The Endlock Tumor Prosthesis With Short-Length Fixation: A Clinical Study

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Abstract

Anchorage of segmental replacement prostheses in diaphyseal bone remains a challenge in lower limb reconstructions. We developed and studied a new prosthesis design that features an intramedullary anchorage system for which finite element analysis predicted favorable bone remodeling. We retrospectively analyzed the cases of all patients who underwent implantation of the new stem. Their data were prospectively collected.

Twenty-four patients (25 prosthetic reconstructions using diaphyseal fixation of the prosthesis) had 18 primary implantations and 7 revision cases. At a mean follow-up of 61 months, TESS (Toronto Extremity Salvage Score) and MSTS (Musculoskeletal Tumor Society Rating Scale score) were 80% and 65% that of a normal extremity, respectively. SF-36 (36-Item Short-Form Health Survey) Mental and Physical scores were 54 and 44 points, respectively. Minimum follow-up was 31 months (mean, 61 months; range, 31-107 months). Radiographic evaluation (1991 International Symposium of Limb Salvage [ISOLS] Radiological Implant Evaluation System) revealed 65% excellent and 35% good bone remodeling around the implant as a whole, 65% excellent and 35% good results for the anchorage proper, and 70% excellent and 30% good findings for lucencies at the bone–metal interface. Two patients (1 traumatic event) developed a loose stem.

The results support the expectations as shown by finite element analysis—that the risk for loosening is reduced and that favorable bone remodeling occurs around the stem over time.

Anchorage of segmental replacement prostheses in diaphyseal bone remains a challenge in lower limb reconstructions. Various intramedullary anchorage systems have been proposed with fixation by ongrowth of bone to the shaft of the prosthesis.[1-9] Excellent early stability has been reported,[10] and the advantages of cementless fixation in revision cases have been maintained.

However, fixation over a long length of stem has the disadvantage of potential stress-shielding of the surrounding bone.[8,10-18] Interestingly, the prosthetic design is seldom implicated as a possible cause of aseptic loosening.[10,19] Encouraged by the good clinical and radiologic results reported with the thrust plate hip prosthesis,[20] a device with a very short segmental fixation to bone, we proposed a new design of diaphyseal anchorage and explored its theoretical advantages by finite element analysis.[21] The short-length fixation in this design has shown a definitive advantage over long-length fixation. The stress pattern within the bone surrounding the prosthesis confirmed that shortening of the on-growth area in length increases the stress values at the resection level significantly so that physiologic values might now be expected.

The goal of this investigation was to clinically analyze the behavior of this new short-length fixation design, in combination with a well-proven artificial joint, in view of reducing the risk for loosening.

Materials and Methods

We retrospectively analyzed the cases of all consecutive patients who ever underwent implantation of the new fixation device. Their data were prospectively collected, and all patients gave their informed consent to evaluation and possible publication of the data. Several parameters were assessed: patient outcome regarding tumor disease, functional outcome, reconstruction survival, complications, revisions, salvage measures, and radiographic changes.

We identified 24 patients (18 men, 6 women; mean age, 33 years; age range, 10-78 years) who underwent 25 (bilateral in 1 patient) prosthetic lower extremity reconstruction between 1998 and 2004. In all cases, diaphyseal anchorage was performed with the Endlock stem (Implantcast, Buxtehude, Germany) in combination with the Modular Universal Tumor and Revision System (MUTARS; Implantcast, Buxtehude, Germany). There were 18 primary implantations and 7 revision cases after failed antecedent diaphyseal anchorage using different designs. The stem was always implanted in combination with the uncemented MUTARS.[22] Preoperative diagnoses were osteosarcoma (15 patients), chondrosarcoma (3), and other tumors (6). The tumor was localized in the distal femur (14 cases), in the proximal femur (5), and in the proximal tibia (6). Patients with osteosarcoma underwent preoperative neoadjuvant chemotherapy according to the COSS (Cooperative Osteosarcoma Study Group)

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Figure 1. Stem with 2 different cross-sections. Flange connects stem to segmental replacement system.

scheme,[23] and patients with Ewing sarcoma according to the CESS (Cooperative Ewing's Sarcoma Group) scheme.[24] Minimum follow-up for the surviving patients was 31 months (mean, 61 months; range, 31-107 months). One patient could not be personally reexamined because of her out-of-country relocation, but she was able to provide radiographs, history, and other disease-related details. Clinical follow-up data were available for 19 patients and radiographic data for all patients.

