DISSERTATION ON PROSPECTIVE STUDY OF LIMB SALVAGE SURGERY USING ALLOGRAFT IN MALIGNANT AND AGGRESSIVE BENIGN BONE TUMOURS

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CERTIFICATE

This is to certify that this dissertation entitled "**Prospective study of limb salvage surgery using allograft in malignant and aggressive benign bone tumors**" *submitted by* ***Dr. S. MAGESWARAN*** *appearing for Part II, M.S. Branch II - Orthopaedics degree examination in February-March 2006 is a bonafide record of work done by him under my direct guidance and supervision in partial fulfilment of regulations of The Tamil Nadu Dr. M.G.R. Medical University, Chennai.*

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INTRODUCTION

“Bone is the most commonly transplanted tissue in the body than any other tissue or organ except blood”.

Transplanted bone, tendon and ligaments are used extensively in orthopedics, neurosurgery, dental surgery and plastic surgery for procedures including repair of fractures and damage caused by illness and injury. Allografts are preferred over synthetic implants by value of their desirable features of natural structure, shape and strength and biological capacity of incorporation.

Bone is a unique tissue in that its ability to regenerate is more predictable than any other tissue in the body. Bone is often destroyed by infection, tumor, trauma and implanted materials and has to be replaced to restore structure and function.

Bridging of large bone defects remains a challenging problem in orthopedic practice. The options available are

1. Vascularised autogratfs
2. Non Vascularised autografts
3. Custom made prosthesis
4. Biomaterials e.g. ceramics,
5. Allografts

Custom made prosthesis are available only on certain countries. They are very expensive, more over there are additional disadvantages of delay in fabrication and meeting individual needs of the patients.

Likewise ceramics are available from only in certain countries and very expensive. With the development of bone banks all over the world, bone allografts have become more readily available with high standards of safety for transplantation in patients.

Bone grafting is one of the most frequent operations performed. Autografts remain the gold standard as they are osteoconductive as well as osteoinductive and have osteogenic cells.

Most of the time, amount of graft required is small and harvesting bone from the iliac crest and fibula is enough. When the graft requirement is larger in the massive defects or in children, where the autograft availability is small and harvesting can damage the open growth plates, the role of allografts comes into play. Autografting has many disadvantages like donor life morbidity, increased blood loss and increased operating time.

Allograft have been proved to be useful in massive defects, spinal fusions, large joint defects and reconstructive of bone

tumors in spite of several short timings. Allografts have further extended the reconstruction abilities of surgeon and provide innovative option for biologic reconstruction with less patient morbidity.

The advantages of allografts are

1. Allografts can be stored for long time up to 6 years in case of freeze dried allografts and freeze dried demineralized allografts and 5 years for deep frozen allografts
2. It is cheaper than metallic implants
3. Easy to obtain and enormous availability of the graft
4. Decreased donor site morbidity
5. Biologic form of fixation (i.e., after incorporation allografted area becomes the quality of host bone)
6. Immunologic response is very minimal after storage hence there is no role of immunosuppressive drugs
7. Allografts of all dimensions can be prepared and used for deficient conditions
8. Soft tissues and ligament attachment are possible with allografts .

AIM OF THE STUDY

To evaluate the functional outcome of limb salvage surgery using allografts in malignant and borderline malignant bone tumors.

HISTORY OF ALLOGRAFTS

2500 years back Sushrutha used skin and bone allografts for nasal reconstruction.

In 1881 William Macewen of Glasgow performed the first successful bone allograft and originate the modern practice of bone grafting. He successfully transferred segments of bone from a rachitic patient to the humerus of a three year old child suffering from osteomyelitis, and he performed rib graft to replace mandible.

Lexer in 1908 performed 29 allogenic whole joint transplantation. In 1914 phemister advocated bone grafting to enhance the process of creeping substitution. In 1935 – 1937 Bush and Wilson successfully stored allograft at 10 to 20^{o} C in New York.

Langer of Canada showed that reaction to allografts was greatly reduced by freezing the graft.

In 1956, Albee, the first orthopaedic surgeon started US bone bank in New York.

In 1960, Ethelene oxide sterilization has been used for bones.

In 1974, Radiation sterilization focused to be alterative for ETO sterilization on the grounds of safety and cost. In 1978

Burchand et al described three patterns of allograft incorporation. In 1983 W.W. Tomford suggested the use of glycerol and demethyl sulphoxide to maintain the viability of cartilage during freezing. In 1989 M.R.Urist described the use of bone morphogenic protein.

In 1990 international atomic agency published guidelines for the radiation sterilization. In 1990 there was 30 tissue banks in USA and 31 tissue banks in Europe.

In India the first allograft transplantation was performed in 2003 by Mayilvahanan Natarajan at Madras Medical College and Government General Hospital, Chennai.

In 2005, the first bone bank in India started in Government General Hospital, Chennai.

BIOLOGY AND INCORPORATION OF ALLOGRAFTS

A successful bone graft has to incorporate into the skeletal system of the host; graft incorporation depends on its size, structure, position, fixation and genetic composition. The role of the grafts in stimulating incorporation encompasses osteoconduction, osteoinduction and osteogenesis.

Osteoconduction and creeping substitution are the main mechanisms in the incorporation of allografts, Allografts act as a scaffold for in growth and it is referred as osteoconduction.

Graft Incorporation occurs in following Stages

1. Revascularisation

2. Graft resorption

3. Creeping substitution, new osteons laid over the Allograft.

4. Graft remodeling.

Revascularisation occurs by invasion of the capillary sprouts from the host bed and resorption of the old matrix follows with the investing osteoclasts & osteoblasts around the blood vessels that invade the graft.

After the laid of Osteons, callus formation ensures around the allografts serially which remodels in the course of time to ensure adequate incorporation.

Large Allografts may be incorporated in processing serial stress fractures that results in graft remodeling, periodically a region of stress concentration may microfracture followed by local remodeling. Later it proceeds to the whole length of the massive allografts. It takes a long time for the massive allografts to get incorporated into the skeletal system of the host.

Major type of allografts and their incorporation

Major types of allografts are

1. Demineralized bone matrix allografts

2.Morecellized and cancellous allogenic bone.

3.Cortico cancellous and cortical allograft

4. Massive allogenic osteochondral allograft.

Demineralized Bone Matrix

It gets quickly revascularized and provides no structural support and moderately osteoinductive also. Within 1 hour, Implantation is followed by platelet aggregation, hematoma formation and inflammation characterized by migration of leucocytes.

Fibroblast like mesenchymal cells undergone cellular differentiation into chondrocytes around 5 days. Chondrocytes

produce cartilage matrix, which is mineralized. After 10-12 days vascular invasion with osteoblastic cells, new bone is formed opposite to the surface of the mineralized cartilage. Remodeling and replacement of these compound structures with new host bone ensues. With time, all the implanted DBM is resorbed and replaced with host bone.

2.MORECELLIZED AND CANCELLOUS ALLOGENIC BONE

Limited mechanical support and are osteoconductive only. Derived from either cancellous or cortical bone ranging from chips of sizes 0.5 to 3 mm diameter. They are characterized by an open, porous almost lattice like physical structure so that there is no physical improvement to the in growth of vessels.

The same stage of hemorrhage, inflammation, vascular ingrowth osteoid formation, remodeling and graft integration as in case of allografts take place. They are osteoconductive only and more resistant to compression. This may as weight bearing structures during the process of graft incorporation. They do not suffer the transient loss on mechanical strength that as resorption is not necessary for revascularisation.

Corticocancellous and cortical allografts

They provide structural support and osteoconductive to a limited degree. The process of incorporation is slower than the DBM and cancellous allografts as resorption is necessary for revascu1arisation.

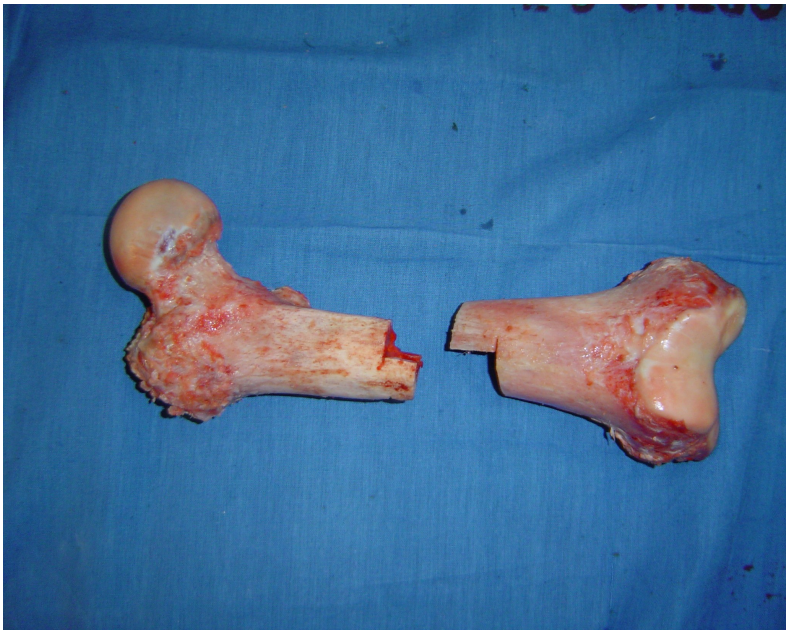
Massive Allografts

The incorporation of massive allografts is a slow and incomplete process. Immune response is produced by the host even through the long storage in the deep freezer in order to reduce the immunogenicity. New bone formation from the periosteum of the host bone at the host graft junction is essential for the union at allograft host junction. Creeping substitution and graft remodeling occurs in the slower phase and taken long time in achieving fusions.

Optimizing the host - interface improves the functional outcome of massive bone allografts. Increasing the host allograft interface can be done by

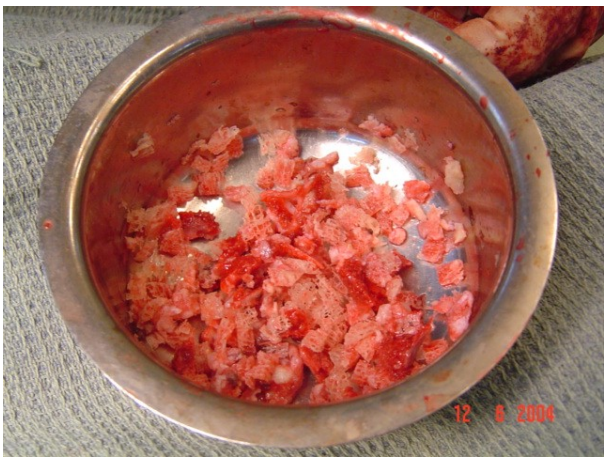
1. Oblique osteotomies or Step cut osteotomies
2. Telescoping Techniques
3. Host periosteal sleeve on the allograft junction.

