The use of Modular Endoprosthesis for Tumors of the Proximal Femur

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ABSTRACT

Background:

Modular endoprosthetic replacements are commonly required to treat primary bone tumors as well as solitary metastasis of the proximal femur. Modular prostheses provide an off shelf availability and can be adapted to most reconstructive situations for proximal femoral replacements.

Patients and methods:

Twelve consecutive patients underwent resection of the proximal femur and modular endoprosthetic replacement. The mean age was 45 years (ranging from 19 to 66 years). The follow-up period of the study ranged from 14 to 120 months with a mean of 40 months. The Musculoskeletal Tumor Society (MTS) score described by Enneking et al. was used to assess functional outcome.

Results:

At latest follow up, two cases with metastatic diseases of the proximal femur were still alive with the disease. Another patient died after 14 months due to systemic metastasis. Eight cases were rated as excellent and one case as good. One case developed a localized soft tissue recurrence in the surgical incision that appears six months after surgery and was excised with safety margin.

Conclusion:

Modular endoprosthetic reconstruction provides good functional outcome in patients after proximal femoral tumour resection. They provide yet another treatment option in limb salvage. These patients have been evaluated and seem to have acceptable functional outcomes.

Introduction:

The proximal femur and mid-femur are common sites for primary bone sarcomas; approximately 16% of Ewing's sarcomas, [1] 13% of chondrosarcomas, [2] and 10% of osteosarcomas develop at these locations. Metastatic tumors are the most common malignant lesion of the proximal femur, with carcinomas being the most frequent. [3]

The principal goal in the management of patients who have a primary bone sarcoma and metastasis is prolonging their survival. Primary bone sarcomas that require surgical resection can be treated by either amputation or limb salvage. Most studies comparing limb salvage and amputation reported that limb salvage had no adverse effect on the long-term survival of patients. [4]

Improved imaging techniques, chemotherapy and implant design have allowed limb sparing surgery to become established in the treatment of malignant bone tumors. [5-7] Surgical options for reconstruction include endoprosthetic replacement, allografts, autografts including vascularised fibular grafts, arthrodesis, rotationplasty and bone transport. [6, 8-10]

Advances in prosthesis design and a systematic approach to the staging and surgical treatment of musculoskeletal tumors have made limb salvage possible in the proximal femoral region. With the use of effective adjuvant therapy, limb salvage is now an option for the majority of patients presenting with locally invasive neoplasms in this area. [11]

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Fig. 1:
(a) a case of metastatic adenocarcinoma of the breast with pathological fracture.
(b) Tc99 bone scans of the same case.
(c& d) follow up X-rays after resection and reconstruction

This study aims to evaluate the functional outcome of 12 patients with primary malignant bone tumors and bone metastasis of the proximal femur that necessitated large bone segment resection and endoprosthetic replacement.

