CUSTOM MEGA-PROSTHESIS IN ORTHOPAEDICS AND TRAUMATOLOGY

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INTRODUCTION

The aim of limb salvage in massive skeletal defects is to retain the integrity of the skeleton and preserve a limb with useful function. Custom prosthesis plays a vital role in the reconstruction of skeletal defects. Limb salvage by Custom Prosthesis is still in infancy in India due to the developing technology for fabrication and high cost. The present paper analyses my personal experience and results with custom prostheses.

CUSTOM MEGA-PROSTHESIS

A metallic prosthesis, tailor made for a particular patient with specific measurement is custom prosthesis. The prostheses are of 3 types (a) Off the shelf - the standard prosthesis. (b) Off the table - the modular prosthesis and (c) Specially made to order - Custom Prosthesis.

Custom Orthopaedic implants is an exciting and expanding field. It has always had an important place in Orthopaedic reconstruction. In recent years, the striking advances in 3 dimensional computer modelling and in CAD CAM technology has led to exciting new possibilities in the area of custom prosthesis. In addition, with the advances in materials such as bone growth stimulating coatings, bone substitutes and polymeric composites, the result is likely to be a steady expansion in the use of custom implants in the future. The International Society for study of custom prosthesis is at the leading edge of custom implant designs and brings together an unique group of individuals - surgeons, engineers, scientists and manufacturers from around the world who interact in this technology of custom prosthesis. The role of custom mega-prosthesis in tumours and trauma has now been well established and is no longer considered experimental.

ROLE IN ORTHOPAEDICS

Custom prosthetic implants have been used in Orthopaedic Surgery for skeletal reconstruction after (1) Resection of bone tumours in the limbs. (2) Traumatic segmental bone loss. (3) Hydatid disease of bone. (4) Vertebrectomy and anterior stabilisation of spine.

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PLACE OF WORK

The present work on Limb Salvage by Custom Prosthesis is at the Cancer Institute and College of Oncological Sciences, M.G.R. Medical University and M.N. Orthopaedic Hospital, Madras.

CLINICAL MATERIAL

Custom Prosthesis has been used mainly in skeletal reconstruction after bone tumour excision. A total of 243 cases have been treated by this technique. The period of this study is 9 years from January 1988 to December 1996. Custom Prosthesis has also been used in traumatic segmental loss of bone in 8 cases. 1 case of hydatid hip disease had a custom megaprosthetic replacement. In spinal tumour, anterior stabilisation after vertebrectomy has been by prosthetic replacement in 9 cases.

BONE TUMOURS

Orthopaedic Oncology is a new, still developing field of Cancer Surgery. It deals with the diagnosis, treatment and research of benign, malignant and pseudo tumoural conditions of musculo skeletal system. Sarcomas are rare malignant and pseudo tumoural conditions of musculo skeletal system. Sarcomas are rare malignancies which affects children and young adults. A major task in this subspeciality is the management of sarcomas of the extremities, shoulder and pelvic girdle and spine of all age groups. In the past, these tumours were considered fatal to limb and life and no real treatment options were offered to the patient except amputation surgery. In the last decade rapid advances in chemotherapy, imaging, surgery, bioengineering have changed our historic nihilistic attitude towards these tumours and contributed to the emergence of the modern concept of Limb Sparing Surgery, the Hallmark of Orthopaedic Oncology Management of patients with musculo-skeletal neoplasms has always been one of the most challenging areas in oncology. Historically the treatment of malignant bone tumours of the extremity was mostly by amputation. The past decade of witnessed an explosion of knowledge in the frontiers of science and technology. Current concepts in the biologic behaviours of tumours, clinical staging, oncologic surgery and adjuvant chemo and radiotherapy have enabled local tumour control by resection with ablation. The most recent advance in the reconstruction of tumour resection defects involves the use of custom made prosthetic joints for replacement.

ERA OF LIMB ABLATION

About 2 decades ago, the standard treatment of malignant bone tumours was amputation. This was considered necessary for durable local control.

