Should megaprosthesis implants be a viable option in elderly patients after distal femur and periprosthetic distal femur fractures?—a retrospective cohort study

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Background: Distal femur fractures (DFF) and periprosthetic distal femur fractures (PDFF) in elderly patients are challenging to manage, often requiring the use of distal femur replacement (DFR) implants to manage severe bone loss and comminution. The study's main purpose was to analyze outcomes and complications of DFR implant after DFF or PDFF at our institution to understand the feasibility and reliability of this treatment considering a review of the current literature.

Methods: Fourteen consecutive patients undergoing total knee replacement with megaprosthesis implant from January 1st, 2017 to January 1st, 2021, at our institution were retrospectively analyzed. Inclusion criteria were age \geq 65 years and DFF or PDFF after primary total knee arthroplasties (TKA) implantation. Patient-reported outcome measures (PROMs) such as Knee Society Score (KSS) and Oxford Knee Score (OKS) were analyzed, as well as radiographic pre- and post-operative imaging. Complications were recorded from the early postoperative period to the last follow-up.

Results: Nine patients were diagnosed with PDFF and five with DFF. At a mean follow-up of 30.7 months (range, 12 to 69 months), the mean KSS knee score was 79.5 ± 11.2 ; the mean KSS function score was 69.0 ± 17.9 . The mean OKS was 31.6 ± 8.9 . The mean age at intervention was 82.1 ± 7.6 years. Two delayed wound closures and one chronic prosthetic joint infection (PJI) were observed. No death was observed at the last follow-up.

Conclusions: Megaprosthesis implants could be a suitable option in elderly, arthritic patients diagnosed with complicated DFFs and PDFFs, allowing joint function preservation and a rapid return to daily activities. DFR remains an intervention burdened by devastating complications that must be considered in the treatment choice.

Keywords: Megaprosthesis; elderly; distal femur replacement (DFR); periprosthetic femur fractures; distal femur fractures (DFF)

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Introduction

Distal femur fractures (DFFs) account for 3-6% of adult femoral fractures and 0.3% of overall fractures. DFFs are characterized by a bimodal distribution with a higher incidence among young men following high-energy injuries and older women after low-energy accidents. Risk factors such as osteoporosis, obesity, and neurologic disorders are common in elderly patients (1-4). Periprosthetic distal femur fractures (PDFFs) represent a consistent part of DFFs and are expected to grow dramatically in the following years due to the rising number of primary total knee arthroplasties (TKA) and the aging population (1). PDFFs are the most frequent fracture around knee prosthesis, with a reported incidence between 0.3-2.5% of primary TKAs, followed by tibial and patellar periprosthetic fractures (1,2). Older women are more typically involved in these fractures, and several risk factors, such as osteoporosis, obesity, rheumatoid arthritis, chronic steroid use, diabetes mellitus, and neurologic disorders, have been described (1-3). Surgical-related risk factors were also reported, including anterior femoral notching, component malalignment, and rotationally constrained implants (5,6).

The primary treatment for DFFs and PDFFs is open reduction and internal fixation (ORIF) with a locking plate or retrograde intramedullary nailing (RIMN) with different indications (7,8). RIMN provides a less invasive

Highlight box

Key findings

• Megaprosthesis may be a reliable treatment in elderly patients with distal femur fractures or periprosthetic distal femur fractures with good patient-reported outcomes at the minimum follow-up of 12 months.

What is known and what is new?

 The treatment of distal femur fractures and periprosthetic distal femur fractures in elderly patients represents a complex challenge for knee surgeons. Not all fractures may be treated with retrograde intramedullary nailing or plate because of comminution, poor bone quality or implant loosening. This study aims to analyze the clinical outcomes and complications of patients undergoing megaprosthesis replacement in the management of these fractures.

What is the implication, and what should change now?