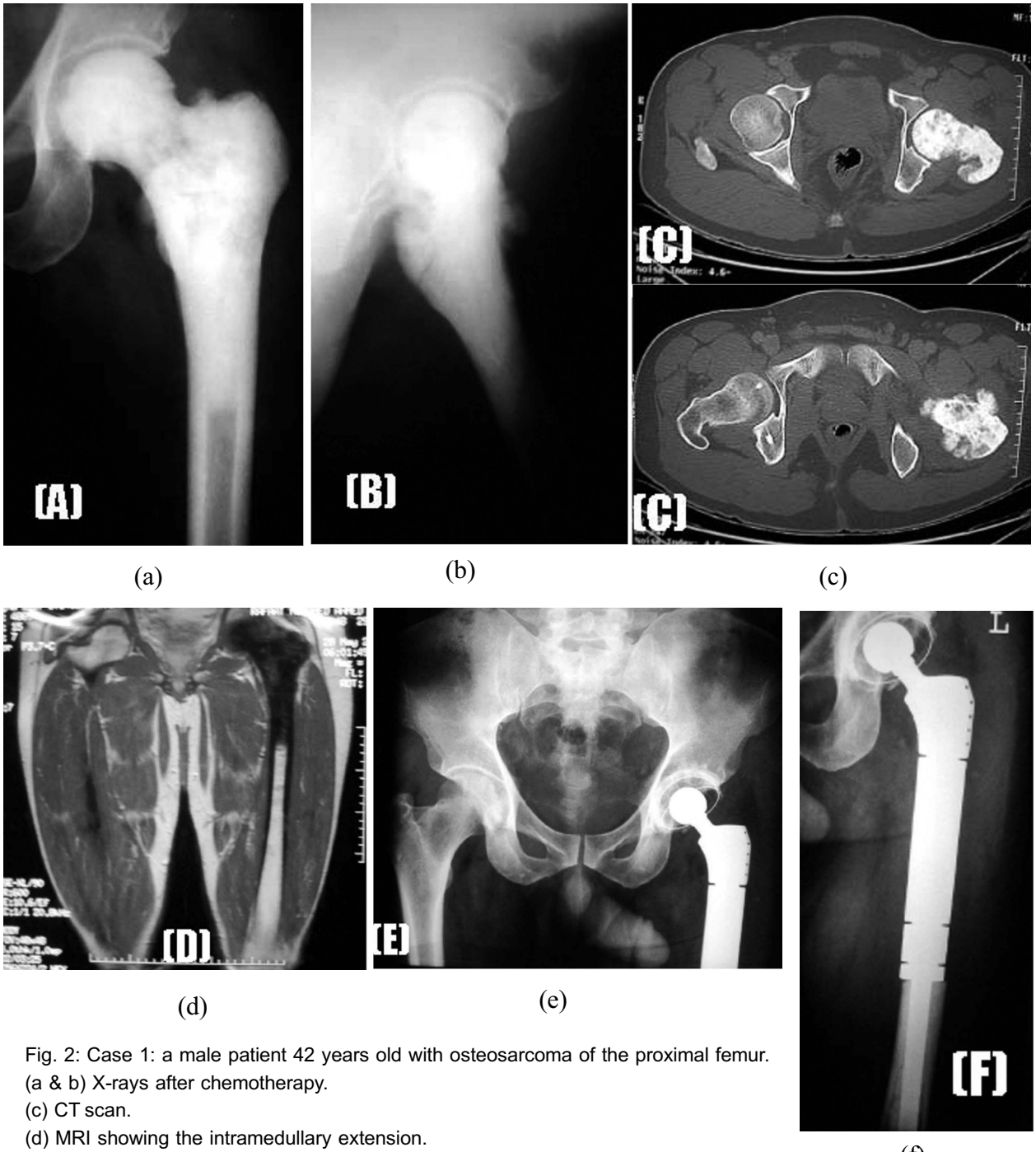
Patients and Methods:

Twelve consecutive patients underwent resection of the proximal femur and modular endoprosthetic replacement for the diagnosis of osteosarcoma (*n*=3), chondrosarcoma (*n*=3), metastasis (*n*=3), haemangiopericytoma (*n*=1), recurrent liposarcoma (*n*=1) and giant cell tumor (*n*=1). There were 7 males and 5 females. The mean age was 45.25 ranging from 19 to 66 years.

The primary tumor in the metastatic patients was adenocarcinoma of the breast in 2 cases and renal cell carcinoma in one case. One case (Case 10) presented to us with recurrent liposarcoma of the proximal femur one year after having marginal excision and replacement of the cavity with bone cement and composite plate fixation. The staging system of Enneking et al. [12] was used to classify primary bone tumors, accordingly, there was 5 cases graded as stage IIB, one case IIA, one case IA and one case was IB.

The follow up period of the study ranged from 14 to 120 months with a mean of 40 months.

Before surgery, the extent of disease and the presence of metastases were determined by clinical assessment and staging studies including, plain radiographs, CT, MRI and isotope bone scan (Fig.1 &2). Angiography also was done to evaluate tumor relation to the femoral bundle. Open biopsy was performed in all cases to make a histological diagnosis.



(a) (b) (c)

(d) (e) (f)

Fig. 2: Case 1: a male patient 42 years old with osteosarcoma of the proximal femur.
(a & b) X-rays after chemotherapy.
(c) CT scan.
(d) MRI showing the intramedullary extension.
(e & f) Follow up X-rays after resection and prosthetic reconstruction.