STEPCUT OSTEOTOMIES



DEMINERALISED BONE

MORSELLISED ALLOGRAFT



IMMUNOLOGY OF BONE ALLOGRAFTS

Organs and tissues transplanted into host incompatible animals or humans will induce an immune response. There is substantial evidence that bone, like other allogenic tissues, also induces such a response as a result of the recognition of a variety of potential alloantigens by the host's immune system. These antigens are capable of stimulating the full range of immune activities including cellular responses, antibodies and cytokine release.

IMMUNOLOGICAL COMPONENTS

Bone is a complex tissue comprised of many constituents capable of acting as sources of antigen. These include the non-cellular antigens of the extra cellular matrix such as collagen together with non-collagenous proteins (proteoglycans, glycoprotiens, etc.) as well as cells that express the major histocompatibility antigens. The primary cause of the host immune response in bone allograft transplantation are the cells of the bone marrow, primarily leukocytes. Reduction or removal of such cells by processing, freezing, freeze-drying or irradiation reduces these cellular elements and thus lowers the likelihood of an immune response.

Several studies have demonstrated that after transplantation of frozen bone or soft tissue grafts that an immune response is generated causing antibody formation in up to 75% of the patients. This does seem to affect the outcome of massive bone transplantation. For tendon allografts it does not seem to have clinical importance. Transplantation of freeze-dried grafts does not cause antibody formation. Freezing and freeze-drying procedures decrease the antigenicity of bone. Irradiation of bone not only sterilizes the bone but also destroys its antigenicity.

HISTOCOMPATIBILITY MATCHING

Experimental results shows that matching does reduce immunogenicity and improves the outcome of bone allografts. However, its potential benefit in clinical practice is still controversial and unresolved.

ALTERING THE GRAFT

The selective manipulation of grafts prior to transplantation helps prevent rejection without totally suppressing the immune system. This method not only reduces immunogenicity but also solves the problem of storage methods for grafts. Some methods of alteration are freezing, freeze drying, autoclaving, deprotenization, decalcification and exposure to high doses of radiation.

PRESERVATION OF ALLOGRAFTS

The three most commonly used preservation methods are

1. Deep freezing
2. Cryopreservation
3. Freeze drying

Fresh frozen allograft (deep freezing)

In this method the graft is collected and frozen slowly in two steps; first to -20 degree Celsius for 8 hours, followed by freezing to -80 degree Celsius in order to stop all enzymatic activity. Allografts can be preserved by deep-freezing up to 5 years. Advantages of deep freezing are

1. Long bones such as femur and tibia are stored as fresh frozen allografts.
2. Storage up to 3 months reduces the immunogenicity of the allografts, so the chances of graft resorption are very long.
3. Fresh frozen bone has got superior strength

Disadvantages are

1. High cost of purchasing, operating and maintaining the freezer.
2. Requires regular monitoring for the inside temperature of the freezer.

Cryopreserved allografts

The lower the temperature the greater the reduction of molecular activity, including enzymatic activity. At -160 degree Celsius the temperature of the liquid nitrogen, essentially all-molecular action is stopped and tissue can be stored indefinitely.

By cryopreservation allografts can be stored for life. Most of the bone banks in the world don't prefer the cryopreservatives due to its high cost and

1. Electrical deep freezer is as effective as liquid nitrogen preservation.
2. Rapid turn over of tissue makes it unnecessarily to store them indefinitely.
3. Liquid nitrogen may increase the brittleness of bone due to immediate crystallization of water that occurs upon rapid exposure to very low temperature.

Freeze drying (freeze dried allografts)

Freeze drying on lyophilisation is a process in which frozen bone is dehydrated by sublimation. Tissue moisture passes directly from the solid phase to the vapor phase and is converted to ice on the condenser of the freeze nitrogen.

A vaccum is maintained in the freeze dryer during the process, ensuring that bottles of bone allografts are sterilely sealed.This process allows tissue to maintained at room temperature for at least years or as long as the vaccum, seals remain unbroken.

Advantages of freeze-drying are

1. It can be kept at room temperature so storage made easy and cheap.
2. Reduced antigenicity as compared to deep freezing.
3. Transfer of disease is likely

Disadvantages are

1. Decreased torsional and bending strength of cortical grafts.
2. Not a suitable technique to preserve long bones.
3. It should be reconstituted by immersion in normal saline before use

STERLIZATION OF ALLOGRAFTS

The implantation of an allograft into the body carries with it an inherent risk of infection. It is extremely important to reduce the rate of infection by appropriate sterilization of the allografts. Sterilization has been defined as the process or act of inactivating all form of life, especially microorganisms. Aseptic procurement of allografts from donors who has little risk of infection in sterile operating rooms doesn't need a secondary sterilization. But allografts from the cadaveric bones need secondary sterilization wherever the procurement has taken place. The sterilization of allografts is an important inevitable process needs to be taken strictly in order to get the success of bone transplantation.

The commonly used sterilization methods are

1. Autoclaving
2. ETO sterilization
3. Radiation sterilization

Autoclaving

Bacteria are more readily killed by moist heat than dry heat. Steam kills bacteria by denaturing their protein. 121 degree Celsius for 15 to 20 minutes is the best method of steam sterilization. Autoclaving is not recommended by American Association Of Tissue Banks because it alters the structure of protein and alters the bone strength.

Ethylene oxide

Ethylene oxide is applied in a gaseous state in mixture with inert diluents such as carbon dioxide, Freon (dichioro difluro methane). After sterilization the residual ethylene oxide is replaced by flushing inert gas like carbon dioxide. Ethylene oxide sterilization of allografts also has lost its popularity because of its carcinogenic property of allografts.

Radiation sterilization

Two types of radiation are employed for sterilization namely ionizing radiation and non-ionising. Ultra violet rays are a non-ionising radiation most effective at 253.7 micron wavelength. It is mainly used for surface sterilization as it has very low penetration. Ionizing radiation includes high energy electrons generated from accelerated electro magnetic rays such as gamma rays emitted by radioisotope Cobalt60 and Caesium 137 and X-rays generated by X-ray machine. Ionizing radiation kills all types of microorganisms

through the ionization process and usually has enough energy for useful penetration into solids and liquids of tissue. These rays can break and change the DNA strands. The treatment does not heat up tissue materials significantly and are widely used for industrial sterilization of the heat sensitive medical and laboratory products. Therefore this has gained popularity in sterilization of allografts.

Effect of preservation & sterilization:

Freezing bone decreases its tensile and compression strength by about 10 %. Freeze drying decreases torsional strength by about 5O% and compressive by 10%. Bending strength has been shown to be lowered up to 20% by each of its methods. Other physical modes of sterilization like autoclaving and pasteurization affects mechanical properties to greater extent. So that the graft can be used only where there is no need for structural support.

Radiation sterilization causes little change in the strength of structural allograft (3 mega rads of irradiation).

METHODS OF FIXATION OF ALLOGRAFTS

Three common methods used to fix allografts with host bone after tumor resection.

1.Alloarthrodesis

2.Osteoarticular allograft reconstruction.

3.Allograft prosthetic composite arthroplasty(APC).

I) Alloarthrodesis

Arthrodesis of joints can be achieved with the allografts as limit salvage option in tumor reconstruction.

Indications are.

a) Excessive soft tissue involvement by a malignant tumor.

b) Infective focus presence.

c) Custom made prosthesis/APC failure

d) Younger patients with high functional demand.

e) Poor patients who cannot afford for prosthesis.

Technical aspects

1. Fusion of the joint in adequate functional position using corticocancellous allografts and available cancellous allografts with internal fixation.

2. Good results were achieved when good principles of internal fixation and osteosynthesis were followed.

II) Osteoarticular allograft reconstruction

The allograft with an articular surface is called osteoarticular allograft. Osteoarticular allografts can be used in reconstructing the partial intraarticular defects and total intraarticular defects. Cartilage preservation is the main factor in their grafts This can be done with glycerol / DMSO infiltration or cryopreservation.

Fresh frozen allografts are now days rarely preferred as cartilage damage ensues after long storage.

Technical aspects and advantages

a) Exact matching of the articular detect is made out using

X-rays

b) Principles of internal fixation should be followed strictly to allow the early union and reconstructions.

c) Soft tissue reconstructions with ligaments is possible and provides better option for non-weight bearing joints like shoulder.

d) This type of reconstructions and limbs salvage surgery can be done to all joints like proximal humerus (shoulder), distal femur (knee), proximal femur (hip), proximal tibia.

e) The disadvantages of cartilage destruction and osteoarthritic changes are more in weight bearing joints like knee and hip so APC is preferred than osteoarticular allograft reconstruction.

3) Allograft prosthetic composite arthroplasty

This is a combination of biologic and implant reconstruction.

Large diaphyseal allograft with a custom made metallic joint threaded through the allograft. Composite prosthesis has the following functions and it is superior to CMP alone.

a. Facilitates muscle and ligament reattachment to the implant and thus improving stability and active motion.
b. Restore bone stock after tumor resection.
c. Prevents loosening by changing the lever arm of the large prosthesis to short one.
d. Decreases bone resorption by stress shielding.
e. Bony fusion is mandatory to achieve all these functions

Technical aspects for APC:

a. Modular prosthesis (joint)- long conical stemmed prosthesis, which goes to the host diaphysis.
b. Implant should be MRI compatible so that follow up for tumor recurrence will be easy.

c. Host-allograft function should be packed with autografts for better union and incorporation.

d. Implant should precisely fit to the allograft so cementation should be done.

e. Good soft tissue cover and good surgical technique result in better clinical results

SURGICAL TECHNIQUES

Bone tumor surgery has three main steps.

