



Lower limb salvage surgery with MUTARS® endoprostheses : 2 to 7 year results

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The reconstruction of bone defects remains a challenge in orthopaedic oncology. Allogenic and autologous bone grafts, as well as megaprotheses are well-recognised methods for bone reconstruction. Modular, both cemented and cementless, endoprosthetic systems have become more popular to bridge defects of different sizes.

The clinical and radiological results of 50 consecutive patients treated with MUTARS® endoprostheses between 1995 and 2000 were evaluated in a prospective clinical study. The average follow-up was 46 months (25-86 months). Clinical evaluation showed good results with an average Enneking-Score of 72% (33-100%, SD ± 19). Radiological evaluation showed various patterns of bone remodelling including extracortical bone bridging. Early symptomatic loosening occurred in 11 cases, necessitating revision surgery.

In conclusion, the use of the MUTARS®-Endoprosthesis may be a valuable tool in the treatment of major bone defects in the lower limb, if the problems with the first-generation design can be solved.

INTRODUCTION

The guidelines for the treatment of massive bone defects caused by bone resection due to tumours or failed endoprostheses have changed over the past two decades (1). Limb salvaging surgery is performed in most of the cases and only a small group of patients require amputation of the limb. This procedure is mostly a consequence of tumour infiltration and expansion rather than of bone loss (2). Arthrodesis with the loss of joint function and the rotationplasty described by Borggreve and Van

Ness remain alternatives to amputation and limb salvage surgery. These techniques are less accepted by the patients due to the cosmetic limitations of both procedures (11), despite their excellent functional and clinical results (25).

Endoprosthetic reconstruction plays the main role in the treatment of bone defects today, but remains problematic if outcomes are compared to primary total hip or knee arthroplasty (4). A higher complication rate is well known and accepted because of the extended bone and soft tissue defects, the longer operation times and the size of the implants (4, 7, 20). Many different custom made (6, 9, 11, 14, 15, 20, 23) and modular prostheses (2-4, 7, 10, 12, 14, 19, 24) are currently available.

In this study we report the results of the first 50 MUTARS® prostheses which were implanted in our department. The main aim of the study was to

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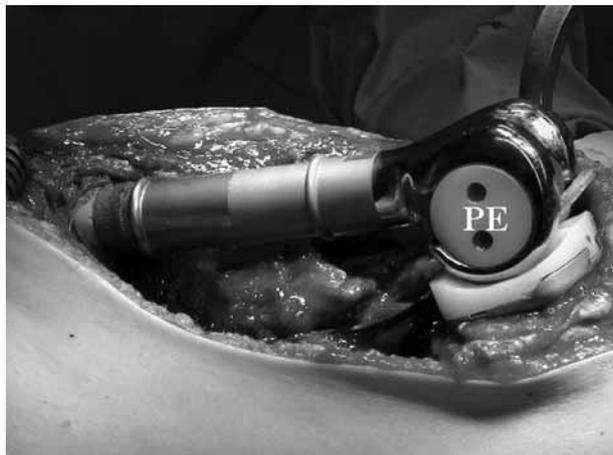


Fig. 1. — Intraoperative documentation of an implanted prosthesis at the distal femur, PE = polyethylene locking insert.

evaluate and if possible explain complications and revision cases.

MATERIALS AND METHODS

The prosthesis

The MUTARS® system (Implantcast, Buxtehude, Germany) has been used in our hospital since 1995. Over this period we prospectively followed-up all patients who received a lower limb implant. With this modular system, it is possible to bridge any bone defect from the proximal femur to the proximal tibia. The fixation is achieved with an intramedullary stem, which can be inserted cementless or cemented. The stem has a hexagonal cross section and is made of titanium alloy in the cementless version and of CoCrMo alloy in the cemented version. Different intermediate pieces can be connected to this stem to reconstruct the individual length and joint function of the affected extremity. The stem is curved to follow the anterior bow of the medullary cavity of the femur and the correct size of the stem is determined preoperatively with templates on AP and lateral radiographs. At the hip joint a conventional acetabular component can be used. At the knee a hinged system with minimal rotation is used with an axis fixed to the tibial base plate that fits into a polyethylene locking device (fig 1). For muscle and tendon reattachment, a Trevira tube is available. This textured tube is pulled over the prosthesis and fixed by non-resorbable sutures.

