# Efficacy Of Cooling Materials Composites In Sustaining Freezing Temperature Of Bone Allografts During Gamma Irradiation

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## INTRODUCTION:

Dry ice (DI) is the most common cooling material used as stated in standards to keep allograft bones in frozen state preferably below -40ºC throughout irradiation[1,2,3]. Detrimental radiation effects on biomechanical properties can be minimized in frozen condition. However, the supply of DI is limited and getting expensive. A comparative study was conducted on temperature profiles when using composite of DI and gel ice (GI) against the standard practice (DI only). Temperatures of frozen allografts before and after radiation sterilization process were monitored as well as radiation dose uniformity of the irradiated boxes.

## MATERIALS & METHODS:

Femoral heads were procured from screened living donors during arthroplasty surgeries. Medical records were screened and bacteriology and virology results must be negative before the heads were accepted as bone allografts. Each bone was triple-packed in polyethylene bags and stored in -80ºC freezer. Five bones were packed in a polystyrene box (49.5cm x 36.5cm x 33.5cm) surrounded with either DI only (20kg) or the composites DI (10kg) & GI bags to fill up the spaces. The boxes could not exceed 20 kg to ensure of equal density and sent to Malaysian Nuclear Agency for sterilization at 25kGy by gamma rays emitted from cobalt-60 radioactive. Temperatures before and after irradiation were recorded by calibrated thermocouple thermometer (EBRO-Xylem, Germany). Absorbed minimum (Dmin) and maximum (Dmax) doses from Dosimetry Analysis were used to determine dose uniformity ratio (DUR=Dmax/Dmin).

## RESULTS:

During 2015 and 2016, 11 radiation batches of bones were irradiated packed with 20 kg DI and 3 batches with 10kg DI plus GI bags. Average time for irradiation sterilization process was 24h including 4h for packaging and transportation to irradiator and another 2h to bring back to Bone Bank for storage. Temperatures of allografts packed with DI and DI&GI after radiation process were still deep frozen at -65.20 ± 6.38ºC and -60.30 ± 8.81ºC respectively (Table 1). Dose Uniformity Ratios (DUR) for all boxes were close to 1: 1.00 to 1.05 for DI and 1.01 to 1.03 for DI&GI indicating the dose distribution in the irradiated boxes was uniform and the boxes were of equal density.

**Table 1:** Temperature of the allografts packed with different cooling materials

| | Before radiation | After radiation |
|---|---|---|
| DI (20 kg) | -74.42 ± 5.22 ºC | -65.20 ± 6.38ºC |
| DI (10 kg) & GI | -69.10 ± 3.19 ºC | -60.30 ± 8.81ºC |

## DISCUSSION:

The bones were confirmed below -40ºC during irradiation in accordance to AATB Standards[1]. The amount of DI used could be reduced to 10kg as a cost effective measure, from RM123.00 for 20kg DI at RM 6.15 per kg (slab) to only RM 61.50. GI is cheap and reusable.

## CONCLUSION:

Composites of DI & GI can be used to maintain the frozen bones below -40ºC for sterilization process. Check on dose uniformity is vital to ensure each irradiation batch gets the required minimum radiation dose (25 kGy) to sterilize the allografts while the maximum dose is not too high to cause any damage.

## REFERENCES:

1. AATB Standards for Tissue Banking 2008, USA.

2. Bryce S et al. Cell Tis Bank 2010; 11(3): 291-4.

3. Garcia R et al. in Kennedy JF et al. (eds) Sterilization of tissues using ionizing radiation, CRC Press, England 2005; 105-15.