• Megaprosthesis implants could provide a rapid return to daily activities with immediate full weight-bearing, range of movement recovery, and joint function preservation in elderly patients. However, complications could be challenging to manage.

surgical procedure, while ORIF improves fixation in osteoporotic bone (9,10). In contrast, RIMN and ORIF are not always feasible: RIMN is not suitable in comminuted articular fractures and closed box prosthetic components configurations, while both RIMN and ORIF are not available in cases of severe bone loss, poor bone quality, or periprosthetic fractures with femoral component loosening (9.11.12). Moreover, ORIF and RIMN in treating DFFs and PDFFs can lead to long-lasting, technically challenging surgeries and long-term postoperative recovery with prolonged bed rest and no weight-bearing (8). Due to these limitations, knee prosthetic replacement with distal femur replacement (DFR) implant to manage bone loss could be a viable solution for some DFFs and PDFFs, providing a rapid return to daily activities with immediate full weightbearing, full range of motion (ROM), and joint function preservation (11,13,14).

The appropriate treatment, especially in elderly patients with symptomatic knee osteoarthritis, multi-fragmentary fractures, poor bone quality, or femoral prosthetic loosening, is still under debate (7-15). This study aims to analyze patient-reported outcomes measures (PROMs) and intra- and postoperative complications of elderly patients undergoing megaprosthesis implants for DFFs or PDFFs. We present this article in accordance with the STROBE reporting checklist (available at https://aoj.amegroups.com/article/view/10.21037/aoj-23-21/rc).

Methods

A retrospective cohort study was carried out on a consecutive series of 20 patients treated with DFR at the Orthopaedic and Traumatology Department at Orthopaedic and Trauma Center (CTO) Hospital of Turin between January 1st, 2017 and January 1st, 2021.

The Institutional Review Board (IRB) of the CTO Hospital of Turin defined this study as exempt from IRB approval (retrospective study on a well-established surgical procedure) and conducted in accordance with the Declaration of Helsinki (as revised in 2013). All patients were informed about the study and consented to participate.

Inclusion and exclusion criteria

Inclusion criteria were age over 65 years, diagnosis of DFF or PDFF treated with DFR implant, and a minimum of 12-month follow-up (FU) after surgery.

Study exclusion criteria were previous prosthetic

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Figure 1 Patients' inclusion procedure. Two patients were lost at follow-up; four patients were excluded due to previous ORIF or RIMN failure. Finally, 14 patients were included in the study. DFR, distal femur replacement; ORIF, open reduction internal fixation; RIMN, retrograde intramedullary nailing.

infection, aseptic tibial or femoral component loosening, failure of previous distal femur treatment with ORIF or RIMN, polytrauma patients, and patients diagnosed with the oncologic disease. Two different authors (D'Antonio, F Bosco) evaluated each eligible case independently. A third author (F Giustra) was involved in solving any doubts.

Twenty patients underwent DFR during the study period. Two patients were lost at the final FU; three were excluded because of previous ORIF failure, and one was due to RIMN failure. Fourteen consecutive patients were thus selected in the analysis of this study according to the inclusion and exclusion criteria. The patients' inclusion procedure is summarized in *Figure 1*.

Preoperative assessment

At the time of the study, the indication for DFR after DFF or PDFF was based on clinical and radiographic parameters. Elderly patients with DFF and a history of knee osteoarthritis, multi-fragmentary fracture, poor bone quality, or PDFF with severe bone loss or femoral component loosening were eligible for DFR surgery. The patient's fractures were evaluated with standard anteroposterior (AP) and lateral X-rays and a targeted computed tomography (CT) scan of the involved body segment. Moreover, three-dimensional (3D) CT scans are routinely developed at our institution. Hence, each patient received personalized preoperative planning based on CT scans to correctly determine the resection height, megaprosthesis design, and modular characteristics. The Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) classification was applied to analyze DFFs. Rorabeck and Taylor's classification, Su's, and Kim's classification were all used to analyze PDFFs (16-18). Rorabeck and Taylor described three types of periprosthetic distal femoral fractures that require different treatments according to component stability, fracture displacement, and comminution (16). Su et al. described an operative classification for PDFF according to the height of the fracture relative to the femoral component (17). Kim's classification was recently developed to analyze bone stock quality, prosthesis fixation, and reducibility of the fracture (18). Patients with DFF were also assessed for osteoarthritis history and according to the Kellgren-Lawrence (KL) scale before surgery.