The stem of the prosthesis consists of 3 sections, the stem itself with 2 different cross-sections (1 hexagonally fluted, 1 round) and a flange connecting the stem to the segmental replacement system (Figure 1). The prosthesis is made entirely of cobalt-chromium alloy, the hexagonally shaped part of which is coated with a layer of plasma-sprayed titanium. This is to encourage bone on-growth. This part of the stem is designed to transfer load from the bone (axial compression, torque, bending moments) to the artificial joint. The remaining long, slender part of the stem is cylindrical and has a polished surface that provides correct positioning and stability in the medullary canal. A flange at the resected end of the bone serves as a connection to the articulating part of the prosthesis and also limits possible early migration of the stem into the medullary cavity before bone on-growth has taken place. Its undersurface is also plasma-coated with titanium. The flange is equipped with an antirotation feature in the taper lock mechanism, allowing stepwise (5°) adjustment of rotation after the stem has been fixed to the bone.

Clinical and radiographic follow-up examinations were performed by 2 observers (Dr. Ramseier, Dr. Werner) other than the operating surgeon (Dr. Exner). The examination included structured interview, physical examination, radiographic examination, and 3 standard scoring systems: TESS (Toronto Extremity Salvage Score),[25] MSTS (Musculoskeletal Tumor Society Rating Scale score),[26] and SF-36 (36-Item Short-Form Health Survey general status).[27]

The implant–bone interface was analyzed on radiographs using the 1991 International Symposium of Limb Salvage (ISOLS) Radiological Implant Evaluation System.[28] The evaluation criteria addressed remodeling signs, development of interface between implant and recipient bone, and possible changes in the implant itself.

There were minimal deviations with reference to single points, but for the total score the results of both observers did not differ.

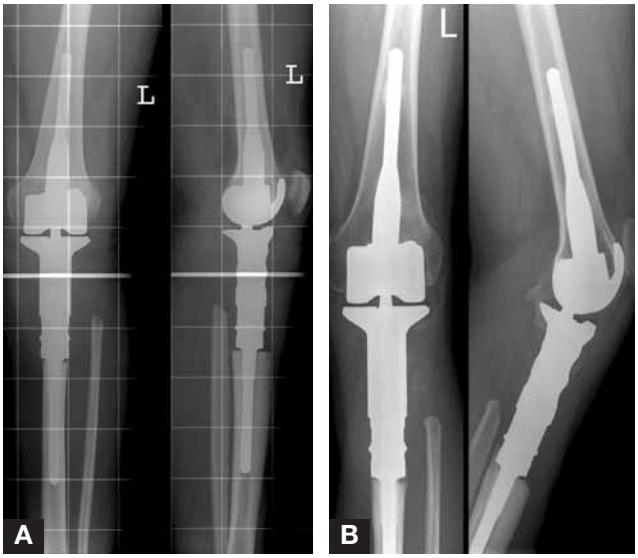

Figure 2. (A) First postoperative documentation with Endlock stem at tibial side. (B) Radiographic documentation almost 3 years after implantation shows no sign of loosening.

Results

At the latest follow-up, 20 patients were alive (Table I). Four patients (5 prostheses) had died of metastatic disease. TESS and MSTS score were 80% and 65% that of a normal

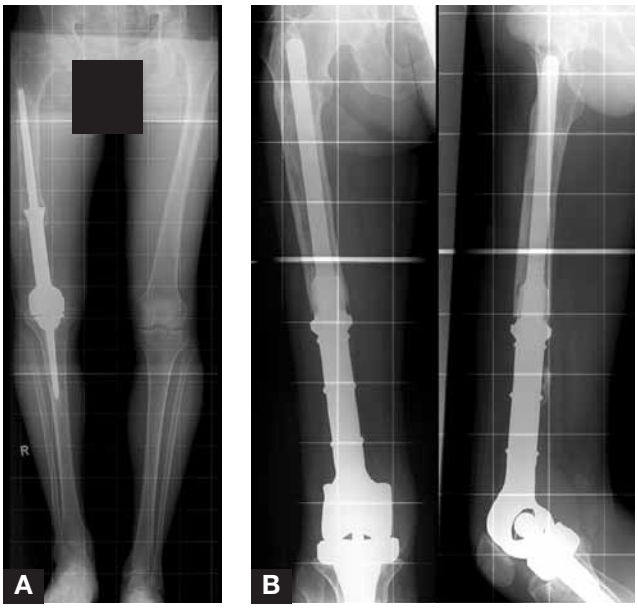

Figure 3. (A) Preoperative image with loosened stem. (B) Radiographic documentation 17 months after implantation of Endlock stem at femoral side shows stable situation with no sign of loosening.

