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Early Mechanical Failure of a Tumoral Endoprosthesic Rotating Hinge in the Knee: Does Bumper Wear Contribute to Hyperextension Failure?

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Abstract

Background Tumor surgeons use a variety of endoprosthetic designs for reconstruction after bone tumor resection. However, functional results and implant survival have not been evaluated for each design. Because the outcomes and failure modes (for example, implant breakage, loosening) may differ between prosthetic design types, it is important to examine the problems associated with different designs. Because of experiences in our practice, we became concerned about a surprisingly high frequency of device breakage with one particular design, and we wished to report on that experience.

Question/purposes (1) In a small series of patients, what proportion of a particular design (Zimmer® Segmental [Zimmer Inc, Warsaw, IN, USA]) of rotating-hinge endoprosthesis experienced implant breakage at short-term follow-up? (2) What patient symptoms were associated with this finding? (3) What is the function as assessed by Musculoskeletal Tumor Society (MSTS) score with the use of this implant before and after revision?

Methods We treated 87 patients in our tertiary center from 1987 to 2014 who had sarcomas around the knee with wide resection and reconstruction with tumoral endoprosthesis; five patients were lost to follow-up. In all, 33 of the remanining 82 prostheses, treated from 1987 to 2006, were reconstructed with fixed-hinge designs. From 2006 to 2014, 49 patients were reconstructed with a knee endoprosthesis, and 48 of them had a rotating-hinge prosthesis. In our center, we mostly used four designs: 16 of 49 patients were reconstructed with GMRS™ (Stryker Howmedica, Kalamazoo, MI, USA), seven received the LPS™ (DePuy Synthes, Warsaw, IN, USA), 20 of 49 had the METS (Stanmore, Hertfordshire, UK), and six of 49 received the Zimmer Segmental. The focus of this report is on the six patients with the Segmental. We retrospectively gathered clinical and radiologic data from these six patients' records and we assessed radiographic images. We evaluated function with the MSTS score of the 49 patients.

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All the authors have read and agree with the content of the manuscript.
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The median follow-up duration of the Segmental prosthesis reconstruction was 65 months (range 24 to 85).

Results Three of the six patients had posterior instability and recurrent joint effusion on physical examination. Three patients who did not have hyperextension presented with restricted knee ROM. Six revision procedures were performed in three patients. The median MSTS score at 6 months for the Segmental® prosthesis was 15 of 30 (range 6 to 24). The score in the three patients who had posterior instability was 9 of 30 (range 6 to 15) and it improved to median 25 of 30 (range 19 to 30) 6 months after revision. The patients with the Segmental® prosthesis who did not undergo revision had a median MSTS score of 20 (range 16 to 24).

Conclusions The Zimmer Segmental rotating-hinge tumoral prosthesis underwent revision for implant breakage at short term in three of six patients after tumor resection and reconstruction of the knee. Bumper breakage was associated with posterior instability that was related to wear of the bushing blocking system. We are unaware of reports of these issues by other observers or in other prosthetic designs, but we feel larger registries should be created to see if this failure mechanism has been observed by others. If so, this design needs to be improved or the blocking system should be avoided.

Level of Evidence Level IV, therapeutic study.

