

## Outcomes and Risk Factors of Peri-Implant Hip Fractures after Short Femoral Nail Fixation

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### Abstract

Fractures of the hip occur frequently in elderly individuals and create a heavy load on healthcare resources owing to elevated morbidity and substantial financial implications. The rising preference for intramedullary nailing in hip fracture repair has inadvertently introduced new hazards; these devices alter bone flexibility and create areas of concentrated stress that may lead to fractures around the implant. This study seeks to analyze the clinical outcomes of peri-implant hip fractures, explore potential contributing factors, identify the treatments administered, evaluate their effectiveness, and suggest ways to enhance future management. A retrospective observational analysis was carried out on 33 patients who experienced peri-implant hip fractures (PIFs) and underwent operative care at Río Hortega University Hospital between 2010 and 2022. The collected information included patient demographics, details of the primary fracture, classification of the peri-implant fracture, characteristics of the implant, surgical findings, functional assessments, and any complications. Functional status was assessed via the Parker Mobility Score (PMS). The study population (91% women, average age 87.6 years) comprised 34 peri-implant fractures. The mean period between the original fracture and the subsequent PIF was 47.2 months, although nine patients sustained a PIF within 2 months. The majority of fractures (76%) were treated by removing the existing implant and replacing it with a long intramedullary nail; cement augmentation was used in 31% of these procedures. The average operative duration was 102 minutes, and the mean length of hospital admission was 9.6 days. Complications after surgery developed in 27% of cases, and the perioperative death rate stood at 9%. Functional ability declined markedly, reflected by an average reduction of 4.16 points on the PMS. One-year mortality following the PIF reached 36% and climbed to 83% by five years. Radiographic union was achieved in 72% of fractures at a mean of 6.04 months, yet 24% of patients passed away before signs of healing. Significant statistical associations were detected with the PMS recorded before the initial fracture (PMS1:  $r = 0.354$ ,  $P < 0.05$ ), before the PIF (PMS2:  $r = 0.647$ ,  $P < 0.001$ ), and after the PIF (PMS3:  $r = 0.604$ ,  $P < 0.001$ ). Peri-implant hip fractures pose demanding clinical problems due to their technical complexity and profound influence on patient movement and long-term survival. Optimal care necessitates a tailored strategy that accounts for the specific fracture pattern, implant location, and individual patient characteristics. The outcomes emphasize the value of prevention, particularly through careful implant selection and the adoption of overlapping or interlocking fixation techniques, to lower the likelihood of secondary fractures.

**Keywords:** Proximal femur fracture, Short femur nail, Peri-implant fracture, Fragility fracture

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**Received:** 15 January 2026

**Revised:** 28 March 2026

**Accepted:** 03 April 2026

**How to Cite This Article:** El-Kholy A, Abdelrahman N, Hassan K. Outcomes and Risk Factors of Peri-Implant Hip Fractures after Short Femoral Nail Fixation. Bull Pioneer Res Med Clin Sci. 2026;6(1):152-60. <https://doi.org/10.51847/Q80X3dFP4N>

## Introduction

Hip fractures impose a considerable economic, societal, and medical burden because of their frequent occurrence among people older than 65 years. In Spain, nearly 40,000 hip fractures are recorded every year, corresponding to an incidence of roughly 500 cases per 100,000 population. The associated healthcare expenditure totals 2.5 billion euros annually, accompanied by a loss of 7,218 quality-adjusted life years [1]. The typical age at presentation is 81.4 years [2]. Mortality ranges between 5% and 10% within the first month and between 20% and 30% at one year after the injury. Among those who survive, approximately half require assistance with daily activities, while 10%–20% eventually reside in nursing homes. Nonetheless, the unique challenges posed by peri-implant fractures and the specific role of Short Proximal Femur Nails (SPFNs) in their development have received limited attention in the published literature.

SPFNs are now widely employed for treating unstable extracapsular fractures due to their less-invasive approach and favorable biomechanical properties [3, 4]. These nails have also become the implant of choice for many stable fractures [5, 6]. Yet their application is associated with distinct complications, notably reduced bone elasticity and localized stress accumulation, both of which increase the risk of peri-implant fractures [7, 8]. The likelihood of a fracture occurring at the distal tip of the device is more than three times greater with intramedullary implants than with extramedullary ones [9]. While such fractures can arise during the initial operation, they more often develop between 6 and 10 weeks afterward or at a later stage. These injuries are usually low-energy events triggered by simple falls from standing height, although rotational forces on the operated leg or inappropriate manipulation can also be responsible. Managing these fractures is demanding due to complex biomechanical conditions, the challenge of achieving stable fixation, and the risk of significant functional deterioration. Despite their growing clinical significance, relatively few studies have focused on these specific problems.