1. Preoperative planning
2. Tumor resection
3. Reconstruction

1.Preoperative planning:

Cooperative preoperative planning that involves both oncologic and reconstructive surgeons is essential to determine the amount of tissue excise and how to deal with scars and zones of irradiated and injured tissues, The timing of surgery and dosages of chemotherapy and radiation therapy must be coordinated with the oncologist and radiation therapist as well, particularly concerning the dates when platelet, red blood cell, an white blood cell counts reach their lowest points. Appropriate preoperative antibiotics administered, Foley catheter inserted, and care taken to protect peripheral nerves and pressure points (especially the heels) with padding during this long operative procedure.

The pre operative planning done in the following areas,

a. Planning the resection part
b. Planning the reconstruction part
c. Planning the method of fixation

Planning the resection part

The extent and dimension of resection is decided mainly with the X – rays, CT, MRI and angiography and bone scan.

CT scan is useful in find out cortial destruction and MRI is more helpful in determining intramedullary and extraosseous extension.

Planning the reconstruction

The allograft identical to the resection bone is selected. Radiological size matching is the most commonly used method. Computerized matching for osteoarticular grafts done in advanced centers.

Planning the method of fixation

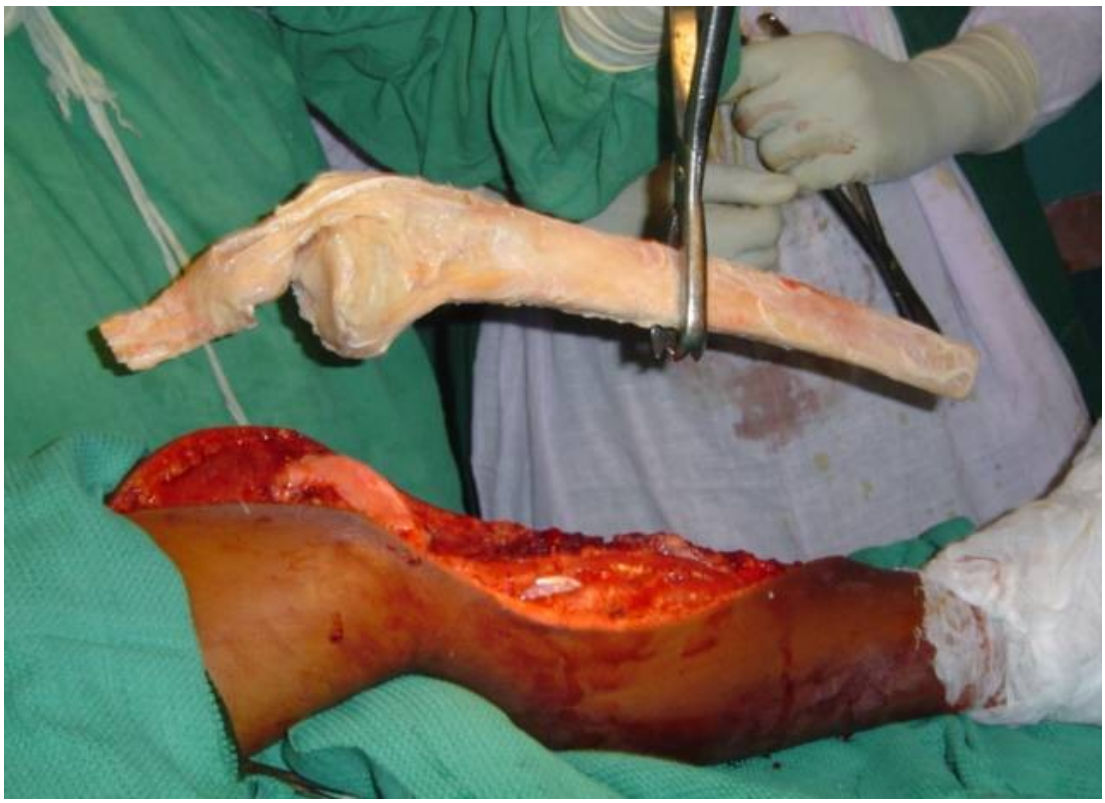
Preoperatively the method of fixation is determined. Plate fixation and intramedullary fixation are the more commonly used method. Intramedullary fixation is a weight sharing device and it should always preferred over plate fixation.

If ligament reconstruction is planned, allografts with ligament and ligament substitutes should be kept ready.

2.Tumor Resection

It is the most crucial step in terms of recurrence and survival of the patients. Strict surgico oncological principles followed. Adequate incision and wide surgical exposure was done. All areas of involved skin and incisional sites were excised widely.

PROXIMAL TIBIAL ALLOGRAFT WITH PATELLAR TENDON



Adequate margin of excision was decided on the type and aggressiveness of the tumor. Normally for a malignant lesion 4 – 5 cm clearance on bone given on either side and tumor resection with 1 cm cuff of normal muscles.

RECONSTRUCTION

Reconstruction was done in 2 steps.

1. Implantation and fixation of allografts
2. Soft tissue reconstruction

IMPLANTATION AND FIXATION OF ALLOGRAFTS

After the tumor resection, the required bone length measured and allograft fashioned to fill the defect.

Reconstruction done by any of the following methods

1. Osteoarticular allograft
2. Alloarthrodesis
3. Alloprosthetic composite arthroplasty
4. Intercallary allografting.

Fixation done with either plate osteosynthesis (or) intramedullary fixation.

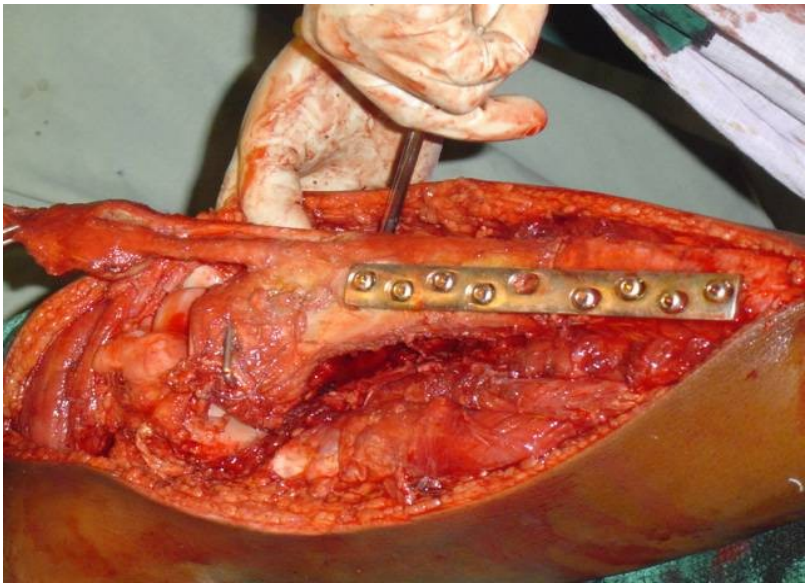
SOFT TISSUE RECONSTRUCTION

PRINCIPLES OF SOFT TISSUE RECONSTRUCTION

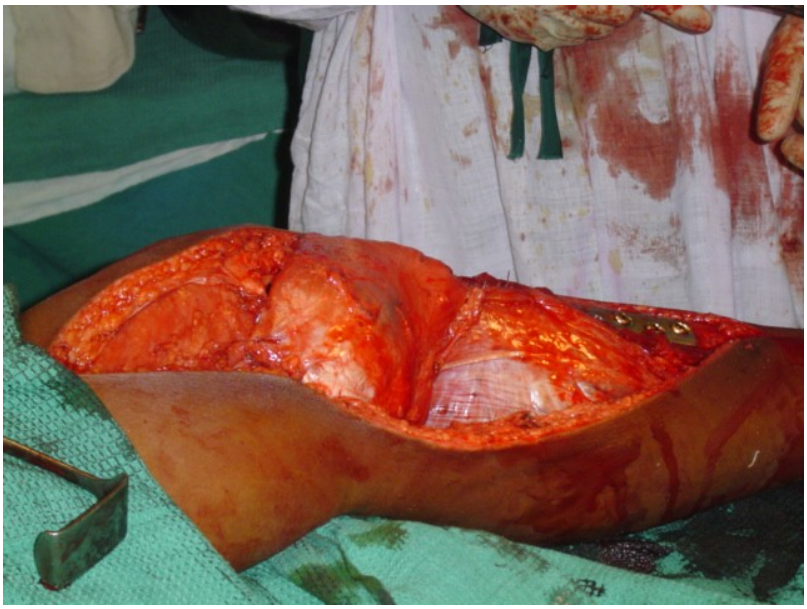
The main goal is to promote uncomplicated primary wound healing. The wide oncologic resection of the tumor and subsequent orthopaedic reconstruction of the bone or joint defect interrupts major regional blood

vessels, depriving the wound margin of its axial blood supply. The tenuous vascularity of these flaps and the creation of a large defect with potential dead space, combined with the superficial location of the prosthesis, demands reliable well-vascularized, durable, and flexible soft tissue coverage. It is important to emphasize that tension-free closure of the defect must be obtained and dead space obliterated, which makes it necessary to add more tissue. To achieve this, local muscle transposition has been the mainstay of soft reconstruction with distant micro vascular free tissue transfer and fasciocutaneous flaps used when necessary.

The most common and potentially limb - threatening complications of these limb procedures include failure of wound healing, flap necrosis, and infection, which can ultimately lead to exposure of the allograft or loss of the limb. Any patients receive preoperative adjuvant chemotherapy or radiation therapy, and they are therefore immunosuppressed and have decreased wound-healing capabilities at the time of surgery. Satisfactory postoperative soft tissue healing is absolutely required to resume chemotherapy and/or radiation if necessary. Problems such as infection; exposure of the implant, and with holding of chemotherapy, radiation therapy, or antithrombotics threaten a successful result from the limb surgery and even the patients life. Complications increase the length of hospital stay and delay ambulation and range of motion (ROM) exercises, increasing the possibility of loss of some limb function.



BONY RECONSTRUCTION



SOFTTISSUE-RECONSTRUCTION

COMPLICATIONS OF ALLOGRAFTS

The following are the various complications of allografts.

1. Infection
2. Nonunion
3. Graft fracture
4. Transmission of infectious diseases
5. Graft resorption
6. Cartilage fragmentation
7. Implant failure

Infections are the most dreadful enemy for allograft reconstruction. Proper sterilization techniques, proper surgical techniques and good soft tissue cover will decrease the incidence of infection. Chemotherapy and radiotherapy will increase the incidence of infection by suppressing the immune mechanisms of the individual and revascularisation potential of the graft. Staphylococcus epidermidis is found to be the most common bacterial infection in the allografts.

