BONE DEFECTS MANAGED BY AUTOGRAFT AND ALLOGRAFT - RETROSPECTIVE AND PROSPECTIVE ANALYSIS.

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CERTIFICATE

This is to certify that the dissertation entitled **"BONE DEFECTS MANAGED BY AUTOGRAFT AND ALLOGRAFT - RETROSPECTIVE AND PROSPECTIVE ANALYSIS"** *is a bonafide record of work done by* ***Dr. K. SOMA SUNDAR*** *in the Institute of Orthopaedics and Traumatology, Government Rajiv Gandhi Government General Hospital, Chennai, under the direct guidance of me.*

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DECLARATION

I hereby, declare the dissertation entitled **"BONE DEFECTS MANAGED BY AUTOGRAFT AND ALLOGRAFT-RETROSPECTIVE AND PROSPECTIVE ANALYSIS"** *submitted for the degree of M.S is the record work carried out by me during the period of* ***July 2014 to September 2015*** *under the guidance of* **PROF.N.DEEN MUHAMMAD ISMAIL M.S.Ortho.,D.Ortho**., Professor of *Orthopaedics & Director I/C Institute of Orthopaedics and Traumatology, Madras Medical College, Chennai. This dissertation is submitted to the Tamilnadu Dr.M.G.R. Medical University, Chennai, in partial fulfillment of the University regulations for the award of degree of* ***M.S.ORTHOPAEDICS*** *(BRANCH-II) examination to be held in April 2016.*

This work has not formed the basis for the award of any other degree or diploma to me previously from any other university.

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CONTENTS

INTRODUCTION

Bone is the most commonly transplanted tissue in our body more than any other tissue or organ except blood. Approximately 5, 00,000 bone transplantations occur in USA every year. For every ten heart transplantations and twenty five kidney transplantations,one hundred bone transplantations occur world wide.

Transplanted bone, tendon and ligaments are used extensively in Orthopaedics, Neurosurgery, Dental surgery and Plastic surgery for procedures including repair of fractures and damage caused by illness and injury. Unlike other tissues bone can regenerate and repair itself [80].

In the body autografts remains the gold standard as they are osteoconductive as well as osteoinductive and have osteogenic cells, BMP etc. Most of the time, the amount of graft required is small and harvesting graft from the iliac crest or fibula is sufficient. These grafts are nonimmunogenic and

represent a good alternative to replace missing bone, ligaments, and cartilage. Cancellous autograft also possesses living cells that participate in the bone repair process. This type of graft, however,does not provide structural support.

Autografting has many disadvantages such as additional blood loss, increased operative time, cutaneous nerve damage, persistent pain at the donor site, vascular injury, iliac bone fracture, herniation into the defect and morbidity. Also the amount of morbidity is in direct proportion to the quantity of graft retrieved. When the graft requirement is large as in case of tumor resection in children, revision hip surgeries, traumatic bone defects, spinal fusion and decompression surgeries allograft comes into play. Bone defects in tumor cavities and traumatic bone defects are treated by various methods such as

- Autograft -vascularized and non vascularized graft
- Bone cementation(tumors)
- Implants
- Biomaterials ceramics(Bioceramics)

- Synthetic bone substitutes
- Demineralized bone matrix and Bone Morphogenic Protein
- Bone allograft

Custom made prosthesis is available only in certain countries. They are very expensive.

Likewise, ceramics are available only in a few countries and are very expensive. With the development of bone banks all over the world, bone allograft has become more readily available with high standards of safety for transplantation in patients.

Allografts are preferred over synthetic implants by value of their desirable features of natural structure, shape and strength and biological capacity of incorporation.

Allograft have several advantages such as easy to obtain more amount of the graft, nil donor site morbidity, availability in all dimensions, cheaper than metallic implants and biologic

form of fixation. It can be stored for 3-5 years in case of freeze dried allograft and for 3-5 years for deep frozen allograft.

The clinical application of bone allografting became prevalent in the first two decades of the 20th century after experimental work by Ollier and Axhauen. From then various forms of bone allograft are being used with variable success.

Allograft are used in various forms like morsellized allograft, osteochondral and intercalary allograft for various defects.Femoral head can be harvested (from the donors undergoing primary THA,hemiarthroplasty) processed, stored and can be used in other patients.

Bone allograft

- Fresh bone – limited use
- Frozen bone – Freezing does not adversely affect strength of allograft and also reduces immunogenicity while retaining sufficient osteoinductive potential.

- Freeze dried bone – Freeze dried in vaccum. It has the advantage of storage at room temperature, long shelf life but resorption rate is high and bone becomes mechanically weak[90] with little osteoconductive ability.
- Demineralized bone- DBM is prepared by simply demineralizing the bone in hydrochloric acid until the calcium content is reduced to less than 2%. It has no structural strength,has high resorption rate, has both osteoconductive and osteoinductive potential [81]. It has only limited application in situations where a large gap has to be filled.

Cancellous bone is most often used for filling cysts or cavities. Cortical bone is optimal for reconstructing defects that require a certain form and strength.

Although technique for allograft bone storage was described in the late 1940s and whole segmental graft were used for tumor surgery in 1960s, the use of femoral head

allograft as structural bone graft was started in 1976 for revision hip surgeries. Initially, bone grafting was performed most commonly during complex primary hip arthroplasties such as for dysplasia, protrusio acetabuli, but currently it is also being done for revision hip arthroplasty, foot and ankle surgeries, tumors and fracture non unions.

The technique and practice of bone allografting in India is yet to take a firm footing. The facility for proper processing of the harvested bone allograft, its storage and strict donor screening is available only at a few tertiary heath centers in India.

The bone bank in Rajiv Gandhi Government General Hospital started in the year 2005 is one such place aimed at optimum utilization of the allograft.

Very few studies till date are available regarding the various uses of (femoral head bone) allograft in orthopaedic surgery including trauma, tumor, revision hip arthroplasty, spine, ankle and foot surgeries etc.

Ours study brings out the various uses of bone auograft and allograft in orthopaedic surgery

AIM OF THE STUDY

1. To analyze the management of bone defects with autograft and allograft.
2. To retrospectively and prospectively analyze the outcome of autograft and allograft done in these conditions.

HISTORY

Bone grafting is a very old surgical procedure. The first recorded bone grafting was performed in 1668.

Sushrutha 2500 yrs – Used various skin and bone allograft and nasal bone reconstruction.

1682 - Jole Van Meekren – Russian Church records a successful use of piece of dog skull to repair a defect in the skull of the soldier.

William Maceman (1881)

- First successful bone allograft.
- Started the modern practice of bone grafting.
- Successfully transferred segments of bone from rachitic patients to the humerus of a three year old child with osteomyelitis.
- Rib graft to replace mandible.

- 1893 - Barth – Concept of creeping substitution.

- 1908 - Lexer – 25 allogenic whole joint transplantation.
- 1908 - Axhauser – Supports the view that repair of bone defects and replacement of bone graft are affected by deposition of bone by periosteum and the endosteum.
- 1914 - Phemister – Technique of bone grafting to enhance the process of creeping substitution.

During World war time

- 1935 – 1937 Bush & Wilson – Bone storage at 10° to 20°c in New York.
- From 1940 - 1970 – M. Volkov Russia – Successful procedures using processed bone.
- 1941 – H.B. Boyd – Fresh bone allograft in the treatment of pseudoarthrosis.
- 1942 – Inclan – Storage of autogenic and allogenic bone.
- 1948 – M.O. Henry,
    - Fresh bone allograft procured from the parents in the treatment of cysts and tumor.

- 1952 – US Navy – George Hyatt – Founded Navy Tissue Bank.
- 1952 – First tissue bank by Rudolph Klen at Faculty hospital at Hardee Kralore Czechoslovakia.
- 1956 - Albee, First Orthopaedic surgeon to start a bone bank in New York.
- 1960's – Ethylene oxide sterilization has been used for bones.
- 1961 - Goser coined the term Allograft.
- 1965 - Mohammed Al Gafeqin of Cordoba – advocates spinal fusion using fish bones.
- 1974 - Radiation sterilization focus to be an alternative for Ethylene Oxide sterilization on the grounds of safety and cost.
- 1978 – Burchand et al – Described three patterns of allograft incorporation.
- 1980 - H.J. Martin at Massachusetts – Active programme for allografting.

- 1983 - W.W. Tomford – Use of Glycerol and Dimethyl sulfoxide to maintain the viability of cartilage during freezing.
- 1987 - G.E. Friedlaender – Current concepts review, bone graft, basic science rationale for clinical application.
- 1989 - M.R. Urist – Bone Morphogenic Protein bone regulation, heterotopic ossification and bone marrow consortium.
- 1990 - International Atomic Energy Agency published guidelines for radiation sterilization.
- 1990 - 30 Tissue banks in US.
- - 31 Tissue banks in Europe.
- P.H. Custus, S.W.Chare, C.H. Herdone – Suggested freezing cadaveric bone reduces the Immunogenicity.
- Dr. F. Langer Canada – Reaction to allograft is greatly reduced by freezing the graft.

FEMORAL HEAD ALLOGRAFT

The use of femoral head allograft as structural bone graft was started in 1976. The earliest reported use of structural bone grafting in hip replacement was in 1973 by Horn's et al [(1)]

- In 1978 McCollum and Nunley showed the potential of morsellized allograft to bone stock deficiency in protrusio acetabulum[2].
- In 1983 Roffman et al reported the survival of bone chips under a layer of bone cement. In a study in animals[3], the graft appeared viable and new bone was formed along the cement interface.

- In 1984, Sloof et al., described the technique of impaction of bone graft[4].

BIOLOGY AND INCORPORATION OF AUTOGRAFT AND ALLOGRAFT

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 graft in stimulating incorporation encompasses osteoconduction, osteoinduction and osteogenesis. Cancellous graft undergoes stages of healing.Initially there is hemorrhage

and inflammation. The grafted cancellous bone cells subsequently die except for the surface osteoblasts, which remain viable. The cancellous graft is next invaded by blood vessels that deliver osteoclasts from the peripheral circulation. These osteoclasts remove the cancellous bone while it is replaced by living bone by osteocytes. Osteoblasts line the nectotic bone graft, and eventually osteoid is produced. This process continues until the osseous defect is replaced with living bone. The final phase of graft incorporation is remodeling.

Osteoconduction and creeping substitution are the main mechanisms in the incorporation of allograft. Allograft

act as a scaffold for ingrowth and this is referred to as osteoconduction.

Graft incorporation occurs in the following stages

1. Revascularization.
2. Graft resorption.
3. Creeping substitution, new osteons laid over the allograft.
4. Graft remodeling.

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

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

Large allograft may be incorporated in processing serial stress fractures that result in graft remodeling periodically. A region of stress concentration may have microfractures followed by local remodeling. Later it proceeds to the whole

length of the massive allograft. It takes a long time for the massive allograft to get incorporated into the skeletal system of the host.

TYPES OF AUTOGRAFT

Multiple cancellous chips or strips

This is the most osteogenic and most widely used graft. The best source of cancellous bone graft is the ilium. It is the principle type of graft used for fractures, nonunions and for arthrodesis of the spine.

Single onlay cortical bone graft

Until relatively inert metals became available, the onlay bone graft was the simplest and most effective treatment for most ununited diaphyseal fractures. Usually the cortical graft was supplemented by cancellous bone for osteogenesis. The onlay graft is still applicable to a limited group of fresh, malunited, and ununited fractures and after osteotomies. Cortical grafts also are used when bridging joints to produce arthrodesis, not

only for osteogenesis but also for fixation. Fixation as a rule is best furnished by internal or external metallic devices. Only in an extremely unusual situation would a cortical onlay graft be indicated for fixation, and then only in small bones and when little stress is expected. For osteogenesis the thick cortical graft has largely been replaced by thin cortical and cancellous bone from the ilium. The single-onlay cortical bone graft was used most commonly before the development of good quality internal fixation and was employed for both osteogenesis and fixation in the treatment of nonunions.

Dual onlay cortical bone graft

Boyd developed the dual – onlay cortical bone graft technique in 1941 for the treatment of congenital pseudo-arthrosis of tibia[79]. Dual onlay bone grafts are useful when treating difficult and unusual nonunions or for the bridging of massive defects. The treatment of a nonunion near a joint is difficult, since the fragment nearest the joint is usually small, osteoporotic, and largely cancellous, having only a thin cortex.

It is often so small and soft that fixation with a single graft is impossible because screws tend to pull out of it and wire sutures cut through it. Dual grafts provide stability because they grip the small fragment like forceps. The advantages of dual grafts for bridging defects are as follows: (1) mechanical fixation is better than fixation by a single onlay bone graft; (2) the two grafts add strength and stability; (3) the grafts form a trough into which cancellous bone may be packed; and (4) during healing the dual grafts, unlike a single graft, prevent contracting fibrous tissue from compromising transplanted cancellous bone. The disadvantages of dual grafts are the same as those of single cortical grafts: (1) they are not as strong as metallic fixation devices; (2) an extremity must usually serve as a donor site if autogenous grafts are used; and (3) they are not as osteogenic as autogenous iliac grafts, and the surgery necessary to obtain them has more risk.

Inlay bone graft

By the inlay technique a slot or rectangular defect is created in the cortex of the host bone, usually with a power saw. A graft the same size or slightly smaller is then fitted into the defect. In the treatment of diaphyseal nonunions, the onlay technique is simpler and more efficient and has almost replaced the inlay graft. The latter is still occasionally used in arthrodesis, particularly at the ankle. Albee popularized the inlay bone graft for the treatment of nonunions [88, 89]. Inlay grafts are created by a sliding technique, graft reversal technique, or as a strut graft. Although originally designed for the treatment of nonunion of the tibia, these techniques are also used for arthrodesis and epiphyseal arrest.

Sliding graft

Drill four holes at each corner of the sliding graft. Cut the rectangular graft with a water-cooled saw blade.