As femoral peri-implant fractures (PIFFs) become more prevalent, several classification systems have been introduced, but broad agreement remains lacking. The first notable system, proposed by Duncan CP and Haddad FS [10] in 2013, was the Unified Classification System (UCS), which covers both peri-implant and periprosthetic fractures across any long bone [10]. In 2018 and 2019, Chan *et al.* [11] and Egol *et al.* [12], respectively, described classifications of periprosthetic fractures that were not limited to the femur. Also in 2019, a Spanish group headed by M Videla introduced a specific classification for PIFFs [8]. This system categorizes fractures according to their position relative to the implant

(at the tip, traversing the implant, or remote from it). It employs an alphanumeric format drawing from the AO/OTA and Vancouver systems.

Treatment possibilities range from complete removal of the original implant followed by revision osteosynthesis with a longer device, which increases operative difficulty and infection risk. Alternative strategies such as overlapping or interlocking constructs can improve overall stability by protecting the full length of the femur, as recommended in the 2024 Peri-Implant Spanish Consensus (PISCO) [13].

Although PIFs are becoming more common in aging societies, important gaps remain concerning associated risk factors, optimal treatment choices, and effective preventive measures. The present study aims to help close these gaps by reviewing the outcomes of surgically managed peri-implant hip fractures at our center, examining potential causative factors, documenting the treatments performed, evaluating treatment success, and outlining practical strategies to achieve better results.

## Materials and Methods

Following Ethics Committee approval (Ref. CEIm: 23-PI043), we conducted a retrospective, observational, analytical investigation. The study included all patients who underwent operative treatment for peri-implant hip fractures at the Orthopedic Surgery and Traumatology Service at Río Hortega University Hospital (HURH), a tertiary referral center, from 2010 to 2022.

Inclusion criteria required that patients had been operated on for a peri-implant hip fracture occurring around a short cervicocephalic nail at our facility between 2010 and 2022 and had been followed for a minimum of 12 months. Cases involving mechanical failures such as cut-out, cut-in, or cut-through in fractures that had not achieved union were deliberately omitted, since these events were viewed as direct complications of the primary fixation rather than genuine peri-implant fractures. Such exclusions were implemented to reduce confounding variables and to keep the analysis centered exclusively on authentic peri-implant fractures. Altogether, 33 consecutive patients met the criteria and were enrolled, with identification maintained through their medical record numbers throughout the review. Surgical planning was guided by the specific fracture configuration, the patient's associated medical conditions, and the properties of the existing implant. Longer nails were typically chosen for fractures located in the diaphysis to improve overall stability, whereas condylar plates were selected more often for distal fractures to enable overlapping fixation methods. When choosing implants, particular attention was paid to avoiding pressure on the anterior cortical bone and to preserving biomechanical balance.

All patients were observed until the completion of the study in December 2023.

Information was extracted from the hospital's digital medical records system. The variables recorded comprised: demographic details (date of birth, gender), features of the primary fracture (affected side, fracture pattern, peri-implant fracture classification [8, 14]), peri-implant fracture categorization, implant characteristics (implant model, length, diameter, angle, cephalic screw configuration, Tip–Apex Distance [15], Cleveland quadrant position [16], and distal locking mode of the initial nail), operative results (date of index procedure, date when the peri-implant fracture occurred, date of revision surgery, implant selected for the second operation, application of augmentation, duration of surgery, length of hospitalization, need for blood transfusions, evidence and timing of fracture union), functional assessments (mobility level before and after the revision using the Parker Mobility Score [PMS]), and adverse events (postoperative issues and mortality).

In addition, patients or their next of kin were contacted by telephone to assess functional capacity both prior to and following the revision surgery using the Parker Mobility Score (PMS). This score measures the individual's capacity to walk inside the house, outside on the street, and during shopping trips. Each task receives 3 points when performed independently without difficulty, 2 points when an assistive device is needed, 1 point when assistance from another person is required, and 0 points when the activity cannot be completed. The overall score spans from 0 to 9, with decreasing values corresponding to progressively lower functional independence [17].