Non-union is most commonly encountered in intercalary defect reconstructions and allograft prosthetic composite arthroplasty. Chemotherapy and radiotherapy have deleterious effects over union of allograft-host junction.

Following surgical techniques may decrease non-union complication

1.Step cut osteotomy of the allograft autograft junction.

2.Avoiding infections.

3.Good soft tissue cover like medial gastronemius flap cover for proximal tibial allograft

4.Addition of autograft at the junction of allograft autograft junction.

5.Proper internal fixation techniques like load sharing implants. Eg.intramedullary IL nailing.

8.Precision fixation of the allografts to the implant with cementing.

Bone allografts have been implicated in transmitting tuberculosis, HIV, Hepatitis and bacterial infections to recipient. To prevent or at least minimize the risk of transmission of infectious disease, several steps are taken by surgeons and bone banks. An important initial approach is to judiciously use bone allografts only when needed and to consider the use of auto grafts, alternative non human graft material or sterilized bone allografts whenever possible. However, the most important approach is exercised by the tissue bank donor coordinator who carefully

obtains a medical and social history excluding those suspect to be at risk of HIV, hepatitis or other viral or bacterial infections.

Graft fracture and failure of graft incorporation are frequently found when massive allografts are used. This is not a problem with demineralised allografts, cancellous chips when used for fusion for spinal surgeries, cavity defects and impaction grafting in revision hip arthroplasty.

Articular fragmentation is one of the complications found in osteoarticular allografts. These patients remain asymptomatic supporting the notion that the osteoarticular allografts create a Charcot type of joint, which despite a poor radiographic appearance can function well clinically.

Graft resorption occur in some individuals to immune reactions of individual toward the graft. This occurs usually in patients frozen articular grafts. This is usually rare complication.

Disease transmission with allografts

Allografts arc prone for disease transmission if the proper preventive steps and adherence to strict donor screening steps are not followed.

Bacterial and virus transmission have been reported with fresh frozen bone allografts. The disease transmission is rare in freeze dried bone allografts and demineralized freeze dried bone allografts.

The following bacterial and viral disease infectious agents have been reported in the use of allografts

1. Group A Streptococci
2. HIV virus
3. Hepatitis C virus
4. Hepatitis B virus
5. Treponema pallidum

Preventive Steps

Transmission of infection can be prevented by strict adherence to certain guideline with respect to procurement processing and sterilization of bone grafts

1. Procurement of the allografts is the most important step in preventing the transmission of infection. Following exclusion criteria should be considered while collecting the allografts.

a) High risk group donors

b) Testing for HIV / HCV / HBsAg / VDRL.

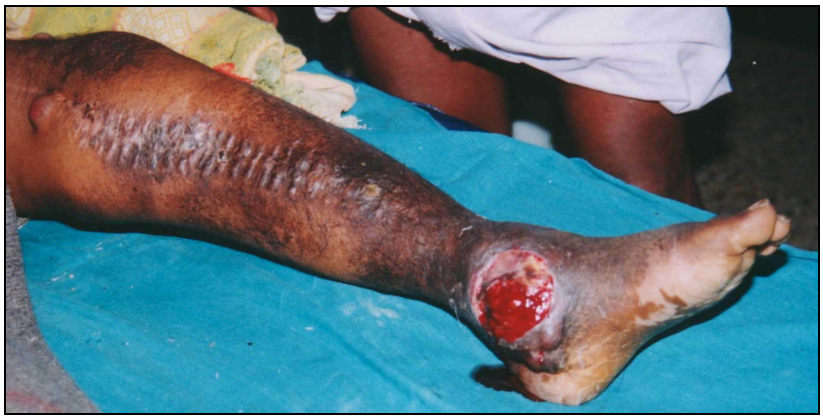
Always one should retest for HIV/ HCV antibodies after the donation to exclude donor during window period

c) Occult disease in donor on autopsy.

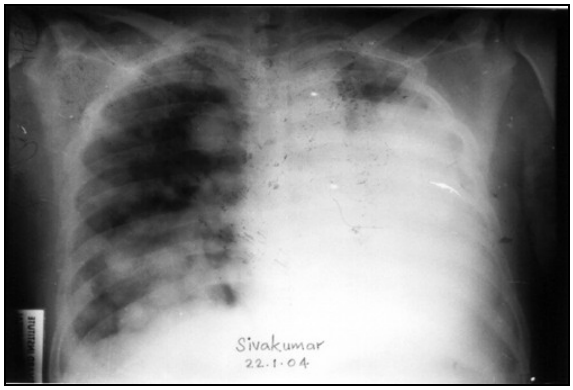
d) Donor bone tip should be tested for bacterial contamination at the time of procurement and final packaging. Tissue should be culture negative at that time of official packaging

3. Adherence to strict guidelines with the respect to processing and sterilization of the bone grafts.

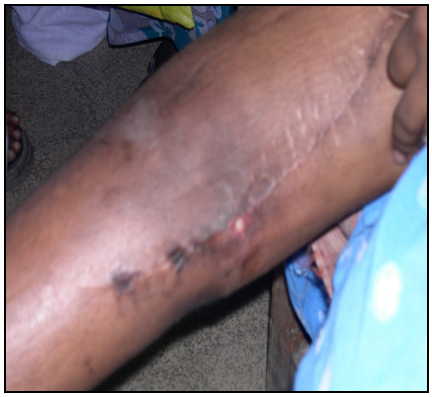
COMPLICATIONS



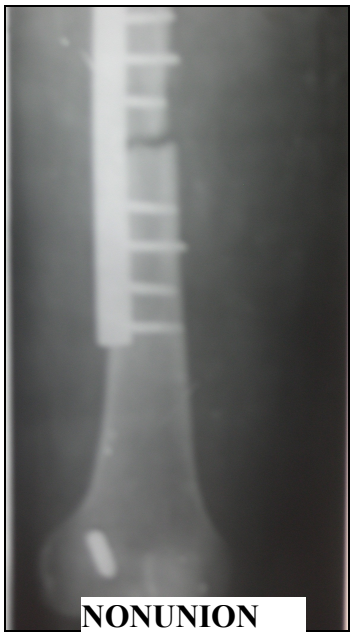
SKIP LESION



METASTASIS



INFECTION



NONUNION

MATERIALS AND METHODS

The materials for this study was based on a prospective study conducted at the Department of Orthopaedics and Traumatology, Government General Hospital, Chennai from a period of July 2003 to August 2005.

Our inclusion Criteria for allografting are

1. Malignant bone tumors - Enneking staging I A to II B.
2. Aggressive benign tumors.

Exclusion criteria are

1. Presence of metastasis
2. Involvement of major neurovascular structure
3. Biopsy scars in atypical sites.
4. Presence of infection

In our 16 cases, 8 cases were malignant bone tumors and 8 cases were aggressive benign bone tumors. In malignant tumors, 3 tumors were belonging to Enneking grade II A and 5 tumors belonging to Enneking grade II B. All benign tumors were aggressive tumors according to Enneking grade.

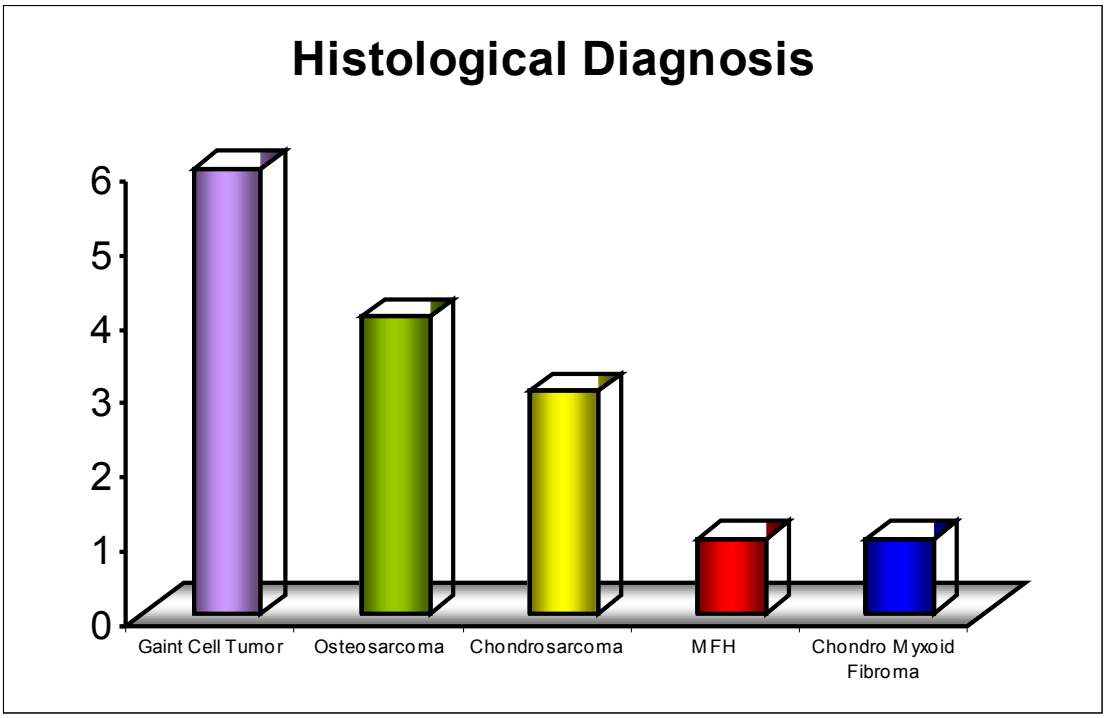
The histological diagnosis is given in Table 1

Giant cell tumor	6
Osteosarcoma	4
Chondrosarcoma	3
Malignant fibrous histiocytoma	1
Desmoid tumor	1
Chondromyxoid fibroma	1

The patients are group were from 11 years to 58 years with an average age of 27.01 years.

According to age group the distribution is given in Table 2.

0 – 10	Nil
11 – 20	5
21 – 30	5
31 – 40	2
41 – 50	3
51 – 60	1


Histological Diagnosis
6
5
4
3
2
1
0
Gaint Cell Tumor
Osteosarcoma
Chondrosarcoma
MFH
Chondro Myxoid Fibroma

The site of tumor is given in Table 3. Distal femur is the most common site.

