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# Allograft-prosthesis Composites after Bone Tumor Resection at the Proximal Tibia

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**The survival of irradiated allograft-prosthesis composites at the proximal tibia is mostly unknown. However, allograft-prosthesis composites have proved beneficial at other reconstruction sites. We presumed allograft-prosthesis composites at the proximal tibia would improve survival and facilitate reattachment of the extensor mechanism compared with that of conventional (megaprostheses) reconstructions. We retrospectively reviewed 26 patients who underwent resection of proximal tibia tumors followed by reconstruction with allograft-prosthesis composites. Patients received Guepar® massive custom-made fully constrained prostheses. Allografts were sterilized with gamma radiation, and the stems were cemented into the allograft and host bone. The minimum followup was 6 months (median, 128 months; range, 6–195 months). Fourteen patients had one or more components removed. The median allograft-prosthesis composite survival was 102 months (95% confidence interval, 64.2–infinity). Of the 26 allografts, seven fractured, six showed signs of partial resorption, and six had infections develop. Seven allografts showed signs of fusion with the host bone. Six extensor mechanism reconstructions failed. Allograft-prosthesis composites sterilized by gamma radiation yielded poor results for proximal tibial reconstruction as complications and failures were common. We do not recommend irradiated allograft-prosthesis composites for proximal tibia reconstruction.**

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The use of allograft-prosthesis composites for reconstruction after bone tumor resection at the proximal femur[2,8,10,13,26,27,36] and proximal humerus[4,13,19,26] has generated considerable interest since the mid 1980s. The potential benefits of allograft-prosthesis composites include possible reattachment of tendons to the graft, improved longevity through load-sharing properties of the allograft, and restoration of bone stock.[5] However, only a few cases of allograft-prosthesis composites at the proximal tibia have been reported. Wunder et al[35] reported five proximal tibia allograft-prosthesis composites in which two had infections develop. Hernigou et al[14] reported infections and failure of the extensor mechanism in four of 19 reconstructions. Survival was not reported in either study.

Based upon results from other locations, we presumed allograft-prosthesis composites at the proximal tibia would improve survival compared with that of conventional (megaprostheses) reconstructions. We also analyzed the mode of failure of the allografts and evaluated extensor mechanism function.

## MATERIALS AND METHODS

We retrospectively reviewed 26 patients who had resections of knee tumors followed by reconstruction with an allograft-prosthesis composite from December 1985 to July 1993. All patients who were treated for benign or malignant tumors of the knee were identified electronically from our computer database; those who received an allograft-prosthesis composite at the proximal tibia then were selected from hospital notes. Data regarding survival of the reconstruction and extensor mechanism function were retrieved from hospital records. All patients at our institution are included in a healthcare program and followed accordingly. Historical controls from the literature were identified for comparison. Relevant studies were identified in

