Clinical and Functional Outcomes using the Kyocera Modular Limb Salvage System for Lower Extremity Reconstruction

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Research article

Keywords: Clinical Outcome, Functional Outcome, Kyocera Modular Limb Salvage System, Limb Salvage Surgery

Posted Date: July 21st, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-37321/v1>

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Abstract

Background: Segmental metallic endoprostheses are widely used and important in reconstructive procedures of the lower limb. Most of the currently available endoprostheses are made in Europe or the United States of America and are too large for Asian knees. The Japanese Musculoskeletal Oncology Group developed a tumor prosthesis better suited for Asian skeletal anatomy, the Kyocera Modular Limb Salvage System (KLS).

Methods: We performed a retrospective review of the records of patients who underwent reconstruction using KLS implants. Thirty-five patients fulfilled the inclusion criteria, 20 having undergone limb salvage surgery for tumor and 15, joint arthroplasty. Functional outcomes were evaluated using the revised Musculoskeletal rating scale for the tumor group and the Japanese Orthopedic Association Knee Score for the arthroplasty group. Complications and survivorship of the implants were also assessed.

Results: At the latest follow-up, in the tumor group, 13 were alive with no evidence of recurrence, 6 died of disease, and 1 was alive with evidence of disease. The average MSTS scores on latest follow-up were 63 for the proximal femur, 67 for the distal femur, and 92 for the proximal tibia. The mean prosthesis survival was 28 months. Complications include 4 cases of aseptic loosening, 2 deep infections, 1 superficial infection, 1 valgus deformity, 2 periprosthetic fractures, 2 incidences of excessive polyethylene wear, and 2 local tumor recurrences.

In the arthroplasty group, 1 patient had a persistent low grade infection on the latest follow-up. The post-operative JOA score was 61(mean). Complications included 3 cases of aseptic loosening, 2 deep infections, 2 implant failures, 1 superficial infection, 1 valgus deformity, and 1 soft tissue defect.

Conclusion: Early results of the KLS implant system are encouraging, with comparable clinical outcomes to other systems in the literature. A longer follow-up study with increased numbers of patients is necessary to further validate the functional outcomes and prosthesis survival using the KLS system for limb salvage surgery.

Background

Segmental metallic endoprostheses are becoming increasingly important in limb reconstruction following tumor surgery and revision total joint replacement [1-2]. However, this type of reconstruction does not come without risks. Postoperative complications can occur and these include infection, aseptic loosening, joint instability, and structural and implant-related failures. [1, 3-4]

Infection, aseptic loosening and instability can be devastating complications and are considered the 3 most common causes of morbidity after primary and revision joint arthroplasty and in limb salvage surgery using an endoprosthesis [1, 5-10].

Most of the currently available endoprotheses are made in Europe or the United States of America and are designed for Caucasians patients. A problem noted with these implants is that they can be too large for Asian knees. In Japan, the Japanese Musculoskeletal Oncology Group developed a tumor prosthesis better matching Asian skeletal anatomy, the Kyocera Modular Limb Salvage System (KLS system). It is designed with a semi-rotating hinge joint with the metallic parts made of titanium alloy [11].

The purpose of this study is to evaluate the clinical and functional outcomes and complications of using the KLS system implants for limb salvage surgery and in primary and revision joint arthroplasty.

Methods

A retrospective review of the records of patients who underwent reconstruction using the KLS implants was done. Data were obtained from the computer database of the Department of Orthopedic Surgery, Kanazawa University, Japan. This study was approved by the Institutional Review Board of the Kanazawa University Hospital, Kanazawa, Japan, and this study complied with the ethical standards outlined in the Declaration of Helsinki

Patients who underwent reconstruction using the KLS system implant (whether for reconstruction after limb salvage surgery or for primary/revision arthroplasty) and with at least 1 year follow-up were included in the study. All patients underwent surgery by the Department of Orthopedic Surgery at Kanazawa University Hospital.

Over a period of 5 years (2008-2013), a total of 48 patients underwent reconstruction using titanium implants. We limited our study, however, to those who specifically underwent reconstruction using the KLS endoprosthesis. Thirty-five patients fulfilled the inclusion criteria, 20 from limb salvage surgery and 15 from arthroplasty, and were assigned to the Tumor or Arthroplasty group for analysis.

