Role of cancellous femoral head allografts in orthopaedic surgery

Mayilvahanan Natarajan; KSP.Yoganandan; R.Selvaraj; Nalli R Uvaraj; B.Pasupathy

Abstract:
Structural allograft offer several potential advantages as compared with autograft. Unlike autograft, structural allograft prevents the morbidity associated with the harvest of autogenous graft and markedly reduces the time of surgery. 38 cases of cancellous femoral head allografting were perfomed in government general hospital, Chennai. All the femoral heads were collected from live donors who had fracture neck of femur treated with hemiarthroplasty. Heads were procured in sterile theatre during hemiarthroplasty, processed, rinsed, packed with double jar technique and stored at -80° in deep freezer. They were used after 3 to 4 months after ruling out HIV, HBsAg, HCV, malaria and culture negative for pyogens.

The age of the patient who received the allografts ranged from 6 to 46 of which 23males and 15 females. 23 cases were benign bone tumors, of the remaining cases there were 7 cases of nonunion femur, 2 cases nonunion tibia, fracture calcaneum 4 cases; spinal ring allograft in 2 cases, posterior spinal fusion 1 case and revision total hip replacement 2 cases.

Curettage and allograft impaction was done in all the cases of bone tumors. This was supplemented with fibular cortical allografting in 4 cases, cortical screws in 1 case, and plates and screws in 2 cases. All the femoral and tibial nonunions were stabilized with either nails or plates and screws and bone grafted. Calcaneal fractures were treated with bone grafting and cancellous screws. For revision hip whole femoral head was used.

Out of the 23 benign tumor cases good to excellent results were achieved in 14 cases, fair result in 7 cases and poor result in 3 cases. The average time for allograft incorporation was 6 months with a range from 5 months to 7 months. 3 cases got infected (which were our early cases) and were termed as poor result. Among the other cases excellent results were achieved in 7 cases, fair result in 6 cases and poor result in 2 cases.

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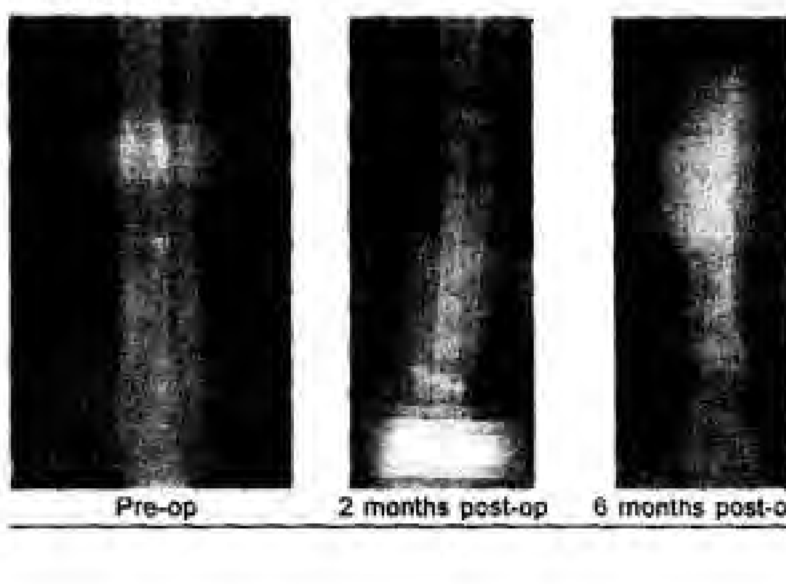
Introduc1tion

Bone grafting has been used to treat conditions including delayed union and nonunion of fractures. It is also used to treat osseous defects from trauma, infection, and tumors and to augment arthrodeses. Bone remains the second most common transplanted tissue or organ, blood being the first. Bone grafts may be cortical, cancellous, or corticocancellous. Cortical bone exhibits superior structural properties, whereas cancellous bone demonstrates superior osteogenic properties. If structural strength is required, cortical or corticocancellous bone grafts are used. Traditionally, corticocancellous bone graft has been autograft harvested from the iliac crest. Although this graft can successfully span large defects, the potential complications at the harvest site include pain, bleeding, infection, nerve injury, and fracture. In addition, when a large amount of structural bone graft is necessary, the amount of autograft available may not be sufficient. For these reasons, many surgeons have turned to alternative sources of graft material.

