Classification and Reconstruction of Femoral Bone Defect in the Revision of Aseptic Loosening of Distal Femoral Endoprostheses: A 10-year Multicenter Retrospective Analysis

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Research Article

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Abstract

Objective

This study proposes a system for classifying the aseptic loosening of distal femoral prostheses and discusses reconstruction methods for revision surgery, based on different classification types.

Methods

We retrospectively analyzed the data of patients who received revision surgery for aseptic loosening in distal femoral tumor endoprosthesis from January 2008 to December 2018 at 3 bone tumor treatment centers in China. On the basis of the patient imaging data, we proposed a classification system for the aseptic loosening of distal femoral endoprostheses and discussed its revision surgery strategy for various bone defects.

Results

A total of 29 patients were included in this study, including 20 males and 9 females aged 15–64 y (average: 43.2 y). First-revision surgery was performed on 25 patients, whereas second-revision surgery was conducted on 4 patients. The 29 patients were classified into different types based on the degree of aseptic loosening: Type Ia, 5 patients (17.2%); Type Ib, 7 patients (24.1%); Type IIa, 9 patients (31.0%); Type IIb, 7 patients (24.1%); and Type IIIb, 1 patient (3.4%). Four Type Ia patients used the longer-stem rotating hinge prosthesis, and 1 Type Ia patient used the original prosthesis. Six Type Ib patients used a longer-stem rotating hinge, and 1 Type Ib patient used the original prosthesis plus bone grafting with an allograft bone plate for revision. Eight Type IIa patients underwent revision with a longer-stem rotating hinge prosthesis, and 1 Type IIa patient received revision surgery with the original prosthesis plus bone grafting with an allograft bone plate. Meanwhile, 5 Type IIb and 1 Type IIIb patients used a longer-stem rotating hinge prosthesis, and 2 Type IIb patients used the original prosthesis for revision.

Conclusions

Aseptic loosening of the distal femoral prosthesis can be divided into 4 types and 8 subtypes. Different types of bone defect can be repaired with the appropriate reconstruction.

Introduction

Currently, tumor prosthesis is the most commonly used technique to reconstruct bone defects after bone tumor resection. [1–4] With the continuous progress in material science and manufacturing, tumor prostheses have been widely applied because of their ability to rapidly recover keen joint function and good biological fit. Despite numerous advances in the design and production of tumor prostheses, the complication rate of tumor prostheses is considerably higher than that of ordinary knee joint prostheses.[43] Revision surgery due to complications of tumor prostheses is frequently performed. [2, 5–7]

Henderson et al. [8] identified tumor endoprostheses failures and classified them into five modes: soft tissue failure (type 1), aseptic loosening (type 2), structural failure (type 3), infection (type 4), and tumor progression (type 5). Aseptic loosening is the most common failure mode in the literature. The causes and prevention of the aseptic loosening of prostheses have often been the focus of clinical research.[9] In the previous literature, the aseptic loosening rate of tumor prostheses ranged from about 3–16.9%.[2, 4, 5, 10–21] Literature reports indicate that the main factors affecting the aseptic loosening of prostheses are the length of resection, the type of prosthesis, the diameter of the prosthesis, and the bone-to-stem ratio.[22–26] Several studies suggest that aseptic loosening is caused by poor mechanical structure, such as the loosening or breaking of the prosthesis, are attributable to biomechanical problems. [9] These issues ultimately lead to the failure and revision of prostheses. Numerous studies have also demonstrated that aseptic loosening can be prevented by uncemented fixation; [27, 28] using a rotating hinge structure [29] or a large-diameter stem [23]; altering the shape of the intramedullary stem;[30] and adding hydroxyapatite coating (HA). [29, 31]

Currently, revision for aseptic loosening of the tumor prosthesis presents a serious challenge to bone oncologists.[32] The degree of prosthesis loosening results in bone defect and residual length to varying degrees. Correct evaluation of the cortical bone of the medullary cavity is a key concern for revision surgery. No research on the assessment of aseptic loosening has been reported in the previous literature, and only few studies are conducted on the selection of reconstruction methods and surgical techniques for revision. [6, 33–37] Generally, owing to the small number of cases and large differences in location, the volume of these research evidence is insufficient. The revision strategy for tumor prostheses thus far remains inconclusive. Therefore, the classification and reconstruction of the aseptic loosening of tumor prostheses needs to be proposed.

