Reconstruction of Massive Segmental Distal Femoral Metaphyseal Bone Defects After Open Injury

A Study of 20 Patients Managed with Intercalary Gamma-Irradiated Structural Allografts and Autologous Cancellous Grafts

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Background: Our aim was to examine the outcome of gamma-irradiated intercalary structural allografts combined with autologous cancellous grafts in treating large metaphyseal bone defects of the distal femur following open injuries.

Methods: We prospectively included 20 consecutive patients with large metaphyseal bone defects of >4 cm located in the region of the distal femur following open injuries treated between 2010 and 2018, with a mean follow-up of 2 years (range, 2 to 10 years). Of these patients,18 were men and 2 were women. The mean age was 39 years (range, 22 to 72 years). The mean length of the bone defects was 10.1 cm (range, 5.5 to 14.5 cm), and all were in the metaphysis of the distal femur. The surgical technique included initial early debridement and external fixation followed by reconstruction of the bone defect using structural allograft combined with autologous cancellous bone graft harvested from the iliac crest and locking plate fixation. Definitive fixation was performed at an average period of 22.5 days (range, 3 to 84 days) after injury. Osseous union, rate of infection, complications, need for secondary procedures, and functional outcome using the Lower Extremity Functional Scale (LEFS) at the final follow-up were assessed.

Results: After excluding 1 patient who was lost to follow-up, 19 patients with complete follow-up were available for analysis. Of those, 13 patients (68%) achieved complete union at both ends of the allograft with host bone without any further intervention. Three patients (16%) developed aseptic nonunion of the proximal end of the allograft requiring 1 additional procedure each to achieve union. Four patients (21%) developed a deep surgical site infection. Of those, 1 elderly patient required above-the-knee amputation following uncontrolled diabetes and infection. A second patient required 2 additional procedures, and a third patient needed 4 additional procedures to achieve union. The fourth patient developed infection after achieving union, and the infection subsided after debridement and implant removal. The mean LEFS score for all 19 patients was 55 (range, 41 to 75).

Conclusions: Use of allograft was a reasonable single-stage alternative solution for massive distal femoral bone defects, which united without additional surgery in two-thirds of the patients and without limb-length discrepancy.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

P rimary bone loss in open injuries occurs either at the site of injury by ejection through an open wound or by removal of comminuted fragments devoid of soft-tissue attachment during debridement¹. Open injuries require thorough wound debridement and skeletal stabilization on day 1 for a successful salvage and a good outcome²⁻⁵. Bone gaps of ≤4 cm can be managed by either acute shortening or corticocancellous bone-grafting^{1,6,7}. Management of bone loss

of >4 cm is difficult and often requires multiple procedures for reconstruction of bone defects⁸. The problem of reconstruction in open distal femoral fractures with bone loss is compounded by an increased rate of infection⁹, more secondary procedures, and a high chance of nonunion^{9,10}. A short distal fragment, limited bone stock, and anterior soft-tissue injury are associated with a poor outcome for these fractures¹¹.

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RECONSTRUCTION OF MASSIVE SEGMENTAL DISTAL FEMORAL METAPHYSEAL BONE DEFECTS AFTER OPEN INJURY

Reliable reconstructive options available are free vascularized fibular graft and distraction osteogenesis¹². Also, the technique of long structural allografts combined with free fibular bone (the modified Capanna method) has been described to tackle massive bone loss, with good results reported for selected patients¹¹. Recently, the Masquelet technique has been described for treating bone defects, especially following infection in selected patients^{13,14}. Despite these multiple methods currently available, massive bone loss still poses a great challenge in reconstruction. Complications, such as infection, pain, joint stiffness, and nonunion, are frequently described, and failure of reconstructive procedures can lead to a poor outcome and ultimately the need for secondary amputation^{1,15}.

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The use of structural allografts in tumor surgery is well documented¹⁶⁻¹⁸. However, their role in the open injury setting has not yet been studied. There are few case reports on the usage of osteoarticular allografts for hemicondylar bone defects and osteochondral allografts for large articular cartilage defects¹⁹⁻²¹. Intercalary structural allografts may be an alternative solution for treating these complex metaphyseal distal femoral bone defects following open injuries. The advantages of such allografts include the provision of immediate structural support when placed in the bone defect, a reduction in donor-site morbidity, and the availability of large quantities in desired shapes and sizes. We studied a select group of 20 patients with large segmental bone defects of the distal femur following open injuries that were treated with use of intercalary gammairradiated structural allografts combined with iliac crest autografts. Our study objective was to examine the results of this technique, and our primary objectives were to determine the rate of union, rate of infection, and functional outcome.