After the graft is removed, if there is a solid fibrous union between sections A and B, it is simply flipped end

for end and then impacted back into the slot. If it is in two pieces, section A is slid distally, and section B is placed proximally. Section A now bridges the fracture site. This technique is rarely used today, because internal fixation combined with onlay cancellous bone graft provides a better result. This technique may be combined with internal fixation if there is limited space to place a cancellous graft. The disadvantages of the sliding or reversed bone graft are that, after the cuts are made, the graft fits loosely in the bed, and it creates stress risers proximally and distally to the nonunion site. It is most safely used in metaphyseal rather than diaphyseal regions.

H–graft

The H-graft is a corticocancellous graft usually harvested from ilium specifically designed to achieve posterior fusion of the cervical spine.

Peg and dowel graft

Dowel grafts were developed for the grafting of nonunions in anatomic areas, such as scaphoid and femoral neck. In most instances, dowel grafts have been replaced by micro vascularized fibular grafts. Peg grafts have also been used to bridge the tibia and fibula to produce proximal and distal tibio fibular synostosis.

Medullary graft

Medullary grafts are not indicated for the diaphysis of major long bones. Grafts in this location interfere with restoration of endosteal blood supply because they are in the central axis of the bone, they resorb rather than incorporate. The only possible use for a medullary graft is in metatarsals and metacarpals.

Osteoperiosteal graft

In osteoperiosteal grafts, the periosteum is harvested with chips of cortical bone. They are rarely used today.

Pedicle graft

Pedicle grafts may be local or moved from a remote site using microvascular surgical techniques. In local muscle-pedicle bone grafts, an attempt is made to preserve the viability of the graft by maintaining muscle and ligament attachments carrying blood supply to the bone or in the case of diaphyseal bone, by maintaining the nutrient artery.

Advantages are high percentage of cell survival, rapid incorporation and increased active participation of the grafted cells in the healing process.

TYPES OF ALLOGRAFT

1. Demineralized bone matrix allograft.

2. Morsellized cortical and cancellous allogenic bone.

3. Cortico cancellous and cortical allograft.

4. Massive allogenic osteochondral allograft.

1. Demineralized bone matrix (DBM)

It gets quickly revascularized, has no structural support and is moderately osteoinductive.Within 1 hour of implantation, platelet aggregation, haematoma formation and inflammation characterized by migration of leucocytes occurs. Fibroblast like mesenchymal cells undergoes cellular differentiation into chondrocytes around 5^{th}day. Chondrocytes produce cartilage matrix which is mineralized. After 10 -12 days vascular invasion with osteoblastic cells occurs and new bone is formed on 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. Morsellized cortical and cancellous allogenic bone

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

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

3. Corticocancellous and Cortical Allograft

They provide structural support and are osteoconductive to a limited degree. The process of incorporation is slower

than the DBM and cancellous allograft as resorption is necessary for revascularization.

4. Massive Allograft

The incorporation of massive allograft is a slow and incomplete process. Immune response is produced by the host despite long storage in the deep freezer aimed at reducing 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 takes a long time in achieving fusions. Optimizing the host-allograft interface improves the functional outcome of massive bone allograft. 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.

IMMUNOLOGY OF BONE AUTOGRAFT AND ALLOGRAFT

Organs and tissues transplanted into incompatible hosts (animals or humans) will induce an immune response. There is no antigenic response for autograft transplantation. There is substantial evidence to show that bone, like other allogenic tissue also induces such a response as a result of 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

The immune response to an allograft is the result of a cell-mediated process to cell surface antigens. Class I and Class II antigens are recognized by key lymphocytes and are responsible for the immune response [72]. Allograft rejection can occur via cell-mediated cytotoxicity as well as antibody formation. Class I antigens are present on organs and tissue and generally are the first antigens to initiate the immune response. The most active immune response, however, is mediated by CD4 and CD8 cytotoxic T cells. These cells secrete

cytokines that can result in allograft resorption. Patients demonstrate an immune response to class II antigens after allograft implantation and generally have a less successful clinical outcome than do non reactors.

HISTOCOMPATIBILITY MATCHING

Experimental results show that matching does reduce immunogenicity and improve the outcome of bone allograft. However, its potential benefit in clinical practice is still controversial and unresolved [72]

ALTERING THE GRAFT

The selective manipulation of graft prior to transplantation helps prevent rejection without total suppression of the host immune system. This method not only reduces immuogenicity[73] but also solves the problem of storage methods for graft. Some methods of alteration are freezing, freeze drying, autoclaving, deproteinization, decalcification and exposure to high doses of radiation.

GRAFT PREPARATION

MATERIAL

The original technique of impaction bone grafting described by Sloof et al. Rosenberg et al made use of morsellized cancellous bone for protrusion acetabuli[82]. The argument for using cancellous bone as the base material was that, the structure of cancellous bone would allow more rapid angiogenesis of the opposition cancellous trabeculae would enhance osteoclast – driven remodeling[5, 6]. Although cortical allograft might weaken during the resorption phase, it will still remain stronger than cancellous graft[7].Several investigators have tried to optimize the mechanical performance of morsellized bone graft under compaction by manipulating the particle size and the range of sizes (the grade) as well as supplementing it with particles of other materials that are stronger and stiffer than bone[9]. Turner et al. showed in a canine model, that the combination of calcium sulfate pellets and demineralized bone matrix is more effective as a bone-graft substitute than is either calcium sulfate or demineralized bone matrix alone[83]. Nijmegen group has shown that large (8 mm to 10 mm) unrinsed cancellous chips produced by hand with a rongeur achieved 25% greater

stability in a dynamic in vitro acetabular model than smaller (2 mm) unrinsed chips produced with a bone mill[(84)]. Henmann and Finlayson (2000)[8] analyzed the convention of ordering bone from tissue banks in terms of numbers of the femoral heads. Authors state that this approach results in great variability in the quantity of graft available for impaction because of the variability in size and density of femoral heads. This variability may compromise the stability of the graft. They recommended the allograft by weight not by quantity, which predicts more accurately the volume of graft after impaction.

MORSELLIZATION

The size and grade of the bone particles is important to the early mechanical stability of compacted morsellized graft. The general consensus is that the particle should be large to ensure stability. Another advantage of larger particles is that they are more porous (more permeable) than compacted bone graft. Dunlop et al. 2003[10], suggested removal of fat and marrow fluid from milled femoral head allograft by washing the graft which allows the production of stronger compacted graft that is more resistant to shear as it is the usual mode of failure. Shear strength of the graft layer is improved by using morsellized graft with fine particles.

However, using this range of particle sizes reduces graft permeability, as the pores between larger particles will be filled with smaller particles.

RINSING

Fluid plays an important role in compaction[15]. By simply washing the graft with warm saline to remove the excess fat, the force required to displace a grafted implant can be almost doubled[12]. Rinsing may further enhance stability by improving the shear strength of the graft[13.] Processing the graft is the elimination of bone marrow and cellular debris with fluid and detergents, which, by its clearing effect, will improve the osteoconductive capacity of the bone and safety [(85)]. Processing of this allograft involves pasteurization, centrifugation, sonication and repeated washing in warm distilled sterile water[14]. Removing lipid from the graft has been shown to increase the rate of incorporation[14].

The contamination of the graft is a concern during pulse lavage. The real contamination is low after pulse lavage washing of the femoral head[15]. Pulse lavage washing with sterile saline solution can be recommended for allograft decontamination[15.] By rinsing the total tissue,there was increased ingrowth in the allograft

group in a study (Vander Donk et al., 2003)[16]. Rinsing after impaction did not additionally alter bone ingrowth.

Moderate heat treatment of bone allograft at 65°c has less adverse effects on osteointegration in rabbit femoral condyle (Kuhne et al 1992)[17]. Knaepler noted heat inactivation at 60°C showed no effect; 80°C resulted in a diminution of the yield point and the maximum stress ($p<0.005$), while energy absorption and compressive modulus were not affected. No reduction in the stability was seen when ethanol was used instead of Lactated Ringer. At a temperature of 100°C, all measured parameters were reduced to approximately 60% compared with the control group. (1990 – Knaepler et al) [18].

Even though strict donor screening programmes are carried out, these measures do not completely rule out the possibility of HIV transmission as there is a window period before infection is revealed by blood testing. Accordingly there is a need for virus inactivation methods. Moderate heat treatment and autoclaving are viable options for allografting in countries where there is difficulty in obtaining large quantities of fresh frozen allograft.

STERLIZATION OF ALLOGRAFT

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 allograft. Sterilization has been defined as the process of inactivating all forms of life, especially microorganisms. Aseptic procurement of allograft from live donors who have little risk of infection in sterile operating rooms does not need a secondary sterilization. But allografts from the cadaver need secondary sterilization wherever the procurement has taken place. The sterilization of allograft is an important inevitable process that needs to be undertaken strictly in order to succeed in bone transplantation.

The commonly used sterilization methods are

1. Autoclaving
2. ETO sterilization
3. Radiation sterilization

1. Autoclaving

Bacteria are more readily killed by moist heat than dry heat. Steam sterilization at 121^{o}c for 15 to 20 mins is the best method to kill the bacteria by denaturing their protein. Autoclaving is not recommended by American Association of Tissue Banks because it alters the structure of proteins and bone strength.

2. Ethylene Oxide

Ethylene oxide for use as a fumigant and sterilizing agent used to be available in mixtures with nitrogen, carbon dioxide or dichlorodifluoromethane [(86)].After sterilization the residual Ethylene oxide is replaced by flushihg inert gas like Carbon dioxide.

3. Radiation Sterilization

Two types of radiation are employed for sterilization namely ionizing radiation and non-ionizing radiation. Ultra violet rays are non- ionizing 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 electromagnetic rays such as gamma rays emitted by radioisotopes like Cobalt 60, 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 solid and liquid component 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 method has gained popularity in sterilization of allograft.

Effect of preservation & sterilization:

Freezing the bone decreases its tensile and compression strength by about 10 %. Freeze drying decreases torsional strength by about 50% and compression strength by 10%. Bending strength has been shown to be lowered upto 20% by each of these methods. Other physical modes of sterilization like autoclaving and pasteurization affect mechanical properties to a greater extent, so such graft can only be used where there is no need for structural support.

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

EXPERIMENTAL FINDINGS

Heekin et al (1995) in a post mortem retrieval analysis of morsellized allograft used for acetabular reconstruction showed that at 18 months vascularized tissue had penetrated the allograft fragments to a depth of 4mm in peripheral area, the vascularized ingrowth was accompanied by partial osteoclastic resorption of graft trabeculae and application of living bone to allograft fragments[19]. After 53 months in situ, graft fragments had remodeled and showed progressive vascular ingrowth and by 83 months graft had got almost completely incorporated

CLINICAL RESULTS

Morsellized cancellous bone grafting dates back to early 60's and 70's .Spence et al 1969, in a study have treated 177 cases of simple bone cyst at various sites with freeze – dried cancellous bone allograft and have shown good results in most of their cases[20]. Delayed union and bacterial infection were the main problems necessitating repeat procedures.

Spence et al and Bright et al 1976 have treated 144 cases of solitary unicameral bone cyst with curettage and packing with freeze dried crushed cortical bone allograft and have shown 88% of healing rate in those cysts that were completely packed [(21)]. High rates of recurrence were seen in young patient (10 years) active cysts in females and incompletely packed cysts. Data shows freeze – dried allogenic crushed cortical bone is superior to similarly processed cancellous bone and comparable to cancellous autograft.

Gordon et al performed total hip arthroplasty in 13 hips with acetabular bone graft for secure component fixation. The incorporation and healing of acetabular bone graft were investigated with the aid of roentgenogram; planar bone scans SPECT with 3dimensional imaging and a newer scintigraphic technique [(87)]. The conventional radiographs proved unreliable in evaluating because of overlapping trabecular pattern. There was no evidence of graft failure or acetabular loosening. Bone graft during late follow up exhibited normal nucleotide activity while fresh graft < 1 year showed increased activity.

Jaffee et al (1990)[41] treated 7 patients with benign lesions of femoral head and neck with curettage and fibular strut grafting in

conjunction with a sliding hip screw. They had excellent functional result in 5 cases and fair in 2 cases. This construct with fibular strut and sliding hip screw provides strength and prevents deformity and fracture, though it does not eradicate the disease. Internal fixation promotes union of the cortical graft to host cancellous bone and eliminates the need for plaster casts.

Sethi et al (1993) treated 17 patients with benign cystic osseous lesions by curettage and grafting using allogenic decalcified bone [26]. The time of adequate incorporation of the graft varied from 6 – 9 months in children and 9 – 15 months in adults. The overall response compares favorably with that of allograft from bone banks.

Shih et al and Cheng et al (1996) treated 35 patients with benign lesion of the femoral neck or trochanter with pathological fracture in 11 cases [30]. They were treated with curettage and bone grafting with sliding hip screw and plate. The bone grafting included deep frozen allogenic cortical strut with autogenous iliac cancellous bone to fill the remaining defect space after lag screw and cortical strut had been implanted. All patients had good bony

healing and incorporation of the implanted graft with excellent functional result.

Shih et al (1997) treated 16 patients between the ages of 11 and 16 years with benign lesion of the humerus[29]. They were treated with subtotal excision or curettage and allogenic cortical strut associated with or without cancellous bone grafting. There were no local recurrences or fractures of the shaft or allograft implants. The overall functional results were good to excellent. This reconstruction with biologically safe and active material provided increased strength and prevented refracture.

Shih et al and Haung et al (1998) treated 22 patients with fibrous dysplasia in the femoral neck or trochanter with curettage and bone grafting with a sliding hip compression screw [31]. Bone graft included deep frozen allogenic cortical strut and cancellous allograft. All patients had good healthy bone and complete incorporation.

Guile et al (1998) reviewed the long-term outcomes of treatment of fibrous dysplasia of the proximal femur in 22 cases [33]. Curettage and bone grafting with cancellous or cortical graft did not appear to have any advantage compared with osteotomy alone

in symptomatic lesions as all graft resorbed with persistence of the lesion. A satisfactory clinical result was achieved in 20 patients (9 – mono osteotic and 11 – poly osteotic disease). Poor results were in those presented with endocrinopathy. Varus deformity was treated with valgus osteotomy with or without medial displacement.

