Results of Using Modular Mega Prosthesis after Proximal Femoral Tumor Resection

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ABSTRACT
Background: Proximal femoral replacement (PFR) is a commonly performed procedure to restore extensive bone defects for different indications with variable reported outcomes.
Objective: This retrospective study aimed to assess the functional outcomes and complication rates of PFR with MUTARS or Hipokrat modular femoral mega prosthesis after oncological resections and to highlight the overall patient, limb, and implant survivorship.
Patients and methods: A total of 18 patients had PFR after oncological resection. 14 patients had bipolar hemiarthroplasty (BHA) and 4 patients had total hip arthroplasty (THA). At the final follow-up, the patient's functional outcome was assessed by Muscloskeletal Tumor Society score (MSTS) and Toronto Extremity Salvage Score (TESS). Complications were recorded and classified according to the Henderson classification.
Results: The mean follow-up was 47.78 months (14-103 months). The mean MSTS and TESS score was 65.7 (range 23-97%) and 81 (range 56-98) respectively. Overall limb, implant, and 5-year patient survival were 94%, 94%, and 66% respectively. The overall complication rate was 39%; 11% instability, 17% periprosthetic fracture, 5.6% infection, and 5.6% local tumor recurrence. **Conclusion**: PFR is a valid option for reconstruction of huge bone loss after oncological resection of the proximal femur with acceptable longevity, functional outcome, and complication rate with better BHA over THA reconstructive option for stability issues.
Keywords: Proximal femur, Tumor, Endoprosthesis, Sarcoma, Metastasis.

INTRODUCTION

Primary malignant and benign lesions as well as metastatic illness frequently occur in the proximal femur. It is the primary site for metastases after the spine and the third location for bone sarcoma after the distal femur and proximal tibia [1].

Amputation was once the standard of care for bone sarcoma, but now, because of improvements in surgical skills and adjuvant therapies, limb salvage is possible. The gold standard for limb salvage now is broad local excision followed by reconstruction[2].

Large defects in bone and soft tissue may be left behind after surgical removal of proximal femur bone cancers. Following such excision, three main reconstructive alternatives are viable: a composite biological reconstruction, an osteoarticular allograft, and the use of a tumor prosthesis. The most common technique nowadays is endoprosthetic reconstruction, which can be either modular or custom constructed. The femoral neck length, angle, and anteversion angle may all be adjusted with the modular prosthesis. As a result, it enables intraoperative adaptation to the patient's specific defect[3].

Despite recent developments in the prosthetic PFR, there are still numerous obstacles to overcome and conflicting data concerning implant failure. To achieve a large margin, it is frequently necessary to sacrifice crucial components including the joint capsule, the greater trochanter where the gluteal muscles attach, and the lesser trochanter where the ileo-psoas muscle inserts, leading to joint instability[2]. Between 1% and 37% of patients who have had proximal femoral replacement (PFR) with an endoprosthesis experienced hip instability, which is the most frequent cause of failure in multiple datasets[4]. This study concentrates primarily on clinical, oncological, and functional outcomes of PFR after oncological resection with implant longevity and patient survivorship as secondary outcomes.

PATIENTS AND METHODS

A retrospective study was conducted, from 2014 to 2022, targeting patients who had proximal femoral modular mega prosthesis for oncological indications using prospectively collected data from the registry for patients and their follow-up for a minimum of one year at the outpatient clinic.

Preoperative evaluation included radiographs and magnetic resonance imaging of the pelvis and the proximal femur and computed tomography (CT) of the lungs. CT-guided or open biopsy was obtained to confirm the pathological diagnosis. Pre and post-chemotherapy and or radiotherapy regimens were decided by a multidisciplinary team, which included an orthopedic surgeon, a histopathologist, a medical oncologist, and a radiation oncologist. Two patients (11%) were presented with pathological fractures.