Structural allograft offer several potential advantages as compared with autograft. Unlike autograft, structural allograft prevents the morbidity associated with the harvest of autogenous graft and markedly reduces the time of surgery. Unlike iliac crest autograft, allograft is available in unlimited supply and shape, for they are harvested from cadavers and have prolonged storage capacity. Allograft is generally available as particulate intercalary or osteochondral transplant material. The use of structural cadaveric allograft for surgical procedures is in practice for several decades now. Many studies suggest similar or even better results when substituting allograft for autograft. The use of allograft is well documented in the treatment of benign and malignant bone tumors, wrist arthrodesis, large defects in fractures, spinal arthordesis and in foot and ankle surgery.

Figure 1: Chondromyxoid fibroma of tibia trated using, femoral head and fibular allograft



Pre-op | 2 months post-op | 6 months post-op

Figure 2: Femoral head allograft used in revision THR

This paper reviews the rationale for using structural allografts and femoral head allografts in orthopaedic surgery.

Material and methods

The period of study was from 2003-2006. 38 cases of cancellous femoral head allografting were perfomed in government general hospital. The age of the patient ranged from 6 to 46 of which 23males and 15 females. Benign bone tumors were 23 cases of which the histopathological diagnosis was fibrous dysplasia in 8 cases, giant cell tumor in 9 cases, aneurismal bone cyst in 2 cases, chondroblastoma in 2 cases, chondromyxoid fibroma in 1 case and simple bone cyst in 1 case. Among the 15 trauma cases there were nonunion femur 7 cases, nonunion tibia 2 cases, fracture calcaneum 4 cases, spinal ring allograft in 2 cases, posterior spinal fusion 1 case and revision total hip replacement in 2 cases.

For tumors preoperative staging studies included are conventional radiology, CT scan, MRI scan, biopsy by percutaneous or open methods. X-ray and CT chest were taken to rule out lung metastasis in selected cases. Only stage 1 and stage 2 Ennekings cases were included in our study.

Curettage and allograft impaction was done in all the cases. This was supplemented with fibular cortical allografting in 4 cases, cortical screws in 1 case, and plates and screws in 2 cases. All the femoral and tibial nonunions were stabilized with either nails or plates and screws and bone grafted. Calcaneal fractures were treated with bone grafting and cancellous screws. For revision hip whole femoral head was used.

All the femoral heads were collected from live donors who had fracture neck of femur treated with hemiarthroplasty. Heads were procured in sterile theatre during hemiarthroplasty, processed, rinsed, packed with double jar technique and stored at -80° in deep freezer. They were used after 3 to 4 months after ruling out HIV, HBsAg, HCV, malaria and culture negative for pyogens.

The processing includes the removal of the soft tissues and the cartilage from the head cut into pieces or blocks, rinsed in sterile saline and then packed in a sterile jar one inside the other and kept inside the deep freezer at -80°c. allografts were flash autoclaved at 121°c for 10 to 15min on the day of surgery before use.