Woodgate et al (2000) described a minor column (shelf) allograft as graft used for uncontained defects that involve less than 50% of the acetabulum[35]. Authors reviewed records of radiographs of 47 patients (51 hips) who had undergone minor column structural acetebular allograft reconstruction during revision hip arthroplasty. The purpose was to identify factors that may influence the longevity of the allograft, the study revealed that the acetabular abduction angle was not a predictor for failure and good results can be achieved with structural acetabular allograft especially if there is restoration of near normal hip biomechanics.

Thein et al (2001) studied mid-term result of bone impaction grafting using freeze-dried bone in 7 acetabular revisions operated from 1989-1994[36]. All 7 patients were followed annually at final review (March 2000), one hip had revision performed for septic loosening 5 years after the previous septic loosening.

Radiographically, the freeze dried allograft seemed to incorporate in all cases but in the infected one, progressive radiolucent lines were not seen, although 1 case had a stable line 1 zone. The overall survival rate for the 7 acetebular reconstructions at an average follow up 7 years was 86%. At midterm follow up there was no aseptic loosening.

Somers et al (2002) cemented revision hip arthroplasty with the use of block allografts can give acceptable results in the medium to term to long term follow up of 61 consecutive cemented acetabular revisions in which block allograft were used to reconstruct large defects [37]. After a mean follow up of 6.5 years they observed satisfactory results when graft had been rigidly fixed, additional buttress plating was found to improve the outcome. Cup migration had a 56% predictive value for failure. There was a good improvement in functional outcome which did not deteriorate upto maximum follow up of 11 years.

Aro et al. (2003) discussed the various areas of allograft usage such as Oncological limb-salvage surgery. Revision Hip replacements, Traumatic bone defects etc [40]. They suggested the use of autograft at the graft host junction for induction of repair in

cortical graft. Infection of allograft is a disastrous complication. Nonunion, fracture of the graft are other complications. Osteochondral allograft show gradual deterioration of the articular cartilage necessitating occasional resurfacing.

Jaffe et al. (2003) have treated fifteen patients with benign lesion of the proximal femur by intralesional curettage and fibular cortical allograft strut in conjunction with sliding Hip screw [41]. Clinical results were evaluated using the functional evaluation of reconstruction procedures described by the Musculo Skeletal Tumor Society. Clinical results were excellent in all these patients. Radiographic assessment of the patients showed no evidence of recurrence of tumor, fracture or graft resorption at the most recent follow up.

Lin-Hsiu Weng et al. (2004) have treated 18 patients who had nonunion of fracture femur with internal fixation, autogenous bone graft and cortical strut allograft [44]. The average follow up was 32.2 months. They have undergone 1.8 operations on an average before surgery. All 18 nonunions healed on an average period of 8 months.No significant complications were encountered except for screw irritation and protrusion of graft necessitating additional

procedures. Strict adherence to the principles of the treatment of nonunion and addition of strut allograft to enhance stability and repair potential proved to be a good alternative.

Basarir and Selek et al. (2005) have treated bone defects after resection or curettage of musculoskeletal tumors with structural fibular autograft or allograft [46]. This study compared the clinical and radiological results of nonvascularized fibular auto and allograft. 57 patients were treated by this method with autograft in 30 and allograft in 27. Internal fixation was used in selected cases. The results were evaluated with respect to union, time of union and complications. Radiologically union was obtained in 80.7% cases with a mean of 5.9 months (6.8 months in 20 autograft and 5.1 months in 26 allograft) non union (19.3%) in 4 allograft and seven autograft. Reconstruction of cavity and segmental bone defects with autologous or allogenic non vascularized fibular graft is a reliable method and no significant difference was found between auto and allograft in terms of union ($p>0.05$).

ON Nagi compared the use of formalin preserved bone allograft in the form of a paste and as bone chips in fresh femoral shaft fractures with communition in 20 cases and found that the

bone chips had 80% good to excellent result (Union) and they take an average period of 6.5 months (range 5-8 months) for fracture union[49]. They suggested that the formalin preserved bone chips may be better suited for use in bony cavities and joint replacements, and they are good alternative to bone autograft, especially in poly trauma.

PRESERVATION OF ALLOGRAFT

The three most commonly used preservation methods are

1. Deep freezing
2. Cryopreservation
3. Freeze drying

I) DEEP FREEZING

In this method the graft is collected and frozen at-80^{o}c.Allograft can be preserved by deep-freezing upto 5 years.

Advantages

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

Disadvantages

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

II) CRYOPRESERVED ALLOGRAFT

Lower the temperature the greater the reduction of molecular activity, including enzymatic activity. Graft procured and transported at 4^{o}c.The grafts are soaked in antibiotic solution for 24 hours at room temperature and undergoes a slow, controlled rate freezing down to -135^{o}c leading to reduced crystal formation.The process involves the extraction of cellular waste with dimethyl sulfoxide or glycerol and storage in liquid nitrogen.

By cryopreservation allograft can be stored upto 10 years. Most of the bone banks in the world do not prefer the cryopreservation due to

- Its high cost.
- Rapid turnover of tissues makes it unnecesary to store them indefinitely.
- Liquid nitrogen may increase the brittleness of bone due to

immediate crystallization of water that occurs on rapid exposure to very low temperature.

III) FREEZE DRYING (FREEZE DRIED ALLOGRAFT)

Freeze drying or lyophillisation is a process in which frozen bone is dehydrated by sublimation and frozen slowly first to -80°c for 1 week followed by lyophillyzed at -40^{o} centigrade for 24hours and stored.A vaccum is maintained in the freeze dryer during the process, ensuring that bottles of bone allograft are sealed in a sterile manner. In this process, the tissue is maintained at room temperature for atleast two years or as long as the vaccum seals remain unbroken. ADVANTAGES:

1. It can be kept at room temperature so storage is made easy and cheap.

2. Reduced antigenicity as compared to deep freezing.

3. Transfer of diseases is less likely.

DISADVANTAGES:

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

METHODS OF FIXATION OF ALLOGRAFT

Three common methods used to fix allograft with host bone after tumor resection is

1. Alloarthrodesis
2. Osteoarticular allograft reconstruction.
3. Allograft prosthetic composite arthroplasty(APC).

I) ALLOARTHRODESIS

Arthrodesis of joints can be achieved with the allograft as limb salvage option in tumor reconstruction.

Indications

a. Excessive soft tissue involvement by a malignant tumor.
b. Presence of Infective foci.
c. Custom made prosthesis/APC failure
d. Younger patients with high functional demand.
e. Poor patients who cannot afford for prosthesis.

Technical aspects

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

b. 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 allograft can be used in reconstructing the partial intraarticular defects and total intraarticular defects. Cartilage preservation is the main factor in these grafts. This can be done with glycerol / DMSO infiltration or Cryopreservation.

Fresh frozen allografts are nowadays rarely preferred as cartilage damage occurs after long storage.

Technical aspects and advantages

a. Exact matching of the articular defect is made using X-rays.

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

c. Soft tissue reconstructions with ligaments are possible and provide better option for non-weight bearing joints like shoulder.

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

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

III) ALLOGRAFT PROSTHETIC COMPOSITE ARTHROPLASTY

This includes both biologic and implants reconstruction.

It consists of a 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.

a. Facilitates muscle and ligament reattachment to the implant and thus improving stability and active motion.

b. Restores 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 the follow up for tumor recurrence will be easy.

c) Host-allograft junction should be packed with autograft for better union and incorporation.

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

COMPLICATIONS:

Donor site-

Early Complications

- Wound dehiscence
- Infection
- Seromas and Haematomas
- Neurovascular injury
- Ureter injury

Late Complications

- Painful Scar
- Contour deformity
- Chronic Pain
- Reflex symphathetic dystrophy

ALLOGRAFT

The following are the various complications of allograft.

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 allograft.

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.

Bone allografts have been implicated in transmitting tuberculosis, HIV, Hepatitis and bacterial infections to recipient. To prevent or atleast 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 allograft only when needed and to consider the use of autograft alternative to sterilized bone allograft 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 suspected 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 allograft, 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 allograft. These patients remain asymptomatic supporting the notion that the osteoarticular allograft creates a

Charcot type of joint which despite a poor radiographic appearance can function well clinically.

Graft resorption occurs in some individuals due to immune reactions of individuals toward the graft. This occurs usually in patients with frozen articular graft. This is usually a rare complication.

DISEASE TRANSMISSION WITH ALLOGRAFT

Allografts are 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 unprocessed fresh frozen bone allograft. Aho et al reported two deep bacterial infect ions during use of 63 large allografts apparently caused by transplantation of the unprocessed frozen large bone allografts (Aho et al, 1998)[92]. Tomford and co-workers (Tomford et al, 1990) reported an infection rate of about 4 to 5% in use of 324 culture-negative, non-sterilized unprocessed frozen bone allografts at Massachusetts General Hospital [91]. The disease transmission is rare in freeze dried bone allograft and

demineralized freeze dried bone allograft.

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

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

PREVENTIVE STEPS

Transmission of infection can be prevented by excluding the harvest from following circumstances

- Donors positive for HIV antibody.
- Identifying high risk group donors.
- Autopsy reveals occult disease.
- Donor bone positive for bacterial contamination.
- Donor positive for HbsAG or HCV
- Donor positive for syphilis.

TESTING FOR HIV / HCV / HBSAG / VDRL

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

- Occult disease in donor on autopsy.
- Donor bone tip should be tested for bacterial contamination at the time of procurement and final packaging. Tissue should be culture negative at the time of official packaging.

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

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 barrier.

MATERIALS AND METHODS

Between SEP 2012 –SEP 2015, cases of autografting and cortical and cancellous allografting has been carried out at the Institute of Orthopaedics and Traumatology, after getting ethical committee approval at Madras Medical College, Chennai. This was a prospective and a retrospective study conducted in patients, of which 9 were males and 6 were females. The Age groups of these patients were ranged between 12-75 years.

Diagnosis	No of Cases
Benign bone tumours	8
Trauma cases	5
Fragility #	1
Revision hip arthroplasty	1

CASE DETAILS

Benign tumours- histopathological diagnosis: 8

Fibrous dysplasia - 4

Giant cell tumour - 2

Aneurysmal bone cyst - 2

Revision hip arthroplasty: 1

Trauma cases : 5

- Neglected acetabular fracture -3
- Femur non union -1
- Tibial non union -1

Fragility fracture : 1

PRE OPERATIVE WORKUP

Each patient was clinically assessed in the preoperative period, the data obtained included in addition to the demographic data, patient's symptoms, clinical findings and details of prior procedures if any.

In the benign bone tumor cases preoperative workup of conventional radiographs, CT scan and MRI scan (in affordable patients) and biopsy by percutaneous (core needle biopsy) or open method was done. X-ray chest and when necessary CT chest was done to rule out pulmonary metastasis in GCT cases.

Neglected acetabular fracture, tibial,femur nonunions were assessed for active foci of infection, discharging sinuses etc. Radiographs were taken for them as a part of preoperative workup.

INCLUSION&EXCLUSION:

All benign tumours, trauma cases, neglected fracture cases, non union, osteopenic fractures, age from 15-75,both males and females included. Donors positive for HIV antibody, donor bone positive for bacterial contamination, donor positive for HbsAG or HCV, Donor positive for syphilis, infective foci, malignant tumour are excluded.

MANAGEMENT PROTOCOL

As a rule all the patients were screened for HIV, HBsAg and HCV pre operatively.

The benign tumors were graded with Enneking staging and extended curettage was done in Latent and Active type of lesion. The defects were treated with cancellous femoral head allograft with or without autograft and with or without implants.

Osteopenic bone defect in one case (humerus fracture) was treated with radius cortical strut graft and internal fixation.

Neglected acetabular fractures (3 cases) were treated by freshening the surfaces, allograft impaction and reconstructed with THA. Tibial non union was treated by freshening the fracture ends, filling with the autograft , fibular strut graft along with cancellous

bone allograft and stabilised with Ilizarov fixator.Femur non union case was managed with tibial cortical allograft and LCP.

In one case of revision hip after removing the spacer and further reaming, the cavity was filled with cancellous femoral head allograft and finally reconstructed with acetabular cup and SROM prosthesis.

ALLOGRAFT RETRIEVAL AND PROCESSING

Femoral heads were retrieved from patients undergoing total hip replacement or hemiarthroplasty for fracture neck of femur, osteoarthritis and degenerative or post traumatic arthritis. Lower end of femur or upper ends tibial graft retrieved from patients undergoing total knee arthroplasty were also harvested and kept as a source of allograft bone.

After informed consent from patients and patient attenders graft was harvested under aseptic conditions. Bone was thoroughly washed to remove blood and cellular elements. After removing all soft tissues and articular cartilage they were washed with saline, wiped, dry packed in a sterile container and stored in a deep freezer at -80°C.Sterilisation of the allograft is done by ETO sterilizer and after that we store that allograft in a sterile cover provided along with ETO sterilizer. The blood of the donors were screened twice

for HIV I, HIV II, HBV, HCV and VDRL once at admission and again after 3 months (window period) at review. Only after both serologies were negative, graft was used.

Informed written consent was sought and obtained from every receipent prior to the use of bone allograft.

Intraoperatively femoral heads were morsellized and the morsellized femoral head was then washed with aqueous betadine for 5-10 mins, again washed with saline for four rounds and it was impacted in the patient's diseased part.

Cortical strut allografts procured from the amputated limbs of our RGGGH patients were used.For that donors also we investigate for HIV,HCV,HBsAg at the time of admission and after 3 months (window period)

Similarly a post operative antibiotic protocol was followed for all patients. Inj.Cefotaxim 1gm iv bd and Inj.Amikacin 500 mg iv bd for 5 to 7 days.

