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## Proximal femoral reconstructions: A European “Italian” experience. A case series

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### ABSTRACT

#### Background:

The aim of the study was to analyze our experience with a single system of modular proximal femoral replacement, evaluating oncologic results, complications, and functional results.

#### Methods:

We reviewed data on 38 patients (21 men and 17 women; mean age 59 y) treated with proximal femoral reconstructions by two orthopaedic surgeons. Reconstruction was performed in all patients with a MUTARS® modular proximal femoral prosthesis and an acetabular reconstruction in eight patients. Diagnoses included primary bone sarcomas (21), bone metastases (15), and radioinduced osteonecrosis (2). The stem was press fit in 11 patients and cemented in 27.

#### Results:

At a mean follow-up of 1.9 yr, 12 patients were alive with no evidence of disease, three have no evidence of disease after treatment of a recurrence or metastasis, 12 were alive with disease, and nine had died. The two with osteonecrosis were not included in this analysis. Complications occurred in seven patients: four type I (wound dehiscence in one and dislocation in three), one type II, one type IV, and one type V failures, while type III failures did not occur. At last follow-up, 89% of patients (34/38) had retained their implant. The mean Musculoskeletal Tumor Society (MSTS) score was 24.7 (14-30), with excellent or good results in all patients except one.

#### Conclusion:

The overall survival of this prosthesis was satisfactory with good implant survival in proximal femoral reconstruction. The most

frequent cause of failure was dislocation. The incidence of infection was low. Functional results were good or excellent.

#### Level of Evidence:

IV; case series.

#### Key Words

modular endoprosthesis, limb reconstruction, proximal femur, tumor

### INTRODUCTION

Until the early 1970s, amputation was the most frequent treatment for malignant bone and soft-tissue tumors; the introduction of chemotherapy and radiotherapy, and the advances in diagnostic and surgical techniques made limb salvage surgery possible in about 90% of patients with bone sarcomas involving the upper and lower limbs.<sup>1</sup> Arthrodesis, allografts, allograft-prosthetic composites, rotationplasty, and modular prostheses have all been used for reconstruction after limb-salvage surgery, but in the last 30 yr megaprotheses have widely replaced other reconstructive options because of their availability and relative ease in application, providing immediate fixation with early weight bearing and restoration of function.<sup>2</sup> Since Salzer introduced the first ceramic prosthesis for humeral reconstruction in 1972,<sup>2</sup> several types of megaprotheses were developed.<sup>3-9</sup> The MUTARS® system (Modular Universal Tumor And Revision System, Implantcast, Buxtehude, Germany) was first introduced in 1995. The curved intramedullary femoral stem follows the anterior bow of the medullary cavity of the femur and can be inserted press-fit or cemented. The hexagonal-shaped design of the stem provides rotational stability, reducing the incidence of loosening and stem breakage. The knee is a rotating-hinge system. This system has been widely used in Germany.<sup>10-18</sup> In Italy the first MUTARS® prosthesis was implanted in 1996 by Rosa *et al.*<sup>19</sup> and subsequently the use of this prosthesis became more frequent.<sup>20-22</sup> The proximal femur is one of the most common sites of localization both for primary bone tumors and for metastases. Consequently, it is one of the major sites reconstructed with megaprotheses.<sup>22-32</sup>

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The aim of this study was to analyze our experience with the use of a single-system modular proximal femoral replacement, evaluating oncologic results, incidence of complications, and functional results.

## MATERIALS AND METHODS

### Ethical Approval and Study Design

As this case series consists of anonymized clinical data, Research Ethics Committee Approval was not deemed necessary. All patients or their relatives provided written informed consent to be included in scientific studies upon admission to the hospital.