Distal femur	5
Proximal tibia	4
Proximal femur	1
Proximal humerus	1
Distal radius	1
Distal tibia	1
Diaphysis of femur	1
Pelvis (pubis)	2

The preoperative staging studies included are conventional Radiology, CT scan, MRI scan, biopsy by percutaneous or open methods. We used angiography in 3 cases and radioisotope scan in one case.

In the surgical indications we did not take into account the Enneking's criteria for intra (or) extra compartmental involvement. We also took an X- ray and CT scan of the lung to rule out metastatic disease. We did not include metastatic disease in this study. Tumors with neurovascular involvement were excluded from this study.

The four patients with osteosarcoma underwent neoadjuvant chemotherapy. Our oncology unit's protocol for neoadjuvant chemotherapy for osteosarcoma is

3 cycles of neoadjuvant therapy with three drugs,

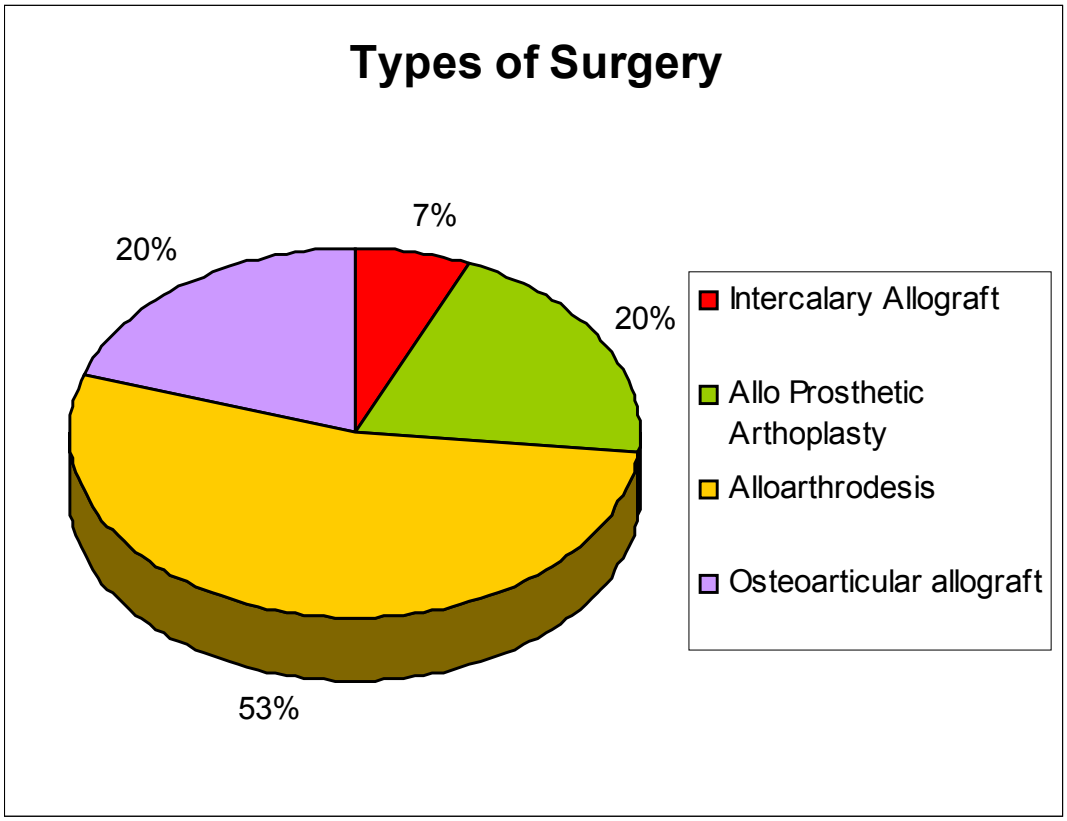
1. Adriamycin 60mg/m^2 on day 1.
2. Cisplatin 20mg/m^2 from day 2 – 6 (5 days)
3. Ifosphomide 1.5g/m^2 from day 2 – 6 (5 days)

The next cycle repeated after 21 days.

In all the 15 patients wide resection of tumor was done. The method of reconstruction is given in Table 4.

Osteoarticular allografts	3
Alloarthrodesis	9
Alloprosthetic arthroplasty	3
Intercalary allograft	1

In the osteoarticular allografts 2 were proximal tibial osteoarticular allografts and one was distal femoral osteoarticular allograft. Ligament reconstruction was done according to standard principles.


Types of Surgery
7%
20%
20%
53%
Intercalary Allograft
Allo Prosthetic Arthoplasty
Alloarthrodesis
Osteoarticular allograft

In Alloarthrodesis, knee was the most common site(Table5).

Knee Arthrodesis	5
Ankle Arthrodesis	1
Wrist Arthrodesis	1
Iliofemoral arthrodesis	2

Method of Arthrodesis

Plating was the most common method(Table6)

Plate fixation	8
Intramedullary fixation	1

In alloprosthetic arthroplasty the details are given in Table 7.

Bipolar hemiarthroplasty	1
Proximal tibial APC with custom pending knee prosthesis	1
Proximal femoral APC with custom made prosthesis	1

In one case of intercalary allograft, the allograft was fixed with host bone with long DCS Plate.

Allografts:

All allografts were provided by tissue bank from Sri Lanka. All the allografts removed from organ donors were irradiated with

Gamma radiation & was frozen at – 30° C. The allografts transported from Sri Lanka to Chennai by Air cargo with maintenance of low temperature with dry ice & preserved and stored in -20°c in Madras Medical College.

The details of allografts are

Distal femoral allograft	5
Proximal tibial allograft with patellar tendon	2
Proximal tibial allograft without patellar tendon	2
Proximal femoral allograft	1
Distal tibial allograft	1
Complete femoral allograft	1
Proximal humeral allograft	1
Pelvic allograft	2

Prosthesis:

2 custom made prosthesis and one bipolar hemiarthroplasty used in our series, they are

Bipolar prosthesis	1
Bending knee prosthesis with rotating hinge	1
Proximal humeral CMP	1

Two implants were custom made prosthesis with individualized sizes. All implants were made of stainless steel.

The knee prosthesis was a rotating hinge prosthesis with stainless steel axis with polythene bearing. All implants have provision for muscle & tendon attachment.

Operative technique:

In all the tumors, wide resection was done. The allograft was removed from the freezer three hours before operation, cut with an oscillating saw according to the required length. In the 3 cases of alloprosthetic arthroplasty, prosthesis cemented with allograft and host bone. In Arthrodesis, fixation was done with either plate (or) Intramedullary fixation.

In osteoarticular allograft, ligament reconstruction was done with either host or allograft patellar tendon using interferential screws**.** In pelvic allograft reconstruction plate was used. In 6 cases, autogenous cancellous bone grafts were used in allograft host junction to enhance union.

Post operative protocol:

Drains were removed after 48 – 72 hours, suture removal done on 12^{th} postoperative day. After suture removal weight bearing was allowed with braces but active motion was restricted

for 8 weeks in patients whom ligament reconstruction was done. Until solid union, patient was protected with braces.

4 patients with osteosarcoma underwent postoperative chemotherapy.We did monthly follow up in the first 6 months and every 3 months there after.

CASE I

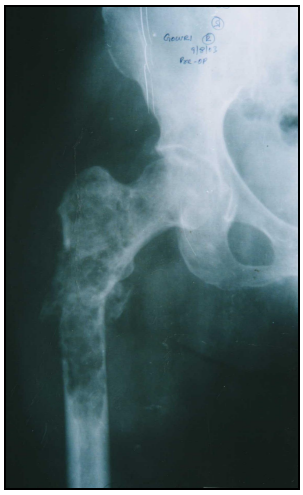
58 year old female with Chondromyoxid Fibroma of proximal femur right side with pathological fracture.

Patient was treated with wide resection and alloprosthetic composite arthroplasty.

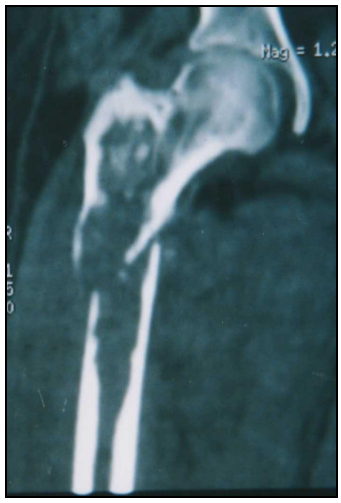
Total duration of follow up was 22 monthly. No major complications. Knee stiffness is present.

Enneking functional score is 59.4%.