Materials and Methods

Were women. The mean age was 39 years (range, 22 to 72 years).

Except for 1 patient (after 7 days of initial management elsewhere), all of the patients presented to us within 24 hours after injury. All were classified as having Gustilo type-III injuries (18 had type IIIA, and 2 had type IIIB), and the mean total Ganga Hospital Open Injury Score²² was 12.6 (range, 10 to 16). On arrival, the mean serum lactate tested in the laboratory was 4.1 mmol/L (range, 2.1 to 10.1 mmol/L), and all patients with these major injuries and substantial blood loss required adequate resuscitation. Hence, only surgical procedures for damage control were performed. Senior orthopaedic and plastic surgeons were involved in the initial debridement on day 1. All wounds were extended both proximally and distally. Skin edges

were debrided until bleeding margins were visualized. The bone segment exposed through the rent in the quadriceps muscle was thoroughly debrided. Loose cortical bone fragments without any soft-tissue attachment were excised. Intraarticular fractures of the femoral condyle were stabilized using cancellous screws. In the presence of bleeding margins, tension-free primary closure of skin with a suction drain was performed, and an external fixator was applied spanning the knee joint. Of the 20 patients, 18 had primary skin closure and 2 required soft-tissue coverage, which was performed within 72 hours. All of the primarily closed wounds were inspected in the ward once every 48 hours for any signs of infection. Systemic antibiotics were given for only 2 days after each surgical procedure, and no local antibiotic beads were used in any of the patients in the initial management.

Of the 20 patients, 8 underwent reconstruction with allograft after 2 weeks of external fixation. Polytrauma with poor general condition, associated injuries, and financial constraints of the family were the main reasons for delay in definitive reconstruction. All 8 patients underwent definitive fixation with a minimum interval of 14 days after external fixator removal. During this interval period between external fixator removal and open reduction and internal fixation, the limb alignment was maintained in a high above-the-knee posterior plaster cast. Definitive fixation was performed at an average period of 22.5 days (range, 3 to 84 days) after the injury. Osseous union and functional outcome were evaluated using the Lower Extremity Functional Scale (LEFS) at the time of the final follow-up²³. Infection, mechanical failures, and nonunion were assessed (Table I).

International Atomic Energy Agency standards and guidelines were followed for proper selection and screening of allograft donors^{24,25}. The source of the structural allografts was mainly from amputated limbs following vascular injuries around the knee that had presented late and were not candidates for vascular repair. Structural allografts are readily available in different sizes in the tissue bank located inside the hospital premises. Processing of allografts starts with obtaining informed consent from donors; harvesting and preparation of the distal femoral allografts, which includes the removal of external soft tissues, blood stains, and medullary canal contents; thorough washing initially with high-pressure jet lavage using sterile water followed by 70% ethyl alcohol therapy for 1 hour; sterilization by gamma irradiation (25 kGy); and storage at a temperature of -80° . Radiographic images of all structural allografts are stored in the PACS (picture archiving and communication system) so that the length can be easily measured and matched to the size of the defect. Prior to using the grafts clinically, thawing is done in the operating room using 1 g of vancomycin powder in 500 mL of normal saline solution.

Surgical Technique of Bone Defect Reconstruction

Preoperatively, the size of the defect was measured, and a distal femoral structural allograft of the same size was chosen. Through an anterolateral incision over the distal thigh, the bone defect was exposed, and the bed was prepared. Allografts were selected by matching the length of the allograft and the THE JOURNAL OF BONE & JOINT SURGERY 'JBJS.ORG VOLUME 104-A · NUMBER 2 · JANUARY 19, 2022 RECONSTRUCTION OF MASSIVE SEGMENTAL DISTAL FEMORAL METAPHYSEAL BONE DEFECTS AFTER OPEN INJURY

 TABLE I Demographic Data, Details of Injury and Treatment, and Results of Patients Who Had Complete Union Primarily without Secondary Intervention*