CLINICAL DATA AND FOLLOW-UP

All the benign tumor patients were reviewed up every month for first 3 months and then every 3 months till date.

The humerus fracture case, nonunions, revision hips cases were also followed up in a similar manner as for the tumor group upto the period of incorporation(3-6 months) and then every 6 months to one year.

ANALYSIS

All the cases except humerus and revision hip were analyzed based on the ENNEKING'S Scoring System for functional outcome. Revision hips and hip arthoplasty were analysed with Harris hip score.Graft incorporation was analyzed by radiological methods, comparing the preoperative with serial post operative x-rays.

RADIOLOGICAL REVIEW

Radiological assessment for union was done for all patients. AP and lateral views of the treated parts were taken and compared with the preoperative X-rays and those taken at previous reviews.

The radiographic analysis of cortical allograft incorporation was comprised of two aspects: the first aspect involved estimating the volume of the lesion in cubic centimeters using the method described by Glancy et al.,[93] while the second aspect involved determining the healing of the lesion and the

extent of incorporation of the allogenous cortical struts into the host bones. Each radiograph was examined for trabeculation, internal callus formation,bone density, and borders between the cortical struts and the cavity. A lesion was considered healed if the preoperative cavity was completely obliterated. The lesion was considered partially or incompletely healed when residual lytic areas remained. The union was considered a failure if the cavity was not obliterated, no evidence of trabecular formation existed, or the graft was resorbed. Allograft incorporation into the host bone was considered complete if the host-graft space was completely obliterated. Incorporation was considered partial if the graft was still visible but its border was blunted, and no incorporation if the contour of the allograft was unchanged from that of the initial postoperative radiograph.For tumour reconstruction with allograft incorporation judged by the presence trabecular ingrowth, no resorption,medullary canal obliteration,absence of gap between the host and bone .

For THA with allografting radiological review is done by assessing three DeLee and Charnley's zones for acetabulum and the seven Gruen zones for the femur.It quantify the graft over the

host bone with radioluminescence, density, bone trabeculate formation components' migration and flocculation. Each of the criteria, except migration, received an individual score from 0 to 2 in each of the three De Lee e Chanrley's zones for acetabulum and of the seven Gruen zones for the femur, with 0 being a poor result and 2 a good result. Once the scoring of each gap was provided, the scores for each component, acetabular and femoral, were summed up. For migration, 0 was established for above 6 mm, 1 for 3-5 mm, and 2 for less than 3 mm.These summed up scores gives better knowledge about the state of implant in acetabulum and femur.It consists of 3 zones and five parameters and 10 points for each zone ,totally 30 and 70 for acetabulum and femur respectively.

Distribution of acetabular and femoral scores.

Classification	**Acetabulum**	**Femur**
Very good	24 –26	54 – 58
Good	21 – 23	49 –53
Moderate	18 – 20	44 – 48
Fair	15 – 17	39 – 43
Poor	> 15	>39

In case of revision hip radiological failure was defined as cup migration of more than 4mm, cement fracture, evidence of graft resorption, presence of radiolucencies at host graft interface and absence of trabecular bridging.

Incorporation of the cortical graft could not be assessed in terms of trabecular continuity between graft and host and needs further long-term follow up for analysis.

OBSERVATION AND RESULTS

Demographic Data of study group

Between SEP 2012 –SEP 2015, 15 cases of cancellous femoral head and cortical allografting were carried out for various trauma and orthopaedic conditions at the Institute of Othropaedics and Traumatology, Madras Medical College and Govt. General Hospital, Chennai. 9 of these patients were males and 6 patients were females, the mean age was 43.5 years with a range of 12 to 75 years.

Sex distribution

Males	Females
9	6

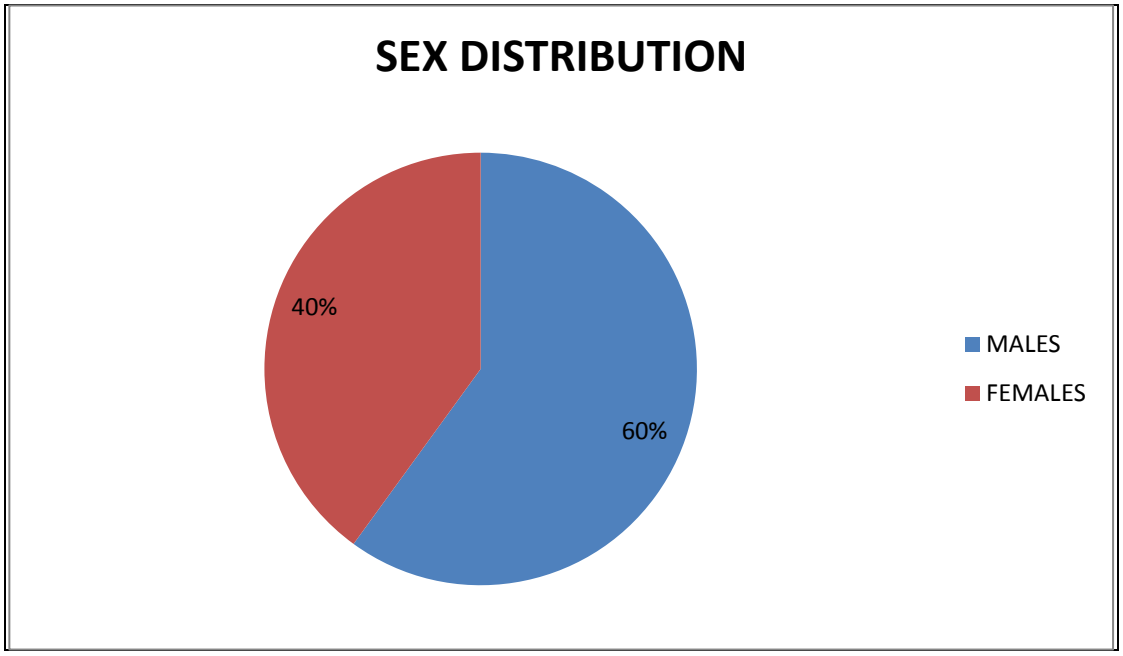
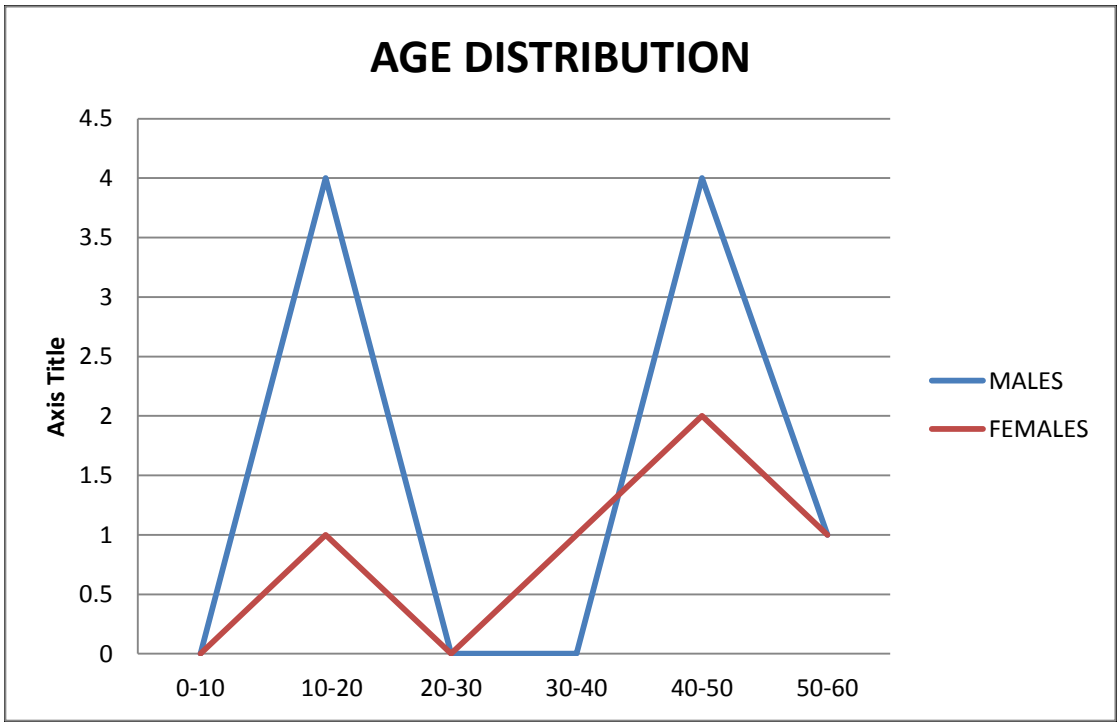


TABLE: AGE DISTRIBUTION OF PATIENTS

Age in Years	Males	Females
1 – 10	0	0
11 – 20	4	1
21 – 30	0	0
31 – 40	0	1
41 – 50	4	2
51 – 60	1	1
>60	0	1



DISTRIBUTION OF CASES ACCORDING TO CASES

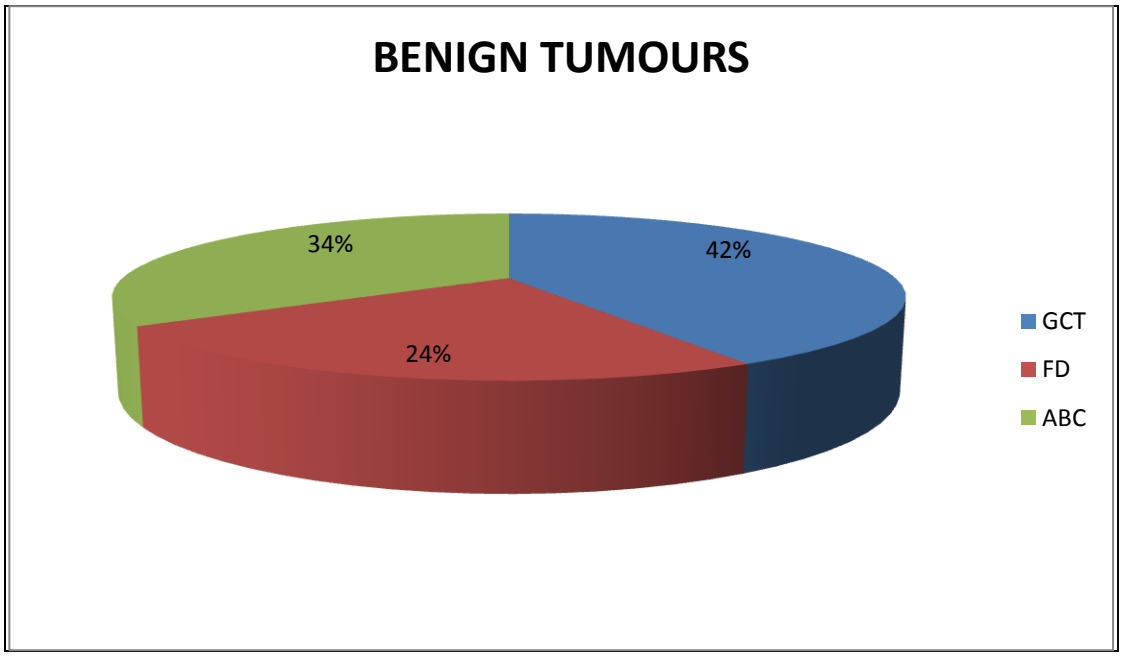
Among the 15 patients 8 were (53.3%) benign bone tumor cases, 5 were (33.3%) cases of traumatic non unions and 1 was (6.66%) revision hip and 1 fragility fracture (6.66%).

DISTRIBUTION OF TUMORS ACCORDING TO SITE

Site Of Benign Bone Tumors	***No. of Patients***
Proximal Femur	2
Distal Femur	2
Proximal Tibia	1
Shaft of tibia	1
Metatarsal	1
Calcaneal	1

BENIGN BONE TUMORS

Type of Lesion	Primary	Recurrent	Total
Giant cell tumor	2	-	2
Aneunysmal bone cyst	2	-	2
Fibrous dysplasia	4	-	4
Total	**8**	**-**	**8**



GRADING OF LESIONS

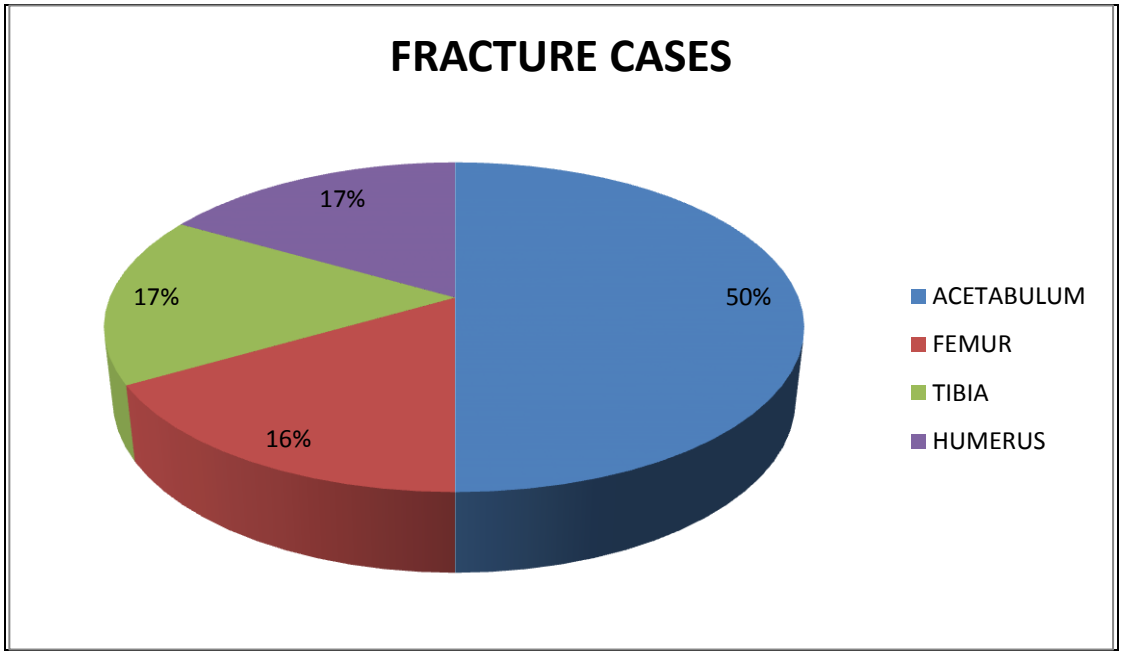
Benign bone tumors were classified based on ENNEKING BENIGN TUMOUR staging.