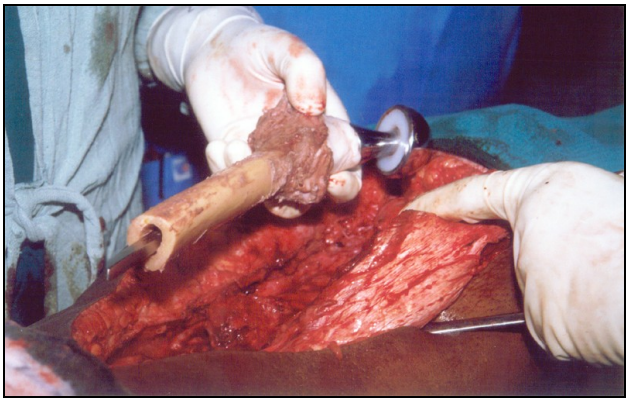
PRE OP X-RAYS



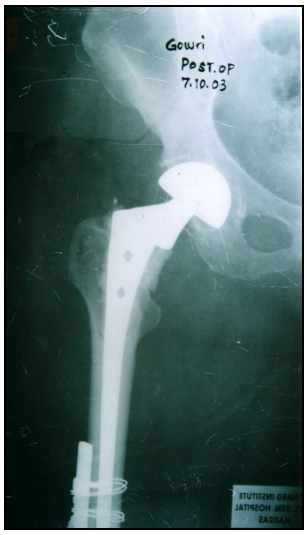
PRE OP CT SCAN



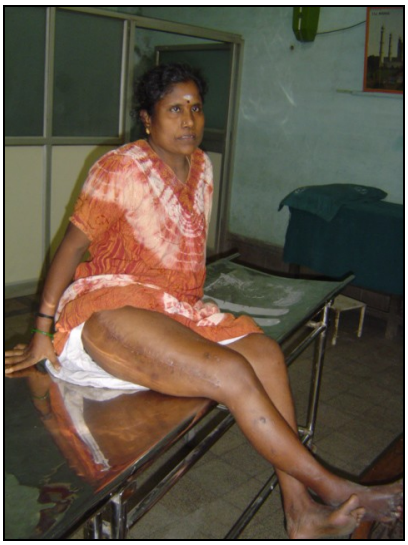
OPERATIVE PICTURE



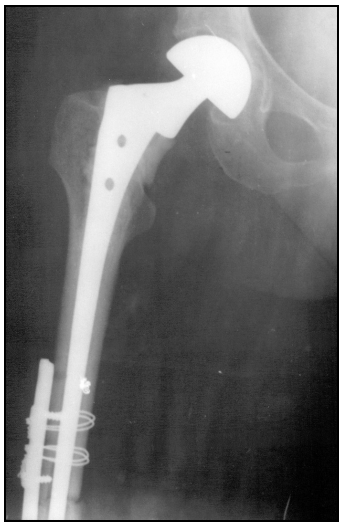
POST OP X-RAY



9 MONTHS POST OP



9-MONTH X-RAY



CASE II

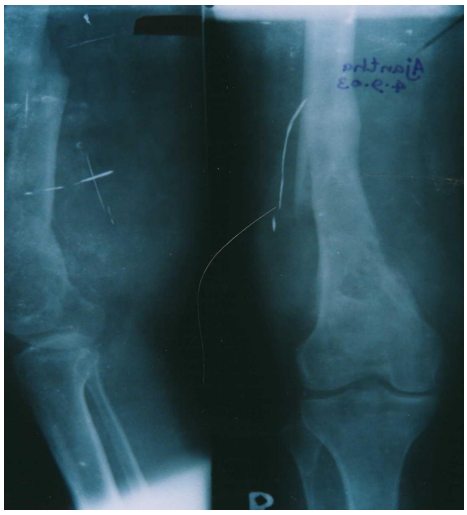
19 year female with Malignant Fibrous Histiocytoma of distal femur right side.

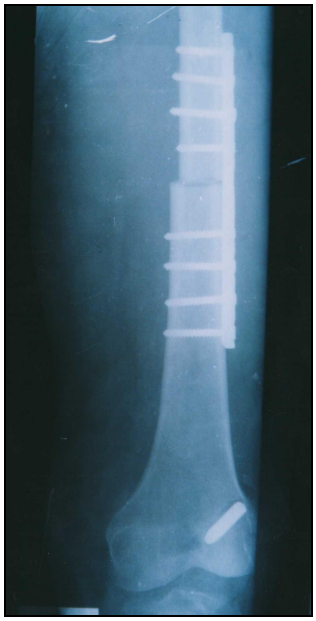
Patient was treated with wide resection and osteoarticular allograft reconstruction.

The follow up period was 24 months, complications were infection and nonunion, treated with Ilizarov fixation. Infection subsided and union occurred. Enneking functional score is 62.7%.

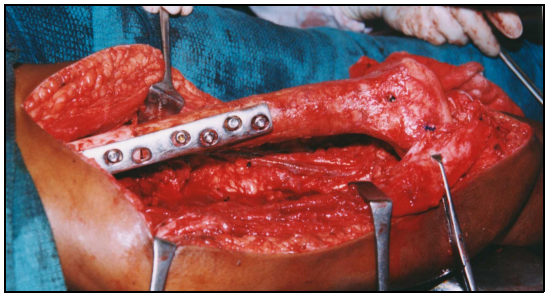
POST OP X RAY

PRE OP X RAYS

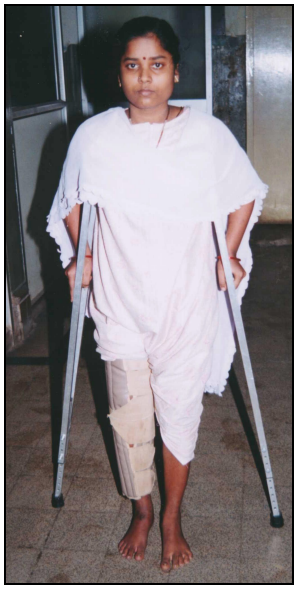




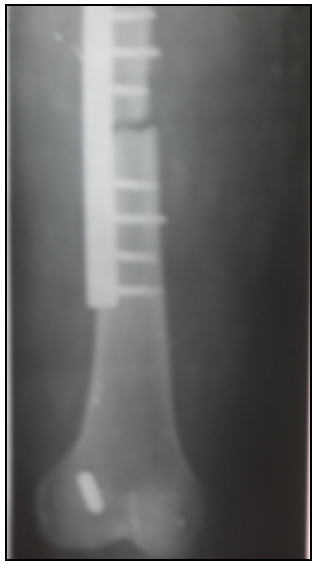
OPERATIVE PHOTO



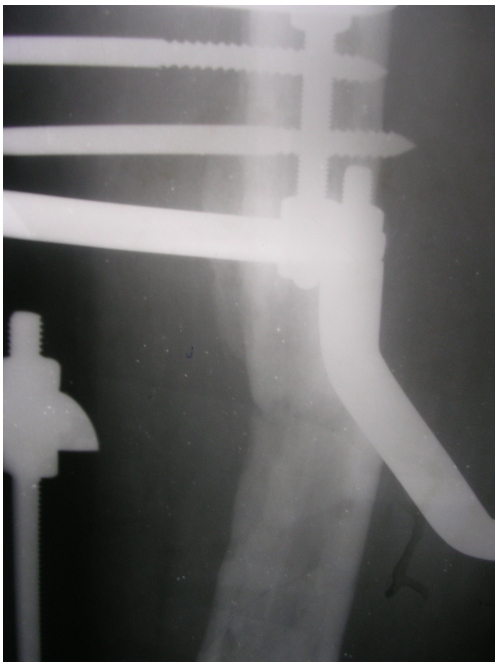
6 MONTH POST OP



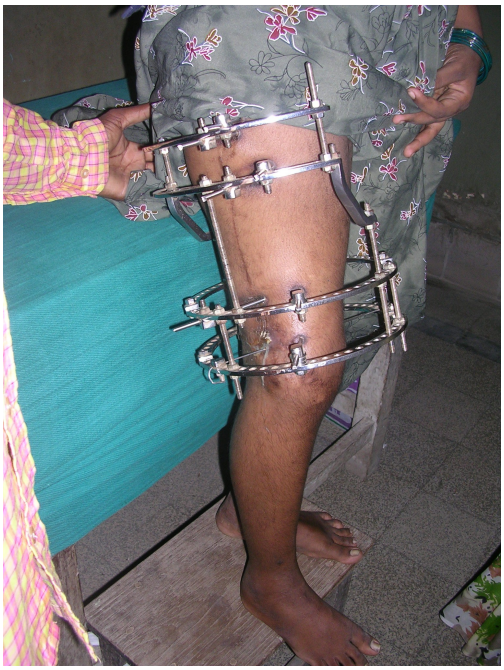
NONUNION



ILIZAROV FIXATOR FOR NONUNION



CLINICAL PICTURE 1.5 YEARS



CASE III

22 year male patient with Desmoid tumor of proximal humerus right side.

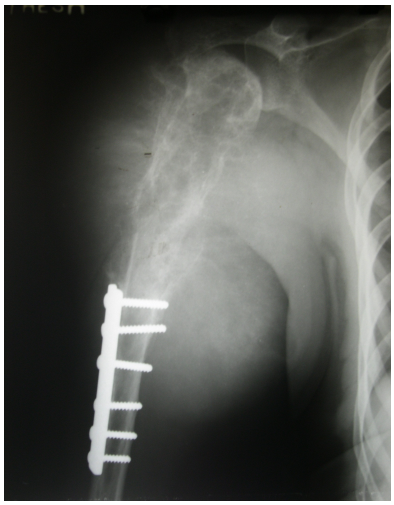
Patient was treated with wide resection and alloprosthetic composite arthroplasty using custom made prosthesis.

Follow up period 15 months, no major complication.

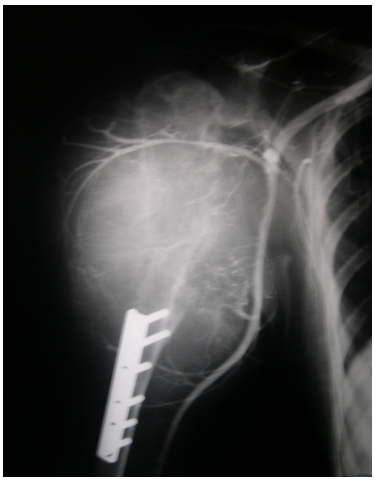
Enneking functional score is 69%.

PRE OP X RAY

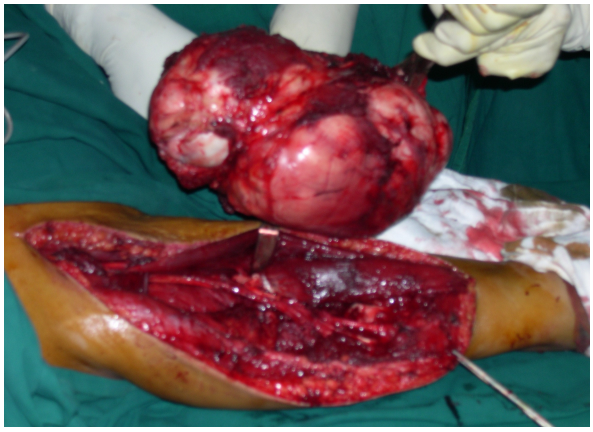
PRE OP ANGIOGRAM



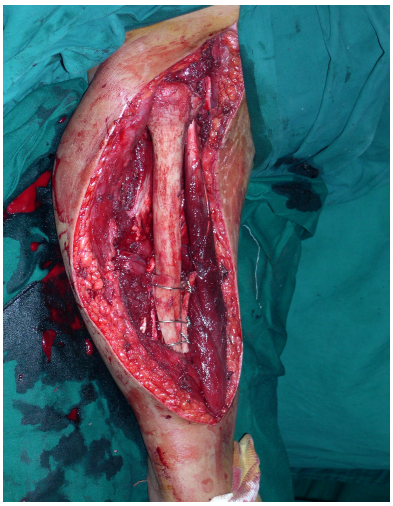
TUMOR RESECTION



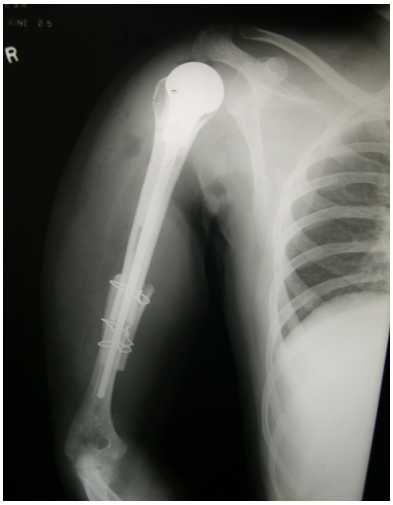
RECONSTRUCTION

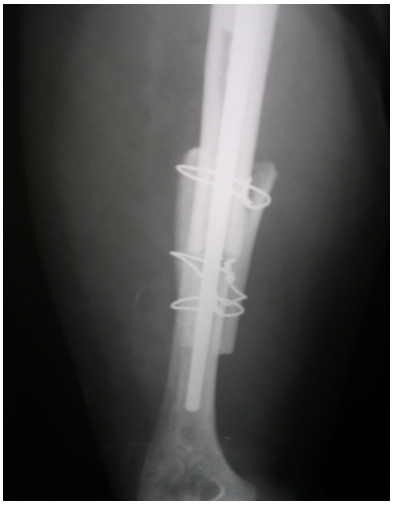


POST OP X RAYS



6-MONTH POST OP





CASE IV

28 year old male with recurrent Chondrosarcoma of pubic bone right side.