Limb-sparing surgery was planned, if wide excision could be performed, without sacrificing major nerves or vessels as decided by the staging studies. Imaging studies were used to determine the level of resection and to calculate the proportion of the femur resected.

Neo-adjuvant (pre-operative) chemotherapy was used in 3 cases all were osteosarcoma. All of them were managed with the same preoperative *chemotherapy protocol* of three cycles at three-weeks-interval. In each cycle the patient was given Adriamycin 75mg/m2 and cisplatin 150mg/m2 for three days. After completion of the three cycles, restaging of the tumor was done using the same preoperative imaging studies.

All patients underwent wide excision of the tumor with clear margins. The patient was put in a lateral position, and the proximal femur was

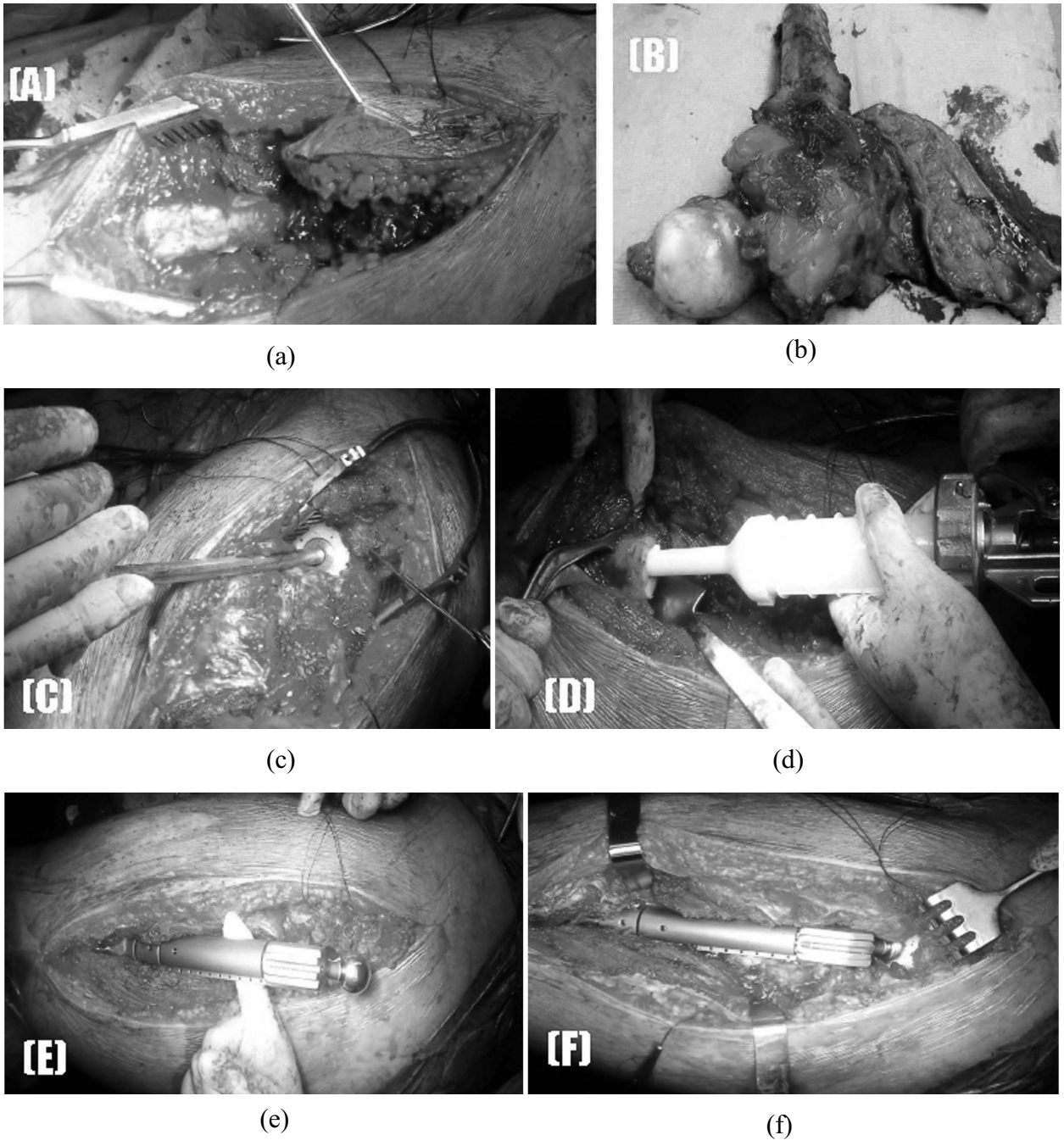


Fig. 3: Intra-operative photos of the surgical procedure.
(a) The surgical approach including the biopsy scar.