Fractures in the present series were categorized according to the Videla classification system [8, 14]. This system assigns an alphanumeric code that begins with two digits denoting the anatomical location of the fracture, followed by two or three letters specifying the morphological pattern. The initial two digits derive from the AO/OTA system, where the first digit indicates the femur (3) and the second indicates the segment as proximal (1), diaphyseal (2), or distal (3). The subsequent letters draw from the Vancouver classification used in periprosthetic fractures: "A" indicates fractures located at the upper end of the femur, "B" describes short or oblique fractures situated at the nail tip or involving the distal locking screw, and "C" denotes fractures lying distal to the nail. Furthermore, the letter "N" represents a nail while "P" represents a plate. The final (fifth) character indicates whether the implant was introduced in an antegrade (P) or retrograde (D) direction. The classification's reliability was previously assessed by 35 orthopedic trauma surgeons of differing experience levels, revealing no meaningful differences between observers and thereby establishing it as a valid and reproducible tool. To eliminate any potential

variability arising from individual judgment, every fracture was classified only after full agreement had been reached between two independent evaluators.

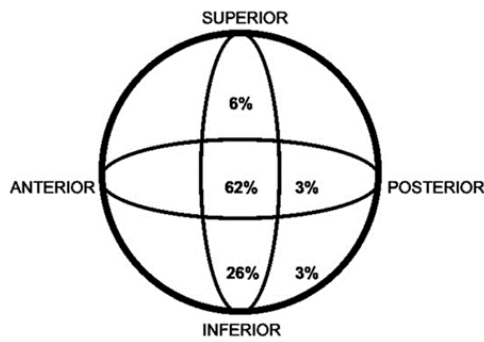
All information was entered into a Microsoft Excel spreadsheet (Microsoft Excel for Mac v16, Microsoft Corporation, Redmond, WA, USA). This database was used to compute derived variables, including time from admission to surgery, the interval between the initial fracture and the peri-implant fracture, patient age at the time of each fracture, age at the time of death, and post-peri-implant fracture survival duration. The spreadsheet also enabled the production of graphical representations and supported statistical processing, which was conducted with SPSS Statistics (SPSS Statistics for Mac v27, IBM Corporation, Armonk, NY, USA).

## Results and Discussion

The series consisted of 33 patients, of whom 91% were female, presenting with a total of 34 peri-implant fractures (PIFs). Mean age when the peri-implant fracture occurred was 87.6 years (standard deviation (SD) 6.2, range (R) 70–98 years).

For the initial fractures, the average age at occurrence was 83.6 years (median 85, SD 6.2, R 65–97). The average interval from the primary fracture to the peri-implant fracture measured 47.2 months (median 28, SD 41, range 0–194 months). Nine patients sustained the peri-implant fracture within the first 2 months following their initial procedure. Mean delay from PIF diagnosis to operative fixation was 2.56 days (SD 1.13, R 0–7 days). Fracture patterns were categorized according to the classification developed by the Miquel Videla group as follows: 13 fractures classified as 32-BNP, 8 as 32-CNP, 6 as 33-CNP, 5 as 32-BND, 1 as 31-ANP, and 1 as 32-BNP + BPD.

The fractures developed around short intramedullary nails, distributed as 9 (27%) TFN, 8 (24%) GAMMA, 14 (42%) PFNA, 1 (3%) AFFIXUS, and 1 (3%) ZNN. One individual whose fracture occurred on a GAMMA nail and who received revision with a LISS plate later developed a second PIF. Nail lengths varied between 17 cm and 24 cm, diameters ranged from 10 mm to 12 mm, and the cervicodiaphyseal angle was 130° in all nails except one AFFIXUS nail that measured 125°. Cephalic fixation was performed with screws in 13 cases (38%) and plates in 21 cases (62%). Positioning of the proximal screw or blade inside the femoral head was evaluated using the Cleveland quadrants together with Baumgaertner's Tip–Apex Distance (TAD), achieving a center–center location and TAD below 25 mm in 61.7% of the cases (**Figure 1**).

