all led to preliminary results that are useful and promising. Furthermore, it leads us to believe that this method will have great intra- and inter-observer reproducibility.

Our results show that fractures through a correctly implanted nail or plate are not uncommon; we have mostly seen them around nails with a diaphyseal location (13 patients, 9%). Although it may seem that they are responding to high-energy trauma, this was not always the case, even in those fractures where the nail was broken. We have also often seen them in atypical fractures related to prolonged treatment with bisphosphonates and caused by low-energy trauma [25]. On the other hand, the rigidity of the assembly plays an important role in the extramedullary synthesis due to stress riser at the end of the plate. The weakness caused by the drilling holes for the locking bolds, the micromovement of the nail inside the medullary cavity and the discrepancy between the radius of curvature of the femur and that of the nail, which can cause a weak point in the anterior femoral cortex and becoming the starting point of the periimplant fracture. Therefore, it is important to bear in mind any medical history of thigh pain and prior limping, as these are important pointers to consider with regard to clinical suspicion, meaning that action is necessary before any fracture in the femur or rupture of the implant appears.

Some 30% of the cases behaved as a first fracture event, subsequently establishing a cascade of fractures in the same femur. Possibly because of bone frailty or due to the rigidity of the assembly used, a second fracture appeared in this group, and in 4 of the cases a third fracture even occurred. We have defined these fractures as inter-implant when the fracture occurs between implants. The femoral inter-implant fracture lies in an area without any protection, in a weak zone with high stress, which means added technical difficulty when dealing with these injuries in elderly and frail patients who have undergone multiple previous surgeries [26,27].

Some limitations need to be considered for interpretation of the results of this cohort study. In this first phase, for the classification of peri-implant femoral fractures, this was performed only by the coordinator group. This fact could lead us to under- or over-estimate the generalizability of the results. The same could be said of the lack of sample size calculation. Notwithstanding, it should be mentioned that the results of this first phase will be validated in a second phase, which is currently in progress. Thirty of the peri-implant femoral fractures will be randomly selected and will be sent to each collaborating hospital, with a request that a (senior) AOTrauma member and a resident of each centre perform classification of these 30 peri-implant femoral fractures, and return their results to the study coordinator within 15 days. Once the coordinator receives all the evaluations, the same 30 peri-implant femoral fractures, but in a different order, will be sent once more to the centres for their classification by the same AOTrauma member and resident.

In summary, the proposed classification for peri-implant femoral fractures appears to be useful and user-friendly. Future studies will be necessary to validate it and to demonstrate the effectiveness of its application in clinical practice.

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Authorship attributions

MV-C and SV wrote the study protocol and all of the authors approved the final version of it. MV-C, JMS-P, RS-N and ER-P performed the classification of peri-implant femoral fractures. MV-C and SV drafted the manuscript and all of the authors assisted in the successive revisions of the final manuscript. All of the authors participated in the analysis and interpretation of the data, all of the authors read and approved the final version of the manuscript, and they all assume responsibility for both the integrity of the data and the accuracy of the analysis.

Peri-implant femoral fractures study group

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Conflicts of interest

All of the authors declare that they have no conflict of interest.

Dr. Miquel Videla-Cés is a PhD candidate in the Universitat de Barcelona, Spain.

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