### Study Conception, Set-up, and Patient Criteria

From the experience of eight institutions in Italy an Italian intergroup was created in 2013 to evaluate the results of reconstructions using the MUTARS® (Implantcast, Buxthude, Germany). During the 17<sup>th</sup> International Society Of Limb Salvage meeting in Bologna in 2013, the results of this multicentric study were presented. The study included 430 patients treated between 2000 and 2013 with resection for a benign or malignant extremity tumor and reconstruction with the modular megaprosthesis. Proximal femoral reconstructions included 121 cases (53 male and 68 female patients; mean age 59 yr, range 12-85 yr). However, in this analysis there were biases due to lack of homogeneity in follow-up between different institutions and lack of data about implants and surgical treatments. Starting with these data, we recently updated our experience with the MUTARS® prosthetic reconstruction. This study was conducted with selective criteria in order to have an homogeneous series of patients. These included (1) patients treated with proximal femoral resection and reconstruction using the same type modular prosthetic system, (2) treatment performed by the same orthopaedic surgeons (PR and VI), and (3) minimum follow-up of 9 mo.

One hundred eighty-six patients were treated between 2000 and 2018; however, only 38 patients with proximal femoral reconstructions were included in this retrospective analysis: 21 male and 17 female patients with a mean age of 59 yr (range, 12-89 yr). Histologic diagnoses were: 21 (55.2%) primary bone sarcomas, 15 (39.5%) metastases (from breast in seven patients, kidney in three patients, multiple myeloma in three patients, and lung in two patients) and two (5.3%) nononcologic disease. The two patients with nononcologic disease were treated for osteonecrosis caused by radiotherapy for treatment of thigh soft-tissue sarcoma.

### Surgery

Reconstruction was performed with a MUTARS® modular proximal femoral prosthesis in all patients; a stemmed-cup or custom-made pelvic reconstruction was required in eight patients. Adjuvant and neoadjuvant chemotherapy and radiotherapy were administered according to histologic diagnosis after multidisciplinary evaluation. Resection was performed in all patients through a lateral approach, and reconstruction was performed with silver-coated prostheses in 29 patients (76%). Stems were cemented in 27 (71%) patients (elderly patients with poor bone stock or those with metastatic disease) and press-fit in 11 (29%) patients. When feasible, a meticulous capsular repair was performed after implantation to decrease the risk of dislocation. A pelvic-thigh

brace was applied to guarantee immobilization at 10 degrees of hip abduction and with extension allowing from 0 to 30 degrees for 1 mo, then hip flexion was limited up to 90 degrees for another month. Weight bearing with two crutches was started after 1 wk in patients with a cemented stem or after 1 mo in patients with a press-fit stem.

### Follow-up

Functional and oncologic evaluations, including hip radiographs, chest CT, and physical examinations, were routinely performed every 3 mo during the first 3 yr, every 4 mo in the fourth year, every 6 mo in the fifth year, and then annually up to 10 yr. Oncologic results were noted according to local recurrence, metastasis, or death, classifying patients at follow-up as: no evidence of disease; no evidence of disease after treatment of local recurrence or metastasis; alive with disease; or dead with disease. Prosthesis failures were classified according to Henderson *et al.*<sup>27</sup> Functional results were evaluated according to the Musculoskeletal Tumor Society (MSTS) scoring system.

### Statistical Analysis

We analyzed survival of patients (36 oncologic cases) and implants (38 cases) using the Kaplan–Meier curves, performing comparison with the log-rank test; a *P*-value of 0.05 or less was set as statistically significant.