Introduction

Bone defects after tumor resections have been reconstructed with a wide range of methods. The three principal reconstruction methods are bone allografts [3, 15, 16, 22], endoprostheses [4, 8], and allograft-prosthesis composites [5]. Tumoral endoprostheses became popular reconstruction methods after chemotherapy was introduced for sarcomas; they allow for limb-sparing surgery [11, 19] because they permit rapid weightbearing and surgeons do not have to depend on the availability of bone grafts. The first implants were custom-made and were manufactured during neoadjuvant chemotherapy. Today, most endoprostheses in the extremities are modular [21]. Modular implants allow surgeons to intraoperatively select an appropriate prosthesis length that matches the length of resection. In practice, these prostheses are a useful reconstruction method after sarcoma resection [8, 20, 9]. The survival rates of modular endoprostheses of all locations, excluding those with local recurrence, are 76% to 80% at 5 years [4, 12, 19, 23] and around the knee 70% to 80% at 4 years to 5 years [3, 18]. More recent implant designs have included a hydroxyapatite coating between the modules (body segments) and stem, to seal the bone, as well as the stem interface and rotating hinges [2, 17]. Infection is a major reason for revision (6% to 34%) in the early years after implantation, and it has a cumulative risk of about 1% per year that persists during the life of the prosthesis [20, 21]. Aseptic loosing is the main reason for long-term revision, with a revision rate of 25% at 10 years [12, 13], which increases to 35% to 37% in the knee prosthesis. In their classification, Henderson et al. [11] defined Type IIIA mechanical structural prosthesis failure complications as the breakage or wear of implant components. Although this complication is less common, occurring in 12% to 17% of failed protheses, it is of great concern in young patients [3, 17, 20]. Because of experiences in our practice, we became concerned about a surprisingly high frequency of device breakage with one particular rotating-hinge endoprosthesis design, the Zimmer® Segmental (Zimmer Inc, Warsaw, IN, USA], and we wished to report on that experience.

In our study, we asked: (1) In a small series of patients, what proportion of a particular design (Zimmer Segmental [Zimmer Inc, Warsaw, IN, USA]) of rotating-hinge endoprosthesis experienced implant breakage at short-term follow-up? (2) What patient symptoms were associated with this finding? (3) What is the function as assessed by Musculoskeletal Tumor Society (MSTS) score with the use of this implant before and after revision?

Patients and Methods

This is a retrospective case series that drew data from a hospital-based longitudinally maintained registry at our institution that has been maintained since 2006. The ethics committee at our institution approved this study.

From 1987 to 2014, we treated 87 patients with sarcomas around the knee with wide resection and reconstruction with tumoral endoprosthesis in our tertiaty center. Five patients were lost to follow-up. From 1987 to 2006, 29 of 82 patients were reconstructed with fixed-hinge prostheses. In 2006, we started a hospital registry and from 2006 to 2014, 49 endoprosthesis implants about the knee after tumoral resection were included, of which 48 were rotating-hinge prostheses. In our center, we used four different types of rotating-hinge designs: 16 patients were reconstructed with GMRS™ (Stryker Howmedica, Kalamazoo, MI, USA), seven received the LPS™ (DePuy Synthes, Warsaw, IN, USA), 20 of 49 received the METS (Stanmore, Hertfordshire, UK), and six of 49 received the Segmental prothesis. We started using the Segmental prosthesis because in our hospital system, it seemed an effective and more economical option for endoprosthesis knee reconstruction. We discontinued its use when we had the first bumper breakage episode.

The Segmental prosthetic system is a rotating hinge prosthesis (Fig. 1A) designed to replace bone defects after

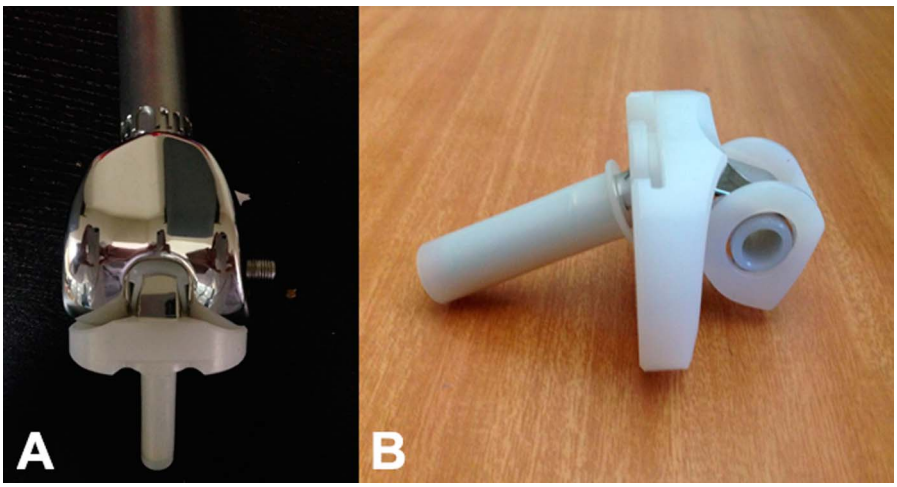

Fig. 1 A-B This image shows the anteroposterior view of the Zimmer® Segmental System (Zimmer Inc, Warsaw, IN, USA) rotating hinge prosthesis blocking system. (**B**) This lateral view of the central post of the Segmental prosthesis shows the polyethylene bumper.

tumor resection with modules manufactured in titanium alloy and articular surfaces in cobalt-chromium-molybdenum alloy. It is modular and has a unique central post with a height of 40 mm to avoid dislocation and allow rotating movements and a bumper around the post to avoid hyperextension (Fig. 1B).