Case	Sex, Age <i>(yr)</i>	Gustilo Fracture Type	GHOIS	Wound Management	Serum Lactate on Arrival (m mol/L)	Bone Loss (cm)	Time to Definitive Fixation (days)	Duration of Follow-up (mo)	Time to Distal Host-Graft Union <i>(mo)</i>	Time to Proximal Host-Graft Union <i>(mo)</i>	Time to Allograft Incorporation (mo)	Knee Range of Motion	LEFS Score
1	M, 34	IIIA	10	PSS	3.6	10.2	76	120	5	12	32	0°-130°	65
2	M, 42	IIIA	12	PSS	3.4	8.6	5	96	5	8	14	0°-110°	75
3	M, 54	IIIA	14	PSS	5.2	12.4	3	72	7	9	16	0°-120°	58
4	F, 28	IIIB	14	Local flap	2.4	9.7	84	60	9	11	16	0°-130°	59
5	M, 22	IIIA	14	PSS	4.2	10.5	7	41	6	15	20	0°-45°	56
6	M, 38	IIIA	16	PSS	4.4	9.5	10	42	8	5	18	0°-110°	51
7	M, 42	IIIA	12	PSS	2.3	8.6	7	27	5	7	18	0°-120°	55
8	M, 27	IIIA	12	PSS	4.0	7.1	52	25	5	16	20	0°-45°	61
9	F, 34	IIIA	16	PSS	2.7	10	34	26	4	12	25	0°-130°	43
10	M, 36	IIIA	12	PSS	6.5	14.5	3	24	4	9	24	0°-125°	71
11	M, 40	IIIB	14	SSG	2.7	12.5	4	30	7	18	22	0°-135°	49
12	M, 35	IIIA	14	PSS	5.6	11.4	16	38	5	12	18	0°-10°	61

*All patients had a locking compression plate (LCP; Synthes), and no patient had a secondary procedure or shortening of a limb. GHOIS = Ganga Hospital Open Injury Score, PSS = primary skin suturing, SSG = split skin grafting, and LEFS = Lower Extremity Functional Scale.

size of the defect measured on a radiograph. The allograft was trimmed to the desired length and shape of the defect. The edges were trimmed such that there was good contact between the host bone and the allograft after fixation. The medullary canal of the allograft was reamed and packed with cancellous autografts harvested from the anterior aspect of the iliac crest. When required, the remnants of trimmed cancellous allograft from the structural graft were mixed with iliac crest graft to increase the volume. Allograft was placed in the bone defect, provisionally fixed with Kirschner wires both proximally and distally to the host bone, and then was stabilized with a distal femoral locking compression plate of adequate working length.

In all patients, a titanium distal femoral locking compression plate (LCP; Synthes) was the choice for osteosynthesis. An additional antegrade cephalomedullary nail was used in 1 patient with an ipsilateral subtrochanteric fracture. Cancellous grafts were placed at both ends of the allograft, which was in contact with native bone (Fig. 1).

Postoperatively, gradual knee joint mobilization by continuous passive motion (CPM) was initiated on the first postoperative day along with static quadriceps exercises. Nonweight-bearing walking with crutches was initiated at 48 hours after surgery, with gradual weight-bearing with crutches allowed after a 6-week period, and independent walking was allowed once the host-allograft junction united. The graft-host junction was considered united when the junction gap was no longer visible or was bridged by periosteal bone on both anteroposterior and lateral radiographs^{26,27}. Patients were advised to use a CPM machine at home regularly for 3 to 4 months to achieve a good range of motion. Patients were followed regularly every 6 weeks for the first 6 months and then every 3 months for the next year to monitor knee movement, assess for surgical site infections (SSIs), and look for bone healing and allograft incorporation.

Radiographic union was thought to have occurred when trabecular bridging across the graft-host junction was seen and the incorporated graft acquired the same density as the host bone. Clinical union was considered to have occurred when the graft-host junction was healed on radiographs, and there was physiologic weight-bearing without fracture or pain²⁷.

Source of Funding

No external source of funding was utilized for the study; support for manuscript preparation was received from the Ganga Orthopaedic Research and Education Foundation (GOREF).

Results

A fter excluding 1 patient who was lost to follow-up, 19 patients with complete follow-up were available for analysis. Of those, 13 patients (68%) achieved primary complete union at both ends of the allograft with host bone without any further intervention. The mean time to union of the distal graft and host junction was 5.83 months (range, 4 to 9 months), and time to union of the proximal end of the allograft and the host bone was 11.2 months (range, 5 to 18 months). The mean allograft incorporation time was 20.25 months (range, 14 to 32 months). The mean knee flexion achieved was 100.8° (range, 10° to 135°). None of the patients showed any limb-length discrepancy. The mean LEFS score was 58.6 (range, 43 to 75).

