

## Bone Banking at Patna Medical College & Hospital

Dr. Qamrul Hoda, Dr. Adnan Qamar, Dr Ashwini Gaurav

Assistant Professor, Dept. of Ortho. PMCH, Patna

Dept. of Ortho. DMCH, Darbhanga

Senior Resident, Dept. of Ortho. PMCH, Patna

Corresponding Author: Dr. Adnan Qamar

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**Abstract** -Bone grafting is most common procedure in orthopaedic, it has been estimated that over 2050-3010 thousand people worldwide receive bone transplant every year, more than 25 times the number of people undergoing kidney transplant. But still Bone bank is not quite popular specially among the Indian people. Main indications for bone graft include 1) malignancies, 2) spinal surgery and bone loss following trauma. Sushruta, about 2500 years ago started bone transplant, but still not popular in India. The application and processing of human tissues for transplantation is covered by the Transplantation of Human Organs Act 1994 and must be registered with the State Health Authorities. Surprisingly, Bone Allograft has the same stringent law as kidney transplant. we are planning to harvest bones from our institute which are discarded after day to day operation and the allograft material is quarantined until then, the results of re-testing are available.

Preparation of graft - Gamma irradiation of allograft bone with 25 Gy from a cobalt-60 source is a recognised practice in bone banks all over the world. Recent reports have suggested that irradiating the allograft bone at low temperatures (-78°C) causes less alteration in the mechanical properties of the allograft by causing less collagen damage. "Ethylene oxide sterilisation can also be used but the risk of subsequent elution of the agent from the allograft segment has rendered this method unpopular. Once sterilised, the allograft segments are stored.

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### I. HURDLE (In Allografting)-

Organ donation is not yet popular in India and most people (including a large number of medical personnel) have no idea about bone banking. This is further complicated by the fact that the dead body in the majority of cases is cremated and there is a ritual of collecting the ashes for dispersal in holy rivers. Also, an autopsy of the donor, considered vital to prevent transmission of disease, is for most people akin to mutilating the body. Thus, the most important step in solving these problems remains education of the masses. Public awareness, created with the help of various social and non-governmental organisations, would go a long way in encouraging people. (NATIONAL MEDICAL JOURNAL OF INDIA VOL. 12, NO. 4,1999-). Indian law for allograft- a) No hospital, unless registered under this Act, shall conduct, or associate with, or help in, the removal, storage or transplantation of any human organ. b) No medical practitioner or any other person shall conduct, or cause to be conducted, or aid in conducting by himself or through any other person, any activity relating to the removal, storage or transplantation of any human organ at a place other than a place registered under this Act. c) No place including a hospital registered under subsection (1) of section 15 shall be used or cause to be used by any person for the removal, storage or transplantation of any human organ except for therapeutic purposes

### II. Allograft-

It is widely used for reconstruction of bone defects that arise from Trauma, Infection, Resection of bone and in spinal fusion, and as impaction grafting in revision of total joint arthroplasty. Although autologous bone is generally preferred because of its osteo-conductive and osteo-inductive activity, but not sufficiently available & comes with donor site morbidity. Therefore, allogenic bone grafts are often used in orthopaedic procedures, that is provided by an orthopaedic bone bank.

### III. Material And Methods

It might be financially attractive for a hospital. The main advantage of managing a hospital bone bank is, the easy accessibility and availability of allograft. The bone allografts in a hospital bone bank are femoral heads obtained from suitable patients, who underwent total or partial hip replacement surgery. An orthopaedic bone bank has a complex process. The national law states the technical requirements of -Coding, Processing, Preserving, Storing, and distributing of human tissue. Human tissue should be traceable and serious side effects

and incidents with human tissue and cells should be reported. Because of the potential risk of transmission of diseases from donor to recipient we performed routine histological examination in the screening protocol. It has been found a relatively high percentage of pathological conditions in retrieved femoral heads. Therefore, we recommend the routine histopathological evaluation of all femoral heads removed during elective total hip arthroplasty. It is well known and extensively described in literature (Stevenson & Horowitz 1992). Fresh allografts which have not been frozen, cause a massive vascular reaction, (Holzmann et al. 2010). However, freezing of the femoral heads to  $-80^{\circ}\text{C}$  for only three days caused a significant reduction of early vascularisation. Keeping the allografts frozen for longer than one month to minimises the angiogenic potential.