Surgical technique

All patients were operated, under spinal anesthesia enhanced with epidural catheterization, using the posterolateral approach in the lateral position, including the biopsy track. The gluteus maximus was detached from its osteo-facial insertion and reflected posteriorly exposing the sciatic nerve and short rotators of the hip, then the Gluteus Medius and Minimus detached with a safety margin away from their tendinous insertion, except in a single patient the greater trochanter was preserved. The hip joint capsule was opened longitudinally along its anterolateral

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aspect and detached circumferentially from the femoral neck with preservation of its acetabular attachment in all patients for capsular repair around the prosthesis. Osteotomy of the femur was carried out at the appropriate level, 3 to 4 cm beyond the most distal point of the tumor for primary sarcoma and 1 to 2 cm for metastatic and benign lesions. A normal tissue sleeve was excised circumferentially for wide local excision in 1ry sarcoma excision. After the resection of the tumor, modular trial prosthetic components were then assembled to match the length of the defect, and an assessment of stability, range of motion, limb length discrepancy, and distal vascularity were conducted before implanting the actual prosthesis.

A purse string suture capsular repair reinforced by suturing the remnant hip muscles such as the pectineus, the external rotators, and the psoas to the capsule was performed. The reattachment tube, either a MUTARS treveira tube or traditional nylon mesh for hernia repair molded circumferentially around the prosthesis, was sutured proximally to the remanent of the capsule and held tightly to the body of the prosthesis using nylon tape. The remaining hip abductor muscles and vastus lateralis were sutured to the holes of the prosthesis using a nonabsorbable Ethibond suture in all patients and enforcement sutures were added to the underlying capsule and attachment tube.

A hip abduction brace was used for three weeks following surgery. After three weeks, partial weight bearing was permitted, and full weight bearing was permitted after six weeks. Next surgery, patients were regularly monitored for the first three months, then every three months for the following two years, every six months for the following five years, and once a year for the following ten years. Clinical evaluation, femur, and pelvic radiographs, and a chest CT were all performed as part of the follow-up.

Functional outcomes were assessed utilizing the MSTS[(5)] and TESS[(6)] at the time of final follow-up. Conserved abduction force, the abduction force of diseased limb compared to that of healthy limb, was measured using a manual muscle test. Complications were classified according to Henderson's classification[(7)]. All revision surgeries with their causes and outcomes, besides overall implant, limb and patient survival were recorded.

Ethical consent:

The Ethical Institutional Review Board at Mansoura University approved the study. After explaining our research objectives, written informed consent was obtained from all study participants. This study was conducted in compliance with the code of ethics of the world medical association (Declaration of Helsinki) for human subjects.

Statistical analysis

SPSS software, version 18 (SPSS Inc., PASW Statistics for Windows version 18), was used to conduct the statistical analysis. SPSS Inc., Chicago. A p-value less than 0.05 was regarded as significant. To determine overall survival and disease-free survival, the Kaplan-Meier test was utilized, along with log-rank X^2 to identify the impact of risk variables on survival.

RESULTS

Demographic data

A total of 22 patients underwent proximal femoral replacement (PFR), of them four patients were excluded as they passed away before the one-year follow-up. There were 8 females (44.4%) and 10 males (55.6%), with a mean age at the time of surgery of 40.44+_17.33 years (range, 14-59 years). Patients were followed for a mean of 47.78 ± 31.24 months (range 14-103 months).

Table (1): Demographic data in the cases of the study

Items		Study cases (N = 18)	
Age (years)	Mean ± SD	40.44 ± 17.33	
	Median (min-	49 (14-62)	
		Number	**Percent**
Sex			
Male		10	55.6
Female		8	44.4

Clinical and operative data

As shown in **Table 2**, 50% of patients had a primary tumor, while 39% had bone metastasis. 2 patients (11%) were presented with pathologic fracture and the most common pathologic diagnosis was Ewing sarcoma.

Table (2): Clinical data in the cases of the study

Items	Study cases N = 18	
Diagnosis	**value**	**%**
Primary tumors	9	50.0
Secondary tumors	7	38.9
Benign tumors	2	11.1
Pathological fractures	**2**	**11.1**
Chest metastasis	**4**	**22.2**
Biopsy results		
BFH	1	5.6
breast cancer	2	11.1
Chondrosarcoma	2	11.1
Ewing sarcoma	4	22.2
Fibrosarcoma	1	5.6
HCC	1	5.6
MM	3	16.7
Osteochondroma	1	5.6
Osteosarcoma	2	11.1
RCC	1	5.6

BFH: benign fibrous histiocytoma. HCC: hepatocellular carcinoma. MM: multiple myeloma. RCC: renal cell carcinoma.

