General

Interprosthetic and interimplant femoral fractures: is bone strut allograft augmentation with ORIF a validity alternative solution in elderly?

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Background

Nowadays orthopedic surgeons have a new challenge to treat the interimplants fractures. Although fixation strategies exist for periprosthetic hip and knee fractures, there is no standard of care regarding the more complex interprosthetic and interimplants fractures.

Objective

The aim of our study is targeting the focus on the bone strut grafting to avoid the metal hardware failure and to achieve the bone healing in these injuries.

Methods

A prospective case note review of all interprosthetic or interimplants femoral fractures admitted to our trauma center. There were 11 patients (2 males and 9 females) with a mean age over 85 years old. We treated all the patients by ORIF and medial graft strut allograft to reduce the main complication leading to re-operations and morbidity or mortality is the nonunion or delayed union. The criteria to evaluate the patients during the follow-up were: the survival and complication after the surgery; the objective quality of life measured by Activities of Daily Living Score (ADL). The bone healing was measured by X-rays control as the alignment was measured by radiographic UNION SCORE, and postoperative complications.

Results

All the patients reduced their ADL. In the most of cases we had a good x-rays reduction. We had not: No nonunion or Not delayed union. All patients died within 2 years from the surgery but not due by surgical complications.

Conclusions

According us, the purpose of this surgery is to limit comorbidities and early mortality not to improve optimal restoration of lower limb function.

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INTRODUCTION

In 2060, in the United States, the estimated population will be older than 65 years about 98 million.[1] The simultaneous increase in the number of annual implants and the average age of the population has inevitably led to an increase in the percentage of the population having more than one prosthetic implant. In addition, the incidence of periprosthetic fractures and therefore the presence of implant to fix those kinds of fractures will continue to increase as well.[2]

Interprosthetic or interimplant fractures of the femur were described by Dave et al[3] in 1995 whilst the name "interprosthetic" was introduced by Kenny and Quinlan[4] in 1998 to describe a femoral shaft fracture between a total hip arthroplasty (THA) and a total knee arthroplasty (TKA).

In scientific literature, the incidence of interprosthetic or interimplant femoral fracture ranges between 1.25% to 8.8%.[2]

These fractures are particularly difficult to treat because they occur in elderly with several comorbidities. For this reason, the interprosthetic femoral fracture represents a unique challenge for the surgeon and requires a detailed multidisciplinary management strategy, involving both fracture fixation technique and often complex revision ability. The management issues raised by an interprosthetic fracture between ipsilateral hip and knee devices are yet more extensive.[2]

According to the standard procedures in these injuries with stable components are usually treated by internal fixation without bone grafting. For fixation, it was exclusively used internal fixation with different locking plates with cerclage, cables and/or interfragmentary screws, and stabilization the long locking plate overlapping any stem with a minimum of four to five holes or at least two cortical diameters. In the prosthesis area, a combination of cables, unicortical locking screws, and/or a locking attachment plate was used.[2] Other standard procedures to treat these injuries with loose hip stems were treated using monobloc or modular revision stems.[5] This type of treatment included removal of the loose stem, including cement extraction in cases of cemented stems, open reduction and fixation of the fractures with cables or wires, and reimplantation during one-stage exchange. Distal femoral replacement was performed for these injuries with loose knee prostheses.[2]

Other authors used Tumoral Prosthesis for all femoral to treat these injuries where there is bone loosening or both loose prosthesis or higher grade of osteoporosis.[2]

The aim of the paper is to target the focus on the bone strut grafting to avoid the metal hardware failure and to achieve the bone healing in these injuries.

MATERIALS AND METHODS

From January 2013 to December 2019, before the COVID-19 pandemic had begun,[6,7] at three Level I Trauma Center we enrolled 11 interprosthetic or interimplant femoral shaft fractures around the orthopaedic devices.