Complications for both groups were assessed. Functional outcomes were also evaluated using the revised Musculoskeletal Tumor Society (MSTS) Score for the tumor group and the Japanese Orthopedic association (JOA) score for the arthroplasty group [12-13]. Range of motion (ROM) was documented using a basic goniometer.

Survivorship of the KLS implant was also evaluated. Implant failure was defined as one requiring an unplanned revision of a failed portion of the prosthesis, a periprosthetic fracture needing fixation, soft-tissue reconstruction needed to restore joint stability, and endoprosthetic removal without revision and amputation [1].

Shirai et.al. [14] reported the efficacy and antimicrobial properties of the iodine coated titanium implants; all the KLS implants in this study were iodine coated to deter or treat periprosthetic infection.

Results

A total of 35 patients were included and evaluated in the study (Table 1).

Tumor Group

The most common indication for reconstruction using the KLS system in the tumor group was osteosarcoma and the most common bone involved was the distal femur (Table 1). Nine patients underwent wide excision and immediate reconstruction using the iodine coated KLS endoprosthesis and 11 underwent a two-staged revision, with the initial surgery being a wide excision and reconstruction using other techniques (recycled bone by liquid nitrogen freezing and reconstruction with either an intramedullary nail, plate, or non-iodine coated endoprosthesis) and then a second stage revision using the iodine coated KLS endoprosthesis from complications from the index surgery (6 infections, 2 local recurrences, 1 periprosthetic fracture, 1 nonunion and collapse of lateral condyle and 1 implant failure). Eight patients underwent cemented fixation while 11 patients received the cementless type of KLS implant. One patient underwent total femur replacement.

On the latest follow-up, 13 were alive with no evidence of recurrence, 6 died of disease, and 1 was alive with evidence of disease. The average MSTS scores on latest follow-up were 63 for the proximal femur (range: 40 to 100), 67 for the distal femur (range: 40 to 100) and 92 for the proximal tibia (range: 80 to 100). Mean ROM was 1 to 87° flexion arc (range 0-10 degrees extension and 45-120 degrees flexion) for the knee and 90 degrees flexion, 60 degrees abduction, 0 adduction and 0 external rotation for the hip. The mean prosthesis survival was 28 months (range: 12-56 months).

Modes of failure for the Tumor group are summarized in Table 2. Ten revisions of the iodine coated titanium implant were done to treat these complications (3 cases of aseptic loosening, 2 deep infections, 1 valgus deformity, 2 cases of excessive polyethylene wear, 1 local tumor recurrence). For the two patients who had local recurrence, one underwent total femur replacement for a local recurrence of a distal femur osteosarcoma and the other one underwent hind quarter amputation due to a diffuse local recurrence of the distal femur osteosarcoma. The limb salvage rate was 95% (19/20).

Arthroplasty Group

The knee was the affected joint in all patients. Three patients underwent immediate reconstruction using the iodine coated KLS endoprosthesis after undergoing debridement and application of cement spacer as an index surgery (2 TB arthritis and 1 osteomyelitis) and 12 patients underwent 2-stage revision, the index case being total knee arthroplasty, which became infected and required revision using iodine coated KLS endoprosthesis after the initial infection was controlled. Five patients had cemented implants and 10 had the cementless type of the KLS prosthesis.

At latest follow-up, 14 patients were infection free and 1 had a consistent low grade infection (suppressed with oral antibiotics). Post-operative JOA score (mean) was 61 (range: 30 to 85) and mean ROM was 3 degrees to 81 degrees of knee flexion (range: 0 to 30 degrees extension and 40 to 105 flexion). Mean prosthesis survival was 27 months (range: 12 to 62 months).

Modes of failure for the Arthroplasty group are summarized in Table 3. Two of the three cases of aseptic loosening were at the side plate and screws of the cementless KLS implant. Five revision surgeries were necessary to treat these complications (2 cases of aseptic loosening, 2 implant failures and 1 infection)

Discussion

Segmental metallic prostheses have several advantages over biologic reconstruction in limb salvage surgeries, which include initial reliability with lower complication rates, ready availability and immediate stability allowing rapid return to full weight bearing with predictable function. However, long term risks for infection, local tumor recurrence, aseptic loosening, and implant failure are significant concerns for tumor surgeons [15].