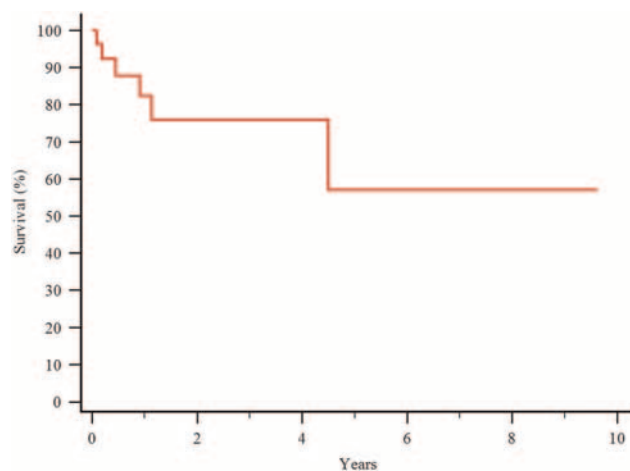
## RESULTS

### Overall Survival

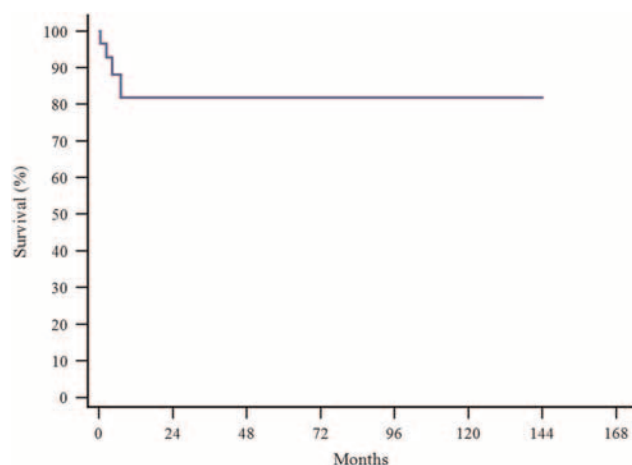
At a mean follow-up of 1.9 yr (range, 9 mo–12 yr) in 36 oncologic patients (two nononcologic cases were excluded from this analysis), 12 patients were alive with continuously no evidence of disease, three patients showed no evidence of disease after treatment of a recurrence or metastasis, 12 patients were alive with disease, and nine patients died, with an overall survival rate of 56% at 10 yr (Figure 1).

### Implant Survival, Failures, and Complications

At last follow-up, 89% of patients (34/38) had retained their implant. The overall failure rate in our series was 18% (7/38).



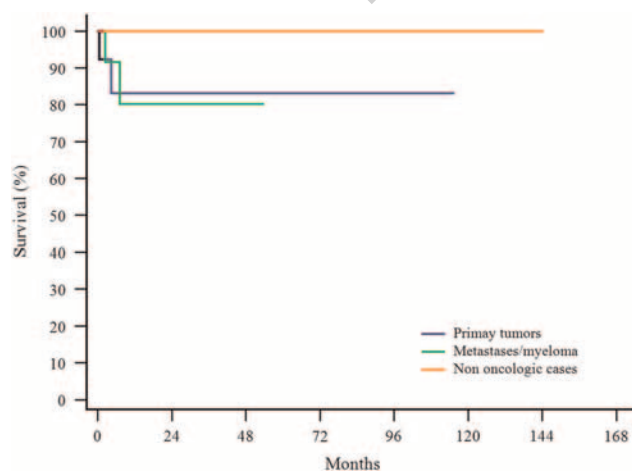
**FIGURE 1.** Kaplan–Meier survival curve showing overall survival that was 56% at 10 yr.



**FIGURE 2.** Kaplan–Meier survival curve showing implants overall survival that was 82% at 4, 8, and 12 yr.

There were mechanical failures including: four type I (wound dehiscence in one and dislocation in three) and one type II. Type III failures did not occur. Wound dehiscence was treated with surgical debridement and dislocations were treated with closed reduction (two patients) or with open reduction and surgical revision, elongating prosthesis spacer, changing the version of the components and using a Trevira tube (one patient). There also was a case of aseptic loosening of a stemmed prosthesis that was revised using a pelvic custom-made prosthesis, maintaining the proximal femoral replacement. Nonmechanical causes accounted for two failures including one type IV and one type V failure. Infection occurred 7 mo after surgery in one patient who had a silver-coated implant. This was treated with removal of the prosthesis and placement of a cement spacer. One patient who had a periacetabular resection and reconstruction with a stemmed cup and proximal femoral prosthesis developed local recurrence of the chondrosarcoma that required internal hemipelvectomy.

