대 한 골 관 절 종 양 학 회 지
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탄력성 있는 골수강 내고정물과 회전경첩형 슬관절 전치환물을 조합한 종양인공관절로 자가골의 골 용해를 감소시킬 수 있는가?

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목적: 슬관절 주위에서 탄력성 있는 골수강 내고정물과 회전경첩 슬관절 전치환물을 이용한 재건술이 종양인공관절과 자가골 경계부위의 골 흡수를 억제할 수 있는지를 35례에서 분석하였다.

대상 및 방법: 재건 술식은 다음과 같다. 1) 종양 절제, 2) 근위부나 원위부의 골수강에 다수의 Ender 정 삽입, 3) Ender 정과 Endo-Link 형 슬관절 전치환물을 강선 과 골 시멘트를 이용하여 결합

결과: 평균 추시기간은 53개월(30~79개월) 이었다. 최종 추시 상 29명의 환자가 가동관절을 유지하였다. 장관골 길이의 40% 이상을 절제한 군에서 종양인공관절과 자가골 경계부위 골질의 비후가 나타났다(p=0.028). 내고정 금속정의 파괴가 8례 있었으며, 조기 및 지연 감염으로 8례의 내고정물을 제거하였다. 본 재건술의 생존율은 6년에 33%였다. Musculoskeletal Tumor Society System 평가 법에 따른 기능적 결과는 26.8(89.3%)였다.

결론: 본 술식의 단-중기적 결과는 양호하였으며 합병증 발생시 재수술이 매우 용이하였다. 본 술식에서 관찰된 종양인공관절-자가골 이행 부위의 골 비후 소견은 추후 더 연구해 볼 문제로 생각된다.

색인 단어: 악성골종양, 종양인공관절, 재건술

Introduction

Endoprosthetic reconstructions for the bone tumor around knee provide an effective and reasonable option by allowing immediate weight bearing, the maintenance of joint mobility, and an early return to daily activities[1,12].

Custom made prostheses, which have been superseded, were problematic in terms of delivery and an inability to meet changing operative conditions. The introduction of the

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modular type prosthesis, has popularized the limb salvage procedures and given surgeons operative freedom.

There are two types of endoprosthetic knee joint mechanism. However, the fixed hinge joint is reported to have a high rate of stem loosening and hinge mechanism failure[2,11]. On the other hand, the rotating hinge design is said to produce superior functional results and its rotational laxity reduces forces and moments across the joint component. Moreover, this design is believed to reduce stem micromotion, and thus, to be less prone to loosening[5,8,10,12].

Nevertheless, the rotating hinge design does not appear to reduce the host bone-prosthesis junctional osteolysis. We hypothesized that a combination of a rotating-hinge total knee device and long flexible intramedullary fixation would minimize stress shielding and possibly prevent junctional osteolysis.

We asked these two questions: 1) Does the rotating hinge-flexible intramedullary nail composite alleviate junctional osteolysis? 2) Is this composite reconstruction feasible in terms of survivals, complication rates, and functional results?

Materials and Methods

From 1998 to 2002, thirty-five cases of benign aggressive, and malignant primary bone tumors around knee were eligible for this study. There were 29 men and 6 women who ranged in age from 7 to 63 years (mean, 19.5 years). Tumor locations were; distal femur in 23 and proximal tibia in 12. The pathologic diagnoses were; osteosarcoma in 31 cases, malignant fibrous histiocytoma in 2 cases and chondrosarcoma and giant cell tumor in one case apiece.

The 34 malignant tumors were; IIB in 31 cases, III in 2 cases, and I in one case, according to the staging system of Enneking et al[7].

Thirty-one cases of osteosarcomas completed pre- and postoperative chemotherapy based on our modification of the T-10 protocol devised by Rosen et al[12]. One of the two malignant fibrous histiocytoma cases was treated using the osteosarcoma protocol and remaining case skipped chemotherapy due to an advanced age.

1. Operative technique

A long curvilinear incision was made along the medial or lateral aspect of the thigh, so as to follow tumor extension or biopsy site location. All resections were intra-articular and a cuff of normal soft tissue and bone(3 cm margin) was included to secure a wide surgical margin. In cases of femoral resection, tibial side preparation and component fixation were done first. The same sequence was utilized for proximal tibial tumors.