(b) The resected segment with safety margin.

(c) The application of the cemented constrained cup.

(d & e) Cementation of the femur and application of the stem.

(f) The prosthesis after complete application and reduction.

dissected through a direct lateral approach. The previous biopsy scar was included en bloc with resected segment (Fig.3a). Following resection of the proximal femur, the length of the resected femur or the defect was measured (Fig.4). The resultant defects ranged from 16 cm to 26 cm with a mean of 19.7 cm. The size of the femoral head, or the acetabular component was measured. Bipolar head was used in three cases while acetabular replacement with cemented constrained (captive) (Fig.3c) cup was used in 9 cases.

The diameter of the distal medullary canal was measured. The largest possible stem diameter was used. A 1-mm cement mantle is required around

the stem. The intramedullary canal is therefore reamed 2 mm larger than the chosen stem diameter.

Following trial positioning of the prosthesis (Fig.3E), the pulses are palpated distally; if diminished, a shorter prosthesis is used. The joint capsule is pulled over the femoral head component, and the range of motion of the hip joint is tested. The prosthesis should be stable in flexion, adduction, and internal rotation. The cementing technique involved lavage, and pressurization (Fig.3D).

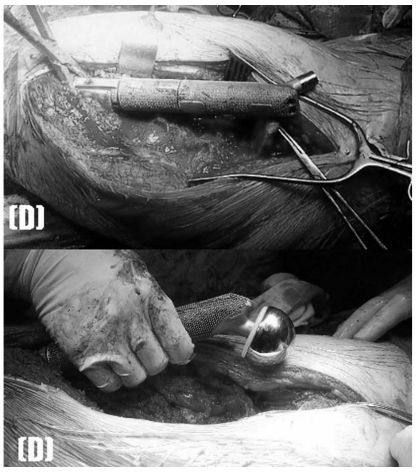
The modular prosthesis is assembled and cemented into the medullary canal. Cementless stem with extra-cortical fixation through a side plate was used in one case (case 12) (Figure 4). The orientation of the prosthesis is critical. With the linea aspera as the only remaining anatomic guideline the prosthesis is placed with the femoral neck anteverted about 5-10ºwith respect to an imaginary perpendicular line from the prosthesis and a line drawn from the linea aspera through the body of the prosthesis. Leg length is evaluated and the neurovascular bundle is assessed again for excessive tension.

Local soft-tissue reconstruction was performed with emphasis on securing the hip abductors onto the prosthesis as well as the remnant of the vastus lateralis and Dacron tape were used to secure the remnant of the capsule to the prosthesis (capsulorraphy).

(a)

(b)

(c)



(d)

(e)

Fig. 4: A case of low grade chondrosarcomas of the proximal femur.
(a & b) Pre-operative X-rays.
(c) The resected segment.
(d) Intra-operative photos showing the application of the prosthesis.
(e) Follow-up X-rays.

(a) (b) (c)

Fig. 5:
(a) plain X-ray of a case of haemangiopericytoma of the proximal femur with pathological fracture.
(b & c) post-operative and follow up X-rays

Continuous suction is required for 3-5 days after surgery, to prevent fluid collection. Per-operative intravenous antibiotics are administered until the sutures are removed on day 15.

All patients underwent the same rehabilitation protocol. Non-weight bearing on crutches/walker was allowed at week 3, followed by conversion to a cane for the next 3 to 6 weeks. Weight bearing was allowed after good abduction strength was regained.

Post-operative adjuvant therapy was used in 6 cases in the form of chemotherapy for three cases of osteosarcoma and radiotherapy in three cases of metastasis.