The overall implant survival to all types of failure was 82% at 4, 8, and 12 yr (Figure 2). Major complications requiring



**FIGURE 3.** Kaplan–Meier survival curves showing implant survival according to diagnosis with no statistical significant difference ( $P=0.85$ ).

implant removal (aseptic loosening and infection) occurred in 5.2% of patients (2/38); implant survival to major complications was 94% at 4, 8, and 12 yr with no difference between histologies (primary bone tumors, malignant, or nononcologic cases) ( $P=0.85$ ) (Figure 3).

## MSTS Results

Functional results (evaluated with MSTS system) in 27 of 38 (71%) patients was 24.7 (range, 14–30) with excellent or good results except in one patient (Figure 4).

## DISCUSSION

The proximal femur is one of the most common sites of localization both for primary bone tumors and for metastases; consequently it is one of the major sites reconstructed with modular prostheses.<sup>10–18</sup> The advantages of megaprotheses include: (1) immediate stability that allows early mobilization and (2) modularity that allows standardized prostheses ready for use but adaptable to the length of the bone defect. The aim of this study was to analyze our experience with the use of a single-system modular proximal femoral replacement, evaluating the incidence of complications and functional results.

Oncological results are satisfactory after proximal femur resection and endoprosthesis reconstruction.<sup>10,27,29</sup> Streitberger *et al.*,<sup>18</sup> in a study of 99 patients treated with proximal femoral resection and reconstruction for bone tumors, reported that 64 patients had no evidence of disease at a mean follow-up of 65 mo (range, 3–135 mo), four were alive with disease, and 31 died of the disease. Due to systemic involvement by tumor, the prognosis of patients with metastases is lower than those of patients treated for primary bone tumor, as reported by Calabrò *et al.*<sup>23</sup> In their series of 109 oncologic patients treated with a megaprosthesis after proximal femoral resection, most (64%) were affected by metastasis, and at a mean follow-up of 2.5 yr, 16 patients were alive with no evidence of disease, three patients had no evidence of disease after treatment of metastasis, and 29 patients were alive with disease, while 54 patients died of their disease, and one patient died of another disease. Houdek *et al.*,<sup>32</sup> in a series of 204 patients treated with proximal femoral resection and prosthetic reconstruction for malignancies (59% with metastatic disease), reported that 166 (81%) patients died of disease at a mean follow-up of 7 yr (range, 2–22 yr). Overall survival was 41%, 25%, 13%, respectively at 2, 5, and 10 yr. However, modular replacements are satisfactory reconstructive options also in patients with bone metastasis, allowing better oncological results compared with intramedullary nailing and endoprosthetic replacement. Indeed, Angelini *et al.*,<sup>22</sup> in a study of 40 patients with pathologic fractures (29 patients) or impending fractures (11 patients) due to a metastatic lesion of the proximal femur, reported that 23 patients were alive with disease, three patients were alive without evidence of disease, and 14 patients were dead with disease. They noted a significantly better survival in patients treated with proximal femoral reconstruction compared with intramedullary nailing and endoprosthetic replacement ( $P=0.0080$ ). In line



**FIGURE 4.** A, Preoperative radiograph and CT that showed an osteolytic lesion with a soft-tissue component. B, Postoperative radiograph after resection and proximal femoral replacement. C, Functional results of the patient (MSTS score 27).

with the literature, our study on patients with primary bone sarcomas (55.2%) and metastases (39.5%) of the proximal femur showed at last follow-up that 12 patients had no evidence of disease, three had no evidence of disease after treatment of a recurrence or metastasis, 12 were alive with disease, and nine had died of the disease.