Inclusion Criteria were: Interimplants or Interprosthesic, stable hip and knee device, higher grade osteoporosis

Exclusion criteria included: fractures caused by haematological or oncological pathologies, the age of less than 75, prosthesis with loose components recurrent IFF, treatment of nonunion following the initial interimplants or interprothesic fracture.

All fractures were classified according the Pires et al Classification.[8] All anaesthesiologic risk of patients were classified according the American Society of Anaesthesiologists (ASA) classification[9]

At the admission to the department, we asked all patients to provide us with axial bone densitometry data (DEXA).[10] To understand and study the capacity of bone healing in patients, we used the Non-Union Scoring System (NUSS).[11]

All patients were informed clearly and comprehensively of the treatment and other possible surgical and conservative alternatives. Patients were treated according to the ethical standards of the Helsinki Declaration and were invited to read, understand and sign the informed consent form.

The chosen criteria to evaluate the cases during the clinical and radiological follow-up were: the survival and complication rates after surgery; the objective quality of life measured by Activities of Daily Living Score (ADL)[12]; The bone healing was measured by RADIOGRAPHIC UNION SCORE (RUS)[13] and the bone fracture alignment by X-rays; and postoperative complications. The clinical and radiographical follow up endpoints after the surgery were: 1 months; 3 months; 6 months; 12 months and after the 12 months one check every year. Monthly telephone interview has done after the surgery to monitor the survival.

ETHICAL CONSIDERATIONS

All procedures performed in the current study were in accordance with the 1964 Helsinki declaration and its later amendments. As this retrospective analysis consists of anonymized clinical routine data. Informed consent was obtained from all individual participants included in the study. Orthopedic unit council provided authorization for this study.

SURGICAL TECHNIQUE

In all cases, the surgeon performed the surgery in a supine position using the direct modified lateral approach to the femoral shaft. All patients underwent to spinal anaesthesia, the antibiotic protocol was 2 gr of Cefamezin 30 minutes before the surgery, 1 gr 3 hours after the surgery and after 6 hours 1 gr of Cefamezin each 6 hours for a day. After exposing the fracture site, it was prepared and the allogeneic bone splint was prepared on a separate table after performing swabs (swab dye tests) for the risk of infection. The modelling of the cortical strut always measured two and a half times the extent of the fracture site and applied on the medial side. The margins of the fracture site were mod-

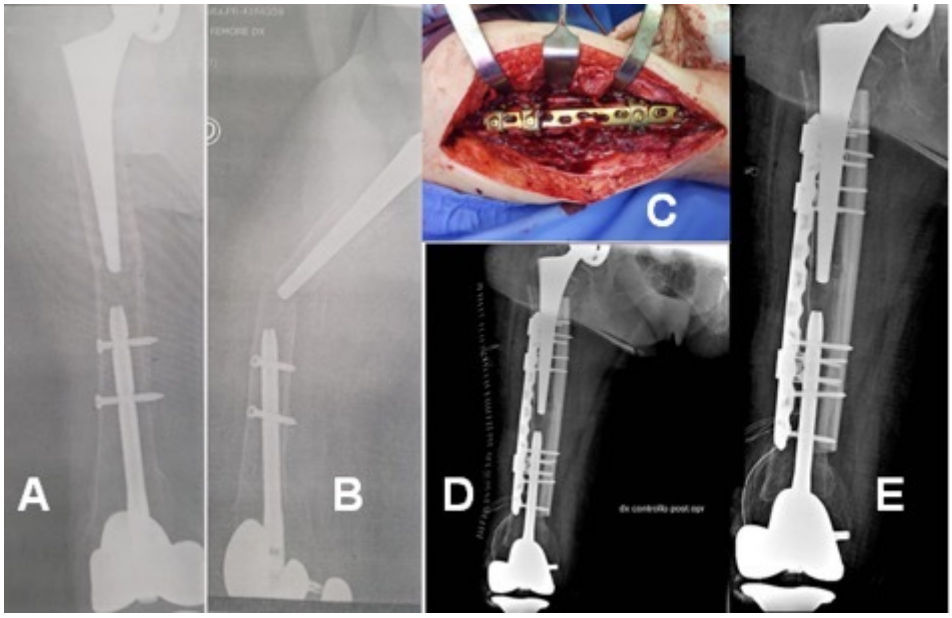

Figure 1. For the description of the case see Case 1 in Table 1.