Table I. — List of diagnoses, n = 50

Diagnosis	Quantity
Osteosarcoma	23
Metastasis	11
Giant cell tumour	3
Malignant fibrous histiocytoma	3
Chondrosarcoma	3
Ewing's Sarcoma	2
Multiple myeloma	2
Rhabdomyosarcoma	1
Liposarcoma	1
Failed total knee replacement	1

Patients and Evaluation Methods

Since 1995 the MUTARS® system has been implanted in more than 80 patients. The first 50 consecutive patients, 24 male and 26 female with a mean age of 40 years (range 10 to 79 years, SD ± 21) have been included in this study. The follow-up period was 2 to 7 years with an average of 46 months (SD ± 17). All patients were seen in the first two years at least every six months and annually after this time. The left side was operated in 31 patients, the right side in 19 cases. The indication for surgery was in 49 cases a malignant lesion (table I). The implantation of a megaprosthesis was performed in only one case in a revision operation for loosening of a condylar prosthesis after multiple previous revisions. Neoadjuvant chemotherapy was performed in cases with tumours responding to chemotherapy. The distal femur was the most common localisation (20 cases), followed by the proximal tibia in 14 and the proximal femur in 13 cases. In three patients a total femur was implanted. The adjacent joints were replaced completely, except in one case where a bipolar head was used at the hip joint. The implant fixation was cementless in 27 cases, 7 stems were fixed with bone cement and in 16 patients a hybrid fixation was performed. The mean length of the bridged defect area was 17.7 cm (range 6 to 39 cm, SD ± 6.8). In 26 patients with major bone resection the use of a Trevira tube was necessary at the proximal femur and the proximal tibia. This procedure allowed a secure fixation of the soft tissues, particularly the patellar tendon. A gastrocnemius flap was necessary in 11 cases and a mesh graft in six cases with major skin and soft tissue defects.

The clinical outcome was assessed using the Enneking score (5). The radiological evaluation was based on the classification of the International Society of Limb Salvage (ISOLS) (8).

Table II. — Complications in all 50 patients

Complications	Quantity
Loosening	11
Infection	6
Knee joint dislocation	5
Soft tissue relapse	5
Wound healing disturbance	4
Hip joint dislocation	3
Reduced knee motion	2
Patella fracture	2
Intraop. femoral fracture	2
Total	40

Statistical analysis was performed using the Stata 5.0 software (Stata Corporation, College Station, TX, USA). The distributions of the different parameters are described by mean and standard deviation. To evaluate the influence of various variables on loosening, Fisher's exact test or a two-sample Wilcoxon rank-sum test was used. A p-value of ≤ 0.05 was considered statistically significant.

RESULTS

Oncological outcome

Seventeen patients (35% of the patients with a neoplastic diagnosis) had died during the follow-up due to their underlying malignancy; four of them already had systemic involvement of their disease before surgery. The oncological evaluation showed the absence of a tumour in 21 patients with a diagnosed neoplastic disease (42%). Eight patients were alive with treatment (16%) and three patients (6%) had a local recurrence.

Clinical assessment

Thirty-three patients were followed-up clinically for more than two years. Thirteen of the 17 deceased patients did not have a two-year follow-up when they died, two patients underwent amputation of their limb, one patient (TKR revision) was lost to follow-up and another patient moved to Africa and could not be evaluated. A mean Enneking score (5) of 72% (33-100, SD = ± 19) was recorded at the last follow-up. Thirty-one patients



Fig. 2. — 79-year-old patient with aseptic loosening of a cementless stem 3 months after surgery (left), and the same patient 34 months after revision (cemented stem) with recurrent aseptic loosening and hypertrophic bone formation.

(94%) had a score over 50% which corresponds to a good or very good result. The best postoperative results regarding isolated parameters were achieved with respect to reduction of pain and walking ability; the most obvious postoperative impairment was the negatively affected gait.

Complications and revisions

All 50 patients were included in the evaluation of complications. Thirty-one (62%) patients presented 40 different complications (table II). Thirty complications in 25 patients (50%) were treated with further revision surgery. The main complication was aseptic loosening in 11 cases (22%). Implant loosening occurred at the distal femur (6), proximal tibia (4), and proximal femur (1). Eight of these patients have already undergone revision surgery. In one patient the exchanged cemented implant came loose again three years later (fig 2). We looked at different variables influencing the incidence of aseptic loosening but side ($p = 0.117$), localisation ($p = 0.385$), the use of cement for stem fixation ($p = 0.467$), body mass index ($p = 0.495$), gender ($p = 0.56$), defect length ($p = 0.561$),

Enneking Score ($p = 0.613$), and age ($p = 0.761$) all showed no significant influence. However, some typical radiological signs were seen in combination with aseptic loosening and are reported in the radiological analysis section.

Five patients (10%) experienced dislocation of their constrained knee joint. The polyethylene locking (fig 1) which connects the metal post on the tibial plate with the distal femoral implant failed and the knee joint became unstable. All these patients had to be revised and the polyethylene locking was exchanged.

Six patients developed deep infections (12%). Further complications included three dislocated hip joints which were treated twice with open reduction and once with closed reduction. All other complications are shown in table II.

Radiological analysis

Thirty-four patients with sufficient radiographs and follow-up were assessed in the radiological analysis. In patients with loosening or revision of the implant the postoperative radiograph was compared to the last radiograph before revision.