Follow-up examinations with standard x-ray series were performed at 1, 3 and 6 months, followed by every six months for 2 years and then annually. We analyzed the prosthetic survival, the functional outcome, the risk of revision of the prosthesis, the incidence of failure of limb salvage because of amputation and complications like dislocation and infection following the use of the modular prosthetic replacement of the proximal femur.

The Musculoskeletal Tumor Society (MTS) score described by Enneking *et al*. [13] was used to assess functional outcome. Functional outcomes were evaluated after one year and at the latest follow up Numerical values from 0 to 5 points were assigned for each of the following 6 categories: pain, function, emotional acceptance, use of supports, walking ability and gait. These values were added, and the functional score was presented as a percentage of the maximum possible score (The full score is 30). The results were graded according to the following scale: Excellent - 75% to 100%; good - 70% to 74%; moderate - 60% to 69%; fair - 50% to 59% and poor <50%.

Results:

At the latest follow up, two cases with metastatic diseases of the proximal femur were still alive with the disease.

Case 7 was a female patient with metastatic adenocarcinoma of the breast who underwent radical mastectomy one year before being presented with proximal femoral metastasis for which she had resection and proximal femoral replacement followed by post-operative radiotherapy also

the patient was maintained on chemotherapy for the primary tumor. One year later she developed lung metastasis and still living for 20 months post-operatively. Case 9 was a male patient 62 years old with metastatic renal cell carcinoma that developed spine metastasis for which he received local radiotherapy and still living for 32 month post-operatively. Another patient (case 8) died after 14 months due to systemic metastasis.

The remaining 9 patients were evaluated functionally at the end of follow up (table 2). Eight cases were rated as excellent and one case as good. The mean pain relief score was 4.8 (range, 4-5), the mean functional score was 3.7 (range, 3-4), the mean emotional acceptance of the procedure and its outcome was 4.8 (range, 4-5), the mean lower extremity score for support use was 3.3 (range, 1- 4), for walking ability was 3.8 (range, 3-4), and for gait was 4.3(range, 3-5), and the mean total score was 24.7 or 82.3% (range, 21-27 or 70-90%).

The study reports only one case of localized

Table 1: The epidemiological characters of the study group.

Case	Age	Sex	Diagnosis	Stage	Type of prosthesis	Neo-adjuvant therapy	Adjuvant therapy (m)	Length of the resected segment (cm)
1	42	M	OS	IIB	THR with constrained cup	Chemotherapy	Chemotherapy	20
2	34	M	OS	IIB	THR with constrained cup	Chemotherapy	Chemotherapy	22
3	19	M	OS	IIB	THR with constrained cup	Chemotherapy	Chemotherapy	20
4	48	M	CS	IIB	THR with constrained cup	None	None	20
5	42	F	CS	IIA	THR with constrained cup	None	None	18
6	45	M	HP	IIB	THR with constrained cup	None	None	16
7	56	M	Mets	–	Bipolar head	None	Radiotherapy	20
8	66	F	Mets	–	THR with constrained cup	None	Radiotherapy	26
9	62	F	Mets	–	THR with constrained cup	None	Radiotherapy	18
10	48	F	Rec.LS	IB	Bipolar head	None	None	24
11	26	F	GCT	III	THR with constrained cup	None	None	16
12	55	M	CS	IA	Cementless stem with Bipolar head	None	None	16

Table 2: The results.

Case	Follow up (m)	Functional results (%)	Complications	Second operations
1	36	90	Localized soft tissue recurrence	Excision
2	28	27	None	None
3	23	25	None	None
4	44	21	None	None
5	26	25	None	None
6	49	25	None	None
7	Still living 20 months with lung metastasis	–	None	None
8	Dead of the disease after 14 months	–	None	None
9	32 months still with spine metastasis	–	None	None
10	120	23	None	None
11	60	25	None	None
12	36	24	None	None

soft tissue recurrence in the surgical incision that appeared six months after surgery and was excised and had no impact on the oncological or the functional outcome of the patient (case 1).No complications were reported related to prosthetic failure, revision or dislocation.No infections or vascular complications were also reported in the study.