**TABLE 1. Clinical Characteristics and Results of the 26 Proximal Tibia Allograft Prosthesis Composites**

| Patient | Age (years) | Diagnosis | Resection Length (cm) | Adjuvant Treatment | Type of Allograft | Surgical Sacrifice | Medial Gastrocnemius Flap | Postoperative Complication |
|---|---|---|---|---|---|---|---|---|
| 1 | 18 | Osteosarcoma | 14.5 | Chemotherapy | Distal femur | | Yes | |
| 2 | 18 | Ostesarcoma | 15 | Chemotherapy | Proximal tibia | | Yes | |
| 3 | 22 | Osteosarcoma | 12 | Chemotherapy | Proximal tibia | | No | |
| 4 | 27 | Osteosarcoma | 10 | Chemotherapy | Proximal tibia | | No | |
| 5 | 58 | GCT | 14 | Chemotherapy | Proximal tibia | | Yes | |
| 6 | 68 | Choncrosarcoma | 9.5 | | Distal tibia | | No | |
| 7 | 16 | Osteosarcoma | 20 | Chemotherapy | Proximal tibia | ATA | Yes | ATM necrosis |
| 8 | 36 | Fibrosarcoma | 12 | Chemotherapy | Distal tibia | | Yes | |
| 9 | 12 | Osteosarcoma | 10 | Chemotherapy | Distal tibia | | Yes | CPN palsy |
| 10 | 23 | Osteosarcoma | 16 | Chemotherapy/ radiotherapy | Distal femur | | Yes | |
| 11 | 60 | GCT | 9 | Radiotherapy | Distal femur | | No | |
| 12 | 19 | Osteosarcoma | 11 | Chemotherapy | Proximal tibia | | No | |
| 13 | 38 | Fibrosarcoma | 15 | | Distal tibia | | Yes | |
| 14 | 64 | Chondrosarcoma | 15 | | Proximal tibia | | Yes | |
| 15 | 44 | Periosteal sarcoma | 12 | | Distal femur | POP/TN | Yes | TN palsy |
| 16 | 18 | Osteosarcoma | 12 | Chemotherapy | Distal femur | | Yes | |
| 17 | 17 | Osteosarcoma | 14 | Chemotherapy | Proximal tibia | | No | |
| 18 | 25 | Osteosarcoma | 16 | Chemotherapy | Distal tibia | | No | ATM necrosis/ wound dehiscence |
| 19 | 17 | Osteosarcoma | 13 | Chemotherapy | Proximal tibia | CPN | No | CPN palsy |
| 20 | 69 | Chondrosarcoma | 10 | | Proximal tibia | | No | |
| 21 | 17 | Osteosarcoma | 20 | Chemotherapy | Proximal tibia | | Yes | CPN palsy |
| 22 | 55 | Metastasis | 11 | Chemotherapy/ radiotherapy | Proximal tibia | | No | Wound oozing |
| 23 | 41 | MFH | 13 | | Proximal tibia | | Yes | |
| 24 | 16 | Osteosarcoma | 14 | Chemotherapy | Distal femur | ATA/CPN | Yes | CPN palsy |
| 25 | 55 | Chondrosarcoma | 20 | | Proximal femur | | No | |
| 26 | 18 | Osteosarcoma | 18 | Chemotherapy | Proximal tibia | ATA/CPN | Yes | CPN palsy |

GCT = giant cell tumor; MFH = malignant fibrous histiocytosis; ATA = anterior tibialis artery; POP = popliteal vessels; TN = tibial nerve; CPN = common peroneal nerve; ATM = anterior tibialis muscle; *arthrodesis; †amputation; NA = not available

MEDLINE and after cross-checking the reference lists of retrieved articles.

There were 12 males and 14 females with a median age of 24 years (range, 12–69 years), a median body weight of 60 kg (range, 37–95 kg), and a median height of 166 cm (range, 149–188 cm). The right limb was affected in 12 patients. The minimum followup was 6 months (median, 128 months; range, 6–195 months). Diagnoses included osteosarcoma in 16 patients, chondrosarcoma in four patients, fibrosarcoma or malignant fibrous histiocytoma in three patients, benign giant cell tumor in two patients, and metastatic bone disease in one patient (Table 1). Eighteen patients were treated with adjuvant chemotherapy and three patients were treated with preoperative radiation therapy. Metastases were detectable in five patients at the time of surgery.

We used an anteromedial approach in 21 patients and an anterolateral approach in five patients. Surgery involved tumor resection and joint reconstruction as follows. The biopsy site was included with a 2-cm margin. The neurovascular bundle was exposed from Hunter's canal proximally to the upper part of the tibia distally. The medial gastrocnemius and the medial hamstrings were detached to allow for wide exposure of the popliteal vessels and sciatic nerve. We made a mark on the tibial shaft, in line with the tibial tuberosity, to allow for transverse prosthesis alignment. The tumor resections conformed to principles for management of benign and malignant bone tumors: for benign tumors a marginal excision was performed; for malignant tumors a cuff of normal tissue was left with the tumor and the biopsy track was left in continuity with the specimen with a 2-cm margin. We excised the anterior tibialis artery and common peroneal nerve in two patients, the anterior tibialis artery in one patient, and the common peroneal nerve in one patient. In one patient, excision of the popliteal vessels and the tibial nerve required bypass surgery (Table 1). Reconstruction was performed during the same surgery. The medullary canal was reamed 2 mm larger than the planed stem diameter. We performed a trial with the implant to control kinematics, length, and rotation. Cementing involved lavage, use of a cement restrictor, and pressurizing the cement. We first prepared the allograft to match the length and shape of the skeletal defect. We then cemented the prosthesis into the allograft on a back table and performed a second trial after cement polymerization was complete. The composite was fitted into the medullary canal. If necessary, the cuts were adjusted to match perfectly and maximize contact surface between the host bone and the allograft. The composite was cemented into the host bone, and care was taken so that no cement was caught between the allograft and the host bone. Bone retrieved from the reaming products was placed at the allograft-host bone