**Bone Donor –(Cadaver)**-Identity of donor, Relationship of consenting person, Description of cells/tissue being harvested, Statement granting permission, Statement around blood tests, Description of use of products are needed

**Storage and Processing-** Retrieval of the femoral head is performed at the time of routine orthopaedic partial or total hip replacement under aseptic conditions. The removed femoral head is Inspected. And capsule and synovial tissue are cultured on aerobic and anaerobic bacteria. In order to exclude malignancies, auto-immune processes, or infections, a biopsy of 1 cm<sup>3</sup> corticospongiuous bone and capsule is collected for histopathological examination. After determining its size, the femoral head is wrapped in three layers of sterile packing material, labeled and stored in the freezer within 30 min. The freezer has a temperature of  $-80^{\circ}\text{C}$ , and has a continuous temperature registration device installed. Should the temperature fall outside the acceptable range of  $90$  and  $-70^{\circ}\text{C}$ , an alarm system gives off a warning signal to the Technical Service, guaranteeing a 24- hours security against temperature-induced damage. A nitrogen tank is fitted onto the freezer, as backup cooling mechanism in case of mechanical breakdown of the freezer. In deep frozen condition, the allogenic bone tissue can be preserved for a maximum of 5 years. The temperature data is stored and managed by the bone bank administrator for a period of at least 5 years. The femoral head is bathed in physiological saline; after being defrosted, then the theatre nurse takes a bacterial culture swab.

#### **Hospital Bone Bank Protocol**

A bone bank procedure should be described in a protocol concerning the five components:1. Organisation 2. Donor selection 3. Documentation 4. Storage and processing, 5. Implementation. The HOD of the Department of Orthopaedics and the bone bank administrator will make this protocol.

#### **IV. Review Of Literature**

The first human allograft ever reported describes a case of a bone transplant in a young male, who suffered an osteomyelitis of the entire humeral shaft (MacEwan 1881). In the following seven years these allografts slowly but successfully incorporated in the recipient humeral shaft (MacEwan 1909). In the following decades the technique of transplantation of large allografts in septic arthritis and osteomyelitis was further developed and popularised by a German surgeon. He used fresh long bones of amputated limbs and used them as osteoarticular allografts. The first case ever of the transmission of viral disease by frozen bone was reported by Shutkin in 1954. The donor had undergone an above the knee amputation. The allograft bone was cut into portions under aseptic conditions, placed in double sterile containers and frozen at a temperature of  $10$  to  $-20^{\circ}\text{C}$ . Five months later, the bone was implanted into a medical student and transmitted hepatitis B. In the early 1980's the first publications concerning a new disease AIDS were published (Centres for Disease Control [CDC] 1981, 1982). Only a few years later in 1984 the first transmission of disease by bone allograft was reported (CDC 1988). A serological test was not yet available at the time of transmission. Even with the first serological tests used for screening purposes another transmission occurred in 1985, due to a very recent donor infection in the so-called "window period" of testing, with a less accurate test. Therefore, in an expert conference guidelines and recommendations were developed (CDC 1988.) The most important conclusion drawn was that the disease was transmitted by blood and bone marrow containing allografts. Recommendations concerned donor screening, testing and re-testing of living donors after 6months However, donor screening methods are constantly updated and revised with the introduction of new infectious diseases, like SARS (Lam et al. 2004). The safety allograft bone transplants can never be taken for granted, but recent safety records for bone allografts are excellent. As more complex orthopaedic surgical procedures are performed nowadays the need for(safe) bone allografts has increased (Nielsen et al. 2001).

**Examination of Donor** -All criteria must be met. The orthopaedic surgeon examines the patient thoroughly. Blood samples are collected to determine-Blood type, Rhesus-factor, And Erythrocyte Sedimentation Rate (ESR). During surgery, Bacterial culture swab samples from the hip capsule are collected, and a biopsy of 1 cm<sup>3</sup>- corticospongiuous bone is sent for histopathological analysis.

**Documentation-** Accurate documentation and coding are of the utmost importance, A unique registration code is allocated to each femoral head. Only the bone bank administrator is able to trace the donor based on this code. Of every registered femoral head, a file, containing the consent forms and results of ESR, bacteriological and

histopathological examination, is kept updated. When the file is completed (which takes at least 6 months due to the serological examination), and no abnormalities are recorded, both bone bank administrator and the responsible orthopaedic surgeon sign the forms. The femoral head is now available for transplantation. In case a file cannot be completed in full, or any abnormal values are recorded, the femoral head will be destroyed according to hospitals' protocol

**Exclusion Criteria** -In the past 3 months, did you suffer any infection? If so, what infection? In the past 3 months, did you have any vaccination or inoculation, or have you been injected with narcotic drugs? In the past 6 months, did you have a malaria attack or did you use anti-malarial medication? Have you ever been infected with a sexually transmitted disease? Have you ever been diagnosed with jaundice or liver illness? In the past 6 months, have you been in contact with patients diagnosed with jaundice/hepatitis? In the past 6 months, have you been in contact with patients diagnosed with AIDS,

**Conclusion**-Steps for the bone banking programmed in India will be -The establishment of facilities, Availability of technical know-how, Education of the masses to dispel their myths and fears, and Training of personnel in various aspects of the complex and intricate process of bone banking.

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