We reviewed and analyzed case data from 3 three bone tumor diagnostic and treatment centers in China, limited to the distal femur; classified the various manifestations of the aseptic loosening of tumor prostheses; and proposed the classification of aseptic loosening of femoral bone defects in distal femoral tumor prostheses; and presented our suggestions for various types of reconstruction.

Patients And Methods

Inclusion and exclusion criteria

The inclusion criteria were as follows: (1) Tumor site at the distal femur; (2) Primary bone tumor diagnosed using clinical methods, imaging, and histopathology; (3) Reconstruction knee joint with a tumor prosthesis; and (4) Revision surgery due to the aseptic loosening of the prosthesis. The exclusion criteria were as follows: (1) Patients with allograft prosthesis composite reconstruction in the initial operation; (2) Patients with incomplete data; and (3) Patients with tumor recurrence during and after revision surgery.

With the inclusion and exclusion criteria considered, 29 patients with distal femoral bone tumors were finally included in the study. These patients received prosthesis revision surgery at 3 bone tumor Chinese diagnostic and treatment centers from January 2008 to December 2018.

Preoperative evolution

We reviewed the previous surgical data of each patient and recorded the preoperative clinical symptoms and function of the affected limb before the revision. Pre-revision imaging examination included a full-length positive X-ray of the lower limbs; a full-length lateral X-ray of the affected lower limb; computed tomography (CT) of the affected limb; and whole-body bone scan Emission Computerized tomography (ECT) . Other imaging examinations were performed following normal procedures in accordance with the postoperative follow-up requirements for bone tumors. Preoperative X-ray, CT, and ECT examination were discussed by 1 bone and soft tissue tumor imaging expert and 2 bone tumor surgeons to determine the type of aseptic loosening of the tumor prosthesis. The preoperative examination included a routine blood test and determination of the erythrocyte sedimentation rate, C-reactive protein, and so on. Periprosthetic infection and other surgical contraindications were excluded.

Surgical technique

Antibiotics are applied 30 min before surgery to prevent infection. During the operation, the original incision is taken to expose the prosthesis, and the loose femoral prosthesis is removed. If the prosthesis is difficult to remove, the bone cement around the prosthesis is carefully removed, followed by the femoral prosthesis. The bone cement in the medullary cavity is taken out as much as possible. The medullary cavity is opened, the inflammatory interfacial membrane tissue around the prosthesis is removed, and the blood vessels and nerves of the popliteal fossa are protected. For patients using the original prosthesis for revision, the femoral prosthesis is removed and then disinfected during surgery; the tibial prosthesis is preserved, the femoral prosthesis is again fixed with bone cement; and the polyethylene component is replaced. Patients using extended-stem prostheses for revision should decide whether to perform revision tibial prosthesis based on the fit of the femoral prosthesis and tibial prosthesis during the operation. For all revision operations, the tibial prosthesis stem is not extended; the femoral intramedullary stem of the revision prosthesis is defined as a longer stem if the length of the femoral medullary stem is $\geq$ 4 cm, compared with the original prosthetic stem. For patients using a biologically fixed shank for revision, bone grafting is first performed in the femoral medullary cavity, and the biological shank prosthesis is implanted. Biological fixation is only used in the femoral medullary cavity, and all tibial fixation stems are fixed with bone cement. When the cortical bone of the femur has a large defect, an allograft bone graft plate is used outside the femur.