Implant-related complications are still common in Orthopedic surgery and pose a serious problem. Several innovations were developed to counter or minimize these complications. One of these is the development of an endoprosthesis better matched to Asian knees by the Japanese Musculoskeletal oncology group. Nakamura et. al. [11] reported that the average MSTS score for the KLS system was 21.8 (72.5%). The complication rate was 34% (28 out of 80 patients), infection rate 8.5% (7 out of 82) and aseptic loosening rate 6% (5 out of 82). In another study, Tome et. al. [16] investigated the clinical outcome of the KLS system for malignant bone tumors of the femur. The 3 year prosthesis survival rate was 87.5% and the 5 year survival rate was 58.3%. The mean MSTS score was 81% and no prosthesis-related complications were noted.

This implant was further improved by coating it with iodine to prevent and/or treat periprosthetic infection. Tsuchiya et.al. [17] performed a clinical trial on the efficacy and safety of the iodine coated implants. A total of 222 patients with postoperative infection or compromised states were treated using iodine coated titanium implants. The mean age was 49 and the mean follow-up was 18 months. Iodine coated implants were used in 158 patients to prevent infection and 64 patients to treat active infections. In the prevention group, 3 (1.9%) patients developed infection, however, all 3 recovered without implant removal. In the treatment group, infection was eliminated in all patients. Despite using iodine coated implants, no abnormalities related to the thyroid gland were detected and good bony ingrowth was noted.

In our series, the most common complications for both groups were infection and aseptic loosening, which are consistent with published reports [1, 5-10].

It is reported that the infection rate after primary total joint replacement ranges from 0.2% to 4% [5, 7, 18]. For revision total joint arthroplasty, the risk of infection was 10-fold higher than for patients undergoing primary total knee arthroplasty [7]. In one study, the incidence of infection after revision joint surgery was 46% [6].

In our series, the infection rate after revision total knee arthroplasty was lower, 17% (2 of 12) and only one patient required removal of the implant for re-revision. All of the single-staged reconstruction patients were infection free at latest follow-up.

In limb salvage procedures, the infection rates are higher because patients are often immunocompromised. These patients undergo long and complex reconstructive procedures, often with large areas of dead space created after removal of bone and soft tissue, and have large wounds that often lack soft tissue coverage [19]. The incidence of infection after limb salvage surgery and endoprosthesis reconstruction ranges from 1% to 36% [20].

In a multicenter study reviewing the modes of failure after using an endoprosthesis for tumor reconstruction, Henderson [1] et al. reported that infection is the most common cause of failure after surgical reconstruction with an incidence of 34%. In our series, the infection rate was 10% (2 of 20 cases). Both patients required removal of the implant and revision using an iodine-coated endoprosthesis.

The incidence of aseptic loosening after primary joint arthroplasty ranges from 19% to 31%, and for revision arthroplasty, it was reported to be 19% [6, 10]. Contributing factors for loosening include patient specific factors (e.g. activity level, body mass index and body weight, gait mechanics, etc.), surgeon specific factors (e.g. surgical approach, component positioning, soft-tissue balancing, etc.) and implant specific factors (e.g. implant design, material, bearing couples, etc.) [21]. For limb salvage surgery and reconstruction using a tumor endoprosthesis, the incidence of aseptic loosening ranges from 5% to 27% [20]. Factors contributing to aseptic loosening of tumor endoprostheses include the extended length of the prosthesis and constrained joint design, both of which create high bending stresses at the prosthesis-bone interface [1].

The incidence of aseptic loosening was 20% for both our study groups and was within the reported incidence [6, 10, 20]. All cases of aseptic loosening were noted in the cementless KLS prosthesis subgroup. Most of the causes of aseptic loosening in our series were attributed to the side plates/screw fixation of this implant; 1 of 4 in the tumor group and 2 of 3 in the arthroplasty group. The femur is not tubular over its distal aspect and the endoprosthesis side plate follows this tapered end of the distal femur. The cortical fixation by the screws, however, is not rigid enough to maintain the straight side plate compressed along the cortical taper of the distal femur and combined with a high stress area; micromotion occurs at this interface postoperatively. This usually happens before any bony in-growth occurs thus, loosening results (Figure 1).