Surgical technique

Careful preoperative planning is performed before the surgery based on CT scans, AP, and lateral X-rays. It is crucial to properly establish the transection height as distal as possible above the fracture. The surgical access is a median skin incision and a medial parapatellar arthrotomy obtaining extensive exposure, sometimes requiring a tibial tuberosity osteotomy to preserve the extensor mechanism from iatrogenic injuries. After identifying the fracture, if a femoral component is present, it is removed in combination or separately with the fractured area, and subsequently, the tibial component is removed. Tibial preparation is then performed according to the surgical technique. Transection of the distal femur is performed after marking the correct height on the distal femur. The new cemented prosthesis is implanted following the specific surgical procedure. Three different implant types were used for DFR during the study period: the Zimmer Orthopedic Salvage System (OSS[®]), the Zimmer Segmental System (ZSS[®]), or the Megasystem-C[®] Link, depending on hospital availability. Pre- and postoperative images of DFF and PDFF treatment with megaprosthesis implant are reported in Figures 2,3.

Postoperative program

After surgery, early knee mobilization exercises for full ROM recovery, quadriceps strengthening, and gait rehabilitation were performed from the first postoperative



Figure 2 Pre- and post-operative imaging of DFF demonstrating an articular, multi-fragmentary DFF in an arthritic patient (AO/OTA 33C3, KL IV). A comminuted fracture involving femur's condyles is shown. The fracture was treated with OSS (Zimmer) megaprosthesis replacement. (A) Preoperative CT scan. (B) Preoperative 3D CT scan. (C) Postoperative AP X-ray. (D) Postoperative lateral X-ray. DFF, distal femur fracture; AO, Arbeitsgemeinschaft für Osteosynthesefragen; OTA, Orthopaedic Trauma Association; KL, Kellgren-Lawrence; 3D, three-dimensional; AP, anteroposterior; OSS, Orthopedic Salvage System; CT, computed tomography.

day under the supervision of a physiotherapist. Early full weight-bearing with crutches or walkers was allowed for 4 weeks. At the first-month clinical and radiographic FU, progressive removal of walking aids was permitted.

Data extraction

Data were obtained from departmental databases, FU examinations, and telephone interviews. All the patients involved in the study were investigated for the following demographic characteristics and clinical parameters: trauma energy, age at the time of surgery, gender, body mass index (BMI) and comorbidities, operative time, length of hospital stay (LOS), time to total weight bearing. Blood loss was assessed by evaluating the need for transfusions; intra and postoperative complications and death after surgery were also reported. Patients were examined one, three, and six months after surgery and followed up with clinical and radiographic examinations every six months for a minimum of 12 months. At the final FU, postoperative ROM, the Knee Society Score (KSS) knee score, KSS function score, and the Oxford Knee Score (OKS) were assessed for each patient (19,20).

Statistical analysis

Statistical analysis was performed using the Statistical Software MedCalc (MedCalc Software, Ostend, Belgium). All data were analyzed with descriptive statistics developing mean and median values and standard deviation for continuous variables. Absolute frequencies and percentages were calculated for categorical variables. Microsoft Excel spreadsheets (Version 2019, Microsoft, Redmond, WA, USA) were used to collect data.

Results

Demographic data

The main demographic characteristics and comorbidities are shown in *Table 1*. Thirteen women and one man were included in the study. Five patients were diagnosed with DFF, and nine were diagnosed with PDFF. The mean age



Figure 3 Pre- and post-operative imaging of comminuted unstable PDFF involving the femur distal to the prosthetic component (Rorabeck-Taylor type 3; Su type 3; Kim type 3) treated with Megasystem-C[®] Link megaprosthesis replacement. (A) Preoperative lateral X-ray. (B) Preoperative anteroposterior X-ray. (C) Postoperative lateral X-ray. (D) Postoperative anteroposterior X-rays. PDFF, periprosthetic distal femur fracture.