It was even believed that this kind of ablation should include the entire totality of the affected bone, i.e. for a lesion of the distal femur, disarticulation through the hip joint was advocated to include the skip lesions also. These radical mutilating cancer clearance surgeries led to marked disability and disfigurement.

Amputation is the most merciful of surgeries when it is the only resort, but the meanest of surgeries when better alternatives are available. Amputation not only removes a physical part of the human body but also removes a part of the personality of the patient.

In order to overcome the functional, psychological and social problems associated with amputation, the concept of limb salvage was evolved. Orthopaedic Surgeons, firmly believe in the motto, "Mobility is Life and Life is Mobility". As experience with persons amputated for several conditions increased, there was a strong case of preserving the 'Quality of Life and Dignity of Death' with the slogan 'Limbs are not dispensable'. A surgeon who amputates the limb to save the life of a patient is a good surgeon. A surgeon who saves the limb and life of a patient is a better surgeon. Nowadays amputations should be done only as the last resort in locally advanced disease and for failures and recurrences following other forms of treatment.

EVOLUTION OF LIMB SALVAGE

Over the past 2 decades, there has been an enthusiastic and uninhibited proliferation of limb salvaging (LS) procedures for the management of musculo skeletal tumours. Limb salvaging resection is not new. In 1870, it was condemned by Samuel Gross because of almost universal local recurrence, excessive shortening and marked instability of the salvaged extremity. Resection was only reluctantly performed until the 1930s when it was recognised that certain low grade varieties like secondary chondrosarcoma could be safely managed in this fashion. In the late 1960s with the advent of adjuvant chemotherapy and radiation therapy, limb salvage was cautiously embarked upon for classical high grade sarcomas. A surgical staging system for sarcomas was developed, and with it definitions of surgical margins, that made it possible to begin assembling data on which to base surgical decisions. All these developments have contributed to our ability to perform more limb sparing resection for bone tumours since the 1970s.

LIMB SALVAGE

The aim of limb salvage in bone tumour management is to eradicate the disease, retain the integrity of the skeletal system and preserve a limb with useful function. Sir John Bruce, a Cancer Surgeon has said, "Drastic clearance and reconstruction surgeries, exact from the surgeon, the imagination of an artist, the courage and ruthlessness of a battle field soldier and technical virtuosity of a high order".

Limb salvage should be based on accurate staging to ensure an oncologically sound surgical procedure, an orthopaedically sound reconstructive procedure and most importantly be customised to the individual patient. For a limb salvage procedure to be a viable alternative in the management of patients, it must meet 2 criteria. First is local control of the tumour. This requires that the recurrence rate must be comparable to that with ablative surgery. Second, the resection must be compatible with maintenance of a functional status that is an improvement over the status after amputation and fitting of a prosthesis.

INTERNATIONAL SYMPOSIA ON LIMB SALVAGE

The international Society of Limb Salvage was formed at the global level and Symposia were held every other year since 1981. The participants shared their experience, problems and solution in various aspects of limb salvage.

I. Rochester, U.S.A. (1981). 522 L.S. 18% local recurrence 15% reconstructive failures.

II. Vienna, Europe (1983): 643 L.S. 11% recurrence rate 10% reconstructive failures.

III. Orlando U.S.A. (1985): 1309 L.S. 7% recurrence 5% reconstructive failures.

IV. Kyoto, Japan (1987): 10% combined failure rate.

V. St. Malo, France (1989). VI. Montreal, Canada (1991)

VII. Singapore (1993). VIII. Florence, Italy (1995).

Survival rate of II-B Sarcomas rose from the historic 16-20% to the modern 50-70%. Limb salvage in terms of survival rates caused no greater risk of metastasis and death than amputation. In those instances in which limb salvage resulted in local recurrence, there was a significantly greater risk of metastasis and death.

The Consensus Conference of Limb Sparing in adult soft tissue and Osteosarcomas was held in December 1984 by the National Institute of Health, Consensus Development Panel, USA. The Conference considered the results in over 200 patients with high grade sarcomas and concluded that limb sparing treatment programmes have now been clearly established. They have been shown to be appropriate and feasible options and no longer need to be considered experimental.