For the tumor group, the mean MSTS scores were 63 for the proximal femur, 67 for the distal femur and 92 for the proximal tibia and it is comparable to average reported MSTS from the literature (60%-90%) [11,20]. The best results were noted in patients who underwent proximal tibia reconstruction with the worst being in the proximal femur. These results are consistent with the study done by Gosheger et.al [22]. The 2 year prosthesis survival in our study was 79%. In the literature, reported 5 year survival of the lower extremity prostheses ranges from 69% to 87% [16, 20]. Currently, it is difficult to compare our results to published reports because of our short follow-up.

In the Arthroplasty group, the post-operative mean JOA score was 61 and the 2 year prosthesis survival was 84%. At present, there are no available reports on functional outcomes of the KLS system used for non-tumor cases.

No knee instability was noted in either group on the latest follow-up. This may be attributed to the constrained design of the KLS implant. Constrained knee prostheses provide great inherent stability to the knee by means of a link between the femoral and tibial components which prevents varus-valgus and translational stresses [2].

Limitations of our study include the small number of patients studied and the limited follow-up. To more accurately determine the functional outcomes and prosthesis survival, an increased population size and longer follow-up are needed.

Conclusion

Early results using the KLS implant system are encouraging, with comparable functional and clinical outcomes to those reported in the literature. The cementless type of distal femur implant may have a higher incidence of aseptic loosening compared with the cemented type. A long term follow-up study and increased number of patients are necessary to further validate the functional outcomes and prosthesis survival using this system for limb salvage surgery.

Declarations

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of the Kanazawa University Hospital, Kanazawa, Japan, and this study complied with the ethical standards outlined in the Declaration of Helsinki. Written informed consent was obtained from all participants.

Consent for Publication

Written informed consent was obtained from all participants.

Availability of Data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

Not applicable

Author's Contribution

DAR, YA, TH, AHA and HK collected and organized the data and helped in the analysis of the data. DAR, KH, NY, TS, AT, and HT analyzed the data and help edit the manuscript. DAR wrote the manuscript. All authors read and approved the final manuscript.

Acknowledgement

Not Applicable

Abbreviations

JOA score – Japanese Orthopedic Association score

KLS system – Kyocera Modular Limb Salvage System

MSTS score Musculoskeletal Tumor Society score

ROM – Range of Motion

TB arthritis– Tuberculous Arthritis

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Tables

Table 1 - Summary of Demographics for the Tumor and Arthroplasty Group

	Tumor Group (N=20)	Arthroplasty Group (N=15)
Gender	Male = 12 Female = 8	Male = 7 Female = 8
Mean Age	44 (16 to 80 years old)	73 (49 to 85)
Mean Follow-up	39 months (12 to 73 months)	28 months (13 to 62 months)
Diagnoses	Osteosarcoma = 14 Malignant Fibrous Histiocytoma = 2 Metastatic Bone Disease = 2 (Breast Cancer and Renal Cell Carcinoma) Giant Cell Tumor = 1 Desmoplastic Fibroma = 1	Degenerative Osteoarthritis = 9 Tuberculous Arthritis = 2 Septic Arthritis = 1 Rheumatoid Arthritis = 1 Osteomyelitis = 1 Previous trauma = 1
Affected region	Proximal Femur = 6 Distal Femur = 10 Proximal Tibia = 4	Knee = 15

Table 2 - Summary of Failure Modes for the Tumor Group

Mechanical Complications	(N)
Aseptic Loosening	4
Valgus Deformity	2
Periprosthetic Fracture	2
Excessive Polyethylene wear	2
Nonmechanical Complications	
Deep Infection	2
Local Recurrence	2
Superficial Infection	1

Table 3 - Summary of Failure Modes for the Arthroplasty Group

Mechanical Complications	(N)
Aseptic Loosening	3
Implant Failure	2
Valgus Deformity	1
Nonmechanical Complications	
Deep Infection	2
Soft Tissue defect	1
Superficial Infection	1

Figures

Figure 1

Aseptic Loosening of Uncemented KLS Tumor prosthesis