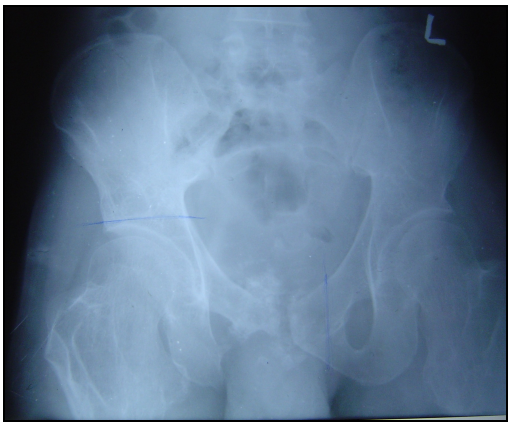
Patient was treated with wide resection and reconstruction using allograft with reconstruction plates. Iliofemoral arthrodesis done with cancellous screws.

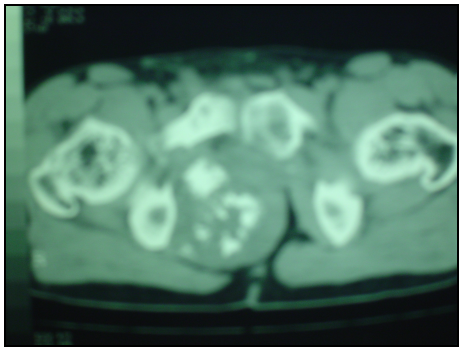
Follow up period 12 months, wound infection present.

Enneking functional score is 69%.

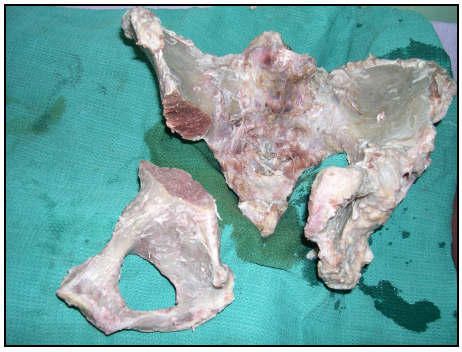
PRE OP X RAY

PRE OP CT SCAN

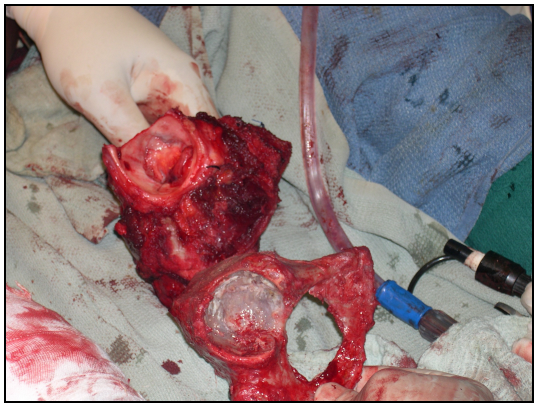




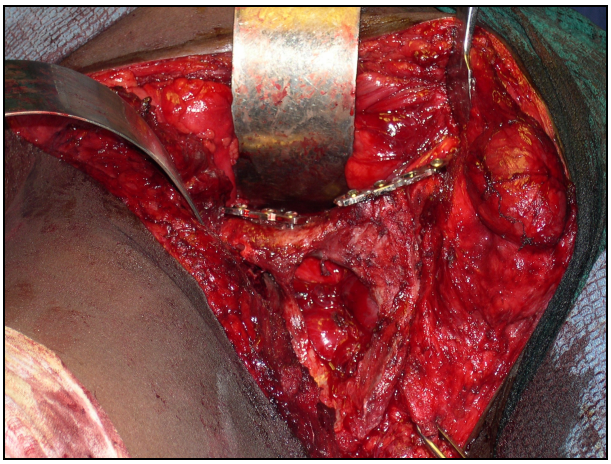
ALLOGRAFT



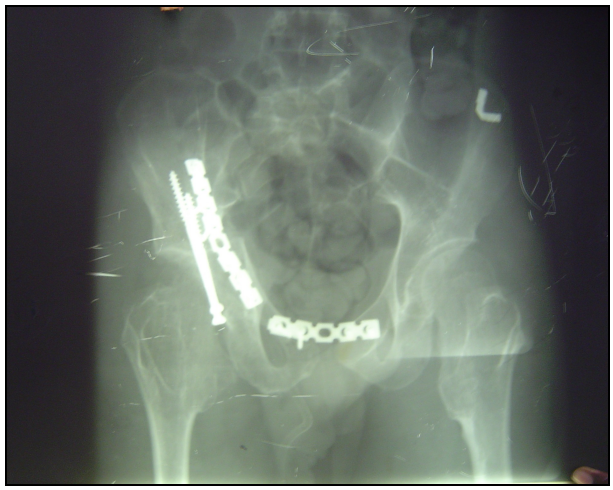
SIZE MATCHING



PER OP PICTURE



POST OP X RAY



RESULTS

The results were evaluated by using Enneking scoring system.

This system of functional evaluation has been adapted by the Musculoskeletal Tumor Society (MSTS) And International Symposium Of Limb Salvage (ISOLS).

This system assigns numerical values (0-5) for each of six categories. Pain, function and emotional acceptance in upper and lower extremities supports, and walking and gait in the lower extremity, and hand positioning, and dexterity and lifting ability in the upper extremity. For details see Annexure – I.

In our 16 cases amputation was done in 6 cases (for local recurrence in 3 cases and for infection in 3 cases). The remaining 10 cases were evaluated by Enneking scoring system.

In our 10 cases, the average Enneking score was 19.9 and 66.6%, ranging from 69% (21) to 52% (16), showing good functional results in these patients.

Excellent	0 cases
Good	7 cases
Fair	3 cases
Poor	0 cases

COMPLICATIONS

9 patients have complications & 7 patients have no complications.

More then one complication occurred in 2 patients. Amputation was done in 6 cases for various indications. Out of the six amputations, 2 were performed for local recurrence of osteosarcoma, one was performed for local recurrence of chondrosarcoma and 3 were done for severe wound infection in Giant cell tumors

Recurrence of tumor occurred in 3 cases (2 cases of osteosarcoma, and one case of chordrosarcoma). Skip lesion occurred in one case of proximal tibial osteosarcoma, tumor recurred in distal tibia after resection. Amputation was done in all the 3 patients.

In the above three patients metastasis occurred in 2 patients. One patient developed pulmonary metastasis. One patient developed cerebral metastasis. In the above two patients one patient died of metastasis and one patient is under treatment.

Infection is the most common and dreaded complication which occurred in 5 cases. In three cases infection was not controlled with antibiotics and repeated wound debridement. Infection causes

necrosis of soft tissue cover over allograft bone and desiccation of the allograft. In two cases amputation was done primarily to control infection. In one case the allograft was removed and infection was controlled with external fixation but local recurrence of tumor occurred and amputation was performed. In two cases infection was controlled.

Our follow up period was too short to comment on nonunion of allograft host junction. Nonunion was present in early two cases. One of these case was infected nonunion,and managed with ilizarov fixation. Infecion controlled and union occurred after eight months.In our series no allograft fracture occurred.

Death	1
Local recurrence	3
Metastasis	2
Infection	5
Non union	1
Allograft fracture	0

DISCUSSION

Allografting is a revolutionary procedure in the treatment of patients with malignant and aggressive benign bone tumors. Allografts offer advantages over metallic implants such as the ability to replace articulating joint surfaces, allowing union to host bone and attachment of soft tissues.

In our study, the mean age was 27 years. It was slightly higher comparing with other studies of allografts. In M. San Jutian - S, Amilto et al series it was 19.6 years. The reason for increased mean age was, mainly due to inclusion of more aggressive benign tumors in our study.

In our study the graft failure occurred in 6 out of 16 patients (40%) for various indications. In Mankin and Springfield et al series graft failure occurred in 18 out of 53 patients (36%). The graft failure rates are comparable with western series.

In our study the mean Enneking functional score was 66.6% (Good). According to Enneking scoring system the results in 8 salvaged limbs were good and fair in other 2 cases. Wunder JS et al of University of Toronto showed mean Enneking functional score of 57% in his series. Yokoyama et al showed good result in 4 cases and fair result in 3 cases out of 11 cases. Our results are comparable with their study.

Complication rates are high in allograft surgery. In our series, 9 patients (59%) had one (or) more then one complication. Hornick et al of university of Miami observed 55% overall complication rate. Capanna R, Campanacci

D et al experienced 75% complication and suggested that by proper pre operative planning and accurate surgery complication rates can be reduced.

In our study, the infection rate was 33%. Mankin and Springfield et al from orthopaedic oncology unit of Massachuettes experienced infection in 16 out of 53 patients (32%). Infection rate in our series is comparable with standard series.

Tomford et al observed 20% of nonunion in his series. Radiation sterilization adversely affects union. The average period for union of diaphyseal osteotomy site was 16 months in most of the series. In our series the follow up period was too short to comment on nonunion.