TABLE – 3: GRADING OF THE LESIONS TREATED

Grade	No. of Cases	Percentage
Latent	5	62.5%
Active	3	37.5%
Aggressive	0	0%

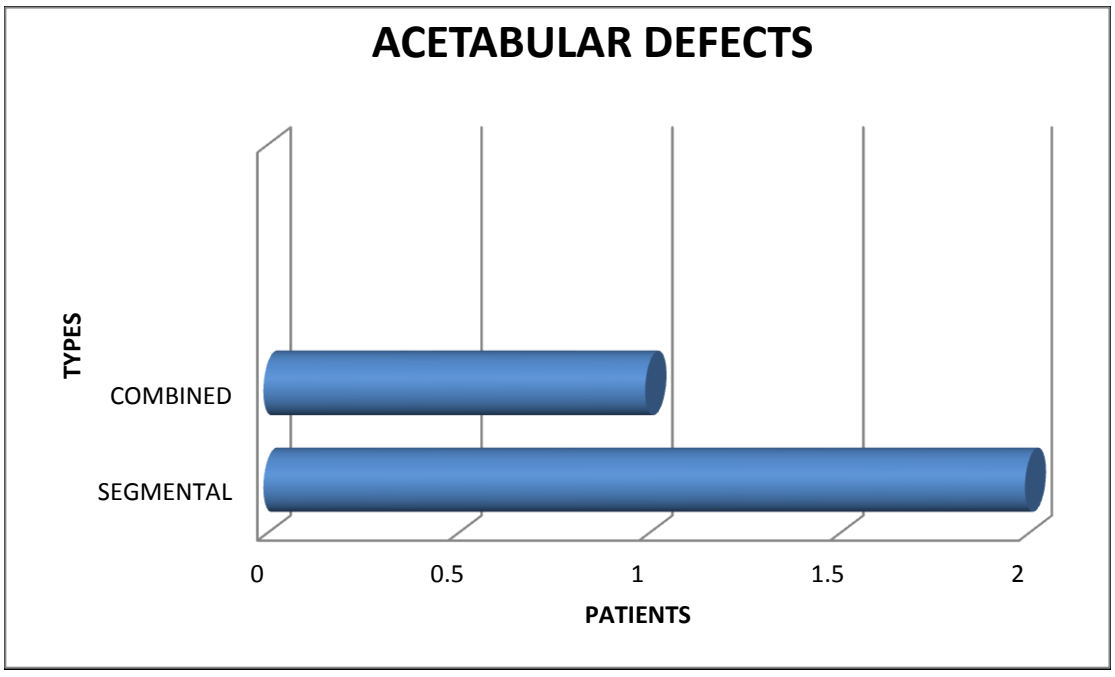
DISTRIBUTION OF FRACTURE CASES

Diagnosis	No. of Cases	Percentage
Acetabular fracture	3	37.5%
Femoral Non union	1	12.5%
Tibial Nonunion	1	12.5%
Humerus fracture	1	12.5%



DISTRIBUTION OF ACETABULAR DEFECT ACCORDING AAOS

Type of defect	No. of Hips
Type I Segmental defect	2
Type III combined defect	1



OPERATIVE DATA

Among the 8 (53.5%) benign tumor cases extended curettage or marginal resection was done depending on the grade of the lesion.

SURGICAL TECHNIQUE ADOPTED

S.No.	Surgical Technique	No. of Cases
1.	Curettage or Extended curettage (Intra lesional treatment)	7cases
2.	Marginal resection	1 case

TYPES OF GRAFT USED

S.No.	Surgical Technique	No. of Cases
1.	Femoral Heads alone	5
2.	Fibular strut graft (allograft)	1
3.	Radius strut allograft	1
4	Femoral Heads and autograft	8
5	Tibial strut allograft	1

TYPES OF IMPLANTS AND INSTRUMENTATION

In addition to cortical strut allograft, implants such as Dynamic Hip Screw,Narrow Dynamic Compression Plates,Locking compression plate, Ilizarov and THR were used.

OUTCOME ANALYSIS

Clinical observation and results

Patients were followed up for an average of 13.5 months (Range 3 months – 36 months). 3 cases did not have regular follow up. All the other cases had been followed up in detail and therefore their data were included in the study.

PERIOD OF FOLLOW UP OF TWELVE CASES
Minimum: 3 months
Maximum: 36 months
No follow up: 3 cases

Patients with tumour and complex fracture except humerus fracture were analysed based upon the Enneking scoring system and by radiological evaluation. According to the Ennekings scoring system (Annex – 1)[53]

Excellent result - ≥ 80% (≥ 24/30)

Good result - 60 – 79% (18/30 – 23/30)

Fair result – 40 – 59% (12/30 – 17/30)

Poor result - < 40% (< 12/30)

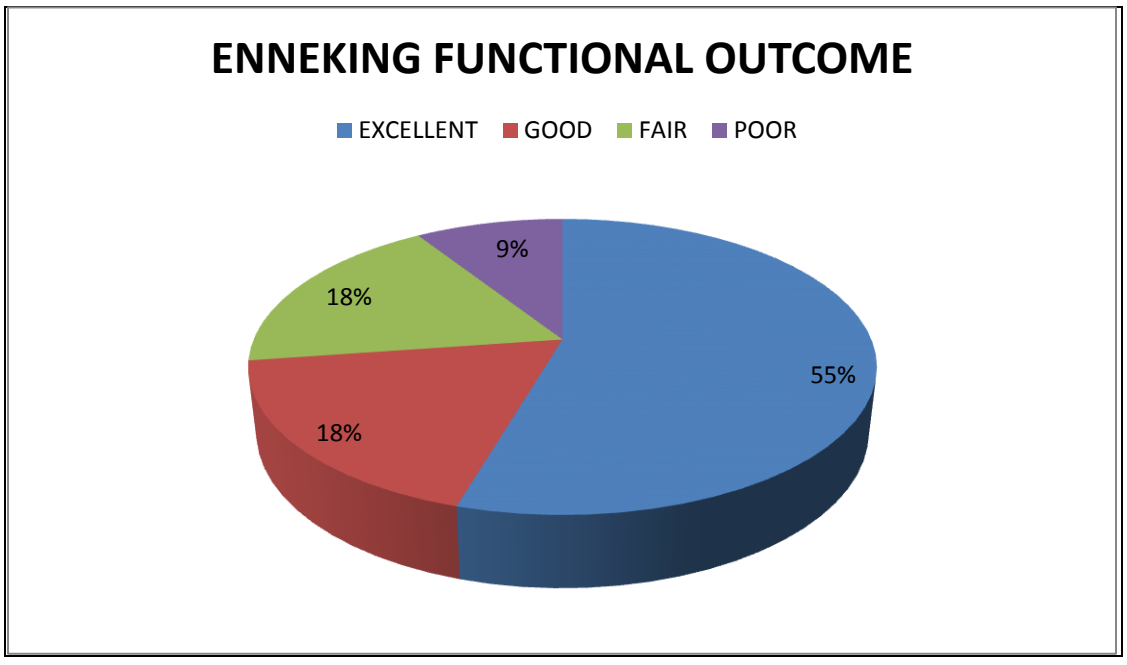
We have analysed this scoring system for totally 11 patients including tumours and complex fractures[(97)]. We got excellent results in 6 cases (54.5%) and Good results in 2 (17.6%) cases,and fair results in 2 (17.6%) cases and poor result in 1 case. The poor result was due to earlier compound injury and wound gaping in which we had to remove the graft for control of infection. This was termed as failure.

GRADING OF ENNEKINGS FUNCTIONAL EVALUATION

SCORE

TUMOUR AND TRAUMA CASES

Group	No. of Patients	Percentage
Excellent ≥ 24	6	54.5%
Good (18 – 23)	2	17.6%
Fair (12 -17)	2	17.6%
Poor < 12	1	8.7%



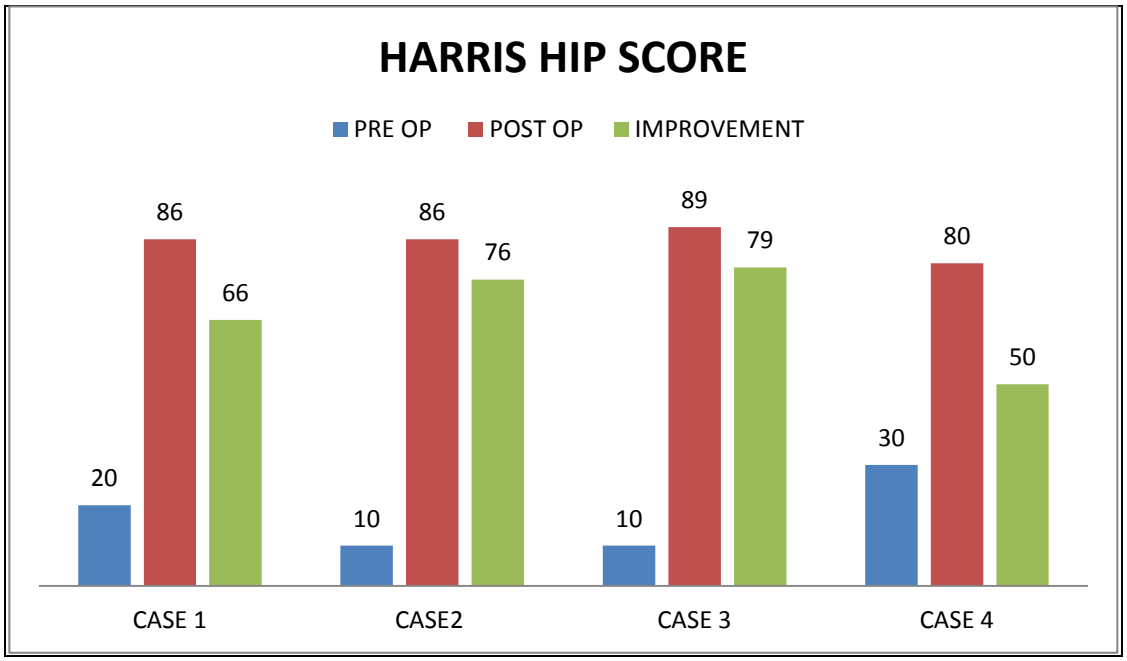
AGE GROUP WISE RESULT

Age in years	No. of patients	Good to excellent Result
1 – 10	0	0
11 – 20	4	3
21 – 30	1	1
31 – 40	4	2
41 – 50	3	1
51 – 60	2	1
>60	1	1
TOTAL	15	9

Revision hip and hip arthroplasties were analysed separately by Harris hip Scoring System.

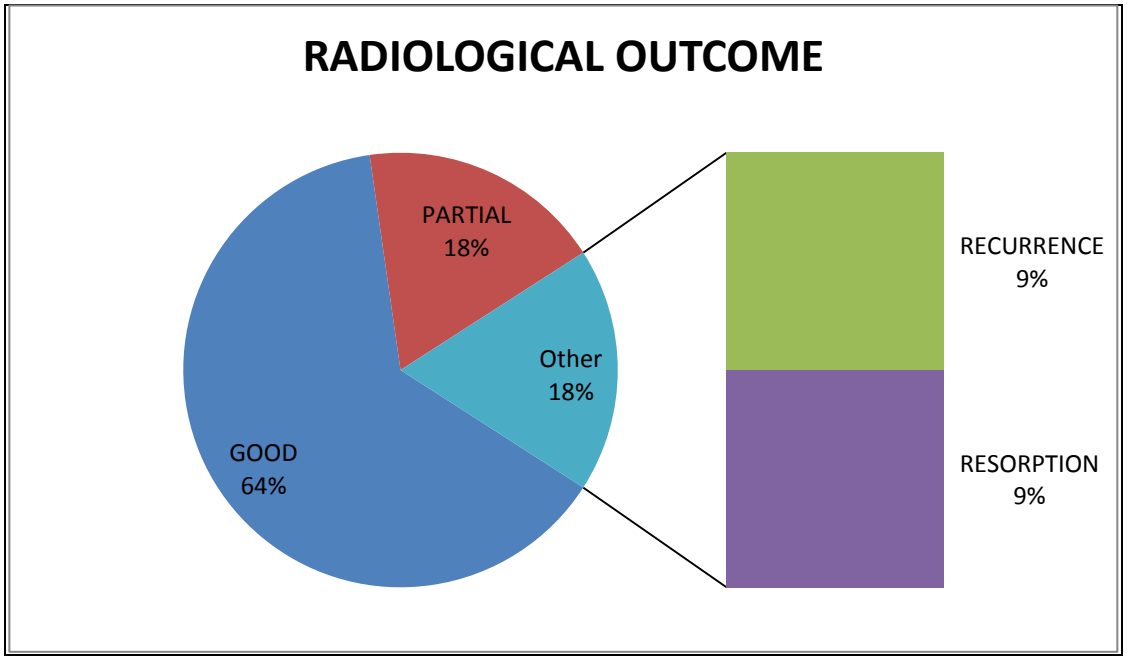
ANALYSIS OF HIP ARTHROPLASTY CASES BY HARRIS HIP *SCORE*

	Pre operative score	Post operative score	Improvement in Hip Score
Case I	20	86	66
Case II	10	86	76
Case III	10	89	79
Case IV	30	80	50



Radiological Observation and Results

Radiological data were available for 12 cases which came for follow-up.