After reaming the host bone medullary canal, three to five C-shaped Ender nails were straightened and impacted into the canal. The impacted nails were positioned up to the intertrochanteric area in femoral case and 2~3 cm above the tibial plafond in tibial cases. The impacted nails protruded about 5~10 cm according to the size of the excised tumor. The knee joint mechanism applied here was the Link® Endo-Model® Rotational Knee System (Hamburg, Germany). In each case, an appropriately positioned tibial or femoral component of the total knee device was assembled to the multiple Ender nails with tension band wiring. Component to host bone defects were filled with bone cement (Fig. 1). After composite

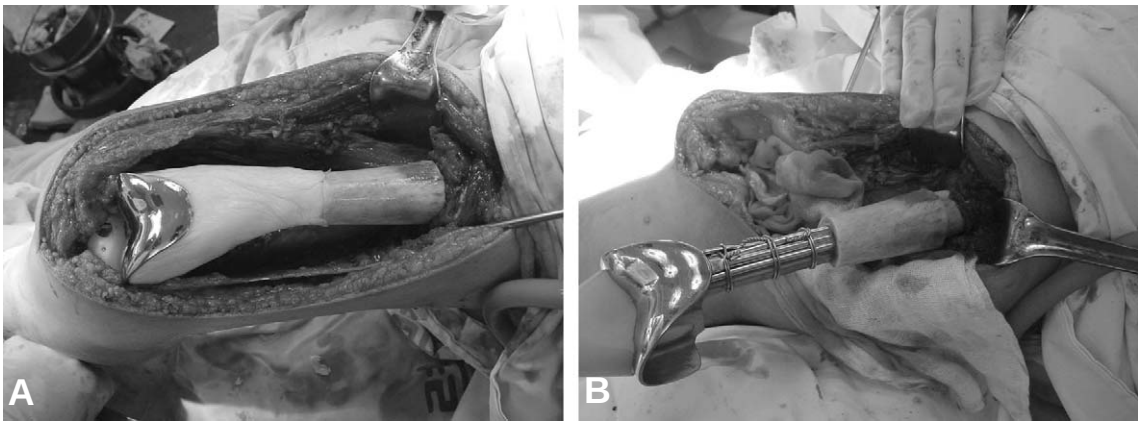

Fig. 1. (**A**) After wide tumor excision, part of the distal femoral cortical segment was pasteurized in water-bath at 65° C. The proximal canal was filled with Ender nails and then the heat-treated recycled bone was interposed. The Endo-link type total knee component was assembled to the multiple Ender nails with tension band wires. (**B**) The defect between the prosthesis and host bone was filled with cement and molded to the original contour of the distal femur.

reconstruction reduction, rotational stability and range of motion and were evaluated.

In 14 cases, a cortical cylindrical block (average length 6-cm, range 5~8 cm) of the excised tumor specimen was pasteurized(650 C for 30 minutes), retrieved, and then interposed, between the prosthesis and host bone (Fig. 3A).

The average number of Ender nails used for fixation was 4.5(femur: 4.8, tibia: 3.8).

Postoperatively, quadriceps setting exercises were started within 1 week; CPM exercises and parallel bar walking followed.

2. Radiographic evaluation

Plain antero-posterior and lateral radiograph were checked monthly until 2 years postoperatively, and 3 monthly thereafter. The evaluation points were loosening or breakage of metal components. Unions in the 14 cases that received heat-treated recycled bone were determined by the presence of bridging callus or the disappearance of the osteotomy line.

3. Functional analysis

Functional outcome was assessed based on the examinations performed at last follow-ups. The Musculoskeletal Tumor Society[6] (MSTS) scoring system was used to calculate functional scores. This system is based on six outcomes that are each assigned a score from 0 to 5: pain, walking distance, supports, gait, functional limitations, and emotional acceptance. Total scores of the affected limbs are as percentages of normal(30 points).

4. Follow up and statistical analysis

Follow-up was calculated from index operation to last review or death. Prosthesis survival was estimated using Kaplan-Meier[9] method based on period between index operation and revision. Device failure were defined as any failure requiring hardware removal, except local recurrence.

The relationship between the resection percent and observed cortical hypertrophy was

analyzed using Fisher's exact test. Two-sided p values of 〈0.05 were considered to indicate significance.

Results

1. Oncologic outcome

Of the 34 cases with a primary malignant bone tumor, 23 cases were continuous disease free, 7 had no evidence of disease, and 1 remained alive with disease, 1 had succumbed to disease at last follow-up. The 10-years disease free survival of the 31 osteosarcomas was 67% by Kaplan-Meier plot.

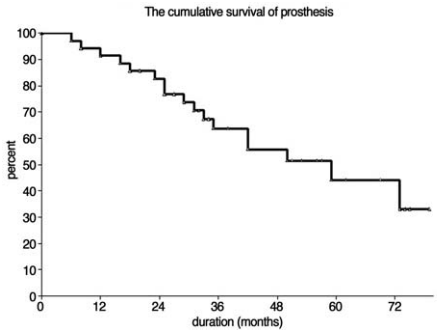

Fig. 2. Cumulative survival of this reconstruction was 33.1% at 6 years.