**TABLE 1. Clinical Characteristics and Results of the 26 Proximal Tibia Allograft Prosthesis Composites (*Continued*)**

| Patient | Extensor Mechanism Rupture | Allograft Complication | Allograft-host Bone Union | Active Flexion (degrees) | Passive Extension (degrees) | Active Extension (degrees) | Reason for Revising the Prosthesis | Followup (months) |
|---|---|---|---|---|---|---|---|---|
| 1 | No | Resorption | No | 120 | 0 | 0 | | 23 |
| 2 | Yes | Fracture | Yes | 125 | 0 | 30 | | 106 |
| 3 | Yes | Fracture | No | 90 | 0 | 0 | Aseptic loosening | 142 |
| 4 | No | Resorption | Yes | 90 | 0 | 0 | Aseptic loosening | 90 |
| 5 | No | | Yes | 100 | 0 | 0 | Tibial stem fracture | 195 |
| 6 | No | Infection | No | 60 | 0 | 0 | | 179 |
| 7 | No | Infection | No | 45 | 0 | 0 | | 7 |
| 8 | No | | No | 100 | 0 | 0 | | 35 |
| 9 | No | Infection | No | 65 | 30 | 30 | Septic loosening* | 149 |
| 10 | No | Infection | No | 0 | 0 | 0 | Infection† | 65 |
| 11 | No | | No | 90 | 0 | 0 | Metallosis | 140 |
| 12 | No | Fracture | No | 90 | 0 | 0 | Aseptic loosening | 164 |
| 13 | No | | Yes | 90 | 5 | 5 | | 138 |
| 14 | Yes | Fracture | No | 80 | 0 | 30 | | 63 |
| 15 | No | Resorption | Yes | 90 | 0 | 0 | Local recurrence† | 186 |
| 16 | No | Fracture | No | 110 | 0 | 5 | Aseptic loosening | 85 |
| 17 | No | | No | NA | 5 | 5 | | 6 |
| 18 | Yes | Infection | No | 50 | 0 | 20 | Septic loosening* | 172 |
| 19 | Yes | | No | 0 | 0 | 0 | Local recurrence† | 89 |
| 20 | No | Fracture | No | 30 | 10 | 10 | Aseptic loosening | 191 |
| 21 | No | Infection | Yes | 120 | 0 | 0 | Septic loosening | 150 |
| 22 | No | | No | 90 | 0 | 20 | | 62 |
| 23 | No | Resorption | No | 120 | 0 | 0 | | 212 |
| 24 | No | Fracture | No | 130 | 0 | 0 | | 117 |
| 25 | No | Resorption | No | 110 | 0 | 0 | Aseptic loosening | 150 |
| 26 | Yes | | Yes | 110 | 0 | 60 | | 32 |

GCT = giant cell tumor; MFH = malignant fibrous histiocytosis; ATA = anterior tibialis artery; POP = popliteal vessels; TN = tibial nerve; CPN = common peroneal nerve; ATM = anterior tibialis muscle; *arthrodesis; †amputation; NA = not available

junction, but no rigorous bone grafting was performed. The median resection length was 13.5 cm (range, 9–20 cm).

All allografts were obtained from the institution's bone bank and were sterilized by gamma radiation (25 kGy precisely controlled by dosimeters). The donors were 18 years or older but younger than 65 years for males and 60 years for females. The allografts were irradiated unfrozen and stored at −80°C. The desired length and site were prepared by the bone bank. In the operating room, the allografts were thawed in room temperature saline solution with rifampicin (600 mg/L). All allografts were cultured before delivery and implantation. There was one proximal femoral allograft, six distal femoral allografts, 14 proximal tibial allografts, and five distal tibial allografts. During the proximal tibia allograft procedures, the tendon allograft was preserved and used during extensor mechanism reconstruction in seven patients. All patients had extensor mechanism reconstruction. Periosteal elevation preserved partial continuity in nine of these patients. When a gastrocnemius flap was rotated over the anterior part of the composite, the host patellar tendon was first sutured to the allograft and then to the muscle. When no gastrocnemius flap was used for reconstruction, two or three tunnels were drilled in the anterior part of the allograft and the host tendon was reattached to the allograft using nonabsorbable sutures with the knee in full extension; however, this suture served only as protection to allow for the extensor mechanism to heal to surrounding soft tissues. Reinforcement of the reconstruction was performed in 21 patients using a medial gastrocnemius flap (12 patients), the surrounding fascias (six patients), or a combination of the medial gastrocnemius flap, tendons (pes anserinus, anterior tibialis, plantaris), and fascias (three patients). Seven patients had reconstructions with the allograft tendon preserved with the allograft bone.