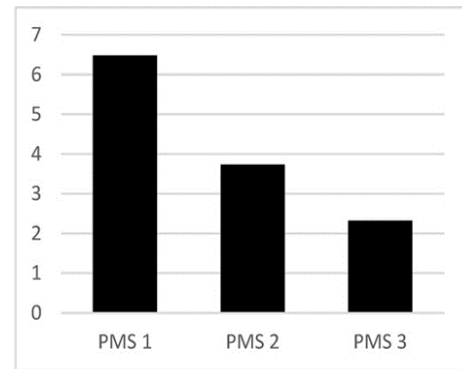


**Figure 1.** Position of the nail’s proximal screw/blade within the femoral head according to Cleveland and Bosworth quadrants.

Surgical management consisted of the removal of the prior fixation hardware and insertion of a long intramedullary nail in 26 (76%) instances. This strategy covered all 26 fractures (76%) located in the femoral diaphysis (classified as 32-BNP, 32-CNP, and 32-BNP + BPD). Cement augmentation was added in 8 (31%) of these 26 procedures (five long PFNA® nails and three long TFNA® nails). Seven fractures (six of type 33-CNP and one inter-implant 32-CNP) underwent fixation with a condylar plate. The overlapping technique was applied in six of those seven cases. In the single instance without overlap between the condylar plate and the existing femoral nail, an additional fracture (BNP + BPD) appeared after only 2 months. The sole fracture located in the cervicotrochanteric zone (type A) was managed with a cemented hemiarthroplasty using a Thompson prosthesis. Time from admission for the PIF until the revision operation averaged 2.56 days (SD = 1.13, R = 0–7). Average surgical duration was 102 minutes (SD = 26.45, R = 40–170 minutes), and mean hospitalization length reached 9.6 days (median = 8, SD = 3.13, R = 4–29 days). Thirty-one patients received blood transfusions, averaging 2.65 units of packed red blood cells per patient (SD = 1.17, R = 0–8 units). Among the 33 patients, 24 (73%) had no postoperative complications. Two patients were diagnosed with SARS-CoV-2 infection; one developed infection at the plate site, one sustained an atypical fracture, one experienced popliteal thrombosis, and 3 (9%) died before hospital discharge. Radiological union was confirmed in 24 fractures (72%) after a mean of 6.04 months (median = 3, SD = 4.76, R = 1–36 months). Eight patients (24%) passed away before achieving union; among them, one suffered a refracture before any healing occurred, and another remained in a state of delayed union.

On average, patients showed a reduction of 4.16 points on the Parker Mobility Score (PMS) from the time of the first hip fracture until the peri-implant fracture, corresponding to a 64.19% drop in functional ability. The further decline caused specifically by the peri-implant fracture amounted to 1.31 points (35.12%). The progression of mean

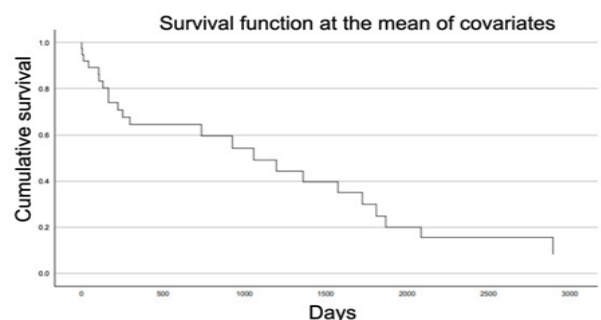
functional capacity over the three time points is displayed in **Figure 2**.



**Figure 2.** Evolution of functional capacity (PMS—Parker Mobility Score) before the index fracture (PMS1), after the index fracture (PMS2), and after the peri-implant fracture (PMS3).

Examination of the link between functional capacity and survival revealed statistically significant positive correlations with the Parker Mobility Score recorded before the index fracture (PMS1: correlation coefficient 0.354,  $P < 0.05$ ), before the peri-implant fracture (PMS2: correlation coefficient 0.647,  $P < 0.001$ ), and after the peri-implant fracture (PMS3: correlation coefficient 0.604,  $P < 0.001$ ).

Patient survival following PIF is illustrated by the Kaplan–Meier curve (**Figure 3**). Mortality stood at 36% one year after the PIF and increased to 83% at five years. Survival rates showed no statistically significant difference between cases managed by hardware removal plus long intramedullary nail insertion and those treated with condylar plate fixation ( $P = 0.75$ ). No significant survival difference was also found when comparing BNP-type peri-implant fractures with CNP-type fractures ( $P = 0.124$ ). Pearson’s correlation analysis indicated a statistically significant negative relationship between age at the time of peri-implant fracture and subsequent survival ( $r(34) = -0.424$ ,  $P < 0.05$ ). Furthermore, Spearman’s correlation analysis demonstrated a strong, statistically significant association between PMS values and overall survival (**Table 1**).