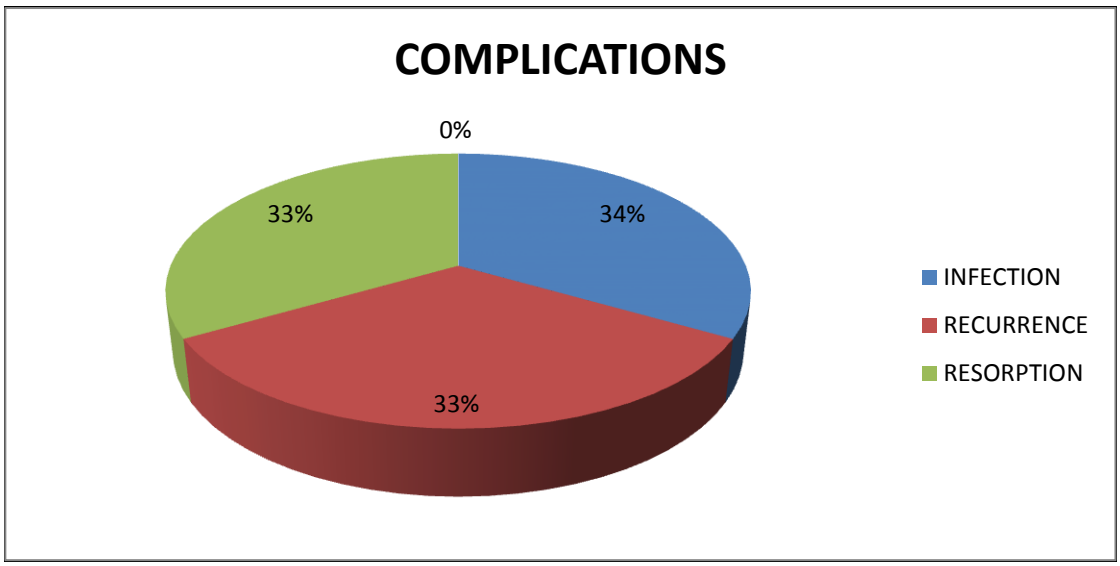


Complications

Infection was seen in 1 (6.6%) case,which had deep infection developed after third month of surgery. Debridement with antibiotic beads was done and infection still persisted at last follow up.Resorption seen femoral non union treated with cortical allograft.Recurrence seen in ABC.

COMPLICATION

Complication	No. of patients
Superficial	0
Deep	1
Recurrence	1
Resorption	1



DISCUSSION

The use of allograft bone dates back to the early 1900s, the first long term follow-up evaluation showing that these graft were partially replaced and incorporated by the host. Della Valle showed that the use of cementless porous-coated cups have a 96% survival in terms of aseptic loosening at 15 years [93].

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

But when the graft requirement is larger as in massive defects or in children where the autograft availability is small and harvesting can damage the open growth plates, the role of allograft comes into play.

There are a variety of options such as autograft, cancellous and cortical allograft for treating these bone deficiencies in various orthopaedic conditions such as benign bone tumors, non union,fragility fracture and revision hip arthroplasties.

Though autografts are the best their availability and donor site morbidity limits their use. Bone substitutes such as calcium hydroxy apatite are studied extensively; they are osteoconductive to an extent but are partly not incorporated in the long run. Bone morphogenic proteins are osteoinductive.

In our study we have evaluated the clinical and radiological outcome of the allografts in terms of Ennekings functional evaluation score in all the cases and Harris hip score in hip and revision hip arthroplasty cases.

The allografts have several advantages when used alone or in combination with autograft. Under filling the cortical bone defects delays bone formation whereas no harm results from over filling cortical bone defects. One study noted that autograft in comparison with demineralized bone matrix allograft, resulted in a longer operative time subsequently greater blood loss associated with autograft collection and over all higher cost to patients[55, 56].

Allograft provides the form and matrix of bone tissue but no viable cells are transplanted. In addition, bone allograft are more slowly incorporated into the host and induce an immune response

which may delay the osteoinductive phase of bone graft incorporation[57,58]. Despite complication structural allograft are widely used. We autoclaved the graft so as to denature the proteins thereby reducing immunogenicity and to reduce the risk of infection.

Concerns with allograft use

Studies have shown that freezing of cortical and cancellous graft may improve their incorporation[57]. We routinely freeze the femoral head allografts and cortical allografts after processing.

Overt graft rejection is extremely rare and clinical studies have not shown any adverse effects secondary to the immunogenicity of allograft[61, 62, 63·]. Allograft is most weak during revascularization and the mechanical property of the bone graft may be affected by preservation techniques. The freeze – dried allograft is weaker in its torsional and bending strength than autoclaved allograft. Comparatively the frozen allograft has better torsional and bending strength. The compressive strength of these graft are equivalent. However these factors may not apply to small sized graft such as the cancellous femoral head allograft used in

this study and no fracture of a graft was noted during the study period in these patients

Another concern is with the use of structural allograft is possible transmission of infection. Although extremely rare, transmission of infection is possible. An audit from a bone bank in Leicester, England showed contamination of femoral head graft from both live and cadaveric donors and one clinical infection was documented in the nine large allograft implant[68].

To prevent the possibility of the infection (pyogenic as well as other viral diseases) many of the fresh frozen allograft we autoclaved (at 121°C for 30 min) and some of them we sterilized with ETO in addition to donor screening procedures that is done routinely in any bone bank. This has shown to improve safety in human transplantation even though they have adverse effects on incorporation which is not much disturbed in our study of cancellous and cortical allograft.

Conventionally, bone allografts are ordered depending on intra operative findings in the form of number of femoral heads. But Henman and Finalyson[67] stated that this approach results in great variability in size and density of femoral heads. This

variability may compromise the stability of the impacted graft and recommended requesting allograft by weight not quantity which predicts more accurately the volume of graft after impaction.In our study ordering for allograft was done in the form of number of morsellized heads in the pockets.

Jaffe et al. (2002)[41] Fifteen patients with a benign lesion of the proximal femur were surgically treated with augmented intralesional curettage and bone grafting using an allogenic fibular strut graft in conjunction with internal fixation with a sliding hip screw. Mean age was 26 years (range, 13-46 years). Patients were followed up for a mean of 30 months (range, 7-110 months). Clinical results were assessed using the functional-evaluation-of-reconstruction procedures described by the Musculoskeletal Tumor Society (Enneking score). Radiographic outcomes were assessed by comparing preoperative radiographs with radiographs taken at the most recent follow-up. Clinical results were excellent in all patients. Radiographic assessment of the patients showed no evidence of recurrent tumor, fracture, or graft resorption at the most recent follow-up. This method of treatment leads to excellent functional results and lessens the morbidity associated with autograft harvest.

Lobo Gajiwala and Agarwal (2003)[42] Tumour excision leaves behind large defects. Allografts provide an excellent alternative to autografts without donor site morbidity and are especially useful in large defects or in children where the quantity of available autograft is limited. Bone allografts were used in 41 patients. They were used morsellised and used in 32 cases. Of these, 25 cases were available for follow-up. These included 21 patients in whom the allograft was used in contained cavities. Complete incorporation of the graft was seen between 6 and 9 months in all these 21 patients. In 4 patients the allograft was layered onto autograft. In only one of these the allograft incorporated with the host bone.

In our study we have used Ennekings scoring system for the functional evaluation and the clinical outcome of surgery. The mean Ennekings score at an average follow up of 13.5 months was 26.5points (88.5%). In our study among benign bone tumor fibrous dysplasia was the commonest with 4 cases and proximal femur was the commonest site as compared to international studies. Excellent results were seen with grade I lesion as compared to grade II lesions.Excellent results were seen with 3 cases and good results seen with 2 cases.

Lin-HsiuWeng et al (2004)[44] treated 18 patients of femoral nonunions with internal fixation, cortical strut allograft and cancellous autograft. All 18 nonunions healed on an average period of 8months. No significant complications were encountered except for screw irritation and graft protrusion.

In our case study we included neglected acetabular fracture,tibial non union ,femoral non union.In three cases of neglected acetabular fracture treated with THA, autograft and allograft functional outcome evaluated by Enneking scoring which showed average excellent results of 26.7.We also evaluated Harris hip score with mean preoperative score of 13.3 in three cases ,which improved to a mean posty operative score of 87 with mean improvement score of 73.6.

In one case of type B1 non union tibia treated with autograft allograft and stabilized with Ilizarov we evaluated functional outcome by Enneking score which showed 18 of 30 is good result.

In one case of type B3 femur non union treated with cortical allograft and LCP evaluated by Enneking score showed poor result 10 of 30 and it is termed as poor.

Mean preoperative Harris Hip Score observed was 17.5 points in the four cases, which improved to a mean post operative Harris Hip Score of 88.5 points. The mean improvement in the Harris hip score was 67.5 points. This result was after an average follow up of 18 months.

Avci et al (1998). Reported mean postoperative Harris hip score of 85 and -82.5 points at the end of follow up respectively [69]. Egglis et al reported an average clinical improvement of 40.1 points (as compared to 67.5 points in our study) in 7 patients according to Harris hip score [70].

Higher postoperative Enneking score was observed in patients in whom structural allograft was used as compared to cancellous graft. This might be explained by the fact that the structural allograft had achieved immediate stability in addition to implants and were used along with cancellous autograft for osteoinduction at the graft host junction. But radiologically the cancellous allograft showed an early incorporation in most of the cases and the strut allograft showed delayed incorporation except at the Graft-Host Junction due to autograft.

Radiologically, autograft showed a definite edge over the allograft in their early incorporation and remodelling.

Good graft incorporation seen in 8 cases (63.86%). Partial incorporation seen in 2 (17.78%) and these cases are yet to review with serial xrays.Resorption seen in 1(9%) case and Recurrence seen in 1 (9%)case. Higher rates of incorporation were seen with cancellous allograft and autograft when compared to cancellous allograft and cortical strut allograft.

In four cases of hip arthroplasty with allografting, trabecular bridging is seen in three cases and there is no cup loosening, no tilting of cup,no migration of cup ,no fracture of cement noticed in three cases done during early study period.The average distribution of acetabular and femoral scores is 25 and 55.5 respectively for three cases which comes under very good category. There is incomplete trabecular bridging in one case with minimal follow up.

In four cases of benign tumour,there is no resorption,no radiolucent line around the graft , no lysis,graft incorporation seen in all cases with zero gap distance between the host and the allograft.There is no loosening of the implant.Allograft and

autograft in one case showed incorporation in 1.5 months. Allograft alone for three cases showed incorporation on an average of 2.75 months. In one case of ABC,there is lytic lesion around the graft but graft found to be incorporated to the host in some sites.It is termed as recurrence.

In one case of humerus fracture fixed with radius cortical allograft, cortical bone got merged with host bone, no resorption, no loosening, no fracture noticed. This incorporation was seen in follow up period of 4.5 months.

In one case of tibial non union treated with Ilizarov and allograft and autograft, incomplete graft incorporation was seen with minimal follow up period of 3 months.

The case of femur non union treated with cortical allograft,showed resorption, no incorporation ,loosening of the graft,loosening of the implant noticed .

None of the patients developed systemic infection. This highlights the fact that a thorough donor screening, proper allograft processing and storage is as essential as operative planning and technique for successful outcome of the procedure.

Although the short term results were encouraging, it is required to study these cases for longer periods to reach a conclusion about the state of incorporation of structural bone allograft and need for resurgery at a longer follow up.

CONCLUSION

1. Bone allograft is a safe and reliable adjuvant in the management of bone defect in the setting of tumors and traumatic bone loss and revision hip surgeries.

2. Better results are observed with use of both morsellized bone and autograft, clinically as well as radiologically.

3. Allograft procured and processed in sterile condition and stringent donor screening are very important safe guards for prevention of disease transmission.

4. Autoclaving though weakens the graft, reduces the immunological as well as the risk of disease transmission without much impact on bony union.

5. Cancellous femoral heads are an excellent allografts in the management of bone tumor defects,traumatic bone defects in children. .

6. Cortical allograft and autograft add additional stability to the defect.

7. The clinical results are good and support the recommendations for continued use of the graft and development of the technique.

8. Union rate is more rapid with autograft & allograft combined rather than allograft alone.

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ANNEXTURE – 1

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 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	Continuous narcotics

Function: The value for function is determined by the restrictions in activation (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.

No.	Description
5	Not restricted
4	Intermediate
3	Recreational restriction
2	Intermediate
1	Partial occupational restriction
0	Total occupational restriction

Emotional Acceptance: The value for emotional acceptance is determined by the patients emotional reaction to or perception of the function 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 support and the frequency of use (i.e., none, occasional, mostly, always, etc.) it the patients 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 is desired.

No	Description	Data
5	None	No supports
4	Intermediate	Occasional use
3	Brace	Mostly brace

2	Intermidiate	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 alternations on

restrictions or function. The required data are the type of gait abnormality and resultant restriction 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 alternation 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 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 °
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	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

Harris Hip Score

Hip ID:

Study Hip: ☐ Left ☐ Right

Examination Date (MM/DD/YY): / /

Subject Initials: | | | |

Medical Record Number:

Harris Hip Score

Pain *(check one)*

- ☐ None or ignores it (44)
- ☐ Slight, occasional, no compromise in activities (40)
- ☐ Mild pain, no effect on average activities, rarely moderate pain with unusual activity; may take aspirin (30)
- ☐ Moderate Pain, tolerable but makes concession to pain. Some limitation of ordinary activity or work. May require Occasional pain medication stronger than

Limp

- ☐ None (11)
- ☐ Slight (8)
- ☐ Moderate (5)
- ☐ Severe (0)

Support

- ☐ None (11)
- ☐ Cane for long walks (7)
- ☐ Cane most of time (5)
- ☐ One crutch (3)
- ☐ Two canes (2)
- ☐ Two crutches or not able to walk (0)

Distance Walked

- ☐ Unlimited (11)
- ☐ Six blocks (8)
- ☐ Two or three blocks (5)
- ☐ Indoors only (2)
- ☐ Bed and chair only (0)

Sitting

- ☐ Comfortably in ordinary chair for one hour (5)
- ☐ On a high chair for 30 minutes (3)

Enter public transportation

- ☐ Yes (1)
- ☐ No (0)

Stairs

- ☐ Normally without using a railing (4)
- ☐ Normally using a railing (2)
- ☐ In any manner (1)
- ☐ Unable to do stairs (0)

Put on Shoes and Socks

- ☐ With ease (4)
- ☐ With difficulty (2)
- ☐ Unable (0)

Absence of Deformity (All yes = 4; Less than 4)

Less than 30° fixed flexion contracture ☐

Yes ☐ No Less than 10° fixed abduction ☐

Range of Motion (**indicates normal)*

Flexion (*140°) _____

Abduction (*40°) _____

Adduction (*40°) _____ External Rot

Range of Motion Scale

211° - 300° (5)	61° - 100 (2)
161° - 210° (4)	31° - 60° (1)
101° - 160° (3)	0° - 30° (0)

Range of Motion Score _____

Total Harris Hip Score _____

Enneking staging for Benign and Malignant musculoskeletal tumors.