All patients received a custom-made chrome-cobalt, Guepar II® prosthesis (Stryker Benoist Girard, Hérouville Saint-Clair, France). The Guepar II® is a fully constrained, fixed-hinge prosthesis with 5° valgus femoral stems, 45-mm-width tibial plateau with antirotation flange, and 45-mm-width anterior femoral flange. Polyethylene bushings and antirotation pins (preventing rotation between the axis and the femoral part of the hinge) were added to the hinge mechanism in 1980. Metal bushings were substituted for the polyethylene bushing in 1984, and from 1989 onward bushings no longer were used. The antirotation pins were discontinued in 1992. The median tibial stem length was 30 cm (range, 20–38 cm), and median cemented tibial stem length was 15.5 cm (range, 10–20.5 cm). The patella was resurfaced in nine patients. Gentamicin-impregnated acrylic bone cement was used for all patients.

The study end point was revision for any reason (with implantation of a new component, arthrodesis, or amputation), except where specified otherwise. Quantitative variables (continu-

ous variables) were described as median and range. Categorical variables were presented as counts. We used the Kaplan–Meier survival analysis to determine prosthesis survival. All patients were included in the analysis. The median survival time was derived with 95% confidence intervals (CIs). All analyses were performed using R 2.2.0 software package (The R Foundation for Statistical Computing, Version 2.2.0, 2005; http://www.rproject.org/foundation/). All tests were two-sided, with a significance level of 0.05. Data were retrieved retrospectively by one of the authors (DJB), who did not participate in the treatment of the patients.

## RESULTS

At last followup, 16 patients (62%) were alive and disease-free. Of the 10 deaths, seven were from local recurrence or metastatic disease and three from other causes. Three patients (12%) were followed for less than 1 year: one was lost to followup because he returned to his home country, one died from metastasis, and one had revision surgery. Nine patients (35%) experienced postoperative complications (Table 1). There were no postoperative deaths related to surgery.

The median prosthesis survival was 102 months (95% CI, 64.2–infinity) (Fig 1) (Table 2). When patients with a followup less than a year were considered to have failed results, the median prosthesis survival was 101 months (95% CI, 54.4–infinity). Excluding the two patients who had revision surgery for local tumor recurrence, the median prosthesis survival was 104 months (95% CI, 101–infinity). The 5-year prosthesis survival rate was 68% (95% CI, 51–91%), and the 10-year survival rate was 33% (95% CI, 17–64%). Of the 26 allograft-prosthesis composites, 14 (54%) had at least one component removed at last followup (with implantation of a new component, arthrodesis, or amputation); mechanical failure accounted for 57% of all revisions (eight of 14), infection for 29% (four of 14), and local tumor recurrence for 14% (two of 14) (Table 3). Preservation of the allograft sleeve was not possible during revision surgery. Excluding the two immediate postoperative complications, we performed 47 repeat surgical procedures in 22 patients (85%).

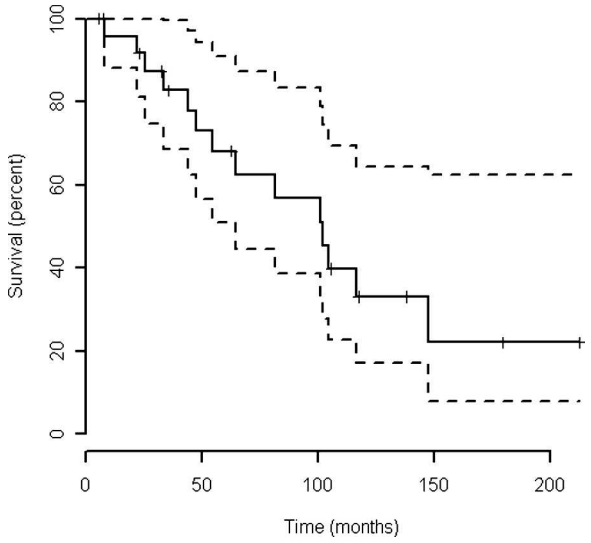


**Fig 1.** A graph shows the overall survival of the allograft-prosthesis composites with revision for any reason (with implantation of a new component, arthrodesis, or amputation) as the end point. The median prosthesis survival was 102 months (95% CI, 64.2–infinity). Solid line = survival Kaplan Meier estimate; dashed line = 95% confidence interval