2. Prosthetic survival

Cumulative prosthesis survival was 33.1% at 6 year and excluding the 8 cases of early and late infection this was 56% at 6 year (Fig. 2). At final follow up, 29 cases had a functional mobile joint and their average observation period was 53(ranged 30~79) months.

3. Functional result

The average functional score of 29 cases

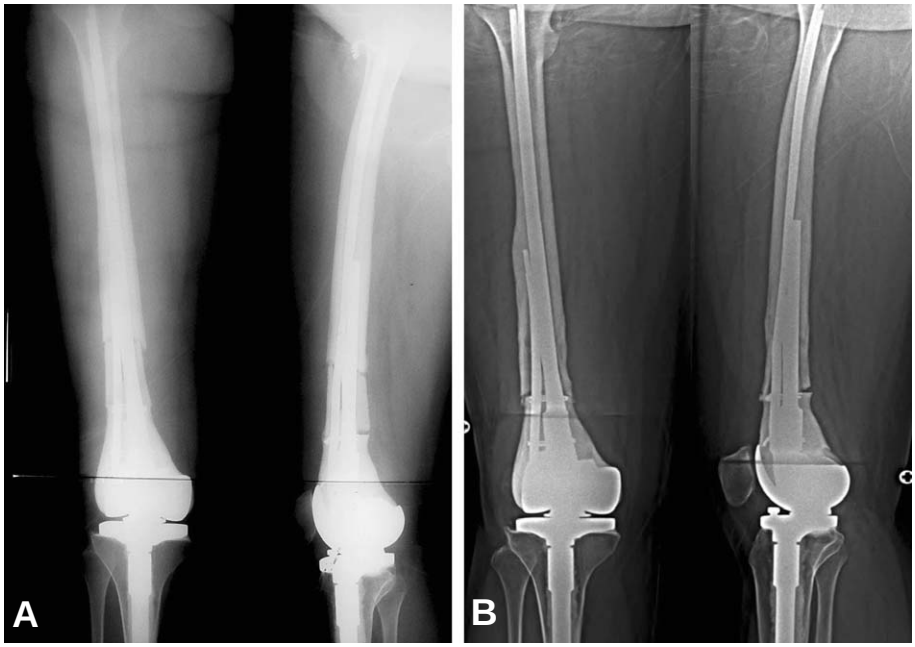

Fig. 3. (**A**) Plain radiograph showing the composite reconstruction devise and the potentially biologic cortical segment of heat-treated recycled bone in situ. (**B**) This radiograph taken at 6 years postoperatively shows solid union and cortical hypertrophy in the junctional area between recycled and host bone.

Table 1.

Variables	Junctional hypertrophy (n = 29)	No junctional hypertrophy (n = 6)	p value
Age (years)	17 (7~37)	30 (16~63)	0.942
Location	distal femur 18 proximal tibia 11	distal femur 5 proximal tibia 1	0.665
Number of Endernails	4 (2~6)	5 (4~8)	0.208
Amount of bone resection (%)	39 (28~76)	31 (23~36)	0.028

Table 2.

Case No. /	Sex Age	Dx.*	Location	Complication	Dur§	Complication Treatment	Final Status	MSTS Score
1	M/22	OS	femur†	infection	6	prosthesis removal / arthrodesis	arthroplasty	28
2	M/16	MFH	tibia‡	infection	8	prosthesis removal / arthrodesis	amputation	26
3	M/14	OS	femur	infection	16	prosthesis removal / arthrodesis	arthrodesis	21
4	F/12	GCT	femur	infection	25	prosthesis removal / arthrodesis	arthroplasty	29
5	F/31	OS	femur	infection	25	prosthesis removal / arthrodesis	arthroplasty	27
6	M/14	OS	tibia	infection	31	prosthesis removal / arthrodesis	arthrodesis	22
7	M/16	OS	femur	infection	33	prosthesis removal / arthrodesis	arthrodesis	19
9	M/25	OS	tibia	infection	73	prosthesis removal / arthrodesis	arthrodesis	25
10	M/18	OS	femur	breakage of Endernails	12	revision to long stem	arthroplasty	27
11	M/12	OS	tibia	breakage of Endernails	8	revision to long stem	arthroplasty	30
12	M/17	OS	femur	breakage of Endernails	23	revision to long stem	arthroplasty	29
13	M/18	OS	femur	breakage of Endernails	29	revision to long stem	arthroplasty	28
14	M/20	OS	tibia	breakage of Endernails	35	revision to long stem	arthroplasty	29
15	M/19	OS	femur	breakage of Endernails	50	revision to long stem	arthroplasty	30
16	F/7	OS	femur	breakage of Endernails	59	revision to long stem	arthroplasty	26
8	M/15	OS	tibia	breakage of Endernails	42	revision to long stem	arthroplasty	27

