

Preliminary Study : Preparation and Clinical Use of Irradiation Sterilized Bone Allografts - the PGH Experience

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ABSTRACT : Seven patients from the Department of Orthopaedic UP-PGH Medical Center underwent irradiation sterilized bone allografts. There were five males and two females with ages ranging from 8-52 years (22.86 years). Follow-up period ranged from 52-779 days for 6 patients with an average follow-up of 417.33 days. One patient was completely lost to follow-up.

Of these seven patients, three had no tissue reactions, two had seromas which eventually healed and two had frank infection. With regards to acceptance or "take", there was good incorporation of the bone grafts in three cases. Two cases were lost to follow-up thus, had insufficient time for proper evaluation of "take". The 2 infected cases were failures. Fever, usually occurring within a 1-3 day post-operative period, was not considered a good of tissue reaction since it could be attributed to other causes.

clinical use because of the immunological reactions that it evokes in the host. Treated foreign bone (frozen or freeze-dried) is for practical purposes dead, and only future research can establish whether or not it will be possible to provide a foreign bone that is as consistent in clinical use as autograft bone.²

Despite the clinical advantage of using autologous bone, there still remains an urgent need for preserved bone stored in tissue banks. Spinal fusion, particularly in children is a typical example where banked preserved bone is necessary because of insufficient autologous bone. Frozen, frozen and sterilized by irradiation, and freeze-dried allograft appear to have produced successful clinical results.²

The purpose of this paper is to explore the possibilities for the use of irradiation sterilized allograft bone in our clinical setting.

INTRODUCTION

The modern use of osteochondral allografts and its therapeutic implications have evolved over the past 30 years. Beginning with a handful of dedicated and resourceful individuals, there are now scores of investigators worldwide responding to the challenges posed by the biology, banking and clinical applications of bone and cartilage allotransplantation.¹ Clinical use of the bone grafts is to provide a bridge of osteogenic tissue, either in part of the skeleton that is deficient or to establish bony fusion of the diseased joint². Two types of bone are generally used for grafting; autologous bone which is generally taken from, and used for the patient at operation, and non-viable foreign human bone which we preserve by freeze-drying.² The disadvantages of autologous are limited availability and donor site morbidity.³ The use of freeze-dried allograft bone as grafting material obviously provides greater convenience both for the surgeon and the patient. Unfortunately however, the clinical results of using foreign bone have been in general less consistent than those obtained using the patient's own bone. Viable foreign bone is unsuitable for

MATERIALS AND METHODS

Seven patients at the Department of Orthopaedics Philippine General Hospital underwent bone grafting procedure using freeze dried allografts. Preparation of the graft included the following stage : Procurement, Processing, clinical use and assessment. Criteria for donor selection were patterned after experiences of other tissue banks. The potential donor was scrutinized as to past history, cause of death, and when available past laboratory studies e.g. blood cultures and serological tests for venereal diseases and hepatitis. History of massive infection, malignant and autoimmune diseases excluded the would be donor. Also, the cause of death must not be due to poisoning or drug overdose. Bones from the donor were harvested in the operating room in clean but not necessarily sterile conditions, after which, they were cut into slices and refrigerated.

Upon harvesting, allograft bone underwent 3 stages in processing : deproteinization and degreasing, freeze drying, irradiation sterilization for quality control deproteinization and degreasing were subdivided into 4 uniform steps : washing

the bone in warm water, continuous washing for 36 hours, immersion of bones in 1 per cent papain solution in 4-8°C overnight and water bath of 50°C for 3-4 hours and periodic removal of surface grease. Freeze drying followed and lasted for 72 hours. Tissues were initially frozen. The water content was then sublimated until residual moisture was less than 5 per cent by means of a freeze dryer.