PRINCIPLES AND TECHNIQUES OF LIMB SPARING RESECTION

Limb salvage surgery is a safe operation in select patients. Successful limb - sparing procedures consist of three surgical phases.

1. **Resection of tumour:** This strictly follows the principles of oncologic surgery. Avoiding local recurrence is both the criteria of success and the main determinant of the amount of bone and soft tissue to be removed.

2. **Skeletal reconstruction:** Based on Principles of Orthopaedic surgery. The average skeletal defect following adequate bone tumour resection measures 15 cm to 20 cm. Techniques of reconstruction (prosthetic replacement, arthrodesis, or allograft) vary and are independent of the resection, although the degree of resection may favour one technique over the other.

3. **Soft-tissue and muscle transfer:** Based on Principles of Plastic Surgery, muscle transfers are performed to cover the resection site and to restore lost motor power. Adequate skin and muscle coverage is mandatory to decrease post operative morbidity. Distal tissue transfers are not used, because of the possibility of contamination.

SKELETAL RECONSTRUCTION

Reconstruction of the skeletal defect after resection for local tumour clearance can be by:

1. **Bone Grafting**
   - Autograft (Non vascularised / vascularised)
   - Allograft
2. **Custom made endoprosthesis**
   - Cemented
   - Uncemented

LIMB SALVAGE BY CUSTOM MADE ENDO PROSTHESIS

The most recent advance in the surgical approach to tumour resection defects involves the use of custom built joints for the replacement of defects near the hip, knee and shoulder. The development of metallurgy and bone cement and their successful use in joint replacement surgery, gave way to the use of endoprosthesis in bridging defects in joints and long bones. An individually designed, custom made bone and joint replacement prosthesis is the optimum method of obtaining the best possible results for the patient.

Moore and Bohlman (1940) were among the first to remove a GCT from the proximal femur in a 46 years old man and fill the defect with a custom made metal prosthesis to replace the head and neck area., when the patient died after 1 1/2 years of a heart attack, there was no evidence of recurrence at autopsy.

The next encouraging report in literature was from Stanmore, UK. Burrows, Wilson, Scales (1975) related their experience with 24 patients with malignant bone tumours treated between 1950 - 1969. Their initial attempts using polyethylene or acrylic resin failed. They then advanced to CO-CR-MI alloys with success. There was only one infection and 2 local recurrences.

Several reports appeared in the Orthopaedic literature over the next decade on the use of total joint replacement for pathological fractures secondary to metastatic carcinoma. However, little has been written in regard to total joint replacement in primary tumours of bone.

Marcove and Rosen (Memorial Sloan Kettering Cancer Centre, New York) (1980) reported on 66 patients treated for osteogenic sarcoma of extremities by enblock resection and chemotherapy. They opined that enblock resection with chemotherapy is a realistic alternative to radical amputation. For complications amputation was done, five for local recurrence, one for prosthesis breakage and one for skin necrosis due to prior radiation. The mean survival time of 44 months indicated that this surgery was feasible.

Eliber et al (UCLA School of Medicine, California 1980) reported their 7 year experience with limb salvage. 50 Patients with bone sarcomas were treated by pre-operative intra arterial adriamycin, 35,000 rads of rapid faction radiation and radical enblock, 22 cadaver allografts and 2 autografts.

Post operative chemotherapy was by adriamycin and high dose methotrexate. Local tumour control was achieved in 91% without amputation.

Sneath et al (1983) Birmingham Bone Tumour Service UK reported that prior to 1977 all cases of osteosarcoma underwent amputation. Of 113 patients between 1977 - 1983, 91 had an endoprosthesis, 7 had grafting and only 15 had primary amputation.

Bradish, Kempf et al (1987) reported on 40 distal femoral replacements done between 1964-80. The custom prosthesis used was the Stanmore fully constrained knee joint made from a cobalt-chromium-molybdenum alloy. 19 were done for giant cell tumours and 12 for osteosarcomas. The complications encountered include fracture of stems in 2 cases, infection and loosening in 3 and local recurrence in 5.