Stage	**Description**
Latent	Well-demarcated biorders
Active	Indistinct borders
Aggressive	Indistinct borders

Stage	**Grade**	**Site**	**Metastasis**
IA	Low(G1)	Intracompartmental (T1)	No metastasis(M0)
IB	Low(G1)	Extracompartmental(T2)	No metastasis(M0)
IIA	High(G2)	Intracompartmental(T1)	No metastasis(M0)
IIB	High(G2)	Extracompartmental(T2)	No metastasis(M0)
III	Any(G)	Any(T)	Regional or distant metastasis

PROFORMA

Name: **Age/ Sex** **IpNo.**

Hospital: **Unit:** **ward:**

Address :

Phone No: **Date of Admission:**

Date of Surgery:

Diagnosis:

Procedure:

Clinical Features:

O/E

Investigations:

X-ray

CT Scan/ MRI

Treatment

Type of Allograft Used

Method of Sterilization

Thawing

Antibiotic protocol

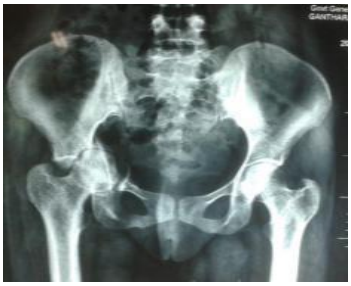
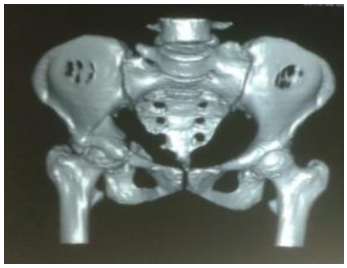
Follow Up

S.No.	Name	Age/Sex	Ip No	Diagnosis	Duration of illness	Site Of Lesion	Type of lesion	CT/MRI	FNAC/ Biopsy	Prior Surgery	D.O.S.	Fem. Head	Graft used		Implants	Complications	Failure	Follow up(months)
													Cortical Allograft	Autograft				
1	Savithri	44/F	90063	Non union	2 yrs	Acetabulum	--	N	N	N	15.3.14	Y	N	Y	Y	-	-	17
2	Balan	48/M	11516	Non union	2 yrs	Acetabulum	--	N	N	N	10.3.14	Y	N	Y	Y	-	-	21
3	Jeyakumari	36/F	78440	FD	6 Months	PF	E.grade I	Y	Y	N	10.4.13	Y	N	N	Y	-	-	30
4	Kantharuvi	56/F	11422	Non union	2 yrs	Acetabulum	--	N	N	N	2.4.14	Y	N	Y	Y	-	-	16
5	Preetha	16/F	77179	FD	6months	PT	E. grade I	Y	N	N	14.11.12	Y	N	N	N	-	-	36
6	Yuvaraj	18/M	**68261**	FD	5Months	PF	E. grade I	N	Y	N	18.12.13	Y	N	Y	Y	-	-	23
7	Ramu	44/M	61285	GCT	4 mnths	DF	E. grade I	N	Y	N	8.6.15	Y	N	N	N	-	-	3
8	Hari	16/M	25417	ABC	3 months	PT	E. grade I	Y	Y	N	27.5.15	Y	N	N	N	Rec	-	4
9	Kamatchi	75/F	23340	Fragility #	2 weeks	SOH	-	N	N	N	20.3.15	N	Y	N	Y	-	-	6
10	Kesavan	30/M	33672	Gap Non Union	4 months	DF	P. type B3	N	-	Y,1	14.4.15	N	Y	N	Y	Inf	-	5
11	Ayyanar	16//M	**61788**	GCT	7months	Calcaneum	E.grade II	Y	Y	N	8.9.12	Y	N	Y	N	1	-	34
12	Mekha	14/F	69267	ABC	6months	Metatarsal	E grade 1	Y	Y	N	25.4.15	Y	N	N	N	-	-	5
13	Marriyappan	61/M	68948	failed THR	8months	Right HIP	I	Y	-	Y,1	21.6.15	Y	N	N	Y	-	-	3
14	Subramani	40/M	74655	Non Union	7months	Tibia	P. type B1	N	-	Y,1	14.6.15	Y	Y	Y	Y	-	-	3
15	Aravindan	21/M	90361	FD	6 mnths	DF	E. grade I	Y	Y	N	9.7.15	Y	N	Y	Y	-	-	3

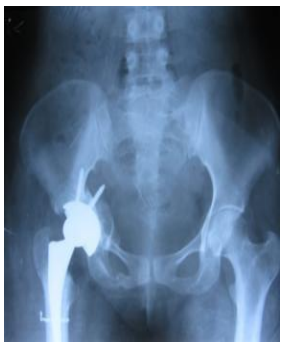
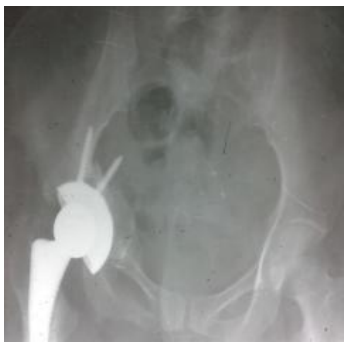
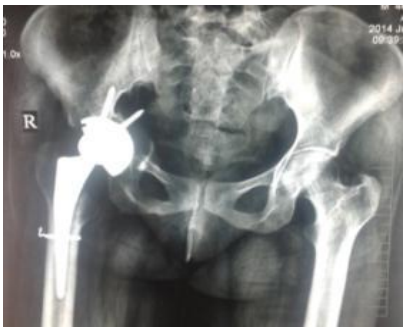
Savithri / 50 yrs/f 90063 .RTA

Acetabulum# with Protrusio right

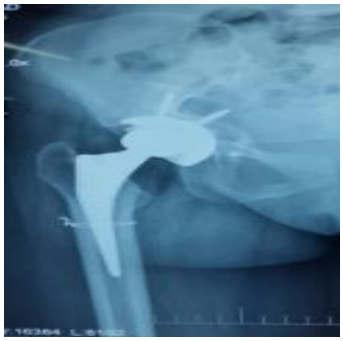
THR with ALLOGRAFT.

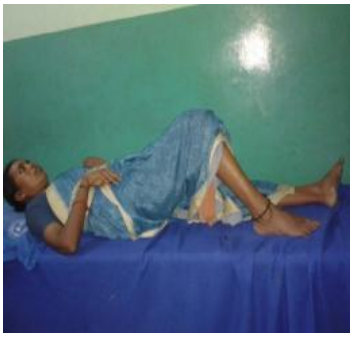



Immediate 3 months 6 months

17 months



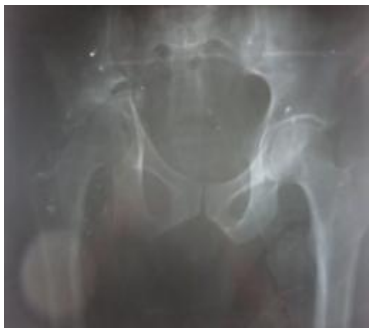


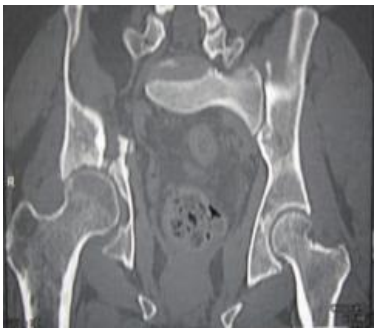
CASE 2

Balan / 50 yrs/m. 11516 /RTA

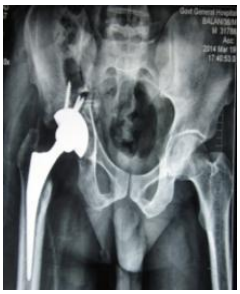
Acetabulum# with Protrusio right

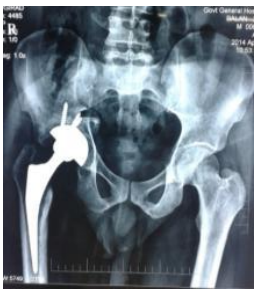
THR with ALLOGRAFT.

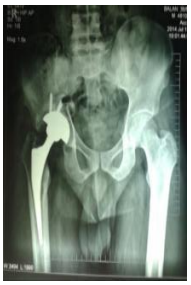




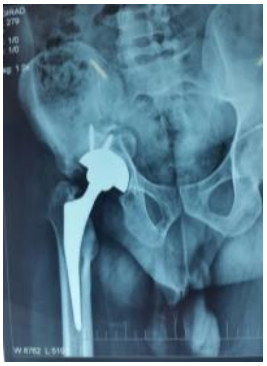
immediate 3 months 6 months





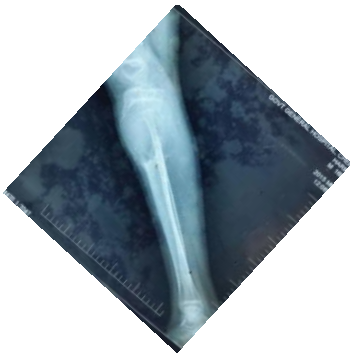


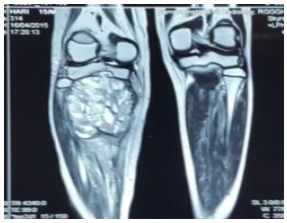
22 months



Hari/ 13 yrs/m 25417 .Aneurysmal bone cyst

curretaging &allografting





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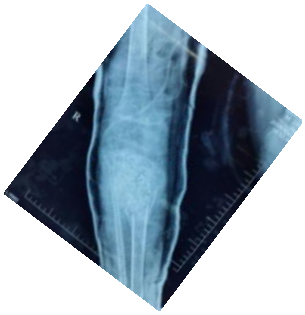
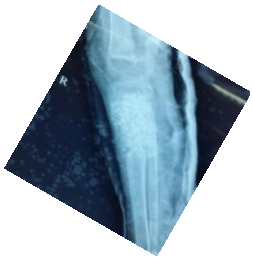
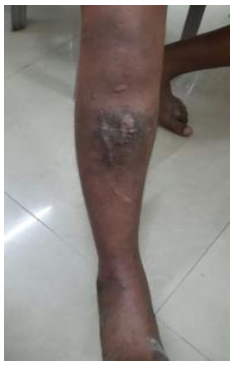
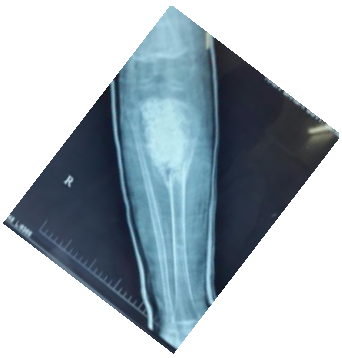
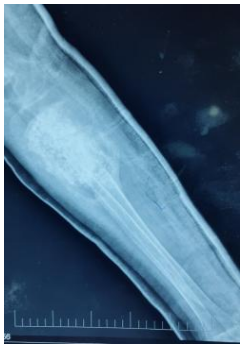


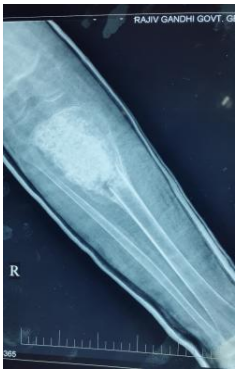




3months 4months



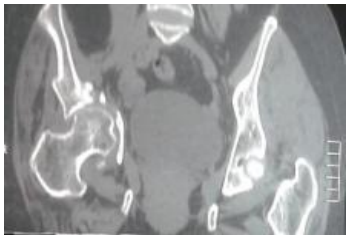




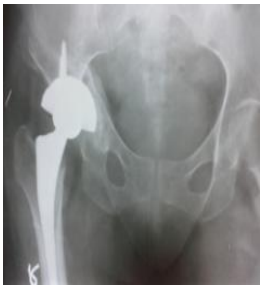
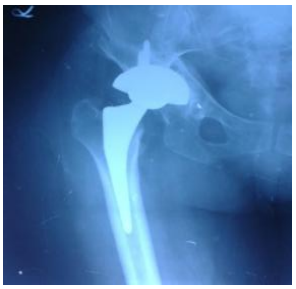
Kantharuvi 50/f yrs. 11422 RTA

ACETABULAR FRACTURE right

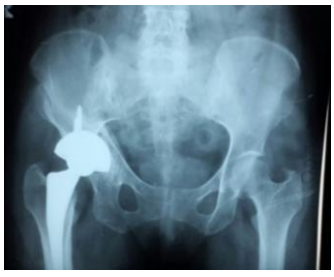
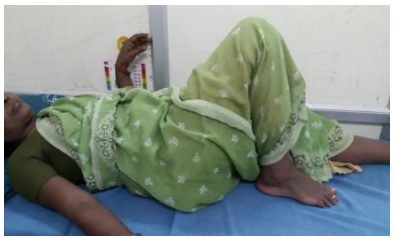
THR & allografting