*Diagnosis : OS=osteosarcoma, MFH = malignant fibrous histiocytoma of bone, GCT=giant cell tumor,
†distal femur, ‡proximal tibia, §duration from initial operation

with a mobile joint at final follow-up was 27.4(91 percent), and the average score of 21 distal femur was 27.1, and of 8 proximal tibia was 28.2.

4. Radiographic result

Twenty-nine cases showed hypertrophy around the implant-bone junction and proximal or distal cortical bone and these were

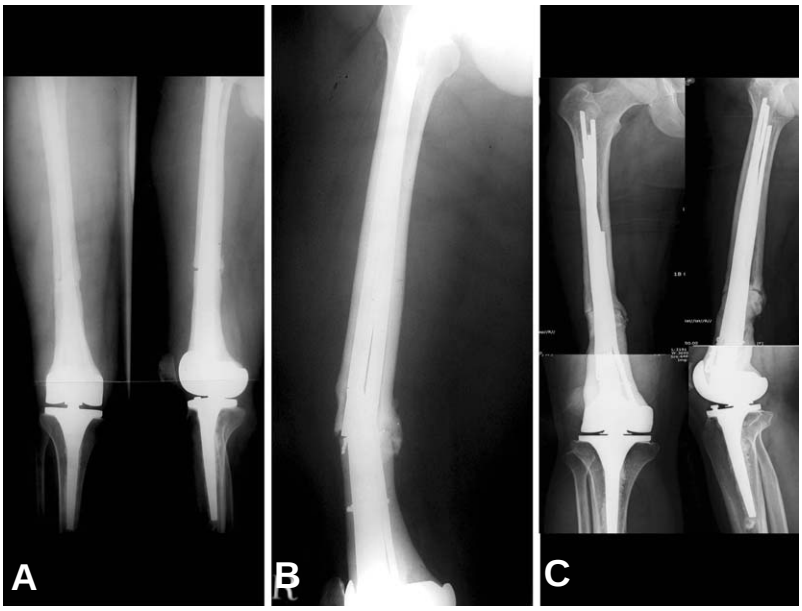

Fig. 4. (**A**) At 12 months postoperatively, the device was well positioned without problems. (**B**) At 50 months postoperatively, some Ender nails were found to have broken at the junctional site. Moderate cortical hypertrophy at the junctional site was also noted. (**C**) The devise was revised with a stem that was long enough to engage the host medullary canal by more than 5 cm .

observed as early as 3 months and averaged 9 months (range 3~23 months) (Fig. 3).

Resection of more than 40% bone was found to be positively correlated with junctional hypertrophy (P=0.028). The age, location, and the number of Ender nail used showed no correlation (Table 1).

5. Complications

Eight patients showed nail breakage and eight prostheses had to be removed due to early or late infection (Table 2). All metal failures occurred at the host bone-prosthesis junction. Average duration until failure was 33.5 months (range 12~59 months).

There were five distal femoral failures (12, 23, 29, 50, 58 months from index operation) and three proximal tibial failures(18, 35, 42 months from index operation).

All failed components were switched to a new stem design (Endo-Model® Modular Intracondylar Total Knee Joint Prosthesis, Hamburg, Germany), which is long enough to purchase the subtrochanter or distal tibial metaphysis (Fig. 4). All revised patients were able to walk without support and no further mechanical problems were identified.

Eight cases of early and late infections occurred at 6, 8, 16, 25, 25, 31, 33, and 73 months postoperatively. All cases underwent hardware removal and extensive debridement followed by temporary arthrodesis with antibiotics impregnated bone cement.

Two of eight patients achieved a mobile joint after a salvage procedure. One patient elected above knee amputation after three sequences of debridement. The remaining 5 patients were in the infection control quarantine period at the time of writing.

Discussion

The ideal tumor prosthesis offers a long-term durability and ease of revision in case a complication arises. The main issues affecting of tumor prosthesis longevity are infection, loosening, mechanical breakage and autoimmune reactions to polyethylene liner micro-debris. At present, two methods of fixation stem to host bone are available, i.e. cemented and non-cemented. The advantages of a non-cemented press fit are well known. However, osteolysis at the prosthesis-host bone junction is an ongoing problem that threatens prosthesis longevity. We tried to minimize osteolysis by using a long intramedullary flexible nail fixation technique. In cases involving the resection of more than 40% of host bone, we identified intact host bone and some hypertrophy of junctional area during follow up.