Table I. Patient Data

Pt No.	Age (y)/ Sex	Diagnosis	Resection	Procedure Type	Stem Localization (Length)	Complication(s) & Management	Follow-Up (mo)
1	37/M	Leiomyosarcoma	Distal femur & proximal tibia	Revision, failed allograft/other prosthesis as result of infection	Distal femur (220 mm)	None	66
2	62/M	Chondrosarcoma	Proximal two thirds of femur	Primary	Proximal femur (280 mm)	Death	—
3	49/F	Osteosarcoma	Distal two thirds of femur & proximal tibia	Revision, failed other prosthesis type as result of aseptic loosening	Distal femur (310 mm)	Hematogenous infection, therapy, several arthroscopic débridements, IV antibiotics	107
4	19/M	Osteosarcoma	Distal half of femur & proximal tibia	Primary	Distal femur (200 mm)	1. Rotational malalignment. 2. Revision with Endlock. 3. Infection. 4. Borggreve-Van Nes rotationplasty.	48
5	23/M	Osteosarcoma	Proximal half of tibia & fibula, distal femur	Primary	Proximal tibia (120 mm)	Postoperative compartment syndrome, fasciotomy, complete healing	87
6	33/M	Chondrosarcoma	Proximal half of femur	Primary	Proximal femur (170 mm)	None	80
7	51/M	Osteosarcoma	Distal half of femur & proximal tibia	Revision, failed other prosthesis type as result of aseptic loosening	Distal femur (140 mm)	None	73
8	47/M	Osteosarcoma	Distal half of femur & proximal tibia	Primary implantation after pathologic femoral fracture	Distal femur (110 mm)	Traumatic loosening (fall) 10 months after primary implantation, revision with Endlock	85
9	15/M	Osteosarcoma	Proximal half of tibia & distal femur	Primary	Proximal tibia (115 mm)	Compartment syndrome, skin necrosis, fasciotomy, skin graft, complete healing	102
10	21/M	Osteosarcoma	Proximal half of tibia & fibula, distal femur	Primary	Proximal tibia (115 mm)	None	53
11	15/F	Osteosarcoma	Proximal half of tibia & distal femur	Primary	Proximal tibia (110 mm)	Infection, replacement by cement spacer, reimplantation of Endlock	66
12	20/F	Osteosarcoma	Distal half of femur & proximal tibia	Primary	Distal femur (150 mm)	Compartment syndrome, fasciotomy, skin graft, complete healing	68
13	72/M	Liposarcoma	Distal half of femur & proximal tibia	Revision, failed other prosthesis type as result of aseptic loosening	Distal femur (240 mm)	None	102
14	17/M[a]	Osteosarcoma	—	Primary	Proximal tibia (115 mm)	Death[a]	—
14	17/M[a]	Osteosarcoma	—	Primary	Proximal femur (180 mm)	Death[a]	—
15	51/M	Metastasis	Distal half of femur & proximal tibia	Primary	Proximal femur (155 mm)	None	37
16	15/M	Osteosarcoma	Distal half of femur & proximal tibia	Primary	Distal femur (110 mm)	Death	—
17	78/F	Mesenchymal tumor	Distal half of femur & proximal tibia	Primary	Distal femur (110 mm)	Death	—
18	51/M	Osteosarcoma	Proximal half of tibia & fibula, distal femur	Primary	Proximal tibia (140 mm)	1 aseptic loosening 16 months after primary implantation, 2 revisions with new Endlock	50
19	40/M	Osteosarcoma	Distal half of femur & proximal tibia	Revision, failed other prosthesis type as result of aseptic loosening	Distal femur (170 mm)	None	33
20	51/F	Chondrosarcoma	Distal half of femur & proximal tibia	Primary	Distal femur (110 mm)	Skin necrosis, gastrocnemius flap, skin graft, complete healing	41
21	30/F	Giant cell tumor	Distal half of femur & proximal tibia	Several bony operations	Distal femur (110 mm)	None	37
22	10/M	Osteosarcoma	Proximal two thirds of femur	Revision after osteosynthesis of pathologic femoral fracture	Proximal femur (205 mm)	Hip ankylosis 1. Mobilization hip joint under anesthesia. 2. Implantation of new hip joint.	37
23	24/M	Osteosarcoma	Distal half of femur & proximal tibia	Primary	Distal femur (110 mm)	None	32
24	18/M	Histiocytoma	Distal two thirds of femur & proximal tibia	Primary	Distal femur (250 mm)	1. Infection. 2. Revision of new Endlock. 3. Persistent infection. 4. Borggreve-Van Nes rotationplasty.	31

[a] Same patient.