Discussion:

Limb sparing surgery is now widely accepted as appropriate treatment for primary sarcoma of the femur in selected patients. Endoprosthetic replacement of the proximal femur may be required to treat primary bone tumours or destructive metastases either with impending or established pathological fracture. [14]

Endoprosthetic proximal femur replacement is a well-accepted method for treatment of primary bone tumors; however the functional results of treatment are not well documented. [15]

Methods of skeletal reconstruction include resection- arthrodesis, [16] massive osteoarticular allograft, [17] endoprosthetic reconstruction, [18-19] and prosthetic-allograft composites. [20] Osteoarticular allografts, which were popular in the 1970s and 1980s, attempt to restore the natural anatomy of a joint by matching the donor bone to the recipient's anatomy; however, over time they are associated with increased rates of infection, nonunion, instability, fracture, and subchondral collapse that lead to failure. [21]

Megaprosthetic reconstruction has many advantages. It provides immediate stability which allows earlier rehabilitation with immediate full weight-bearing. Most endoprosthesis are modular, thus allowing incremental prosthetic replacement in response to the length of resected bone. In addition, improvement in implant materials has greatly increased the durability of modern endoprosthesis. They are able to achieve their primary aim of providing long-term function for some patients with relatively low physical demands. [22]

Ilyas et al. [23] treated fifteen patients with proximal femoral tumors with resection and limb salvage with an uncemented Kotz (HMRS) megaprosthesis. There were five osteosarcomas, four chondrosarcomas, one hemangioendothelioma, three fibrosarcomas, and two Ewing's sarcomas. The mean follow-up was 6.7 (range 3-10) years. Two patients died of causes not related to the prosthesis. The post-operative Musculoskeletal Tumor Society score (MSTS) was 19 (range 12-26) for the remaining 13 patients. There were one aseptic loosening, two infections, and one local recurrence. The most frequent complication was hip dislocation at 20%.

Our study included 9 patients who had primary bone tumors and 3 patients with metastasis disease of the proximal femur that were treated with modular endoprosthetic reconstruction after tumor resection with a follow up period ranging from14 to 120 months with a mean of 40 months revealed a mean MSTS functional score of 82.3% (21-27). This result is comparable with those in other studies. [14, 15, 20, 22]

There have been few reports on the longevity of proximal femur replacement prosthesis. Dobbs et al. [24] reported 81 patients who underwent proximal femur resection and reconstruction with custom-made prostheses. Event-free survival rates were 73% and 63% at 5 and 10 years, respectively. Unwin et al. [25] reported a series of 263 patients who underwent proximal femur resection with endoprosthetic reconstruction. They reported a 93.8% probability that patients would not experience aseptic loosening during the 10 years following surgery.

Dislocation is a well recognized complication with proximal femoral endoprosthetic replacement with the reported rates of dislocation varying from 1.7% to 20 %[26-28] .This is due to the extensive resection of soft tissues around the hip, including muscles and hip capsule in most cases.

No dislocation had been reported in the current study, this may be attributed to the meticulous repair of the remaining muscle sleeve specially the abductor muscle group and the vastus lateralis to the prosthesis. Another explanation is the use of large bipolar heads in three cases or the use of constrained cups for acetabular replacement.

There is a greater tendency for hip dislocation after massive proximal femur resection than after total hip arthroplasty, in which the abductor mechanism is preserved. [29, 30] It is therefore important that these muscles be preserved following resection. Muscle group tenodesis provides a balanced tension from the lateral and medial

aspects of the femur, reinforces stability, and allows range of motion. [31] A final factor in stabilization is the formation of scar tissue that bridges the joint capsule and adjacent musculature.

We concluded that in our patients a modular proximal femoral endoprosthesis has fulfilled its aim of providing reasonable function with a low rate of complications improving the quality of life for the patients with primary bone tumors and metastatic disease of the proximal femur.

We recommend the use of proximal femoral endoprosthetic replacement for patients with proximal femoral metastases with gross destruction of the proximal femur not suitable for internal fixation and metastatic disease with good prognosis. Reconstruction of proximal femoral tumors with a modular megaprosthesis is a good procedure, but hip instability remains a major problem's bipolar head can be safely used for most patients and if there is acetabular involvement or degeneration a cemented acetabular replacement with constrained cup can be used and together with proper soft tissue repair help to decrease the rate of dislocation.

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