The median follow-up period was 65 months (range 24 to 85), and no patients with a Segmetal implant was lost to follow-up. One patient died of disease 24 months after surgery.

We included patients older than 18 years who underwent surgery at our center and had a bone tumor near the knee. The exclusion criteria were revision surgery, radiotherapy, and a final implant that was different from the Segmental prosthesis. The low number of patients is because we discontinued using this implant after the first episode of implant breakage. Unlike the bumper on other rotating-hinge designs, this implant system has a central bushing to block hyperextension. All patients were individually evaluated in a multidisciplinary meeting and underwent surgery after a histologic diagnosis was made.

Three of six patients underwent neoadjuvant treatment (Table 1). The operating team was the same for all six patients, and there were no intraoperative complications. The resection type was intraarticular in five patients and extraarticular in one. The median length of bone resection was 18 cm (range 12 to 42). The margins were wide in all patients. The implants were cemented in the femur and tibia in four patients; in one, the implant was cemented in the femur and tibial plateau but not in the tibial stem. One patient was treated with uncemented implants because she was young and had a long estimated survival (Table 2). We used intraoperative and postoperative antibiotic prophylaxis of cefazolin 1 g every 8 hours until we removed drains. Patients were permitted to sit 3 days postoperatively and were allowed to walk with crutches 1 week postoperatively. The patient who underwent

Table 1. Epidemiologic data of the cases included in the study

Patients	Diagnosis	Location	Age (years)	Time to failure (months)	Adjuvant therapies	Tumor Volumen (cc)	Length of resection (cm)	BMI (kg/m^2)	Enneking stage
1	OS	Distal femur	18	16	No	60	19	23	IIB
2	GCT	Distal femur	25	60	No	120	14	26	3
3	OS	Distal femur	16	14	CT	616	23	24	IIB
4	OS	Distal femur	26	NF	CT	1050	42	19	III skip
5	OS	Distal femur	36	NF	CT	240	14	22	IIB
6	Renal cancer	Proximal tibia	59	NF	No	56	12	23	III

OS = osteosarcoma; GCT = giant cell tumor; NF = no failure; CT = chemotherapy; BMI = body mass index.

extraarticular resection and proximal tibia resection wore an external orthosis for 8 weeks. The rehabilitation program was the same in all the patients with knee endoprostheses, and it started at hospital. After hospital discharge, they were included in an outpatient rehabilitation program with follow-up monitored by a rehabilitation physician. Patient 1 underwent an extraarticular resection and had a patellar tendon avulsion that was treated with an orthosis for 3 months. Patient 6 developed the only postoperative wound problem. This patient did not undergo further surgery; the issue resolved in 2 weeks with wound care without antibiotics (Table 2.).

We extracted demographic and clinical variables (age, gender, histologic diagnosis, stage, grade, and location of disease) and clinical and radiologic data (tumor size, margins, local recurrence, metastasis, and loosening, mechanical changes) from clinical records and images and evaluated function at regular follow-up visits. The visits were scheduled every 3 months for 2 years and included a chest CT and ultrasonograph in patients with sarcoma to look for distant and local recurrence as well as plain radiographs to monitor the reconstruction. Between 2 years and 5 years, the oncological and mechanical condition was checked every 6 months. Between 5 years to 10 years postoperatively the patients had annual visits. The preoperative and postoperative function was measured with the MSTS score [6], and failure was classified according to the Classification of Limb-sparing Reconstructions [7]. The endopoint of the study was revision. Our indication to revise the prosthesis was clinical evidence of posterior instability. We defined mechanical hinge failure as evidence during revision surgery of the enlargement of the central hole or the breakage of the central post polyethylene that causes the malfunction of the posterior bumper.