**Figure 3.** Kaplan–Meier curve of survivorship after PIF.

**Table 1.** Correlation coefficients (Spearman). There was a strong correlation between the Parker Mobility Score before and after the peri-implant fracture (PMS2 and PMS3) and survivorship.

Variable	Statistic	PMS1	PMS2	PMS3
<b>Survival</b>	Correlation coefficient	0.354	0.647	0.604
<b>Status</b>	Significance (P-value)	0.04	< 0.001	< 0.001
<b>PMS1</b>	Correlation coefficient	—	0.583	0.371
	Significance (P-value)	—	< 0.001	0.03
<b>PMS2</b>	Correlation coefficient	—	—	0.807
	Significance (P-value)	—	—	< 0.001

Available scientific publications on peri-implant femoral fractures (PIFFs) remain scarce, largely because no universally accepted classification system exists. Nevertheless, several classification schemes have been proposed in recent years to improve comprehension and guide treatment decisions. These include the systems proposed by Chan *et al.* [11], Egol *et al.* [12], and Videla *et al.* [8, 14]. Given the rising frequency of these injuries, it is expected that additional research similar to the current work will appear in the near future. The majority of published series involve small sample sizes, which limits the ability to draw robust conclusions. Among the largest groups described so far are the series by Müller *et al.* [9], reporting 18 PIFFs (15 of which occurred specifically around nails), and Kruse *et al.* [18], which included 41 cases but only 3 around nails. The largest investigation to date was performed by Chan *et al.* [11] in 2018; they identified 60 peri-implant fractures overall, 38 of which involved the femur and merely 3 around short femoral nails. The present series, with 34 cases focused exclusively on fractures around short cephalomedullary nails, ranks among the largest cohorts reported for this specific subgroup.

The actual frequency of periprosthetic femoral fractures is still not clearly established. In the 1990s, initial designs of intramedullary nails were associated with rates reaching 15% [19]. Thanks to improvements in fixation devices for intertrochanteric fractures, the current incidence has dropped to roughly 1%–2%. Large cohort studies support this: Kruse *et al.* [18] observed 0.8% in 1965 patients, while Müller *et al.* [9] recorded 2.1% in 1314 patients. In those two studies, the mean interval between the original fracture and the peri-implant fracture was 27 months and 23.6 months, respectively, whereas our analysis showed a longer average of 47.2 months. This discrepancy likely stems from differences in follow-up duration; Müller *et al.* [9] tracked patients for an average of 12 years, Kruse *et al.* [18] for 9 years, whereas our retrospective review included cases from more than 10 years earlier. Even so, our median interval of 28 months is consistent with values reported in

the existing literature. Overall, these observations underline the need for extended patient counseling and monitoring when femoral implants are used.

Regarding mortality linked to PIFFs, Kruse *et al.* [18] reported a 34% rate in the first year after injury, Müller *et al.* [9] reported a 23% rate, and the present study found a 36% rate. The marginally higher figure in our series could be related to the older demographic profile in the Valladolid region relative to other areas. Although the mortality rates are broadly comparable to prior reports, specific strategies are needed to address the demographic and medical issues specific to our patient population.

Jennison and Yarlalagadda [20] reviewed 29 peri-implant fractures retrospectively in 2018 and noted that 34% of patients walked without assistance before the injury (15% in our group), 17% used a single cane (15% in ours), and 17% needed two canes (18% in ours). Additionally, 31% relied on a walking frame in their series (18% in our cohort, plus another 35% who were unable to walk at all). These differences may arise from small sample sizes and variations in how mobility was assessed; for instance, some patients recorded as wheelchair-dependent might still be able to walk limited distances with support. The average time to surgery in Jennison and Yarlalagadda [20] was 86.1 hours (R 16–277), compared with 61 hours in our study, while the mean hospital stay was 13 days (R 6–144) versus 9.6 days (R 4–29) here. Our data suggest that these fractures receive higher priority at our center, resulting in shorter delays to theatre and briefer admissions. The reduced waiting times and hospital stays observed in our setting may contribute to improved functional recovery, even though initial mortality remained relatively high.