X–rays showed a transverse femoral(A, B) shaft fracture between a THA stem and the tip of retrograde locked femoral nail implanted for previous supracondylar TKR periprosthetic fracture. The image C showed the intraoperative fixation of the peri implant fracture. Post operative X-Rays(D) Showed the fracture fixation with bone metal and screws plate and medial femoral strut allograft from the little trochanter to medial femoral condyle. The X –ray after 6 months (E) reported the bone strut allograft modeling.

elled in such a way to create a wide surface for a compression osteosynthesis. The hardware for the osteosynthesis used in all cases was an anatomically pre-contoured low-profile plates LCP® (Synthes™, Oberdorf, Switzerland). At least two compression cortical screws distal and two proximal were also applied to stabilize the strut bone, placed to reinforce the medial wall of the diaphysis and proximal and distal metaphysis. Furthermore, the free space between the strut and bone was filled with allograft morselized bone and bone paste. Finally, the subcutaneous and cutaneous soft tissues were sutured (Fig.1 and Fig.2).

STATISTICAL ANALYSIS

Descriptive statistics were used to summarize the characteristics of the study group, including means and standard deviations of all continuous variables. The t-test was used to compare continuous outcomes. The exact test was used to compare Categorical variables. The statistical significance was defined as $p<0.05$. The Pearson correlation coefficient (r) was used to compare the predictive score of outcomes and quality of life. Mean ages (and their standard deviations) of the patients were rounded at the closest year. The predictive score of outcomes and quality of life and their standard deviations were approximated at the first decimal while at the second decimal was approximated Pearson correlation coefficient (r). The reliability and validity of the correlation between osteosynthesis and bone healing were determined by Cohen's kappa(k). Statistical analyses were performed with SPSS v.15.0 (SPSS Inc., an IBM Company, Chicago, IL, USA).

RESULTS

The average Cortical thickness of femoral shaft was 4.03 (± 1.21; 2.87-6.03) millimeters.

The average point of the NUSS was 58.92(±16.92; range 45-70). The average survival months of the population after surgery was 10.09 (±4.01; range 3-17) (Table 1).

The x-ray reduction after the surgery were: anatomic in 5 cases as good in 5 cases and sufficient in 1 case (Table 1).

After surgery, the average follow up was 9.73 (±3.98; range 3-16) in months while the average death was 10.73 (±3.98; range 3-16) (Table 1).

The average activity daily life (ADL) of the population before the surgery was 2.91(±0.07; range 2-4) while average ADL the population after the surgery was 1.45(±1.44; range 0-3), $p<0-05$ for the ADL before surgery. The X-Rays Reduction after the surgery was anatomic in 6 cases($p<0.05$), 4 good and only 1 sufficient (Table 1). The PS's X-rays Bone healing measured by RUS occurred in cases on average of 96.3 (±24.2; range 62 -142) days after surgery. The Average Correlation between Osteosynthesis and Bone Healing at the moment of X-Rays Callus were correlated with osteosynthesis were k=0.84 (±0.12; range 0.73-1).

DISCUSSION

In 2014 there was a great interest in the paper by Solarino et al.[2] wrote about the controversial treatment for the interprosthetic femoral fracture in this era. Nowadays the orthopaedic surgeons have a new challenge to treat the interimplant fractures.[14] The incidence of elective arthroplasty and those treated with fracture implants after lower extremity fractures will continue to increase as well.[14] Although fixation strategies exist for periprosthetic hip and