Moreover, the complication rate after proximal femoral reconstruction is lower than other sites.<sup>27</sup> The most frequent complication is instability of the hip, whereas infection is quite rare. In the multicentric study with the biggest series of modular tumor prostheses published by Henderson *et al.*,<sup>27</sup> 2174 patients treated with primary modular tumor megaprotheses between 1974 and 2008 at five institutions were analyzed. Of these patients, 403 (19%) had proximal femoral replacement. Failures occurred less frequently in proximal femoral replacement, where the incidence of complications

was 16% compared to the proximal humerus (17%), distal humerus (17%), total humerus (19%), total femur (27%), distal femur (27%), proximal tibia (34%), or combined distal femur-proximal tibia prosthesis (43%). Type I was the most frequent complication (5.2%), followed by type V (4%) and type IV (3%) failures. Henderson *et al.*<sup>28</sup> published the results of a multicentric study on 527 proximal femur modular prosthesis reconstructions after resection of bone tumors in five centers between 1982 and 2011. The incidence of dislocation was 4% (20/527) at a mean time of 35 days postoperatively without association between capsular repair and a reduction of instability. Multivariate analysis showed age older than 60 yr, female gender, malignant primary bone tumor, and benign condition as variables significantly related to instability; while a posterolateral approach was protective against instability.<sup>16</sup> Angelini *et al.*<sup>22</sup> reported an overall

complication rate of 22.5%; dislocation was the most frequent complication (3/12, 25%) followed by wound dehiscence (2/12, 16.6%) and deep infections (2/12, 16.6%). Dislocation was treated in all patients with closed reduction. Houdek *et al.*<sup>32</sup> found an incidence of revision surgery of 11%; it was necessary to treat recurrent instability in only 9% of patients (2/22) and to treat deep infection in 22.7% of patients (5/22). Amputation was necessary in two patients with infection. Calabrò *et al.*<sup>23</sup> reported dislocation (3.9%) and infection (5.8%) as the most common complication after proximal femoral reconstruction, even if no patient required revision surgery for dislocation. Infection risk, however, could be decreased using a silver-coated prosthesis, such as reported by Streitbuerger *et al.*<sup>18</sup> The authors presented a study of 99 patients with proximal femoral prostheses, made by titanium (in 35) and silver-coated (in 64). Infections were observed in 14.3% of the patients (5/35) in the titanium group and in only 9.4% (6/64) in the silver-coated group. Prosthesis survival to infection at 5 and 10 yr was better in the silver-coated group than in the titanium group (90% vs. 83%) but without a statistical difference ( $P=0.568$ ). In our series, the overall failure rate was 18.4%, and dislocation was the most frequent complication (7.9%). Dislocation required revision surgery in one patient, while closed reduction was most frequently used. Infection occurred in one patient only (2.6%). We believe that the low incidence of infection in our series could be related to the use of silver-coating.

After proximal femoral replacement, functional results are satisfactory, with patients able to recover autonomy and daily life activity.<sup>10,27–29</sup> Also patients with a poor prognosis related to metastatic disease could benefit from prosthetic reconstruction, with improvement in quality of life resulting from reduction in pain<sup>18,28</sup> and could live their last years walking, without major limitations and with good functional results.<sup>10,27–29</sup> In our series the mean MSTS score was 24.7 (range, 14–30) with excellent or good results in all patients except one.

### Limitations

This study has some limitations: First, this is a retrospective study of patients treated with proximal femoral reconstruction for bone tumor, and second, there was no homogeneity in diagnosis of the patients with bone tumors. However, in order to obtain more homogeneous data, we included in the analysis only patients treated by the same orthopaedic surgeons and with the same modular prosthetic system for proximal femoral replacement.

### CONCLUSIONS

In proximal femoral reconstruction with modular prostheses, we recommend (1) capsular repair (even if it was not significantly associated with a reduced rate of instability); (2) the use of synthetic augmentation, when necessary to improve stability; (3) the use of hemiarthroplasty over total hip arthroplasty, considering the optimal functional results of the latter with decreased operating time and the possibility to preserve bone stock; and (4) the use of abduction bracing in the early postoperative period in female or older patients to decrease the risk of dislocations due to better healing of the remaining soft-tissue around the prosthesis.

The overall survival of MUTARS® prostheses was satisfactory with good implant survival in proximal femoral reconstruction.

Dislocation was the most frequent complication followed by infection. Silver-coating is one of the main advantages of this system and seems to be associated with a reduction in infection rate. Functional results were good or excellent in most proximal femoral reconstructions; however, multicentric cooperative studies and research are the key to further progress.

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