Table II. Clinical and Radiologic Results

Pt No.	Implant Radiographic Evaluation (ISOLS)			SF-36 Score		TESS (%)	MSTS Score(%)
	Bone Remodel	Interface	Anchorage	Physical	Mental		
1[a]	Excellent	Excellent	Excellent	—	—	—	—
2[b]	Good	Good	Good	—	—	—	—
3[c]	Excellent	Good	Excellent	—	—	—	—
4	Excellent	Excellent	Excellent	41.60	50.80	81.40	67.00
5	Excellent	Good	Excellent	62.30	33.90	68.30	90.00
6	Excellent	Excellent	Excellent	46.00	61.80	73.00	46.70
7	Good	Excellent	Excellent	46.90	58.80	72.40	70.00
8	Excellent	Excellent	Excellent	38.30	60.70	84.00	73.00
9	Good	Good	Excellent	48.90	54.90	81.40	67.00
10	Excellent	Excellent	Excellent	34.80	61.10	76.70	70.00
11	Good	Excellent	Excellent	54.70	54.90	93.00	80.00
12	Good	Excellent	Excellent	36.30	29.70	86.80	33.30
13	Good	Good	Good	55.40	56.40	76.60	96.70
14[b]	Excellent	Excellent	Excellent	—	—	—	—
14[b]	Excellent	Excellent	Excellent	—	—	—	—
15	Excellent	Good	Excellent	38.20	46.60	87.60	50.00
16[b]	Excellent	Excellent	Good	27.40	55.60	69.60	70.00
17[b]	Excellent	Excellent	Good	—	—	—	—
18	Excellent	Excellent	Excellent	34.70	54.30	76.00	53.30
19	Good	Excellent	Good	50.20	64.20	73.80	57.00
20	Excellent	Excellent	Good	48.90	55.20	87.40	55.00
21	Excellent	Excellent	Good	31.90	60.30	81.40	53.30
22	Excellent	Excellent	Good	37.40	56.30	73.60	50.00
23	Excellent	Excellent	Good	57.60	51.30	97.80	93.00
24	Good	Good	Good	36.30	59.00	72.40	67.00

Abbreviations: Pt, patient; ISOLS, International Symposium of Limb Salvage Radiological Implant Evaluation System; SF-36, 36-Item Short-Form Health Survey; TESS, Toronto Extremity Salvage Score; MSTS, Musculoskeletal Tumor Society Rating Scale.

[a]Lost for clinical follow-up. [b]Died. [c]Scoring not possible (psychiatric patient).

extremity, respectively. On the SF-36, the Mental score was 54 points, and the Physical score was 44 points.

Radiologic evaluation[28] revealed 68% excellent and 32% good bone remodeling around the implant as a whole, 60% excellent and 40% good results for the anchorage itself, and 72% excellent and 28% good findings for lucencies at the bone–metal interface. When subdivided into primary stems (n = 18; Figures 2A, 2B) and revision stems (n = 7; Figures 3A, 3B), radiographic evaluation (ISOLS)[28] revealed 43% (78%) excellent bone remodeling around the implant for revisions (primary stems), 71% (56%) excellent results for the anchorage, and 71% (72%) excellent findings for lucencies at the bone–metal interface (Table II). The estimated cumulative proportion of Endlock stems surviving was 93% (SD, 0.049%) at 1 year, 89% at 2 years, and 72% at 5+ years, respectively (Figure 4). In that surviving curve, the patients who died were included.

Two patients developed aseptic loosening (1 chronic, 1 acutely symptomatic after a fall with a heavy rotational trauma) at 16 and 10 months, respectively. Both were doing well 1 and 7 years after revision with a larger Endlock shaft.

After surgery, 3 patients developed compartment syndrome that required urgent fasciotomy, the result being complete healing with no muscular deficiency (Table I).