Follow-up

This study required a follow-up by revision surgeons on all patients. The follow-up was completed by outpatient review once every 3 months for 2 y after surgery, once every 6 months during 2–5 y, and once annually after 5 y. The follow-up content mainly included the presence of pain of the affected limb and new symptoms of discomfort, the Musculoskeletal Tumor Society (MSTS) functional score to evaluate the function of the affected limb [38], the X-ray examination of the surgical site, and so on. Other routine examinations were conducted in accordance with the requirements for follow-up after the primary tumor surgery.

Classification of aseptic loosening

Type Ⅰ: The prosthesis has no displacement, and the femoral defect is the smallest.

Type Ⅰa: The bone structure around the prosthesis is normal, and the cortical bone loss at the proximal femur is ≤ 50% (Figure 1).

Type Ⅰb: The bone around the prosthesis is thinned, but the encapsulation remains intact, and the cortical bone loss of the proximal femur is >50% (Figure 2).

Type Ⅱ: The prosthesis is displaced, the femoral shaft is extensively defective, and the normal bone length of the proximal femur is ≥ 5 cm.

Type Ⅱa: The prosthesis does not penetrate the cortical bone, and the cortical bone loss at the top of the prosthesis is ≤ 50% (Figure 3).

Type Ⅱb: The prosthesis penetrates the cortical bone, and the cortical bone loss at the top of the prosthesis is > 50% (Figure 4).

Type III: Severe femoral shaft defect involves the isthmus, and the normal bone length of the proximal femur is < 5 cm.

Type Ⅲa: The remaining length of the femoral isthmus is ≥ 4 cm (Figure 5).

Type Ⅲb: The remaining length of the femoral isthmus is <4 cm (Figure 6).

Type Ⅳ: The proximal femur is severely defective, and only the lesser trochanter is retained, or even lost.

Type Ⅳa: The proximal femoral lesser trochanter is present (Figure 7).

Type Ⅳb: The proximal femur lesser trochanter is lost (Figure 8).

Statistical analysis

This research is a retrospective study. Owing to the rare occurrence of clinical cases and small sample size, no statistical comparison and analysis were conducted. All data presented are descriptive.

Results

A total of 29 patients, which consist of 20 males and 9 females aged 15–64 y (average age: 43.2 y), were included in this study. Of this number, 25 patients underwent a first-revision surgery, and the remaining 4 patients received a second-revision surgery. The patient counts with their corresponding types of aseptic loosening (of the distal femoral tumor prosthesis) were as follows: Type Ia, 5 patients; Type Ib, 7 patients; Type IIa, 9 patients; Type IIb, 7 patients; and Type IIIb, 1 patient. Ultimately, 24 patients underwent MSTS functional score evaluation.

The cases classified as Type Ia included 5 patients aged 15–64 y; 3 patients had osteosarcoma, and 2 patients were diagnosed with giant cell tumor of bone. Rotating hinge prostheses were used in the first operation for all patients. Biological fixation of the prosthesis stem was performed on 1 patient for the first operation, and bone cement was used to fix the other prosthesis stems. The prosthesis had been in place for 1–4 y, with an average time of 2.8 y. One patient aged 49 y used the original prosthesis for revision, and the other 4 patients used the longer-stem rotating hinge prosthesis for revision. The patient who underwent original prosthesis revision died of lung metastasis 2 y after the operation. One patient survived with lung metastasis after the operation. The other 3 patients followed up for 3–4 y had no significant limb shortening. The MSTS functional score was 27–29.