Of the 26 allograft-prosthesis composites, six patients developed infections (23%) and seven had aseptic loosening (27%). Infection developed early and is a cause for poor implant survival (Fig 2). Of the seven patients who had aseptic loosening develop, five had fracture of the allograft (Fig 3) and two had resorption. Two other allografts fractured and four others had resorption. Therefore, 13 allografts (50%) showed signs of fracture or resorption. Of the 23 allograft-prosthesis composites with followup greater than 1 year, seven (30%) showed radiographic evidence of fusion with the recipient bone. When aseptic loosening occurred, fusion with the host bone was seen only once.

The reconstructed extensor mechanism failed in six patients (23%). Three ruptures occurred from trauma, one was associated with infection, one occurred during a manual joint mobilization, and one had no evident cause. These ruptures occurred among patients without partial continuity preservation. Only four of the six patients had revision surgery. Seven patients had an extensor lag greater than 5° (Table 1). Two patients developed knee rigidity (knee fixed in extension); one with chronic infection who had an amputation and another with multiple local recurrences in the quadriceps who had hip disarticulation.

## DISCUSSION

In the mid1980s, surgeons questioned whether an allograft-prosthesis composite would offer better survival than megaprostheses. However, the question of which has better survival remains controversial.

Several aspects of our study may limit our conclusions regarding allograft-prosthesis composites survival. The use of irradiation for sterilization may have played a role in the poor results because of the reduced fatigue crack propagation resistance.[14,24,28] The use of a rotating-hinge mechanism may decrease torque transmitted to the implant interfaces,[21] but its clinical benefit remains debatable.[11,20] Although the design of our study is retrospective and could

**TABLE 2. Life Table for Implant Survival**

| Time (years) | Number at Risk | Number of Events | Survival | Standard Error | Lower 95% CI | Upper 95% CI |
|---|---|---|---|---|---|---|
| 0 | 26 | 0 | 1.00 | 0.00 | 1.00 | 1.00 |
| 1 | 23 | 1 | 0.96 | 0.04 | 0.88 | 1.00 |
| 2 | 21 | 1 | 0.92 | 0.06 | 0.81 | 1.00 |
| 3 | 17 | 2 | 0.83 | 0.08 | 0.69 | 1.00 |
| 4 | 15 | 2 | 0.73 | 0.10 | 0.57 | 0.94 |
| 5 | 14 | 1 | 0.68 | 0.10 | 0.51 | 0.91 |
| 6 | 11 | 1 | 0.62 | 0.11 | 0.45 | 0.87 |
| 7 | 10 | 1 | 0.57 | 0.11 | 0.39 | 0.83 |
| 8 | 10 | 0 | 0.57 | 0.11 | 0.39 | 0.83 |
| 9 | 6 | 3 | 0.40 | 0.11 | 0.23 | 0.70 |
| 10 | 4 | 1 | 0.33 | 0.11 | 0.17 | 0.64 |
| 11 | 4 | 0 | 0.33 | 0.11 | 0.17 | 0.64 |
| 12 | 3 | 0 | 0.33 | 0.11 | 0.17 | 0.64 |
| 13 | 2 | 1 | 0.22 | 0.12 | 0.08 | 0.62 |

CI = confidence interval

have underestimated the number of failures, it is suitable for assessing our primary objective (survival of the reconstruction).