Irradiation sterilization was the last stage in processing. Bone were packed in double plastic bags and sealed. There were then exposed to 2.5 M rads of cobalt 60. This step was done care of the Philippine Atomic Energy Agency. Control as to sterility was done by culture and sensitivity studies for bacteria and fungi. General guiding principles were the following :

1. The surgical approach in selected patients must entail minimal soft tissue dissection.
2. In pseudarthrosis, excision of fibrous tissue between bone ends was not necessary.
3. In cases where bioimplants were used, bone grafts should be in tight contact with fresh bleeding bone.
4. Bone grafts may be cut and shaped to fit area defects to be grafted.
5. Reconstitution of bone grafts in blood or saline was not necessary.

After clinical use, assessment of results followed. Patients were evaluated for the presence of any form of tissue reaction e.g. fever, wound discharge, or infection and for the presence of bone healing, bony fusion or bone graft incorporation as the case may be.

RESULTS

Seven patients from department of orthopaedics UP-PGH Medical Center underwent bone grafting procedures using irradiation sterilized bone allografts. There were 5 males and 2 females. Ages ranged from 8-52 years (22.86 years). Follow-up period ranged from 52-779 days for 6 patients with an average follow-up of 417.33 days. One patient was completely lost to follow-up.

Of the seven cases, two tumors, two involved the spine and the remaining three were open fractures. There were four infected cases, three being open fractures and the fourth, Pott's disease. The two tumor cases were that of an enchondroma and a probable bone cyst. The other case was that of scoliosis secondary to arthrogryposis multiplex congenita. Of these seven cases, five involved a closed surgical wound while the other were open fracture that underwent Papineau technique. These were the two tumor cases and a posterolateral bone grafting case for an open fracture. All had no tissue reaction. Two cases of spinal surgery developed seromas, one after posterolateral fusion for tuberculosis and another after Luque rod instrumentation.

There were two frank infection, both were open fractures, type III of the tibio-fibula with bone loss that underwent

Papineau technique using irradiation sterilized bone allografts. The infection was controlled by repeated debridement and removal of the infected bone graft.

DISCUSSION

In this preliminary study, out of seven cases, three had no tissue reaction, two had seroma which eventually healed, and finally two cases of frank infection. Five out of seven cases were quite successful three good and two fair results. This study showed good incorporation of the bone grafts in three cases. Two cases were lost to follow-up and the two infected cases were failures.

Agcaoili¹, et al, in a local preliminary study had fairly good results in terms of acceptance and take of the bone allografts. They had one case of infection in seven cases, the other six cases had no tissue reaction.

Vajaradul⁶, et al, reported only five complications in 122 cases using irradiation sterilized bone allografts. They had two cases of infection involving posterior spinal fusion in spondylolisthesis, two cases of bone graft breakage and one mortality post-operatively due to an unrelated condition. In this study, chip bone grafts were primarily used. In five febrile cases, fever ensued within 1-3 days post-operatively in four cases. Only once did fever occur on the 6th day after bone graft application and this was in an infected Papineau technique. Infected bone grafts were removed 2 weeks after application. There are many causes of fever within the 1-3 day post-operative period which precluded its use as indicator of tissue rejection.

There are several limitations to this study. In the procurement stage, there is a limited number of cadaver donors due to: (1) exclusion criteria, where causes of death disqualify the donor, (2) accident victims being autopsied by an agency of the National Bureau of Investigation, (3) sentiments of our people regarding the dead-religious beliefs or cultural factors - "desecration" of the dead, and (4) lack of a more definite legislation. Most of the donors are living donors-victims of traumatic amputations and patients who have undergone partial hip replacement wherein the femoral heads are used. Regarding the processing of bone allografts, we now have a UP-PGH Tissue Bank at the UP College of Medicine. Regarding clinical use of irradiation sterilized bone allografts, many surgeons still prefer using autogenous bone since it is still the ideal for grafting. In certain situations, however, allograft is more practical. In assessing results, the limitation was with patient follow-up. One patient went home to a distant province. Two patients followed-up for some time and no longer came back. They did not reply to telegrams sent them.

We therefore recommend continuing the study to further explore the possibilities for use of irradiation sterilized bone allografts, assess tissue reactions and the acceptance or "take" of these bone allografts.

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