Cases	Age (years)	Sex	BMI (kg/m ²)	Comorbidities
1	71	F	43.0	Hypertension, allergic asthma
2	84	F	43.0	MADD, UTI, spinal stenosis
3	89	F	21.5	Hypertension
4	72	F	30.9	*
5	87	F	23.0	MADD, hypertension
6	72	F	31.3	Hypertension, multiple sclerosis
7	84	F	20.8	*
8	93	F	26.8	Chronic gastritis, venous insufficiency, osteoporosis
9	84	F	23.4	Dyslipidemia
10	85	М	26.4	Diabetes mellitus, hypertension, pacemaker wearer
11	88	F	22.9	Hypertension, Arrhythmia
12	75	F	30.5	Hypertension, PHR, bilateral glaucoma
13	75	F	23.3	Bilateral TKA, hypertension, MADD
14	91	F	33.9	MADD, hypertension, COPD, breast cancer, NHL, left THA

Table 1 Main demographic characteristics of patients collected

*, no comorbidities. F, female; M, male; BMI, body mass index; MADD, mixed anxiety depressive disorder; UTI, urinary tract infections; PHR, partial hip replacement; TKA, total knee arthroplasty; COPD, chronic obstructive pulmonary disease; NHL, non-Hodgkin lymphoma; THA, total hip arthroplasty.

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Table 2 Types of fractures	, fracture classification.	clinical parameters	, implants characteristics
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		Fracture classification				-	Surgical			Implant characteristics		
Cases	lype of fracture	Kellgren- Lawrence	AO/OTA	Rorabeck and Taylor	Su	Kim	duration (minutes)	Length of stay (days)	Transfusions	Femur	Tibia	
1	PDFF	NA	NA	3	3	3	195	20	Х	ZSS (Zimmer)	RHK (Zimmer)	
2	PDFF	NA	NA	2	3	2	240	63	-	ZSS (Zimmer)	RHK (Zimmer)	
3	PDFF	NA	NA	3	2	2	135	10	Х	ZSS (Zimmer)	RHK (Zimmer)	
4	DFF	Ш	33C2	NA	NA	NA	155	9	-	Megasystem-C (Link)	Megasystem-C (Link)	
5	PDFF	NA	NA	3	3	3	145	14	-	OSS (Zimmer)	OSS (Zimmer)	
6	PDFF	NA	NA	3	3	3	160	14	-	Megasystem-C (Link)	Megasystem-C (Link)	
7	PDFF	NA	NA	3	3	3	155	17	-	OSS (Zimmer)	OSS (Zimmer)	
8	PDFF	NA	NA	3	2	3	120	15	-	OSS (Zimmer)	OSS (Zimmer)	
9	DFF	Ш	33C2	NA	NA	NA	140	12	-	OSS (Zimmer)	OSS (Zimmer)	
10	PDFF	NA	NA	3	3	3	120	14	-	ZSS (Zimmer)	RHK (Zimmer)	
11	DFF	IV	33C3	NA	NA	NA	205	25	х	OSS (Zimmer)	OSS (Zimmer)	
12	DFF	Ш	33C3	NA	NA	NA	140	20	х	OSS (Zimmer)	OSS (Zimmer)	
13	PDFF	NA	NA	3	3	3	140	17	-	OSS (Zimmer)	OSS (Zimmer)	
14	DFF	Ш	33C3	NA	NA	NA	140	29	-	OSS (Zimmer)	OSS (Zimmer)	

AO, Arbeitsgemeinschaft für Osteosynthesefragen; OTA, Orthopaedic Trauma Association; PDFF, periprosthetic distal femur fracture; NA, not applicable; ZSS, Zimmer Segmental System; RHK, rotating hinge knee; DFF, distal femur fracture; OSS, Orthopedic Salvage System; X, transfusion performed; –, no transfusion.

at intervention was 82.1 ± 7.6 years. The median age value at intervention was 84 (range, 71–93) years. The mean BMI was 28.6 ± 7.3 . The median value of BMI was 26.6 (range, 20.8–43.0). The mean FU period was 30.7 ± 18.1 months. The median value of FU was 26.5 (range, 69.0-12.0) months.