Allograft fracture is one of the common complication. In Mankin et al series allograft fracture rate was 19%. In our series no allograft fracture. The reason was partially due to good reconstruction techniques and partially due to apprehension on patient part to full weight bearing.

The local recurrence rate in our series was 20%. In Springfield series it was 10%. The local recurrence in our series is slightly higher than standard series. It was partially due to high grade of resected tumors and partially due to non availability of frozen section biopsy to determine the adequacy of resection.

In overall, the functional results as well as complication rates in our series are comparable with standard series.

CONCLUSION

Massive bone allografts are one of the options for reconstruction after resection of bone tumors.

Adequate tumors resection is the most important factor in determining local recurrence there by limb and patient survival.

Since infection is the most common and dreaded complication all measures to be taken to reduce the change of infection. Improved theatre environment, maintenance of strict asepsis, meticulous surgical techniques are necessary to reduce the infection rate. Once infection acquired, aggressive measures to be taken to control infection. It is very difficult to control infection.

Autogenous cancellous bone grafting to be done in all cases at allograft host junction to improve union.

Whenever proximal tibial resection done, medial gastronemius flap cover to be done. The vascularity of the flap should be adequate. If flap failure occurs it will end up in catastrophe.

Complication rates are higher in limb salvage therapy using allograft than amputation, and the patients should be properly motivated for long postoperative rehabilitation therapy.

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PROFORMA

Thesis Topic **:** Limb salvage surgery using allografts in malignant and aggressive benign bone tumors.

Name: **Age:** **Sex:** **Hospital No:**

Address:

Date of Admission:

Date of Surgery:

Date of Discharge:

Brief History:

Past Medical History:

Past Treatment History:

Clinical Examination:

General Survey:

Weight:

Local Examination:

Inspection:

Palpation:

Movements:
Measurements:

Radiological Findings:

Enneking Grading:

Surgical Data:

Allograft Used:

Prosthesis Used:

Method of Fixation:

Side:

Approach:

Intraoperative Complication:

Duration of Surgery:

Postoperative Period:

DT removal:

Suture removal:

Complications:

FOLLOW UP

Date:

ANNEXURE I

ENNEKING SCORING SYSTEM

Criteria for either extremity

Pain. The value for pain is determined by the amount and effect of pain on the patients function.

The required information is the medication or equivalent measures currently used by the patient for pain relief.

No	Description	Data
5	No Pain	No medication
4	Intermediate	
3	Modest / Non disabling	Non-Narcotic analgesics
2	Intermediate	
1	Moderate / Intermittently disabling	Intermittent narcotics
0	Severe / continuously disabling	Continues narcotics

Function. The value for function is determined by the restrictions in activities (actual or prohibited and the effect of these restrictions on the patients lifestyle. the required data are the pretreatment occupation and the degree of occupational disability caused by the restriction (s).

No	Description	Data
5	No restriction	No disability
4	Intermediate	

3	Recreational Restriction	Minor disability
2	Intermediate	
1	Partial Occupational Restriction	Major disability
0	Total Occupational Restriction	Complete disability

Emotional acceptance. The value for emotional acceptance is determined by the patients emotional reaction to or perception of the functional result.

No	Description	Data
5	Enthused	Would recommend to others
4	Intermediate	
3	Satisfied	Would do again
2	Intermediate	
1	Accepts	Would repeat
0	Dislikes	Would not repeat

CRITERIA SPECIFIC TO THE LOWER EXTREMITY

Supports. The value for supports is determined by the type and frequency of external supports to compensate for weakness or instability as they affect standing and/or walking. The required data are the type of supports and the frequency of use (i.e., none,occasional, mostly, always, etc.). if the patient is an amputee and uses a prosthetic limb, the type of prosthesis and frequency of its use as well as the type and use of external supports were

recorded. Additional data on instability and strength may be entered here if desired.

No	Description	Data
5	None	No supports
4	Intermediate	Occasional use of brace
3	Brace	Mostly brace
2	Intermediate	Occasional cane / crutch
1	One cane or crutch	Mostly cane / crutch
0	Two canes or crutches	Always canes / crutches

Walking ability. The value for walking ability is determined by the limitation on walking imposed by the procedure. If limitations are imposed by other considerations (cardiac, respiratory, neurological) do not consider these. The required data are the maximal walking distance and limitations in type (inside/outside, uphill, stairs, etc.,). Other pertinent data related to walking ability (i.e., oxygen consumption) may be entered here if desired.

No	Description	Data
5	Unlimited	Same as preoperative
4	Intermediate	
3	Limited	Significantly less
2	Intermediate	
1	Inside only	Cannot walk outside
0	Not independently	Can walk only with assistance or wheelchair bound

Gait. The value for gait is determined by the presence or absence of gait alteration and the effect of these alterations on restrictions or function. The required data are the type of gait abnormality and resultant restrictions or deformity. Pertinent data from gait analysis, joint motion., and deformation may be entered if desired.

No	Description	Data
5	Normal	No alteration
4	Intermediate	
3	Minor cosmetic	Cosmetic alteration only
2	Intermediate	
1	Major cosmetic	Major functional deficit
0	Major handicap	Major functional deficit

Criteria specific to the upper extremity

Hand positioning. The value for hand positioning reflects the patients ability to actively position the hand of the reconstructed extremity in space for functional activities. Passive or assisted positioning is not considered. The required data are the degree to which the hand can be elevated in the frontal plane and restrictions in pronation / supination. Additional pertinent data concerning range of motion of involved joints. Stability, and deformity may be entered if desired.

No	Description	Data
5	Unlimited	180° elevation
4	Intermediate	
3	Not above shoulder or no pronation supination	90° elevation
2	Intermediate	
1	Not above waist	30° elevation
0	None	0° elevation

Manual dexterity. The value for manual dexterity is determined by the patients ability to perform increasingly complex functions with the hand. Pinch and grasp can be performed in any fashion. Fine movements are those used in buttoning, writing, eating etc. The required data are limitations in dexterity and/or sensory loss in the hand.

No	Description	Data
5	No limitations	Normal dexterity and resistibility
4	Intermediate	
3	Loss of fine movements	Cannot button, etc or minor loss of sensitivity (specify)
2	Intermediate	
1	Cannot pinch	Major sensory loss
0	Cannot grasp	Anesthetic hand

Lifting ability. The value for lifting ability is determined by the patients ability to actively lift objects and place them unassisted. Normal is the amount that can be lifted with the opposite extremity (or expected when the extremity is absent or impaired). Limited indicates limitations in independent lifting. Helping means no independent lifting but useful in assisting the contralateral extremity. The data required are the strength of the extremity expressed in the international system (0-5) for rating muscle power.

No	Description	Data
5	Normal load	Matches normal
4	Intermediate	Less than normal
3	Limited	Minor load
2	Intermediate	Gravity only
1	Helping only	Cannot overcome
0	Cannot help	Cannot move

MASTER CHART

S. No.	Name	Age / Sex	IP No.	Dos	Histological diagnosis	Anatomical Site	Enneking Grade	Chemo therapy	Surgery	Complications	Enneking Score	Follow Up Personal
1	Sivakumar	22/M	601093	July '03	Osteosarcoma	Proximal tibia (L)	Malignant IIB	Yes	Osteoarticular allograft	Skip lesion, Metastasis, Death	NA	7 months
2	Ajantha	19/F	598052	Aug '03	Malignant fibrous histerocytoma	Distal femur (R)	Malignant	No	Osteoarticular allograft	Infection,Nonunion	19 (62.7%)	24 months
3	Gowri	58/F	600284	Oct '03	Chondromyxoid Fibroma	Proximal femur	Benign Aggressive	No	Alloprosthetic arthroplasty	Nonunion	18 (59.4%)	22 months
4	Baskar	41/M	637627	Mar '04	Giant Cell tumor	Proximal tibia (R)	Benign Aggressive	No	Alloarthrodesis	Infection, Amputation	NA	2 months
5	Chethankumar	11/M	642960	Apr '04	Osteosarcoma	Distal tibia (R)	Benign IIA	Yes	Alloarthrodesis	Local recurrence Amputation	NA	6 months
6	Jidesh	22/M	-	May '04	Desmoid tumour	Proximal humerz (R)	Malignant II A	No	Alloprosthetic arthroplasty	Nil	21 (69.3%)	15 months
7	Karthik	16/M	662777	Jul – 04	Osteosarcoma	Distal femur(R)	Malignant IIB	Yes	Alloprosthetic arthroplasty	Infection,Local recurrence Amputation	NA	5 months
8	Uma	19/F	662758	Aug -04	Chondrosarcoma	Distal Radius (R)	Malignant IIB	No	Alloarthrodesis	Local recurrence Amputation	NA	4 months
9	Prakash	28/M	662987	Aug 04	Chondrosarcoma	Pubic bone (R)	Malignant IIB	No	Pelvic allograft ileofemoral arthrodesis	Superficial infection	21 (69.3%)	12 months
10	Palanisamy	35/M	663172	Aug 04	Giant Cell tumor	Distal femur(R)	Benign Aggressive	No	Alloarthrodesis	Nil	19 (62.7%)	12 months
11	Duraisamy	30/M	663214	Jan –05	Giant Cell tumor	Distal femur(L)	Benign Aggressive	No	Alloarthrodesis	Infection, Amputation	NA	2 months
12	Venkatesh	28/M	729141	May 05	Giant Cell tumor	Proximal tibia (L)	Benign Aggressive	No	Osteoarticular allograft	Nil	19 (62.7%)	3 months
13	Umadevi	13/F	736140	Jul – 05	Osteosarcoma	Femur dysphasia (L)	Malignant IIB	Yes	Intercallary allograft	Cerebral metastasis	16 (52.8%)	2 months
14	Radhamani	24/F	733833	Jul – 05	Giant Cell tumor	Distal femur(R)	Benign Aggressive	No	Alloarthrodesis	Nil	19 (62.7%)	2 months
15	Vijayakumari	44/F	730179	Jul - 05	Giant Cell tumor	Proximal tibia (R)	Benign Aggressive	No	Alloarthrodesis	Infection	16 (52.8%)	2 months
16	Jaganathan	41/M	-	Jul 05	Chrondrosarcoma	Pubis (R)	Malignant II A	No	Alloarthrodesis	Nil	19 (62.7%)	2 months