Ross and Wilson (1987) reported on their experience with 25 proximal humeral endoprosthetic replacements done between 1950-1982. There were 4 osteoclastomas, 7 chondrosarcomas and 4 parosteal sarcomas. The prosthesis used since 1978 is the Titanium 318 (TAI) prosthesis. The mean follow up is 11 years. There was no deep infection or stem loosening in this series.

Tomito and Tsuchiya (1989) presented a 2-7 year follow up report from Japan on 105 patients who underwent limb salvage surgery. 43 patients had a metallic endo prosthesis,

measure the dimensions and a custom prosthesis designed and fabricated. Wide excision of the tumour with custom knee replacement was done. She was mobilised with a weight relieving caliper for 1 year. 5 years follow up, she was walking well with a knee flexion upto 80 degree.

b) *Proximal Humerus*

Sridevi 13/F, presented with an osteosarcoma upper 1/3 of left humerus. 3 cycles of Pre-operative chemotherapy was given. Wide excision and custom humoral replacement was done. 6 months follow-up showed good elbow and hand function with a satisfactory shoulder function. She had 3 cycles of post operative chemotherapy. 5 years follow-up shows excellent function.

c) Proximal Tibia

Dasartharaman, 26/M presented with a painful swelling proximal 1/3 of right tibia of 3 months duration. He had treatment for a osteoclastoma tibia, by curettage and grafting 2 years ago elsewhere. He developed a recurrence of the tumour for which he had 6 sittings of radiotherapy. CT Scan was done for designing and fabricating the prosthesis. A wide excision and custom prosthetic replacement was done for him. To avoid flap necrosis in the upper tibia, the medial gastrocnemius was transposed with the intact blood supply to cover the prosthesis. At 6 years follow up he had a range of 90 degree of flexion of the knee.

d) Proximal Femur

Sukanya Sen 15/F, a case of multiple exostosis, presented with increasing size of swelling upper end of left femur 7 months duration. An open biopsy done proved it to be a low grade chondrosarcoma. The swelling was extending anteriorly, laterally and posteriorly in the upper femur. There was no neuro vascular deficit. Wide excision and custom upper femoral endoprosthesis was done on 18/4/90. The post operative period was smooth and she was mobilised with crutches for 6 months.

At 7 years follow-up she is walking independently with no support and good movement at the hip.

e) Uncommon Sites

The bare sites include the distal tibia, diaphysis of femur and humerus, distal humerus, proximal ulna and distal radius.

COMPLICATIONS

The complications of this major surgical procedure fall into 3 groups - biological, oncological and mechanical.

The biological complications include skin necrosis, superficial infection, and deep infection. Intra operative complications include injury to the vessels and nerves.

The oncological complications include local recurrence and distal metastasis. Local recurrence is an indication for limb ablation. Chest metastasis will require aggressive excision of the metastatic nodule or lobectomy.

The mechanical complication of the prosthesis include aseptic loosening, stress fracture of the psosthesis, subluxation or dislocation of the prosthesis. Radiographic evaluation include bone remodelling, interface, anchorage, implant body problems, implant articulation problems and extra cortical bone bridging.

The complications which arise after limb salvage surgery are many, but can be successfully resalvaged with good results in a majority of cases. Mechanically failed implants can be revised with useful function. Flap necrosis can be avoided by adequate soft tissue coverage. Deep infection can be controlled in a staged procedure of debridement and removal of prosthesis and later after control of infection, reimplantation. Failure will lead on to amputation.

CUSTOM PROSTHESIS IN TRAUMATIC SKELETAL DEFECTS

In the trauma series there were 8 patients with segmental bone loss. The locations were distal humerus (2 cases), proximal humerus (1 case), proximal femur (4 cases) and intercalary humerus (1 case).

They were mainly after road traffic accidents. The initial treatment was done elsewhere.