In 17 patients remodelling of the bone with resorption of cortical bone around the stem was detected and three cases showed reduction of the cortical thickness of more than 50%. There were no fractures around the bone-prosthesis junction. The 17 cases with cortical resorption attributable to stress shielding showed a higher incidence of aseptic loosening than cases without these radiological changes ($p = 0.011$). Fourteen patients also showed radiolucent lines corresponding to the ISOLS poor or fair category and these patients also had a significantly higher incidence of clinical loosening ($p = 0.001$). There were no problems affecting the various implanted components, but the constrained knee joint mechanism failed in 5 patients (see complications). We also evaluated extracortical bone bridging (EBB) which was detected in 11 patients. This phenomenon had no influence on the stability of the prosthesis or on the prevention of loosening ($p = 0.359$). Three of the 11 loose prostheses and four of the 23 stable prostheses showed extracortical bone bridging.

DISCUSSION

From the surgical and oncological point of view, control of the tumour disease is the most important issue. Recently reported results have demonstrated that limb salvage surgery, in combination with chemo- or radiotherapy, has achieved similar recurrence rates as amputation; it has therefore become more and more accepted (12, 13, 17, 18, 21). This was also shown in our study where 65% of the patients were alive after a follow-up of up to 7 years. Beside the oncological result, the restored function of the limb is essential. The proportion of good and very good clinical results achieved in the reported patient group attests sufficient functional restoration.

On the other hand there are still a few serious problems associated with the implantation of tumour prostheses, which have not been solved so far. This is demonstrated in the literature by the usually high complication rate after implantation of megaprotheses, including infection, mechanical failure and loosening. The complication rates in the literature range from 25 to 92% (3, 6, 7, 10, 13-15, 20), but a comparison is not always possible due to different definitions and classification systems used. Shin *et al* (20) for example reported a complication rate of only 25% after 12 years and Mascard *et al* (15) in contrast found complications in 92% of their patients after only 4.3 years. Our postoperative complication rate was 62%, and 50% of all patients underwent further revision surgery.

The infection rate at 12% is comparable to the results in the literature where postoperative infection rates are reported to range from 2 to 13% (3, 14-16, 23). This seems to be due to the relatively long and extensive operations in tumour surgery.

In five cases the prosthesis developed mechanical failure with unlocking of the insert that connects the tibial post to the distal femur. As a consequence the manufacturer has introduced a new locking mechanism. A close follow-up of this newly designed locking insert is necessary to see if this complication can be prevented.

Of greater concern was the aseptic loosening of the prosthesis in 11 patients, because its cause remains uncertain. This corresponds to a rate of

22% after a mean follow-up of 4 years. Other authors have reported aseptic loosening rates from 0 to 22% (3, 10, 15, 16, 23). Capanna *et al* (3) did not report any aseptic loosening in their patients after 4.3 years, but most of the results with well accepted systems have reported between 3.2 and 5.8% aseptic loosening after a mean follow-up of 3.9 years (10, 16, 23). Our loosening rate was nearly four times higher. The anatomical shape of the distal femur, and also of the proximal tibia, varies from patient to patient, but both have a cone-shaped medullary canal. The more distal the resection is carried out, the more distinct is the conical shape of the bone. This is a weakness of a modular system where the stem is not individually produced for every patient but has to meet the requirements of the differing shapes. Suboptimal press-fit at the anchorage of the intramedullary stem entails the risk for loosening of the implant.

Statistical analysis of our functional data did not reveal any significant correlation between function and aseptic loosening. However, large prostheses, implanted in cases with long bone defects, may increase the lever arm on the intramedullary stem, and extraarticular resections with wide soft tissue resection may additionally increase the stresses on the interface between bone and the stem or the cement.

Additionally, changes in the bone attributable to stress shielding can often be found, which results in hypertrophy of the cortical bone at load-transferring areas and bone resorption in unloaded parts of the bone (3). A significant bone resorption at the bone prosthesis interface can be a sign of an unphysiological load transfer and can subsequently lead to aseptic loosening and failure. A few authors also hold hypertrophy of the bone at the bone-implant interface, which is described in the literature as "extracortical bone bridging", responsible for an increased stability of the prosthesis (4, 9, 19, 23, 24). Tanzer *et al* (22) found in a radiological and histological study that extracortical bone formed around all of their prostheses, but analysis of the retrieved implants revealed that the extracortical bone was never grown onto the surface of the prostheses. Extracortical bone bridging did not increase stability of the prostheses in our patients.

Extracortical bone bridging is a common radiological finding after implantation of a megaprosthesis, and it does not seem to contribute additional stability.

In conclusion, the implantation of a megaprosthesis seems to be a valuable treatment for major bone defects in the lower limb despite the existing problems with fixation to bone. The investigated design showed a disturbing rate of aseptic stem loosening during the follow-up period. The second generation of the MUTARS® system, which includes computer-assisted preoperative planning, provides a wider range of intramedullary stem shapes, and a new broaching system may improve the stability of these prostheses in the future. Long-term studies and a comparison of the first and second-generation implants are necessary in order to resolve the existing problems with the fixation of this prosthesis.

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