We found a prosthesis survival rate of 68% after 5 years and 33% after 10 years. Survival of massive knee replacements after proximal tibial tumor resection in series ranging from seven to 151 patients varies from 44% to 85% at 5 years and from 30% to 63% at 10 years.[11,22,25,30,33,35]

Infection is a major concern after proximal tibial reconstruction with megaprostheses, with reported rates ranging from 4% to 23% in series of 13 to 133 patients,[1,3,17,18,20,25,30] and with osteoarticular allografts, with rates from 13% to 18% in series of 16 to 38 patients.[6,16] Common factors associated with infection after proximal tibia reconstruction include a long operating time, extensive soft tissue dissection, and compromised vascular supply.[11,20,30,35] The immunosuppressive effect of radiotherapy and chemotherapy contributes to infection.[11,30] We did not use a skin graft combined with a gastrocnemius flap to minimize skin tension at the time of closure. However, some authors advocate routine skin grafting on the gastrocnemius flap to allow for closure without tension.[9,13] Of the six infections, two were from ischemic necrosis of the anterior tibialis muscle, one from a repeat surgical procedure, and one from wound dehiscence (Table 1).

Other series had lower survival rates for massive knee replacement after proximal tibial tumor resection compared with reconstruction after distal or proximal femoral tumor resection.[22,25,33–35] Of the seven patients who had stem loosening, all showed signs of fracture or resorption and six had no signs of fusion between the allograft and the host bone. Therefore, we speculate the improved stability expected from allograft-prosthesis composites de-

**TABLE 3. Number and Cause for Repeat Operations**

| Cause | Numbers of Operations (number of patients) | Revisions | Total |
|---|---|---|---|
| Mechanical | 19 (11) | 8 | 27 (15) |
| Infectious | 9 (4) | 4 | 13 (6) |
| Tumoral | 5 (3) | 2 | 7 (4) |
| Total | 33 (16) | 14 | 47 (22) |

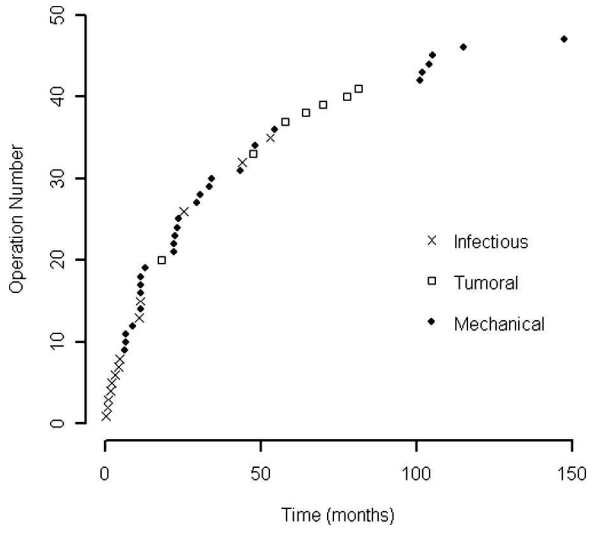


**Fig 2.** A graph shows the timing of repeat operations depending on the cause for surgery. Infection is the main cause for early reoperation.