THE JOURNAL OF BONE & JOINT SURGERY • JBJS.ORG VOLUME 104-A • NUMBER 2 • JANUARY 19, 2022 RECONSTRUCTION OF MASSIVE SEGMENTAL DISTAL FEMORAL METAPHYSEAL BONE DEFECTS AFTER OPEN INJURY



Fig. 1



Three patients (16%) developed aseptic nonunion at the proximal end of the allograft-host junction requiring 1 additional procedure each to achieve union (Table II). One of them had plate removal and application of an Ilizarov frame along with bone-grafting and achieved union after an 8-month period with a stiff knee. Two of them required retrograde nailing, additional plating, and bone-grafting, and both achieved union after a 6-month period with knee range of motion of 110° and 90°.

A deep SSI or infected nonunion was identified in 4 patients (21%). One patient had a deep SSI after achieving complete union and required only implant removal, and the remaining 3 patients with infection required debridement and allograft removal. One elderly patient with a deep SSI at 3 months after the definitive procedure and uncontrolled diabetes required above-the-knee amputation after multiple procedures, including the Masquelet technique, had failed. The

second patient developed an early deep SSI requiring allograft removal, cement spacer application, and bone-grafting after a 6-week period. The third patient developed late infection and needed 4 additional procedures to achieve union. Wound management after deep SSI required negative pressure therapy for a period of 12, 8, and 14 days, respectively, to achieve closure of the thigh wound in all 3 patients. A cement spacer, which was prepared by mixing polymethylmethacrylate with local antimicrobial drugs, both gentamicin and vancomycin, was used in all 3 patients. All 3 patients with infection achieved only 30° of knee flexion. The microorganisms grown were coagulasenegative *Staphylococcus aureus* in 2 patients and *Klebsiella pneumoniae* in 2 patients.

Discussion

R econstruction of major bone defects following open injuries continues to be a challenge for orthopaedic surgeons

The Journal of Bone & Joint Surgery · JBJS.org Volume 104-A · Number 2 · January 19, 2022

RECONSTRUCTION OF MASSIVE SEGMENTAL DISTAL FEMORAL METAPHYSEAL BONE DEFECTS AFTER OPEN INJURY

Case	Sex, Age (yr)	Gustilo Fracture Type	GHOIS	Serum Lactate on Arrival (mmol/L)	Wound Management	Loss	Time to Definitive Fixation (days)	Complications	Microorganism	No. of Secondary Procedures	Secondary Procedures	Follow-up (mo)	Outcome	LEF Sco
1	M, 72	ЗА	16	6.9	PSS	8.9	3	Infected nonunion	Coagulase- negative <i>Staphylococcus</i> <i>aureus</i>		 Debridement Allograft removal Repeat debridement and cement spacer application Spacer removal and bone-grafting Plate removal and Orthofix fixator application Above-the-knee amputation 	96	Amputation	60
2	M,45	ЗА	12	10.1	PSS	7.6		Aseptic nonunion of proximal end with implant failure	NA		1. Plate removal and Ilizarov application after 8 mo	43	United but with stiff knee	47
3	M, 38	ЗА	10	2.2	PSS	13.7	10	Infected nonunion	Klebsiella pneumoniae		 Allograft removal and cement spacer Cement spacer removal and bone-grafting Repeat debridement and implant removal Retrograde nailing, plating, and bone-grafting 	42	United (0°-30° of knee ROM)	60
4	M, 48	ЗА	12	4.3	PSS	9.7	4	Early deep SSI	Klebsiella pneumoniae		1. Allograft removal and cement spacer application in 2 wk 2. Bone-grafting	22	United (0°-30° of knee ROM)	41
5	M, 34	ЗА	10	2.7	PSS	12.3	7	Aseptic nonunion of proximal end with implant failure	NA		1. Broken plate removal, retrograde nailing, plate augmentation, and iliac crest bone-grafting after 16 mo	36	United (0°-110° of knee ROM)	41
6	M, 45	ЗА	12	2.8	PSS	7.5	6	Aseptic nonunion of proximal end with implant failure	NA		1. Broken plate removal and retrograde nailing, plate augmentation, and iliac crest grafting after 14 mo	38	United (0°-90° of knee ROM)	50
7	M, 24	ЗА	10	2.1	PSS	11.5		Late deep SSI following complete union	Coagulase- negative Staphylococcus aureus		1. Debridement and implant removal	30	United (0°-30° of knee ROM)	45

