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Midterm Outcome after Mega-Prosthesis Implanted in Patients with Bony Defects in Cases of Revision Compared to Patients with Malignant Tumors

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ABSTRACT

Use of mega-prostheses is a common option for the treatment of patients with malignant tumors as well as in patients with large osseous defects at the time of revision surgery. No studies have compared the two groups to determine whether there is a relative difference in clinical outcomes. We performed a midterm-outcome-study to evaluate our results in these two patient populations. Deep infection was found more often in our revision group (29.5% vs. 9.1%), however no significant differences in WOMAC-results could be found between the two groups. Surgeons should recognize the high complication rate as well as the differences in results using mega-prostheses in these two distinct groups of patients.

Initially designed to treat patients with malignant bone tumors, "mega-prostheses" such as total femurs, proximal and distal femur arthroplasties or custom made pelvic arthroplasties are commonly used in revision procedures [1,2] for patients with bony defects or complex fractures. Complications are reported to be five to ten times higher when using mega-prostheses than in the use of standard implants [3–11]. The rate of complications is mainly due to infections and ranges from 3% [12] to 41.7% [13]. We carried out a retrospective midterm-outcome-study, in order to analyze the complication rate in our patients depending on the reason for surgery.

Materials and Methods

Patients

From 2005–2010 a total number of 68 patients (37 men and 31 women) with a median age of 70 years (interquartile ranges 59–77 years, minimum age 10 years and maximum age 98 years) received a mega-prosthesis. After receiving approval from the ethics committee, patients were included after giving written informed consent.

44 of these patients were "revision-patients" with large bony defects, 16 patients received the mega-prosthesis due to a malignant tumor and six patients underwent a revision-procedure of their "mega-implant" after primary implantation due to a malignant tumor. The two remaining patients received their implant due to an osteoporotic fracture and sequela after osteomyelitis, respectively.

The types of prosthesis were a total femur/so called "Durchsteckprothese," a proximal or distal femur arthroplasty or a custom made partial pelvic arthroplasty (Fig. 1) made of a variety of materials: 40 chrome-cobalt prostheses, 20 implants were made of titanium, six prostheses were coated with silver and two prostheses had other surfaces.

The median follow-up-time was 42 months (interquartile range 35–65 months, minimum 4 months and maximum 82 months).

Method

We focused on complications (mechanical complications and infections), as well as the patients' reported outcome with regard to their implant according to the Western Ontario and McMaster Universities Arthritis-index in its German translation [14] (WOMAC-score). Patients were interviewed and examined in the clinic whenever possible, while additional information was taken from patients' records and X-rays. If the patients were unable or unwilling to meet in person, they were interviewed over the telephone and the patients filled out the

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Institutional review board approval was given (University of Frankfurt/Main) and all patients have given written informed consent.

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Fig. 1. 17 (25.0%) of the patients got a total femur arthroplasty (a), 18 (26.5%) a proximal femur arthroplasty (b) 32 (47%) a distal femur arthroplasty (c) and one patient (1.5%) a custom made pelvic arthroplasty.

WOMAC-score via mail. A total number of 39 of the 68 patients completed the WOMAC-score.

With a range between 0 and 10 points for each of the 24 WOMAC questions, a maximum score at 240 points was achievable, with 0 points meaning no problems and no pain and 240 points meaning maximum problems and pain. We adapted the score's total of 240 points to 100%, in order to ease the analysis and improve the comparability of the results. We focused on the difference in WOMAC-points between the tumor group and the revision group with regard to patient reported outcome. As a secondary endpoint we compared the differences in patient reported outcome of patients with a deep infection compared to those without any infection in their history.

20 patients came to the clinic; four other patients could be interviewed and examined during a hospital stay. 25 patients answered the questions via telephone, as their follow-up examinations had already been performed at another institution. We were not able to contact 19 patients due to missing data or because they had died in the meantime. In these cases, the latest documentation concerning complications from the patients' records was analyzed.

During the standardized examinations the outer appearance of the joint (rubor, scars and efflorescences), the condition of the soft tissues (synovitis, fluid effusions) and joint function (gait, use of crutches, stability, range of motion, pelvic position, Trendelenburg's, Lasègue's and Menell's signs) were documented. X-rays were considered for patients who were present at the hospitals with regard to the prosthesis' position, osteolysis, signs of fracture or bony defects, as well as signs of loosening (radio lucent lines = 2 mm) or material damage.

Statistics

Statistical calculations were performed using SPSS for Windows 21.0 (IBM Corporation, NY, USA). Medians, interquartile ranges as well as maximum and minimum values were calculated. To determine whether there is a relevant difference in outcome between the "tumor group" and the "revision group" the significance to the 5%-limit was determined using the Wilcoxon-test for the WOMAC-score. This was performed for both groups as mentioned above (primary endpoint), as well as for patients with a deep infection compared to patients without any infection (secondary endpoint).

Theory/Calculation

The purpose of the study was to determine whether there are differences in outcome in patients receiving large implants due to a malignant tumor compared to patients getting their implant after several revisions or due to a complex periprosthetic fracture. Since the patients in the "tumor group" were younger and had less comorbidities, we expected a better patient-reported outcome in this group despite the loss of muscle tissue due to compartment-resection.

Results

The following complications were observed:

(1) Wound disorders
(2) Deep infections
(3) Luxation
(4) Breakage of prosthesis
(5) Periprosthetic fracture
(6) Aseptic loosening

Table 1 gives the number and percentage of patients affected by the above complications.

Deep infection was the most commonly observed complication and occurred in 15 cases at a median follow-up time of 10 months after implantation (interquartile range (IQR) 0–26 month, and at a maximum of 49 months). Bacteria-cultures from intraoperative soft tissue-material were positive in four patients.