Results

Three of the six patients with Segmental prostheses underwent one or more revisions. The median time to failure was 30 months (range 14 to 60). At the time of revision procedure, we noted wear of the central post polyethelene (we noted one case of breakage in the second revision of the first patient) without other findings. We removed and changed this bumper to repair the hyperextension blocking system (Fig. 2). The wear of the polyethylene occurred three times in Patient 1 and twice in Patient 2. Two failures were treated with a bumper revision, and one was treated with a complete prosthesis revision to a MUTARS® Distal femur (MK Implantcast, Buxtehude, Germany). The median time to failure was 30 months (range 14 to 60).

The main symptom among the three patients who experienced implant breakage was hyperextension instability noted on examination and by the patient (Fig. 3). The first symptoms of early failure were anterior knee pain and recurrent joint effusion. On physical examination, three patients had posterior instability; a fourth patient had instability but refused revision. The clinical observation showed a short-stance phase of the operated limb during walking, and the patients needed one or two crutches to walk long distances. The three patients who did not have instability had restricted knee ROM, at a median (range) of 10° (5 to 20) (Table 3). The median (range) ROM with other implants in our center was 95° (30 to 130). We did not see radiologic signs other than knee hyperextension on radiographs. Nevertheless, in the early postoperative phases, all patients had anterior pain, and ultrasonography studies showed patellar tendon thickness and inflammation. One patient had 10° of rotational malposition and an inferior patellar fracture that was identified and treated nonoperatively with an orthosis for 2 months.

The patients who were operated on in our center and reconstructed with endoprostheses other than Segmental had a mean (range) postoperative MSTS score at 6 months of 25 (12 to 29). The MSTS score at 6 months in the patients with the Segmental prosthesis was mean (range) of 15 of 30 (6 to 24). The mean (range) preoperative MSTS score in the patients who had posterior instability was 9 of 30 (6 to 15); the mean (range) postoperative score in these three patients improved to a mean of 25 of 30 (19 to 30) 6 months after revision. During the follow-up period, one

Table 2. First surgery data

Patients	Resection	Reconstruction	Surgical complications	Complication treatment
1	WR ea	Cemented femur plus hybrid tibia	Wound problem without infection	Wound care
2	WR ia	Not cemented	No	No
3	WR ia	Cemented femur plus hybrid tibia	No	No
4	WR ia	Complete femur plus hybrid tibia	No	No
5	WR ia	Cemented femur plus hybrid tibia	No	No
6	WR ia	Cemented	Wound problem	Antibiotic therapy, no surgery

WR ea = wide resection extraarticular; WR ia = wide resection intraarticular.