Immediate MONTHS 6 MONTHS

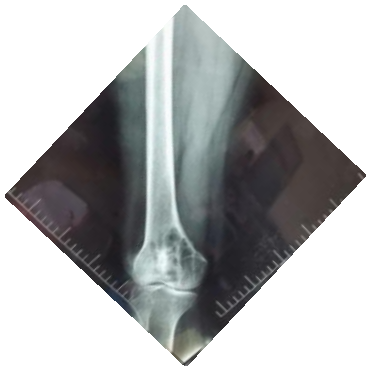
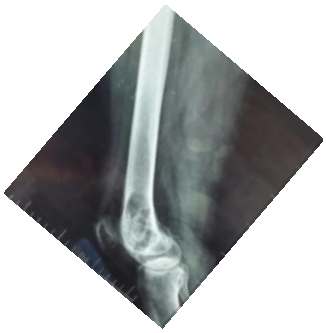
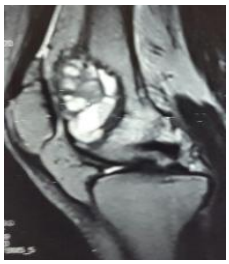
17 months

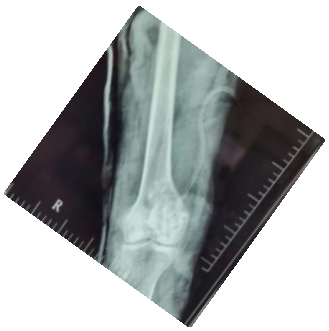
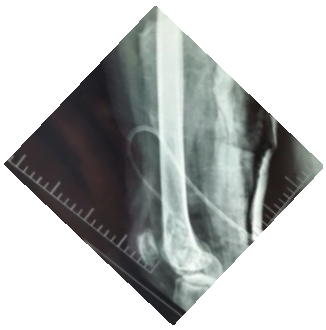
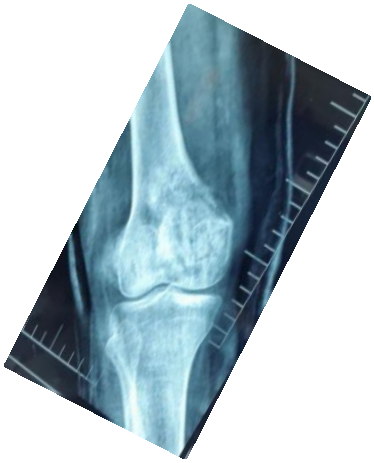
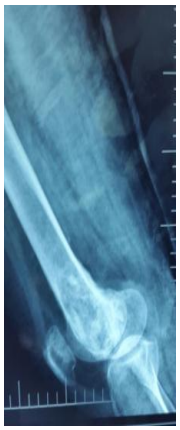
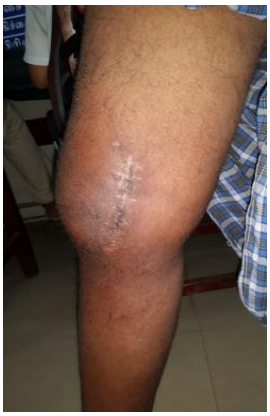

Ramu/ 43 yrs/m 61285 .

Gaint cell tumour right distal femur

curretaging &allografting.

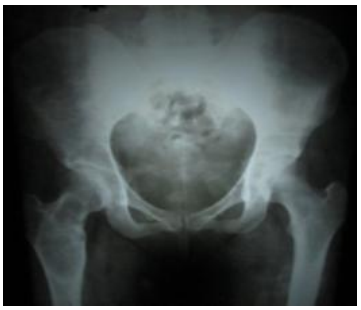
Immediate

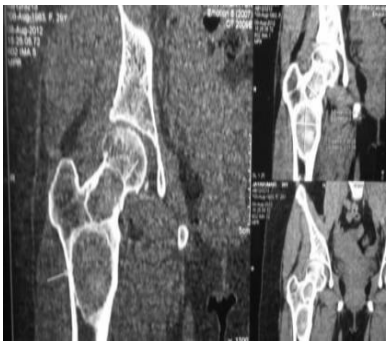
Jeyakumari / 34 yrs/f 78440

FIBROUS DYSPLASIA right

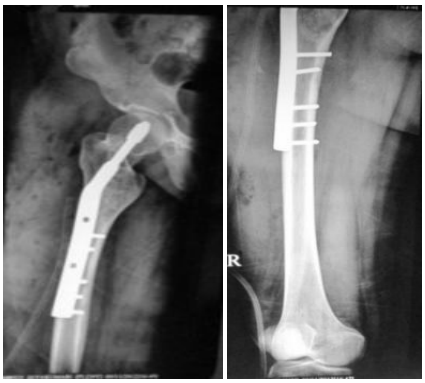
DHS and allografting.



Immediate



3 months



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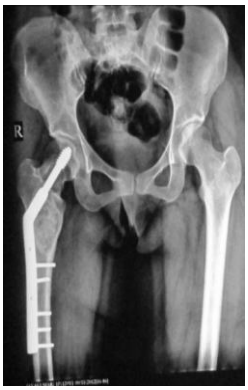
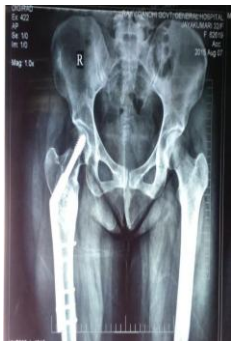
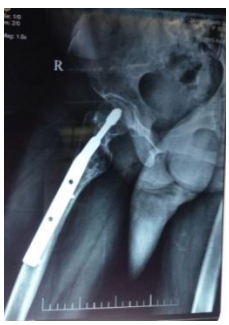


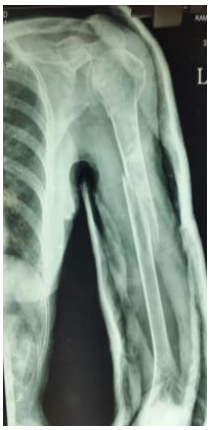
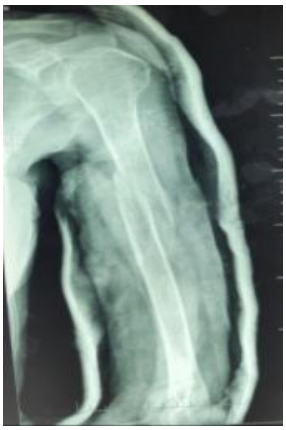




Kamatchi / 60 yrs/f 23340 .

Osteoporotic (fragility) #

NDCP and cortical allografting.

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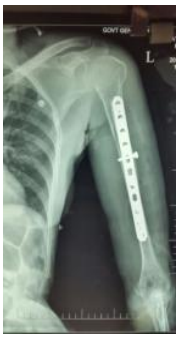
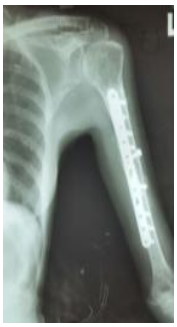
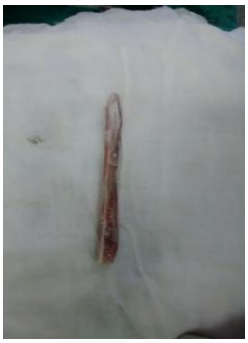
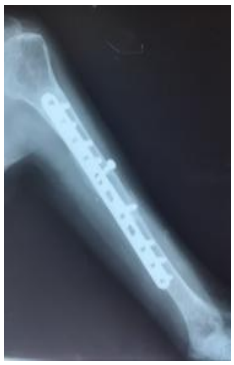
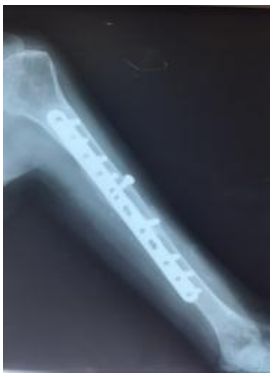




6months

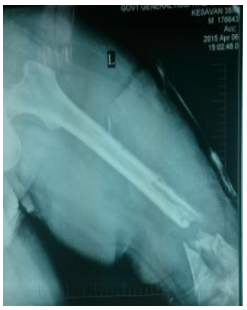



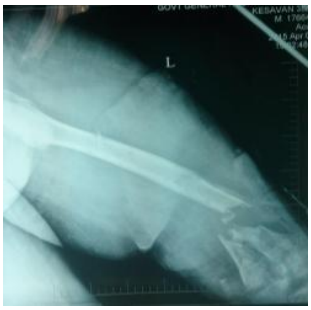
Kesavan / 46 yrs/m 33672

TRAUMATIC BONE LOSS

LCP WITH CORTICAL

BONE ALLOGRAFT





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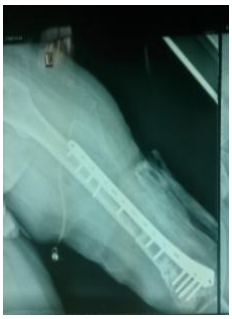
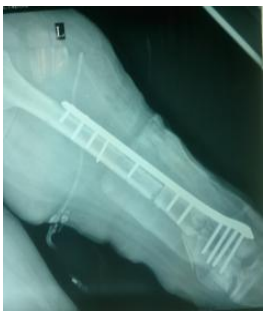
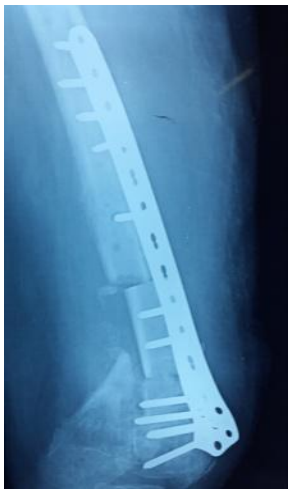
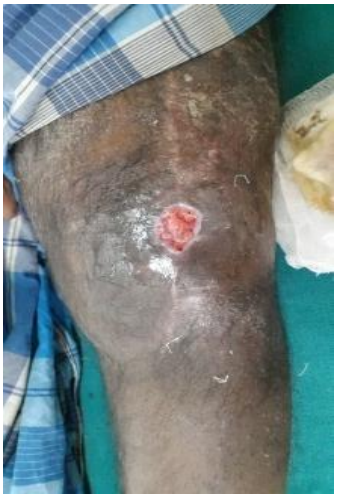




5 months





INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003

EC Reg.No.ECR/270/Inst./TN/2013
Telephone No.044 25305301
Fax: 011 25363970

CERTIFICATE OF APPROVAL

To
Dr. Somasundar.K.
PG in M.S. (Orthopaedics)
Madras Medical College
Chennai 600 003

Dear Dr. Somasundar.K.,

The Institutional Ethics Committee has considered your request and approved your study titled **"BONE DEFECTS MANAGED BY AUTOGRAFT AND ALLOGRAFT - RETROSPECTIVE AND PROSPECTIVE ANALYSIS " No.33052015.**

The following members of Ethics Committee were present in the meeting held on 12.05.2015 conducted at Madras Medical College, Chennai 3.

1. Prof.C.Rajendran, MD	:Chairperson
2. Prof.R.Vimala,MD.,Dean,MMC,Ch-3	: Deputy
Chairperson	
3. Prof.B. Kalaiselvi,MD.,Vice Principal,MMC,Ch-3	: Member
Secretary	
4. Prof.B. Vasanthi,MD.,Inst.of Pharmacology,MMC	: Member
5. Prof.P.Ragumani, MS., Professor, Inst.of Surgery,MMC	: Member
6. Prof..Saraswathy,MD.,Director, Inst. of Pathology, MMC	: Member
7. Prof. Srinivasagalu,MD.,Director,	
Inst.of Internal Medicine,MMC	: Member
8. Thiru S.Rameshkumar, B.Com., MBA.	: Lay Person
9. Thiru S.Govindasamy, BA., BL.,	: Lawyer
10.Tmt.Arnold Saulina, MA., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary – Ethics Committee

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INTRODUCTION

Bone is the most commonly transplanted tissue in our body than any other tissue or organ except blood. Approximately 5,00,000 bone transplantations occur in USA every year. For every ten heart transplantations, of twenty five kidney transplantations, hundred bone transplantations occur world wide.

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

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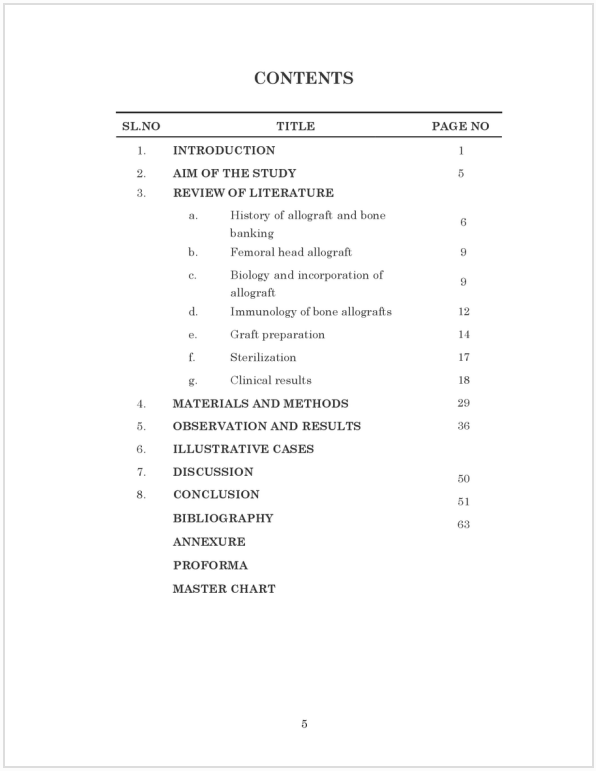

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