*All patients had a locking compression plate (LCP; Synthes). GHOIS = Ganga Hospital Open Injury Score, PSS = primary skin suturing, SSI = surgical site infection, LEFS = Lower Extremity Functional Scale, NA = not applicable, and ROM = range of motion.

despite the availability of various surgical techniques^{1,7,8,15}. Commonly followed techniques are distraction osteogenesis with a fixator (Orthofix) or an Ilizarov frame and free vascularized fibular grafting. Vascularized fibular bone grafts can be used in defects of up to 20 cm, and they are vascular, viable bone with structural strength. The disadvantages include the complexity of the surgical procedure, possible failure of anastomosis, the need for prolonged protection, and a mismatch in sizes^{12,28}. A

bone transport technique can be used in massive defects of up to 20 cm with promising results. However, this technique has very poor patient compliance, is cumbersome to the patient, and may lead to pin-track infections, septic arthritis, soft-tissue contractures, and poor results. Failure of these methods ultimately results in secondary amputation^{29,30}.

The induced membrane technique for treating bone defects described by Masquelet et al.¹³ has gained much

THE JOURNAL OF BONE & JOINT SURGERY · JBJS.ORG VOLUME 104-A · NUMBER 2 · JANUARY 19, 2022 RECONSTRUCTION OF MASSIVE SEGMENTAL DISTAL FEMORAL METAPHYSEAL BONE DEFECTS AFTER OPEN INJURY





Figs. 2-A through 2-L A 54-year-old man who had an open floating knee injury and was in hypovolemic shock on arrival with a high lactate level of 5.2 mmol/L. Figs. 2-A, 2-B, and 2-C Preoperative radiographs and a photograph showing the injury. Fig. 2-D Photograph showing the damage control procedure involving debridement and application of an external fixator that was performed initially after the patient had been resuscitated adequately. Figs. 2-E through 2-H The original bone defect was measured, an allograft of a similar size was prepared (Fig. 2-E), cancellous graft (Figs. 2-F and 2-G) was packed at the host-allograft interface, and fixation with a locking plate was used for both the distal femur as well as the proximal tibia (Fig. 2-H). Figs. 2-I through 2-L Radiographs showing that a good outcome was achieved with complete union by 7 months distally and by 9 months at the proximal end of the allograft, and with good incorporation of the allograft by 16 months (Figs. 2-I and 2-J), and the patient had good limb alignment (Fig. 2-K) and knee flexion of 120° (Fig. 2-L).

popularity in recent times. This technique was initially described for infections and currently is used even for defects with clean open wounds. The disadvantages are that it is a 2staged procedure and has had limited success in duplicating the originally described results¹⁴. Acute shortening followed by lengthening can be performed if the defects are <4 cm without any neurovascular compromise^{7,31}. The Capanna technique³² and the modified Capanna technique, which was recently described by Jayaramaraju et al.¹¹ for posttraumatic defects, include a combination of structural allograft and free vascularized fibular bone to bridge massive bone defects, and they have shown satisfactory outcomes. However, the disadvantages include a longer surgical duration, a need for microsurgical skills, an increased rate of donor-site morbidity, and a high cost. A novel technique of internal bone transport using a motorized magnetic nail has been described^{33,34}. However, it is very expensive, requires patient compliance, and is not widely available.

We are the first, to our knowledge, to describe a singlestage procedure using intercalary structural gamma-irradiated allografts in combination with morselized cancellous autografts for large open fracture defects. The advantages of this technique are that it avoids multiple-stage complex procedures and donor-site morbidity, is cost-effective, has a shorter duration that minimizes blood loss, and achieves satisfactory outcomes. Intercalary allograft provides structural support to allow early weight-bearing and joint mobilization. Finally, many centers may not have a large tissue bank on the hospital premises to easily match defect sizes. Soft-tissue adherence to the allograft by the formation of a thin layer of new bone on the THE JOURNAL OF BONE & JOINT SURGERY • JBJS.ORG VOLUME 104-A • NUMBER 2 • JANUARY 19, 2022 RECONSTRUCTION OF MASSIVE SEGMENTAL DISTAL FEMORAL METAPHYSEAL BONE DEFECTS AFTER OPEN INJURY