Figure 2: Femoral head allograft used in fibrous dysplasia of femur

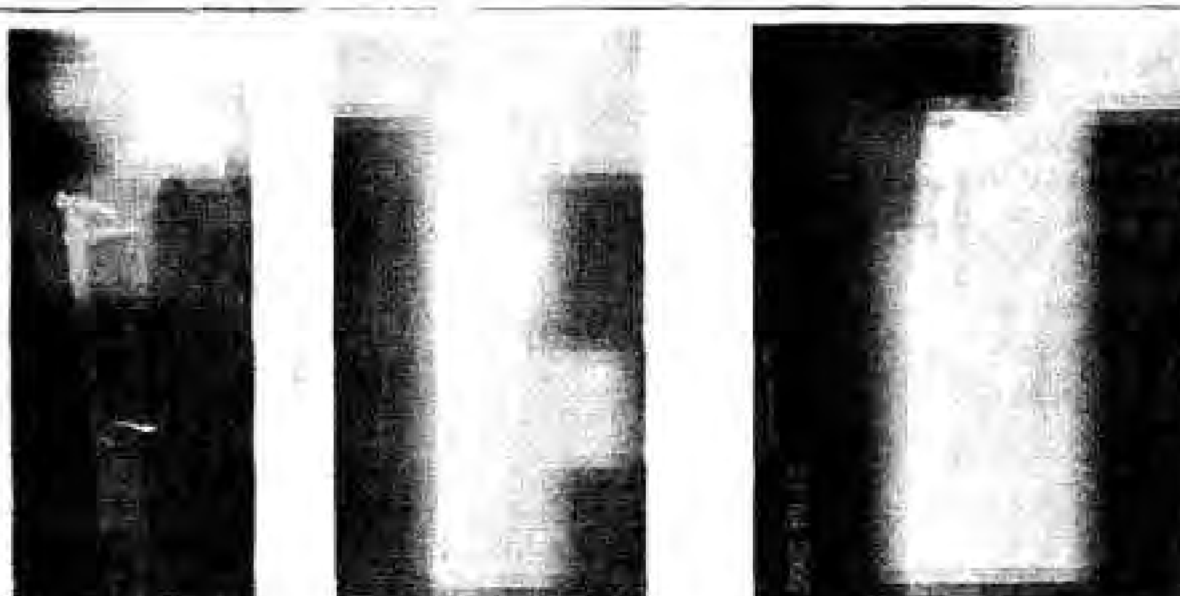
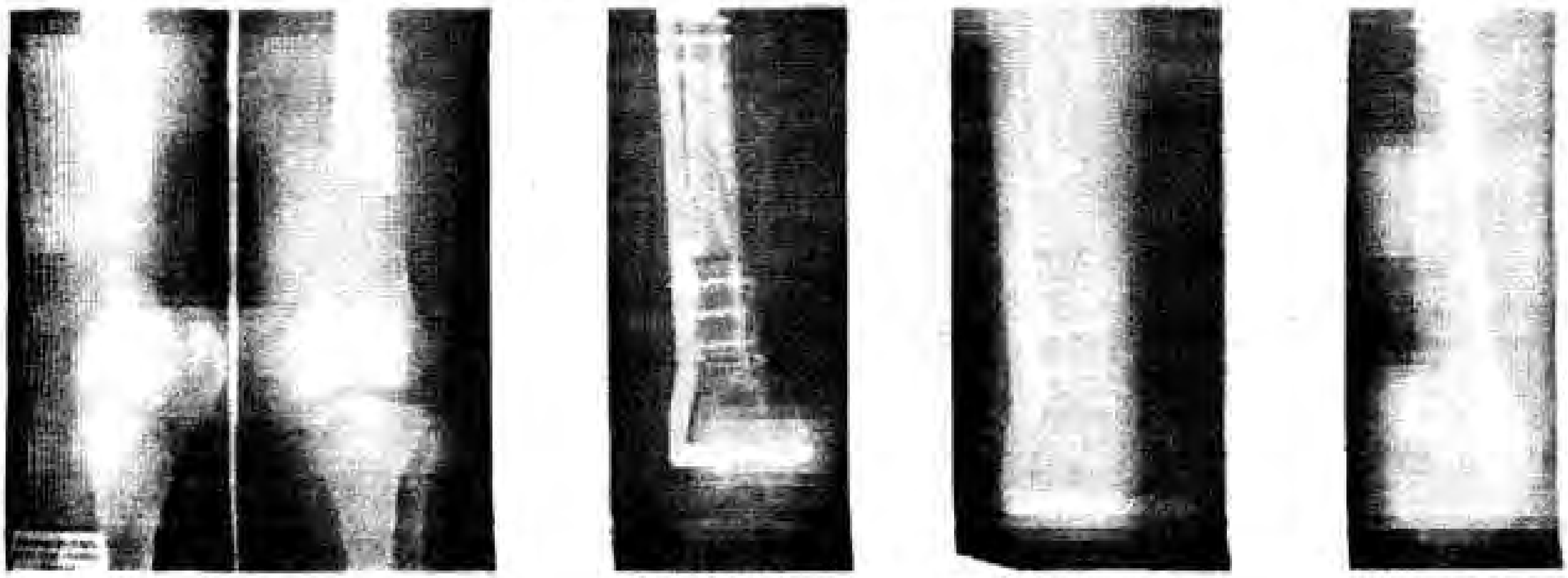


Figure 4: Femoral head allograft with tibial strut graft used in gap nonunion femur