In 6 patients (33.3%), Modular Universal Tumor and Revision System (MUTARS, Implantcast Corp., Buxtehude, Germany) was used and in 12 patients (66.7%), Hipokrat Bone Reconstruction System (HBRS) was used. Acetabular resurfacing was done in only 4(22.2%) patients, all cemented, while in the remaining 14(77.8%) patients bipolar hemiarthroplasty (BHA) was the selected choice. 7 patients (39%) had cemented stem fixation, while 11 patients (61%) had cementless stem fixation. Operative details are summarized in **Table 3**.

Table (3): Operative data of the studied cases:

Operative data	n=18	%
Length of defect	15.89±3.91 (8-24) CM*	
Use of attachment tube	15	83.3
Type of implant		
MUTARS	6	33.3
Hipokrats	12	66.7
Stem fixation		
Cemented	7	38.9
Cementless	11	61.1
Acetabular resurfacing		
BHA	14	77.8
THA	4	22.2
Femoral offset		
Standard	10	55.6
Short	8	44.4

*Continuous data expressed as mean±SD and (range).

Follow-up and oncological outcomes

In the current study, a single patient (5.6%) had local recurrence managed by palliative amputation and then died one month later. By the end of the study, 5 patients passed away, of them 4 patients due to complications of the disease and the fifth due to complications of COVID-19 infection. The limb salvage rate was 94.4% and The Kaplan-Meier 5-year overall patient survivorship estimate was 66% (95% confidence interval (CI), 76.63(57.69-95.57).

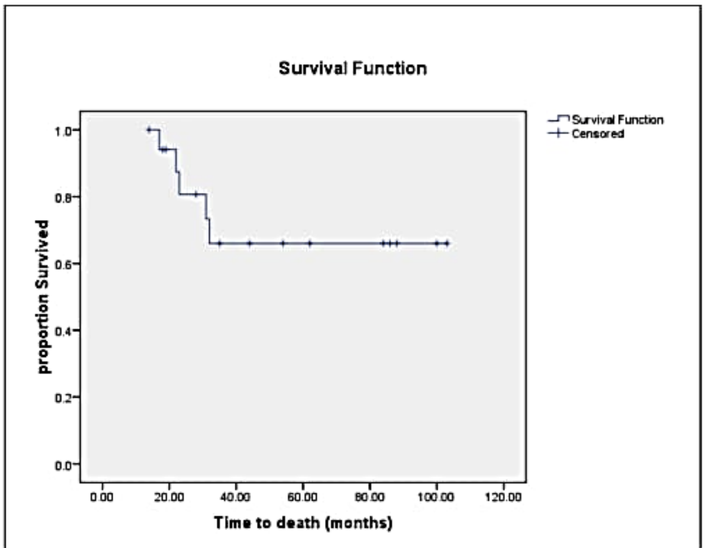

Figure (1): Kaplan-Meier overall patient survivorship estimate.

Clinical and Functional outcomes

The mean conserved abduction force was 66.67 ± 16.61. A statistically significant difference was obvious among study groups "1ry, 2ry and benign" with a high score as expected for benign lesions. The mean MSTS score was 65.72 ± 15.62 (range 23-97%) while the mean TESS was 81.06 ± 11.02 (range 56-98). There was a statistically significant difference between the type of gender and methods of fixation according to MSTS score with higher scores for male gender and cementless fixation. Also, a statistically significant correlation between the MSTS and TESS scores (r=0.867, p<0.001) was observed. The mean femoral resection length was 15.89±5.38 (8-24) Cm and did not correlate significantly with MSTS score (r=0.380, p=0.120).

Table (4): Clinical and functional outcome of studied cases:

Items		Study cases N = 18
MSTS (%)	Mean ± SD	65.72 ± 15.62
	Median (min-max)	67 (23-97)
MSTS categories	No.	%
Excellent	4	22.2
Good	9	50.0
Fair	4	22.2
Poor	1	5.6
TESS	Mean ± SD	81.06 ± 11.02
	Median (min-max)	81 (56-98)
Conserved abduction force	Mean ± SD	66.67 ± 16.61
	Median (min-max)	60 (40-100)

Complications and implant longevity

Overall complications occurred in 7 patients (39%). Instability, type 1 failure, occurred in 2 patients (11%), both were managed by closed reduction. No implant was revised for aseptic loosening, type 2 failure, implant failure, and type 3a failure. Three patients (17%) had a periprosthetic fracture, type 3b; two distal to the stem managed by open reduction and internal fixation, and one around the acetabular component managed conservatively. One patient (5.6%) had an acute superficial infection, type 4 failure, that was managed by debridement and irrigation with retention of the implant. Finally, local recurrence, type 5 failure, occurred in a single patient that had palliative amputation "**Figure 2**". At the end of the study, the overall reoperation rate for any cause was 17% with implant survivorship of 94.4%.