Figs. 3-A through 3-L A 22-year-old man presented with an open floating knee injury. **Figs. 3-A, 3-B, and 3-C** Preoperative photograph and radiographs of the injury, which was treated by the same protocol as that used in the patients in Figures 1 and 2. **Figs. 3-D and 3-E** Initially, an external fixator was applied, and an allograft similar in size to the defect was prepared. **Fig. 3-F** Cancellous graft was packed at the host-graft interface, and a locking plate was applied. The patient had a complete rupture of the quadriceps tendon. **Figs. 3-G through 3-J** Anteroposterior radiograph made immediately postoperatively (**Fig. 3-G**), anteroposterior and lateral radiographs of distal femur made at 41 months (**Figs. 3-H and 3-I**), and an anteroposterior radiograph of the tibia made at 41 months (**Figs. 3-J**), showing fracture union and incorporation of the graft. **Figs. 3-K and 3-L** At the final follow-up at 41 months, the patient had good limb alignment but could achieve only 45° of knee range of motion (**Fig. 3-L**) because of the complete rupture of the quadriceps tendon.

allograft improves the functional outcome¹⁶. Allograft helps to maintain the limb length and alignment. No patient in our series had a limb-length discrepancy.

Allografts are mainly osteoconductive and to a lesser extent osteoinductive as they do not contain any viable osteocytes³⁵. Union at the proximal diaphyseal host-graft junction is delayed and takes place by external callus formation from host periosteum, and union of the distal metaphyseal host-graft junction occurs quickly by creeping substitution. Once the osseous bridging is established between the graft and host bone, transfer of stress results in remodeling of the allograft²⁶. In our patients, the average time to union was 5.83 months for the distal metaphyseal host-allograft junction and 11.2 months for the proximal cortical host-allograft junction. Host-allograft union, although delayed, is influenced by the stability of the fixation and the contact between host bone and allograft^{35,36}. In all 19 patients with complete data, good compression was achieved across the transverse ends of the host-allograft junction, and stable fixation was achieved to withstand the deforming forces for a long time.

The use of cancellous autografts at the host-allograft interface has been reported to increase the amount of callus formation but not the rate of union²⁷. Iliac crest cancellous grafts were packed at both host-graft interfaces and within the reamed medullary canal of the allograft. In our series, 12 patients achieved primary complete union and the allograft incorporated well with the host bone without any further surgeries (Fig. 2).

Donati et al. reported nonunion of the host-allograft junction (27%), graft fracture (23.8%), and infection (8.7%) following the use of allografts for reconstructing bone defects following tumor surgery¹⁶. Poor host environment and postoperative radiation

178

The Journal of Bone & Joint Surgery · JBJS.org Volume 104-A · Number 2 · January 19, 2022

therapy and chemotherapy have been associated with wound-healing problems, infection, nonunion, and poor revascularization of allograft³⁷. Poor revascularization of the allograft results in only limited and superficial substitution of a vital allograft bone with viable host cells. The center of the allograft remains acellular. This accounts for the occurrence of fatigue fracture of the allograft (16% to 50%)^{37,38}. In our series, 1 elderly patient developed an infection that ultimately required amputation, and 5 patients required secondary procedures to achieve complete union. The risk of viral transmission is <1 in 1,000,000 for human immunodeficiency virus, 1 in 63,000 for hepatitis B, and 1 in 100,000 for hepatitis C³⁹.

In our series, 10 patients achieved knee flexion of $>100^\circ$, which was possible by initiating early knee motion. The reason for limited knee range of motion in the remaining patients was either infection or severe crushing and rupture of the quadriceps tendon (Fig. 3).

The limitations of our study are that it was a single-center study, had a small size sample, and had no comparison with alternative treatment methods. Also, this procedure still had considerable morbidity (a 26.3% rate of nonunion, 36.8% rate of secondary procedures, and 5.2% rate of severe knee stiffness), which needs to be considered while selecting the suitable patient.

RECONSTRUCTION OF MASSIVE SEGMENTAL DISTAL FEMORAL METAPHYSEAL BONE DEFECTS AFTER OPEN INJURY

Conclusions

The use of structural allograft is a reasonable single-stage alternative solution for massive distal femoral bone defects, as union occurred without additional surgery in two-thirds of our patients and with no limb-length discrepancy.

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The Journal of Bone & Joint Surgery · JBJS.org Volume 104-A · Number 2 · January 19, 2022

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RECONSTRUCTION OF MASSIVE SEGMENTAL DISTAL FEMORAL METAPHYSEAL BONE DEFECTS AFTER OPEN INJURY

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