Under TypeⅡa were 9 patients aged 25–64 y; 6 of the patients were diagnosed with giant cell tumor of the bone, and 3 patients had osteosarcoma. Two patients underwent a second revision, and the other 7 patients underwent a first-revision surgery. Before the revision surgery, 3 patients used the fixed hinge prosthesis, and 6 patients used the rotating hinge prosthesis; all prosthetic stems were fixed with bone cement. The prosthesis had been in place for 4–20 y, with an average time of 9.8 y. One patient used the original prosthesis and allograft for revision, and 8 patients used the extended-handle rotating hinge knee for revision. Biological fixation was performed on 1 patient, and bone cement was conducted on the other patients. All patients survived, tumor-free. The postoperative follow-up was 2–11 y. The patients' limbs were shortened by 1–8 cm, and the MSTS function score was 21–27.

TypeⅡb consisted of 7 patients aged 38–60; 6 patients were diagnosed with giant cell tumor of the bone, and 1 patient had a malignant peripheral nerve sheath tumor. All patients underwent primary revision. Fixed hinge prostheses were used in 2 patients, and rotating hinge prostheses were used in 5 patients before revision surgery; all prosthetic stems were cemented. These prostheses had been in place for 3–27 y, with an average time of 12.3 y. Revisions were conducted using the original prosthesis in 1 patient; original prosthesis and allograft bone graft in 1 patient; the longer-stem prosthesis and bone grafting with allograft in 1 patient; and longer-stem rotating hinge prosthesis in 4 patients. Biological fixation was performed to fix the prosthetic stem in 1 patient, and bone cement fixation was conducted on the others. All patients survived, tumor-free, and were followed up for 2–11 y postoperatively. The limbs of the patients were shortened by 1–6 cm, and their MSTS functional scores ranged from 20 to 26.

The case under Type IIIb was 1 patient aged 31 y, who was diagnosed with osteosarcoma. The patient underwent reconstructive surgery with a fixed hinge prosthesis before 14 y. The knee was again revised with a longer-stem rotating hinge knee, which was fixed with bone cement. After a 10-year follow-up, the limb was found to have been shortened by 9 cm, and the MSTS functional score was 20.

Discussion

Limb salvage surgery is major surgical technique for a malignant bone tumor in the extremities [39, 40]. Currently, prosthetic reconstruction is widely used in clinical practice after tumor resection. Despite continuous improvement in the material and design of the prosthesis, the implantation failure rate of tumor prostheses remains higher than that of nontumor prostheses. Previous literature reviews showed that the 5-year survival rate of patients with knee tumor prostheses ranged from 57–93%, and the 10-year survival rate of the same was 50–88%. [1, 4, 8, 41] Aseptic loosening is a common prosthesis failure mode [8], and its occurrence may be related to age, tumor resection length, prosthetic stem size, and the biomechanical instability [9, 22–26].

Distal femoral replacement (DFR) comprises a large proportion of prosthetic replacement and is prone to aseptic loosening and revision surgery. [9, 42, 43] Aseptic loosening of DFR prostheses often results in bone absorption to varying degrees and even destruction. Consequently, residual bone mass is lost, and the proximal femur is shortened, inevitably causing challenges to revision surgery. [32, 44] Therefore, correct understanding and evaluation of bone defects after aseptic loosening are important prerequisites for revision surgery.

We reviewed the data of 29 patients with aseptic loosening and revision after DFR from 3 bone tumor diagnostic and treatment centers in China. The aseptic loosening of the distal femoral tumor prosthesis was classified by 1 expert in bone and soft tissue tumor imaging and 2 bone tumor surgeons. On the basis of the aforementioned classification, the differences in the performance of prosthetic displacement, periprosthetic bone, femoral residual bone mass, and length on X-ray, a new classification of bone defects was proposed. Under the new classification system, the defects were divided into 4 types and 8 subtypes. We also summarized the revision techniques performed on 29 patients by different types and suggested specific revisions. We hope that the proposed classification of aseptic loosening is expected to elucidate the aseptic loosening of distal femoral tumor prostheses, as well as provide a new revision strategy for DFR.