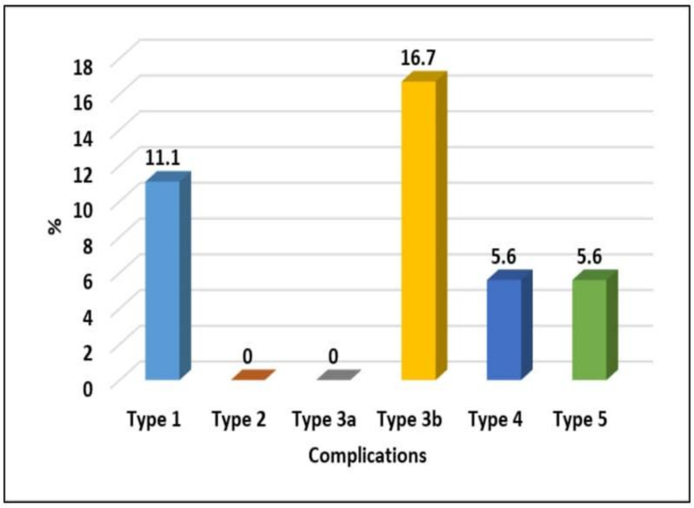

Figure (2): Complications in the study group.

DISCUSSION

Limb salvage through wide local excision followed by reconstruction by any method has become the gold standard for the treatment of proximal femoral tumors [8]. The most common reconstruction methods are allograft prosthetic composite (APC) and endoprosthetic PFR. Bone stock preservation, tendon reattachment, and better implant stability and function are the main advantages of the APC technique. However, the results of this technique have been variable, with generally increased complication rates[9-10].

After proximal femoral resection, a considerable length of the bone and surrounding soft tissue were excised. The mean length of the defect in this study was 15.89 Cm (range 8-24 Cm) which is comparable to the literature[11-15]. In this study, there was no correlation between functional outcome and implant longevity with femoral resection length. Prior studies have examined the relationship between resection length and implant longevity with varying results either significant or not[16-17].

The primary outcome of the current study was assessing the functional outcome of patients after PFR. The mean MSTS score was 65.72 ± 15.62 (range 23-97%) which is comparable to the literature [18-22]. The mean TESS was 81.06 ± 11.02 (range 56-98) which is higher than reports in the literature [14, 19, 21]. **Potter and associates**[20] reported that increasing age, associated pathological fracture, and metastatic disease were statistically significant predictors of worse MSTS scores while no relation to the length of femoral defect, but unlike the literature, there was no relation between functional scores and these factors in the current study may be due to low power of this study. Finally, as reported by **Crenn and associates**[23]**,** this study shows a statistically significant relation between MSTS and conserved abduction force.

Type 1 failure in Henderson classification, instability, is considered the most common complication in several series[4] with a variable incidence in literature [15, 21-22]. In this study, 2 patients (11%) had single dislocation that was successfully reduced by closed reduction and bracing. Comparing our results with the literature, it appears that BHA is inherently more stable than THA thanks to its large head size. However, some authors raise the option of THA in selected populations for the theoretically high risk of acetabular erosion necessitating conversion from BHA to THA[4].

Aseptic loosening is considered the most common endpoint for the endo-prosthetic implant necessitating its removal and may occur in 0–11% of PFR[24]. In this study, no obvious sign of aseptic loosening or significant relating complaint was detected in any patient in intermediate-term FU i.e. the overall implant survival with aseptic loosening as an endpoint was 100%, but with longer FU time aseptic loosening may occur necessitating implant revision. Despite the numerosity of the literature, it is still inconclusive if cemented or cementless diaphyseal stems show better results regarding the risk of aseptic loosening and implant survival in PFR[20, 25-27].