This study is limited by two factors. First, by the presence of many confounding factors in a relatively small study group. We acknowledge the heterogeneity imposed by factors, such as, initial tumor burden, amount of bone and soft tissue resection, and the use of chemotherapy. Further studies with larger numbers of cases are needed to substantiate our findings. Second, we did not perform in vitro mechanical tests to secure a sound fixation.

Notwithstanding tumor prostheses, the main issue for arthroplasty of any kind is its longevity. Moreover, the long-term result of tumor prostheses are controversial[8,11]. Nevertheless, as survivals of tumor patient continue to increase, especially in the young, prostheses have high chance of failure. Reported prostheses complications include loosening, mechanical failure, and infection[10,14], and the tentative end result of last complications is amputation.

Early and late infections appear to be related to operation time and the degree of soft tissue damage, but until now, no specific method has been available to prevent this.

Capana et al[2] reported the result of 95 cases treated with a fixed-hinge Kotz type prosthesis; 55% experienced aseptic loosening and their infection rate was up to 12%. The now popularized rotating hinge design, has been reported to improve knee mechanics. In particular, rotational laxity reduces forces and moments across the joint component by allowing soft tissue and muscular structures to absorb some energy[5,10].

Aseptic loosening has two patterns of presentation. The early one occurs within 2 years and the later one between 5 to 10 years postoperatively[8]. Although cemented stem fixation has the advantage of immediate stability, and thus, allows early weight bearing, stress shielding and resulting osteolysis might lead to loosening[3].

Chao et al[3], 4 reported extracortical bone-bridging and ingrowth of bone along the porocoated implant. However, Choong et al5 found that extracortical bone bridging is quite variable and not correlated to bone remodeling, interface lucent lines, anchorage, or implant body problems.

In the present study, cortical hypertrophy of host bone-prosthesis junction was observed as early as 3 months postoperatively. One possible mechanism of this seems to involve expansile stress at the inner cortex during ambulation due to flexible nail micromotion. In the current study, degree of cortical hypertrophy was found to be proportional to the percentage of long bone resected , which concurs Kawai et al's[10,15] finding concerning increased prosthesis loosening in resection of

more than 40% of long bone.

Junctional bone formation suggest a means of improving prosthesis fixation. However, 8 cases of Ender nail failure, which is unacceptable, suggests a mechanical weakness in the current design. We believe that stress concentration at the cement-host junction due to the short stem length of the rotating-hinge component may be responsible for this high rate of Ender nail breakage. The revision process in failed cases was conducted with a focus on extending the stem attached to the rotating-hinge component. Moreover, eight cases switched to a long stem show no further mechanical problems.

We suggest that the use of current reconstruction be considered: 1) when the remaining length of bone stock is too short for fixation (less than 9 cm), 2) when bone is immature bone with narrow medullary canal that necessitates a custom made prosthesis.

In conclusion, long-term follow up and biomechanical studies are needed to reveal the mechanism of junctional cortical hypertrophy, and to determine how to take advantage of this phenomenon to improve tumor prosthesis longevity.

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Abstract

Do the Rotating Hinge-Flexible Intramedullary Nail Composites Alleviate Junctional Osteolysis in Megaprothesis Reconstruction for Bone Tumor?

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Purpose: The authors investigated whether 35 flexible nail-rotating hinge composite reconstructions around knee joint minimize junctional osteolysis of host bone.

Material and Method: The reconstructive technique was as follows: 1) en bloc tumor resection, 2) filling of the host bone marrow cavity with multiple Ender nails, 3) assembling the Ender nails and an Endo-Link type total knee component with wire and bone cement.

Result: Mean follow-up was 53 months (ranged 30~79). At final follow-up, 29 patients retained a mobile joint. Resection of more than 40% of bone showed a positive relationship with junctional hypertrophy (p=0.028). Eight patients showed nail breakage and eight prostheses were removed due to early or late infection. The cumulative prosthetic survival rate was 33% at 6 year. Average functional score according to the MSTS criteria was 26.8.

Conclusion: Mid-term evaluations showed that results were fair. The revision process was straightforward. Junctional hypertrophy observed appears to give some clues as to how to minimize osteolysis at the prosthesis-host junction after modular prosthesis fixation.

Key Words: Malignant, Bone tumor, Tumor prosthesis, Reconstruction

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