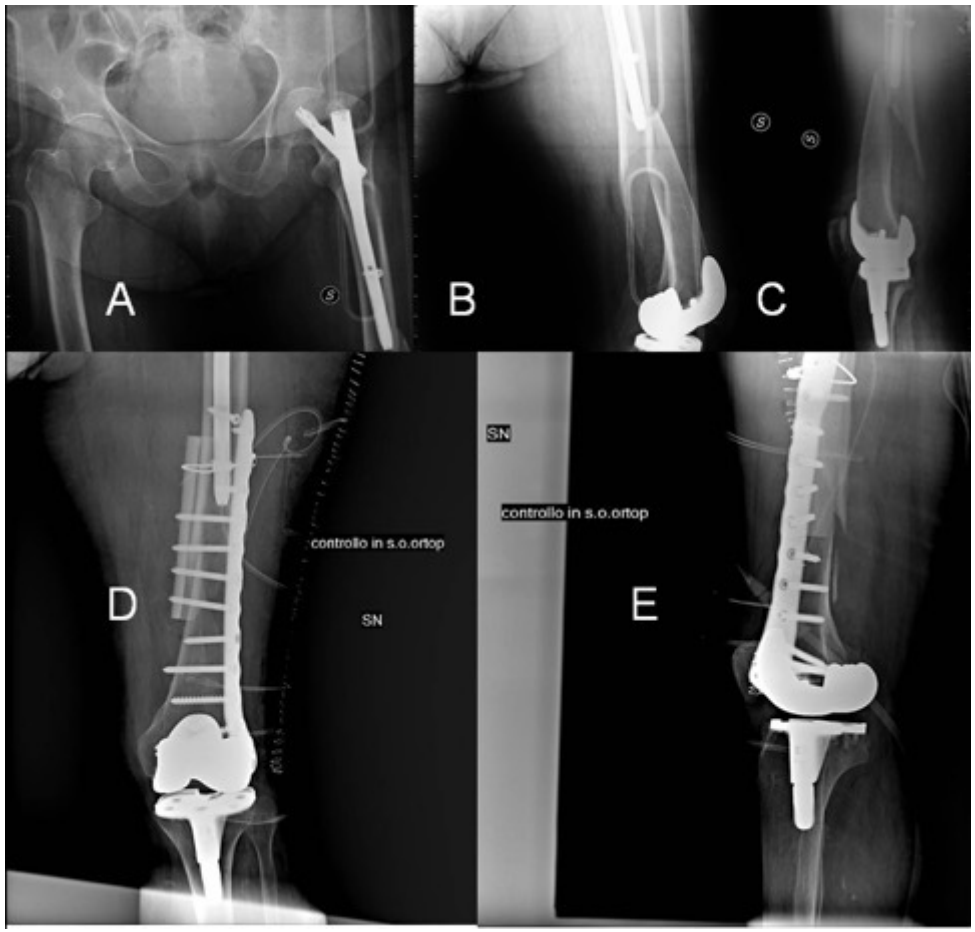

Figure 2. For the description of the case see Case 4 in table 1.

X–rays showed a spiroid femoral (A, B and C) shaft fracture between a nail (PFNA) of 24 cm length and TKR. Post operative X-Rays (D and E) Showed the fracture fixation with bone metal and screws plate over the nail's tip and medial femoral strut allograft.

Table 1. Characteristics of Subjects Undergoing to Interprosthetic or Interimplants surgery fixation with ORIF and medial strut allograft.