A 46 years male presented with instability of right upper limb. He was involved in a road traffic accident 1 year earlier where in he was hit by a car on his right humerus. He sustained a compound fracture of right humerus with a segmental loss of the distal half of humerus. This was treated elsewhere by debridement and the wound had healed well. A custom humerus and elbow joint was designed and fixed with cement. 4 1/2 years follow up showed he had good stability of the right upper limb and 90 degree of active flexion at elbow.

CUSTOM PROSTHESIS IN HYDATIDOSIS OF BONE

Hydatid disease is caused by the parasitic tapeworm Echino coccus. This parasite in the larval stage can thrive in any part of the body, most frequently the liver. Hydatid disease in bone is rare. In areas where Hydatid disease is endemic it must be considered in the differential diagnosis. One case of Hydatid bone disease treated surgically is reported. The treatment of choice is a combination of chemotherapy and surgery. The principles of surgery are like that of oncological surgery, wherein the affected area should be resected with a margin of healthy tissue to prevent recurrence.

A 38 years female sustained a pathological fracture neck of femur right. Replacement arthroplasty was attempted elsewhere which ended in excision arthroplasty. Hydatid hip was diagnosed. MRI showed involvement of the proximal femur and acetabulum with cystic collection of fluid from the right hip. In August 1994, a wide resection of the proximal femur, cyst and acetabulum roof was done. Cavity in the acetabulum was packed with grafts. Cemented cup and proximal femur seated. 2 years follow-up showed no recurrence with full hip function.

CUSTOM PROSTHESIS IN SPINAL TUMOURS

In the spine 9 cases underwent vertebrectomy and prosthetic replacement of vertebral body. They were done for GCT (2 cases) Secondaries (5 cases). Hemangioma (2 cases). The cervical spine was involved in 1 case, dorsal spine 6 cases, and lumbar spine 2 cases.

The aim of spinal tumour surgery is tumour resection, decompression of neural structures, restoration of spinal function and reduction of pain. A total vertebrectomy is indicated for malignant primary or secondary tumours of the spine as well as for benign tumours with risk of local recurrence (GCT ABC). Stabilisation of the spine after resection by prosthetic replacement offers immediate stability and the patient is mobilised.

9 cases of vertebral body tumours have been treated by anterior excision and prosthetic replacement. The prosthesis is made of titanium and is the prototype developed by One of Japan. It is held in position by bone cement. 2 patients with GCT in D7 body and L2 body improved their neurological status. 1 patient with a secondary in L5 body developed quadriplegia.

When the indications are carefully followed and surgery performed in an appropriate manner, the procedure of prosthetic replacement of a vertebral body affected by tumour contributes significantly to the avoidance of pain and neural deficit.

A 28 years old male, presented with pain back and weakness of both lower limbs - one month duration. The motor power was 3/5 in both lower limbs. The deep tendon jerks were absent and there was diminished sensation below L2. Xray revealed a destructive lesion of L2 body. CT assisted closed biopsy diagnosed it as an osteoclastoma. Myelogram showed an incomplete block at the level. An anterior decompression was done. A metallic prosthesis was used to span L1 and L3 between grooves for stability. He was mobilised with a Taylor's brace for 1 year. At 4 years follow up, the patient has regained full power in the limbs and is doing all normal activities.

DISCUSSION

In Madras, the actual technique of the limb salvage surgery has been the same as followed in Western Countries.

In the performance of such a major surgical procedure, the socio-cultural background of the patients, does influence decision making in the choice of surgery. The non acceptance of the limb ablation by the Indian patients even in advanced stages throws a challenge to the surgeon in the choice of patients.

Hence, it is often difficult to adopt the strict criteria laid down in terms of indications and contraindications for limb salvage.

The lack of high technology back up for the Indian surgeon, strains ones capacity for innovation and narrows his field of choice in the selection of the material and design of the prosthesis. The constraints of the surgical resource base in terms of infrastructure and cost of adjuvant chemotherapy often forces the surgeon to accept the second best in survival rates.

The role of custom prosthesis in skeletal reconstruction is a well established and an accepted technique and is no longer considered experimental in the global scenario.

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