Fractures' characteristics

The fractures' characteristics and classification are described in *Table 2*. The injury was related to low-energy trauma in all patients. Concerning the implant types, the choice was consequent to hospital availability. Only two patients with PDFF had previously undergone surgery at our institution; the other seven received primary TKA in a different hospital. The average time between the first implantation and DFR surgery was 7.2 ± 4.4 years.

Clinical data

The mean hospital stay was 19.9 ± 13.6 days. The median value of hospital stay was 16 (range, 9–63) days. Four patients received red blood cell (RBC) transfusions after surgery. All patients effectively underwent the previously described rehabilitation program and achieved full weight-bearing between the first and third postoperative month.

PROMs

All PROMs are reported in *Table 3*. At the final FU, the mean KSS knee score was 79.5 ± 11.2 ; the mean KSS function score was 69.0 ± 17.9 . The median value of the KSS knee was 82 (range, 58-94); the median value of the KSS function was 70 (range, 40-91). The mean OKS score was 31.6 ± 8.9 . The median value of the OKS score was 33.5 (range, 15-42). The mean ROM was $99.3^{\circ}\pm9.8^{\circ}$. The median value of ROM was 100° (range, $80^{\circ}-120^{\circ}$).

Complications

The reported complications are shown in Table 3. The

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Cases –		PROMs		Postoperative ROM	Complications	Follow-up duration
	KSS knee	KSS function	OKS	(degrees)	Complications	(months)
1	74	65	25	95	Anemia, prosthetic infection, implant loosening	69
2	64	45	16	95	Delayed wound healing	59
3	94	90	42	120	Anemia, delayed wound healing	49
4	90	85	36	105	-	38
5	89	90	40	105	-	37
6	87	80	39	100	-	35
7	85	80	41	95	-	29
8	92	91	38	100	-	24
9	85	75	35	105	-	19
10	73	65	31	90	-	18
11	76	60	30	110	Anemia	15
12	67	50	23	100	Anemia	14
13	79	50	32	90	-	12
14	58	40	15	80	-	12

PROMs, patient-reported outcome measures; KSS, Knee Society Score; OKS, Oxford Knee Score; ROM, range of motion; -, no complication.

overall complication rate was 35.7% (five patients), with a re-intervention rate of 21.4% (three patients) and implant removal of 7.1% (one patient). Two delayed wound healings requiring surgical wound debridement were recorded. One prosthetic joint infection (PJI) case with chronic osteomyelitis and implant mobilization was reported. There were no intraoperative fractures or extensor mechanism injuries. No peroneal nerve palsy was reported. No deaths were observed at the last FU.

Discussion

The main result of this study is that DFR after DFF or PDFF seems to be a suitable option in elderly patients with comminuted multi-fragmentary fractures, prosthetic implant loosening and lack of residual bone stock with good clinical outcomes and an early return to ambulation.

Regarding demographic characteristics, this study reveals a higher incidence of DFFs or PDFFs in older women with comorbidities such as osteoporosis, obesity, rheumatic disease, diabetes mellitus, and neurologic disorders, as described in the literature (21-25). The mean operative for DFR after DFF or PDFF reported in the literature varies widely. Jassim *et al.*, in their case series, described a mean operative time of 140 minutes (24), Matar *et al.* reported a mean operative time of 128 minutes (22), while Sukhontamarn *et al.* showed a mean operative time of 125 minutes (25). In this study, the mean operative time is slightly higher than reported in the literature; however, no major intraoperative complications were observed.

Blood loss is difficult to assess. Some studies report intraoperative blood loss, while others emphasize the need for transfusions as an indirect parameter of blood loss. Some studies report transfusion rates over 50% after DFR (26,27); others described minimized bleeding (24). Similarly, in this study, bleeding was relatively limited, with 4 of 14 patients transfused (28.6%) and no patients requiring intensive transfusion treatments after surgery.