Patient	Sex	Age (yrs)	Side	Follow-up (mo)	Comorbidity	Arthroplasty	Fracture pattern	Fractures Classification[5]	Anesthesiology Risk According ASA	Fracture fixation	X-Rays Reduction	Complications	Prevous Trauma Activities of Daily Living Score	Post Trauma Activities of Daily Living Score
1([Fig.1](100802))	F	85	R	16	Diabetes Ischaemic heart disease Previous fragility fracture Osteoarthritis Hypothyroidism	THR 10 years ago TKR 11 years ago 3 year ago supracondylar fracture treat with locked retrograde nail.	Interimplants	IIIB	IV	ORIF LCP® Periproshetic System Plate + Screws With Medial Strut Allograft	Anatomic	Heart attack Death at 17th month after surgery	3/6	2/6
2	F	78	L	12	Rheumatoid arthritis Osteoporosis Heart disease COPD	THR 8 years ago TKR 12 years ago	Interprosthetic	IIA	III	ORIF LCP® Periproshetic System Plate + Screws With Medial Strut Allograft	Good	Chest Infection Death at 13th month after surgery	3/6	3/6
3	F	82	L	14	Diabetes Ischaemic heart disease Previous fragility fracture	THR 14 years ago TKR 10 years ago	Interprosthetic	IA	III	ORIF LCP® Periproshetic System Plate + Screws With Medial Strut Allograft	Good	deep venous thrombosis Death at 14th month after surgery	3/6	3/6
4([Fig.2](100803))	F	87	L	6	Previous fragility fracture Diabetes Ischaemic heart disease Neprhopaty Osteoarthritis Hypothyroidism Severe COPD	Trochanteric Nail(PFNA) 8 years ago TKR 18 years ago	Interimplants	IIIB	IV	LCP® Periproshetic System Plate + Screws+ proximal metal cable cerclage With Medial Strut Allograft	Good	Urinary Tract Infection Death at 7th month after surgery	2/6	0/6
5	F	81	L	12	Diabetes Ischaemic heart disease Previous fragility fracture	THR 12 years ago TKR 15 years ago	Interprosthetic	IIA	III	ORIF LCP® Periproshetic System Plate + Screws With Medial Strut Allograft	Anatomic	Death at 12th month after surgery	4/6	3/6
6	F	79	L	3	Previous fragility fracture Diabetes Ischaemic heart disease Neprhopaty Osteoarthritis Hypothyroidism Severe COPD	THR 20 years ago TKR 10 Years ago	Interprosthetic	IIIB	IV	ORIF LCP® Periproshetic System Plate + Screws With Medial Strut Allograft	Good	Death at 3rd month after surgery	3/6	0/6
7	M	86	L	5	Diabetes	Trochanteric	Interprosthetic	IIA	III	ORIF LCP®	Anatomic	Death at 6th	2/6	0/6

Patient	Sex	Age (yrs)	Side	Follow-up (mo)	Comorbidity	Arthroplasty	Fracture pattern	Fractures Classification[5]	Anesthesiology Risk According ASA	Fracture fixation	X-Rays Reduction	Complications	Prevous Trauma Activities of Daily Living Score	Post Trauma Activities of Daily Living Score
					Ischaemic heart disease Previous fragility fracture	Nail(PFNA) 8 years ago TKR 9 years ago				Periprosthetic System Plate + Screws With Medial Strut Allograft		month after surgery		
8	M	87	R	8	Rheumatoid arthritis Osteoporosis Heart disease COPD	THR 18 years ago TKR 15 years ago		IIIB	III	ORIF LCP® Periprosthetic System Plate + Screws With Medial Strut Allograft	Anatomic	Death at 8th month after surgery	3/6	3/6
9	F	85	L	9	Previous fragility fracture Diabetes Ischaemic heart disease Neprhopaty Osteoarthritis Hypothyroidism Severe COPD	Trochanteric Nail(PFNA) 8 years ago TKR 15 years ago		IA	IV	ORIF LCP® Periprosthetic System Plate + Screws With Medial Strut Allograft	Good	Death at 9th month after surgery	4/6	0/6
10	F	94	R	10	Rheumatoid arthritis Osteoporosis Heart disease COPD	THR 20 years ago TKR 14 years ago PREVIOUS THR REVISION		IIIB	III	ORIF LCP® Periprosthetic System Plate + Screws With Medial Strut Allograft	Sufficient	Death at 10th month after surgery	3/6	2/6
11	F	92	L	12	Rheumatoid arthritis Osteoporosis Heart disease COPD	THR 10 years ago TKR 11 years ago 3 year ago supracondylar fracture treat with locked retrograde nail.		IIIB	III	ORIF LCP® Periprosthetic System Plate + Screws With Medial Strut Allograft	Anatomic	Death at 12th month after surgery	2/6	0/6