Type 3 failure, structural failures, is classified into; 3a, Implant wear or breakage necessitating revision, and 3b, periprosthetic fracture[7]. In the current study, close to literature [14, 20, 22, 28], no one had type 3a failure, but 3 patients (17%) had type 3b failure: 2 patients had significant trauma ended with periprosthetic fracture, one of them was managed conservatively and the other one surgically. The third patient, Multiple Myeloma, was presented with a pathological fracture and managed surgically.

Cancer patients are more prone to infections, type 4 failure, because of wide resections, tissue loss, prolonged surgical time, and radiotherapy or use of chemotherapeutic agents[29]. **Menendez and associates**[22] reported 6 patients (6.3%) with infection of them 3 were managed by just debridement, 2 needed two-stage revision and one required disarticulation, while **Stevenson and associates**[27] reported 4 infected patients were successfully managed by debridement, irrigation, and retention of implant “DAIR”. In the current study, a single patient (5.6%) acquired early postoperative infection that was successfully managed by debridement.

Tumor recurrence, type 5 failure, is classified into soft tissue or bone recurrence and can be managed by re-excision plus adjuvant therapy, amputation, or palliative therapy[7]. Local recurrence has variable incidence in literature from 0 to 10%[14, 21, 22, 28]. In the current study, a single patient (5.6%) with fibrosarcoma had local recurrence, managed by palliative disarticulation. Like the report of **Houdek and associates**[30], this study shows no relation between local recurrence with age, gender, pathological fracture, chemotherapy, radiotherapy, and length of the defect. Moreover, **Houdek and associates**[30] found no relation between contaminated margins and high-grade tumors with the risk of local recurrence.

Implant survival is defined as the percentage of implants which required no revision or removal of any part. In the current study with a mean FU close to 4 years, implant survival was 17 (94%) which is close to 5-year implant survival in literature [15, 21, 22, 27]. However, there is no debate that the implant survival rate will decline with longer FU as reported in the same literature [15, 21, 22, 27].

In this intermediate-term study, mild acetabular erosion was obvious in some patients, but no single patient acquired protusio acetabuli necessitating conversion to THA. The potential of late acetabular wear necessitating conversion to THA has been reported with a range from 0 to 12%[27, 28]. Putting into consideration the previously mentioned superiority of BHA over THA in stability issues, many authors prefer BHA in oncology patients[20, 31].

Limb salvage surgery is nowadays the standard of care, whenever possible, in oncological resections. percentage of individuals who did not have amputations during FU duration is defined as limb salvage rate. The limb salvage rate in the current study was 94.4%, close to the literature [10, 22, 328]. The main risk factors for amputation are local recurrence and or infection[14, 22, 27, 28]

At the end of this study, 5 patients(28%) have already died with an overall 2 and 5-year survival rate of 80.7% and 66% respectively. **Houdek and associates**[30] reported 2, and 5-year overall survival of 41%, and 25% respectively, while **Puchner *et al.*** [14] **and Chandrasekar *et al.*** [15] had a 1-year survival of 65% and 94.9 and 5-year survival 30% and 90.7% respectively. This variation in literature is due to the diversity of study groups and predictors of mortality. In the current study, like the literature[30], a statistically significant relationship between mortality and age of the patients was obvious, while, unlike the literature [14, 20, 30], no relation with other factors like associated pathological fracture, chest metastasis, and nature of the disease. This is likely due to the inadequate power of this study.

STUDY LIMITATIONS

- Despite having prospectively collected data, this study was a retrospective series, therefore had the same limitations and biases as all retrospective studies.
- Our current duration of follow-up was intermediate; mean follow-up approaching 4 years with a 1-year minimum FU.
- The number of patients involved in the study is limited giving sometimes false statistical errors.
- Finally, even though repeatedly supported by many kinds of literature, the study population wasn't homogenous "primary and metastatic".

CONCLUSION

PFR is a valid option for the reconstruction of huge bone loss after oncological resection of the proximal femur with acceptable longevity, functional outcome, and complication rate in an intermediate-term study in comparison to other reconstruction methods. Bipolar hemiarthroplasty is a better option than THA in PFR for stability issues despite the low risk in a certain population of acetabular erosion necessitating conversion to THA.

RECOMMENDATION

The number of patients in the study needs to be expanded to get more valid results, besides, longer-term FU, more than 10 years, is needed to confirm longevity and detect accurate revision rate after PFR. The study population needs to be grouped according to the nature of the disease "1ry, 2ry" and compared to each other to get more valid results.

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