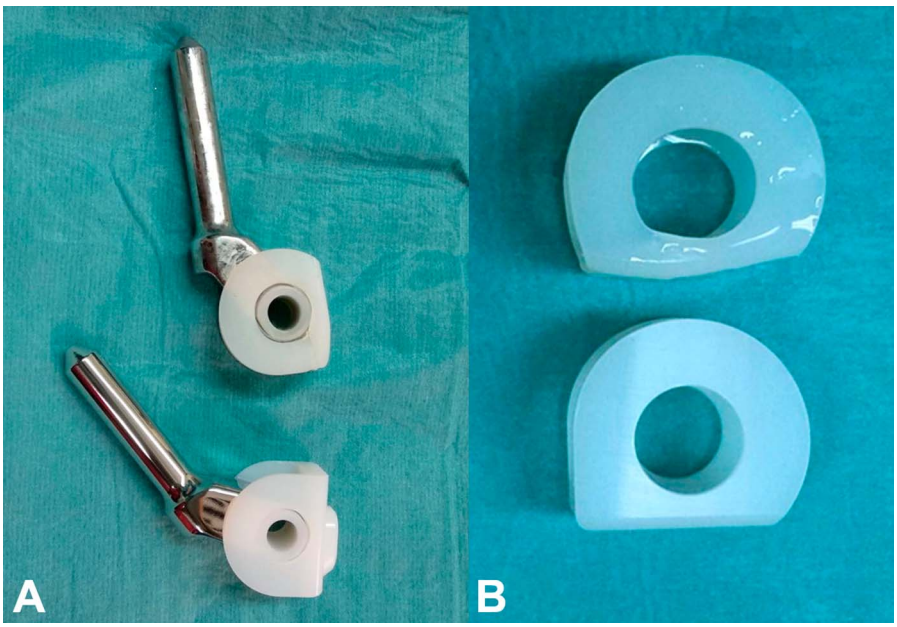

Fig. 2 A-B These images show the difference between the polyethylene bumper in revision surgery compared with a new implant without wear. We can also observe the enlargement and deformation of the hole.

patient (Patient 4) died of the disease, and one patient had a local recurrence with a wide-resection and is live with the disease. In our series, six of 42 patients with other designs had to be revised before 5 years: three for early infection, two for local recurrence, and one for early aseptic loosening, which occurred 50 months postoperatively.

Discussion

Numerous endoprosthetic designs are in common use for patients undergoing segmental tumor resections around the knee. The rotating hinge designs have different mechanisms to allow platform rotation but avoid hyperextension. One is a central post that fits inside the tibial implant that has a polyethylene-bearing surface between the post and implant that is fixed with a hinge to the femur. The tibial stem allows the rotational movement (this is the case for the LPS, the GMRS, and the Segmental). The second mechanism, designed by MK Implantcast, consists of a metal ball that is inserted in the femoral component and screwed to the tibial component [3]. There are several mechanisms to avoid hyperextension in the prostheses that include a design with a central post. The bumper system of Segmental prosthesis is different from the other designs. It has a central polyethylene bushing that avoids hyperextension at the proximal side of the central post (Fig. 2A-B). Although there are studies about survival and the causes of revision, prosthesis survival in the knee, and survival of popular implants such as the GMRS and MUTARS [3, 18], we could not find publications about

Fig. 3 Lateral picture showing clinical instability in a patient with a left distal femur Zimmer® Segmental (Zimmer Inc, Warsaw, IN, USA) endoprosthesis.

Table 3. Treatment results: functional and oncological

Patient	Signs	Imaging findings	ROM	Revision	MSTS score	MSTS score 6 months postoperatively	Number of revisions	Complications in follow up	Treatment	Oncological status at the end of treatment
1	Recurvatum Recurrent knee effusion	26° tibial internal rotation US: patellar effusion	0 to 120°	PE revision x 2 Prosthesis revision	15	30	3	Patellar fracture	Orthosis	Alive without disease
2	Recurvatum	US: patellar effusion	0 to 120°	PE revision	6	19	2	Local recurrence	Wide resection	Alive without disease
3	Recurvatum	US: patellar effusion, sinovitis	0 to 100°	PE revision	6	22	1	No complications	No	Alive without disease
4	[a]Subjective instability in stance phase	No	10 to 30°	No	19	[a]	0	Pelvic metastasis	Hemipelvectomy	Died of disease
5	No signs	US: patellar effusion	30 to 60°	No	22	[a]	0	No complications	No	Alive without disease
6	No signs	US: patellar effusion	10 to 90°	No	23	[a]	0	Humeral pathological fracture	Marginal resection	Alive with disease

[a]No data after revision; US = ultrasonography; PE = polyethylene of the post; MSTS = Musculoskeletal Tumor Society.

the long-term result of these implants with an extension blocking system similar to the Segmental prosthesis. The control of the design has previously been addressed for some implants such as the Kotz Prosthesis (KMFTR®, Howmedica, Kiel, Germany). In this implant, a poorly designed bearing polyethylene shift of knee modular endoprostheses leads to early revision surgery. This insert was changed in later designs [10, 18]. Additionally, the Stanmore total knee prosthesis was constructed of pure titanium in the initial design. These stems were fraught with high fracture rates [1] and the manufacture was changed afterwards. We detected early symptoms of instability in three of the six patients in whom we used this design and are reporting our concerns with this prosthesis design.