Literature-reported LOS varies widely from 6 to 26 days (24,26-28). In this study, the reported LOS was 19.9 days ranging from 9 to 63 days. LOS was thus largely variable among patients undergoing DFR at our institution. This finding could be explained by the patients' complex

background, comorbidity, and invasive procedure, which resulted in variable and often long-lasting LOS.

The main advantage of DFR is the knee's early mobilization with free ROM and full weight-bearing from the first postoperative day, preserving the articular function and preventing the risk of prolonged bed rest (29). There is a wide range in the literature regarding PROMs after DFR: Angers-Goulet *et al.*, in their case series, reported a mean postoperative KSS knee score of 42 and KSS function score of 60, while Vertesich *et al.* found a mean postoperative KSS knee score of 60 and KSS function score of 20 (30,31). Vaishya *et al.* and Matar *et al.* reported mean postoperative KSS knee scores of 78 and 80, respectively (21,22). The mean KSS knee score and OKS score described in our study are within this range and in line with those reported by Meluzio *et al.* in their systematic review (23).

The literature reports several intraoperative and postoperative complications ranging from 7% to 36% (22,25). The most frequent one is periprosthetic joint infection (PJI) which may require deep debridement, mobile parts replacement, prolonged antibiotic therapy, and sometimes limb amputation; the second one is aseptic component loosening (21,25,30). Periprosthetic fractures, extensor mechanism injuries and patellar maltracking, peroneal nerve palsy, bleeding and delayed wound healing are also widely described as DFR-related complications (24).

In our study, only one patient had a PJI that led to limb amputation after several salvage procedures, such as deep debridement and prolonged antibiotic therapy. The other complications were two delayed wound healing requiring surgical debridement and four cases of anemia. No deaths were reported at the last FU, while the literature describes a high incidence of mortality (14,32). This finding could be partially explained by the study's relatively short FU period and the attention to the postoperative rehabilitation program.

Finally, it should be noted that ORIF and RIMN are often considered more conservative treatments than DFR. However, some studies comparing ORIF and RIMN show a slow postoperative recovery with no weightbearing permission and restricted knee ROM (33,34). Moreover, other studies comparing DFR and ORIF show no differences in mortality and complication rates (14,32) and comparable postoperative PROMs (11), thus suggesting DFR could be a viable option in DFF and PDFF in elderly patients.

This study has several strengths. First, the study findings align with those reported in the literature, thus

suggesting a certain reliability. Second, the results on PROMs and mortality provide some confidence concerning the feasibility of DFR after DFFs and PDFFs in elderly patients. Third, all the reported complications were successfully treated except one. This could be considered a good outcome in terms of complications management. Fourth, in our institution, patients diagnosed with PDFF were examined using three different classification systems, and each classification provides helpful information for decision-making.

This study also has several limitations. First, it is a retrospective study, therefore, has all the intrinsic limitations due to its design. Second, the small patients' number could influence the strength of the results. Third, the patients lost at FU could represent a selection bias. Fourth, different megaprosthesis implants were employed on the patients selected in the study: this could also be a bias concerning the results. Further studies with more patients and a longer FU are needed to fully understand the feasibility and reliability of DFR implants after DFFs or PDFF in terms of postoperative PROMs and complications, including mortality.

Conclusions

Megaprosthesis implant in DFFs and PDFFs seems feasible, especially in elderly patients with previous symptomatic knee osteoarthritis, poor bone quality, multifragmentary fractures, or patients with loosening of the femoral prosthetic component. DFR could ensure a rapid return to walking, preserving knee function and reducing complications due to prolonged bed rest. However, a high complication rate and a lack of limb salvage procedures are reported; therefore, careful patient selection should be performed.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The Institutional Review Board (IRB) of the CTO Hospital of Turin defined this study as exempt from IRB approval (retrospective study on a well-established surgical procedure) and conducted in accordance with the Declaration of Helsinki (as revised in 2013). All patients were informed about the study and consented to participate.

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