A meta-analysis conducted by Ma KL *et al.* [21] detected no meaningful difference in the occurrence of PIFFs when comparing PFNA® nails with GAMMA® nails. However, they noted a greater risk of refracture with intramedullary devices than with sliding hip screw–plate constructs (DHS). Concerning surgical timing, another meta-analysis of 3000 periprosthetic fractures [22] found an average delay from admission to operation of 64 hours. It emphasized that earlier intervention was associated with markedly lower mortality compared with postponed surgery. Shorter inpatient stays were also associated with fewer general medical problems, lower transfusion requirements, and lower reoperation rates, although the overall evidence quality was considered low. In our series, the mean surgical delay was 61 hours; nevertheless, with only 33 patients, we could not demonstrate clear differences, and we observed only a weak, non-significant link between mortality and time to surgery (Pearson correlation coefficient ( $r$ ) = 0.26,  $P$  = 0.143).

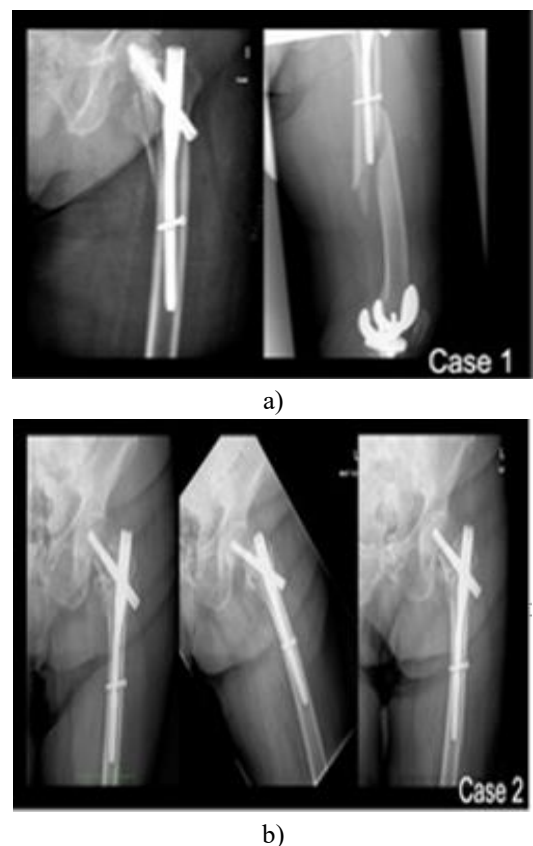
Nail length constitutes yet another key element worth examining. Some previous investigations have shown that the risk of peri-implant fractures remains roughly the same

regardless of whether short or long nails are selected [23-26]. Cinque *et al.* [27] observed no important variation in peri-implant fracture frequency between the two nail lengths. They preferred short nails for pertrochanteric fractures, citing advantages such as decreased blood loss, shorter operating times, and fewer overall complications. The present work examined only short cephalomedullary nails that had been placed during the primary fracture repair. As for distal locking, every case in this group featured intramedullary nails secured distally, with dynamic locking used in the great majority (88%). Skála-Rosenbaum *et al.* [28] determined that adding distal locking reduces the occurrence of peri-implant fractures and advised its routine application, while noting that unlocked nails could be considered in certain stable pertrochanteric fractures as long as the nail provides a snug fit inside the medullary canal. Of particular interest, 15% of the peri-implant fractures in our series developed precisely at the distal locking screw site, which calls for additional investigation. We suspect these fractures may be related to the pressure exerted by the surgeon during tightening of the distal screw, especially because, in most instances, the screw only marginally crossed the far femoral cortex. This configuration can serve as a focal point of stress, establishing a localized weak spot in the bone.