There were several limitations to our study. One was the low number of patients. However, the high proportion (three of six) who underwent premature revision for similar kinds of implant breakage caused us to feel this was important to report. We also encountered some possible patient-specific factors, such tumor size or extraarticular resection (occurred in one patient). Even though we did not have enough patients to perform a statistical analysis, the mean MSTS, ROM, and revision operations are higher compared with other endoprosthesis designs and with similar indications. Additionally, we have no comparison group to assess whether other prosthetic designs are associated with similar failure rates. However, we are not aware of any similar reports, and although implant breakages have been reported with other designs [1, 6, 7, 10], we have not seen this problem in such high proportion in our practice with other devices, so we feel that calling attention to our findings might be valuable to others.

We noted failure in the bushings of these prostheses in three of our six patients, and all of these patients underwent surgical revision. The mean time to revision was 30 months. This time to revision is shorter than reports of other implant breakage as Hauer et al. [10] (7 years) but similar to Myers et al. [16]. Two of them had more than one procedure and each revision procedure showed the central post bumper wear or breakage as the only problem. This polyethylene breakage is greater than the mean mechanical breakage in other prosthesis designs, which have been previously reported as 12% to 17% [3, 16-20] and it may be associated with the polyethylene; in the three patients in which we revised the polyethylene, the instability returned. As we saw in the first patient, the patient may undergo another revision if we do not revise the entire prosthesis; however, longer follow-up is needed to confirm that finding.

Four patients had pain and symptoms of instability and three presented with a hyperextended knee. These symptoms were less severe in three patients, who had restricted ROM. The initial instability may have prevented successful rehabilitation and may be the cause of reduced knee movement in these patients, but we evaluated too few patients to be sure. The three patients without contracture presented with hyperextension instability, anterior pain, and abnormal gait in the short-stage phase, and they needed one or two crutches to walk long distances. On physical examination, we observed posterior instability with frequent joint effusion and patellar tendon tenderness. Other authors [7] observed instability that resulted in revision with rotating-hinge prostheses, but the problem was the implant yoke breakage before revision. We propose that the cause is wear the blocking bushing system, which prevents genu recurvatum. This was confirmed in the operating room (Fig. 1). Replacing the bushing system was studied in other designs (METS); it is not rare in primary endoprostheses (3% of rotating hinges undergo revision), but it usually does not occur before 2 years [7]. The revision after the bushing wear occurs after a long, slow functional deterioration whereas the stem breakage seen in the Kotz prosthesis causes a sharp functional decline without symptoms to suggest breakage.

The median function of Segemental prosthesis appeared to be inferior to the median MSTS scores we observed from other reconstructions performed in our center although we cannot document this by statistical analysis because of small numbers of patients. Four patients had low MSTS scores mostly due to instability, but the remaning two patients had reduced ROM, one of them had pain and both had an MSTS score less than the median in observed in our center. All three patients who underwent surgical improved, suggesting that the posterior blocking system wear was the main cause of the symptoms. Patient 1 underwent extraarticular resection, which is associated with greater instability because the extent of resected soft tissues that might have contributed to earlier polyethelene wear through greater stress on the polyethylene bushings. There are reports of other mechanical implant failures such as the KMFTR. With this prosthesis, the functional scores were not worse in those that had implant breakage (stem fracture) compared with those that did not fail [10]. We did not find another study reporting on posterior instability in patients with tumor prostheses, but Lee et al. [14] reported on a failure of a Segmental revision knee prosthesis; signs of instability were seen in this patient, similar to our patients. We think it is important to be aware of this type of problematic wear in patients who have this implant and avoid using this blocking system in new patients.

In our experience, the Segmental rotating-hinge tumoral prosthesis failed in three of the six patients because of posterior instability. Instability appears to be related to

wear of the bushing blocking system, which prevents hyperextension. This type of mechanical failure, when detected, can be treated by prosthesis revision, and we have elected to discontinue using this blocking system in rotating-hinge endoprostheses. We feel it is important to report these patients with complications and encourage the creation of a endoprosthesis national registry to highlight this and other failure modes with the hope that if others are experiencing similar implant-related complications, they might likewise report it. If others are observing the breakage we report, a redesign of this mechanism might be considered.

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