Abbreviations: F, female; L, Left; M, male; R, Right; THR, Total Hip Replacement; TKR, Total Knee Replacement; LCP, Low Contact Plate.

knee fractures, there is no standard of care regarding the more complex interprosthetic and interimplant fractures.[14] The variety of methods and implants used, and their combinations implies that no "gold standard" exists. The topic is now raising with great interest in the scientific community and clinical practice with fervid literature focusing on the topic. In Solarino et al[2] the review it is highlighted that the average patient who suffers from these injuries is fragile very old and suffering from diseases of the bone metabolism, most of the time lured or walking very little and suffering from numerous comorbidities. If we analyse the problems to obtain a correct osteosynthesis of these fractures we find it necessary to implant plaques and screws in malacic bone with a poor seal, femoral canals occupied by stems, nails or cement or types of fractures peri adjacent to both implants (Fig.1). The use of metal cable cerclage should be limited to only one level as their higher rate of ischemia can collapse the medial wall of the femur leading to failure of the osteosynthesis.[2,14] Indeed, Peters reported in his 2003 study how important it is to guarantee greater resistance to the medial femoral wall.[15] According to our modern experience, lateral plate and medial strut allograft is the best choice to treat the perimplants failure[16] and periprosthetic femoral fracture.[16–18] The cortical strut only allografts confer stability to the fracture site, and they can incorporate and ultimately increase the femoral bone stock.[19] They also "lengthen" the working length of the screws. In scientific literature, only one case in elderly patients has used bone strut allograft for the treatment of inter-prosthetic fracture.[20] In our cases series of 11 patients with limited Activities of Daily Living (Table.1), we treated all ORIF and medial graft patients because the main complication leading to re-operations and morbidity or mortality is the non-union or delayed union.[21] A recent paper reported the importance of bone strut allografting in the treatment of periprosthetic femoral nonunions.[22] The grafting with cortical strut only offers better stability of the construct but from the other side an additional tissue dissection (Fig.2). Wide dissection could result in decreased periosteal blood supply to the fracture site and this can be a reason for of non-union, which can lead to new implant failure and high infection rates after surgical treatment. For this reason, it should be judiciously utilized.[23] There is a dynamic change in allograft biomechanics during the incorporation and re-modelling process (Fig.1). Our studies have suggested that cortical struts predictably unite, remodel, mature and not breakage's risk.[16–19] To obtain the maximum stability of the metal-biological construct the osteosynthesis with screws should always be used (Figure 1 and Figure 2) because the use of metal cerclage cables can lead to implant failures and subsequent revisions.[22,24] Other authors suggested Total femur replacements or a megaprosthesis are typically reserved for patients with limited bone stock and loose implants or in the situation of multiple failed fracture fixation or persistent fracture nonunion, revision to a megaprosthesis may provide a route to definitive treatment.[25–27]

CONCLUSION

According to us, the purpose of this surgery is to limit comorbidities and early mortality not to improve optimal restoration of lower limb function. To conclude the data currently available, however, do not yet allow for definitive conclusions about the appropriate treatment and the best choice for Interprosthetic or Interimplants femoral fractures around stable implants regarding complications and clinical outcomes but ORIF with bone allografting is the preferred treatment option for this type of injury to improve osteosynthesis-related outcomes.

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AUTHORS' CONTRIBUTION

G.P., F.L., M.R., L.M, D.D.M, A.S., E.D.C., and G.R. contributed to the design and implementation of the research, to the analysis of the results and to the writing of the manuscript.

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CONFLICT OF INTEREST STATEMENT

All authors disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations and grants or other funding.

HUMAN AND ANIMAL RIGHT

For this type of study is not required any statement relating to studies on humans and animals. All patients gave the informed consent prior being included into the study. All procedures involving human participants were in accordance with the 1964 Helsinki declaration and its later amendments.

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