Pre-op | Immediate post-op | 6 months post-op | 10 months post-op

Bone and tissue banking

The availability, safety, and efficacy of structural allogenic bone depend largely on the methods used for banking these tissues. The goals of bone banking are to preserve the physical integrity of the allograft and its inductive proteins, reduce immunogenicity, and ensure sterility. Guidelines for the procurement, processing, and clinical use of bone have been established by the American Association of Tissue Banks (AATB, McLean, C effectively decreases immunogenicity and maintains°VA). Freezing at –70 sterility, but decreases both the tensile and the compressive strength of the allograft by approximately 10%.[3] Ethylene oxide sterilization is also effective, but may destroy the inductive proteins of the bone. With this method, the ethylene oxide is removed and the bone is preserved by freeze-drying. Freeze-drying decreases torsional strength by about 50% and compressive strength by 10%.34 In general, bone subjected to freeze-drying, deproteinization, or freezing incorporates more slowly than fresh autograft.[11, 23] Decalcified allograft undergoes repair and incorporation at a faster rate than allograft that is frozen without decalcification, although decalcified allograft is mechanically weaker. Autoclaving is an effective method of sterilizing the femoral head allografts though it destroys the osteogenic potential of the graft.

Biology of allograft incorporation

A successful bone graft will eventually become incorporated into the host's native bone. When rigid fixation is used, massive frozen allografts are incorporated well and are clinically successful. The host replaces the donor bone tissue by depositing new bone, and the speed of incorporation depends on the size, structure, position, fixation, and genetic composition of the graft. It is well known that allograft provides the form and matrix of bone tissue, but no viable cells. Allograft is more slowly incorporated into the host than autograft. Fresh allograft induces an immune response that may delay the osteoinductive phase of bone graft incorporation by eliciting antibody production and cell-mediated immunity. Ultimately, the donor tissue is destroyed. When allograft preparation has not destroyed the bone morphogenic proteins within the grafts, osteoinduction as well as osteoconduction is possible. An osteoinductive graft may incorporate more rapidly than one that is merely osteoconductive. Incorporation of any bone transplant requires callus formation at the bone graft-host junction and internal repair of the allograft. Furthermore, if successful host-graft union occurs by 1 year, the differences between an allograft and an autograft gradually diminish. Long-term studies show no statistically significant difference in the morphology of repair between autograft and allograft.

In addition to creeping substitution, which involves the invasion of the allograft by osteoclasts followed by a blood vessel bud and new osteoblasts, structural allograft may be incorporated by a process of serial stress fractures resulting in graft remodeling. If the graft is subjected to excessive strain, microcracks may develop, followed by local remodeling. This process may occur in other parts of the graft and can become apparent by complaints of pain, often after very minor trauma. Even though radiographs may be normal in such cases, the patient should be on crutches or other support until the pain is gone to prevent a catastrophic failure of the graft.

Risks associated with femoral head allografts

In addition to understanding the methods of processing and storing bone allograft, it is important to screen for and protect against bacterial, fungal, or viral pathogens. Measures taken should include a detailed patient history and screening tests for hepatitis, HIV, and syphilis. One concern with the use of structural allograft is the possible transmission of disease or malignancy. This risk is small. In an analysis of 1,146 femoral head allografts, there was one case of a low-grade chondrosarcoma and two lymphocytic lymphomas. A review of 303 allografts provided by the United States Navy Tissue Bank revealed one case in which a contaminated allograft was potentially responsible for clinical infection. There are a few sporadic case reports of viral transmission through allografts, and the risks may be related to the type of allograft used. For example, the risk of viral transmission through processed, freeze-dried allograft chips is practically zero, whereas the risk of transmission through transplantation of a frozen, unprocessed femoral head is similar to the risk of transmission of a disease through transfusion of a unit of blood. Procedures designed to ensure the supply of safe allogenic bone of good quality for clinical use are well established and include donor selection, tissue procurement, preservation, and storage. Screening is undertaken to exclude donors with potentially serious transmissible diseases, malignancy, and systemic disorders.

Infections from structural allograft result from a combination of host factors and possible contamination of the graft. Host factors include systemic disease, debilitation, and multiple surgeries. Most of this information comes from studies using structural allograft in total hip arthroplasty, total knee arthroplasty, spine fusion, or malignancy reconstruction. Most infections occur within the first postoperative month and are related to wound problems. Pin tract infection, skin slough, or skin necrosis are the most frequent risk factors in many series. These reports show an infection rate of 10% to 15% with the use of massive allografts. There was a 0% infection rate in a study of 113 patients requiring smaller allografts in the form of cancellous or corticocancellous chips

Follow-up assessment

All the patients were followed up every month for the first three months, then after every three months for 1 year ,then every 6months for the 2nd year and then yearly. All the patients were evaluated based on Enneking scoring system in addition to bony union based on the radiological features.