Discussion

A stem with short segmental diaphyseal fixation (Endlock) to be used with tumor reconstruction systems was recently designed and subjected to theoretical analysis.[21] We assumed this stem would allow more physiologic transmission of forces between reconstruction system and recipient bone, leading to improved long-term stability. The finite element investigation was made to validate the theoretical features of the stem design. This numerical model has shown that short fixation keeps loading on the host bone nearly physiologic over a longer length without increasing the peak loading of bone beyond an acceptable limit within the fixation area. With longer fixation length, the amount of unloaded surrounding bone increases in the vicinity of the insertion level. This stress shielding may cause atrophy and finally lead to aseptic loosening. Given the finite element studies, a fixation length of about 1.2 times the outer diameter of the bone appears to be a good compromise between the need for primary stability and the long-term biome-

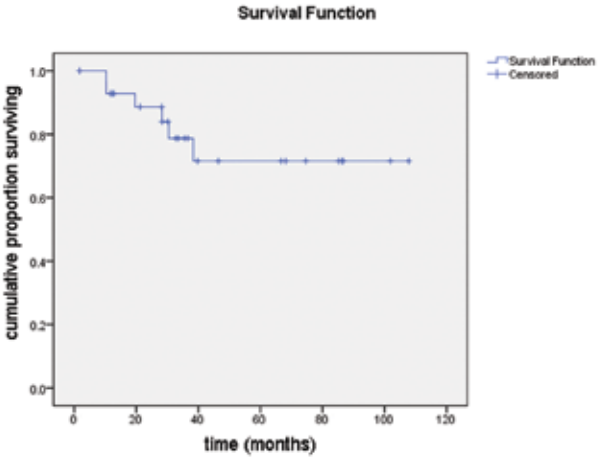

Figure 4. Kaplan-Meier survival rates with component removal for any reason as endpoint. Death of patient is represented by censor without decrement in cumulative survival values.

chanical effect that is sought. This stem was implanted with a commercially available MUTARS[22] after patients provided informed consent. The data of the first 24 consecutive patients (Table I) thus treated and having a clinical follow-up of more than 2.5 years were analyzed with regard to overall oncologic, functional, and radiographic outcomes. The relatively small number of patients is attributed to the rarity of the diseases and therefore the limited indication for tumor prosthesis reconstruction.

Four patients died from their diseases, and none had had a local recurrence. Four patients developed late infection. Three had staged replacement with reimplantation of a new prosthesis with an uncemented Endlock stem after removal and use of temporary cement spacers[29]; 1 of these 3 regained prerevision function, and the other 2 opted for "biological" reconstruction with removal of the implant and conversion to rotationplasty (Borggreve–Van Nes). One was treated with repeated knee arthroscopies and intravenous antibiotics.

Three patients developed acute postoperative compartment syndrome, which was managed successfully with fasciotomies. This high incidence of postoperative compartment syndrome is probably related to "overactive" analgesic management, including epidural together with general anesthesia.

The results of survival with the Endlock stem can be favorably compared with the results published by Gosheger and colleagues,[30] who also used MUTARS but with different stem designs (long-fixation hexagonal cementless stems and a few cemented stems).

In both studies, the overall percentage of aseptic loosening was 8%. In our series, 1 of the 2 cases of loosening was traumatic (resulting from a fall). Furthermore, we reported only lower leg reconstructions, the results of which were clearly inferior to results of upper extremity reconstructions (included in the series by Gosheger and colleagues[30]). The infection rates in these studies were identical (12%). With 1 local recurrence in the large series by Gosheger and colleagues[30] and none in our smaller series, local control has been excellent. Limb survival after local resection was also comparable: 88.7% in the series by Gosheger and colleagues[30] and 92% in our series. With the lack of raw data, statistical comparison was not possible, but a tendency toward higher prosthetic survival was found with the Endlock system.

Comparing our results with those of another short-fixation device, the Compress system,[31] we found similarities in infection rates and loosening rates but a longer follow-up for our study (61 vs 26 months). Estimated cumulative survival at 2 years was also comparable (89% in our group, 84.6% in the Compress group).

A possible weakness of our study is that its design was not randomized. Comparing it with another stem design with the same MUTARS would be interesting. In addition, this specially designed stem has been implanted only by a single operator at a single center. There are no data on the reproducibility of the results.

In conclusion, our clinical and radiographic results support the hypothesis based on biomechanical studies[21] that the Endlock stem design may contribute to improved long-term stability of endoprosthetic reconstructions. Further multicenter studies are needed to compare this stem design with others.

Authors' Disclosure Statement

The authors report no actual or potential conflict of interest in relation to this article.

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