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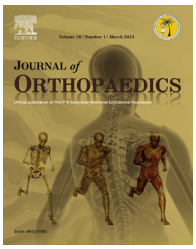

Original Article

Radiological and histopathological examination of apparent lytic lesions in allograft long bones—No cause for concern

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ABSTRACT

Objective: Identify the nature of apparent lytic lesions within human allograft specimens from patients with no known malignancy, using radiological and histopathological analysis
Methods: 123 Post-retrieval radiographs from 23 donors were examined. Sixty-seven radiographs were noted to show apparent lytic lesions. The number, size, character and position of the apparent lesions were recorded.
Results: CT scanning of 9 specimens confirmed the lesions to be of air pockets causing artefact. Histopathological analysis showed no malignant or pathological process.
Conclusions: Apparent lesions were not pathological.
Practice implications: Specimens with similar appearances, in donors with no malignancy, can be safely used in donation.

1. Introduction

Human bone allografts are crucial in orthopaedic reconstructive procedures including tumour surgery, (most commonly Ewing's sarcoma, osteosarcoma and giant cell tumour), failed arthroplasty and trauma.[1–3] It is difficult and expensive to identify and screen donors, and allograft is expensive to process, prepare and store. As such this is a rare and valuable resource. Retrieval of such specimens from donors involves assessment against strict inclusion/exclusion criteria, including screening for previous or active malignancy.[4–7]

There are several bone and tissue banks in Australia, each required to be licensed by the Therapeutic Goods Administration. PlusLife (Perth Bone and Tissue Bank) procure processes and stores donated bone and tissue, distributing an average of 537 allografts to Western Australia, and 236 allografts across the country each year over the last five years.[8]

PlusLife allograft bone is retrieved from two main sources: 'live' femoral head donation during total hip replacement,

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which is mainly used as milled graft and cadaveric long bone and tendon cadaveric retrieval following or associated with organ donation. These larger retrieved specimens are usually used as allograft in tumour reconstruction and arthroplasty procedures. A proportion of retrieved tissue is stored and used for basic science and clinical research purposes, provided research consent was obtained.[9]

Once a potential donor is identified, a number of strict medical and social inclusion/exclusion criteria need to be met in order for the tissues to be retrieved and to ensure the safety of the recipients. These include screening for blood-borne communicable diseases, previous malignant disease and certain medical conditions, to ensure the safety of recipients.

Following retrieval, tissues are stored for several months at −70 °C, awaiting review of medical and social history, serological, histological and microbiological testing; and where appropriate post mortem results. Graft may be stored for up to 5 years from the date of retrieval. Long bone allograft specimens are X-rayed to assess for previously unrecognised bony pathology (neoplastic/traumatic/metabolic), which may deem the specimen unsuitable for transplant. These radiographs and the screening results are assessed by a qualified reviewer. Once the clearance review of all donor information and testing results is performed tissues are thawed and processed.

Processing occurs in a clean room (equivalent to an operating theatre) using sterile equipment and consumables. Extraneous material is removed from the tissue, which is then portioned, and the produced allografts are then washed in warm sterile normal saline. Individual grafts are then measured, weighed, photographed, and sampled. At the completion of processing, allograft is packed, refrozen and stored in a quarantine freezer at −70 °C pending microbiological clearance. It is then irradiated at Australian Nuclear Science and Technology Organisation (ANSTO) at a minimum target dose of 25 kGy. The grafts are finally released for distribution and implantation following a final set of reviews of all donor history, retrieval and processing information.

It should be noted that the conditions under which the X-rays are performed are somewhat different from the clinical X-ray. The bones under analysis here have been surgically removed from the donor and stored frozen at −70 °C for a short period of time, prior to the x-ray being performed.

PlusLife noted an apparent lytic lesion on a post-retrieval radiograph (Fig. 1) within a retrieved specimen from a cadaveric donor with no known previous or active malignancy. This solitary lesion was contained within the proximal metaphyseal region of a retrieved femur. It was an eccentrically placed medullary lytic lesion, approximately one third of the diameter of the diaphysis and had similar appearances of a myelomatous deposit (Fig. 2). Similar findings were identified by the Donor Tissue Bank of Victoria (DTBV),[10] and for quality control purposes it was decided to reassess the archived radiographs of PlusLife donors, which led to this study.

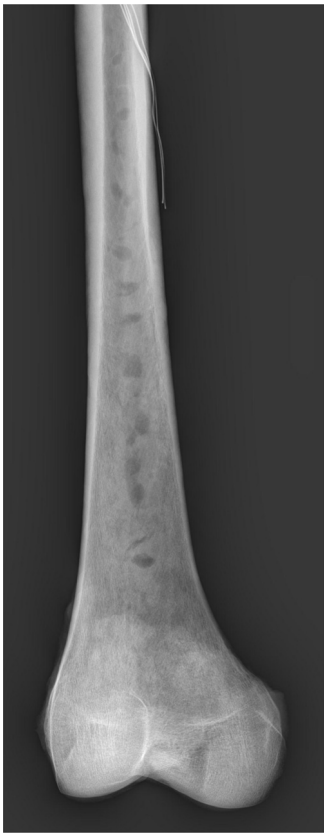

Fig. 1 – Plain radiograph of a femoral long bone allograft showing apparent lytic lesions within the diaphysis and metaphysis.

2. Materials and methods

Following Institutional Review Board and PlusLife Scientific Sub-Committee approval, a protocol was proposed where previous X-rays of donated material would be re-assessed for the presence of any similar possible lytic lesions, and where possible, CT examination and histological analysis would be performed to further characterise the observed lytic lesions, and identify a cause.

2.1. *Radiology*

The post-retrieval radiographs of 123 long bone specimens from 23 donors contained within the PlusLife archive were re-examined by a Biomedical Scientist, an Orthopaedic Surgeon and a Radiologist. Assessment of bony lucencies was performed both quantitatively and qualitatively. Quantitative analysis included determination of the number of lucencies. Qualitative analysis included the presence, shape (ovoid or linear) and distribution (epiphyseal, metaphyseal and shaft) of the lucencies.

The donor files pertaining to these specimens were re-examined to confirm that none of the donors had a medical reason for the lesions, and no abnormal results had been identified on screening.

Nine long bone specimens containing apparent lytic lesions from 6 donors, where consent to biomedical research had been obtained, were identified. These tissues had not met the criteria for transplant (identified post retrieval) and were being held for potential use in *education/validation/investigation*