Aseptic loosening under Type Ia usually occurs shortly after surgery. The literature shows that tumor prosthesis failure has the highest incidence rate in the early stages, comprising 69% of the total within 5 y [4]. Five patients with Type Ia loosening underwent revision surgery, with a median of 3 y after surgery; of this number, 3 patients had osteosarcoma. Early loosening may be attributed to perioperative chemotherapy and extensive resection boundaries. Aseptic loosening under Type Ia has no displacement, and the bone structure around the prosthesis is normal; the revision is relatively simple and similar to the initial prosthetic replacement. Similarly, aseptic loosening under Type Ib has no displacement, but the bone around the prosthesis is absorbed and thinned. Seven patients with Type IB loosening underwent prosthesis revision, with a median of 11 y postoperatively. Although the bone around the prosthesis becomes thinner, the bone inclusivity is still complete, providing a good bone implantation environment for the prosthesis. Moreover, the bone structure in the proximal femur has a certain normal length, which can be revised by longer-stem tumor prosthesis. In Type 1 aseptic loosening, the prosthesis has no displacement, the bone defect caused by loosening is less, and the amount of bone available for fixation in the proximal femur is sufficient. Therefore, the use of original or extended stems prostheses for reconstruction should be considered in revision surgery. In addition, the use of extended stem prosthesis, combined with an autologous bone or allogeneic bone graft, may also be considered by a small number of patients with severe bone loss but no displacement of the prosthesis.

The prosthesis with Type IIa loosening showed displacement and absorption of bone absorption, but its inclusion still existed. Under this type, 9 patients underwent revision surgery, with a median of 8 y postoperatively, and the affected limbs had a certain degree of shortening. The limb shortening that can be corrected by revision surgery is limited, which should be communicated to the patient before the operation. Generally, Type □ loosening can be repaired with longer-stem prostheses. The prosthesis with Type IIb loosening showed a large displacement, and the prosthesis stem pierced the broken bone cortex. Seven patients were reported to show this type of bone defect in 11 y postoperatively. This type is usually accompanied by a bad force line and limb shortening. In this case, an allogeneic bone graft, combined with a lengthened stem prosthesis, is a more reliable approach to revision. The allogeneic bone can effectively help to fill the bone defect. Lengthening the stem can avoid the stress concentration point of the original prosthesis, as well as reduce the possibility of stem of prosthesis penetrating the cortex of bone once again. In revision and reconstruction, the longer and larger stem, combined with autogenous bone or allogeneic bone plate fixation, should be considered first for type □ aseptic loosening.

In Type □ aseptic loosening, the residual normal bone length of the proximal femur is less than 5 cm, the isthmus bone cortex is absorbed by more than 50%, and the bone cortex is fragile. This type of loosening often occurs when long segmental bone defects are reconstructed with prostheses after large segmental resection of distal femoral tumors. The reason is that the proximal end of the femur is short, the contact surface between the prosthesis stem and bone is reduced, and the holding force of the stem is inadequate. Only 1 patient was classified under Type III loosening in our study; the normal bone length of the proximal femur was less than 5 cm, and the bone defect of the isthmus was serious; thus, the defect was classified as Type □b. After the original prosthesis was removed, the prosthesis with a longer and thicker stem was implanted. Postoperative X-ray examination showed that the stem of prosthesis pierced out of the proximal femur, the limb shortening was noticeable, and the MSTS function score was 20.