Results

Our analysis was based on the radiological criteria for bone union for all the cases. In addition tumor cases were analyzed based on the Ennekings scoring system also.

Table 1 shows the grade of the lesion treated

Grade of the lesion	No. of cases
Grade 1	13
Grade 2	8
Grade 3	2

Based on the Ennekings and musculoskeletal tumor society grading.

Table 2 shows the surgical technique adopted in our cases

Surgical technique	No. of cases
Intralesional treatment	18
Marginal resection	2

Table 3 shows the no. of cases in which femoral head was used *with or without fibular strut*

Grafts used	No.
Femoral heads alone	13
Fibular onlay strut	1
Tibial strut	2
Femoral ring allograft	2

In addition to the femoral head and fibular strut grafts implants were used in few cases such as screws, DHS, plates and K wires. Out of the 23 benign tumor cases we have good to excellent results in 14 cases, fair result in 7 cases and poor result in 3 cases. The average time for allograft incorporation was 6 months with a range from 5 months to 7 months. 3 cases got infected (which were our early cases) and were termed as poor result.

Among the trauma cases there were 7 femoral nonunions, 2 nonunion tibia, 3 cases of fracture calcaneum. The allografts were used in 2 cases of posterior spinal fusion, 2 case and revision total hip replacement. The good to excellent results were achieved in 7 cases, fair result in 6 cases and poor result in 2 cases.

Table 4

Cases	**No.**
Femoral nonunion	7
Tibial nonunion	2
Fracture calcaneum	3
Revision THR	2
Spine	2

Two cases had immediate post op infection of which the wound debrieded and graft was removed in one case and wound debriedment alone for one case.

Table 5

Grafts used	No.
Femoral heads alone	13
Fibular onlay strut	1
Tibial strut	2
Femoral ring allograft	2

Trauma cases were assessed based on the radiological signs of union. *average time of* bony union in trauna cases were 6.5 *months* with an average *of 5 to 8 months. Calcaneal fracture showed painless* union but had collapse of the calcaneal height in one case which was termed as fair result.

Table 6
Final results

Cases/results	Good to excellent	Fair	Poor	Total
Trauma cases	7	5	2	15
Tumor cases	14	7	3	23
Total	21	12	5	38

Complications

Out of 38 cases there were deep infection in 5 cases, all of which were treated appropriately with wound debridment with or without removal of the graft and one case did not turn up. Two cases developed recurrence-one GCT distal femur after 21months and the other case fibrous dysplasia tibia after 22 months. There was one stress fracture of the femur at the inlay strut- host junction, treated conservatively.

Discussion

Cancellous femoral head allografting is an excellent alternative to cancellous autografts in that it reduces the operative time, availability in various shapes and sizes and quantity. Though the superiority of fresh cancellous autograft over allograft is well established, there are often limitations to its use in the form of limited quantity, shape, size and patient morbidity. Cancellous allograft provides a good alternative especially in cases with polytrauma, where minimal surgery is desirable.

The selection of patients suitable for donation to a bone bank relies on careful evaluation of the history and examination in order to avoid the transfer of infection, malignancy, systemic disorders, toxins, or potentially transmissible diseases of viral or unknown etiology. In our institution bone is collected under aseptic conditions and a microbiological culture from the femoral head is taken before storage. The head is then stored at -80°C. The stored bone is flash autoclaved at 121°c for 10 to 15 min before use as allograft. Allografts with bacterial contamination and positive for donor screening were discarded. Thus, prevention of transfer of disease from donor to recipient was prevented.

Autoclaving though weakens the graft reduces immunogenicity as well as reduces further the risk of disease transmission without much compramise on bony union.

The demand for bone allograft is likely to increase in the future, it is important that appropriate safeguards are taken to ensure that the safety of both donor and recipient is not compromised It is important to screen donors critically and to ensure that histopathological examination is included as part of the protocol for the collection of bone allograft.

Conclusion

*Cancellous femoral head allografting is an excellent method in the management of bone tumor defects.

*Cancellous femoral head grafts are a viable option in traumatic bone defects and in children.

*Femoral heads procured and processed in sterile conditions and flash autoclaving helps in reducing the chance of infection.

*Fibular cortica. allografts give additional stability

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