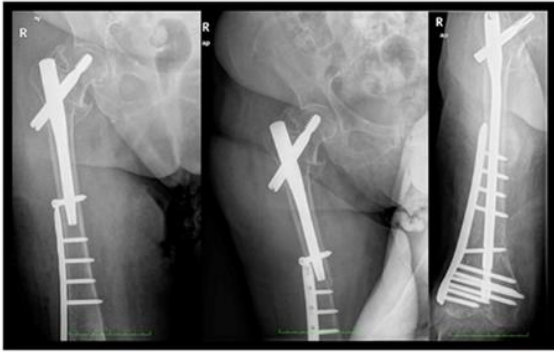
Treatment choices for PIFFs remain a matter of ongoing discussion, and the selected method varies according to the type of hardware already in place. Retained implants often hinder proper fracture alignment and can obstruct the medullary canal, thereby making insertion of replacement devices more difficult. A common strategy is to remove the initial implant and replace it with a longer device for revision fixation. However, this approach requires greater surgical exposure, results in greater blood loss, and increases the risk of infection. Furthermore, bone strength is further compromised after implant extraction owing to existing osteopenia and the cortical defects created by previous screw holes. Alternative strategies that combine the original and new implants — such as adding a femoral plate or interlocking the two constructs to form a solid assembly that spans the entire femur — can provide better stability and help eliminate vulnerable areas susceptible to repeat fractures. A recent consensus statement from a Spanish group (PISCO) [13] on PIFF management highlights the value of biological approaches and recommends closed reduction, along with minimally invasive methods, when appropriate. It also supports the use of overlapping or “kissing” implant configurations when possible, retention of the original fixation material, and protection of the femoral neck region.

Because 26.4% of patients in this series experienced fractures within the first 2 months after the index operation, we strongly recommend refined surgical

practices to improve outcomes and reduce the likelihood of PIFFs. Specific measures include the following. Surgeons must avoid over-tightening distal locking screws against the lateral femoral cortex. Selecting short femoral nails that avoid the anterior cortex (or choosing anatomically shaped left- and right-specific nails) can offer clear benefits. When other implants are already present in the femur, overlapping techniques should be used while avoiding the technical pitfalls depicted in **Figures 4-6**. In addition, initiating bone-protective therapy, such as anti-resorptive agents, soon after the diagnosis of the first (index) fracture may improve patient outcomes.



**Figure 4.** Error #1—anterior cortical impingement. Using longer short nails (those exceeding 200 mm) often results in the nail tip pressing directly against the anterior surface of the femoral cortex. This contact creates a localized area of increased mechanical stress that can eventually lead to a fracture. To avoid this problem, it is preferable to choose nails specifically shaped to match the natural anatomy of the femur (available in separate left- and right-hand versions) or to switch to a standard long nail.



**Figure 5.** Error #2—improper overlapping. For fractures classified as type C, keeping the original hardware in place is advisable whenever possible, as it helps shield the femoral neck from further damage. In these scenarios, applying a retrograde plate from the distal end and ensuring proper overlap with the existing implant is the suggested approach. Greater safety is achieved when the overlapping segment extends as high up the femur as technically feasible. Additional stability can be gained by selecting appropriate hardware such as specially designed periprosthetic plates, dedicated periprosthetic screws, adjustable-angle locking plates, or supplementary locking attachment plates.



a)



b)

**Figure 6.** Error #3—the overtightened screw. Precise measurement of the distal locking screw length is vital. When the selected screw falls short, surgeons may compensate by applying excessive force to secure engagement with the opposite cortical wall of the femoral shaft. This combination—a hole that already

weakens the bone plus the additional stress from excessive tightening—frequently leads to fracture formation.

The current investigation provides meaningful insights into peri-implant hip fractures. Among its positive aspects are the in-depth examination, concrete operative suggestions, and consistent application of the Parker Mobility Score. On the other hand, its retrospective character, single-institution origin, relatively small number of cases that restricts detailed subgroup evaluation, and absence of prolonged follow-up limit how widely the findings can be applied. Even with these drawbacks, the study helps bridge significant knowledge gaps and provides a practical guide for managing these difficult fractures.

## Conclusion

Peri-implant fractures (PIFs) among elderly individuals carry high mortality and lead to major reductions in functional mobility. A substantial proportion of these fractures occur during the first 2 months after surgery, underscoring the critical role of precise operative technique in preventing early repeat fractures. The marked reduction in mobility observed after a PIF directly affects patients' daily living and is clearly associated with survival. Greater attention should therefore be directed toward refining both surgical methods and subsequent care to assist these fragile patients better and enhance their overall outlook.

**Acknowledgments:** None

**Conflict of interest:** None

**Financial support:** None

**Ethics statement:** The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board (or Ethics Committee) of ASVAO (23-PI043, 15 February 2023).

Patient consent was waived due to the study's observational design.

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