The revision of type □ loosening presents a challenge; thus, a good implantation environment is necessary for the prosthesis. Currently, the commonly used methods reported in the literature are the telescope tube-like allograft prosthesis [45–47] and the Compress® Compliant Pre-stress (CPS) prosthesis [50–52]. The telescope technology was first proposed by Healey et al. [45] and succeeded allogeneic bone grafts used in reconstruction and revision. [48, 49] With telescope technology, the grafted bone and the host bone are overlapped to maximize the surface contact between the host bone and the allogeneic bone to realize a stable fixation of the distal end of the prosthesis.[45] Hindiskere et al [47] confirmed the effectiveness of telescope technology. In 14 patients with endoscopic bone allograft, the bone healing rate was 100%, and the MSTS score was 27 at the final follow-up. Another commonly used technique reported in the literature is compressive osseointegration, which uses the axial pressure between the implant and the bone surface for initial implant fixation [53]. With this approach, the large prosthesis can be fixed to a considerably short backbone segment. In addition, compressive osseointegration can effectively avoid stress shielding, which can induce bone hypertrophy and inward growth at the interface between bone and prosthesis. [52–54] CPS prosthesis can be used to repair distal femoral prosthesis with a short femoral stump and numerous bone defects. [50, 51]

In Type ▯ loosening, the bone defects have involved the lesser trochanter of the proximal femur, and the loosening of this type is rarely reported in the clinical study. Its occurrence is usually observed in the middle and late stages of prosthesis survival. This failure belongs to large-segmental or ultralong bone defects. Revision of this type of defect is challenged by three issues: (1) The bone defect is serious, and the residual bone is too short to support and fix the traditional lengthened stem prosthesis; (2) The defect area is too long, and conventional bone transplantation fails to meet reconstruction needs; (3) Severe limb shortening and unequal length of both lower limbs were observed in the late stages of unreserved epiphysis. Therefore, this revision is faced with considerable challenges, and whether to retain the hip joint determines the choice of revision. The main methods applied for the reconstruction of this kind of femoral defect include customized lateral plate locking femur prosthesis [55], 3D-printed short femoral stem prosthesis [37], and total femoral replacement [57].

Conclusion

In conclusion, the classification of the aseptic loosening of distal femoral prostheses can be used to accurately assess residual bone and bone mass in the proximal femur. Appropriate reconstruction methods for different types of bone defects can help in the revision of aseptic loosening.

Limitation

First, this study is a retrospective descriptive study. Owing to the small size of the sample, no statistical analysis was performed between groups. Moreover, the level of clinical evidence for the proposed treatment strategies is limited. Second, the classification proposed in this study is based on imaging, and the understanding of aseptic loosening is inevitably limited. Finally, although the study included clinical data from 3 bone tumor diagnostic and treatment centers, the accumulated clinical cases remain small. Moreover, some special cases may have imaging findings that cannot be classified into a certain type or subtype. In future research, large sample size is needed to verify the accuracy of this classification.

Abbreviations

MSTS
Musculoskeletal Tumor Society

DFR
Distal femoral replacement

Declarations

Ethics approval and consent to participate

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethic Committee of the 960th Hospital of the People's Liberation Army (protocol code 2020-74 and date of approval 2020/01/22). Written informed consent was obtained from all individual participants and from the legally authorized representatives or from the guardians for minors in the study.

Consent for publication

Written informed consent for publication were obtained from patients.

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to their containing information that could compromise the privacy of research participants but are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

ZWH did the study, analyzed the data, and wrote the manuscript.

MingX,KaiZ,XCY were involved in the design, data management, and analysis of the study. All authors read and approved the final manuscript.

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Figures

Figure 1

Ia The bone structure around the prosthesis is normal, and the loss of cortical bone at the proximal femur is ≤50%.

Figure 2

Ib The bone around the prosthesis is thinned, but the encapsulation is intact, and the cortical bone loss of the proximal femur is>50%.

Figure 3

IIa The prosthesis does not penetrate the cortical bone, and the loss of cortical bone at the top of the prosthesis is ≤50%.

Figure 4

IIb The prosthesis penetrates the cortical bone, and the loss of the cortical bone at the top of the prosthesis>50%.

Figure 5

a The remaining length of the femoral isthmus ≥ 4cm.

Figure 6

b The remaining length of the femoral isthmus <4cm.

Figure 7

a The proximal femoral lesser trochanter exists.

Figure 8

b Loss of the proximal femur lesser trochanter.