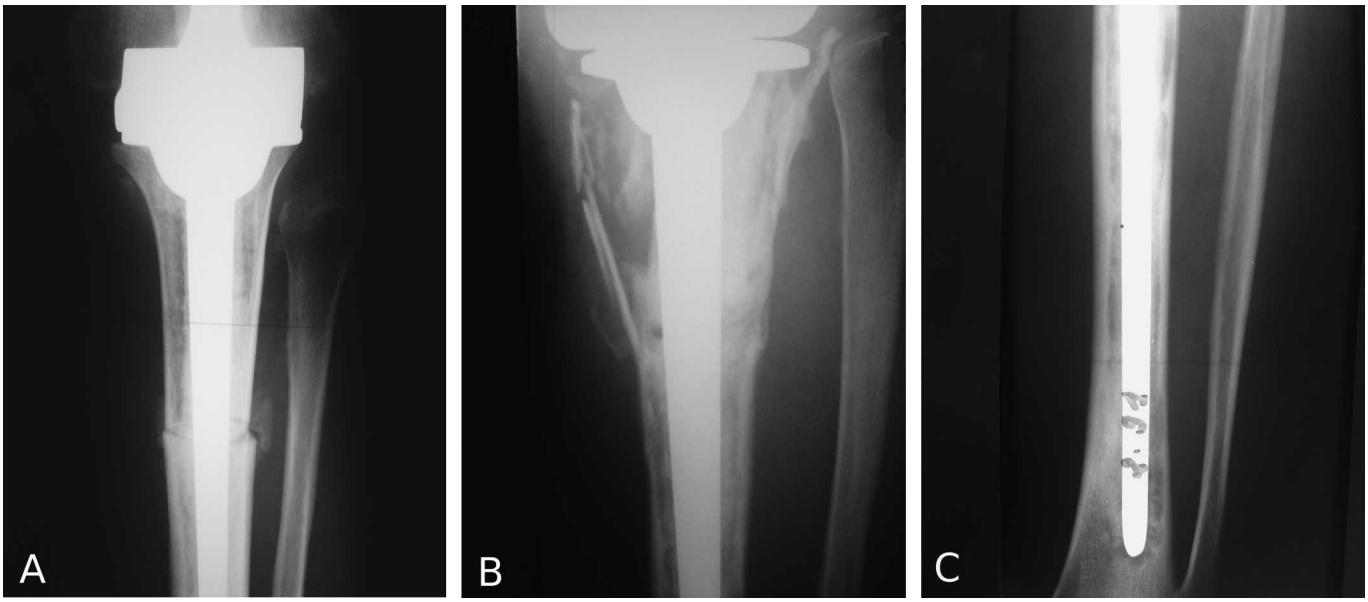


**Fig 3A–C.** The radiographs show (A) an allograft-prosthesis composite of the proximal tibia 1 month postoperatively, (B) an allograft fracture 21 months postoperatively, and (C) tibial stem loosening at 21 months postoperatively.

pends on their integration into surrounding soft and hard tissue. Abnormal peak stresses with loss of extension control may have played a substantial role in mechanical failure of the implants.[22,23,29] The use of a rotating-hinge mechanism may decrease torque transmitted to the implant interfaces,[21] but its clinical benefit remains debatable. Jeon et al[20] reported no improvement in survival with the use of rotating-hinge megaprostheses in a series of 31 patients whereas Grimer et al[11] reported some improvement in the revision rate after changing from fully constrained megaprostheses to rotating-hinge megaprostheses in a series of 151 patients.

Three factors may have played a role in occurrence of fracture or resorption of the allografts: irradiation of the allografts, perforation of the cortex to reattach the extensor mechanism, and the low rate of union. Fracture of allografts is an issue, with reported rates ranging from 6% to 36% in series of 24 to 127 patients.[14,24] Radiation affects the structural properties of the allografts and should not be used routinely for sterilization.[28] Perforation of the allograft may induce revascularization and creeping substitution and consequently enhance incorporation.[7] However, perforation of the cortex may increase stress and initiate crack propagation and is not recommended.[31] The low rate of union (30%) at the allograft-host bone junction could be attributed to the use of chemotherapy and the absence of rigorous bone grafting.[12,15] Irradiation of the allograft also may be detrimental. Nonunion between the allograft and the host bone is a cause for failure of the allograft.[15] However, the use of intramedullary cement offers stability without adverse effects on healing and was not considered a cause of nonunion.[32] Nevertheless, the graft-host bone junction should be rigorously bone grafted.[12] We believe preoperative radiotherapy is a contraindication to the use of allograft reconstruction because of the theoretic inability of irradiated tissues to integrate with the implanted tissue.

Secondary rupture of the extensor mechanism in series of 22 to 55 patients ranged from 9% to 15% after implanting megaprotheses.[1,3,20] The high rate of graft resorption could explain the difficulty in obtaining durable fixation of the tendon to the allograft with time in our series and its relative sensitivity to trauma. Seven patients had an extensor lag greater than 5°, a figure comparable to other studies. Abboud et al[1] reported an extensor lag greater than 5° (7°, 10°, 10°, 20°, and 30°) in five of 11 patients available for evaluation; of 25 patients evaluated for extension lag after proximal tibia reconstruction, Jeon et al[20] reported 14 patients with an extensor lag less than 20° and 11 with an extensor lag greater than 20°. Natarajan et al[30] and Grimer et al[11] reported a mean extensor lag of 18° (range, 10°–35°) and 30° (range, 0°–90°) after 133 and 151 proximal tibia megaprostheses, respectively.

The results of allograft prosthesis composites at the proximal tibia with the method we report did not prove better than megaprosthesis reconstructions, therefore we do not recommend use of such composites. The potential benefits of allograft-prosthesis composites to improve long-term stability of the reconstruction and reattach tendons were not supported by this series. However, the poor

results could be explained by failure to obtain integration of the allografts to surrounding host tissues. The use of irradiated allografts and the absence of rigorous bone grafting at the allograft-host bone junction likely played a substantial role in the poor results.

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